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Glossary of Judicial Claim Constructions in the Chemical, Pharmaceutical and Biotechnology Arts

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"a concentration level" — "permit[s] varying concentration levels because there is no evidence of clear intent to limit the article." *Whirlpool Corp., et al. v. LG Electronics, Inc., et al.*, 423 F. Supp. 2d 730 (W.D. Mich. 2004).[1]

"a morphologically identifiable chromosome or cell nucleus" — "since the patent specification and history indicate that the narrower construction of the last phrase of step (b) of claim 1 is at least as plausible as the broader construction, the court concludes that it refers to a single chromosome or cell nucleus." *Regents of the University of California, et al. v. Oncor, Inc.*, 1997 U.S. Dist. LEXIS 15068 (N.D. Cal., Aug. 19, 1997).[2]

"a solution consisting of water and a sodium phosphate" — "Norian argues that its claims read on any solution made from a single sodium phosphate as well as any solution made from a combination of different sodium phosphates. ... The district court rejected Norian's argument ... We agree with the district court's construction of the claim language." *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356 (Fed. Cir. 2005).[3]

"about" — "approximately." *Roche Diagnostics Operations, Inc., et al. v. Abbott Diabetes Care, et al.*, 2009 U.S. Dist. LEXIS 84423 (D. Del., Sep. 15, 2009).[4]

"about" — "We reverse the district court's construction of 'about' and hold that such term should be given its ordinary meaning of 'approximately.'" *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005).[5] "[T]he district court did not err in construing the disputed claim terms 'about 70/35 mg' to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories." *Id.* (Rader, J., dissenting).[6]

"about"; *[absence of]* "about" — "Claim 1 contains a mixture of imprecise and precise claim limitations. Specifically, claim 1 uses the word 'about' to qualify the values of many variables: the range of the maturing temperature, the coefficient of thermal expansion, the leucite crystallite sizes, and the weight percentage of leucite crystals. In contrast, the claim recites precise ranges for the weight of dental compositions. Under these circumstances, the district court correctly limited the weight ranges to those recited precisely in the table of claim 1." *Jeneric/Pentron, Inc. v. Dillon Co., Inc., et al.*, 205 F.3d 1377 (Fed. Cir. 2000).[7]

"about" — "I recommend different constructions for each set of 'about' claims in dispute." *Abbott Laboratories, et al. v. Lupin Ltd., et al.*, 2010 U.S. Dist. LEXIS 60743 (D. Del., Jun. 18, 2010).[8]

"about" — "approximately the value as stated." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[9]

"about" — "encompasses only measurement errors inherently associated with PXRD testing." *Lupin Ltd. v. Abbott Laboratories, et al.*, 484 F. Supp. 2d 448 (E.D. Va. 2007).[10]

"about" — "Because 'about' is a lay term that does not require construction, the Court will not construe the term for any of the patents-in-suit." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[11]

"about" — "approximately." *Novartis Pharmaceuticals Corp., et al. v. Apotex Corp., et al.*, 2006 U.S. Dist. LEXIS 10130 (S.D.N.Y., March 13, 2006).[12]

"about" — "approximately." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[13]

"about 0.001 to 0.03 parts ascorbic acid" — "approximately 0.001 to 0.03 parts ascorbic acid." *Yoon Ja Kim v. Dawn Food Products, Inc.*, 2004 U.S. Dist. LEXIS 20837 (N.D. Ill., Oct. 12, 2004).[14]

"about 0.20 mg to about 1.0 mg of said supplement" — "approximately 0.20 mg to approximately 1.0 mg of said supplement." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[15]

"a density below <u>about 0.91 g/cm^3</u>" — "a number between 0.905 and 0.914." *Viskase Corp. v. American National Can Co.*, 947 F. Supp. 1200 (N.D. Ill., Oct. 10, 1996).[16] "[W]e hold that the correct construction of the claims of the first family patents is that 'below about 0.91 g/cm^3' means 'below about 0.910 g/cm^3.' We need not decide what range is reasonably encompassed in the 'about' in 'about 0.910,' for in all events it can not reach films having a density of 0.912, a product at issue in this suit." *Id.*, 261 F.3d 1316 (Fed. Cir. 2001).[17]

"less than <u>about one percent, by weight, protein</u>" — "less than approximately one percent, by weight, protein." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[18]

"a particle size of <u>about 1.0 micron or less</u>"; "a particle size of <u>about 1.0 microns or less</u>" — "a particle size of approximately 1.0 micron or less." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[19]

"the total amount of methylphenidate hydrochloride present is <u>about 10 to 40 mg</u>" — "the total amount of methylphenidate hydrochloride present is approximately 10 to 40 mg." *UCB, Inc., et al. v. KV Pharmaceutical Co.*, 2009 U.S. Dist. LEXIS 72764 (D. Del., Aug. 18, 2009).[20]

"about 100 IU" — "from some reasonably close number below 100 IU to some reasonably close number above 100 IU." *Aventis Pharma S.A., et al. v. Amphastar Pharmaceuticals, Inc., et al.*, 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).[21]

"weight ratio of cyclosporin to water of <u>about 1:300 to about 1:1500</u>" — "a weight ratio of cyclosporin to water of 1:250 to 1:1549." *Novartis Pharmaceuticals Corp., et al. v. Eon Labs Manufacturing, Inc.,* 215 F. Supp. 2d 452 (D. Del. 2002).[22]

"about 1:5" — "encompasses ratios up to and including 1:7.1 and ratios down to and including 1:3.6." *Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc., et al.*, 482 F. Supp. 2d 478 (D.N.J. 2007).[23]

"about 1:5" — "a weight ratio of approximately 1:5, encompassing a range of ratios of no greater than 1:3.6 to 1:7.1." *Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Labs., Ltd.*, 2005 U.S. Dist. LEXIS 24998 (E.D. Mich., Oct. 19, 2005);[24] "we see no error in the district court's construction." *Id.*, 476 F.3d 1321 (Fed. Cir. 2007).[25]

[i] "about 2 minutes to about 4 minutes"; [ii] "about 190 º F. to about 205 º F." — [i] "30 seconds to ten minutes"; [ii] "150 º F. to 300 º F." *Schreiber Foods, Inc. v. Saputo Cheese USA Inc.*, 83 F. Supp. 2d 942 (N.D. Ill. 2000).[26]

"about 25%" — "At this point Saputo argues only that Schreiber cannot recapture concentrations below 21.25%. We agree based on the prosecution history, but decline to delineate any more specific boundaries for 'about 25%.'" *Schreiber Foods, Inc. v. Saputo Cheese USA Inc.*, 83 F. Supp. 2d 942 (N.D. Ill. 2000).[27]

[i] "from about 4 to about 12 nucleotide triplets"; [ii] "from about 4 to about 12 L-amino acid residues" — [i] "is sufficiently indefinite to include a range whose boundaries are delimited by 3 and 13"; [ii] "means a range of from 3 to 13 of such residues." *Pieczenik, et al. v. Dyax Corp.*, 226 F. Supp. 2d 314 (D. Mass. 2002).[28]

"about 5:1 to about 7:1" — "did not include the ratio of 4:1." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995).[29]

"about 5 to about 50% by weight" — "a pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and from 4.75% to 52.5% by weight of pharmaceutically acceptable polymer." *Ranbaxy Laboratories Ltd., et al. v. Abbott Laboratories, et al.*, 2005 U.S. Dist. LEXIS 27753 (N.D. Ill., Nov. 10, 2005).[30]

"about 5-75% by weight starch"; "up to about 80 º" — "approximately 5-75% by weight starch, but not less than 2.5% by weight starch nor more than 77.5% by weight starch"; "up to approximately 80 º but not to reach 88 º." *MGP Ingredients, Inc. v. Mars, Inc., et al.*, 494 F. Supp. 2d 1231 (D. Kan. 2007).[31]

"about 50-70%" — "this term does not require construction." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[32]

"about 60 mg/ml" — "approximately 60 to approximately 200 mg/ml." *Chiron Corp. v. Sourcecf Inc., et al*., 2005 U.S. Dist. LEXIS 34450 (N.D. Cal., Dec. 1, 2005).[33]

"about 70 kDa mediator substance" — "biologically active TNFa." *Rockefeller University, et al. v. Centocor, Inc.*, 2006 U.S. Dist. LEXIS 43143 (E.D. Tex., June 13, 2006).[34]

"about 70/35 mg" — "the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories." Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 288 F. Supp. 2d 601 (D. Del. 2003).[35]

"about 95% of the cumulative total of said particles" — "approximately 95% of the aggregate of the individual percent values for all measurable particles in the oral unit dose form based on volume distribution (claim 7) and approximately 95% of the aggregate of the individual percent values for all measurable particles in the oral unit dose based on a volume distribution (claim 16)." *Apotex, Inc. v. Cephalon, Inc., et al.*, 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).[36]

"[*absence of*] linear"; "[*absence of*] branched" — "[b]ecause the terms 'linear' and 'branched' do not appear in, nor are they required by, the language of the claims-in-suit, the claims do not contain any limitation based on the 'linear' or 'branched' nature of the claimed composition, or of its ingredients." *Penederm, Inc. v. Alzo, Inc.*, 1996 U.S. Dist. LEXIS 18706 (N.D. Cal., Dec. 6, 1996).[37]

"heating ... in the absence of pressure or shear sufficient to convert the binder particles" — "any pressure and shear applied to the mixture must not be sufficient to convert the mixture to a continuous web matrix or forced point-bonds until the mixture has been heated to a temperature substantially above the softening temperature of the binder." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[38] "The court finds, as it did in *Culligan*, that 'heating ... in the absence of pressure or shear sufficient to convert the binder particles' allows some pressure or shear to occur during the heating step. Accordingly, the court construes the phrase to mean that any pressure or shear applied to the mixture during heating must not be sufficient to convert the mixture into a continuous webbing structure or forced point bonds. In compression molding, however, the court agrees with PUR that Koslow disclaimed applying any level of pressure or shear during heating." *KX Industries, L.P., et al. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2D 380 (D. Del. 2000).[39]

"said additive being present in an amount sufficient to accelerate the rate of hardening of said hydraulic cement mix and to increase its compressive strength after hardening" — "said admixture being present in an amount sufficient to: (1) decrease the amount of time it will take for an hydraulic cement mix to reach final set, relative to a plain mix; and (2) increase the compressive strength of the hydraulic cement mix, relative to a plain mix, when measured at a like time interval after hardening." *SKW Americas, et al. v. Euclid Chemical Co.*, 231 F. Supp. 2d 626 (N.D. Ohio 2002).[40]

"accelerated rate of healing and accelerated rate of symptom relief" — "a faster resolution of symptoms or effects of a disease, compared to omeprazole." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[41]

"accelerated release" — "means that the rate of release of the blowing agent occurs more quickly than what the rate of release would be without channels perforating the foam." *Dow Chemical Co. v. Astro-Valcour, Inc.*, 47 F. Supp. 2d 294 (N.D.N.Y. 1999).[42]

"an accelerator/cure package for said rubbery polymer" — "a package that includes a compound to cross-link the polymer chains of the rubbery polymer, and for reducing the time needed to complete such cross-linking." *Adco Products, Inc. v. Carlisle Syntec Inc.*, 110 F. Supp. 2D 276 (D. Del. 2000).[43]

"acceptable level suitable for intravenous administration"; "increased level of anticomplement activity"; "then incubating the solution of step a)"; "increased anticomplement activity of the solution" — These phrases are not indefinite. *Talecris Biotherapeutics, Inc. v. Baxter International, Inc., et al.*, 510 F. Supp. 2d 356 (D. Del. 2007).[44]

"acetylation" — "a chemical reaction that introduces an acetyl functional group onto a molecule." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[45]

"4-amino-1-hydroxybutane-1, 1-biphosphonic acid" — "include[s] both free acid and sodium salt forms." *Merck & Co. v. Teva Pharmaceuticals USA, Inc., et al.*, 228 F. Supp. 2d 480 (D. Del. 2002).[46] "We affirm the district court's holding that the claimed method of treatment by administration of the biphosphonic acid is infringed whether administered as the pure acid or in the form of the acid salt." *Id.*, 347 F.3d 1367 (Fed. Cir. 2003).[47] "I believe that the district court erred in its claim construction by concluding that the term 'acid' as used in the claim should be construed to encompass both acids and salts." *Id.* (Mayer, C.J., dissenting).[48]

"acid labile pharmaceutically active substance"; "acid labile compound" — "a compound that is sensitive to acid but has better stability in alkaline conditions." *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007).[49]

"actinic radiation" — "radiation capable of effecting a chemical change in an exposed moiety." *MacDermid Printing Solutions, L.L.C. v. E.I. Du Pont De Nemours & Co.*, 2010 U.S. Dist. LEXIS 23746 (D.N.J., Mar. 15, 2010).[50]

"activated SAH-hydrolase" — "SAH hydrolase that is capable of acting as a catalyst." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[51]

"shape memory activation temperature" — "the crystallization point of a given thermoplastic, calculated according to the following formula: $T_c \approx (T_m + T_g)/2$ where T_c is the crystallization temperature, T_m is the melting temperature and T_g is the glass transition temperature." *Pipe Liners, Inc., et al. v. Pipelining Products, Inc.*, 1999 U.S. Dist. LEXIS 17271 (D. Del., Oct. 22, 1999).[52]

"active" — "producing an intended action or effect: active ingredients." *Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc*., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).[53]

"activity of cytochrome p450 isozyme" — "the specific activity of the isozyme as well as the metabolic effect of that activity." *King Pharmaceuticals, Inc., et al. v. Sandoz, Inc.*, 2010 U.S. Dist. LEXIS 27274 (D.N.J., Mar. 22, 2010).[54]

"added"; "adding" — "to join or unite so as to bring about an increase or improvement." *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, et al.*, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).[55]

"adding a mixture of labeled nucleic acid from the two cell types to an array" — "adding a mixture of labeled nucleic acid from the two cell types to the array in a single step, wherein 'labeled nucleic from the two cell types' means samples of mRNA, DNA, or cellular other nucleic acid obtained from the two cell types." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[56]

"[*adding*] substantially [to claim limitations]" — "*AFG Industries, Inc. v. Cardinal IG Co*., 239 F.3d 1239 (Fed. Cir. 2001) [does not] justify a 'substantially' addition to claim limitations." *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[57]

"an addition rate at which catalyst is introduced into the FCC unit" — "a ratio of the catalyst added into the FCC unit over time, or a ratio of the catalyst additive added into the FCC unit over the fresh catalyst." *Intercat, Inc. v. Nol-Tec Systems, Inc., et al.*, 2005 U.S. Dist. LEXIS 344 (D. Minn., Jan. 7, 2005).[58]

"additional" — "deletion of the word 'additional' from the phrase 'additional bleaching agent' ... has no effect on the interpretation of claim 2." *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., et al.*, 924 F. Supp. 1101 (D. Utah 1996).[59]

"fuel additive" — "a material added to fuel, usually in small amounts, to impart or enhance desirable properties or to suppress undesirable properties." *Maxma, et al. v. ConocoPhillips Inc.*, 2005 U.S. Dist. LEXIS 34020 (E.D. Tex., Jul. 19, 2005).[60]

"adhesive" — "is a generic term which includes cohesives." *Moore North America, Inc. v. Adams Investment Company Inc.*, 2000 U.S. Dist. LEXIS 20958 (S.D. Iowa, Jul. 27, 2000).[61]

"adipose-derived" — "derived from fat tissue." *University of Pittsburgh, et al. v. Hedrick, et al.*, 573 F.3d 1290 (Fed. Cir. 2009).[62]

"adjuvant" — "that subset of inactive ingredients that is intimately mixed with gabapentin to form the drug mixture, and thus ... not ... the ingredients of capsule shells or tablet coatings." *In re Gabapentin Patent Litigation*, 395 F. Supp. 2d 140 (D.N.J. 2005).[63] "We agree with Warner Lambert that the district court did not err in concluding that the adjuvant claim limitation refers to ingredients intimately mixed with gabapentin, and thus excludes ingredients located in the capsule shell or tablet coating." *Id.*, 503 F.3d 1254 (Fed. Cir. 2007).[64]

"administer"; "administration" — "delivering the formulation-in-question into a person's body." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[65]

"administering" — "would include giving a patient a drug in any normal manner (i.e., providing a tablet to a patient under circumstances where it is reasonable to believe that a patient is going to take the tablet)." *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).[66]

"administering" — "whether levofloxacin [is] formed as the claimed compound inside the body or outside the body, as long as it is given remedially as medicine, then levofloxacin has been administered." *Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al*., 348 F. Supp. 2d 713 (N.D. Va. 2004).[67]

"administering orally to a patient in need thereof" — "a patient in need of therapeutic blood plasma levels of venlafaxine, such as a patient suffering from one or more depressive or anxiety disorders, and the patient is being treated by a formulation that is swallowed." *Wyeth v. Mylan Pharmaceuticals, Inc.*, 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009).[68]

"a method for the treatment of Campylobacter infections comprising <u>administering to a patient suffering therefrom an amount of [omeprazole] or a pharmaceutically acceptable salt thereof sufficient for the treatment of said infection</u>" — "claims 1) the administration of omeprazole alone 2) for the express purpose of treating H. Pylori." *In re Omeprazole Patent Litigation*, 258 F. Supp. 2d 221 (S.D.N.Y. 2001).[69]

"administration"; "administered"; "administering" — "application; to bring into use or operation into the body." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[70]

"admixture" — "Because the patentee's only description of admixture involves limiting the term to 'encapsulating' or 'binding' the seed with the mulch material, the term should include this limitation." *Profile Products LLC v. Encap, LLC*, 2009 U.S. Dist. LEXIS 60282 (W.D. Wis., Jul. 15, 2009).[71]

"admixture" — "a mixture of sulfated heparinic polysacchandes having a variety of molecular weights, regardless of how the mixture was prepared." *Aventis Pharma S.A., et al. v. Amphastar Pharmaceuticals, Inc., et al*., 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).[72]

"admixture" — "means two or more items are commingled and interdispersed to obtain a homogeneous product." *Biovail Corp. International, et al. v. Andrx Pharmaceuticals, Inc.*, 158 F. Supp. 2d 1318 (S.D. Fla. 2000).[73] "This case turns on whether the 'admixture' limitation in claim 1 of the '791 patent must be 'homogeneous.' ... The prosecution history of the '396 application clearly indicates that at least the 'bead' described in the '396 application, in claims 1, 6, and 11 of the '505 patent, and in claim 1 of the '791 patent must be 'homogeneous.' ... Therefore, the admixture of diltiazem salt and wetting agent that comprises the bead of claim 1 of the '791 patent must be homogeneous." *Id.*, 239 F.3d 1297 (Fed. Cir. 2001).[74]

"an admixture comprising" — "an admixture including, but not limited to." *SKW Americas, et al. v. Euclid Chemical Co.*, 231 F. Supp. 2d 626 (N.D. Ohio 2002).[75]

"sufficient <u>aeration ... to enhance sensitivity</u>" — "is understood by those of ordinary skill in the art to include both interstitial and porous air." *Atlas Powder Co., et al. v. Ireco Inc., et al.*, 190 F.3d 1342 (Fed. Cir. 1999).[76]

"aerosol" — "a substance dispensed from a pressurized container as a suspension of fine liquid particles in gas." *Miller Products Co., Inc. v. Veltek Associates, Inc., et al.*, 2004 U.S. Dist. LEXIS 1798 (D. Del., Feb. 10, 2004).[77]

"affected area" — "the area of the skin which comes into contact with urushiol." *Yarbrough Foundation, et al. v. Rite Aid Corp., et al.*, 2007 U.S. Dist. LEXIS 53443 (W.D. Mich., July 24, 2007).[78]

"less <u>affinity for</u>" — "could include zero affinity." *Procter & Gamble Co. v. McNeil-PPC, Inc.*, 2009 U.S. Dist. LEXIS 6947 (W.D. Wis., Jan. 26, 2009).[79]

"air quality" — "the concentration of pollutants or contaminants in the air." *PureChoice, Inc. v. Honeywell International, Inc.*, 2009 U.S. App. LEXIS 11702 (Fed. Cir., Jun. 1, 2009) (unpublished).[80]

"an alkali or alkaline earth metal carbonate" — "the salt of an alkali metal or alkaline earth metal cation, and a carbonate (CO_3^{-2}) anion; it does not include a bicarbonate (HCO_3^{-1}) anion." *Warner-Lambert Co. v. Teva Pharmaceuticals USA*, 289 F. Supp. 2d 515 (D.N.J. 2003).[81]

"alkaline reacting compound" — "(1) a pharmaceutically acceptable alkaline, or basic, substance having a pH greater than 7 that (2) stabilizes the omeprazole or other acid labile compound by (3) reacting to create a micro-pH of not less than 7 around the particles of omeprazole or other acid labile compound." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002)[82]; *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[83]

"an <u>alkalinity of less than 30 ppm</u>" — "a raw water measuring less than or equal to 30 ppm of equivalents of Calcium Carbonate [$CaCO_3$] in solution; equivalent calcium includes Calcium [Ca], and equivalent carbonate includes Carbonate [CO_3], as well as Bicarbonate [HCO_3] and Hydroxide [OH]." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[84]

"water of raw alkalinity of less than or equal to 50 ppm" — "a raw water measuring less than or equal to 50 ppm of equivalents of Calcium Carbonate in solution; equivalent calcium includes Calcium, and equivalent carbonate includes Carbonate, as well as Bicarbonate and Hydroxide." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[85]

"alkoxy" — "the name of a substituent group, such as 'alkoxy,' requires a restrictive definition which excludes substituted variations, unless possible substitutions are specifically listed ... the ordinary and customary definition of 'alkoxy' is an unsubstituted alkyl radical attached to the remainder of the molecule by oxygen." *Dow Agro Sciences LLC v. Crompton Corp., et al*., 381 F. Supp. 2d 826 (S.D. Ind. 2005);[86] "we agree with the district court that the term 'alkoxy' refers only to unsubstituted alkoxy groups." *Id.*, 2006 U.S. App. LEXIS 11320 (Fed. Cir., May 5, 2006) (unpublished).[87]

"alkyl" — "an acyclic saturated hydrocarbon radical." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al*., 2005 U.S. Dist. LEXIS 5999 (E.D. Pa., March 31, 2005).[88]

"allow penetration of the dermis of mammals by the complex carbohydrate" — "the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief." *Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc*., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).[89]

"allowing the microorganisms within the fluid to biodegrade the hydrocarbons"; "retaining the hydrocarbons within the fluid in the tank while the microorganisms biodegrade the hydrocarbons" — "let or permit the microorganisms within the cleaning fluid to biodegrade the hydrocarbons"; "the hydrocarbons remain in the cleaning fluid while the microorganisms biodegrade them." *ChemFree Corp. v. J. Walter, Inc., et al*., 2007 U.S. Dist. LEXIS 51677 (N.D. Ga., July 17, 2007).[90]

"a substrate with an alloyed layer" — "an adjacent, underlying material which includes a layer that is a mixture of a metal and one or more different metals or non-metallic elements." *Collins, et al. v. Gillette Co.*, 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).[91]

"β (1,3) glucan of altered carbohydrate structure" — "the Court construes 'altered' to mean that the glucan structure has been modified or changed in some way, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucans." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[92]

"alum" — "another name for aluminum sulfate, as well as aluminum ammonium sulfate and aluminum potassium sulfate." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[93]

"aluminum" — "commercial grade aluminum." *Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc., et al.*, 1998 U.S. Dist. LEXIS 13142 (N.D. Cal., Aug. 24, 1998).[94]

"aluminum and aluminum oxide" — "refers solely to substantially pure aluminum and its native layer of aluminum oxide, and not to alloys such as aluminum silicon or aluminum silicon copper." *Northern Telecom Limited v. Samsung Electronics Co., Ltd., et al*., 1996 U.S. Dist. LEXIS 21786 (N.D. Cal., Sept. 13, 1996).[95] "[T]he district court's construction of 'aluminum and aluminum oxide' in claim 1 was correct." *Id.*, 215 F.3d 1281 (Fed. Cir. 2000).[96]

"aluminum chloride" — "$AlCl_3$; aluminum chloride is normally provided in either a dry form or in an aqueous solution. In its dry form it is often referred to in a hydrated form, such as $AlCl_3$ $6H_2O$." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[97]

"aluminum polymer" — "a polynucleate aluminum compound, such as polyaluminum hydroxychloride, polyaluminum chloride and polyaluminum silicate sulfate (PASS), or the like." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[98]

"aluminum salt" — "a compound formed when the hydrogen of an acid is replaced by aluminum." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[99]

"aluminum sulfate" — "$Al_2(SO_4)_3$; aluminum sulfate is normally provided in either a dry form or in an aqueous solution. In its dry form it is often referred to in a hydrated form, such as $(Al_2SO_4)_3$ $(18H_20)$ or $(Al_2(SO_4)_3$ $14H_2O)$." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[100]

"Alzheimer's disease" — "dementia of the Alzheimer's type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R, and further characterized by the presence of neuritic plaques and neurofibrillary tangles in the brain." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[101]

"the mixture being subjected to a pressure in said mixing zone which is sufficient to maintain said blowing agent in the liquid state at <u>ambient temperatures</u>" — "any interpretation that requires 'ambient temperatures' to refer to the temperature of the blowing agent is unreasonable. We therefore conclude that 'ambient temperatures' refers to the temperature of the mixing zone." *Doyle, et al. v. Crain Industries, Inc., et al.*, 2000 U.S. App. LEXIS 26894 (Fed. Cir., Oct. 25, 2000) (unpublished).[102]

"amorphous" — "completely amorphous." *Kumar v. Ovonic Battery Co., Inc., et al.*, 2002 U.S. Dist. LEXIS 27630 (D. Mass., Jul. 8, 2002).[103] "Because the specification does not clearly and deliberately define the term 'amorphous' as completely amorphous, it does not support a construction of the term contrary to its plain meaning." *Id.*, 351 F.3d 1364 (Fed. Cir. 2003).[104]

"amount effective" — "a quantity that produces a result." *Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc*., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).[105]

"amount effective" — "an amount sufficient to have a cosmetic benefit by removing keratotic plugs." *Kao Corp., et al. v. Unilever United States, Inc., et al.*, 334 F. Supp. 2d 527 (D. Del. 2004).[106]

"an amount of edetate sufficient to prevent a no more than 10-fold increase in growth of each of Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027 and Candida albicans ATCC 10231 for at least 24 hours as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said composition at approximately 50 colony forming units per ml, at a temperature in the range 20º-25º C., whereafter said aliquots are incubated at 20º-25º C. and are tested for viable counts of said organism after 24 hours, said amount of edetate being no more than 0.1% by weight of said composition" — "an amount of edetate, greater than 0% but less than or equal to 0.1% by weight of the pharmaceutical composition, which is sufficient to meet the microbiological test recited in the claim phrase." *AstraZeneca Pharmaceuticals, LP, et al. v. Mayne Pharma (USA) Inc.*, 352 F. Supp. 2d 403 (S.D.N.Y. 2004).[107]

"an amount of fluid to be infused" — "a quantity of fluid to be infused in the patient." *Medtronic MiniMed Inc. v. Smiths Medical MD Inc.*, 2005 U.S. Dist. LEXIS 10583 (D. Del., Jun. 1, 2005).[108]

"amount of signal label producing said detectible signal in said immunosorbing zone is related to the amount of analyte" — "allow[s] for quantitative, semi-quantitative or qualitative analysis of the relation between the amount of signal produced and the amount of analyte in the test solution." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[109]

"an amount sufficient" — "a required dosage." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[110]

"[stem cells] in an amount sufficient" — "in a quantity as much as is needed." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[111]

"an amount sufficient to form a flocculated suspension in the water and to remove turbidity from the water" — "the dosage required in the water to form a flocculated suspension and increase clarity, reduce reported NTU to an appreciable extent." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[112]

"in an amount sufficient to impart color and/or flavor to the foodstuff" — "I do not find at this stage that the term ... is indefinite." *Viskase Cos., Inc. v. World Pac International AG, et al.*, 2010 U.S. Dist. LEXIS 49720 (N.D. Ill., May 18, 2010).[113]

"amplifiable gene" — "DNA corresponding to a gene whose copy number will increase inside a transformed cell in response to manipulation by the operator of a process." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[114]

"amplification" — "any increase in the number of genes, the term should not be interpreted to require a minimum increase, such as a five gene increase." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co*., 1996 U.S. Dist. LEXIS 15989 (D. Del., Oct. 21, 1996).[115]

[i] "amplified foreign DNA I"; [ii] "amplified DNA II" — [i] "Foreign DNA I corresponding to a gene of interest that is present in a cell in increased copy number as a result of gene amplification in the cell"; [ii] "DNA II that is present in increased copy number in a cell as a result of gene amplification in the cell and confers a selectable phenotype of proliferative advantage under specific conditions of culturing the cell, enabling selection of cells which carry an increased copy number DNA II." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[116]

"amplifying" — "encompass[es] only non-specific amplification." *Gen-Probe Inc. v. Vysis, Inc.*, 2002 U.S. Dist. LEXIS 25020 (N.D. Cal., Aug. 2, 2002).[117]

"amplifying domain before hybridization" — "requires no judicial construction. Amplification must occur before hybridization." *Innogenetics N.V. v. Abbott Laboratories*, 2006 U.S. Dist. LEXIS 57142 (W.D. Wis., Aug. 11, 2006).[118]

"an erythromycin derivative" — "The language of the claim is definite ('an erythromycin derivative') but not closed. It does not specify that the pharmaceutically active compound 'is a member selected from the group consisting of A, B, and C.' Thus, clarithromycin is an erythromycin derivative under this meaning." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[119]

"an inert core" — "one or more pharmaceutically inert seeds used to provide a starting material for the preparation of a pharmaceutical." *Mylan Pharmaceuticals, Inc., et al. v. Kremers Urban Development Co., et al.*, 2004 U.S. Dist. LEXIS 391 (D. Del., Jan. 13, 2004).[120]

"analog"; "surrogate" — "are understood by persons of ordinary skill in the art to mean any substitute for human blood cells." *Streck Laboratories v. Beckman Coulter, Inc., et al.*, 2002 U.S. Dist. LEXIS 9808 (D. Neb., May 1, 2002).[121]

"analyte" — "the substance that the test is designed to detect if present in the liquid being tested." *Abbott Laboratories v. Syntron Bioresearch, Inc.*, 334 F.3d 1343 (Fed. Cir. 2003).[122]

"analyzing" — "using Gas Chromatography-Mass Spectrometry (GC/MS) or a similar means to identify compounds by comparison to a library or database of known compounds." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[123]

"analyzing" — "the parties do not dispute the meaning of the word 'analyzing.' Rather, the parties' arguments all appear to relate to the intensity with which one must analyze in order to satisfy the claim, or to the type of information that must be analyzed. These are not claim construction issues, but rather should be taken up when considering whether defendants have infringed, or whether the claims of the patent are valid." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[124]

"analyzing said plurality of amplified DNA sequences" — "observing any variation in the DNA sequence using any technique." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[125]

"anaphylactic manifestations" — "The term does not extend to all symptoms (e.g., hives and bronchospasms) that are (or can be) *associated with* anaphylaxis, regardless of whether the patient is actually suffering from anaphylaxis itself. Rather, the term refers to those symptoms when — and only when — the patient is actually suffering from anaphylaxis." *Aventis Pharma S.A., et al. v. Hospira, Inc.*, 2010 U.S. Dist. LEXIS 101442 (D. Del., Sep. 27, 2010).[126]

"and" — "is properly being used ... to express alternatives." *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., et al.*, 2005 U.S. Dist. LEXIS 34380 (D.N.J., July 18, 2005).[127]

"treatment of urolithiasis <u>and inhibiting bone reabsorption</u>" — "the term 'and' should be construed to mean 'or'. Specifically, the Court concludes that claim 1 of the '077 Patent allows for the treatment of urolithiasis or inhibiting bone reabsorption." *Merck & Co. v. Teva Pharmaceuticals USA, Inc., et al.*, 228 F. Supp. 2d 480 (D. Del. 2002).[128]

"anesthetizing the portion of the eye lid" — "The district court, following what it perceived as the 'ordinary meaning' of the term, held that ... the limitation 'anesthetizing the portion of the eye lid ...' does not encompass 'freezing' or application of 'cold water.' ... the district court correctly construed the claims." *Giora George Angres, Ltd. v. Tinny Beauty and Figure, Inc., et al.*, 1997 U.S. App. LEXIS 15342 (Fed. Cir., Jun. 26, 1997) (unpublished).[129]

"animal" — "The proper construction for the claim term 'animal' is the one explicitly provided by the patentee: 'any organism belonging to the kingdom Animalia,' which includes humans." *Martek Biosciences Corp. v. Nutrinova, Inc., et al.*, 579 F.3d 1363 (Fed. Cir. 2009).[130]

"anion" — "generically refers to an ion that has a single or multiple negative charges." *Iovate Health Sciences, Inc., et al. v. Allmax Nutrition, Inc., et al.*, 639 F. Supp. 2d 115 (D. Mass. 2009).[131]

"anion of a mineral acid" — "refer[s] to anions 'derived from' a mineral acid." *In re Gabapentin Patent Litigation*, 2005 U.S. Dist. LEXIS 37857 (D.N.J., Aug. 22, 2005).[132] "[T]he district court did not err in its construction of the claim term 'anion of a mineral acid.'" *Id.*, 503 F.3d 1254 (Fed. Cir. 2007).[133]

"anodization"; "anodized coating"; "anodized oxide coating" — "mean an electrolytically formed, adherent, porous aluminum oxide coating sufficiently thick (meaning thicker than native oxide) to, (A) protect against the burning and arcing problems addressed by the patent and optionally, (B) to provide a suitable porous base for other electrolytic treatments in the second anodizing cell such as electrophoresis, for metal plating." *Fromson v. Anitec Printing Plates, Inc., et al.*, 132 F.3d 1437 (Fed. Cir. 1997).[134]

"anthracycline glycoside" — "a class of chemical compounds having the following generic structure ..." *Pharmacia & Upjohn Co. v. Sicor, Inc., et al.*, 447 F. Supp. 2d 363 (D. Del. 2006).[135]

"anti-settling agent" — "§ 112, P6 applies to limit the 'anti-settling agent' to structures disclosed in the specification and equivalents that perform the identical function." *Dri Mark Products Inc. v. National Ink Inc.*, 2002 U.S. Dist. LEXIS 6361 (S.D.N.Y., Apr. 10, 2002).[136]

[i] "anti-TNF-α antibody"; [ii] "human variable region"; [iii] "human light chain"; [iv] "human heavy chain" — [i] "an immunoglobulin protein that binds to TNF-α"; [ii] "a variable region that is encoded by a gene derived from human DNA"; [iii] "light chain encoded by a gene derived from human DNA"; [iv] "heavy chain encoded by a gene derived from human DNA." *Centocor Ortho Biotech, Inc., et al. v. Abbott Laboratories, et al.*, 2009 U.S. Dist. LEXIS 28467 (E.D. Tex., Apr. 6, 2009).[137]

"antibiotic" — "a therapeutic agent used to minimize or reduce infection." *Marctec, LLC v. Johnson & Johnson, et al.*, 2009 U.S. Dist. LEXIS 27011 (N.D. Ill., Mar. 31, 2009).[138]

"antibiotic tetracycline compound" — "a compound having antibiotic activity within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure." *Research Foundation of State University of New York, et al. v. Mylan Pharmaceuticals, L.P.*, 2010 U.S. Dist. LEXIS 46791 (D. Del., May 12, 2010).[139]

"antidote" — "a compound which has the effect of establishing herbicide selectivity, i.e., continued herbicidal phytotoxicity to weed species and reduced or non-phytotoxicity to the cultivated crop species; ... the antidote compound need only combine with the 4-b herbicide in an amount which is capable of reducing or eliminating the phytotoxic response a corn crop might have to a 4-b herbicide while, at the same time, interfering as little as possible with the injury which that herbicide causes to the weeds." *Zeneca Ltd., et al. v. Rhone-Poulenc, Inc.*, 1999 U.S. Dist. LEXIS 22137 (D. Del., Jun. 16, 1999).[140]

"an antigen" — "substance to which antibodies bind." *INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, et al.*, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009).[141]

"antigen"; "proteinaceous material" — "cover only antigens having adenylate cyclase activity." *Evans Medical Ltd., et al. v. American Cyanamid Co., et al.*, 11 F. Supp. 2d 338 (S.D.N.Y. 1998).[142]

"human c-erbB-2 antigen" — "the approximately 200kD protein associated with human breast cancer." *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002).[143]

"human breast cancer antigen that is also bound by monoclonal antibody 454 C11" — "The claimed monoclonal antibodies bind to the same breast cancer antigen as the identified reference antibody produced by the identified hybridoma. The 454 C11 monoclonal antibody binds to the human breast cancer antigen now referred to as 'c-erB-2,' sometimes referred to as 'HER2.'" *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002).[144]

"antimicrobial lotion"; "antimicrobial lotion composition"; "effective antimicrobial lotion" — "a lotion that effectively inhibits the growth of or kills microorganisms present on the skin." *Laboratory Skin Care, Inc. v. Limited Brands, Inc., et al.*, 616 F. Supp. 2d 468 (D. Del. 2009).[145]

"antimicrobially effective" — "limits the claim by requiring enough levofloxacin molecules to exhibit antimicrobial activity." *Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al.*, 348 F. Supp. 2d 713 (N.D. Va. 2004).[146]

"an antineoplastically effective amount" — "essentially duplicates the dosage amounts recited in the claims ... The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim." *Bristol Meyers Squibb Co. v. Ben Venue Laboratories, Inc., et al.*, 246 F.3d 1368 (Fed. Cir. 2001).[147]

"an antiretroviral agent" — "at least one substance having or capable of having an effect against a retrovirus, such as HIV." *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 528 F. Supp. 2d 967 (N.D. Cal. 2007).[148]

"antithromobic activity greater than heapann" — "the claimed substance prevents the growth of thrombi better than heparin in at least one in vivo setting." *Aventis Pharma S.A., et al. v. Amphastar Pharmaceuticals, Inc., et al*., 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).[149]

"any combination of an alum and an aluminum chloride" — "every possible proportion of alum to aluminum chloride." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[150]

"thereafter <u>applying pressure and shear to the heated mixture sufficient immediately to convert at least a portion of the binder material</u>" — "mean[s] applying pressure greater than 40 psi and shear sufficient to convert at least a portion of the binder materials after the entire mixture has been heated to a temperature above the softening temperature of the binder." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[151] "The court finds, as it did in *Culligan*, that the phrase 'thereafter applying pressure and shear to the heated mixture' means that the pressure and shear sufficient to convert at least a portion of the binder material occurs after the entire mixture has been heated to a temperature above the softening temperature of the binder material." *KX Industries, L.P., et al. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2D 380 (D. Del. 2000).[152]

"approximately" — "no further construction is warranted." *UCB, Inc., et al. v. KV Pharmaceutical Co.*, 2009 U.S. Dist. LEXIS 72764 (D. Del., Aug. 18, 2009).[153]

"approximately ambient temperature" — "mean[s] that the surface covering is cooled after being cured in step (c) of claim 1 of the '903 patent to a temperature approximately equal to factory or room temperature." *Mannington Mills, Inc., et al. v. Armstrong World Industries, Inc., et al.*, 2002 U.S. Dist. LEXIS 18641 (D. Del., Aug. 20, 2002).[154]

"having <u>approximately 30% by weight vinyl acetate</u>" — "having about, roughly, or around 30% by weight vinyl acetate." *Medtech Products Inc. v. Ranir, LLC, et al.*, 2009 U.S. Dist. LEXIS 103211 (S.D.N.Y., Nov. 5, 2009).[155]

"aqueous dispersion of the calcined gypsum" — "aqueous dispersion of the calcined gypsum and water (and optionally other desired additives)." *United States Gypsum Co. v. LaFarge North America, Inc., et al.*, 2009 U.S. Dist. LEXIS 101603 (N.D. Ill., Nov. 2, 2009).[156]

"aqueous solution" — "a uniformly disbursed liquid mixture of two or more components, one of which is water, and which can contain incidental amounts of insoluble components." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[157]

"arginine α-ketoglutarate" — "arginine α-ketoglutarate which is a salt also known as arginine 2-ketoglutarate, arginine 2-oxoglutamate, and arginine 2-oxopentanedioic acid. Unless specified, the term covers racemic mixture as well as any other (non-50/50) mixture of the enantiomers including substantially pure forms of either the R-(+) or the S-(-) enantiomer. Further, unless specified otherwise the term covers pharmaceutically acceptable salts (e.g. Na and K salts) and amides, esters and metabolites of the acid." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[158]

"arranged in a spacially defined and physically addressable manner" — "located in a particular location and capable of being addressed." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[159]

"array" — "a plurality of polymers arranged on a solid support." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[160]

"array of oligonucleotides" — "a plurality of polymers of nucleotides ranging in length from 2 to about 100 nucleotides, arranged on a solid support." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[161]

"an array of oligonucleotides" — "two or more oligonucleotide sequences located at different regions on a single support." *Oxford Gene Technology Ltd. v. Mergen Ltd., et al.*, 2004 U.S. Dist. LEXIS 19818 (D. Del., Sept. 29, 2004).[162]

"ascorbic acid" — "vitamin C or $C_6H_8O_6$." *Kim v. Earthgrains Co., et al.*, 2005 U.S. Dist. LEXIS 342 (N.D. Ill., Jan. 10, 2005).[163]

"aseptically packaged"; "aseptically packaging"; "aseptic packaging" — "packaged to the exclusion of microorganisms other than those carried by the liquid whole egg product." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[164]

"assaying a sample" — "detecting and quantifying a biochemical screening marker in a sample using a device and reagents designed for such purpose [a process which] changes the composition of the sample." *PerkinElmer, Inc., et al. v. Intema Ltd.*, 2010 U.S. Dist. LEXIS 66452 (D. Mass., Jul. 2, 2010).[165]

"assaying homocysteine in a sample" — "determining the amount or concentration of homocysteine in a sample." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[166]

"associates with" — "associates with, interacts with, binds to, or forms a complex with in a non-specific and charge-dependent manner." *Caliper Technologies Corp. v. Molecular Devices Corp.*, 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).[167]

"crystallizing the granulate to a density of at least 1.390 g/cm^3 under forced motion <u>at a temperature of 220 C to 260 C</u> under an inert gas atmosphere" — "the district court concluded and instructed the jury: 'In this [first] step [of the claimed process], "220 C to 260 C" is the temperature of the heating medium and not the temperature of the granulate or polymer.' Upon review of the entire record, ... this court sustains the trial court's claim interpretation." *Eastman Kodak Co., et al. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547 (Fed. Cir. 1997).[168] "I do not agree that the claim limitation 'crystallizing the granulate ... at a temperature of 220 C to 260 C' refers to the temperature of the heating medium. The claim is clear on its face, when read in light of the specification, that it refers to the temperature of the granulate." *Id.* (Lourie, J., dissenting).[169]

"at least a portion of" — "at least a part of." *Massachusetts Institute of Technology v. Imclone Systems, Inc.*, 498 F. Supp. 2d 435 (D. Mass. 2007).[170]

"at least about" — "equal to or more than approximately." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[171]

"at least about 95% by volume hydrogen" — "[should] be given its ordinary meaning, except that its lower limit is to be interpreted in light of the specification statements that 94% is marginally acceptable and 92% is unacceptable." *AK Steel Corp. v. Sollac, et al.*, 234 F. Supp. 2d 711 (S.D. Ohio 2002).[172]

"having <u>at least 25% water by weight</u>" — "25% or more of the weight of the contact lens in its hydrated state (at equilibrium conditions) is water." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[173]

"having an interfacial tension of <u>at least about 15.0 dynes per centimeter</u>" — "no less than 14.8 dynes per centimeter." *Minnesota Mining and Manufacturing Co., Inc. v. Beautone Specialties Co., Ltd., et al.*, 117 F. Supp. 2d 72 (D. Mass. 1999).[174]

"at least about 40 days" — "at least 40 days." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[175]

"at least an effective amount" — "a minimum dosage required." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[176]

"at least approximately 600 tpi" — "defines an open-ended range starting slightly below 600." *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577 (Fed. Cir. 1995).[177]

"at least three carbon atoms and an indicator molecule selected from the group consisting of fluorescent dyes, electron-dense reagents, enzymes which can be reacted with a substrate to produce a visually detectable reaction product, and radioisotopes" — "at least three carbon atoms and an indicator molecule selected from the group consisting of (i) fluorescent dyes, (ii) electron-dense reagents, (iii) enzymes which can be reacted with a substrate to produce a visually detectable reaction product, or (iv) radioisotopes." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[178]

"at specific locations thereon" — "means that the covalent bonds between the backbone chain and donor and acceptor dyes are predetermined and controlled by the method of synthesis rather than occuring in a random fashion." *Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp.*, 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).[179]

"atherosclerosis" — "a disease, symptom, or condition characterized by a progressive narrowing and hardening of the arteries." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[180]

"atomized precipitated silica particulates" — "mean[s] that a pulverized slurry of precipitated silica is spray dried using a liquid pressure nozzle as an atomizer to form the claimed silica particulates." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[181]

"attaching a plurality of oligonucleotides" — "affixing two or more oligonucleotides." *Oxford Gene Technology Ltd. v. Mergen Ltd., et al.*, 2004 U.S. Dist. LEXIS 19818 (D. Del., Sept. 29, 2004).[182]

"autism condition" — "a condition, feature, or symptom of autism." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[183]

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[i] "BRCA1"; [ii] "BRCA2" — [i] "refer[s] to a human gene, normally integrated into chromosome 17, some alleles of which cause susceptibility to breast and ovarian cancer"; [ii] "refer[s] to a human gene, normally integrated into chromosome 13, some alleles of which cause susceptibility to breast and ovarian cancer." *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.*, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y., Mar. 29, 2010).[184]

"Bacillus stearothermophilus alpha-amylase" — "the functional enzyme product that is produced from the alpha-amylase gene of a Bacillus stearothermophilus organism." *Novozymes A/S v. Genencor International, Inc., et al.*, 446 F. Supp. 2d 297 (D. Del. 2006).[185]

"backbone chain" — "the entire chain of atoms that separate the donor and acceptor dyes." *Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp.*, 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).[186]

"balance" — "aside from the other specified ingredients, including low molecular carbohydrates (or sugars) and chloride salts, and with the possible addition of colorants and thickeners, as well as incidental impurities or harmless ingredients associated with the commercial sources of the key components in the invention, the solution shall contain only water." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[187]

"based on the dried weight of the surface active material" — "mean[s] the dry weight of the lung surfactant extract material before it is combined with a pharmaceutical carrier." *Forest Laboratories, Inc., et al. v. Abbott Laboratories, et al.*, 1998 U.S. Dist. LEXIS 23171 (W.D.N.Y., Aug. 3, 1998).[188] "The Court notes that even if it were not bound to follow Judge Arcara's ruling, it would nonetheless apply the same claim construction--at least with respect to the meaning of the phrases 'surface active material' and 'based on the dry weight of the material.'" *Abbott Laboratories, et al. v. Dey, L.P., et al.*, 110 F. Supp. 2d 667 (N.D. Ill. 2000).[189] "We agree ... that the expression 'based on dry weight' means based on the dry weight of the surface active material before it is combined with a carrier to form a pharmaceutical composition. The surface active material may be part of a pharmaceutical composition, but it is a distinct component of that composition and must be evaluated independently of the pharmaceutical composition in order to determine if it meets the claim limitations to surface active material." *Forest Laboratories, Inc., et al. v. Abbott Laboratories, et al.*, 239 F.3d 1305 (Fed. Cir. 2001).[190]

"basicity equal to or greater than 50%" — "a basicity of equal to or greater than 50% for an aluminum polymer may be expressed chemically as $Al_n(OH)_mCl_{(3n-m)}$, the relative amount of hydroxyl [OH] ions compared to the amount of chloride [Cl] ions and hydroxide [OH] ions." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[191]

"said beads <u>being encoded with an encoding system</u>" — "said beads having a property associated with each bead (separate from the binding polymer) that can be used to distinguish one bead from another." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[192]

"said fibers <u>being uniformly treated</u> with a durable flame retardant of a prepolymer of urea and tetrakis (hydroxymethyl) phosphonium salt which has been applied, ammoniated and oxidized in a manner such that" — "We agree ... that this portion of the claim language refers to a process limitation, rather than a characteristic of the resulting product. ... this court concludes that the phrase 'uniformly treated' refers to a process, but does not require construction." *Itex, Inc., et al. v. Westex, Inc., et al.*, 2010 U.S. Dist. LEXIS 72685 (N.D. Ill., Jul. 20, 2010).[193]

"below limits for imparting smoke flavoring to food" — "The Court here agrees with HISI that the numerical ranges described in the background art may not be read into this particular limitation." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[194]

"a beneficial amount of methylsulfonylmethane" — "the district court's construction of 'a beneficial amount of methylsulfonylmethane' as meaning 'any nonzero amount of methylsulfonylmethane that does not occur naturally in food actually eaten by an animal' ... misses the implication of the word 'beneficial' that the amount must 'promote a favorable result' for the animal." *MSM Investments Co. LLC v. Carolwood Corp., et al.*, 259 F.3d 1335 (Fed. Cir. 2001).[195]

"benzalkonium chloride" — "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C_6H_5-CH_2-NR $(CH_3)_2Cl$, wherein R is C_8H_{17} to $C_{18}H_{37}$." *Novartis Pharmaceuticals Corp., et al. v. Apotex Corp., et al*., 2006 U.S. Dist. LEXIS 10130 (S.D.N.Y., March 13, 2006).[196]

"the besylate salt of amlodipine" — "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt." *Pfizer Inc. v. Synthon Holdings BV, et al.*, 2006 U.S. Dist. LEXIS 10532 (M.D.N.C., March 7, 2006);[197] *Id.,* 2006 U.S. Dist. LEXIS 63063 (M.D.N.C., Aug. 31, 2006).[198]

"between about 3% and about 10%" — "an amount equal to between [reasonably close to] 3% and [reasonably close to] 10%." *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, et al.*, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).[199]

"wherein the length of HPV 52 DNA is <u>between approximately 15 and 8000 nucleotide bases</u>" — "between 15 and approximately 8000 nucleotide bases." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[200]

"bibulous material" — "any material which is able to readily take up fluids or moisture." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[201]

"immunosorbing zone comprising mip non-diffusively bound to at least a portion of <u>a bibulous support serving as an inlet port for liquids into said device</u>" — "cover[s] an immunoassay method where the test solution must enter the immunosorbing zone before proceeding to the liquid absorbing zone, but not all of the solution must necessarily come into contact with mips while in the immunosorbing zone." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[202]

"natural or synthetic <u>binder</u>" — "a substance that holds materials together either by itself or after the materials are processed." *Profile Products LLC v. Encap, LLC*, 2009 U.S. Dist. LEXIS 60282 (W.D. Wis., Jul. 15, 2009).[203]

"binder [for a ligand]" — "a composition of matter that is capable of binding to a ligand. The Court does not construe the term 'binder for a ligand' to require a protein that 'specifically' binds with a ligand; therefore, Acon's devices infringe regardless of whether they use specific binders." *Inverness Medical Switzerland GmbH, et al. v. Acon Laboratories, Inc.*, 323 F. Supp. 2d 227 (D. Mass. 2004).[204]

"each granule consisting essentially of at least one pigment selected from the group consisting of manganese oxide and iron oxide and of at least one <u>binder for promoting the dispersal of the pigment in the concrete</u>" — "Claim 1 requires at least one binder for promoting the homogeneous dispersal of the pigment in the concrete. The '505 patent specification recognizes at least two types of binder mechanisms for promoting homogeneous dispersal. One is moisture-solubility of the binder. Another is susceptibility of the binder to breakdown by shear forces. There is no indication in Claim 1, the '505 patent specification, or in the prosecution history, that water-solubility of the binder is required. Accordingly, the Court finds that a granule that utilizes a binder that promotes homogeneous pigment dispersal either by moisture-solubility, being more susceptible to shear forces than prior art granules, or both, and otherwise satisfies Claim 1's elements, literally infringes the '505 patent." *LaPorte Pigments, Inc. v. Axel J., L.P.*, 2000 U.S. Dist. LEXIS 22302 (W.D. Mo., Aug. 18, 2000).[205] "[T]he term 'binder' describes a material, as shown by the numerous suitable binder materials listed in the '505 patent specification at col. 3, ll. 33-51, that connotes structure to those skilled in the art. Consequently, the presumption against application of § 112, P 6 has not been overcome." *Id.*, 44 Fed. Appx. 960 (Fed. Cir., Aug. 15, 2002) (unpublished).[206]

"binding component comprising multivalent metal ions associated therewith" — "a polycationic component that includes but is not limited to metallic ions, which are metal atoms or groups of atoms, bearing multiple electrical charges, and that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Further, the metallic ions are not limited to the non-exclusive list of Fe^{3+}, Ca^{2+}, Ni^{2+}, and Zn^{2+}, but may include other metal atoms or groups of atoms bearing multiple electrical charges." *Caliper Technologies Corp. v. Molecular Devices Corp.*, 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).[207]

"binds" — "refers to a degree of attachment that is immunologically significant, i.e. a degree of attachment that is (1) above background levels; (2) specific; (3) selective for cancer as opposed to normal cells and/or tissues; and (4) has a useful degree of affinity." *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002).[208]

"binds to a neutralizing epitope of human TNF-α in vivo with an affinity of at least 1 x 108 liter/mole, measured as an association constant (Ka), as determined by Scatchard analysis" — "results in a loss of biological activity when it binds to human TNF-α in vivo; and associates (binds) with human TNF-α with an affinity of at least 1 x 10&t;8&t; liter/mole as calculated using a method for data analysis known as a Scatchard analysis." *Centocor Ortho Biotech, Inc., et al. v. Abbott Laboratories, et al.*, 2009 U.S. Dist. LEXIS 28467 (E.D. Tex., Apr. 6, 2009).[209]

"bioavailability" — "the total exposure of the erythromycin derivative in the bloodstream as measured by the logarithm-transformed area under the plasma concentration-time curve, which is a mathematical and visual representation of the aggregate amount of the drug reaching systemic circulation over a given period of time. Bioavailabilty does not encompass both the rate and effect of release because extended release and immediate release formulations have different rates of release by definition." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[210]

"bioavailability" — "the term bioavailability is indefinite." *Aventis Pharma S.A., et al. v. Amphastar Pharmaceuticals, Inc., et al*., 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).[211]

"biodegradable" — "capable of being broken down in the human body by the action of microorganisms." *Lamoureux, et al. v. AnazaoHealth Corp., et al.*, 2009 U.S. Dist. LEXIS 103846 (D. Conn., Nov. 5, 2009).[212] "On reconsideration, the term 'biodegradable' ... is construed as 'capable of being broken down in the human body by natural biological processes.'" *Id.*, 2010 U.S. Dist. LEXIS 4976 (D. Conn., Jan. 22, 2010).[213]

"biodegradable articles" — "require no further claim construction." *MGP Ingredients, Inc. v. Mars, Inc., et al.*, 494 F. Supp. 2d 1231 (D. Kan. 2007).[214]

"bioequivalent" — "equivalent antagonistic effect." *King Pharmaceuticals, Inc., et al. v. Purdue Pharma L.P.*, 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).[215]

"biological polymers immobilized on a surface" — "two or more surface-immobilized biological polymers that are recognized by a particular target." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[216]

"biologically effective amount" — "an amount of active ingredient -- the 3-isothiazolone -- sufficient to obtain effective control of organisms or microorganisms when used or applied by methods such as spraying, fumigating, dusting, and soaking." *Rohm and Haas Co. v. Lonza Inc., et al.*, 997 F. Supp. 635 (E.D. Pa. 1998).[217]

"**biosynthetic**" — "mean[s] that the human growth hormone must be made by recombinant DNA techniques, consistent with its ordinary meaning." *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp*., 2004 U.S. Dist. LEXIS 14960 (D. Del., Aug.3, 2004).[218]

"biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone" — "'biosynthetic' requires that the human growth hormone be made by recombinant DNA techniques, and 'ripe' indicates that it has the 191 amino acid sequence identical to that of the hormone produced by the human pituitary gland, as well as the full biological activity of the human pituitary gland." *Novo Nordisk A/S, et al. v. Bio-Technology General Corp., Ltd., et al.*, 207 F. Supp. 2d 322 (D. Del. 2002).[219]

"block copolymer" — "refer[s] to an overall polymeric product, ... We conclude that the claims require the block copolymer molecules to contain at least two polymeric blocks that form a not insignificant and identifiable portion of the molecules. We also conclude that the use of the term 'block copolymer' precludes the product or composition from being a blend or a graft copolymer." *Phillips Petroleum Co. v. Huntsman Polymers Corp., et al.*, 157 F.3d 866 (Fed. Cir. 1998) (per curiam).[220]

"blocking nucleic acid" — "the record submitted in connection with Dako's motion is not developed enough to permit construction." *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 448 F. Supp. 2d 1145 (N.D. Cal. 2006).[221]

"blood serum HDL-cholesterol [level]"; "blood serum levels of HDL-cholesterol" — "amount of HDL-cholesterol in blood serum." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[222]

"blood serum LDL-cholesterol" — "amount of LDL-cholesterol in blood serum." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[223]

"blood serum lipids" — "substances found in blood plasma including, for example, triglycerides, cholesterols, or apolipoproteins." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[224]

"boiling point" — "the district court was incorrect in ruling that the codistillate boiling point is determined by measuring the temperature of the reaction mixture. Rather, the boiling point of the codistillate is properly measured in the vapor phase." *Dow Chemical Co. v. Sumitomo Chemical Co., Ltd., et al.*, 257 F.3d 1364 (Fed. Cir. 2001).[225]

"gasoline having a <u>boiling point range of 121 º - 345 º F at 1 atmosphere pressure</u>" — "[is] limited to gasolines having a final boiling point of 345 º F, and excluding gasolines having a higher final boiling point." *Talbert Fuel Systems Patents Co. v. Unocal Corp. Union Oil Co. of California, et al.*, 275 F.3d 1371 (Fed. Cir. 2002).[226]

"bronze" — "refers to the chemical composition of a particular metal and not how that metal conducts electricity." *Belden Wire & Cable v. Cable Design*, 2001 U.S. Dist. LEXIS 25800 (N.D. Ill., Mar. 23, 2001).[227] "Considering the evidence as a whole, the district court correctly concluded that the CDA Handbook defines the meaning of the term 'bronze' for purposes of the '001 patent." *Id.*, 35 Fed. Appx. 905 (Fed. Cir., May 14, 2002) (unpublished).[228]

"budesonide composition" — "budesonide dispersed in a solvent in the form of a solution or a suspension." *AstraZeneca LP, et al. v. Apotex, Inc., et al.*, 623 F. Supp. 2D 579 (D.N.J. 2009).[229]

"buffer" — "a solute that resists a change in pH of the reaction solution." *Roche Diagnostics Corp. v. Inverness Medical Technology Inc., et al.*, 186 F. Supp. 2d 914 (S.D. Ind. 2002).[230]

"concentrated phosphorous fertilizer comprising <u>a buffered composition</u>" — "simply require[s] that the concentrated composition be buffered. The buffering itself need not be provided by a separate agent." *Biagro Western Sales, Inc., et al. v. Grow More, Inc.*, 2001 U.S. Dist. LEXIS 26007 (E.D. Cal., Oct. 18, 2001).[231]

"bulk density" — "the mass-to-volume ratio of the calcium acetate composition immediately prior to compression, as measured by one of two methods set forth in the patent specifications." *Fresenius Medical Care Holdings, Inc. v. Paddock Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 107080 (D. Mass., Oct. 6, 2010).[232]

"bulk volume" — "is amenable to construction and is not indefinite. The court construes 'bulk volume' as the mathematical inverse of bulk density, and 'bulk density' as the mass of a unit volume of a powder including its pore volume and inter-particle voids, measured in its loose state using a Scott volumeter." *Superior Graphite Co. v. Timcal SA, et al.*, 2006 U.S. Dist. LEXIS 29935 (N.D. Ill., May 8, 2006).[233]

"burning a smoking material at 250 º to 400 º C" — "burning a smoking material in a chamber or other medium heated to a temperature between 250 º and 400 º C." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[234]

"by the addition of water" — "means that a quantity of water that was not present during steps 1 and 2 of the four step process must be deliberately and affirmatively placed into the mixture during step 3 (the 'crystallization' step), which takes place following the separation of organic salts from the reaction mixture. I agree with Defendants that there is no basis in the intrinsic evidence to suggest ... that the crystallization need only be 'facilitated' by water that happens to be present, rather than being deliberately put into the process." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 603 F. Supp. 2d 596 (S.D.N.Y. 2009).[235]

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"calcium orthophosphate" — "We need only determine whether the term 'calcium orthophosphate' in claim 1 of the 600 patent covers monocalcium orthophosphate or TSP. In regard to this limited question, we find that the term does not because those compounds were disclaimed during the prosecution of the patent application. We do not find it necessary to determine whether the term 'calcium orthophosphate' is limited to tricalcium orthophosphate." *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002).[236]

"can proliferate within the host" — "capable of increasing in quantity." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[237]

"an addition amount of the catalyst which is capable of raising the concentration of the catalyst from the lower concentration limit to the upper concentration limit" — "an amount of catalyst added to raise the concentration of the catalyst from the previously established lower boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) to the previously established upper boundary (but not necessarily the maximum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage)." *Intercat, Inc. v. Nol-Tec Systems, Inc., et al.*, 2005 U.S. Dist. LEXIS 344 (D. Minn., Jan. 7, 2005).[238]

"capable of transducing" — "the ability to introduce and integrate genetic information carried by a viral vector into a cell." *Sigma-Aldrich, Inc. v. Open Biosystems, Inc.*, 521 F. Supp. 2d 975 (E.D. Mo. 2007).[239]

"which have the capacity to infect some host and to be maintained therein, and the progeny thereof" — "requires that the recombinant DNA segments infect the progeny of the host cells, but not necessarily to be maintained therein." *Schering Corp., et al. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998).[240]

"caplet" — "a capsule-shaped tablet with sufficient integrity to survive insertion into the capsule delivery vehicle." *Fresenius Medical Care Holdings, Inc. v. Paddock Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 107080 (D. Mass., Oct. 6, 2010).[241]

"capsule" — "a capsule within a size range consistent with what a human patient with chronic renal failure can manipulate and swallow." *Fresenius Medical Care Holdings, Inc. v. Paddock Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 107080 (D. Mass., Oct. 6, 2010).[242]

"simulated capsule-like medicament" — "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell enclosing medicine." *McNeil-PPC, Inc. v. Bayer Corp.*, 2000 U.S. Dist. LEXIS 16431 (E.D. Pa., Nov. 7, 2000).[243]

"carbohydrate" — "must be construed to exclude carbohydrates derived from unrefined, inconsistent waste-streams." *Sears Ecological Applications Co., LLC v. MLI Associates, LLC*, 2009 U.S. Dist. LEXIS 78281 (N.D.N.Y., Sep. 1, 2009).[244]

"carbonate" — "include[s] both the carbonate and bicarbonate ions." *Schwarz Pharma, Inc., et al. v. Warner-Lambert Co., et al.*, 2004 U.S. App. LEXIS 1347 (Fed. Cir., July 29, 2004) (unpublished).[245] "There was no ambiguity and it is clear to me from the record that bicarbonate was not part of the definition of carbonate." *Id.* (Lourie, J., dissenting).[246]

"said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition" — "the composition used in dental bleaching in accordance with the claimed method contains from about 3.5% to about 12% by weight of carboxypolymethylene defined as a slightly acidic vinyl polymer with active carboxyl groups." *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., et al.*, 924 F. Supp. 1101 (D. Utah 1996).[247]

"carrier liquid" — "a liquid into which the active ingredients or agents are dispersed as a way of transferring those ingredients or agents so that the intended reaction can occur." *Maxma, et al. v. ConocoPhillips Inc.*, 2005 U.S. Dist. LEXIS 34020 (E.D. Tex., Jul. 19, 2005).[248]

"catalyst" — "a substance that alters the velocity of a chemical reaction without being consumed." *Atofina v. Great Lakes Chemical Corp.,* 441 F.3d 991 (Fed. Cir. 2006).[249]

"catalyzing material" — "a material used to help form bonds between adjacent crystals during the formation of the body of bonded diamonds." *Reedhycalog UK. Ltd., et al. v. United Diamond Drilling Services, Inc., et al.*, 2009 U.S. Dist. LEXIS 32959 (E.D. Tex., Apr. 15, 2009).[250]

"causes" — "The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[251]

"CDR-grafted" — "describe[s] a recombinant antibody where all six CDRs have been replaced with complete non-human CDRs." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[252]

"a prokaryotic or eukaryotic cell" — "applies to both prokaryotic and eukaryotic cells by virtue of the presence of the word 'or'." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[253]

"cells transformed or transfected with an isolated DNA sequence encoding human erythropoitein" — "cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al*., 494 F. Supp. 2d 54 (D. Mass. 2007).[254]

"cerebral ischemia" — "an imbalance of neuronal stimulation mechanisms." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[255] "[T]he court will adopt the Magistrate Judge's construction." *Id.*, 2009 U.S. Dist. LEXIS 86772 (D. Del., Sep. 21, 2009).[256]

"a channeling agent" — "a hydrophilic material (having a greater moisture transmission rate than the polymer based material) that is melted and forms passages throughout a polymer base." *Sud-Chemie, Inc. v. CSP Technologies, Inc.*, 2006 U.S. Dist. LEXIS 54873 (S.D. Ind., Aug. 4, 2006).[257]

"channels" — "solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior." *Sud-Chemie, Inc. v. CSP Technologies, Inc.*, 2006 U.S. Dist. LEXIS 54873 (S.D. Ind., Aug. 4, 2006).[258]

"characteristic of said allele" — "a trait, quality or property, or a group of them, distinguishing an individual, group, or type." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[259]

"characterizable by an efficiency equation" — "the synergistic combinations are determined from the efficiency equation." *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., et al.*, 163 F. Supp. 2d 426 (D. Del. 2001).[260] "Consistent with the intrinsic evidence, we construe the claim term 'characterizable by an efficiency equation' to mean 'capable of being described by an efficiency equation.'" *Id.*, 308 F.3d 1167 (Fed. Cir. 2002).[261]

"chelator of copper ions" — "does not exclude histidine." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 107 F. Supp. 2D 477 (D. Del. 2000).[262]

"an amount of a <u>chelator of copper ions sufficient to bind the copper ions ... protect the immunoglobulin ... and stabilize the ... composition</u>"; "an amount of chelator of copper ions sufficient to stabilize the ... composition" — "require that the 'chelator of copper ions' bind copper ions, and that such bonds protect and stabilize the antibody composition." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[263]

"a chemical label further comprising a signalling moiety" — "a chemical label including, but not limited to, a portion that provides a signal for detection." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[264]

"chemically active species" — "a chemical entity in an energetically reactive state." *Applied Science and Technology, Inc. v. Advanced Energy Industries, Inc.*, 204 F. Supp. 2d 712 (D. Del. 2002).[265]

"said film is <u>chemically bonded with a substrate</u>" — "a chemical bond (i.e., the attractive force that holds together atoms in molecules and crystalline salts) is formed between at least a portion of the film and at least a portion of an adjacent, underlying material." *Collins, et al. v. Gillette Co.*, 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).[266]

"chemically embossing the portion"; "a chemically embossed portion" — "refers to areas depressed after curing is completed as a result of the application of a 'regulator,' 'inhibitor,' 'retarder,' or similar chemical compound to those areas regardless of how patterned the appearance." *Mannington Mills, Inc., et al. v. Armstrong World Industries, Inc., et al.*, 2002 U.S. Dist. LEXIS 18641 (D. Del., Aug. 20, 2002).[267]

"chimeric" — "describes an antibody in which the non-human constant domains are replaced by equivalent domains of human origin, and any additional modifications are only for the purposes of improving the antigen binding ability or altering the effector functioning." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[268]

"Chinese hamster ovary cell" — "a cultured eucaryotic cell originating from the ovary of a Chinese hamster." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[269]

"wherein said cells are <u>CHO cells</u>" — "a cell from the ovary of a Chinese hamster." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al.*, 494 F. Supp. 2d 54 (D. Mass. 2007).[270]

"chromatographic separation" — "a method for separation of the components of a sample, in which the components are distributed between two phases, one of which is stationary while the other moves." *General Atomics, et al. v. Axis-Shield ASA,* 2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[271]

"chromosome DNA fragment of a donor bacterium" — "We discern no error in the district court's finding that the fact that a DNA fragment was subsequently inserted into a plasmid does not change its origin in a donor bacterium." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338 (Fed. Cir. 2000).[272]

"chromium" — "the chromium ion portion of the chemical compound chromic tripicolinate." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[273]

"chromium catalyst" — "a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium without the addition of metal oxides, alkali metal fluorides, or non-inert additives. A substance is catalytically active if it contributes to the catalysis of a reaction. Being catalytically active does not require a substance to catalyze a reaction on its own." *Atofina v. Great Lakes Chemical Corp*., 2005 U.S. Dist. LEXIS 7365 (D. Del., March 16, 2005);[274] "we also agree with its construction of 'chromium catalyst' as a catalyst where the only catalytically active material is chromium without the addition of metal oxides or non-inert additives." *Id.*, 441 F.3d 991 (Fed. Cir. 2006).[275]

"chromic tripicolinate"; "chromic picolinate" — "a chemical compound containing one chromium ion and three picolinate ions." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[276]

"chromosomally integrated" — "the district court did not err in construing this claim term to require the introduction into a host cell of exogenous sequences encoding alpha-Gal A." *Genzyme Corp., et al. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094 (Fed. Cir. 2003).[277] "The majority opinion establishes that the term 'chromosomally integrated' could be used in reference to the incorporation into a chromosome of either endogenous or exogenous DNA, that is to say, DNA sequences that have their origin either inside or outside the cell to which the chromosome is native. The ordinary and customary meaning of the term broadly encompasses both possibilities. It is incorrect to perceive a claim term as ambiguous merely because of its breadth and to require that the term be redefined to encompass only a portion of its ordinary meaning in the name of clarity." *Id.* (Linn, J., dissenting-in-part).[278]

"chromosome DNA fragment" — "is limited to DNA from a chromosome, and does not include DNA fragments from either plasmids or bacteriophages." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co*., 1996 U.S. Dist. LEXIS 15989 (D. Del., Oct. 21, 1996).[279]

"chronic inflammatory condition" — "an inflammatory condition lasting for days to weeks or longer, and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue." *Research Foundation of State University of New York, et al. v. Mylan Pharmaceuticals, L.P.*, 2010 U.S. Dist. LEXIS 46791 (D. Del., May 12, 2010).[280]

"citalopram" — "include[s] 'the S-enantiomer, the R-enantiomer, the racemate, or any other mixture of enantiomers.'" *Infosint, S.A. v. H. Lundbeck A/S, et al.*, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).[281]

"citramalic acid" — "any form of citramalic acid, including citramalic acid, 2-hydroxy-2-methylbutanedioic acid, methylmalic, 2-methylmalic acid, 3-methylmalic acid, 2-hydroxy-3-methyl-butanedioic acid, methylmalate, 2-methylmalate, and 3-methylmalate." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[282]

"emergency fuel providing clean and smooth operation of the internal combustion engine" — "is limited to an emergency fuel having an octane rating of at least 86." *Emergency Fuel, LLC, et al. v. Penzoil-Quaker State Co.*, 71 Fed. Appx. 826 (Fed. Cir., Jul. 25, 2003).[283]

"C_{min}" — "There is no indication from the intrinsic evidence as to how C_{min} should be measured. The extrinsic evidence presented by the parties indicates that one of ordinary skill in the art could use several different methods to calculate C_{min} when the patents were filed. Since measurement of C_{12} occurs 12 hours after dosing, and the claimed mean minimum plasma concentration is measured between the range of 10 to 14 hours, C_{12} (and correspondingly T_{12}) falls within the range of 10 to 14 hours - therefore, the claims do not exclude using C_{12} as C_{min}. Measuring C_{min} as the average of C_0 and C_{12} for a 12-hour formulation also falls within the claimed range since C_0 is at the end of a dosing interval during steady state and C_{12} is the end of the subsequent dosing interval." *Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al.*, 2004 U.S. Dist. LEXIS 10 (S.D.N.Y., Jan. 5, 2004).[284]

"co-micronized" — "mean[s] that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients." *Abbott Laboratories, et al. v. Novopharm Ltd., et al.*, 2002 U.S. Dist. LEXIS 4659 (N.D. Ill., March 19, 2002).[285] "Fournier and Abbott argue on appeal that the district court erred by construing the claim term 'co-micronization' to require micronization of fenofibrate and solid surfactant 'in the absence of other excipients.' ... We disagree." *Id.*, 323 F.3d 1324 (Fed. Cir. 2003).[286]

"coagulate" — "to become a soft, semi-solid mass." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[287]

"coat of Aloe Vera" — "a coating that may include ingredients other than aloe vera but the aloe vera must account for more than 0.5% of the entire coating." *Shen Wei, et al. v. Ansell Healthcare Products, Inc.*, 2004 U.S. Dist. LEXIS 7717 (N.D. Ill., Apr. 30, 2004).[288]

"completely coated" — "means what it says - the pigment must be 100% coated." *Revlon Consumer Products Corp. v. Estee Lauder Co., Inc., et al.*, 2003 U.S. Dist. LEXIS 13004 (S.D.N.Y., Jul. 30, 2003).[289]

"the core being coated with a rate-controlling polymer coat" — "does not require construction." *King Pharmaceuticals, Inc., et al. v. Sandoz Inc.*, 2010 U.S. Dist. LEXIS 105061 (D.N.J., Oct. 1, 2010).[290]

"coating" — "include[s] coatings or layers." *Maxwell Technologies, Inc. v. Nesscap, Inc., et al.*, 508 F. Supp. 2d 837 (S.D. Cal. 2007).[291]

"coating said interior wall of said container with a Lewis acid inhibitor" — "to cover or spread the interior of the container with a finishing, protecting, or enclosing layer composed of any compound that interacts with the empty orbital of a Lewis acid." Abbott Laboratories, et al. v. Baxter Healthcare Corp., 2009 U.S. Dist. LEXIS 85441 (N.D. Ill., Sep. 17, 2009).[292]

"codons preferred" — "does not refer to the codons that are most frequently occurring for each individual amino acid. Rather, a codon is 'preferred' if its addition to the native gene makes its frequency in that gene more like the frequency of that codon in the gene of the intended plant host." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[293] "[T]he district court's claim construction regarding the 'greater number of codons preferred' limitation was correct." *Id.*, 243 F.3d 1316 (Fed. Cir. 2001).[294]

"coextrudate of cojoined layers" — "cover[s] a coextrudate which is a facestock, or plastic film, formed solely by simultaneous, or joint, extrusion of several materials through a die. The immediate result of this simultaneous extrusion, or coextrusion, is a multilayer film wherein the layers are firmly adhered to one another in a permanently combined state, i.e., the patented coextrudate. A facestock formed by adhering preformed layers is not within the scope of claims." *Avery Dennison Corp. v. UCB Films PLC.*, 1997 U.S. Dist. LEXIS 13594 (N.D. Ill., Sept. 3, 1997).[295]

"a first collection of labeled nucleic acid" — "multiple nucleic acid molecules labeled with a first label." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[296]

"colloidal gold particles coupled to the bound target compound" — "one or more gold nanoparticles directly or indirectly linked to the target compound bound to the capture molecule." *Eppendorf AG, et al. v. Nanosphere Inc.*, 2010 U.S. Dist. LEXIS 69072 (D. Del., Jul. 12, 2010).[297]

"colloidal silica sol" — "a dispersion of silica particles, as defined above, in a liquid." *Ondeo Nalco Co. v. Eka Chemicals, Inc.*, 2003 U.S. Dist. LEXIS 4443 (D. Del. 2003).[298]

"colloidal silicic acid" — "a dispersion of silica particles, as defined above, or polysilicic acid in liquid." *Ondeo Nalco Co. v. Eka Chemicals, Inc.*, 2003 U.S. Dist. LEXIS 4443 (D. Del. 2003).[299]

"a color concentrate for coloring thermoplastic polymeric materials" — "the preamble recites a limitation on Claim 5 of the Burlone patent, which is directed to color concentrates for coloring thermoplastic polymeric materials." *E.I. Dupont de Nemours and Co. v. Monsanto Co.*, 903 F. Supp. 680 (D. Del. 1995).[300]

"colorant" — "a substance used for coloring a material: dye, pigment." *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, et al.*, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).[301]

"colorant" — "a substance or material, whether inherent in or separately added to the specified composition, which imparts color to the composition." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[302]

"combinatory immixture" — "require[s] the two ingredients in a single form such as a tablet or elixir." *Richardson-Vicks Inc. v. Upjohn Co., et al.*, 122 F.3d 1476 (Fed. Cir. 1997).[303]

"a comparison of said plurality of probe intensities to each other" — "an examination of the probe intensities of two or more probes in relation to each other." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[304]

"competitively inhibits binding of A2 (ATCC Accession No. PTA- 7045) to human TNF-α" — "competes with A2 (ATCC Accession No. PTA-7045) for binding to human TNF-α." *Centocor Ortho Biotech, Inc., et al. v. Abbott Laboratories, et al.*, 2009 U.S. Dist. LEXIS 28467 (E.D. Tex., Apr. 6, 2009).[305]

"is complementary to a ribonucleotide sequence transcribed from said gene" — "requires the bases of the two RNA strands to precisely or exactly pair together according to the base pairing rules for RNA, such that complete complementarity exists between the two strands." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[306]

"a completely mixed granular material" — "The Court does not agree that the word 'uniformly' is what is meant by 'completely.' Those two words have different meanings and are used in different places in the patent documents to convey specific, not synonymous, meanings." *Harsco Corp. v. North Star Bluescope Steel, LLC*, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).[307]

"complex"; "hexamer"; "formulation" — "The Court essentially adopts Novo's definition of 'complex' and holds that the term 'complex,' as used in the claims (claims 1 and 12), is an individual molecular structure, i.e., 'a chemical association state of two or more molecules held together by non-covalent bonds.' Next, the Court essentially adopts Novo's definition of 'formulation' and holds that 'formulation,' in claims 2-11 and 13, means 'an equilibrium containing molecules and molecular structures.' Finally, the Court essentially adopts both Novo's and Lilly's definitions of 'hexamer,' holding that the term 'hexamer' means different things in different contexts so that 'complex is a hexamer' in claims 1 and 12 and 'Lys<B28>Pro<B29>-human insulin is a hexamer' in claim 13 mean different things. In claims 1 and 12, because it is being used in the context of individual molecules and their structure, the term 'hexamer' refers to the Zn-hIA structure, i.e. 'a type of complex where six molecules of human insulin analog are held together in a single structure.' In claim 13, because it is being used in the context of a 'formulation,' which is an equilibrium, the phrase 'LysPro-human insulin is a hexamer' is shorthand meaning 'in the equilibrium, most of the LysPro-human insulin molecules are in Zn-hIA structures.'" *Novo Nordisk A/S, et al. v. Eli Lilly and Co.*, 1999 U.S. Dist. LEXIS 18690 (D. Del., Nov. 18, 1999).[308]

"complex carbohydrates" — "a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratan sulfate and acemannan, for example." *Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc*., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).[309]

"component" — "a discrete polymer, metal, ceramic or combination of those materials; in liquid, solid, or particulate form; that differs in some chemical or physical property from the other component(s) present in the dispersion; is capable of forming an alloy upon exposure to radiation; and is not already alloyed with the other component(s)." *ImageCube LLC v. Boeing Co. MTS Systems Corp.*, 2009 U.S. Dist. LEXIS 63003 (N.D. Ill., Jul. 22, 2009).[310]

"composed of" — "we think that 'composed of' in this case should be interpreted in the same manner as 'consisting essentially of.' Under this approach, the transition phrase 'composed of' 'excludes ingredients that would materially affect the basic and novel characteristics of the claimed composition.'" *AFG Industries, Inc., et al. v. Cardinal IG Co., et al.*, 239 F.3d 1239 (Fed. Cir. 2001).[311]

"composite composition" — "a solid pellet or a solid linear extrudate, which may subsequently be remelted and extruded to make a structural member." *Andersen Corp. v. Fiber Composites, LLC*, 2002 U.S. Dist. LEXIS 6233 (D. Minn., Apr. 9, 2002).[312]

"composition" — "a physical mixture of CIPC and a substituted naphthalene existing together at approximately the same time. The mixture may be a pre-mixture, i.e., a mixture that comes into being well before being used for sprout suppression, or a mixture that is formed at any time during use, such as through simultaneous application of the constituent chemicals, as long as a mixture is indeed formed." *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235 (Fed. Cir. 2002).[313]

"composition" — "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[314]

"potassium bromate replacer composition" — "the 'composition' may occur within the dough, with the result meeting the requirement that it 'contain[] the specified ingredients at any time from the moment the ingredients are mixed together.'" *Kim v. Earthgrains Co., et al.*, 2005 U.S. Dist. LEXIS 342 (N.D. Ill., Jan. 10, 2005).[315]

"porcelain composition comprising: SiO_2 [in] 57-66 [wt. %,] Al_2O_3 [in] 7-15 [wt. %] ..." — "the Court construes claim 1 as being limited to the exact weight percentage ranges for its chemical components." *Jeneric/Pentron, Inc. v. Dillon Co. Inc., et al.*, 1999 U.S. Dist. LEXIS 6990 (D. Conn., Feb. 3, 1999).[316]

"immunoglobulin composition of IgG 1 containing copper ions"; "a starting composition comprising: i) IgG 1 and ii) copper ions" — "a mixture containing IgG 1 immunoglobulin that can include other substances." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[317]

"a compound" — "a chemically distinct substance formed by union of two or more ingredients (as elements) in definite proportion by weight and definite structural arrangement." *Aventis Pharma Deutschland GMBH, et al. v. Lupin Ltd., et al*., 2006 U.S. Dist. LEXIS 31960 (E.D. Va., May 11, 2006).[318]

"compound" — "the word 'compound' and the accompanying chemical formula comprise a broad compound claim to even a single molecule with that chemical structure." *Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al*., 348 F. Supp. 2d 713 (N.D. Va. 2004).[319]

"compound" — "cover[s] only synthetic sulphenamides." *In re Omeprazole Patent Litigation*, 2001 U.S. Dist. LEXIS 7103 (S.D.N.Y., May 29, 2001).[320]

"compound ..." — "synthetically produced TAM." *Marion Merrell Dow, Inc., et al. v. Baker Norton Pharmaceuticals, Inc*., 948 F. Supp. 1050 (S.D. Fla. 1996).[321]

"compression mixture" — "one mass containing two or more ingredients that are compressed into a tablet." *McNeil-PPC, Inc., et al. v. Perrigo Co., et al*., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).[322]

"comprising" — "raises a presumption that the list of elements is nonexclusive. ... [However,] the presumption raised by the term 'comprising' does not reach into each of the six steps to render every word and phrase therein open-ended." *Dippin' Dots, Inc., et al. v. Mosey, et al*., 476 F.3d 1337 (Fed. Cir. 2007).[323]

"comprising" — "The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps. ... Thus, while the process described by claims 1 and 17 of the '827 patent does not require the presence of a tertiary amine, it certainly cannot be read to exclude it." *Medichem, S.A. v. Rolabo, S.L*., 353 F.3d 928 (Fed. Cir. 2003).[324]

"comprising" — "is inclusive or open-ended and does not exclude additional, unrecited elements or method steps." *Georgia-Pacific Corp. v. U.S. Gypsum Co., et al.*, 195 F.3d 1322 (Fed. Cir. 1999).[325]

"comprising" — "containing the named elements." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al*., 494 F. Supp. 2d 54 (D. Mass. 2007).[326]

"comprising a copolymer ... of lactic acid and ... of glycolic acid" — "include[s] copolymers composed of lactic acid and glycolic acidmers produced by any method, including the use of lactide and glycolide." *Tap Pharmaceutical Products, Inc., et al. v. Owl Pharmaceuticals, L.L.C., et al.,* 419 F.3d 1346 (Fed. Cir. 2005).[327]

"ethylene polymer ... <u>comprising a linear polymer fraction</u>" — "a heterogeneously branched ethylene polymer containing a polymer fraction that is neither highly branched nor medium branched." *Dow Chemical Co. v. Nova Chemicals Corp.*, 629 F. Supp. 2d 397 (D. Del. 2009).[328]

"a DNA segment <u>comprising a segment of said gene</u>" — "this element [] require[s] that the nonnative DNA construct must contain a DNA segment which includes a portion of the targeted gene." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[329]

"comprising at least ..., wherein said portion consists of ..." — "The reasonable interpretation of the claims containing both of the terms 'comprising' and 'consists' is that the term 'consists' limits the 'said portion' language to the subsequently recited numbered nucleotides, but the earlier term 'comprising' means that the claim can include that portion plus other nucleotides." *In re Crish, et al.*, 393 F.3d 1253 (Fed. Cir. 2004).[330]

"comprising incorporating an admixture comprising mixtures of" — "and also an admixture including, but not limited to." *SKW Americas, et al. v. Euclid Chemical Co.*, 231 F. Supp. 2d 626 (N.D. Ohio 2002).[331]

"fraction <u>comprising sucrose</u>" — "a fraction that includes sucrose and may also include other dissolved components." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[332]

"skin medication ... <u>comprising two gels adapted to be simultaneously applied and mixed in situ and to adhere on the skin or lesion surface to be treated</u>" — "the district court properly construed the term 'comprising two gels' to mean two separate and distinct gels prior to mixing." *Alcide Corp. v. ABS Global, Inc., et al.*, 2000 U.S. App. LEXIS 29610 (Fed. Cir., Nov. 22, 2000) (unpublished).[333]

"A comprises at least three carbon atoms and represents at least one component of a signalling moiety capable of producing a detectable signal" — "A comprises at least three carbon atoms and is one or more parts of a signalling moiety, which includes, in some instances, the whole signalling moiety." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[334]

"concentrate" — "a substance which is extracted from the leaves of the Banaba plant (Lagerstroemia speciosa, Linn. or Pers.) and which is concentrated." *Use Techno Corp., et al. v. Kenko USA, Inc., et al.*, 2007 U.S. Dist. LEXIS 55599 (N.D. Cal., July 24, 2007).[335]

"a concentrated phosphorus fertilizer" — "a concentrated fertilizer that contains phosphorus." *Regents of the University of California, et al. v. Actagro, LLC*, 102 Fed. Appx. 681 (Fed. Cir., Jun. 9, 2004) (unpublished).[336]

"concentration" — "the act of process of concentrating a chemical compound (or group of chemical compounds) in relation to other chemical compounds (or groups of chemical compounds)." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[337]

[i] "an upper concentration limit for the catalyst which is capable of producing the desired performance from the FCC unit"; [ii] "a lower concentration limit for the catalyst which is capable of producing the desired performance from the FCC unit" — [i] "an upper boundary (but not necessarily the maximum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) that is capable of producing the desired performance from the FCC unit"; [ii] "a lower boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) that is capable of producing the desired performance from the FCC unit." *Intercat, Inc. v. Nol-Tec Systems, Inc., et al.*, 2005 U.S. Dist. LEXIS 344 (D. Minn., Jan. 7, 2005).[338]

"concomitant administration" — "simultaneous administration." *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).[339]

"condensation" — "the formation of liquid from vapor." *ASM America, Inc. v. Genus, Inc.*, 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).[340]

"a chromatographic simulated moving bed system having at least three chromatographic columns connected in series and adapted for the flow of liquids in a single direction through the columns" — "multiple columns that form a SMB system as it is used in the claim such that all the columns in the system are connected in series so as to form a loop." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[341]

"consisting essentially of" — "[limits] these claims to be limited to genetic constructs (i.e., 'plasmids' and 'transfer vectors') and microorganisms from which human PI is directly expressed." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997).[342]

"consisting essentially of" — "denote[s] that the claim necessarily includes the listed ingredients or steps and is open to unlisted ingredients or steps that do not materially affect the basic and novel properties of the claim." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[343]

"consisting essentially of" — "the invention necessarily includes the listed components and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim." *Use Techno Corp., et al. v. Kenko USA, Inc., et al.*, 2007 U.S. Dist. LEXIS 55599 (N.D. Cal., July 24, 2007).[344]

"consisting essentially of" — "containing no matter other than chromium picolinate that materially affects the basic and novel characteristics of the claimed method." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[345]

"consisting essentially of aluminum" — "permit[s] only up to about 0.5% silicon." *AK Steel Corp. v. Sollac, et al.*, 344 F.3d 1234 (Fed. Cir. 2003).[346]

"consisting essentially of iron" — "the claimed invention necessarily includes iron and is open to unlisted ingredients that do no materially affect the basic and novel properties of the invention and that the claimed invention must necessarily contain material which is more than 90% reduced from iron oxide to elemental iron." *Bayer AG v. Sony Electronics, Inc.*, 229 F. Supp. 2d 332 (D. Del. 2002).[347]

"consisting essentially of ... one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25 ºC and an atmospheric humidity of 50% for one year" — "the Court construes clause (ii) of claim 7 to exclude the eight lactam-promoting adjuvants listed in the specification as those that should be avoided." *In re Gabapentin Patent Litigation*, 2005 U.S. Dist. LEXIS 37634 (D.N.J., Aug. 25, 2005).[348]

"consisting essentially of [particulate glass, which glass has individual particle sizes in the range of] from about 355 to about 710 µm" — "is amenable to infringement actions against compositions which not only contain particles within the size range of 355 to 710 µm ..., but which also contain particles with sizes smaller than 355 µm. However, the Court also concludes that the presence of substantially more than one-third of a composition's particles below the range cited in Claim 1 would ... would remove the composition from infringement." *University of Florida Research Foundation, Inc., et al. v. Orthovita, Inc., et al.*, 1998 U.S. Dist. LEXIS 22648 (N.D. Fla., Apr. 20, 1998).[349]

"consisting of" — "does not exclude additional components or steps that are unrelated to the invention." *Conoco, Inc., et al. v. Energy & Environmental International, L.C., et al*., 460 F.3d 1349 (Fed. Cir. 2006).[350]

"consisting of" — "while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004).[351]

"consisting of" — "indicates closed claim language and closes the claim to the inclusion of unrecited elements, except for impurities ordinarily associated therewith." *Novo Nordisk A/S, et al. v. Eli Lilly and Co.*, 1999 U.S. Dist. LEXIS 18690 (D. Del., Nov. 18, 1999).[352]

"consisting of a cyclic peptide" — "The parties dispute whether this language limits the claim to exactly one cyclic peptide. The Court concludes that it does." *INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, et al.*, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009).[353]

"the first layer <u>consisting of opioid antagonist</u>" — "the first layer contains only the opioid antagonist and other ingredients unrelated to the invention." *King Pharmaceuticals, Inc., et al. v. Purdue Pharma L.P.*, 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).[354]

"consists essentially of" — "excludes the addition of any component B, a solubilizer." *BASF Corp. v. Eastman Chemical Co.*, 1998 U.S. Dist. LEXIS 23054 (D. Del., Mar. 24, 1998).[355]

"consists of all or a fragment of an HPV DNA" — "all or a fragment of one HPV DNA and does not contain any other DNA." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[356] "Nothing in the court's construction suggests or requires exclusion of mutations or subtypes. If the HPV genome from which the HPV 52 DNA must come contains mutations, those mutations will be found in the HPV 52 DNA and will be covered by the claim." *Id.*, 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).[357] "We [] affirm the district court's construction of 'consists of all or a fragment of an HPV DNA' as meaning 'consists of all or a fragment of one HPV DNA that does not contain any other DNA.' We [also] agree with Third Wave that the district court's claim constructions do not exclude possible mutations or subtypes." *Id.*, 323 Fed. Appx. 902 (Fed. Cir., Apr. 1, 2009).[358]

"fraction which <u>consists principally of betaine</u>" — "a fraction consisting of a commercially significant amount of betaine such that the fraction will not materially affect the characteristics of processes described in Figure 1 of the '430 patent." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[359]

"constituents" — "include ingredients of the deicing and anti-icing composition specified." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[360]

"contacting said assay device in a predetermined order with: (a) a solution of a sample suspected of containing said analyte; and (b) a solution components of said signal producing system" — "requir[es] the immunoassay to be contacted with at least two separate components, though those two components may be combined in one solution." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[361]

"contacting said sample with a homocysteine converting enzyme and at least one substrate for said enzyme other than homocysteine" — "joining the sample with a homocysteine converting enzyme and a substrate for the enzyme other than homocysteine prior to the conversion of homocysteine by said enzyme. 'Joining' includes the activation of an inactive homocysteine converting enzyme already present with the sample." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[362]

"containing a mixture of lipid and solid ingredients" — "a composition wholly of lipids and solid ingredients." *Kal Kan Foods, Inc. v. H.J. Heinz Company, L.P., et al.*, 2004 U.S. Dist. LEXIS 16808 (C.D. Cal., Feb. 5, 2004).[363] "[T]he term 'ingredients,' as used in the phrase 'a mixture of lipid and solid ingredients,' refers to the components of the inner component at any time after they have been mixed together. This would include, but is not limited to, the ingredients as found in the final food product. ... [T]he 'containing a mixture of lipid and solid ingredients' limitation does not exclude the presence of additional, unnamed ingredients in the inner component of the claimed invention. The district court's construction to the contrary was erroneous." *Mars, Inc. v. H.J. Heinz Co., L.P., et al.*, 377 F.3d 1369 (Fed. Cir. 2004).[364]

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"treating composition containing the materials released by platelets during the platelet release reaction" — "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components." *Cytomedix, Inc. v. Little Rock Foot Clinic, P.A.*, 2004 U.S. Dist. LEXIS 4804 (N.D. Ill., Mar. 23, 2004),[365] "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components." *Harvest Technologies Corp. v. Cytomedix, Inc.*, 2004 U.S. Dist. LEXIS 18003 (D. Mass., Sept. 9, 2004).[366]

"the phenyl group contains at least one substitutent chosen from the group consisting of: [...]" — "means that the phenyl group contains at least one substituent (and up to five), all of which must be chosen from the enumerated group (a)-(k)." *Dow Agrosciences LLC v. Crompton Corp., et al.*, 2004 U.S. Dist. LEXIS 8532 (S.D. Ind., May 12, 2004);[367] "we agree with the district court ... the phrase 'the phenyl group contains at least one substituent chosen from the group consisting of: . . . ' requires that all substituents on the phenyl group be chosen from the enumerated list." *Id.*, 2006 U.S. App. LEXIS 11320 (Fed. Cir., May 5, 2006) (unpublished).[368]

[i] "method of contraception"; [ii] "oral contraceptive unit" — [i] "a means or manner that effectively prevents conception or impregnation (with contraceptive efficacy comparable to approved or potentially approvable oral contraceptive products)."; [ii] " a plurality of oral contraceptive pills assembled in a package that will allow women of child bearing ability to effectively prevent conception for at least a four week interval or one cycle." *Ortho-McNeil Pharmaceutical Inc., et al. v. Barr Laboratories, Inc.*, 2005 U.S. Dist. LEXIS 46932 (D.N.J., Apr. 19, 2005).[369]

"control region" — "functional control elements involved in the production of a protein and is directed to a sequence of DNA, not a method for constructing such a sequence." *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761 (Fed. Cir. 2002).[370]

"the amount of protic material in step (b) is controlled" — "the amount is controlled so that it is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H_2O based on the volume of the reaction mixture when aniline is utilized as the solvent." *Flexsys America LP v. Kumho Tire U.S.A., Inc., et al.*, 2010 U.S. Dist. LEXIS 10761 (N.D. Ohio, Feb. 8, 2010).[371]

"controlled amount" — "an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H_2O based on the volume of the reaction mixture when aniline is utilized as the solvent." *Sinorgchem Co., et al. v. International Trade Commission, et al.*, 511 F.3d 1132 (Fed. Cir. 2007).[372] "No error has been shown in the Commission's conclusion that 'controlled amount' is not limited to 4%." *Id.* (Newman, J., dissenting).[373] "The Court finds ... no reason to stray beyond the Federal Circuit's decision." *Flexsys America LP v. Kumho Tire U.S.A., Inc., et al.*, 2010 U.S. Dist. LEXIS 10761 (N.D. Ohio, Feb. 8, 2010).[374]

"controlled release" — "the trial court properly held that the term should be given its customary and ordinary meaning--that oxycodone is released in a controlled manner over an extended period of time." *Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al.*, 438 F.3d 1123 (Fed. Cir. 2006).[375]

"controlled release formulation" — "component of a dosage form that provides a release of an active ingredient, which is altered from the release provided by an immediate release formulation." *Janssen, L.P., et al. v. Barr laboratories, Inc., et al.*, 2009 U.S. Dist. LEXIS 12676 (D.N.J., Feb. 19, 2009).[376]

"controlled release oxycodone formulation"; "controlled release dosage formulation" — "require controlling pain relief in 90% of patients with a four-fold dosage range." *Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al.*, 2004 U.S. Dist. LEXIS 10 (S.D.N.Y., Jan. 5, 2004).[377]

"a controlled sustained release tablet comprising an admixture of bupropion hydrochloride and HPMC" — "describ[es] a specific polymer, HPMC, that is blended with bupropion hydrochloride to form an admixture. The addition of HPMC serves to retard the release of bupropion hydrochloride into the bloodstream." *Smithkline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, 214 F. Supp. 2d 581 (E.D. Va. 2002).[378]

"controlling an immunizable disease" — "the district court correctly construed this part of the claim to require only that the vaccine injected is known to be effective, but not that every inoculation into an egg actually confers immunity." *Embrex, Inc. v. Service Engineering Corp., et al.*, 216 F.3d 1343 (Fed. Cir. 2000).[379]

"copolymer" — "either poly(alkyl vinyl ether/maleic acid) copolymer or poly (alkylvinyl ether/maleic acid anhydride) copolymer, but not the salt form thereof." *Kao Corp., et al. v. Unilever United States, Inc., et al.*, 334 F. Supp. 2d 527 (D. Del. 2004).[380]

"a copolymer or homopolymer ... of lactic acid and ... glycolic acid" — "a copolymer, useful as an excipient in producing pharmaceutical preparation, comprised of lactic acid and glycolic acid monomers produced by any method, including the use of lactide and glycolide." *Tap Pharmaceutical Products, et al. v. Atrix Laboratories, Inc., et al.*, 2005 U.S. Dist. LEXIS 15176 (N.D. Ill., July 27, 2005).[381]

"core" — "an inner portion." *King Pharmaceuticals, Inc., et al. v. Sandoz Inc.*, 2010 U.S. Dist. LEXIS 105061 (D.N.J., Oct. 1, 2010).[382]

"core"; "core region" — "the portion of the patented preparation that lies beneath the subcoating and contains the active ingredient and, in the case of omeprazole as the active ingredient, an ARC." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002)[383]; *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007).[384]

"core" — "a geometric sub-region of an acicular particle which is formed by the merging of several individual pores which are no longer separated by matter, but which have substantially the same crystallographic orientation." *Bayer AG v. Sony Electronics, Inc.*, 229 F. Supp. 2d 332 (D. Del. 2002).[385]

"correlating" — "establishing a mutual or reciprocal relationship." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[386]

"correlating" — "to establish a mutual or reciprocal relationship between." *Metabolite Laboratories, Inc., et al. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004).[387]

"correlating the presence and quantification of the precipitate(s) at the discrete region(s) with the identification and/or quantification of said target compound" — "associating a species of capture molecule with the presence of precipitate(s) in one or more discrete regions of the test array and comparing the quantification of the precipitate(s) with the identification and/or quantification of the target compound." *Eppendorf AG, et al. v. Nanosphere Inc.*, 2010 U.S. Dist. LEXIS 69072 (D. Del., Jul. 12, 2010).[388]

"cosmetic article" — "a liquid, semi-solid, or dried preparation used to beautify the body by application." *Kao Corp., et al. v. Unilever United States, Inc., et al.*, 334 F. Supp. 2d 527 (D. Del. 2004).[389]

[i] "cotransforming"; [ii] "cotransformed eucaryotic cell" — [i] "process for carrying out transformation of a recipient cell with more than one different or distinct gene. Cotransformation includes both simultaneous and sequential changes in the genotype of a recipient cell mediated by the introduction of DNA corresponding to either unlinked or linked genes."; [ii] "a eucaryotic cell that has undergone a genotypic change as a result of the introduction into the cell of more than one different or distinct genes." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[390]

"Cottrell current" — "the rate of charge flow of a diffusion controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to $t^{-½}$ within experimental error." *Roche Diagnostics Corp. v. Inverness Medical Technology Inc., et al.*, 186 F. Supp. 2d 914 (S.D. Ind. 2002).[391]

"coupled transcription and translation" — "covers reactions in which there is any simultaneous transcription and translation." *Promega Corp. v. Novagen, Inc.*, 6 F. Supp. 2d 1004 (W.D. Wis. 1997).[392]

"covalently attached" — "directly secured or joined to the solid surface such that every chemical bond between the oligonucleotide and the surface is a covalent bond." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[393]

"covalently bonding different labels to different nucleic acids of said multi-nucleic acid mixture to form labeled nucleic acids" — "means that the labels become covalently bonded to different nucleic acids of the multi-nucleic acid mixture, during nucleic acid extention." *Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp.*, 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).[394]

"covalently coupled" — "Coupled means joined, and 'covalently' indicates joining via covalent bonding." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[395]

"covered" — "'enveloped,' as in 'to be placed on or over the whole surface of.'" *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[396]

"cream-textured matrix" — "a bound mass, which has the consistency of cream." *Kal Kan Foods, Inc. v. H.J. Heinz Company, L.P., et al.*, 2004 U.S. Dist. LEXIS 16808 (C.D. Cal., Feb. 5, 2004).[397]

"cross-hybridizes to the HPV portion of clone of pCD 15 to greater than 50%" — "cross-hybridizes to the HPV portion of clone pCD15 so as to result in the conversion of 50% of the DNAs to fully or partially double-stranded DNA molecules." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[398]

"cross-linking agent" — "a chemical agent that is polyfunctional in that it has at least two double bonds, a double bond and a reactive group, or two reactive groups to link polymer chains together. Polyoxyethylene sorbitol hexaoleate and sorbitan sesquioleate, as well as compounds containing only polyethylene oxide groups and/or impurities with double bonds or hydroxyl groups, are not cross-linking agents." *Ciba Specialty Chemicals Corp. v. Hercules, Inc., et al.*, 436 F. Supp. 2d 670 (D. Del. 2006).[399]

"crude reaction mixture" — "a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent." *Synthon IP, Inc. v. Pfizer Inc.*, 446 F. Supp. 2d 497 (E.D. Va. 2006);[400] *id.*, 457 F. Supp. 2d 668 (E.D. Va. 2006).[401]

"cryopreservation"; "cryopreserving"; "cryopreserved" — "preserving at very low temperatures that may also include an additional agent capable of preserving the cells, blood components, or compositions." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[402]

"cryopreservative" — "an agent capable of preserving at very low temperatures." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[403]

"crystalline" — "means Crystal A as outlined in the specification." *Lupin Ltd. v. Abbott Laboratories, et al.*, 484 F. Supp. 2d 448 (E.D. Va. 2007).[404]

"crystalline" — "Crystal A." *Abbott Laboratories, et al. v. Sandoz, Inc., et al.,* 566 F.3d 1282 (Fed. Cir. 2009).[405]

"crystalline content of less than 5% of starch" — "measur[es] the amount of crystalline lattice structure associated with the native starch compared with the resulting mixture. A resulting mixture has a 'crystalline content of less than 5% of starch' if it has 5% or less of the crystalline content of native starch." *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc., et al.*, 249 F.3d 1341 (Fed. Cir. 2001).[406]

"in crystalline form" — "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[407]

"crystalline paroxetine hydrochloride hemihydrate" — "The record repeatedly shows that artisans in this area of technology at the time of invention would have understood that the claim embraces PHC hemihydrate without further limitation. ... reading claim 1 in the context of the intrinsic evidence, the conclusion is inescapable that the claim encompasses, without limitation, PHC hemihydrate - a crystal form of paroxetine hydrochloride that contains one molecule of bound water for every two molecules of paroxetine hydrochloride in the crystal structure." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al*., 403 F.3d 1331 (Fed. Cir. 2005).[408]

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"a daily dose" — "the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day." *Novartis Corp., et al. v. Lupin Ltd., et al.*, 2009 U.S. Dist. LEXIS 21761 (D.N.J., Mar. 27, 2009).[409]

"1-deamino-8-D-arginine vasopressin"; "DDAVP"; "desmopressin" — "means ... the active compound (or free base) desmopressin, and not ... its salts." *Ferring B.V., et al. v. Barr Laboratories, Inc.*, 2005 U.S. Dist. LEXIS 3597 (S.D.N.Y., Feb. 7, 2005).[410]

"de-icing and anti-icing composition" — "[is] mere preambulatory language not requiring construction by the court." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[411]

"de-icing and anti-icing composition" — "a composition whose intended purpose, through direct or indirect application, is to keep roadways free or rid of ice, or to prevent its formation on such surfaces." *Cargill, Inc. v. Sears Petroleum & Transport Corp., et al.*, 334 F. Supp. 2d 197 (N.D.N.Y. 2004).[412]

"decreased CYP1A induction" — "a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[413]

"decreased interindividual variation in plasma levels (AUC)" — "a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[414]

"degradation by the copper ions"; "copper ion-mediated degradation" — "require degradation of the immunoglobulin composition by copper ions." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[415]

"degrade"; "degradability" — "are most synonymous with 'partially disintegrate' or 'partially dissolve,' and their adjective forms, but also encompass, e.g., dissolve and disintegrate. They cannot be taken to mean what was demonstrated to this Court to be the bursting of a closed envelope via the eruption of inner forces." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 1995 U.S. Dist. LEXIS 18548 (W.D.N.Y., Dec. 7, 1995).[416] "We conclude that the meaning of 'degradable' ... is limited to the dissolution/degradation of the envelope as described in the specification. The [district] court correctly excluded the meaning whereby the envelope 'degrades' by bursting instead of dissolving, and correctly held that 'degradable' means that there must be at least partial dissolution of the envelope." *Id.*, 133 F.3d 1473 (Fed. Cir. 1998).[417]

"dehydration"; "dehydrated" — "the removal of water, but not necessarily all water." *Shen Wei, et al. v. Ansell Healthcare Products, Inc.*, 2004 U.S. Dist. LEXIS 7717 (N.D. Ill., Apr. 30, 2004).[418]

"delay condensation" — "postpone, prevent, or avoid condensation." *ASM America, Inc. v. Genus, Inc.*, 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).[419]

"delayed release tablet" — "a tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer." *Biovail Laboratories International SRL v. Impax Laboratories, Inc.*, 433 F. Supp. 2d 501 (E.D. Pa. 2006).[420]

"at a density exceeding 400 different oligonucleotides per square centimeter" — "is clear and does not require interpretation." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[421]

"derivative of general formula: [x]" — "the precise chemical reactant shown in the claim, permitting variations only to the R group." *Bristol-Myers Squibb Co. v. Rhone-Polenc Rorer Inc., et al.*, 2001 U.S. Dist. LEXIS 24583 (S.D.N.Y., Jun. 4, 2001).[422]

"derived" — "is a commonly understood word and requires no additional construction." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[423]

"derived from a Bt" — "taken, obtained, received, traced, replicated, or descended from Bt. Such derivation may include chemical or biological manipulation of the native Bt gene. Since such manipulation may include such techniques as extraction or mutation, a gene derived from a Bt need not encode a protein that is identical to the protein encoded by the native Bt gene." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[424]

"derived from a feedstock" — "is unambiguous and means 'derived from a feedstock.'" *Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., et al*., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).[425]

"derived from a pyrolyzed material" — "is unambiguous and requires no further construction." *Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., et al*., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).[426]

"derived from said filaggrin by replacing at least one arginine residue in the amino acid sequence with a citrulline residue" — "includes an amino acid sequence of filaggrin (SEQ ID NO: 19) with changes including at least one arginine residue substituted by a citrulline residue." *INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, et al.*, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009).[427]

"dermis" — "the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels." *Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc*., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).[428]

"designed to allow" — "intentionally selected to make possible the detection goals set forth in the claim." *Regents of the University of California, et al. v. Oncor, Inc.*, 1997 U.S. Dist. LEXIS 15068 (N.D. Cal., Aug. 19, 1997).[429]

"wherein said computer is programmed to detect and/or quantitate said target compounds" — "detect and/or determine the specific amount of the target compounds." *Eppendorf AG, et al. v. Nanosphere Inc.*, 2010 U.S. Dist. LEXIS 69072 (D. Del., Jul. 12, 2010).[430]

"presence of detectable HIV-encoding nucleic acid"; "absence of detectable HIV-encoding nucleic acid" — "no construction is necessary." *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 528 F. Supp. 2d 967 (N.D. Cal. 2007).[431]

"detecting a complex as formed" — "requir[es] detection of a complex that is or has been formed." *Innogenetics N.V. v. Abbott Laboratories*, 2006 U.S. Dist. LEXIS 57142 (W.D. Wis., Aug. 11, 2006).[432] "Nothing in defendant's arguments persuades me that it was error to construe the claim as I did or to find as a matter of law that defendant's use of Realtime PCR in its assays to not make the products noninfringing." *Id.*, 2007 U.S. Dist. LEXIS 193 (W.D. Wis., Jan. 3, 2007).[433]

"a method for detecting nucleic acid sequences" — "a method for determining the presence or absence of two or more nucleic acid molecules." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[434]

"detecting said compound or compounds so as to detect said nucleic acid" — "the compounds which are detected do not necessarily have to remain hybridized to the nucleic acid in order to permit detection of the nucleic acid." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[435]

"detecting the labeled nucleic acid fragments which are hybridized to the interphase chromosomal DNA to determine" — "neither party's construction adds clarity to the existing claim language." *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).[436]

"determinable sequence" — "a sequence that can be determined." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[437]

"to determine" — "to conclude or ascertain." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[438]

"determining the glucose concentration in the sample" — "ascertaining the amount of glucose contained per unit volume in the sample." *Home Diagnostics Inc. v. Lifescan, Inc.*, 2001 U.S. Dist. LEXIS 24285 (N.D. Cal., Apr. 23, 2001).[439]

"determining the possible presence and quantification of precipitate(s) in said discrete region(s)"; "detecting and quantifying said precipitate in said discrete region(s)" — "acquiring one or more spatial representation(s) of the array (i) to determine the location(s) of the discrete region(s) having precipitate(s), and (ii) to determine one or more values related to the amount of precipitate(s) in the discrete region(s)." *Eppendorf AG, et al. v. Nanosphere Inc.*, 2010 U.S. Dist. LEXIS 69072 (D. Del., Jul. 12, 2010).[440]

"developed" — "the removal of unexposed, uncured portions of the photosensitive elastomer layer." *E.I. du Pont de Nemours & Co. v. MacDermid, Inc., et al.*, 2010 U.S. Dist. LEXIS 23750 (D.N.J., Mar. 15, 2010).[441]

"DHFR"; "dihydrofolate reductase" — "a proteinaceous material which acts as an enzyme and when present in increased concentrations allows eucaryotic cells to survive in the presence of increased concentrations of methotrexate." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[442]

"DHPPA"; "dihydroxyphenylpropionic acid" — "any form of DHPPA, including any or all of the 49 possible isomer of DHPPA." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[443]

"di-allyl di-methyl ammonium chloride (DADMAC)" — "a polymer of quaternized ammonium moiety formed by the reaction of any allyl with an amine, wherein an allyl is a substance containing the allyl group [CH[2]=CH-CH[2]]+, and wherein an amine is a derivative of ammonia [NH[3]] in which one or more hydrogen atoms have been replaced by an alkyl or aryl group. For example, DADMAC, DMDAAC, DAMEAC, DAEEAC, and DAMPAC are all examples of the DADMAC variety. Polymers of this variety comprise the quaternized nitrogen moiety in a branch from the polymer backbone." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[444]

"detecting <u>differential expression</u>" — "mean[s] the assessment of relative levels of gene activity." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[445]

"diameter" — "value represented by the diameter of a sphere having the same volume as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis." *Apotex, Inc. v. Cephalon, Inc., et al.*, 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).[446]

"diminished incidences of nausea and emesis" — "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day." *Wyeth v. Mylan Pharmaceuticals, Inc.*, 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009).[447]

"diminished incidences of nausea and emesis" — "the degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day." *Wyeth v. Impax Laboratories, Inc.*, 526 F. Supp. 2d 474 (D. Del. 2007).[448]

"discoloration" — "oxidative discoloration." *Warner-Lambert Co., et al. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326 (Fed. Cir. 2005).[449]

"discrete known regions" — "identified localized areas on a surface which are, were, or are intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[450]

"wherein said mixture of excipients comprises <u>a disintegrating agent and swelling agent</u>" — "a combination or blend of non-effervescent inert substances or vehicles which includes at least one substance that causes disintegration and at least one substance that, when contacted with liquid, absorbs the liquid and expands in volume." *Takeda Pharmaceutical Co. Ltd., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2009 U.S. Dist. LEXIS 105328 (D. Del., Nov. 9, 2009).[451]

"an inert meltable carrier containing dissolved or suspended <u>disodium EDTA</u> and a controlled-release matrix" — "the claims ... are expressly limited to disodium EDTA and [] the use of calcium disodium EDTA is not covered." *World Health Products, LLC v. Chelation Specialists, LLC, et al.*, 2006 U.S. Dist. LEXIS 61444 (D. Utah, Aug. 28, 1996).[452]

"disperse" — "distribute throughout the composition." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[453]

"an organic dispersing agent" — "any agent that assists or promotes the dispersion of solid particles in oil." *ICI Uniqema, Inc. v. Kobo Products, Inc.*, 2009 U.S. Dist. LEXIS 71191 (D.N.J., Aug. 13, 2009).[454]

"displacing" — "contacting to permit reduction of." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al.*, 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).[455]

"disposed on" — "does not require that the subcoating be applied using any particular process and that the subcoating need not necessarily be 'physically applied to' the core in a separate processing step." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002)[456]; "does not specify any method or structure involved in application of the subcoating." *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[457]

"by the dissolution and diffusion of said drug out of said matrix by said gastric fluid" — "rapid dissolution of the drug by the gastric fluid, followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate primarily controlled by the rate of diffusion." *Depomed, Inc. v. Ivax Corp., et al.*, 2007 U.S. Dist. LEXIS 91321 (N.D. Cal., Dec. 12, 2007).[458]

"dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate" — "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[459]

"dissolution profile" — "a quality control assay conducted according to instructions found in the United States Parmacopoeia. The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia." *Biovail Laboratories Inc., et al. v. Anchen Pharmaceuticals Inc., et al.*, 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006).[460]

"dissolution profile" — "a quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, i.e., the ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to guidance and instructions found in the United States Pharmacopoeia." *Biovail Laboratories International SRL v. Impax Laboratories, Inc.*, 433 F. Supp. 2d 501 (E.D. Pa. 2006).[461]

"DNA coding for human growth hormone" — "may include chemically synthesized DNA, cDNA, genomic DNA or any combination thereof." *Genentech, Inc. v. Novo Nordisk A/S, et al.*, 935 F. Supp. 260 (S.D.N.Y. 1996).[462]

"DNA encoding human erythropoietin" — "DNA which encodes human erythropoietin, not including the word exogenous DNA which encodes human erythropoietin." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[463]

"domain" — "a structurally and/or functionally discrete portion of a protein, nucleic acid, or membrane." *Enzo Life Sciences, Inc. v. Digene Corp.*, 2004 U.S. Dist. LEXIS 11118 (D. Del., Jun. 10, 2004).[464]

"dosage form" — "the physical form of a drug product." *King Pharmaceuticals, Inc., et al. v. Purdue Pharma L.P.*, 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).[465]

"dosage form" — "includes a variety of known pharmaceutical preparations, including a non-osmotic polymer matrix delivery device." *Alza Corp. v. Mylan Labs., Inc.*, 388 F. Supp. 2d 717 (N.D. W. Va. 2005).[466]

"dose" — "does not require construction." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[467]

"the downstream side of the resin bed" — "the side of the resin bed from which the flow of material exits after it passes through the resin bed." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[468]

"dried fruit" — "fruit from which natural moisture has been removed which has about 10 to 18% moisture remaining." *Amazin' Raisins International, Inc. v. Ocean Spray Cranberries, Inc.*, 2007 U.S. Dist. LEXIS 60808 (D. Mass., Aug. 20, 2007).[469]

"drug-containing matrix" — "drug-containing powder matrix." *Cephalon, Inc., et al. v. Barr Laboratories, Inc.*, 389 F. Supp. 2d 602 (D. Del. 2005).[470]

"drug delivery system constituted by at least 24 separate daily dosage units" — "we interpret the term 'drug delivery system' in claim 18 to refer more generally to a system consisting of at least 24 separate dosage units of the types specified, to be taken in the specified order. The particular form that the drug delivery system takes is not critical. Thus, the drug delivery system could consist of a blister pack, a set of blister packs, a device that dispenses one pill each day over a lengthy period, or any other system that provides for the delivery of the appropriate drug at the specified point in time." *Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc.*, 325 F.3d 1356 (Fed. Cir. 2003).[471]

"drug delivery system" — "a system for administration of drugs." *Oakwood laboratories, L.L.C., et al. v. Tap Pharmaceutical Products, Inc., et al.*, 2003 U.S. Dist. LEXIS 7476 (N.D. Ill., May 2, 2003).[472]

"dry" — "mean[s] that the silica particulates of the patented invention are dry to the touch, not wet. That is, they have little or no residual moisture content." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[473]

"dry mix explosive composition" — "an explosive mixture of an oxidizer, fuel, and bulking agent such that the resulting composition has substantially no separate or free liquid that can be absorbable by some external material (such as paper) - i.e., the composition is substantially 'dry to the touch.'" *Dyno Nobel, Inc. v. LDE Corp.*, 2003 U.S. Dist. LEXIS 27831 (D. Wyo., Aug. 27, 2003).[474]

"dry physical dimension" — "linear dimension." *Hoechst Celanese Corp. v. BP Chemicals Ltd., et al.*, 78 F.3d 1575 (Fed. Cir. 1996).[475]

"replacing said rinsing fluid with said drying vapor" — "the district court construed the claim term 'drying vapor' as 'a vapor that facilitates the removal of liquid from a surface,' wherein a 'vapor' is 'the gaseous state of a substance that, under ordinary circumstances, is usually a liquid or solid.' Additionally, the court construed the claim term 'replacing' as 'taking the place of.' ... [W]e agree with these aspects of the district court's claim construction." *CFMT, Inc., et al. v. Steag Microtech, Inc.*, 1999 U.S. App. LEXIS 9189 (Fed. Cir., May 13, 1999) (unpublished).[476]

"during the same cycle of a chromatographic simulated moving bed system" — "the three product fractions are recovered from the same series of columns during the same cycle defined in the claim." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[477]

"dust-free and non-dusting" — "a level of dust formation associated with the silica particulates of the '234 patent, as measured in percentage weight according to DIN 53 583 3, that has a fines content value less than or equal to 13 and weight loss by abrasion value less than or equal to 0.5." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[478] "We affirm the claim construction of the district court." *Id.*, 402 F.3d 1371 (Fed. Cir. 2005).[479]

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"EPSP synthase" — "is not limited to bacterial EPSP synthase." *Dekalb Genetics Corp. v. Syngenta Seeds, Inc., et al.*, 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007). [480]

"edetate" — "EDTA and derivatives of EDTA, such as salts, but not including structural analogs." *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006).[481]

"edetate" — "EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized, and which can prevent a no more than 10-fold increase in growth of each of Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027 and Candida albicans ATCC 10231 for at least 24 hours." *AstraZeneca Pharmaceuticals, LP, et al. v. Mayne Pharma (USA) Inc.*, 352 F. Supp. 2d 403 (S.D.N.Y. 2004).[482]

"edible mass" — "excludes the presence of lipid material." *Schreiber Foods, Inc. v. Saputo Cheese USA Inc.*, 83 F. Supp. 2d 942 (N.D. Ill. 2000).[483]

"effect" — "is definite enough for a jury to determine whether another pharmaceutical product infringes on the '939 patent, and therefore, does not need to be any further defined." *King Pharmaceuticals, Inc., et al. v. Purdue Pharma L.P.*, 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).[484]

"effect" — "the consequences described in the specification which follow on the application of the composition to the affected area." *Yarbrough Foundation, et al. v. Rite Aid Corp., et al.*, 2007 U.S. Dist. LEXIS 53443 (W.D. Mich., July 24, 2007).[485]

"effective" — "safe and efficacious." *Daiichi Pharmaceutical Co., Ltd., et al. v. Apotex, Inc., et al.*, 441 F. Supp. 2d 672 (D. N.J. 2006).[486]

"effective amount" — "the term 'effective amount' applies to both omeprazole and the ARC and requires an amount of each substance such that the combination of omeprazole plus the ARC meets the stated goal of the invention of stabilizing the omeprazole." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).[487] "'[E]ffective amount' [] limit[s] both the drug component and the ARC [because ARC is not a mere exipient]." *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[488]

"effective amount" — "an amount effective for the treatment of PHN in the mammal in need of such treatment, depending on the severity of the infection and the weight of the mammal and which usually will be in the range of from .2 to 40 mg per kilogram of body weight per day." *Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 97610 (D.N.J., Sep. 17, 2010).[489]

"effective amount" — "an amount shown to cause improvement, in comparison to placebo." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[490]

"effective amount" — "a sufficient amount of treating composition to facilitate healing." *Cytomedix, Inc. v. Little Rock Foot Clinic, P.A.*, 2004 U.S. Dist. LEXIS 4804 (N.D. Ill., Mar. 23, 2004).[491]

"effective amount" — "amount to increase the blood serum levels of HDL-cholesterol in the individual." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[492]

"effective amount"; "effective dose" — "amount to reduce hyperglycemia and stabilize serum glucose." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[493]

"administering <u>an effective amount of</u>" — "administering an amount adequate and suitable for therapeutic use." *Teva Pharmaceuticals USA, Inc. v. Amgen, Inc.*, 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).[494]

[i] "antiproliferative <u>effective amount</u>"; [ii] "antirestenosis <u>effective amount</u>" — [i] "an amount that is capable of reducing the incidence or degree of cell proliferation"; [ii] "an amount that is capable of reducing the incidence or degree of restenosis." *Wyeth, et al. v. Abbott Laboratories, et al.*, 2010 U.S. Dist. LEXIS 75893 (D.N.J., Jul. 27, 2010).[495]

"a target microbe-specific medium ... comprising ... b) <u>an effective amount of a nutrient-indicator which is provided in an amount sufficient to support log phase growth of said target microbe ... said nutrient-indicator being incapable of supporting continued logarithmic growth of any viable non-target microbes in the medium/sample mixture to produce a detectable characteristic signal</u>" — "is limited to those media in which only the target microbes can metabolize and experience log phase, reproductive growth." *Edberg, et al. v. CPI-The Alternative Supplier, Inc.*, 156 F. Supp. 2d 190 (D. Conn. 2001).[496]

"effective amount of the processing additive composition" — "that which either (a) reduces the occurrence of melt defects occurring during extrusion of the host polymer below the level of melt defects occurring during the extrusion of a host polymer that does not employ the multimodal fluoropolymer-based processing additive composition of the invention, or (b) delays the onset of the occurrence of such defects to a higher extrusion rate (that is a higher shear rate)." *3M Innovative Properties Co., et al. v. Dupont Dow Elastomers LLC*, 361 F. Supp. 2d 958 (D. Minn. 2005).[497]

"effective amount of 1 [α]-OH-vitamin D[2] to lower and maintain lowered serum parathyroid hormone levels" — "an effective amount of 1 [α]-OH-vitamin D[2] to lower and maintain lowered blood concentrations of PTH with a lower incidence of hypercalcemia than is associated with the extant conventional Vitamin D[3] treatments." *Bone Care International, LLC, et al. v. Pentech Pharmaceuticals, Inc., et al.*, 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).[498] "On the basis of its reexamination of the language of the specification and the parties' commentary on the prior construction, the Court believes that certain modifications are in order. To begin with, the Court construes 'effective amount' to be 'an amount sufficient to' - a construction that finds support in several Federal Circuit cases. ..." *Id.*, 2010 U.S. Dist. LEXIS 81563 (N.D. Ill., Jul. 30, 2010).[499]

"effective body fat reducing amount"; "effective, lean-body-mass increasing amount"; "effective[,] blood serum lipid[-] reducing amount [dose]"; "effective HDL-cholesterol increasing dose" — "amount to reduce the percentage of body fat in the mammal"; "amount to increase lean body mass in the mammal"; "amount to reduce blood serum lipid levels in the individual"; "amount to increase the blood serum levels of HDL-cholesterol in the individual." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[500]

"amount of triclosan <u>effective to kill microorganisms present on the skin</u>" — "the Court will not limit the claim term to 0.001 to 5% triclosan." *Laboratory Skin Care, Inc. v. Limited Brands, Inc., et al.*, 616 F. Supp. 2d 468 (D. Del. 2009).[501]

"effective to treat" — "safe and efficacious." *Daiichi Pharmaceutical Co., Ltd., et al. v. Apotex, Inc., et al.*, 380 F. Supp. 2d 478 (D.N.J. 2005);[502] *Id.*, 441 F. Supp. 2d 672 (D.N.J. 2006).[503]

"effective treatment of pain" — "means that an individual patient is provided with adequate pain relief from the sustained release opioid dosage form without unacceptable side effects." *Purdue Pharma, L.P., et al. v. F.H. Faulding and Co., et al.*, 48 F. Supp. 2d 420 (D. Del. 1999).[504]

"an efficiency-enhancing amount ... of a mixture of [salts]" — "mean[s] that the salts themselves must enhance the efficiency of the catalyst." *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., et al.*, 308 F.3d 1167 (Fed. Cir. 2002).[505]

"electroactive reaction product" — "a chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode." *Roche Diagnostics Operations, Inc., et al. v. Abbott Diabetes Care, et al.*, 2009 U.S. Dist. LEXIS 84423 (D. Del., Sep. 15, 2009).[506]

"electrooxidize" — "to donate at least one electron at an electrode." *Roche Diagnostics Operations, Inc., et al. v. Abbott Diabetes Care, et al.*, 2009 U.S. Dist. LEXIS 84423 (D. Del., Sep. 15, 2009).[507]

"emulsifying agent" — "an ingredient added to stabilize an emulsion (an emulsion is, e.g., a dispersion of oil in water)." *LP Matthews LLC v. Bath & Body Works, Inc., et al*., 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[508]

"encapsulated" — "filled into a pharmaceutically acceptable capsule." *Wyeth v. Mylan Pharmaceuticals, Inc.*, 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009).[509]

"encapsulated" — "a formulation that is filled into a pharmaceutically acceptable capsule." *Wyeth v. Teva Pharmaceuticals, et al*., 2005 U.S. Dist. LEXIS 20034 (D.N.J., Sept. 6, 2005).[510]

"end stage renal disease" — "a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation." *Bone Care International, LLC, et al. v. Pentech Pharmaceuticals, Inc., et al.*, 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).[511]

"enhance the non-specific defenses of mononuclear cells or macrophages or both"; "enhancing the non-specific defenses of mononuclear cells or macrophages or both" — "The Court declines to import 'but does not result in increased body temperature' into the construction of the disputed terms and concludes that further construction is not necessary." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[512]

"enhancer element at a site within an active region of said vector sufficiently close to said transcription unit to enhance production of mRNA independent of its orientation and position within said active region" — "an enhancer element that is inserted into an active region of the vector at a site close enough to the transcription unit to enhance production of mRNA, and is operative in either position (upstream or downstream) and in either orientation with respect to the transcription unit." *Massachusetts Institute of Technology v. Imclone Systems, Inc.*, 498 F. Supp. 2d 435 (D. Mass. 2007).[513]

"wherein product fractions are <u>eluated</u>"; "wherein each of said product fractions are recoverable during said cycle" — "the product fractions are separated from the molasses feed solution such that they can be recovered"; "at least one each of the three product fractions is recoverable during the same cycle." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[514]

"a product of <u>enzymic conversion</u> of said analyte by said second enzyme" — "a product of the reaction in which the said analyte is a substrate of the second enzyme." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[515]

"epichlorohydrin di-methyl amine (Epi-DMA)" — "a polymer of quaternized ammonium moiety formed by the reaction of epichlorohydrin with an amine, wherein epichlorohydrin comprises a carbon [C] compound containing at least one chlorine [Cl] atom and at least three carbon [C] atoms, wherein two of said carbon atoms, which do not have a site filled with said chlorine [Cl] atom, fill a site for each other and share an oxygen [O] atom, wherein said oxygen [O] atom fills a site on each of two said carbon [C] atoms, thereby forming a triangle of said carbon [C], carbon [C], and oxygen [O] atoms. For example: Epi-DMA, Epi-MEA, Epi-EEA, Epi-MPA, etc. are all examples known in the art as being of the Epi-DMA variety. Polymers of this variety comprise the quaternized nitrogen moiety in the polymer backbone, as compared to those of DADMAC variety which comprise the quaternized nitrogen moiety in a branch from the polymer backbone." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[516]

"equivalent" — "We construe 'equivalent' to require a Cmax that is 80% to 125% of the value to which it is being compared." *Adams Respiratory Therapeutics, Inc., et al. v. Perrigo Co., et al.*, 2010 U.S. App. LEXIS 16189 (Fed. Cir., Aug. 5, 2010).[517]

"essentially devoid of its (+)-enantiomeric contaminant" — "nearly completely lacking an impurity of (+)-omeprazole." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[518]

"essentially free from crystalline material" — "means a maximum crystalline content of less than 10%." *Glaxo Group Ltd., et al. v. Ranbaxy Pharmaceuticals, Inc.*, 262 F.3d 1333 (Fed. Cir. 2001).[519]

"essentially spheroidal in geometrical configuration" — "mean[s] that the geometric shape of the silica particulates essentially resembles a sphere. Less than perfect spheres are embodied by this definition." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[520]

"esterified"; "esterifying" — "a chemical reaction in which the reactants (2R, 3S) 3-phenylisoserine derivative and the C-13 OH, taxane derivative (shown in claims 1 and 16) are linked or coupled to form the ester of the general formula designated as (V) in the '277 Patent (Column 3, lines 29-41)." *Bristol-Myers Squibb Co. v. Rhone-Polenc Rorer Inc., et al.*, 2001 U.S. Dist. LEXIS 24583 (S.D.N.Y., Jun. 4, 2001).[521]

"esterifying the salt to a degree of esterification ranging from 9 5% to 14%" — "[does] not requir[e] a measuring step." *Aventis Pharma S.A., et al. v. Amphastar Pharmaceuticals, Inc., et al*., 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).[522]

"at least one <u>ethylene interpolymer</u>" — "at least one polymer made from ethylene and at least one other comonomer." *Dow Chemical Co. v. Nova Chemicals Corp.*, 629 F. Supp. 2d 397 (D. Del. 2009).[523]

"eucaryotic cell" — "a cell of an organism classified under the Superkingdom Eucaryotes including organisms of the Plant and Animal kingdoms, characterized by true nuclei formed by nuclear envelopes and by meiosis, including both a wild-type and a mutant cell." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[524]

"eugenol" — "is not the same thing as 'clove oil.' That does not, however, mean that 'eugenol' needs to be construed or that defendants' proposed definition is appropriate. Eugenol has meaning to those familiar with the art: the inventor did not think it necessary to explain the term or to provide a definition. ... The Court finds that 'eugenol' need not be construed: plaintiffs will be required to show that the accused products exhibit eugenol in the range recited in the claims." *Pace International, LLC, et al. v. Industrial Ventilation, Inc., et al.*, 2009 U.S. Dist. LEXIS 120554 (W.D. Wash., Dec. 7, 2009).[525]

"evaluating"; "evaluation"; "reevaluating"; "reevaluation" — "do not require construction." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[526]

"exercise regimen" — "to regularly perform physical exertion related to achieving a fitness benefit." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[527]

"wherein <u>the excipient is chosen from [a list of excipients], and mixture thereof</u>" — "wherein the excipient is chosen from [a list of excipients], and mixtures of two or more of the above listed excipients and may include excipients not listed." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[528]

"excipient material" — "any compound forming a part of the formulation which is intended to act merely as a carrier, i.e., not intended to have biological activity itself." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[529]

"an excipient material comprising the remainder of the formulation" — "the formulation includes only AAKG and excipient materials." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[530]

"exogenous to human IGF-I" — "mean[s] any other source other than the human IGF-I sequence." *Genentech, Inc., et al. v. Insmed Inc., et al*., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[531]

"smoking the tuna meat at extra-low temperatures by <u>exposure to the smoke cooled to between 0 º and 5 º C</u>" — "means that the smoke has already been cooled to a specific temperature, namely, to between 0 º and 5 º C." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[532]

"expression" — "cover[s] both fusion and direct expression." *Genentech, Inc., et al. v. Insmed Inc., et al*., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[533]

"extended refrigerated shelf life" — "a longer shelf life than the 7 to 14 day shelf life of refrigerated liquid whole egg products which have been conventionally pasteurized." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[534]

"extended release" — "releasing the active ingredient from the dosage form over time in a manner that reduces the dosage frequency as compared to immediate release dosage forms." *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 221 F. Supp. 2d 535 (E.D. Pa. 2002).[535]

"extended release formulation" — "a drug formulation (other than a hydrogel tablet) that releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." *Wyeth v. Mylan Pharmaceuticals, Inc.*, 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009).[536]

"extended release formulation" — "a formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." *Wyeth v. Impax Laboratories, Inc.*, 526 F. Supp. 2d 474 (D. Del. 2007).[537]

"extended release formulation" — "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration." *Wyeth v. Teva Pharmaceuticals, et al*., 2005 U.S. Dist. LEXIS 20034 (D.N.J., Sept. 6, 2005).[538]

"(a) extending an initializing oligonucleotide along the polynucleotide by ligating an oligonucleotide probe thereto to form an extended duplex; (b) identifying one or more nucleotides of the polynucleotide; and (c) repeating steps (a) and (b) until the sequence of nucleotides is determined" — "We agree with the district court that step (a) includes repeated cycles of extension of extended duplexes. ... we agree with the district court that step (b) requires the identification of one or more nucleotides during each cycle. In other words, in order to repeat steps (a) and (b), one must actually perform step (b). ... We construe step (c), as the district court did, to have its plain and ordinary meaning. To meet the limitations of claim 1, one must repeat steps (a) and (b) until the sequence of nucleotides is determined. There is no need for repetition once the sequence of the polynucleotide has been fully determined." *Applera Corp. v. Illumina, Inc., et al.*, 2010 U.S. App. LEXIS 6250 (Fed. Cir., Mar. 25, 2010) (unpublished).[539]

"extent" — "mean[s] 'amount' or 'degree.'" *Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc.*, 79 F. Supp. 2d 409 (D. Del. 1999).[540]

"extracellular domain" — "the portion of the human breast cancer antigen that is external to the cell." *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002).[541]

"extract of green tea"; "green tea extract" — "a preparation of Camellia sinensis which has been processed to be concentrated in catechols." *Iovate Health Sciences, Inc., et al. v. Allmax Nutrition, Inc., et al.*, 639 F. Supp. 2d 115 (D. Mass. 2009).[542]

"extruded" — "means forcing a polymer gel through a die under a compressive force." *Dow Chemical Co. v. Astro-Valcour, Inc.*, 47 F. Supp. 2d 294 (N.D.N.Y. 1999).[543]

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"feeding" — "covers both nutritional and pharmacological uses of MSM(R)." *MSM Investments Co. LLC v. Carolwood Corp., et al.*, 259 F.3d 1335 (Fed. Cir. 2001).[544]

"fertile transgenic Zea mays plant" — "a corn plant that is transgenic, because it includes DNA that was introduced into the plant or one of its ancestors through genetic engineering and fertile because it can pass that introduced DNA on to its offspring." *Dekalb Genetics Corp. v. Syngenta Seeds, Inc., et al.*, 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).[545]

"fibrous absorbent layer" — "no construction of the term 'fibrous absorbent layer' is necessary or appropriate." *Fort James Corp. v. J.H. McNairn, Ltd.*, 2006 U.S. Dist. LEXIS 36528 (N.D. Ga., April 4, 2006).[546]

"including a bulking agent, comprising from 1-20% (by weight) of a fibrous vegetable protein additive" — "[T]he word 'additive' refers to 'fibrous vegetable protein' and it is added to the 'bulking agent.' ... 'fibrous' should be construed as 'having, consisting of, or resembling fibers, which are slender, elongated structures; a filament or stand.' ... 'vegetable' means 'of, pertaining to, or derived from a plant or plants.' ... the Court construes 'protein' as 'any of a group of complex nitrogenous organic compounds ... that contain amino acids as their basic structural units.' ... the 'fibrous vegetable protein additive' must be 1-20% (by weight) of the bulking agent." *Dyno Nobel, Inc. v. LDE Corp.*, 2003 U.S. Dist. LEXIS 27831 (D. Wyo., Aug. 27, 2003).[547]

"filler" — "need not be construed." *E.I. du Pont de Nemours & Co. v. MacDermid, Inc., et al.*, 2010 U.S. Dist. LEXIS 23750 (D.N.J., Mar. 15, 2010).[548]

"film" — "a thin layer of material. A film may have voids, cracks, or other discontinuities." *OKI Electric Industry Co., Ltd. v. LG Semicon Co., Ltd., et al.*, 1999 U.S. Dist. LEXIS 22625 (N.D. Cal., Jul. 19, 1999).[549]

"filtering" — "is a broadly-defined process including not only passing a gas or liquid through a porous material, but also the cooling and settling of the smoke." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[550]

"fire" — "burning of combustible material." *US Foam, Inc, et al. v. On Site Gas Systems, Inc.*, 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).[551]

"fixing said polynucleotide sequence to a solid support which comprises or is contained within a transparent or translucent, non-porous system, such that a single-strand of the polynucleotide is capable of hybridizing to complementary nucleic acid sequences" — "requires that the sample, which is the substance within which one is looking for the presence of the analyte, must be fixed to the solid support, and that the probe, which is a labeled sequence complementary to the analyte, is not so fixed." *Enzo Biochem, Inc., et al. v. Affymetrix Inc., et al.*, 439 F. Supp. 2d 309 (S.D.N.Y. 2006).[552]

"flexible polyurethane foam reaction mixture" — "We agree with Buszard that it is not a reasonable claim interpretation to equate 'flexible' with 'rigid,' or to equate a crushed rigid polyurethane foam with a flexible polyurethane foam." *In re Buszard, et al.*, 504 F.3d 1364 (Fed. Cir. 2007).[553] "Because the Board must give claim language its broadest reasonable interpretation, I would affirm the Board's construction of 'flexible polyurethane foam reaction mixture.'" *Id.* (Prost, J., dissenting).[554]

"flocculated suspension" — "the agglomeration in water of a solid with a chemical coagulant and/or flocculent." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[555]

"stable flocculated suspension" — "a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with a scaffold-like structure and not a solid cake." *Pharmaceutical Resources, Inc., et al. v. Roxane Laboratories, Inc.*, 2006 U.S. Dist. LEXIS 34474 (D.N.J., May 25, 2006).[556]

"flour" — "the finely ground meal of grain, esp. wheat, separated by bolting." *Yoon Ja Kim v. Dawn Food Products, Inc.*, 2004 U.S. Dist. LEXIS 20837 (N.D. Ill., Oct. 12, 2004).[557]

"flowing said sample solution of substantially constant composition through said immunosorbing zone" — "requir[es] only the sample solution to have substantially the same composition when it first comes into contact with the mips in the immunosorbing zone, not thereafter." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[558]

"fluoropolymer" — "a polymer based on fluorine replacement of hydrogen atoms in hydrocarbon molecules." *3M Innovative Properties Co., et al. v. Dupont Dow Elastomers LLC*, 361 F. Supp. 2d 958 (D. Minn. 2005).[559]

"foam concentrate" — "foamable substance." *US Foam, Inc, et al. v. On Site Gas Systems, Inc.*, 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).[560]

"DNA coding for a human growth hormone conjugate protein ... which is specifically cleavable by enzymatic action" — "is not a 'means plus function' claim." *Genentech, Inc. v. Novo Nordisk A/S, et al.*, 935 F. Supp. 260 (S.D.N.Y. 1996).[561]

"a sustained-release oxybutynin formulation for oral administration to a patient comprising a therapeutic dose of oxybutynin" — "Mylan fails to prove that claims 1 and 2 contain means-plus-function limitations." *Alza Corp. v. Mylan Laboratories, Inc., et al.*, 349 F. Supp. 2d 1002 (N.D. W. Va. 2004).[562]

"a composition for reducing apolipoprotein B production" — "a composition intended for reducing the production of apolipoprotein B." *SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc.*, 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).[563]

"for reducing hematologic toxicity" — "[w]e discern no error in the district court's interpretation of that language as non-limiting, and merely expressing a purpose of reducing hematologic toxicity relative to the toxicity experienced by a patient undergoing a twenty-four-hour infusion." *Bristol Meyers Squibb Co. v. Ben Venue Laboratories, Inc., et al.*, 246 F.3d 1368 (Fed. Cir. 2001).[564]

"for treating a mammal at risk of or suffering from cancer" — "intended to treat a mammal at risk of developing or suffering from cancer." *SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc.*, 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).[565]

"a pharmaceutical composition for treating breast cancer in a human subject" — "a pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject." *SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc.*, 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).[566]

"foreign DNA I" — "a polynucleotide that is inserted into the eucaryotic cell." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[567]

"form of a dosage unit" — "a form suitable for administration to a mammal." *Glaxo Group Ltd, et al. v. Teva Pharmaceuticals USA, Inc.*, 2009 U.S. Dist. LEXIS 37494 (D. Del., Apr. 30, 2009).[568]

"formaldehyde" — "includes 'all synthetically useful forms of formaldehyde including solid forms of formaldehyde such as paraformaldehyde and trioxane.'" *Infosint, S.A. v. H. Lundbeck A/S, et al.*, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).[569]

"a polyurethane elastomeric body formed by the reaction of aliphatic dicarboxylic acid and aromatic diisocyanate" — "the polyurethane must be formed by the reaction of an aliphatic dicarboxylic acid directly with an aromatic diisocyanate." *T.F.H. Publications, Inc. v. Hartz Mountain Corp.*, 67 Fed. Appx. 599 (Fed. Cir., May 30, 2003) (unpublished).[570]

"formed on" — "does not mean 'directly in contact with.'" *AFG Industries, Inc., et al. v. Cardinal IG Co., et al.*, 239 F.3d 1239 (Fed. Cir. 2001).[571]

[i] "a rest molasses fraction"; [ii] "a betaine fraction"; [iii] "a sucrose fraction" — [i] "a product fraction that is separate from the other two fractions (the sucrose fraction and betaine fraction)"; [ii] "a product fraction that is substantially separate from the other two fractions (the sucrose fraction and the rest molasses fraction)"; [iii] "a product fraction that is substantially separate from the other two fractions (the betaine fraction and the rest molasses fraction)." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[572]

"being free flowing to an extent of at least 10 times greater than in powder form" — "mean[s] that the silica particulates of the '234 patent flow into an appropriate receptacle having a calibrated aperture while under slight vibration to an extent of at least 10 times greater than does silica in powder form. In other words, 'flowability' is defined in accordance with the test provided by the inventors in the '234 patent written description." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[573]

"free from" — "does not contain." *King Pharmaceuticals, Inc., et al. v. Purdue Pharma L.P.*, 2010 U.S. Dist. LEXIS 61997 (W.D. Va., Jun. 22, 2010).[574]

"biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone" — "a protein produced by recombinant DNA techniques composed of a 191 amino acid sequence identical to that of hGH produced by the human pituitary gland with the full biological activity of hGH produced by the human pituitary gland, and free of the contaminants present in hGH produced by the human pituitary gland." *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 2004 U.S. Dist. LEXIS 14960 (D. Del., Aug.3, 2004).[575]

"free of pore-forming agent" — "the tablet does not contain a non-polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating." *Biovail Laboratories Inc., et al. v. Anchen Pharmaceuticals Inc., et al.*, 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006).[576]

"free of pore-forming agent" — "lacking a monomeric water-soluble species capable of being eluted from a coating to form minute openings that permit the passage of liquids or gases in either direction." *Biovail Laboratories International SRL v. Impax Laboratories, Inc.*, 433 F. Supp. 2d 501 (E.D. Pa. 2006).[577]

"free of stabilizer" — "the Court does not find that it is necessary to construe the term 'free of.'" *Biovail Laboratories Inc., et al. v. Anchen Pharmaceuticals Inc., et al.*, 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006).[578]

"free of stabilizer" — "lacking any substance or agent that tends to prevent bupropion hydrochloride from changing its form or chemical nature." *Biovail Laboratories International SRL v. Impax Laboratories, Inc.*, 433 F. Supp. 2d 501 (E.D. Pa. 2006).[579]

"friable" — "easily crumbled, pulverized, or reduced to powder." *In re: Manchak Patent Litigation*, 320 F. Supp. 2d 178 (D. Del. 2002).[580]

"an average particle size of <u>from about 2 to about 10 microns</u>"; "an average particle diameter of <u>from about 2 to about 10 microns</u>" — "the arithmetic mean of the diameters of the particles is approximately 2 to approximately 10 microns." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[581]

"from human acceptor immunoglobulin" — "allow[s] the use of a variety of different human framework regions in combination as a basis for the humanized immunoglobulins of Claim 28." *Medimmune, LLC v. PDL Biopharma, Inc.*, 2010 U.S. Dist. LEXIS 21169 (N.D. Cal., Feb. 22, 2010).[582]

"frozen uniformly" — "is limited to devices which freeze the PCM uniformly and completely." *Calmac Manufacturing Corp. v. Dunham-Bush, Inc., et al*., 929 F. Supp. 951 (E.D. Va. 1996).[583]

"an immediate release form which becomes <u>fully bioavailable in the subject's stomach</u>" — "the active pharmaceutical ingredient is thoroughly absorbed in the subject's stomach." *Adams Respiratory Therapeutics, Inc., et al. v. Perrigo Co., et al.*, 2010 U.S. Dist. LEXIS 12008 (W.D. Mich., Feb. 11, 2010).[584] "We agree that nothing in the specification imparts any special meaning to the term 'fully.' This term should be given its plain and ordinary meaning." *Id.*, 2010 U.S. App. LEXIS 16189 (Fed. Cir., Aug. 5, 2010).[585]

"fuming sulfuric acid containing at least 20% SO_3" — "20% SO_3 up to an amount to which sulfuric acid would be considered an impurity." *Infosint, S.A. v. H. Lundbeck A/S, et al.*, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).[586]

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[i] "gas consisting essentially of nitrogen" / "nitrogen containing gas"; [ii] "gas comprising nitrogen" — [i] "gas containing mainly of nitrogen without other gases in sufficient concentrations to support combustion"; [ii] "a gas, other than air, that includes nitrogen and may include additional gases that are not present in sufficient concentrations to support combustion." *US Foam, Inc, et al. v. On Site Gas Systems, Inc.*, 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).[587]

"gas impermeable enclosure" — "an enclosure, into which and out of which gas cannot move or pass." *Heraeus Electro-Nite Co. v. Midwest Instrument Co.*, 2007 U.S. Dist. LEXIS 81685 (E.D. Pa., Nov. 1, 2007).[588]

"a fire extinguishing chemical of a gas type that comprises argon and nitrogen" — "a gas other than air that contains argon and nitrogen, optionally with other components." *US Foam, Inc, et al. v. On Site Gas Systems, Inc.*, 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).[589]

"gastrointestinal environment" — "the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[590]

"gel"; "liquid" — "the term 'gel' is not subsumed within the term 'liquid.' ... nonflowing gels are not within the scope of the Sereboff patent claims." *Minnesota Mining & Manufacturing Co. v. Fellowes Manufacturing Co.*, 76 F. Supp. 2d 972 (D. Minn. 1999).[591]

"gelling agent" — "an agent that has the ability to form a gel." *Procter & Gamble Co. v. McNeil-PPC, Inc.*, 2009 U.S. Dist. LEXIS 6947 (W.D. Wis., Jan. 26, 2009).[592]

"gene associated with drug resistance" — "a gene which encodes a protein that, when expressed at some level or concentration, allows eucaryotic cells expressing the gene to survive or proliferate in the presence of a chemical compound, such as a drug, which would otherwise kill the cells." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[593]

"gene fragment" — "refer[s] to either single or double-stranded DNA, of any length." *Genentech, Inc. v. Boehringer Mannheim GmbH, et al*., 989 F. Supp. 359 (D. Mass. 1997).[594]

"generates a base call identifying said unknown base" — "determines which nucleotide is most likely to be present at a particular position in a nucleic acid sequence." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[595]

"genes controlling the synthesis of a selected aminoacid" — "refers to the amino acid operon." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 1998 U.S. Dist. LEXIS 3833 (D. Del., Mar. 13, 1998).[596]

"method of genotyping" — "a method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype." *Innogenetics N.V. v. Abbott Laboratories*, 2006 U.S. Dist. LEXIS 57142 (W.D. Wis., Aug. 11, 2006).[597]

"a glyphosate resistant, hybrid maize plant" — "a hybrid corn plant that provides the level of glyphosate resistance provided by one of the four specifically identified transformation events." *Rhone-Poulenc Agro, S.A. v. Monanto Co., et al*., 445 F. Supp. 2d 531 (M.D. N.C. 2006).[598]

"golden brown" — "the district court properly considered all intrinsic evidence before determining that none of it could overcome the presumption favoring plain meaning, and only then turned to a dictionary to affix the plain meaning that one of ordinary skill in the art would assign to the color 'golden brown.'" *Unitherm Food Systems, Inc., et al. v. Swift-Eckrich, Inc.*, 375 F.3d 1341 (Fed. Cir. 2004).[599]

"natural rubber graft copolymerized with styrene and methyl methacrylate in the form of a latex" — "the word 'and' means 'together with' or 'in addition to.' Therefore, the natural rubber must be graft copolymerized with styrene in addition to MMA (i.e., present simultaneously on the same natural rubber backbone)." *Moore North America, Inc. v. Adams Investment Company Inc.*, 2000 U.S. Dist. LEXIS 20958 (S.D. Iowa, Jul. 27, 2000).[600]

"grain protein ... heating said formulation ... in order to render the formulation substantially homogeneous and flowable while avoiding any substantial heat denaturation of said grain protein" — "the term 'grain protein' ... mean[s] grain protein that has not been substantially denatured by heat." *MGP Ingredients, Inc. v. Mars, Inc., et al.*, 494 F. Supp. 2d 1231 (D. Kan. 2007).[601]

"granulate" — "one of a number of particles forming a larger unit." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[602]

"granulocytopoietic therapy" — "therapeutically treating a mammal by stimulating the production of granulocytes." *Teva Pharmaceuticals USA, Inc. v. Amgen, Inc.*, 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).[603]

"greater anabolic state in the mammal than achieved using an equivalent dose of IGF-I" — "mean[s] promote total body weight gain or statural growth that is greater than whatever total body weight gain or statural growth would be observed if the same amount of IGF-I as is present in the IGF-I/IGFBP-3 mixture were administered by the same route, regimen, and schedule of administration as used in the administration of the IGF-I/IGFBP-3 mixture." *Genentech, Inc., et al. v. Insmed Inc., et al.*, 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[604]

"greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone" — "a greater analgesic effect than the effect capable of being obtained by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone at the same dose." *Knoll Pharmaceutical Co., Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, 2002 U.S. Dist. LEXIS 17201 (N.D. Ill., Sept. 12, 2002).[605]

"greater number of codons preferred" — "the limitation 'greater number of codons preferred' is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[606]

"growing E. coli cells in a growth-conducive medium at a temperature of 18 ºC to 32 ºC" — "does not address and therefore permits growth before the steps disclosed in the claim at temperatures outside the range of 18 ºC to 32 ºC." *Invitrogen Corp. v. Biocrest Manufacturing, L.P., et al.*, 327 F.3d 1364 (Fed. Cir. 2003).[607]

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"haplotypic pattern" — "data, from an analytical method, that is characteristic of a particular haplotype, without requiring that the data identify a haplotype to 100% accuracy or further specifying the analytical methods to be used." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[608]

"having"; "comprising" — "the Court construes the term 'having' to be intended by the inventors to be a closed term precluding additional elements, while 'comprising' was intended to be an open term." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[609]

"said oligonucleotide population has a coding region <u>having a length from about 4 to about 12 nucleotide triplets</u>"; "each structural gene <u>having inserted therein one member of an oligonucleotide population wherein each member of said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets</u>" — "substituting 'comprising' for 'having' would read the specificity--in particular, the upper bound of 'about 12'--out of the claim. Thus, 'having,' in this context, is closed." *Pieczenik v. Dyax Corp.*, 76 Fed. Appx. 293 (Fed. Cir., Sept. 23, 2003) (unpublished).[610]

"having a molecular weight of at least approximately 500,000 to approximately 3,000,000" — "a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000 as measure by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[611]

"purified beta (1,3) glucan <u>having a particle size of about 1.0 micron or less</u>"; "substantially purified beta (1,3) glucans <u>having a particle size of about 1.0 microns or less</u>" — "require all beta (1,3) glucan particles to be approximately 1.0 micron or less." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2009 U.S. Dist. LEXIS 75767 (D. Minn., Jan. 28, 2009).[612]

"having CDRs from a donor immunoglobulin" — "d[oes] not limit the invention of Claim 28 to the transfer of all three CDRs from each chain, and that it allows the transfer of one or more CDRs from a chain in creating a humanized immunoglobulin." *Medimmune, LLC v. PDL Biopharma, Inc.*, 2010 U.S. Dist. LEXIS 21169 (N.D. Cal., Feb. 22, 2010).[613]

"heating" — "HISI requests that 'heating' not be limited to any particular temperature range in Claims 1 and 67. ... TPI argues that HISI's claim is limited by what the Kowalski Patent has defined as the operable range of the invention. ... The specifications do not support the broad claim language of 'heating'; accordingly these claims are deemed invalid on this ground." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[614] "The Court's Claims Construction Order ... is hereby reconsidered and amended such that (1) the portion of the order invalidating the Kowalski Patent's Claims 1 and 67 is VACATED; and, (2) the Court clarifies that 'heating,' as used in Claims 1 and 67 is not limited to any specific numerical temperature range." *Id.*, 2007 U.S. Dist. LEXIS 84605 (D. Haw., Nov. 15, 2007).[615]

"hematopoietic stem cells" — "cells capable of effecting repopulation of blood and other hematopoeietic organs." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[616]

"the hemicalcium salt of the compound of claim 2" — "the hemicalcium salt of atorvastatin acid." *Pfizer, Inc., et al. v. Ranbaxy Laboratories, Ltd., et al.*, 405 F. Supp. 2d 495 (D. Del. 2005).[617]

"herbicidally effective amount" — "the amount of an herbicide compound which adversely controls or modifies weed growth." *Zeneca Ltd., et al. v. Rhone-Poulenc, Inc.*, 1999 U.S. Dist. LEXIS 22137 (D. Del., Jun. 16, 1999).[618]

"heterogeneous mixture" — "a mixture of labeled fragments comprising many copies each of labeled fragments having different base compositions and/or sizes, such that application of the labeled fragments to a chromosome results in a substantially uniform distribution of fragments hybridized to the chromosomal DNA." *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).[619]

"heterologous DNA construct encoding EPSP synthase" — "DNA (1) that is not normally found in the plant, but parts of the heterologous DNA construct may be identical to DNA sequences originally present in the corn plant and (2) that has the necessary components to produce EPSP synthase." *Dekalb Genetics Corp. v. Syngenta Seeds, Inc., et al.*, 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).[620]

"heterogeneously branched linear ethylene polymer" — "a polymer having a distribution of branching different from and broader than the homogeneously branched ethylene/[alpha]-olefin." *Dow Chemical Co. v. Nova Chemicals Corp.*, 629 F. Supp. 2d 397 (D. Del. 2009).[621]

"high browning flavorless aqueous composition" — "a virtually flavorless water containing composition or product capable of imparting a brown color to foodstuffs, considering smell as well as taste of the product (the product applied to the meat must have virtually no flavor)." *Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., et al*., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).[622]

"high browning, low flavor liquid composition" — "a low flavor liquid solution with substantially no smoke flavoring ability, considering smell as well as taste." *Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., et al*., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).[623]

"high molecular weight di-allyl di-methyl ammonium chloride" — "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having a molecular weight range of about 1,000,000 or greater." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[624]

"high molecular weight epichlorohydrin d-methyl amine (Epi-DMA)" — "a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[625]

"high molecular weight quaternized ammonium polymer" — "a quaternized ammonium polymer having a viscosity of about 1,000 cps or greater at a concentration of about 20% in water, depending on repeating unit moiety and a molecular weight range of about 1,000,000 or greater." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[626]

"highly pure solution of cefuroxime axetil" — "may include a solution that contains excipients along with pure CA." *Glaxo Group Ltd., et al. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004).[627]

"hollow" — "having an empty space within." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[628]

"homocysteine co-substrate" — "a compound which reacts with homocysteine in the homocysteine conversion reaction of the assay." *General Atomics, et al. v. Axis-Shield ASA,*440 F. Supp. 2d 1083 (N.D. Cal. 2006).[629]

"homocysteine conversion products" — "products that actually derive from homocysteine in the enzymic reaction." *General Atomics, et al. v. Axis-Shield ASA*,440 F. Supp. 2d 1083 (N.D. Cal. 2006).[630]

"homocysteine converting enzyme" — "an enzyme that acts on the sample homocysteine being assayed." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[631]

"homogeneous" — "of the same or a similar kind or nature ... of uniform structure or composition throughout." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[632]

"homogeneous" — "means that samples of the product taken anywhere throughout the product should have the same compositions." *Biovail Corp. International, et al. v. Andrx Pharmaceuticals, Inc.*, 158 F. Supp. 2d 1318 (S.D. Fla. 2000).[633]

"homogeneously branched linear ethylene/α-olefin interpolymer" — "ethylene α-olefin interpolymer in which the comonomer is randomly distributed within a given interpolymer molecule and wherein substantially all of the interpolymer molecules have the same ethylene/comonomer ratio within that interpolymer. Such interpolymer has no long chain branching." *Dow Chemical Co. v. Nova Chemicals Corp. (Canada), et al.*, 2009 U.S. Dist. LEXIS 88814 (D. Del., Sep. 24, 2009).[634]

"% homology" — "a percent identity calculation according to the standard whereby the number of exactly matching amino acid residues in two sequences is compared to the total number of residue positions that are present in both sequences, expressed as a percent, e.g., as implemented by the GAP GCG program." *Novozymes A/S v. Genencor International, Inc., et al.*, 446 F. Supp. 2d 297 (D. Del. 2006).[635]

"HPV DNA" — "a full length genome of one human papillomavirus." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[636]

"HPV hybridization probe" — "a nucleic acid molecule that is specific for the DNA of any one type of HPV and differentiates the DNA of that type from DNA of all other HPV types." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[637] "[N]othing in its arguments for reconsideration convinces me that the construction was incorrect." *Id.*, 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).[638]

"HPV 52 DNA" — "a DNA molecule that is only type 52 HPV." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[639] "We [] affirm the district court's construction of 'HPV 52 DNA' as meaning 'a DNA molecule that is only type 52 HPV.'" *Id.*, 323 Fed. Appx. 902 (Fed. Cir., Apr. 1, 2009).[640]

"HPV 52 DNA hybridization probe" — "nucleic acid molecule that is specific for HPV 52 DNA and that differentiates HPV 52 DNA from DNA of all other types." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[641] "[N]othing in its arguments for reconsideration convinces me that the construction was incorrect." *Id.*, 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).[642]

"HPV 52 DNA labeled with a detectable label" — "HPV 52 DNA that has a detectable label that is not DNA." *Digene Corp. v. Third Wave Technologies*, 2007 U.S. Dist. LEXIS 53882 (W.D. Wis., July 23, 2007).[643] "I conclude that plaintiff has failed to show that the construction I adopted for the claim term 'HPV 52 DNA labeled with a detectable label' is erroneous. Therefore, its motion for reconsideration will be denied." *Id.*, 2007 U.S. Dist. LEXIS 73010 (W.D. Wis., Sept. 26, 2007).[644]

"human" — "belonging to, or having the qualities of, man or mankind, including, but not limited to, the human qualities shown in Figures 5, 8 and 9 of the '972 patent." *Hoodlums Welding Hoods, LLC v. Redtail International, LLC*, 2009 U.S. Dist. LEXIS 100356 (E.D. Mo., Oct. 28, 2009).[645]

"human erythropoietin" — "a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al.*, 494 F. Supp. 2d 54 (D. Mass. 2007).[646]

"human growth hormone" — "includes met-hGH and hGH." *Novo Nordisk of North America, Inc., et al. v. Genentech, Inc.,* 1995 U.S. Dist. LEXIS 12588 (S.D.N.Y., June 28, 1995);[647] "properly construed, claim 2 is a process for the direct expression of met-hGH or hGH." *Id.*, 77 F.3d 1364 (Fed. Cir. 2006).[648]

"human IGF-I" — "the Court construes the term 'human IGF-I' as comprising the amino acid sequence corresponding to human IGF native to human tissue; human IGF-I does not include fusion proteins." *Genentech, Inc., et al. v. Insmed Inc., et al.*, 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[649]

"human IGF-I"; "mature human IGF-I" — "refer to bioactive material." *Genentech, Inc., et al. v. Insmed Inc., et al.*, 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[650]

"human patient" — "a recipient of any various personal health services." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[651]

"in a human patient in need thereof" — "the Court declines to construe this phrase." *Use Techno Corp., et al. v. Kenko USA, Inc., et al.*, 2007 U.S. Dist. LEXIS 55599 (N.D. Cal., July 24, 2007).[652]

"human urinary erythropoietin" — "erythropoietin derived from human urine." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[653]

"hybrid DNA molecule" — "refers only to molecules prepared in vitro." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 1996 U.S. Dist. LEXIS 15989 (D. Del., Oct. 21, 1996).[654]

"hybridization" — "the binding of two separate, complementary strands of nucleic acids to form nucleic acid hybrids." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2010 U.S. App. LEXIS 6267 (Fed. Cir., Mar. 26, 2010).[655]

"under hybridisation conditions" — "under conditions suitable for hybridization." *Oxford Gene Technology Ltd. v. Mergen Ltd., et al.*, 2004 U.S. Dist. LEXIS 19818 (D. Del., Sept. 29, 2004).[656]

"hybridizes, under stringent conditions" — "mean[s] that single strands of DNA from two sources form a stable double-stranded structure that remains intact during manipulation in the following conditions: Hybridizing in 50% formamide at SXSSC at a temperature of 420 ºC. and washing the filters in 0.2XSSC at 60 ºC." *Genentech, Inc., et al. v. Insmed Inc., et al*., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[657]

"probes hybridizing to at least one domain" — "hybridizing a probe to a target sequence and not to a non-target sequence." *Innogenetics N.V. v. Abbott Laboratories*, 2006 U.S. Dist. LEXIS 57142 (W.D. Wis., Aug. 11, 2006).[658]

"hydroacrylic monomer units" — "has the same construction as 'hydroxy acrylic monomer units.'" *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[659]

"a material comprising water or a hydrocarbon containing dissolved hydrogen sulfide" — "None of the embodiments of the invention described in the written description relate to gaseous hydrocarbons. We therefore conclude that the Board adopted a construction of the claim beyond that which was reasonable in light of the totality of the written description, and therefore erred in construing the claims to include gaseous hydrocarbons." *In re Baker Hughes Inc.*, 215 F.3d 1297 (Fed. Cir. 2000).[660]

"hydrocarbon fuel"; "hydrocarbon-containing fuel" — "a material that contains hydrocarbon and is capable of releasing energy or power by combustion." *Maxma, et al. v. ConocoPhillips Inc.*, 2005 U.S. Dist. LEXIS 34020 (E.D. Tex., Jul. 19, 2005).[661]

"ion bombardment ... the ions being hydrogen ions"; "hydrogen ion bombardment" — "means that hydrogen ions alone are implanted, i.e., the mono-implantation of hydrogen. Processes in which other gas ions are also introduced (before, after, or with hydrogen) do not satisfy this limitation." *S.O.I.T.E.C. Silicon on Insulator Technologies, S.A., et al. v. MEMC Electronic Materials, Inc.*, 2010 U.S. Dist. LEXIS 109667 (D. Del., Oct. 13, 2010).[662]

"implanting hydrogen ions" — "means that hydrogen ions alone are implanted, i.e., the mono-implantation of hydrogen. Processes in which other gas ions are also introduced (before, after, or with hydrogen) do not satisfy this limitation." *S.O.I.T.E.C. Silicon on Insulator Technologies, S.A., et al. v. MEMC Electronic Materials, Inc.*, 2010 U.S. Dist. LEXIS 109667 (D. Del., Oct. 13, 2010).[663]

"hydrogenated vegetable oil" — "refined, bleached, hydrogenated, and deodorized vegetable oil stearins consisting mainly of the triglycerides of stearic and palmitic acids." *Bristol-Myers Squibb Co., et al. v. Teva Pharmaceuticals USA, Inc.*, 288 F. Supp. 2d 562 (S.D.N.Y. 2003).[664]

"hydrophilic gel system" — "a delivery system of a water soluble gel- and matrix-forming material." *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 221 F. Supp. 2d 535 (E.D. Pa. 2002).[665]

"hydrophilic polymer" — "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[666]

"hydrophobe precursor" — "a precursor is a material from which another material can be formed. A hydrophobe precursor may be, but is not limited to, any organic material combining a site reactive toward starch or cellulose with a long hydrophobic tail, as well as the specific hydrophobic precursors identified in the specification of the '693 patent and materials having the structure of the hydrophobe precursors disclosed in the specification of the '693 patent." *Fort James Corp. v. J.H. McNairn, Ltd.*, 2006 U.S. Dist. LEXIS 36528 (N.D. Ga., April 4, 2006).[667]

"hydrosol" — "a) a synthetic pharmaceutical preparation, i.e., it does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient; and b) all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize." *Novartis Pharmaceuticals Corp., et al. v. Eon Labs Manufacturing, Inc.,* 215 F. Supp. 2d 452 (D. Del. 2002).[668] "In light of the specification and prosecution history, we conclude that the narrower definition of 'hydrosol' applies; that is, the term 'hydrosol' is limited to a medicinal preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside the body." *Id.*, 363 F.3d 1306 (Fed. Cir. 2004).[669] "Novartis's patent should not be limited to injectable hydrosols of cyclosporin made outside the body." *Id.* (Clevenger, J., dissenting).[670]

"hydrosoluble carrier" — "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[671]

"hydroxyl-containing replacement for water vapor" — "is not limited to ethyl alcohol, methyl alcohol or isopropyl alcohol, but includes other substances containing an OH group which serve as a solvent to ionize the hydrogen halide so that the etching reaction can proceed." *ASM America, Inc. v. Genus, Inc.*, 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).[672]

"hydroxy acrylic monomer" — "a molecule corresponding to the following formula: [SEE FORMULA IN ORIGINAL] wherein R is H or a substituted or unsubstituted alkyl; and X is a radical selected from the group consisting of hydroxyalkyloxy, hydroxalkyl amine, and hydroxy; with the alkyl being substituted or unsubstituted, and with the hydroxy on the alkyl being either a single hydroxy or a multiple hydroxy. An (unsubstituted) alkyl group is a hydrocarbon molecule containing only carbon and hydrogen atoms (C and H). A substituted alkyl group has an atom or group of atoms replaced by one or more different atoms or groups." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[673]

"hydroxy acrylic monomer units" — "chemical structures that are part of a polymer and correspond to the structures of hydroxy acrylic monomers in polymerized form, an example of which is shown below. The R and X in the formula are as defined above and may also be sites through with the monomer units are connected to the polymer: [SEE FORMULA IN ORIGINAL]." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[674]

hydroxy-protecting groups" — "any protecting group, or class or category without limitations as to any specific protecting group or class or category." *Bristol-Myers Squibb Co. v. Rhone-Polenc Rorer Inc., et al.*, 2001 U.S. Dist. LEXIS 24583 (S.D.N.Y., Jun. 4, 2001).[675]

"hydroxyalkyl acrylate" — "a type of hydroxy acrylic monomer unit where R may be a hydrogen atom (H) and where X is a hydroxyalkyloxy radical. Like other HAM units, X may have a substituted or unsubstituted alkyl as part of it and may also include more than one hydroxyl group. X may also be a site through which the monomer unit is connected to the polymer." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[676]

"hydroxypropyl methylcellulose"; "HPMC" — "is not limited to the grade and molecular weight of HPMC in the specific examples, but the claims, correctly construed, require that HPMC be present in the stated amount, and that the product have the release rate and duration and plasma levels and other properties set forth in the claims." *Glaxo Wellcome, Inc. v. Andrx Pharmaceuticals, Inc.*, 344 F.3d 1226 (Fed. Cir. 2003).[677]

"hyperglycemia" — "a symptom of diabetes." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[678]

"hyperparathyroidism" — "increased (i.e., above normal) secretion of PTH by the parathyroid gland." *Bone Care International, LLC, et al. v. Pentech Pharmaceuticals, Inc., et al.*, 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).[679]

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"imbalance of neuronal stimulation after Alzheimer's disease" — "a pathophysiological situation characterized by an excessive inflow of calcium through the NMDA receptor channels after Alzheimer's disease." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[680]

"immunoassay" — "refers to a laboratory technique that makes use of the binding between an antigen and an antibody in order to identify or quantify the specific antigen, and more particularly, to a protocol which uses the minimal concentration of the antibody which provides strong staining of the positive control." *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002).[681]

"immunoassay" — "a test that uses antibody specificity to detect the presence (or absence) of a compound of interest in a test sample." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[682]

"immunosorbing zone is <u>immersed in said sample solution</u>" — "requir[es] the immunosorbing zone to be plunged or dipped into the sample solution." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[683]

"impermeable"; "impermeably coated famotidine granules" — "refer[s] to a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide"; "famotidine granules that are coated with a material that is impermeable to the aluminum or magnesium hydroxide, using Wurster coating, rotocoating or another coating process acceptable to a person of ordinary skill in the art." *McNeil-PPC, Inc., et al. v. Perrigo Co., et al*., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).[684] "permitted some imperfections in the coating of famotidine." *Id.,* 2007 U.S. Dist. LEXIS 2937 (S.D.N.Y., Jan. 17, 2007).[685]

"an improved antisecretory effect" — "an enhanced ability to decrease gastric acid secretion." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[686]

"improved competence" — "means that the number or quantity of E. coli cells that take up and establish exogenous DNA is generally increased as compared with the number or quantity generally obtained when cells are prepared by either (1) growing the cells at 37 ºC, rendering them competent, and freezing them, or (2) growing the cells at 37 ºC, rendering them competent, and not freezing them." *Invitrogen Corp. v. Biocrest Manufacturing, L.P., et al*., 327 F.3d 1364 (Fed. Cir. 2003).[687]

"in a first compartment inactive SAH-hydrolase" — "the contents of a first compartment of the kit includes inactive SAH-hydrolase." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[688]

"a solution or dispersion of an effective amount of the active compound <u>in a semi-solid or liquid nonionic solubilizer</u>" — "the intrinsic evidence ... does not suggest ... that the word 'in' must be read as 'in and only in.'" *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 250 F. Supp. 2d 506 (E.D. Pa. 2003).[689]

"in a stabilizing amount" — "[is] not a limitation, but merely describe[s] the intended result[] of using octoxynol 40 in an 'amount between 0.001% and 1.0% wt/vol.'" *Syntex (U.S.A.) LLC, et al. v. Apotex, Inc., et al.*, 407 F.3d 1371 (Fed. Cir. 2005).[690]

"in an aqueous hydrogen peroxide solution having a water content of at least 25%" — "means that the reaction vessel, at the beginning of the oxidation reaction, contains a solution that includes PVPs, at least 25% water by weight, and hydrogen peroxide." *BASF Aktiengesellscaft v. Reilly Industries, Inc.*, 2004 U.S. Dist. LEXIS 27737 (S.D. Ind., Nov. 4, 2004).[691]

"reducing NF-[kappa] B activity <u>in cells</u>" — "taking action inside cells to inhibit (interfere or block) an NF-[kappa] B activity." *Amgen, Inc., et al. v. Ariad Pharmaceuticals, Inc., et al.*, 2009 U.S. App. LEXIS 11704 (Fed. Cir., Jun. 1, 2009) (unpublished).[692]

"in contact with" — "a union or junction of body surfaces, a touching or meeting." *McNeil-PPC, Inc., et al. v. Perrigo Co., et al*., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).[693]

"in crystalline form" — "covers only the stable, crystalline forms of valganciclovir HCl, Forms X and Y, whether as a pure crystalline solid or in a mixture with other amorphous forms, but any other forms of valganciclovir HCl, specifically amorphous and other possible semi-amorphous forms of valganciclovir HCl, are not covered by the patent." *Roche Palo Alto LLC v. Ranbaxy Laboratories Ltd., et al.*, 2009 U.S. Dist. LEXIS 90804 (D.N.J., Sep. 30, 2009).[694]

"in genetic linkage" — "a tendency of DNA sequences on the same chromosome to be linked together." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[695]

"in need thereof"; "in need of" — "one who has a specific perceived need." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[696]

"comprising the following steps in sequence" — "The claim says nothing about the administration of chemicals to achieve the reactions or the order in which such chemicals might be administered. Therefore, it is not limited to a method in which the chemicals are *administered* in sequence, rather than simultaneously, so long as the resulting reactions occur sequentially." *Infigen, Inc. v. Advanced Cell Technology, Inc.*, 65 F. Supp. 2d 967 (W.D. Wis. 1999).[697]

"in situ" — "refers to the formation of the separating layer within the formulation, as compared to its separate application." *In re Omeprazole Patent Litigation*, 2004 U.S. Dist. LEXIS 9447 (S.D.N.Y., May 19, 2004).[698]

"in the form of a briquette" — "the claim is only concerned with the shape of the additive and not how it is formed." *Harsco Corp. v. North Star Bluescope Steel, LLC*, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).[699]

"the compound 7-(4-(4-fluorophenyl)-6-isopropyl-2 -(N-methyl-methylsulfonylamino)pyrimidin-5-yl)-(3R, 5S)-dihydroxy-(E)-6-heptenoic acid in the form of a non-toxic pharmaceutically acceptable salt thereof" — "a non-toxic pharmaceutically acceptable salt of the compound 7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R, 5S)-dihydroxy-(E)-6-heptenoic acid." *In re: Rosuvastatin Calcium Patent Litigation*, 2009 U.S. Dist. LEXIS 98007 (D. Del., Oct. 20, 2009).[700]

"in the presence of acid" — "means that acid, as defined above, is present during the oxidation of PVP." *BASF Aktiengesellscaft v. Reilly Industries, Inc.*, 2004 U.S. Dist. LEXIS 27737 (S.D. Ind., Nov. 4, 2004).[701]

"in the presence of ... an ionic suspension stabilizer" — "requires that the suspension stabilizer be externally added to the reaction vessel and be ionic when so added." *Minnesota Mining and Manufacturing Co., Inc. v. Beautone Specialties Co., Ltd., et al.*, 117 F. Supp. 2d 72 (D. Mass. 1999).[702]

"substantially retaining the in vivo glucan morphology"; "having substantially the in vivo glucan morphology"; "retaining the in vivo glucan morphology" — "substantially retaining the shape that the glucan had in the cell from which the glucan is derived"; "having substantially the shape that the glucan had in the cell from which the glucan is derived"; "retaining the shape that the glucan had in the cell from which the glucan is derived." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[703]

"includes" — "As a patent law term of art, 'includes' means 'comprising.'" *Sandisk Corp. v. Memorex Products, Inc., et al.*, 415 F.3d 1278 (Fed. Cir. 2005).[704]

"pH in a range 4.5 to 6.0, inclusively" — "'Inclusively' means including but not exceeding the endpoints of the range." *LP Matthews LLC v. Bath & Body Works, Inc., et al.*, 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[705]

"incorporated" — "stably integrated into the chromosomal DNA within the nucleus of a cotransformed or transformed eucaryotic cell." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[706]

"incorporating" — "refers to adding argininium to a pharmaceutical composition of t-PA." *Genentech, Inc. v. Boehringer Mannheim GmbH, et al.*, 989 F. Supp. 359 (D. Mass. 1997).[707]

"increase" — "will be read as just that and without the limitation of being 'statistically significant.'" *Iovate Health Sciences, Inc., et al. v. Allmax Nutrition, Inc., et al.*, 639 F. Supp. 2d 115 (D. Mass. 2009).[708]

"an increased average plasma levels (AUC)" — "greater blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[709]

"such that the seal has <u>increased resistance to chemical attack</u>" — "possessing the property of being more resistant to deterioration when exposed to a broad range of harsh chemical agents when compared to the closest prior art seals known as of the filing date of the '107 patent, measured and analyzed according to accepted scientific standards set forth by the scientific community, such as those set forth in ASTM standards." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[710]

"increasing" — "does not require construction." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[711]

"indicating an extent of hybridization" — "indicating the relative strength of binding." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[712]

"indication" — "suggestion or sign of." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[713]

"inert hydrosoluble carrier" — "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[714]

"inert [subcoating]" — "require[s] that the subcoating be chemically, pharmaceutically, and pharmacologically inactive such that the subcoating does not adversely affect the properties of the active ingredient or the enteric coating material in the formulation." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).[715]

"a sufficient amount of the following diaminomethane compound to <u>inhibit hydrogen sulfide gas liberation</u>" — "This language implicitly requires the presence of hydrogen sulfide in the compositions for two reasons. First, the liberation of hydrogen sulfide from a composition cannot be inhibited if it is not present. Second, it would be futile to determine how much diaminomethane would be 'sufficient' to inhibit hydrogen sulfide liberation if hydrogen sulfide were not present." *In re Baker Hughes Inc.*, 215 F.3d 1297 (Fed. Cir. 2000).[716]

"a composition for <u>inhibiting an increase in, or lowering, a blood sugar level</u>" — "the Court declines to construe this language." *Use Techno Corp., et al. v. Kenko USA, Inc., et al.*, 2007 U.S. Dist. LEXIS 55599 (N.D. Cal., July 24, 2007).[717]

"inhibitor or activator of a protein" — "a substance that has a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all." *Housey Pharmaceuticals, Inc. v. Astrazeneca UK Ltd., et al.*, 366 F.3d 1348 (Fed. Cir. 2004).[718]

"inhibits a pathological activity of human TNF α" — "inhibits a TNF-α-mediated biological activity such as cytotoxicity or inflammation, or one associated with a clinical problem such as disease, infection and/or malignancy." *Centocor Ortho Biotech, Inc., et al. v. Abbott Laboratories, et al.*, 2009 U.S. Dist. LEXIS 28467 (E.D. Tex., Apr. 6, 2009).[719]

"one or more ornamental <u>insoluble objects embedded in said gel</u>" — "the claim term 'insoluble' ... is construed to mean 'soluble only with difficulty or to a slight degree, so that the object(s) when embedded in the gel retains its intended ornamental feature.'" *Penreco v. Hanna's Candle Co.*, 2003 U.S. Dist. LEXIS 27844 (S.D. Tex., Nov. 26, 2003).[720]

"insulin types"; "insulin type" — "apply to both insulin solutions and insulin suspensions." *Novo Nordisk A/S, et al. v. Becton Dickinson and Co.*, 997 F. Supp. 459 (S.D.N.Y. 1998).[721]

"intermediate release nicotinic acid formulation" — "a nicotinic acid formulation which, when administered to a patient to be treated, the active ingredient will be released for absorption into the blood stream over a period of time which is greater than about 1 to 2 hours, i.e., slower than immediate release niacin, but less than about 10 to 24 hours, i.e., faster than sustained release niacin." *Abbott Laboratories, et al. v. Lupin Ltd., et al.*, 2010 U.S. Dist. LEXIS 60743 (D. Del., Jun. 18, 2010).[722]

"intratympanically injected through a puncture of the tympanic membrane" — "introduced into the middle ear with an instrument such as a syringe." *Daiichi Pharmaceutical Co., Ltd., et al. v. Apotex, Inc., et al*., 380 F. Supp. 2d 478 (D.N.J. 2005);[723] *Id.,* 441 F. Supp. 2d 672 (D. N.J. 2006).[724]

"and being <u>inverted with respect to said promoter segment and said termination segment</u>" — "this element requires an inverted gene segment, or, in other words, a 'flipped' gene, or a gene that is placed in reverse orientation to the transcriptional promotor and transcription termination segments. The promoter and termination segments, however, must remain in ordinary position and order." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[725]

"having been prepared by aqueous suspension polymerization in the presence of at least one anionic emulsifier at a concentration level above said emulsifier's critical micelle concentration and <u>an ionic suspension stabilizer</u> having an interfacial tension of at least about 15.0 dynes per centimeter" — "the stabilizer must be ionic when it is put into the vessel, [and] we agree that a nonionic stabilizer is not an equivalent substituent." *Minnesota Mining and Manufacturing Co. v. United States International Trade Commission, et al.*, 1996 U.S. App. LEXIS 14585 (Fed. Cir., June 17, 1996) (unpublished).[726]

"isocyanate" — "is not limited to a process using 'free' isocyanates or its chemical formula, -NCO." *Wesley Jessen Corp. v. Coopervision, Inc.*, 2002 U.S. Dist. LEXIS 5172 (C.D. Cal., Mar. 14, 2002).[727]

"isolated" — "separate from forms of human G-CSF not having the amino acid sequences recited in the claim." *Teva Pharmaceuticals USA, Inc. v. Amgen, Inc.*, 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).[728]

"isolated and purified" — "separated from other, unwanted substances. Furthermore, 'isolated and purified' does not mean that the saccharides have to be individually isolated and separated from each other." *Mannatech, Inc. v. Techmedica Health, Inc., et al.*, 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Oct. 29, 2009).[729]

"isolated and purified" — "separated from other, unwanted substances." *Mannatech, Inc. v. Techmedica Health, Inc., et al.*, 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Aug. 28, 2009).[730]

"isolated and purified" — "separated from other, unwanted substances." *Mannatech, Inc. v. Glycobiotics International, Inc.*, 513 F. Supp. 2d 754 (N.D. Tex. 2007).[731] "In light of this construction, defendant argues that the claim term is vague and indefinite because neither the patents themselves nor the intrinsic record provide an objective standard to determine the precise degree of 'isolation' or 'purification' or specify exactly what 'unwanted substances' must be removed in order to practice the invention. The court disagrees." *Id.*, 2007 U.S. Dist. LEXIS 91946 (N.D. Tex., Dec. 14, 2007).[732]

"isolated compound of formula (3)" — "the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation." *Synthon IP, Inc. v. Pfizer Inc.*, 446 F. Supp. 2d 497 (E.D. Va. 2006).[733]

"isolated DNA" — "refer[s] to a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means." *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.*, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y., Mar. 29, 2010).[734]

"isolated form [of the compound of formula (3)]" — "the form of the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation." *Synthon IP, Inc. v. Pfizer Inc.*, 446 F. Supp. 2d 497 (E.D. Va. 2006).[735]

"isolating" — "separating." *Solvay S.A. v. Honeywell International, Inc.*, 622 F.3d 1367 (Fed. Cir. 2010).[736]

"isolating" — "'isolating' (1) generally means 'separating' and (2) does not equate to 'purifying.'" *Synthon IP, Inc. v. Pfizer Inc.*, 446 F. Supp. 2d 497 (E.D. Va. 2006);[737] "separating, generally." *Id.*, 457 F. Supp. 2d 668 (E.D. Va. 2006).[738]

"isolating" — "the term 'isolating' references the recovery of the virus from either the tissue homogenate or a previous passage." *Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp.*, 984 F. Supp. 239 (D.N.J. 1997).[739] "[T]he district court [correctly] held that the virus is 'isolated' not only when the virus is cultured from tissues of an infected animal (the initial recovery of the virus), but also during subsequent serial passages of the virus, when the virus is cultured from an aliquot of an infected cell culture." *Id.*, 320 F.3d 1339 (Fed. Cir. 2003).[740]

"isolating from a crude reaction mixture compound of formula (3)" — "separating the compound of formula (3) from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation." *Synthon IP, Inc. v. Pfizer Inc.*, 446 F. Supp. 2d 497 (E.D. Va. 2006);[741] *Id.,* 457 F. Supp. 2d 668 (E.D. Va. 2006).[742]

"isotonic" — "compatible with body fluids." *EKR Therapeutics, Inc. v. Sun Pharmaceutical Industries, Ltd.*, 633 F. Supp. 2d 187 (D.N.J. 2009).[743]

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"joined end-to-end outside of living cells" — "[is] a structural limitation which may encompass identical products made by different processes." *Schering Corp., et al. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998).[744]

"joined in proper reading frame" — "encompasses DNA constructs such as Genentech's, that have intervening nucleotide sequences between the alpha-factor processing sequences and the human IGF-I sequence, as long as the proper reading frame is maintained between the two joined sequences." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495 (Fed. Cir. 1997).[745]

"jojoba-derived material" — "material derived from the jojoba plant or alternatively any material that is left following the application of the saponification process to jojoba oil." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[746]

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"kinetic energy of ions" — "energy associated with the motion of ions." *Applera Corp., MDS Inc., et al. v. Micromass UK Ltd., et al.*, 186 F. Supp. 2d 487 (D. Del. 2002).[747]

"known dose" — "a dose effective to reduce blood serum lipids and whose amount is known." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[748]

"known equivalent hematocrit value" — "i-STAT argues that, by definition, the hematocrit value of the '479 standardizing solution must be expressed as a positive number, because no other result is possible with a real blood reference, that is, no hematocrit value found in an actual blood sample can be less than zero. This reading of the patent is. I believe, correct." *Nova Biomedical Corp. v. i-STAT Corp.*, 980 F. Supp. 614 (D. Mass. 1997).[749] "The court properly looked to the express definition of 'equivalent hematocrit value' in the written description and concluded that 'equivalent hematocrit values' are those between zero and 100." *Id.*, 1999 U.S. App. LEXIS 21390 (Fed. Cir., Sept. 3, 1999) (unpublished).[750]

"known sequences" — "sequences of monomers identified prior to attachment to the surface." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[751]

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"having a peptide sequence of human factor VIII:C but lacking a peptide region selected from the group consisting of:" — "having the amino acid sequence of the human Factor VIII protein lacking only the particular segment of the human Factor VIII protein in one of the specified alternatives (a), (b) or (c)." *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 2010 U.S. Dist. LEXIS 16150 (D. Del., Feb. 24, 2010).[752]

"laminated"; **"laminate"** — "two or more bonded layers." *Sud-Chemie, Inc. v. Multisorb Technologies, Inc.*, 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).[753]

"layer" — "'a thickness of material of substantially uniform chemical composition, but excluding interlayers having a thickness not to substantially affect the optical properties of the coating.' When determining whether a deposit is optically significant, the focus should be on whether the thickness and composition of the material itself is optically significant, rather than whether the absence of that material would lead to oxidation and discoloration of adjacent layers. Moreover, we make no determination as to whether a chemical compound that has been deposited in multiple separate, sequential applications, without intervening layers or interlayers, constitutes a single 'layer.' This is a matter for the trial court to resolve in a manner consistent with our claim construction." *AFG Industries, Inc., et al. v. Cardinal IG Co., et al.*, 239 F.3d 1239 (Fed. Cir. 2001).[754]

"lean body mass" — "body mass excluding the mass of body fat." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[755]

"linked" — "physically and chemically joining DNA I and DNA II into the same piece of contiguous DNA prior to their insertion into the eucaryotic cell." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[756]

"binding of said target compound to ... capture molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate" — "binding of the target compound to one or more of the species of capture molecules results in a catalytic reduction of a metal present in solution and formation of a metallic precipitate in one or more of the discrete regions." *Eppendorf AG, et al. v. Nanosphere Inc.*, 2010 U.S. Dist. LEXIS 69072 (D. Del., Jul. 12, 2010).[757]

"lentiviral LTR-deleted vector"; "LLD vector" — "a replication-defective vector based on a lentivirus in which (a) one or more LTR nucleotide sequences from the lentivirus, including at least one such nucleotide sequence that is involved in transcription, are not present, and (b) lentiviral LTR nucleotide sequences necessary for reverse transcription and integration are present." *Sigma-Aldrich, Inc. v. Open Biosystems, Inc.*, 521 F. Supp. 2d 975 (E.D. Mo. 2007).[758]

"lentiviral vector" — "a replication-defective viral vector that comprises a sequence of RNA or DNA nucleotides derived from a lentivirus." *Sigma-Aldrich, Inc. v. Open Biosystems, Inc.*, 521 F. Supp. 2d 975 (E.D. Mo. 2007).[759]

"less pronounced increase in gastrin levels" — "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[760]

"lipid-based component" — "an inner component in which lipids constitute a sufficient portion to prevent the migration of water from the outer component into the inner component." *Kal Kan Foods, Inc. v. H.J. Heinz Company, L.P., et al.*, 2004 U.S. Dist. LEXIS 16808 (C.D. Cal., Feb. 5, 2004).[761]

"lipophilic phase component"; "lipophilic component" — "include[s] at least one excipient meeting the following criteria: (1) a pharmaceutically acceptable lipophilic solvent in which cyclosporin is soluble, which is (2) immiscible with both water and the hydrophilic phase component(s) (in the absence of a surfactant), and which (3) lacks the amphiphilic function characteristic of a surfactant (i.e., it must not be a surfactant)." *Novartis Pharmaceuticals Corp., et al. v. Abbott Laboratories*, 294 F. Supp. 2d 552 (D. Del. 2002).[762] "[T]he claimed 'lipophilic component' must contain, at minimum, a pharmaceutically acceptable lipophilic substance capable of dissolving cyclosporin, and that is a non-surfactant excipient. ... We find nothing within the intrinsic record that compels reading the immiscibility limitation into the 'lipophilic component' term." *Id.*, 375 F.3d 1328 (Fed. Cir. 2004).[763] "Abbott can prevail on this claim construction issue only if the specification is read as requiring that the 'lipophilic component' limitation be construed more narrowly. The court today concludes that the specification has that effect, but I do not agree." *Id.* (Bryson, J., dissenting).[764]

"liquid" — "a substance, such as insulin, that is active within the human body." *Medtronic MiniMed Inc. v. Smiths Medical MD Inc.*, 2005 U.S. Dist. LEXIS 10583 (D. Del., Jun. 1, 2005).[765]

"liquid-air interface" — "require[s] an actual interface--molecule-to-molecule--between the amniotic liquid and the air." *Utah Medical Products, Inc. v. Clinical Innovations Associates, Inc., et al.*, 79 F. Supp. 2d 1290 (D. Utah 1999).[766]

"liquid impermeable" — "a material which is designed to prevent the strikethrough of body exudates by retarding the movement of liquid body exudates through the BLC to the outer portion of the diaper." *Procter & Gamble Co.v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547 (D. Del. 1997).[767]

[i] "liquid whole egg"; [ii] "liquid whole egg product" — [i] "liquid whole egg or liquid whole egg blends containing less than 2% added non-egg ingredients. Such non-egg ingredients may include preservatives"; [ii] "products which include liquid whole egg and may have more than 2% added non-egg ingredients. Such non-egg ingredients may include preservatives." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[768]

"long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)" — "an NSAID with a pharmacokinetic half-life of at least about 4-6 hours and preferably about 8-14 hours and a duration of action equal to or exceeding about 6-8 hours." *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).[769]

"low molecular weight carbohydrate" — "a material which includes carbon, hydrogen, and oxygen where the ratio of hydrogen to oxygen is the same as in water, and which is obtained from a refined and consistent source." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[770]

"low molecular weight DADMAC" — "a low molecular weight DADMAC having a molecular weight range of greater than about 50,000 and less than about 1,000,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[771]

"low molecular weight epichlorohydrin di-methyl amine (Epi-DMA)" — "a low molecular weight Epi-DMA having a molecular weight range of greater than about 20,000 and less than about 500,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[772]

"C_{max} ... are <u>lower</u>" — "This Court will not reconstrue claim 4 to include the term 'statistically significantly' to modify 'lower.'" *Abbott Laboratories v. Sandoz, Inc.,* 2007 U.S. Dist. LEXIS 89403 (N.D. Ill., Dec. 4, 2007).[773]

"lowering or maintaining lowered serum parathyroid hormone" — "lowering elevated blood concentrations of parathyroid hormone ('PTH') or maintaining lowered blood concentrations of PTH." *Bone Care International, LLC, et al. v. Pentech Pharmaceuticals, Inc., et al.*, 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).[774]

"lubricant" — "an excipient which, by itself or in combination with another excipient, reduces the ejection forces during tableting of a particular pharmaceutical formulation, and which is present on the surface of the tableting mass during compression in the tablet press so that it can function in that capacity." *Bristol-Myers Squibb Co., et al. v. Teva Pharmaceuticals USA, Inc.*, 288 F. Supp. 2d 562 (S.D.N.Y. 2003).[775]

"a <u>lubricating oil composition</u> suitable as a crankcase lubricant in internal combustion engines comprising ..." — "claims a product, not merely a recipe for making whatever product results from the use of the recipe ingredients." *Exxon Chemical Patents, Inc., et al. v. Lubrizol Corp.*, 64 F.3d 1553 (Fed. Cir. 1995);[776] "I join in the reversal of the trial court's judgment of infringement, based on what I consider to be the correct claim interpretation as advanced by Judge Clevenger." *Id.* (Plager, J., concurring);[777] "I agree with the trial judge's interpretation of the claims that one skilled in the art ... would interpret claims 1 and 61 as covering a lubricating oil composition comprising the product resulting from a combination of the required five ingredients, in the claimed amounts, regardless of any unknown reactions, or metal complexes formed between those ingredients that occurs upon mixing." *Id.* (Nies, J., dissenting).[778]

"the luminal portion of the tunica mucosa" — "the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria." *Cook Biotech, Inc., et al. v. Acell, Inc., et al.*, 460 F.3d 1365 (Fed. Cir. 2006).[779]

"Lutein" — "all isomers of lutein, and not just 'trans-lutein.'" *Kemin Foods, L.C., et al. v. Omniactive Health Technologies, Inc., et al*., 2009 U.S. Dist. LEXIS 88348 (M.D. Fla., Sep. 27, 2009).[780]

"lysis of a chemical bond" — "breaking a chemical bond." *Saffran v. Johnson & Johnson, et al.*, 2010 U.S. Dist. LEXIS 98537 (E.D. Tex., Sep. 20, 2010).[781]

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"macromolecules" — "molecules with a molecular weight of at least approximately 500 Daltons." *Saffran v. Boston Scientific Corp.*, 2007 U.S. Dist. LEXIS 76135 (E.D. Tex., Sept. 28, 2007).[782]

"magnetic or magnetizable" — "is or is capable of becoming a permanent magnet or a residual magnet, that is, a magnet that retains its magnetic field for a period of time." *Ideal Instruments, Inc. v. Rivard Instruments, Inc., et al.*, 498 F. Supp. 2d 1131 (N.D. Iowa 2007).[783]

"main peaks" — "The problem with TorPharm's argument is that it fails to recognize that 'main' is a relative term. In order to be 'chief in size,' the peaks must be measured relative to something. We think it is clear from the intrinsic record, including the prosecution history, that all the word 'main' requires is that the peaks be 'chief in size' relative to the baseline of the pure Form 2 compound." *Glaxo Group Ltd. v. Torpharm, Inc., et al.,* 153 F.3d 1366 (Fed. Cir. 1998).[784]

"to maintain reduced intraocular pressure" — "maintenance of reduced intraocular pressure throughout the course of treatment without development of tachyphylaxis, i.e., throughout the period of time that the claimed method is being used to treat glaucoma." *Stern v. Trustees of Columbia University, et al.*, 2005 U.S. Dist. LEXIS 2418 (S.D.N.Y., Feb. 17, 2005).[785]

"maintaining" — "keeping the plant cell in tissue or as part of a plant, so long as conditions continue that allow the plant cell to divide and multiply." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[786]

"maintaining a therapeutic level of AAKG in the patient's circulatory system" — "the Court has construed 'therapeutic level' and 'patient.' The remaining words in the phrase--'maintaining' and 'circulatory system'--do not require construction." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[787]

"maintaining said compressible layer at a temperature below the melting point of said microcapsules for a time sufficient to cause said elastomeric material to vulcanize to a degree sufficient to substantially fix the positions of said microcapsules within said compressible layer" — "the magistrate judge did not err, in light of the prosecution history, when it construed the 'maintaining' step in claims 1 and 21 to require microcapsules that melted at conventional curing temperatures and when it concluded that the claims require an initial curing step that took place at temperatures below conventional curing temperatures." *Day International, Inc. v. Reeves Brothers, Inc.*, 260 F.3d 1343 (Fed. Cir. 2001).[788]

"a stabilizer which <u>maintains the size distribution</u> of said [cyclosporin] particles" — "a) the stabilizer keeps the size distribution of the solid particles constant, i.e., the stabilizer prevents the solid particles of cyclosporin from increasing or decreasing in size; and b) the stabilizer maintains the size distribution of the particles for at least six hours after the hydrosol is formed." *Novartis Pharmaceuticals Corp., et al. v. Eon Labs Manufacturing, Inc.,* 215 F. Supp. 2d 452 (D. Del. 2002).[789]

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"mammalian" — "the class of mammals or animals which suckle their young, including, but not limited to, a human, dog, and gorilla, as shown in Figures 5 through 9 of the '972 patent." *Hoodlums Welding Hoods, LLC v. Redtail International, LLC*, 2009 U.S. Dist. LEXIS 100356 (E.D. Mo., Oct. 28, 2009).[790]

"mammalian" — "We agree with Amgen that the specification expressly describes humans as a subset of mammals, and mammals, in turn, as a subset of vertebrates." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al*., 314 F.3d 1313 (Fed. Cir. 2003).[791]

"mammalian cell" — "any cell of mammalian origin, including both a wild-type and a mutant cell." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[792]

"mammalian cells" — "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al*., 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[793]

"marker for a haplotype" — "indicator for a haplotype." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[794]

[i] "marker substance"; [ii] "intracellular marker substance" — [i] "an antigen, but ... molecular sub-units, such as those present in the HCG antigen, qualify as antigens under this construction"; [ii] "an antigen existing within a cell." *Goldenberg, et al. v. Cytogen, Inc., et al.*, 373 F.3d 1158 (Fed. Cir. 2004).[795] "From my review of the intrinsic evidence, the 'marker substance,' as described by the specification and set forth in the claims, plainly embraces portions of an antigen, provided that they are inside the cell. Because transmembrane antigens generally have an element that extends into the intracellular region, I would submit that the intracellular portion of such an antigen plainly falls within the scope of 'intracellular marker substance.'" *Id.* (Prost, J., dissenting-in-part).[796]

"material for finishing" — "a material that makes more durable the underlying surface of the floor, and is applied for that purpose." *Middleton, Inc. v. Minnesota Mining and Manufacturing Co.*, 1998 U.S. Dist. LEXIS 19428 (N.D. Ill., Nov.24, 1998).[797]

"layer having <u>material release means for release of an at least one treating material in a directional manner</u>" — "the court construes the recited function as 'releasing a treating material toward the damaged tissue.' ... The court identifies the corresponding structure in the specification that is clearly linked to the claimed function to be chemical bonds and linkages." *Saffran v. Boston Scientific Corp.*, 2007 U.S. Dist. LEXIS 76135 (E.D. Tex., Sept. 28, 2007).[798]

"one or more layers of <u>materials</u>"; "one or more layers comprising <u>materials</u>" — "the court rejects Cheminor's attempt to limit the claims of the '505 and '230 patent to cover only those formulations containing more than one 'material' in the subcoating." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).[799]

"the mature erythropoietin amino acid sequence of Figure 6" — "the fully realized form of amino acid sequence of Figure 6." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al*., 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[800]

"mean fluctuation index" — "the average degree of fluctuation ((C_{max}-C_{min})/C_{avg}) over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[801]

"a mean grain diameter d[50] ≤ 5 µm" — "the Commission erred in construing "mean grain diameter" as the volumetric mean, not the number-based mean." Osram GmbH, et al. v. ITC, 505 F.3d 1351 (Fed. Cir. 2007).[802]

"measuring the HIV RNA copy number" — "no construction is necessary." *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 528 F. Supp. 2d 967 (N.D. Cal. 2007).[803]

"medicament" — "The term's ordinary meaning as understood by those of ordinary skill in the art shall apply." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[804]

"medium" — "while perhaps amenable to a broader interpretation under ordinary circumstances, [the term] was defined by the inventor of the patents at issue to be a specific medium, i.e., one that supports log-phase, reproductive growth of only the target microbes." *Edberg, et al. v. CPI-The Alternative Supplier, Inc.*, 41 Fed. Appx. 426 (Fed. Cir., Jul. 15, 2002) (unpublished).[805]

"melting" — "does not appear to have required 'construction,' or to depart from its ordinary meaning." *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc., et al.*, 249 F.3d 1341 (Fed. Cir. 2001).[806]

"a melting point of about 123-125 º" — "the temperature at which the solid becomes a liquid, of approximately 123-125 º." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al.*, 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).[807]

"melting point of 41 - 42 º C" — "the solid begins to liquefy and becomes liquid throughout at a temperature range between 40.5 º C and 42.4 º C, as measured by a capillary melting point apparatus." *Johnson Matthey Inc. v. Noven Pharmaceuticals, Inc., et al.*, 2009 U.S. Dist. LEXIS 62540 (E.D. Tex., Jul. 21, 2009).[808]

"melting temperature" — "peak of the melting endotherm as reflected by a DSC trace." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[809]

"immunosorbing <u>member</u>"; "liquid absorbing <u>member</u>" — "the Court finds the 'immunosorbing zone' of Claim 1 and the 'immunosorbing member' of Claim 25 have the same meaning. The Court also construes 'liquid absorbing zone' and a 'liquid absorbing member' in an identical manner." *Dade Behring Marburg GmbH, et al. v. Biosite Diagnostics, Inc.*, 1998 U.S. Dist. LEXIS 13438 (D. Del., Jul. 24, 1998).[810]

"menthol" — "menthol, as a distinct and separate substance, as distinguished from being present in mint oils." *William Wrigley Jr. Co. v. Cadbury Adams USA, LLC*, 500 F. Supp. 2d 922 (N.D. Ill. 2007).[811]

"metabolism" — "mean[s] only the breaking down of molecules." *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 1996 U.S. Dist. LEXIS 15989 (D. Del., Oct. 21, 1996).[812]

"a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" — "A method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus time." *Wyeth v. Impax Laboratories, Inc.*, 526 F. Supp. 2d 474 (D. Del. 2007).[813]

"a method for treating induced contact dermatitis" — "breathes life, meaning and vitality into the claim by making clear the purpose of the invention." *Yarbrough Foundation, et al. v. Rite Aid Corp., et al.*, 2007 U.S. Dist. LEXIS 53443 (W.D. Mich., July 24, 2007).[814]

"[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" — "this language is only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claim." *Bristol Meyers Squibb Co. v. Ben Venue Laboratories, Inc., et al.*, 246 F.3d 1368 (Fed. Cir. 2001).[815]

"method of identification and detection of nucleic acids in a multi-nucleic in acid mixture" — "means that different nucleic acids in a multi-nucleic acid mixture that are labeled with different fluorescent labels can be distinguished by irradiating the labels and measuring the fluorescence they emit" *Amersham Pharmacia Biotech, Inc. v. Perkin-Elmer Corp.*, 2000 U.S. Dist. LEXIS 22942 (N.D. Cal., Feb. 28, 2000).[816]

"method of treating atherosclerosis" — "is limiting." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[817]

"a method of treatment for the relief of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for treatment for the relief of nausea and vomiting of [ondansetron]" — "means what it says. The claims reach administration of ondansetron for the treatment of nausea, however induced, but only those manifestations of nausea against which ondansetron, a 5-HT[3] antagonist, is effective. Put another way, TYERS I and II are directed to any use of ondansetron that may work to treat a patient's nausea, but these patents do not claim a method of treatment for the relief of those forms of nausea, such as apomorphine-induced nausea, against which it would be obvious to skilled artisans that a 5-HT[3] antagonist is ineffective." *Glaxo Group Ltd., et al. v. Kali Laboratories, Inc.*, 2005 U.S. Dist. LEXIS 15627 (D.N.J., Jul. 26, 2005).[818]

"method for the treatment of a mammal, including man, suffering from or susceptible to infection by HIV" — "this term requires no further construction." *Glaxo Group Ltd, et al. v. Teva Pharmaceuticals USA, Inc.*, 2009 U.S. Dist. LEXIS 37494 (D. Del., Apr. 30, 2009).[819]

"methotrexate" — "a folate analog that is lethal to cells." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[820]

"micro-environment" — "refer[s] to the regions immediately around or in close proximity to the omeprazole particles." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).[821]

"microbead" — "a product formed by the polymerization of monomers. The microbead must be an integral unit which can be separated from any emulsifier present." *Ciba Specialty Chemicals Corp. v. Hercules, Inc., et al.*, 436 F. Supp. 2d 670 (D. Del. 2006).[822]

"microporous film" — "Because of the patent examiner's comment that in the art, 'film' did not encompass the property of wovenness, the court cannot find a clear and unmistakable disclaimer. Therefore, we conclude that the claim as amended recites a 'microporous film' not narrowed in scope by the amendment deleting 'or nonwoven.'" *Sud-Chemie, Inc. v. Multisorb Technologies, Inc.*, 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).[823]

"minimum antibiotic serum concentration" — "the lowest concentration known to exert a significant antibiotic effect." *Research Foundation of State University of New York, et al. v. Mylan Pharmaceuticals, L.P.*, 2010 U.S. Dist. LEXIS 46791 (D. Del., May 12, 2010).[824]

"said concentrated detergent solution is <u>mixed prior to being directed onto said fabric</u>" — "This claim element means that detergent and water are combined to form the concentrated detergent solution before the resulting solution is sprayed onto the fabric. There is no limitation or restriction as to the location where the mixing occurs, i.e., the mixing is not required to occur in a mixing tank or a zone separate from the fabric and the wash chamber." *Whirlpool Corp., et al. v. LG Electronics, Inc., et al.*, 423 F. Supp. 2d 730 (W.D. Mich. 2004).[825]

"mixing" — "combining two or more ingredients into one mass." *McNeil-PPC, Inc., et al. v. Perrigo Co., et al.*, 443 F. Supp. 2d 492 (S.D.N.Y. 2006).[826]

[i] "mixing"; [ii] "introducing" — [i] "combining"; [ii] "adding." *US Foam, Inc, et al. v. On Site Gas Systems, Inc.*, 2010 U.S. Dist. LEXIS 79286 (E.D. Tex., Aug. 3, 2010).[827]

"mixing the drug and the carbohydrate material" — "combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids." *Cephalon, Inc., et al. v. Barr Laboratories, Inc.*, 389 F. Supp. 2d 602 (D. Del. 2005).[828]

"mixture" — "The word 'mixture' in the claims has the scope given it in the specification, for it is clear that no broader scope was contemplated or intended. We conclude that the '489 claims require that the preform process employs a volume of liquid binder that exceeds the volume of powdered matrix." *Kinik Co. v. International Trade Commission, et al.*, 362 F.3d 1359 (Fed. Cir. 2004).[829]

"exposing the substrate to <u>a mixture of ...</u>" — "the 'mixture' contemplated by the claim language need not occur outside the reaction chamber. Each of the ingredients of the mixture, i.e., the 'hydrogen halide vapor and either water vapor or a vapor of a hydroxyl-containing replacement for water vapor,' must come from outside the reaction chamber, however." *ASM America, Inc. v. Genus, Inc.*, 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).[830]

"a mixture of (1) ..., (2) ..., and (3) ..." — "Defendants have argued ... that ... to be infringing, it must have been created by 'mixing' three separate compositions. ... The Court cannot accept Defendants' interpretation of the term 'mixture' for several reasons. First, the plain meaning of the term 'mixture' is that which consists of different elements; it is a noun which refers to what is contained in a composition, not how a composition is created." *University of Florida Research Foundation, Inc., et al. v. Orthovita, Inc., et al.*, 1998 U.S. Dist. LEXIS 22648 (N.D. Fla., Apr. 20, 1998).[831]

"a 'mixture' of bupropion hydrochloride and 'means for releasing' bupropion hydrochloride over the course of an hour, 'said means comprising [HPMC]'" — "describ[es] a specific polymer, HPMC, that is blended with bupropion hydrochloride to form an admixture. The addition of HPMC serves to retard the release of bupropion hydrochloride into the bloodstream." *Smithkline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, 214 F. Supp. 2d 581 (E.D. Va. 2002).[832]

"heterogeneous mixture of labeled unique sequence nucleic acid fragments" — "a heterogeneous mixture of labeled nucleic acid fragments that includes unique sequence fragments." *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).[833]

"modified chimeric gene" — "the word 'modified,' and variations of the word, including 'modify' and 'modification,' means altered or changed from the naturally occurring gene sequence, irrespective of the manner in which the changes are made. Thus, a 'modified chimeric gene,' as used in the '365 patent, includes a gene designed by either site-directed mutagenesis or a gene designed by chemical synthesis, with changes in the 240 region." *Monsanto Co. v. Mycogen Plant Science, Inc., et al.*, 61 F. Supp. 2d 133 (D. Del. 1999).[834]

"moisturizing composition" — "this term requires no additional construction." *Laboratory Skin Care, Inc. v. Limited Brands, Inc., et al.*, 616 F. Supp. 2d 468 (D. Del. 2009).[835]

"molasses feed solution" — "beet molasses which is diluted with water." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[836]

"molecular sieve" — "mean[s] gel permeation or gel filtration techniques which separate molecules based on size." *Genentech, Inc. v. Boehringer Mannheim GmbH, et al*., 989 F. Supp. 359 (D. Mass. 1997).[837]

"molecular species being characterized by a triple helix conformation" — "has a readily understood meaning such that no construction is necessary." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[838]

"a molecular species which migrates as a single peak when analyzed by gel permeation chromatography" — "needs no construction." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[839]

"molecular weight" — "the sum of the atomic weights of all the atoms in a molecule as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[840]

"molecular weight of at least approximately 1,000,000 to approximately 3,000,000" — "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having a molecular weight range of about 1,000,000 to approximately 3,000,000." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[841]

"determining the existence of acceptable continuity and well interflow paths for the said region by generating a test flow of a solution of hydrogen peroxide from one of said wells and monitoring pH changes at each other of said wells as a function of time to detect a pH drop of at least 0.2" — "is read to require that pH be monitored for the particular purpose of determining the existence of acceptable continuity and well interflow paths." *Cleanox Environmental Services, Inc. v. Hudson Environmental Services, Inc., et al.*, 14 F. Supp. 2d 601 (D.N.J. 1998).[842]

"monoclonal antibody" — "an antibody composition having a homogeneous (essentially identical) antibody population. The term is not limited regarding the species or source of the antibody, nor is it limited by the manner in which it is made. For example, the term includes monoclonal antibodies produced by a methodology other than hybridoma which results in monoclonal antibodies no matter how subcategorized, e.g., hybrid, altered, chimeric, or humanized. The term includes variants that naturally arise during the production of monoclonal antibodies. The term includes whole immunoglobulins." *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002);[843] 2002 U.S. Dist. LEXIS 19126 (E.D. Ca., June 24, 2002).[844]

"monomer" — "small repeating units found within an already formed polymer." *Edizone, LC v. Cloud Nine, LLC, et al.*, 2006 U.S. Dist. LEXIS 68069 (D. Utah, Sept. 21, 2006).[845]

"monomer" — "a molecule capable of being combined with other molecules to form a polymer." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[846]

"more highly expressed" — "refers to the level of messenger RNA produced by the synthetic gene." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[847]

"morphologically identifiable ... cell nucleus" — "refer[s] to a single cell nucleus that contains the full complement of chromosomal DNA." *Regents of the University of California, et al. v. Dakocytomation California, Inc.*, 2006 U.S. Dist. LEXIS 10805 (N.D. Cal., March 10, 2006).[848]

"moxifloxacin" — "indicate[s] the quinolone compound of the same name, whose structure, stereochemistry and other properties were well known as of the priority date." *Alcon, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, 2009 U.S. Dist. LEXIS 97757 (D. Del., Oct. 19, 2009).[849]

"a multilayer pharmaceutical tablet" — "a pharmaceutical tablet with at least two separate, distinct layers." *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).[850]

"multiplicity" — "multiple." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[851]

"murine embryonic stem cell" — "a mouse embryonic stem cell." *Central Institute for Experimental Animals v. Jackson Laboratory*, 2010 U.S. Dist. LEXIS 10548 (N.D. Cal., Feb. 8, 2010).[852]

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"N-ethyl-p-menthane-3-carboxamide" — "an N-substituted-p-menthane carboxamide known by the trade name WS-3." *William Wrigley Jr. Co. v. Cadbury Adams USA, LLC*, 500 F. Supp. 2d 922 (N.D. Ill. 2007).[853]

"N-substituted-p-menthane carboxamide" — "a class of molecules with the chemical formulas set forth in Claims 1 and 12 of the '893 Patent." *William Wrigley Jr. Co. v. Cadbury Adams USA, LLC*, 500 F. Supp. 2d 922 (N.D. Ill. 2007).[854]

"NOD/Shi mouse" — "a non-obese diabetic mouse that: (1) has not been reproductively separated from the NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories or (2) has been reproductively separated from that colony by 20 or fewer generations." *Central Institute for Experimental Animals v. Jackson Laboratory*, 2010 U.S. Dist. LEXIS 10548 (N.D. Cal., Feb. 8, 2010).[855]

"nanophase diamond film" — "a film having nanometer-scale nodules of diamond-bonded carbon displaying characteristics similar to that of diamond." *Collins, et al. v. Gillette Co.*, 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).[856]

"said LA-NSAID is <u>naproxen</u>" — "said LA-NSAID is (S)-6-methoxy-α-methyl-2-naphthaleneacetic acid or a pharmaceutically acceptable salt thereof." *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).[857]

"nebulize" — "to reduce a liquid to a fine spray having a wide range of particle sizes." *Dow Chemical Co. v. Mee Industries, et al.*, 2001 U.S. Dist. LEXIS 26229 (M.D. Fla., Aug. 17, 2001).[858]

"human in <u>need of such treatment</u>" — "a human with acute herpes zoster who is at high risk of developing PHN, for example, the elderly." *Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 97610 (D.N.J., Sep. 17, 2010).[859]

"mammal in <u>need of such treatment</u>" — "a mammal with acute herpes zoster who is at high risk of developing PHN, for example, the elderly, or a mammal who has been diagnosed with PHN." *Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 97610 (D.N.J., Sep. 17, 2010).[860]

"no substantial increase in said internal core temperature" — "an increase in internal core temperature of no more than 1° F." *Unitherm Food Systems, Inc. v. V.H. Cooper & Co., Inc.*, 2010 U.S. Dist. LEXIS 55911 (N.D. Okla., Jun. 4, 2010).[861]

"no traces of toxic chemicals" — "no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994, by a person of ordinary skill in the art." *Kemin Foods, L.C., et al. v. Omniactive Health Technologies, Inc., et al*., 2009 U.S. Dist. LEXIS 88348 (M.D. Fla., Sep. 27, 2009).[862]

"nodules of carbon bonded predominately in three dimensional sp^3 bonds" — "clusters of carbon atoms of rounded or irregular shape wherein approximately 95% or more of the bonds between the carbon atoms in each cluster are three dimensional sp^3 bonds." *Collins, et al. v. Gillette Co.*, 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).[863]

"a nominal addition amount of the catalyst (having a nominal weight)" — "an approximate or assumed amount of catalyst added to raise the concentration of the catalyst from the previously established lower concentration boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) to the previously established upper concentration boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) (having an approximate or assumed but not necessarily actual weight)." *Intercat, Inc. v. Nol-Tec Systems, Inc., et al.*, 2005 U.S. Dist. LEXIS 344 (D. Minn., Jan. 7, 2005).[864]

"non-aluminum modified" — "silica particles that have 'not been surface modified with aluminum.'" *Ondeo Nalco Co. v. Eka Chemicals, Inc.*, 2003 U.S. Dist. LEXIS 4443 (D. Del. 2003).[865]

"non-aqueous" — "the composition does not include water in such an amount that will adversely affect the peroxide stability provided by the overall structure of the invention." *Evident Corp. v. Church & Dwight Co., Inc.*, 1999 U.S. Dist. LEXIS 23231 (D.N.J., Aug. 26, 1999).[866]

"non-chloride sodium salt" — "[can] encompass sodium hydroxide (NaOH)." *Martek Biosciences Corp. v. Nutrinova, Inc., et al.*, 579 F.3d 1363 (Fed. Cir. 2009).[867]

"non-coding region sequence" — "any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[868]

"non-diffusively bound"; "non-diffusively immobilized" — "the plain meaning of 'non-diffusively bound' and 'non-diffusively immobilized' is - a chemical or physical combination of the reagent and the medium, such that the reagent does not dissolve and move within the liquid from a region of high concentration to a region of low concentration." *Abbott Laboratories v. Syntron Bioresearch, Inc.*, 334 F.3d 1343 (Fed. Cir. 2003).[869]

"a non-fibrillating fluorocarbon particulate polymer" — "any fluorocarbon polymer which remains in particulate form and does not fibrillate under typical processing conditions." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[870]

"non-functional lentiviral 5' LTR promoter" — "a lentiviral genetic sequence located at one end (called the 5' end) of the long terminal repeat that is not present or is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription)." *Sigma-Aldrich, Inc. v. Open Biosystems, Inc.*, 521 F. Supp. 2d 975 (E.D. Mo. 2007).[871]

"non-human DNA sequences" — "DNA sequences that are not part of the human genome." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[872]

"non-naturally occurring" — "simply means not occurring in nature." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 314 F.3d 1313 (Fed. Cir. 2003).[873]

"a non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin" — "a glycoprotein (not occurring in nature) that is the product of the expression in a mammalian host cell of a DNA sequence that does not originate in the genome of the host, and which contains the genetic instructions (or a DNA sequence) encoding human erythropoietin." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al.*, 494 F. Supp. 2d 54 (D. Mass. 2007).[874]

"non-polar unsaponifiable fraction" — "the relatively water insoluble fatty alcohols that result from saponification of jojoba oil." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[875]

"non-radioactive moiety" — "a moiety that is utilized in indirect detection, i.e., a moiety that can be detected with a preformed detectable molecular complex." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[876] "[W]e affirm the district court's construction of' 'non-radioactive moiety.'" *Id.*, 2010 U.S. App. LEXIS 6267 (Fed. Cir., Mar. 26, 2010).[877]

"non-specific and charge-dependent" — "an interaction that does not require the presence of a specific recognition site and in which charge is necessary to the interaction." *Caliper Technologies Corp. v. Molecular Devices Corp.*, 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).[878]

"non-toxic liquid antifreeze" — "I construe the phrase 'non-toxic liquid antifreeze' in the 906 Patent as not excluding non-toxic salt solutions and as limiting the 'antifreeze' to 'a liquid used in the radiator of an internal combustion engine to lower the freezing point of the cooling medium.'" *Gentile v. Franklin Sports, Inc.*, 211 F. Supp. 2d 334 (D. Mass. 2002).[879] "I adopt the findings and conclusions contained in Judge Dein's Report." *Id.*, 211 F. Supp. 2d 334 (D. Mass. 2002).[880]

"containing <u>a nonnative DNA construct</u>" — "the Court construes the term 'nonnative' to mean that the DNA construct must not occur naturally in the cell, but instead must be introduced into the cell from an outside source." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[881]

"normal quantity" — "the mean of a given marker compound determined from an analysis of samples of a statistically significant sampling of non-autistic individuals." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[882]

"normally toxic levels of glyphosate" — "the amount of glyphosate that, under similar circumstances, is usually enough to adversely affect or harm a non-transgenic corn plant." *Rhone-Poulenc Agro, S.A. v. Monanto Co., et al*., 445 F. Supp. 2d 531 (M.D. N.C. 2006).[883] "[T]he level of glypohsate applied must be at levels sufficient to kill non- transformed corn." *Dekalb Genetics Corp. v. Syngenta Seeds, Inc., et al.*, 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).[884]

"not detecting an interfering non-(1-84) parathyroid hormone fragment" — "having no detectable binding to an interfering non-(1-84) parathyroid hormone fragment." *Scantibodies Laboratory, Inc. v. Immutopics, Inc., et al.*, 2010 U.S. App. LEXIS 9287 (Fed. Cir., May 6, 2010) (unpublished).[885]

"not interfering substantially with"; "that does not substantially interfere with" — "the linkage group neither substantially interferes with the ability of the compound to hybridize with the nucleic acid nor substantially interferes with the ability of A to be detected." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[886]

"said linkage group <u>not interfering substantially with</u> the characteristic ability of A to form a detectable complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin" — "the linkage group can cause some interference, but that it cannot completely prevent the formation of a detectable complex or cause other considerable levels of interference." *Enzo Biochem, Inc., et al. v. Affymetrix Inc., et al.*, 439 F. Supp. 2d 309 (S.D.N.Y. 2006).[887]

"not known to bind" — "not known with scientific certainty to bind." *Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc.*, 79 F. Supp. 2d 409 (D. Del. 1999).[888]

"nucleic acid binding agent" — "any DNA binding agent so long as in the presence of that agent a net increase in the amount of double-stranded DNA present is reflected in a change in signal intensity that is detectable directly or indirectly." *Applera Corp. v. Stratagene Corp.*, 2007 U.S. Dist. LEXIS 17154 (D. Conn., Mar. 9, 2007).[889]

"a nucleotide or oligo- or polynucleotide sequence comprising at least one of a moiety having the structure -BA" — "requires that the 'nucleotide or oligo- or polynucleotide sequence' at issue be comprised of otherwise naturally-occurring nucleotides which have been modified solely by the addition of at least one label 'A' to a nitrogenous base 'B.'" *Enzo Biochem, Inc., et al. v. Affymetrix Inc., et al.*, 439 F. Supp. 2d 309 (S.D.N.Y. 2006).[890]

"[*numerical limitations*]" — "the court construes the numerical limitations of the 618 patent strictly and the numbers are as stated with no modifications by approximation or otherwise." *Aventis Pharma S.A., et al. v. Amphastar Pharmaceuticals, Inc., et al*., 2004 U.S. Dist. LEXIS 29014 (C.D. Cal., Oct. 21, 2004).[891]

"nutritionally effective amount" — "that amount which will provide a beneficial nutritional effect or response in a mammal." *Mannatech, Inc. v. Techmedica Health, Inc., et al.*, 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Aug. 28, 2009).[892] "[T]his court ACCEPTS the Magistrate Judge's construction that 'nutritionally effective amount' is to be construed as 'that amount which will provide a beneficial nutritional effect or response in a mammal.'" *Id.*, *Mannatech, Inc. v. Techmedica Health, Inc., et al.*, 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Oct. 29, 2009).[893]

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"oat grain derivative product" — "material derived from the grain of an oat (which consists of the kernel and the husk of the grain)." *LP Matthews LLC v. Bath & Body Works, Inc., et al*., 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[894]

"oatmeal" — "material that is derived from the kernel of an oat grain (including liquid extracts and powders)." *LP Matthews LLC v. Bath & Body Works, Inc., et al*., 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[895]

"obtainable by" — "the Eastern District of Virginia correctly construed the process limitations beginning with 'obtainable by' ... as limiting the asserted claims to products made by those process steps." *Abbott Laboratories, et al. v. Sandoz, Inc., et al.,* 566 F.3d 1282 (Fed. Cir. 2009).[896]

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"a process comprising obtaining progeny from a fertile transgenic plant obtained by the process of claim 1 which comprise said DNA" — "Although in a somewhat unusual format, claim 4 is dependent from claim 1 because it only stands if all three steps recited in claim 1 have been performed." *Monsanto Co., et al. v. Syngenta Seeds, Inc., et al.*, 503 F.3d 1352 (Fed. Cir. 2007).[897]

"obtained from lung tissue of a mammal" — "means that the components included within the surface active material are acquired from the lung tissue of a mammal. The manner in which the material is acquired from the lung tissue is not limited to any specific process." *Forest Laboratories, Inc., et al. v. Abbott Laboratories, et al.*, 1998 U.S. Dist. LEXIS 23171 (W.D.N.Y., Aug. 3, 1998).[898]

"obtaining a physiological specimen from said host" — "the court interprets 'obtain' in this context to mean take physical possession of the physiological specimen." *Regents of the University of California, et al. v. Hansen, et al.,* 1999 U.S. Dist. LEXIS 21833 (E.D. Cal., Nov. 5, 1999).[899]

"mixture of particles of fenofibrate and a solid surfactant" — "a mixture of particles wholly of fenofibrate and a solid surfactant." *Abbott Laboratories, et al. v. Novopharm Ltd., et al.*, 2002 U.S. Dist. LEXIS 4659 (N.D. Ill., March 19, 2002).[900]

"heterogeneous mixture of labeled unique sequence nucleic acid fragments" — "a heterogeneous mixture of labeled nucleic acid fragments that includes only unique sequence fragments." *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 448 F. Supp. 2d 1145 (N.D. Cal. 2006).[901]

"oil" — "a slippery or viscous liquid or liquifiable substance that is substantially immiscible in water, including any such substance that would find value in a cosmetic preparation." *ICI Uniqema, Inc. v. Kobo Products, Inc.*, 2009 U.S. Dist. LEXIS 71191 (D.N.J., Aug. 13, 2009).[902]

"oil-based substance" — "a lotion or a greasy or oily substance." *Shen Wei, et al. v. Ansell Healthcare Products, Inc.*, 2004 U.S. Dist. LEXIS 7717 (N.D. Ill., Apr. 30, 2004).[903]

"oil-in-water emulsion" — "a mixture of two or more immiscible liquids held in suspension by one or more emulsifiers, which consists of two phases, an oil phase (disperse phase) and a water phase (continuous phase) such that the two phases are in equilibrium, and the system is kinetically stable and thermodynamically unstable." *Ben Venue Laboratories, Inc. v. Hospira, Inc.*, 2006 U.S. Dist. LEXIS 83404 (N.D. Ohio, Nov. 10, 2006).[904]

"oil-in-water microemulsion" — "Because the '625 Patent describes the characteristics of an oil-in-water microemulsion in such detail, the Court concludes that it is not necessary to provide a construction of this phrase." *Novartis Pharmaceuticals Corp., et al. v. Abbott Laboratories*, 294 F. Supp. 2d 552 (D. Del. 2002).[905]

"oligomer" — "a composition made up of a relatively small number of repeating units joined end to end." *Abbott Laboratories v. Torpharm, Inc., et al.*, 156 F. Supp. 2d 738 (Mar. 29, 2001).[906] "[W]e find no error in the district court's claim construction." *Id.*, 300 F.3d 1367 (Fed. Cir. 2002).[907]

"oligomer" — "There is no question that the basic definition of an oligomer applies here." *Abbott Laboratories v. Alra Laboratories, Inc.*, 1997 U.S. Dist. LEXIS 16611 (N.D. Ill., Oct. 20, 1997).[908]

"oligonucleotide" — "a compound created by the condensation of typically fewer than 20 nucleotides." *Pieczenik, et al. v. Dyax Corp.*, 226 F. Supp. 2d 314 (D. Mass. 2002).[909] "[T]his court holds that 'oligonucleotide' means ... 'a compound made up of two to ten nucleotides.' Even though this court adopts a slightly different claim construction than the district court, any error is harmless." *Pieczenik v. Dyax Corp.*, 76 Fed. Appx. 293 (Fed. Cir., Sept. 23, 2003) (unpublished).[910]

"oligonucleotides" — "polymers of nucleotides ranging in length from 2 to about 100 nucleotides." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[911]

"one or more layers of materials"; "one or more layers comprising materials" — "use of the plural 'materials' ... represents an effort to match the tense of 'layers.' In other words, the plural term does not necessarily require multiple compositions, but instead reflects an attempt to achieve grammatical consistency. ... This term therefore does not exclude subcoatings of only one material." *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[912]

"one-part" — "denotes a composition that can be mixed in a single container without triggering unwanted reactions but does not require homogeneity." *UV Coatings, Ltd. v. SICO, Inc.*, 2000 U.S. App. LEXIS 16990 (Fed. Cir., Jul. 18, 2000) (unpublished).[913]

"oocyte" — "Throughout the patent, the inventors use the term oocyte broadly to refer to cells that are enucleated and to cells that are transferred and fused." *Infigen, Inc. v. Advanced Cell Technology, Inc.*, 65 F. Supp. 2d 967 (W.D. Wis. 1999).[914]

"open, non-pressurized reactor" — "a reactor that allows gases to escape during the reaction, where substantial pressures are not applied or allowed to build up during the reaction requiring a pressure or sealed reactor." *Infosint, S.A. v. H. Lundbeck A/S, et al.*, 603 F. Supp. 2d 748 (S.D.N.Y. 2009).[915]

"operably linked DNA segments" — "means that the segments must function together as they are attached to create the DNA construct." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[916]

"operatively linked" — "the promoter DNA is linked to the EPO DNA in a way that maintains the capability of the promoter DNA to initiate transcription of the EPO DNA." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[917]

"optical purity" — "a measure of the purity of one enantiomer expressed as a percentage of a 100% pure sample of that enantiomer." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[918]

"an optical quality capable of providing a visual appearance of Newton's rings of interference" — "optical characteristics such that the material is capable of exhibiting visible dark, bright, and/or colored rings or lines." *Collins, et al. v. Gillette Co.*, 2005 U.S. Dist. LEXIS 46841 (E.D. Tex., Jun. 22, 2005).[919]

"optically pure" — "'essentially free of the (+)-enantiomer of omeprazole' and 'at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity).'" *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[920]

"optically pure oxaliplatin" — "is not limited to optically pure oxaliplatin produced by HPLC; this is a composition claim, not a product-by-process claim." *Sanofi-Aventis U.S. LLC, et al. v. Sandoz, Inc., et al.*, 2009 U.S. App. LEXIS 20294 (Fed. Cir., Sep. 10, 2009) (unpublished).[921]

"orange oil"; "forty-five percent (45%) or less by volume of orange oil" — "at least 5% by volume of the non-water soluble liquid derived from an orange." *LP Matthews LLC v. Bath & Body Works, Inc., et al.*, 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[922]

"*[order of process steps]*" — "If plaintiff had sought to limit its claims to a specific sequence, it could have added language such as 'then' or 'and thereafter' to the steps of the claim. Without such an indication in the language of the claims themselves, I cannot find that plaintiff intended to limit the scope of its claims in the manner defendant suggests." *Promega Corp. v. Novagen, Inc.*, 6 F. Supp. 2d 1004 (W.D. Wis. 1997).[923]

"ORFs 1-13" — "lengths of translatable DNA between pairs of start and stop codons, corresponding to the 13 ORFs identified in the patent specification." *Intervet Inc. v. Merial Ltd., et al.*, 2010 U.S. App. LEXIS 16104 (Fed. Cir., Aug. 4, 2010).[924] "I agree with the district court that the phrase must be limited to the specific DNA sequences defined as ORFs 1-13 in the '601 patent based on the intrinsic evidence." *Id.* (Dyk, J., dissenting-in-part).[925]

"organic material"— "carbon containing materials, including wood, wood sawdust, and charcoal." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[926]

"organic solvent" — "carbon-based solvent that is substantially free of water." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al.*, 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).[927]

"organic solvent not removable by drying" — "having organic solvent that cannot be removed by conventional drying conditions." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al.*, 2010 U.S. Dist. LEXIS 22154 (E.D. Pa., Mar. 5, 2010).[928]

"organically synthesized" — "the production of a oligonucleotide or fragment of a gene using organic chemistry without the use of an enzyme. It includes DNA made by replication of synthetic DNA." *Genentech, Inc. v. Boehringer Mannheim GmbH, et al.*, 989 F. Supp. 359 (D. Mass. 1997).[929]

"osmolarity ... of between about 400-500 mOsmol" — "encompasses osmolarities as low as 385 mOsmol/L." *Central Admixture Pharmacy Services, Inc., et al. v. Advanced Cardiac Solutions, P.C., et al.*, 482 F.3d 1347 (Fed. Cir. 2007).[930]

"solubility enhancing component <u>other than an cyclodextrin</u>" — "a component that enhances the solubility of the alpha-2 adrenergic agonist component other than a cyclodextrin." *Allergan, Inc., et al. v. Alcon Inc., et al.*, 2005 U.S. Dist. LEXIS 32436 (D. Del., Dec. 8, 2005).[931]

"otopathy" — "bacterial ear infection." *Daiichi Pharmaceutical Co., Ltd., et al. v. Apotex, Inc., et al.*, 380 F. Supp. 2d 478 (D.N.J. 2005);[932] *Id.,* 441 F. Supp. 2d 672 (D. N.J. 2006).[933]

"over a period of time" — "separated by non-insignificant time intervals and not during the same occurrence." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[934]

"oxide coating" — "means a coating that is composed of metal cations and oxygen. ... The dispositive question is how one skilled in the art calculates the percentage which identifies the components of the coating. ... This Court finds that the atomic mass of each element of the OSI coating must be calculated to determine whether OSI's coating contains every element of the claims at issue in the Durel patents." *Durel Corp. v. Osram Sylvania, Inc.*, 1998 U.S. Dist. LEXIS 22592 (D. Ariz., Oct. 16, 1998).[935] "We agree with Sylvania that the district court erred in its construction of the term 'oxide coating.' ... according to the specification's explicit definition of 'oxide coating' and its description of such coatings, the claimed oxide coating must primarily comprise binary metal oxides containing only metal cations and oxygen. Other elements and compounds originating in precursor materials, such as hydrated metal oxides or metal hydroxides, if present at all, may only be present in minor amounts as impurities. Accordingly, we conclude that the district court erred in construing the term 'oxide coating' as not requiring a primary component that is a binary metal oxide." *Id.*, 256 F.3d 1298 (Fed. Cir. 2001).[936]

"oxidizing PVP" — "the process of combining oxygen atoms with a PVP molecule, from the beginning to the end of the process, without regard to the number of oxygen molecules present in the starting PVP and with an eventual end product of PVNO." *BASF Aktiengesellscaft v. Reilly Industries, Inc.*, 2004 U.S. Dist. LEXIS 27737 (S.D. Ind., Nov. 4, 2004).[937]

"3-oxo-glutaric acid" — "any form of 3-oxo-glutaric acid, including 3-oxoglutarate, 3-ketoglutaric, 3-ketoglutarate, beta-ketoglutarate and 3-oxo-pentanedioic acid." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[938]

"oxygen scavenger" — "a chemical compound included in the photocurable layer that reacts with oxygen to counter the effects of oxygen inhibition." *MacDermid Printing Solutions, L.L.C. v. E.I. Du Pont De Nemours & Co.*, 2010 U.S. Dist. LEXIS 23746 (D.N.J., Mar. 15, 2010).[939]

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[i] "parenteral"; [ii] "administering"; [iii] "patient" — [i] "taken or administered into the body by a means other than through the digestive tract"; [ii] "to apply as a remedy"; [iii] "an animal, including a human being, awaiting or under medical treatment." *Novo Nordisk A/S, et al. v. Eli Lilly and Co.*, 1999 U.S. Dist. LEXIS 18690 (D. Del., Nov. 18, 1999).[940]

"parenterally" — "by means other than through the gastrointestinal tract, in particular via injection." *Wyeth, et al. v. Abbott Laboratories, et al.*, 2010 U.S. Dist. LEXIS 75893 (D.N.J., Jul. 27, 2010).[941]

"in vitro parthenogenic activation of a bovine oocyte" — "I conclude that production of embryonic cells is *parthenogenic* if the activation *process* does not involve spermatozoa, regardless whether the *recipient* of activation contains male genetic material." *Infigen, Inc. v. Advanced Cell Technology, Inc.*, 65 F. Supp. 2d 967 (W.D. Wis. 1999).[942]

"modafinil particles"; "said particles"; "particles" — "an aggregated physical unit of acetamide compound, i.e., a piece or a grain of acetamide." *Apotex, Inc. v. Cephalon, Inc., et al.*, 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).[943]

"particles" — "means particles in its ordinary sense without limitation based on the size or shape of millet. Specifically, the court finds that the term 'particles' contemplates small specks of matter, including but not limited to, starch particles, microsphere particles, hard plastic or silicon beads and millet." *Sport Squeeze, Inc. v. Pro-Innovative Concepts, Inc. et al.*, 1999 U.S. Dist. LEXIS 16681 (S.D. Cal., Mar. 31, 1999).[944]

"particles containing a water-soluble drug, the particles being dispersed in a spherical microcapsule matrix" — "the term 'particles' in that limitation [] contain[s] both a drug and a drug-retaining substance." *Tap Pharmaceutical Products, Inc., et al. v. Owl Pharmaceuticals, L.L.C., et al.,* 419 F.3d 1346 (Fed. Cir. 2005).[945]

"particles of titanium dioxide" — "particles that include titanium and oxygen." *ICI Uniqema, Inc. v. Kobo Products, Inc.*, 2009 U.S. Dist. LEXIS 71191 (D.N.J., Aug. 13, 2009).[946]

"particles of zinc oxide" — "particles that include zinc and oxygen having the chemical nomenclature ZnO that may additionally include lesser amounts of other materials or impurities." *ICI Uniqema, Inc. v. Kobo Products, Inc.*, 2009 U.S. Dist. LEXIS 71191 (D.N.J., Aug. 13, 2009).[947]

"particles that pass through a screen" — "The verb 'pass' describes the closest preceding noun: 'particles.' To paraphrase the meaning of this claim, the additive is made up of particles which are of a size small enough to pass through a screen with four inch square openings." *Harsco Corp. v. North Star Bluescope Steel, LLC*, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).[948]

"remains in <u>particulate form</u>" — "when the fluorocarbon polymer is processed under typical processing conditions, the fluorocarbon polymer continue to be well-defined solid pieces and do not lose their solid boundaries." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[949]

"particulate material" — "there is no need for a construction at this point." *E.I. du Pont de Nemours & Co. v. MacDermid, Inc., et al.*, 2010 U.S. Dist. LEXIS 23750 (D.N.J., Mar. 15, 2010).[950]

"passages" — "solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior." *Sud-Chemie, Inc. v. CSP Technologies, Inc.*, 2006 U.S. Dist. LEXIS 54873 (S.D. Ind., Aug. 4, 2006).[951]

"patient diagnosed with Alzheimer's disease" — "a live patient diagnosed with dementia of the Alzheimer's type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[952]

"patient in need thereof"; "patient in need of such treatment" — "have a plain and ordinary meaning readily understood even to a lay judge and do not require any construction." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[953] "[T]he court will adopt the Magistrate Judge's construction for these terms." *Id.*, 2009 U.S. Dist. LEXIS 86772 (D. Del., Sep. 21, 2009).[954]

"peaks" — "is the plural of 'peak;' a 'peak' exists at a powder X-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to 'noise' if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement; 'noise' refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test." *Lupin Ltd. v. Abbott Laboratories, et al.*, 484 F. Supp. 2d 448 (E.D. Va. 2007).[955]

"material peculiarly responsive to a particular form of radiant energy not normally present in ambient light in amounts sufficient to cause said material to discolor" — "a substance which darkens or changes color when exposed to radiant energy (as previously defined by the court) of a type or intensity (or both) that is not ordinarily present in sunlight or normal indoor lighting." *Flashmark Technologies, LLC, et al. v. GTECH Corp., et al.*, 2007 U.S. Dist. LEXIS 65317 (E.D. Tex., Sept. 2, 2007).[956]

"peptide" — "the specification ... does not limit the term 'peptide' to only a linear structure. As the record indicates, the patentee discloses to those skilled in the art both linear and cyclic peptides. The district court correctly construed the term to have its full ordinary meaning in the art." *Integra Lifesciences I, Ltd., et al. v. Merck KGaA, et al.*, 2003 U.S. App. LEXIS 27796 (Fed. Cir., Jun. 6, 2003) (unpublished).[957]

"percentage of body fat" — "the percentage of body mass that excludes the lean body mass fraction." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[958]

"perforating" — "mean[s] using any device that creates 'channels' in the foam, which channels may be any cross-sectional shape, including rectangular, that allow for the accelerated release of a blowing agent." *Dow Chemical Co. v. Astro-Valcour, Inc.*, 47 F. Supp. 2d 294 (N.D.N.Y. 1999).[959]

"perfluorinated cure site monomer which includes a functional group which permits crosslinking of the terpolymer" — "a fluorinated molecule which is incorporated into the terpolymer as a third monomer, which contains a functional group where crosslinking occurs, which can be any functional group including hydrogen." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[960]

"perfluoro alkyl vinyl ether (PAVE)" — "the monomer of structure (II) in the terpolymer where no hydrogen atoms are present, and where the alkyl ether chain ($O\text{-}R_f$) may contain one or more oxygen atoms." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[961]

"perfluoroelastomer" — "an amorphous polymer of one or more perfluorinated monomers being substantially free of hydrogen substituents." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[962]

"perfusion" — "as that term is used in pharmaceutical composition claims, is simply an injectable solution containing the active pharmaceutical ingredient and an aqueous infusion fluid." *Aventis Pharma S.A., et al. v. Hospira, Inc.*, 2010 U.S. Dist. LEXIS 101442 (D. Del., Sep. 27, 2010).[963]

"which permits transmural ingrowth" — "the structure must allow organized host tissue to grow into the pores of the node and fibril microstructure." *Bard Peripheral Vascular, Inc., et al. v. W.L. Gore & Associates, Inc.*, 2006 U.S. Dist. LEXIS 71261 (D. Ariz., Sept. 16, 2006).[964]

"pH-buffering" — "was not used in the patent to convey the traditional characteristics of a buffer in chemistry." *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[965]

"pH-buffering alkaline compound"; "pH-buffering alkaline reacting compound" — "mean the same thing as the term 'alkaline reacting compound' in the patents." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).[966]

"pharmaceutical" — "'containing a medicinal drug' where 'medicinal drug' means 'a substance or preparation used in treating disease.'" *Novo Nordisk A/S, et al. v. Eli Lilly and Co.*, 1999 U.S. Dist. LEXIS 18690 (D. Del., Nov. 18, 1999).[967]

"pharmaceutical composition" — "a medicinal preparation comprising an intimate admixture, prepared outside the body, generally in the form of a dosage unit, such as a tablet or capsule." *Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc., et al.*, 482 F. Supp. 2d 478 (D.N.J. 2007).[968]

"pharmaceutical composition" — "in the absence of other stated limitations, encompasses pharmaceutical compositions in all forms." *Aventis Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, 341 F. Supp. 2d 502 (D.N.J. 2004).[969]

"pharmaceutical composition" — "an aggregated product formed from two or more substances for use as a drug in medical treatment." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[970]

"a pharmaceutical composition comprising ... a pharmaceutically acceptable diluent, adjuvant or carrier" — "a composition suitable for administration to humans, containing a diluent, adjuvant or carrier." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al*., 494 F. Supp. 2d 54 (D. Mass. 2007).[971]

"pharmaceutical compositions" — "mean those that are stable for appropriate periods of time, acceptable in their own right for administration to humans, and readily manufacturable." *Genentech, Inc. v. Boehringer Mannheim GmbH, et al*., 989 F. Supp. 359 (D. Mass. 1997).[972]

"pharmaceutical dosage unit" — "a dosage form such as a tablet or capsule containing a dose of a drug." *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 221 F. Supp. 2d 535 (E.D. Pa. 2002).[973]

"a pharmaceutical formulation" — "no construction of this term is necessary. Rather, the plain meaning of the term as understood by someone of ordinary skill shall apply." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[974]

"pharmaceutically-acceptable" — "as used in the patents does not apply as a restriction on the purity of the fluoxetine hydrochloride compound itself, but rather defines the acids that may be used to form the salts of the claimed compounds: pharmaceutically-acceptable or non-toxic acids which form pharmaceutically-acceptable or non-toxic salts. In other words, the claim language refers to toxicity of the components used to create the compound and the toxicity of the resultant compound, rather than a particular level of purity in the final product, as may be achieved through a process like recrystallization." *Eli Lilly and Co. v. Barr Laboratories, Inc., et al.*, 100 F. Supp. 2d 917 (S.D. Ind. 1999).[975]

"pharmaceutically acceptable carrier" — "a carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof." *Glaxo Group Ltd, et al. v. Teva Pharmaceuticals USA, Inc.*, 2009 U.S. Dist. LEXIS 37494 (D. Del., Apr. 30, 2009).[976]

"pharmaceutically-acceptable moisturizer" — "material that has the effect of adding moisture to or keeping moisture in human skin that is also safe and effective for use on human skin." *LP Matthews LLC v. Bath & Body Works, Inc., et al*., 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[977]

"pharmaceutically acceptable polymer" — "the district court erred at this preliminary stage in limiting the 'pharmaceutically acceptable polymer' term to hydrophilic, water-soluble compounds selected from a list given in the written description of the '718 and '616 patents." *Abbott Laboratories v. Andrx Pharmaceuticals, Inc., et al.*, 473 F.3d 1196 (Fed. Cir. 2007).[978]

"pharmaceutically acceptable polymer" — "any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, and is capable of forming a matrix to extend drug release into the bloodstream. Such a 'pharmaceutically acceptable polymer' must constitute 5 to 50% by weight of the product." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[979]

"pharmaceutically acceptable polymer" — "any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, that extends drug release into the bloodstream either alone or in conjunction with other such polymers or other components, and is capable of forming a gel or a matrix to extend drug release into the bloodstream." *Abbott Laboratories v. Sandoz, Inc.,* 2007 U.S. Dist. LEXIS 89403 (N.D. Ill., Dec. 4, 2007).[980]

"pharmaceutically effective amount" — "In 1984, the earliest effective filing date for the '938 patent, the FDA considered 2.5 to 15 mg/day to be pharmaceutically effective; in fact, that is the range of dosages approved by the FDA as effective through at least 1993. ... The trial court's determination that this range corresponds to that represented by the term 'pharmaceutically effective amount' is logical and appropriate; it does not constitute error." *Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709 (Fed. Cir. 1998).[981]

"pharmacologically effective" — "an amount that is medically effective." *Naturopathic Labs. International, Inc. v. Dermal Research Laboratories, Inc*., 415 F. Supp. 2d 1007 (W.D. Mo. 2006).[982]

"phenotype" — "an observable property of an organism or a cell as produced by the genotype in conjunction with the environment." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[983]

"PHN" — "also known as post-herpetic neuralgia, a complication of a herpes zoster infection characterized by pain after rash healing." *Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 97610 (D.N.J., Sep. 17, 2010).[984]

"a phosphoric acid source" — "acidic phosphates that are sources of the phosphoric component of the composition." *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004).[985]

"phosphorous-containing acid or salt thereof is present is present in amount of about 30 to about 40 weight percent" — "This court agrees with defendant that the claim must be construed to aggregate the salts as a whole." *Biagro Western Sales, Inc., et al. v. Grow More, Inc.*, 2001 U.S. Dist. LEXIS 26007 (E.D. Cal., Oct. 18, 2001).[986] "Plaintiffs Motion for Reconsideration is denied." *Id.*, 2002 U.S. Dist. LEXIS 27886 (E.D. Cal., Aug. 15, 2002).[987]

"physiological cooling agent" — "A compound which is perceived as cold or cool when contacted with the human body and, in particular, with the mucous membranes of the mouth, nose and throat; excluded are traditional flavor-derivatives such as menthol or menthone; and included are those compounds listed in columns 9 and 10 of the '233 Patent." *William Wrigley Jr. Co. v. Cadbury Adams USA, LLC*, 500 F. Supp. 2d 922 (N.D. Ill. 2007).[988]

"physiologically active salt" — "a salt of ibandronic acid that is physiologically active." *Hoffmann-La Roche Inc. v. Apotex Inc., et al.*, 2010 U.S. Dist. LEXIS 87355 (D.N.J., Aug. 24, 2010).[989]

"physiologically acceptable" — "the substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals ." *Pharmacia & Upjohn Co. v. Sicor, Inc., et al.*, 447 F. Supp. 2d 363 (D. Del. 2006).[990]

"physiologically and cosmeceutically acceptable vehicle" — "a solvent, diluent, or dispersant for the constituents of the composition that allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution." *Laboratory Skin Care, Inc. v. Limited Brands, Inc., et al.*, 616 F. Supp. 2d 468 (D. Del. 2009).[991]

"plasma etching" — "refers to a chemical process without excluding the non-chemical process of ion bombardment." *Northern Telecom Limited v. Samsung Electronics Co., Ltd., et al*., 1996 U.S. Dist. LEXIS 21786 (N.D. Cal., Sept. 13, 1996).[992] "[W]e hold that the district court's claim construction of ... 'plasma etching' was correct." *Id.*, 215 F.3d 1281 (Fed. Cir. 2000).[993]

"plasmid" — "the term 'plasmid' cannot be interpreted to include the term 'phage.'" *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co*., 1996 U.S. Dist. LEXIS 15989 (D. Del., Oct. 21, 1996).[994]

"a plasmid vector comprising at least one DNA sequence comprising the leftward promoter and operator derived from bacteriophage λ, P[L]O[L], said DNA sequence further comprising at least one endonuclease recognition site located less than 300 base pairs downstream from P[L]O[L] and located between P[L]O[L] and any sequences of λ DNA downstream of the HaeIII site at 73.1% of bacteriophage λ in said DNA sequence" — "a plasmid vector [that] contain[s] the entire P[L]O[L] of bacteriophage λ as represented in Figure 6 of the patent and at least one endonuclease recognition site inserted at the converted HaeIII site at 73.1% of bacteriophage λ or at another site downstream of HaelIII, said endonuclease recognition site being within 300 base pairs of the HincII site at -33, and prior to any sequences of λ DNA downstream of the HaeIII site." *Biogen, Inc. v. Amgen Inc.*, 18 F. Supp. 2d 105 (D. Mass. 1998).[995]

"a plastic flow temperature above 120 degrees F" — "means that the adhesive must resist flow when exposed for 24 hours to 120 degrees F in both horizontal and vertical orientations." *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563 (Fed. Cir. 1997).[996] "Eaton submitted the declaration of Kenneth A. Nelson, the chemist who developed the claimed adhesive. Mr. Nelson's declaration disclosed a two-prong test for the claim requirement. That test requires, first, placing a 1/16 inch layer of adhesive upside-down in an oven preheated to 120 degrees F for sixteen hours. Second, the test requires that the adhesive be hung vertically in an oven at 77 degrees F for sixty-three hours. An adhesive meets Eaton's requirement if the glue does not flow from the tray during either of these tests. ... The district court properly used that claim interpretation. This court errs in departing from the full context of the administrative record, and importing a false limitation from the prosecution history." *Id.* (Rader, J., dissenting).[997]

"plasticizer" — "a composition that decreases the softening temperature of the polymer to which it is added." *Biovail Laboratories Inc., et al. v. Anchen Pharmaceuticals Inc., et al*., 2006 U.S. Dist. LEXIS 37996 (C.D. Cal., Feb. 8, 2006).[998]

"plurality of days" — "more than one day." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[999]

"plurality of pores of substantially uniform size" — "a large number of pores of substantially uniform size." *Semco Inc. v. Venmar Ventilation, Inc., et al.*, 2002 U.S. Dist. LEXIS 28375 (W.D. Mo., Dec. 17, 2002).[1000]

"pluripotent" — "capable of generating numerous cell types." *Teva Pharmaceuticals USA, Inc. v. Amgen, Inc.*, 2010 U.S. Dist. LEXIS 95288 (E.D. Pa., Sep. 10, 2010).[1001]

"polar hydrophilic salts fraction" — "relatively water soluble fatty alcohols that result from saponification of jojoba oil." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[1002]

"poly-aluminum hydroxychloride" — "also known as aluminum chlorohydrate; an aluminum polymer formed by reacting aluminum chloride [$AlCl_3$] with a base, resulting in a product that may be expressed chemically as $Al_n(OH)_mCl_{(3n-m)}$, normally wherein the basicity is about greater than or equal to 50%." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1003]

"poly-aluminum siloxane sulfate" — "also known as polyaluminum silicate sulfate (PASS); an aluminum polymer compromising a silicate moiety and a sulfate moiety." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1004]

"polyaluminum chloride" — "an aluminum polymer formed by reacting aluminum chloride [$AlCl_3$] with a base, resulting in a product that may be expressed chemically as $Al_n(OH)_mCl_{(3n-m)}$, normally wherein the basicity is about less than or equal to 50%." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1005]

"polycationic component" — "a compound that has a net positive charge and is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Again, the polycationic component may include, among other things, a large molecule, e.g., a protein, that has associated therewith multivalent metal cations selected from, e.g., Fe^{3+}, Ca^{2+}, Ni^{2+}, and Zn^{2+}." *Caliper Technologies Corp. v. Molecular Devices Corp.*, 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).[1006]

"poly-β-1-->4-acetylglucosamine"; "poly-β-1-->4-glucosamine" — "do not include a limitation requiring them to be free of protein." *Marine Polymer Technologies, Inc. v. HemCon, Inc.*, 2009 DNH 103 (D.N.H., Jul. 9, 2009).[1007]

"polyionic polymer" — "a relatively high molecular weight substance comprising relatively lower molecular weight repeating units that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner." *Caliper Technologies Corp. v. Molecular Devices Corp.*, 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).[1008]

"a rubbery polymer comprising a blend of … and <u>polyisobutylene</u>" — "the claim term should not be restricted to high molecular weight polyisobutylene." *Adco Products, Inc. v. Carlisle Syntec Inc.*, 110 F. Supp. 2D 276 (D. Del. 2000).[1009]

"polymer" — "a molecule composed of repeating units." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1010]

"polymeric material" — "exclude[s] paper." *3M Innovative Properties Co., et al. v. Barton Nelson, Inc.*, 2004 U.S. Dist. LEXIS 10578 (D. Minn., Jun. 6, 2004).[1011]

"polymerization catalyst species" — "are confined to polymerization catalyst species consisting of bis-Cp metallocenes." *Exxon Corp. v. Dow Chemical Co., et al.*, 24 F. Supp. 2d 688 (E.D. Tex. 1998).[1012]

"a nonnative <u>polynucleotide construct</u> comprising" — "the term 'polynucleotide construct' [] mean[s] any string of nucleotides, including DNA." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1013]

"a polynucleotide sequence"; "said polynucleotide sequence" — "the polynucleotide sequence to be detected, meaning the analyte." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[1014]

"polynucleotides" — "a polymer of nucleotides of length two or more." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[1015]

"polyolefin foam"; "polymeric composition"; "olefin polymer foam" — "I cannot accept AVI's proposed construction that adds the requirement of 'dimensionally stable' to the claim terms." *Dow Chemical Co. v. Astro-Valcour, Inc.*, 47 F. Supp. 2d 294 (N.D.N.Y. 1999).[1016]

"polypeptide of the IFN-alpha type" — "embrace[s] only the immature form of the polypeptide now known in the art as IFN-alpha-1." *Schering Corp., et al. v. Amgen Inc.*, 222 F.3d 1347 (Fed. Cir. 2000).[1017]

"porcelain powder" — "a medium containing porcelain particles." *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 2006 U.S. Dist. LEXIS 88691 (N.D. Ill., Dec. 7, 2006).[1018]

"porcine circovirus type II" — "a pathogenic pig virus having a circular genome that is at about 96% or more homologous with the four sequences disclosed in the present specification, and about 76% or less homologous with the PK/15 sequence." *Intervet Inc. v. Merial Ltd., et al.*, 2010 U.S. App. LEXIS 16104 (Fed. Cir., Aug. 4, 2010).[1019]

"pore" — "a hole or cavity in a magnetic particle which may be open or closed, and the Court declines to impose any size limitation on the term 'pore.'" *Bayer AG v. Sony Electronics, Inc.*, 229 F. Supp. 2d 332 (D. Del. 2002).[1020]

"a porous membrane of essentially uniform composition and <u>a porosity gradient from one planar surface thereof to the other</u>" — "We agree with the district court that 'porosity gradient', as used in the claims of the '192 patent, requires 'a gradual change in the porosity from one planar surface [of the membrane] to the other.' ... Claim 11 does not require the membrane to have a porosity gradient prior to chemical conditioning, but instead requires that the membrane of the chemically conditioned reagent system have a porosity gradient. In other words, the proper construction of claim 11 requires the membrane to have a porosity gradient, but does not require the gradient to be present prior to chemical conditioning." *Technical Chemicals & Products, Inc., et al. v. Home Diagnostics, Inc.*, 1998 U.S. App. LEXIS 7163 (Fed. Cir., Apr. 9, 1998) (unpublished).[1021]

"porous membrane of essentially uniform composition and a porosity gradient from one planar surface thereof to the other" — "the untreated membrane, to which the dry chemistry reagent system is added, must have a porosity gradient. A porosity gradient is a gradual change in the porosity from one planar surface to the other." *Technical Chemicals & Products, Inc., et al. v. Home Diagnostics, Inc.*, 1996 U.S. Dist. LEXIS 22002 (S.D. Fl., Aug. 15, 1996).[1022]

"the portion of open pores in the material forming said plate is 85 to 95% based on total pore volume" — "the above term needs no construction because it means what it says and is clear on its face." *ITP Interpipe, Inc., et al. v. Technip Offshore, Inc.*, 2007 U.S. Dist. LEXIS 7551 (S.D. Ala., Jan. 31, 2007).[1023]

"potassium bromate replacer" — "ingredients [that] perform essentially the same function in the production of that bread as would potassium bromate." *Yoon Kim v. Conagra Foods, Inc.*, 465 F.3d 1312 (Fed. Cir. 2006).[1024] "[I]n my view, the intrinsic record's repeated defining of a 'potassium bromate replacer' as 'a slow acting oxidant that is functional throughout the entire manufacturing process' overwhelms the portion of the specification upon which the majority relies for its claim construction. Thus, I would conclude that Kim acted as her own lexicographer in defining a 'potassium bromate replacer' as 'a slow acting oxidant that is functional throughout the entire manufacturing process.'" *Id.* (Schall, J., dissenting-in-part).[1025]

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"powder" — "a conglomeration of individual particles. Powder may be loose, free flowing and unaligned, but it need not be." *Bayer AG v. Sony Electronics, Inc.*, 229 F. Supp. 2d 332 (D. Del. 2002).[1026]

"predefined region" — "a localized area on a surface which is, was, or is intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[1027]

"predetermined" — "based upon relevant USDA requirements because the patent specifically incorporates USDA regulations." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[1028]

"preselected" — "known ahead of time." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[1029]

"pre-treated" — "refers to a condition of jojoba oil starting material indicating that the jojoba oil has been subjected to reaction, processing, conditioning, and/or the like, prior to saponification." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[1030]

"pre-treated" — "altered, prior to steps (i) and (ii) of claim 1." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[1031]

"to prevent degradation" — "If the Lewis acid inhibitor prevents the product from becoming so chemically decomposed or altered that it cannot be used during its shelf life, then it can be said to be sufficient to prevent degradation. ... for purposes of the Patent, sevoflurane is degraded if it contains degradants in amounts greater than 300 ppm." *Abbott Laboratories, et al. v. Baxter Pharmaceutical Products, Inc., et al.*, 2005 U.S. Dist. LEXIS 44032 (N.D. Ill., Sept. 26, 2005).[1032]

"prevention of cerebral ischemia" — "prevention of an imbalance of neuronal stimulation mechanisms." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[1033] "[T]he court will adopt the Magistrate Judge's construction for these terms." *Id.*, 2009 U.S. Dist. LEXIS 86772 (D. Del., Sep. 21, 2009).[1034]

"primer" — "must have the following characteristics: 1) ... a free 3' hydroxyl group to allow chain extension by the polymerase. 2) ... be complementary to a unique region 3' of the cloned insert. 3) ... be sufficiently long to hybridize to form a unique, stable duplex. 4) The chromophore or fluorophore must not interfere with the hybridization or prevent 3'-end extension by the polymerase." *Promega Corp. v. Applera Corp.*, 2002 U.S. Dist. LEXIS 26927 (W.D. Wis., Jan. 2, 2002).[1035]

"principal protein source" — "We decline the parties' invitation to 'construe' this phrase except ... We will not determine when the measurement is to be taken because we cannot." *Schreiber Foods, Inc. v. Saputo Cheese USA Inc.*, 83 F. Supp. 2d 942 (N.D. Ill. 2000).[1036]

"[administered] <u>prior to the onset of [a woman's] menstrual period</u>" — "administered prior to the onset of a woman's menstrual period, including those that go on continuously thereafter." *Eli Lilly and Co., et al. v. Teva Pharmaceuticals USA, Inc.*, 2005 U.S. App. LEXIS 14583 (Fed. Cir., Jul. 13, 2005).[1037]

"probe array" — "a collection of probes, at least two of which are different, arranged in a spacially defined and physically addressable manner." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[1038]

"probe intensity" — "intensity from a labeled sample nucleic acid hybridized to a probe location." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[1039]

"a process for stabilizing" — "a method of making a drug product containing an ACE inhibitor in which cyclization has been inhibited." *Schwarz Pharma, Inc., et al. v. Paddock Laboratories, Inc.*, 429 F. Supp. 2d 1116 (D. Minn. 2006).[1040]

"processing" — "producing fractions from a beet-derived sucrose-containing material utilizing the steps described in the claim." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[1041]

"produce a greater anabolic state" — "promoting greater total body weight gain as well as statural growth." *Genentech, Inc., et al. v. Insmed Inc., et al*., 436 F. Supp. 2d 1080 (N.D. Cal. 2006).[1042]

"a thermal fogging mist is <u>produced ...</u>" — "It does not matter how the mist is generated or whether the device utilizes a cylindrical channel. As discussed above, however, the specified attributes of the fogging mist must exist at the time the mist is released or discharged from the fogging device for the treatment of fruits or vegetables." *Pace International, LLC, et al. v. Industrial Ventilation, Inc., et al.*, 2009 U.S. Dist. LEXIS 120554 (W.D. Wash., Dec. 7, 2009).[1043]

"... produced on a commercial scale by a process which comprises ..." — "anticipation by an earlier product patent cannot be avoided by claiming the same product more narrowly in a product-process claim. It makes no difference here whether the '944 patent's product-by-process claims are construed broadly to cover the product made by any process or narrowly to cover only the product made by a dry admixing process. Either way, anticipation by an earlier product disclosure (which disclosed the product itself) cannot be avoided." *Smithkline Beecham Corp., et al. v. Apotex Corp., et al.*, 439 F.3d 1312 (Fed. Cir. 2006).[1044] "It is not correct that, as a rule of claim construction, a claim that contains product and process limitations is free of the process limitations, whatever the nature of the invention." *Id.* (Newman, J., dissenting).[1045]

"progeny cells" — "refers to multiple generations of cells." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[1046]

"progeny plant" — "refers to plants that encode a pesticidal protein toxin." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[1047]

"promoter" — "the plain meaning of the term promoter includes all promoters, and specifically includes the actin promoter." *Dekalb Genetics Corp. v. Syngenta Seeds, Inc., et al.*, 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).[1048]

"a transcriptional <u>promoter segment</u>" — "the promoter is the portion of the DNA construct which facilitates the start of the transcription of the RNA." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1049]

"prophylactic treatment of PHN" — "achieving, by preventative measures (i.e., before PHN manifests itself), a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment." *Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 97610 (D.N.J., Sep. 17, 2010).[1050]

"propofol" — "2,6-diisopropylphenol." *AstraZeneca Pharmaceuticals, LP, et al. v. Mayne Pharma (USA) Inc.*, 352 F. Supp. 2d 403 (S.D.N.Y. 2004).[1051]

"wherein the <u>proportion of hydroxy acrylic monomer units to silicon units in said tear-wettable surface layer is greater than that of said lens body</u>" — "the proportion of hydroxy acrylic monomer units to silicon units is higher in the tear-wettable surface layer than in the lens body, [where] 'silicon units' means 'silicon atoms that are part of a polymer.'" *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[1052]

"prosthetic vascular structure"; "prosthetic vascular graft"; "artificial vascular prosthesis" — "a structure used to replace, repair, augment, or bypass blood vessels." *Bard Peripheral Vascular, Inc., et al. v. W.L. Gore & Associates, Inc.*, 2006 U.S. Dist. LEXIS 71261 (D. Ariz., Sept. 16, 2006).[1053]

"protected from light" — "the 'protected from light' language provides no distinguishing structure to the claim. ... We therefore construe the expression 'protected from light' to be non-limiting." *Research Corporation Technologies, Inc., et al. v. Gensia Laboratories, Inc., et al.*, 2001 U.S. App. LEXIS 4444 (Fed. Cir., March 23, 2001) (unpublished).[1054]

"protect the immunoglobulin from degradation and thus stabilize the IgG 1 composition"; "so that said stabilization (sic) composition is made" — "require that the chelator reduce degradation." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[1055]

"protein sparing" — "means the retention of protein in the body sufficient to trigger a decrease in the level of nitrogen excreted by the body, as measured by urinary nitrogen levels." *Iowa State University Research Foundation, Inc., et al. v. Wiley Organics, Inc.*, 291 F. Supp. 2d 883 (S.D. Iowa 2003).[1056]

"to <u>provide an eluate</u>" — "to provide several fractions from the column, including at least a nonsugar fraction, a sugar fraction, and a betaine fraction." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[1057]

"said formulation <u>providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions</u>" — "The claim language at issue concerns the type of administration (single dose, or multiple dose, steady-state) used to determine the mean time "after administration" at which the maximum mean plasma level of oxycodone ion the specification and the 'fundamental purpose and significance' of the invention,' the district court held n human patients is reached. ... Finding the language of the claim ambiguous, and ultimately relying that the range of values for Tmax 'after administration' encompasses values obtained from multiple dose, steady-state studies. ... We see no error in the district court's initial conclusion and reasoning." *Purdue Pharma L.P., et al. v. Boehringer Ingelheim GmbH, et al.*, 237 F.3d 1359 (Fed. Cir. 2001).[1058]

"pure" — "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[1059]

"X% pure" — "mean[s] that X percentage of polymers within a predefined region have identical sequences." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[1060]

"purified" — "in the claims of the '052 and '120 patents means that the proteinaceous material extracted from the outer membrane of B. pertussis bacteria must be purified at least to the extent that 69k is its major antigenic component." *Evans Medical Ltd., et al. v. American Cyanamid Co., et al.*, 11 F. Supp. 2d 338 (S.D.N.Y. 1998).[1061] "We agree with the district court that the written description compels a construction of 'purified' requiring that the claimed antigen comprise greater than fifty percent 69kD antigen." *Id.*, 1999 U.S. App. LEXIS 18436 (Fed. Cir., Aug. 9, 1999) (unpublished).[1062]

"a purified and isolated TNF α-binding protein" — "covers only the TBP-II protein." *Abbott GMBH & Co. KG v. Yeda Research and Development Co., Ltd.*, 516 F. Supp. 2d 1 (D.D.C. 2007).[1063]

"purified from mammalian cells grown in culture" — "obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al.*, 494 F. Supp. 2d 54 (D. Mass. 2007).[1064] *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[1065]

"a purity of at least 95%" — "CA having no more than 5% degrading, unwanted impurities not including excipients, such as the sorbitol and zinc chloride added by Apotex to its CA product." *Glaxo Group Ltd., et al. v. Apotex, Inc.*, 64 Fed. Appx. 751 (Fed. Cir., Apr. 22, 2003) (unpublished).[1066] "[T]he phrase 'having a purity of at least 95%' ... cover[s] formulations with more than 5% of other ingredients." *Id.*, 376 F.3d 1339 (Fed. Cir. 2004).[1067]

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"quantity" — "a measurable amount." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[1068]

"at least one of the halogens CI, Br or I is present in a quantity" — "I construe 'quantity' to mean a concentration--the amount per unit volume." *U.S. Philips Corp. v. Iwasaki Electric Co., et al.*, 2006 U.S. Dist. LEXIS 106 (S.D.N.Y., Jan. 3, 2006).[1069]

"a quantity between 10^{-6} and 10^{-4} µmol/mm^3" — "means that the halogen is present in the envelope or bulb in a quantity between 1 divided by 1,000,000 and 1 divided by 10,000 micromoles per cubic millimeter." *U.S. Philips Corp. v. Iwasaki Electric Co., et al.*, 2006 U.S. Dist. LEXIS 106 (S.D.N.Y., Jan. 3, 2006).[1070] "The claim construction that we affirm today is 'between 1 x 10^{-6} and 1 x 10^{-4} µmol/mm^3,' not 'between 1.0 x 10^{-6} and 1.0 x 10^{-4} µmol/mm^3.'" *Id.*, 505 F.3d 1371 (Fed. Cir. 2007).[1071]

"quantity of Aloe Vera" — "an indefinite amount of aloe vera." *Shen Wei, et al. v. Ansell Healthcare Products, Inc.*, 2004 U.S. Dist. LEXIS 7717 (N.D. Ill., Apr. 30, 2004).[1072]

"quaternized ammonium polymer" — "a polymer compromising a quaternized nitrogen moiety, wherein said quaternized nitrogen moiety compromises a nitrogen atom, wherein all four atomic orbitals of said nitrogen atom are filled with an organic group." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1073]

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"R"; "R_1" — "a person of ordinary skill in the art at the time the invention was made would understand that 'R,' as used in the claims, can be an alkylene or alkenylene radical containing from one to about 20 carbon atoms, or a cycloalkylene or cycloalkenylene radical containing from about 5 to about 10 carbon atoms, or a mononuclear or fused ring arylene radical containing from about 6 to about 10 carbon atoms, all of which may be unsubstituted or substituted with one or more lower alkyl, lower alkoxy, lower alkoxy-substituted lower alkyl, nitro or amino groups or halogen atoms"; "[s]uch person would also understand that 'R_1,' as used in the claims, can be any alkylene or alkenylene radical, which may be the same or different alkylene or alkenylene radical as 'R,' and which may also be unsubstituted or substituted in various ways, including but not limited to substitutions with one or more lower alkyl, lower alkoxy, lower alkoxy-substituted lower alkyl, nitro or amino groups or halogen atoms. The patent does not limit the number of carbon atoms in 'R_1.'" *Penederm, Inc. v. Alzo, Inc.*, 1996 U.S. Dist. LEXIS 18706 (N.D. Cal., Dec. 6, 1996).[1074]

"radical" — "highly reactive gas fragments that typically possess at least one unpaired valence electron (including certain atoms or molecules produced as a result of a glow discharge) that allow or encourage the desired reaction." *ASM America, Inc. v. Genus, Inc.*, 2002 U.S. Dist. LEXIS 15348 (N.D. Cal., Aug. 15, 2002).[1075]

"rapamycin" — "a compound containing a macrocyclic triene ring structure produced by Streptomyces hygroscopicus, having immunosuppressive and antirestenotic effects." *Wyeth, et al. v. Abbott Laboratories, et al.*, 2010 U.S. Dist. LEXIS 75893 (D.N.J., Jul. 27, 2010).[1076]

"a method for <u>rapid, large scale screening to identify a ligand that binds to a ... target protein ...</u>" — "the court has turned to the patent specifications and the prosecution histories in order to discern what the inventors meant when they used the term 'rapid, large scale screening.' As previously discussed, they described tests which screened thousands of test ligands, not dozens or hundreds. Consequently, the court believes that interpreting the term 'large scale' as meaning that several thousand compounds are to be screened is appropriate. Likewise, in light of the examples set forth in both the specifications and the prosecutions histories, it appears as if these screening methods could be completed within a number of hours or, at most, a number of days, depending upon the technology employed and the number of compounds tested. The court will, therefore, assign these meanings to the phrase 'rapid, large scale screening' so that the asserted claims which contain this language in their preamble may possess this particular life and vitality." *Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc.*, 79 F. Supp. 2d 409 (D. Del. 1999).[1077]

"rapid thermal anneal process" — "a process that employs high temperatures for short periods of time." *IXYS Corp. v. Advanced Power Technology, Inc.*, 301 F. Supp. 2d 1065 (N.D. Cal. 2004).[1078]

"rapidly cooling" — "cooling the mixture to below the softening temperature of the binder material in a sufficiently short enough time to prevent deterioration of the bonds." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[1079]

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"a rate of consumption of the catalyst by the FCC unit" — "a ratio of the catalyst lost by the FCC unit over time, or a ratio of the catalyst additive lost by the FCC unit over the fresh catalyst lost." *Intercat, Inc. v. Nol-Tec Systems, Inc., et al.*, 2005 U.S. Dist. LEXIS 344 (D. Minn., Jan. 7, 2005).[1080]

"a specific ratio of HPMC to bupropion hydrochloride for each tablet" — "a specific polymer, HPMC, blended with bupropion hydrochloride in a specific ratio to form an admixture. The presence of HPMC within the admixture serves to retard the release of bupropion hydrochloride into the bloodstream." *Smithkline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, 214 F. Supp. 2d 581 (E.D. Va. 2002).[1081]

"raw" — "pretreatment; before any chemicals have been added, before any processes have been applied." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1082]

"reacting said lens body with a member selected from the group consisting of" — "the lens body undergoes a chemical reaction with a member selected from the group consisting of." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[1083]

"reactive gas" — "a gas having an ability to combine chemically with another substance." *Applied Science and Technology, Inc. v. Advanced Energy Industries, Inc.*, 204 F. Supp. 2d 712 (D. Del. 2002).[1084]

"recovered liquid hydrocarbon absorbent" — "is limited [] to an absorbent which consisted of internally-created, recovered liquid hydrocarbon." *McGill Inc. v. John Zink Co.*, 736 F.2d 666 (Fed. Cir. 1984).[1085]

"reducing" — "construction is unnecessary to aid the jury in understanding the term." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[1086]

"reducing agent" — "a substance that can restore the catalytic activity of the inactive SAH-hydrolase." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[1087]

"reducing ambient" — "a gaseous atmosphere that adds an electron to an element or compound." *STMicroelectronics, Inc. v. Motorola, Inc.*, 327 F. Supp. 2d 687 (E.D. Tex. 2004).[1088]

"an apolipoprotein reducing amount" — "an amount that reduces the production of apolipoprotein B." *SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc.*, 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).[1089]

"reducing gastrointestinal adverse side effects" — "This Court declines to find that the term 'reducing gastrointestinal adverse side effects' only refers to the most severe GI side effects and the patient discontinuations due to GI side effects." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[1090]

"said modification comprising reducing the number [of XCG codons]" — "means only that the overall modification must include a reduction in the number of XCG codons, not that each change of an XCG codon to a non-XCG codon must satisfy the 'greater number' or 'frequency' limitation." *Mycogen Plant Science, Inc., et al. v. Monsanto Co., et al.*, 1997 U.S. Dist. LEXIS 23736 (D. Del., Dec. 29, 1997).[1091]

"reduction of color" — "a lowering in the amount of measurable Pt Color Units (as defined in Standard Methods for the Examination of Water and Wastewater 20th Edition) present in water, which are often caused by the presence of tannins, lignins, and other humic substances." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1092]

"reduction of turbidity" — "improving clarity, measured as reducing reported NTUs." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1093]

"which construct produces an RNA which regulates the function of a gene" — "the Court concludes that this non-naturally occurring mRNA must 'regulate the function of a gene' by binding with a naturally-occurring mRNA from the gene targeted, and preventing the naturally-occurring mRNA from functioning." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1094]

"relatively low level"; "relatively low value" — "the level or value of kinetic energy below the level at which the ion signal is reduced by further increases of the kinetic energy." *Applera Corp., MDS Inc., et al. v. Micromass UK Ltd., et al.*, 186 F. Supp. 2d 487 (D. Del. 2002).[1095]

"comprising a relatively thick core or base layer" — "[is not] limited to a core composed of a single layer." *Avery Dennison Corp. v. UCB Films PLC.*, 1997 U.S. Dist. LEXIS 13594 (N.D. Ill., Sept. 3, 1997).[1096]

"remove algae" — "a reduction in the amount of a biological organism capable of absorbing chlorophyll A to an appreciable extent." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1097]

"treating a dried fruit with an acidulant ... in an amount and for a period of time which is sufficient to substantially remove the natural flavor of the dried fruit" — "The court construes Claim 1 to require the use of an acidulant to remove the fruit's flavor and also finds that using an acidulant to add flavor back to the fruit is not within the scope of Claim 1." *Amazin' Raisins International, Inc. v. Ocean Spray Cranberries, Inc.*, 2007 U.S. Dist. LEXIS 60808 (D. Mass., Aug. 20, 2007).[1098]

"remove turbidity" — "increase clarity, reduce reported NTU to an appreciable extent." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1099]

"represents at least about 10% of all possible peptide sequences" — "means approximately 10% or more of the possible peptide sequences of a given length within the range of 3 to 13 L-amino acids where the number of possible peptide sequences is equal to 20^L." *Pieczenik, et al. v. Dyax Corp.*, 226 F. Supp. 2d 314 (D. Mass. 2002).[1100]

"a resin" — "a thermoplastic or thermosetting solid or semi-solid substance." *Medtech Products Inc. v. Ranir, LLC, et al.*, 2009 U.S. Dist. LEXIS 103211 (S.D.N.Y., Nov. 5, 2009).[1101]

"resistance" — "should be accorded its broader meaning, i.e. that a transgenic plant is 'herbicide resistant' even if it is severely harmed by herbicides, so long as it is less harmed than the non-transgenic version of the plant would be at the same applied level of glyphosate." *Rhone-Poulenc Agro, S.A. v. Monanto Co., et al.*, 445 F. Supp. 2d 531 (M.D. N.C. 2006).[1102]

"resistance to normally toxic levels of glyphosate" — "the Court to conclude[s] that 'resistance' means any level of resistance above that observed in a non-transformed plant." *Dekalb Genetics Corp. v. Syngenta Seeds, Inc., et al.*, 2007 U.S. Dist. LEXIS 93948 (E.D. Mo., Dec. 21, 2007).[1103]

"retain" — "retain means hold back, not merely delay, but does not require that every red cell be held back." *IDEXX Laboratories, Inc. v. Abaxis, Inc., et al.*, 222 F. Supp. 2d 66 (D. Me. 2002).[1104]

"retention of nitrogen" — "a decrease in the excretion of nitrogen from the body, as measured by the amount of nitrogen in a subject or patient's urine." *Iowa State University Research Foundation, Inc., et al. v. Wiley Organics, Inc.*, 291 F. Supp. 2d 883 (S.D. Iowa 2003).[1105]

"ribosome binding site" — "a DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome, and is thus required for the initiation of translation." *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761 (Fed. Cir. 2002).[1106]

"rich in glucosinolates"; "high Phase 2 enzyme-inducing potential" — "Brassica also asks this court to construe the phrases 'rich in glucosinolates' and 'high Phase 2 enzyme-inducing potential' to require 'at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential at 3-days following incubation under conditions in which cruciferous seeds germinate and grow.' ... Brassica's proposed construction violates this rule by improperly importing limitations from the specification into the claims." *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002).[1107]

"ring-stabilizing amount" — "that the amount of soluble metal nitrate salt is sufficient to stabilize the 3-isothiazolone and deter decomposition." *Rohm and Haas Co. v. Lonza Inc., et al.*, 997 F. Supp. 635 (E.D. Pa. 1998).[1108]

"ripe" — "it would be improper to construe the term 'ripe' as imparting a purity limitation." *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 2004 U.S. Dist. LEXIS 14960 (D. Del., Aug.3, 2004).[1109]

"no detectable <u>RNase H activity</u>"; "lacks <u>RNase H activity</u>" — "the court finds no error in the district court's analysis, under which the complete absence of RNase H activity ... must be shown by the gel assay as set forth in the written description of the '608 patent." *Invitrogen Corp. v. Clontech Laboratories, Inc.,* 429 F.3d 1052 (Fed. Cir. 2005).[1110]

"room temperature" — "an ambient temperature of approximately 72 º F." *Magsil Corp., et al. v. Seagate Technology, et al.*, 2010 U.S. Dist. LEXIS 18086 (D. Del., Mar. 1, 2010).[1111]

"room temperature" — "mean[s] 20 º - 25 º C (68 º - 77 º F)." *Ahlstrom Machinery, Inc. v. Clement*, 13 F. Supp. 2d 45 (D.D.C. 1998).[1112]

"rubber" — "the elastic substance derived from tropical plants and any of various similar synthetic substances." *Sun Coast Merchandise Corp. v. CCL Products Enterprises, Inc.*, 2003 U.S. Dist. LEXIS 27316 (N.D. Cal., Apr. 30, 2003).[1113]

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"S(-)" — "the (-) indicates that the claims refer to an 'optically active' compound." *Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al*., 348 F. Supp. 2d 713 (N.D. Va. 2004).[1114]

"(S)-(-)-1-propyl-2',6'-pipecoloxylidide hydrochloride" — "a compound with an (s)-enantiomer with an optical purity of more than 99.0%." *Abraxis Bioscience, Inc. v. Navinta LLC*, 640 F. Supp. 2d 553 (D.N.J. 2009).[1115]

"an S(-)-pyridobenzoxazine compound"; "S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid" — "refer to the levorotatory enantiomer of racemic ofloxacin, levofloxacin. These terms do not refer to racemic ofloxacin." *Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al*., 348 F. Supp. 2d 713 (N.D. Va. 2004).[1116]

"saccharides" — "the district court did not err in construing 'saccharides' to include polysaccharides." *Pfizer, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.,* 429 F.3d 1364 (Fed. Cir. 2005).[1117]

"saccharides" — "carbohydrates or sugars which can be in the form of mono-, oligo-, and/or polysaccharides." *Mannatech, Inc. v. Techmedica Health, Inc., et al.*, 2009 U.S. Dist. LEXIS 101480 (N.D. Tex., Aug. 28, 2009).[1118]

"one or more <u>saccharides</u>" — "a saccharide or saccharides which are a component of a drug product containing an ACE inhibitor in which cyclization has been inhibited." *Schwarz Pharma, Inc., et al. v. Paddock Laboratories, Inc.*, 429 F. Supp. 2d 1116 (D. Minn. 2006).[1119]

"said"; "the" — "Where subsequent uses of a claim term within a claim make reference to the first usage as an antecedent (through the use of introductory definite articles such as 'said' or 'the'), the claim term must be interpreted consistently across all such uses." *Microprocessor Enhancement Corp., et al. v. Texas Instruments Inc.*, 2007 U.S. Dist. LEXIS 23768 (C.D. Cal., Feb. 8, 2007).[1120]

"said analyte" — "an analyte which is both the 'analyte which is a substrate for said enzyme' and the 'non-labelled analyte' described in claim 1, and is a said conversion product." *General Atomics, et al. v. Axis-Shield ASA,*2006 U.S. Dist. LEXIS 73671 (N.D. Cal., Sept. 26, 2006).[1121]

"wherein R4 is a residue of a nucleophilic compound selected from hydroxyl, mercapto, cyano, azido, amino, carbamoyloxy, carbamoylthio and thiocarbamoyloxy, <u>said group being unsubstituted or substituted by alkyl of up to three carbons, and R5 is hydroxyl or lower alkoxy</u>" — "The words 'said group being unsubstituted or substituted by alkyl of up to three carbons' means that (1) all of the structures named in the Markush group may be used in their unsubstituted form; and (2) all of the structures named in the Markush group that can be chemically 'substituted' by replacing a hydrogen atom with 'alkyl of up to three carbons,' may be so substituted within the meaning of the R4 limitation. This leads to the conclusion that an alkoxy residue such as methoxy ($-OCH_3$) may be substituted for the hydroxyl residue (-OH) within the meaning of the R4 limitation of Claim 1." *Pharmacia & Upjohn Co., et al. v. Ranbaxy Pharmaceuticals, Inc.*, 85 Fed. Appx. 205 (Fed. Cir., Dec. 23, 2003) (unpublished).[1122]

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"whereby a substantially tasteless super-purified smoke is created" and "treating meat having freezing point with said tasteless super-purified smoke" — "The use of 'said' makes it clear that 'said tasteless super-purified smoke' refers to the "substantially tasteless super-purified smoke" that is a result of the processes previously described in the Kowalski Patent." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[1123]

"a salt" — "a salt includes a salt in solution." *IDEXX Laboratories, Inc. v. Abaxis, Inc., et al.*, 222 F. Supp. 2d 66 (D. Me. 2002).[1124]

"salt" — "a compound that contains a positively charged component (cation) and a negatively charged component (anion), other than a hydrogen or hydroxyl ion, and is not an oxide." *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co., et al.*, 163 F. Supp. 2d 426 (D. Del. 2001).[1125]

"sanitize" — "mean[s] that the treated meat has become safe for human handling and post-cooking consumption." *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009).[1126]

"saponification" — "the hydrolysis reaction of jojoba oil starting material with an alkali metal or alkaline earth metal hydroxide to form jojoba-oil starting material." *International Flora Technologies, Ltd. v. Desert Whale Jojoba Company, Inc., et al.*, 2010 U.S. Dist. LEXIS 109273 (D. Ariz., Sep. 29, 2010).[1127]

"saturate"; "saturation" — "dissolving sufficient air or gas into the liquid so that the liquid contains 60% to 90% of its maximum air concentration." *Les Traitments des Eaux Poseidon, Inc. v. Kwi, Inc., et al.*, 135 F. Supp. 2d 126 (D. Mass. 2001).[1128]

"sealed container" — "a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed." *Pharmacia & Upjohn Co. v. Sicor, Inc., et al.*, 447 F. Supp. 2d 363 (D. Del. 2006).[1129]

"seeds" — "radioactive sources." *Lamoureux, et al. v. AnazaoHealth Corp., et al.*, 2009 U.S. Dist. LEXIS 103846 (D. Conn., Nov. 5, 2009).[1130]

"segments of DNA from different genomes" — "refer to DNA segments or DNA sequences in genomes of cells or viruses which may be both naturally occurring and non-naturally occurring." *Schering Corp., et al. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998).[1131]

"selectable phenotype" — "a phenotype which confers upon an organism or a cell the ability to exist under conditions which kill off all organisms or cells not possessing the phenotype. Examples include drug resistance or the ability to synthesize some molecule necessary to cell metabolism in a given growth medium. Selectable phenotypes also include identifiable phenotypes such as the production of materials which pass from or are secreted by the cell and can be detected as new phenotypes either by functional, immunologic or biochemical assays." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[1132]

"passing said liquid through an ion exchange resin selected from the group consisting of mixed bed resin and cation resin to remove at least said dissolved contaminants" — "Demmitt anticipates claim 1 if that claim requires only the removal of dissolved cationic carbon contaminants, rather than all of the dissolved carbon contaminants, both cationic and anionic. ... By claiming a Markush group, Ecolochem has indicated that, for the purpose of claim validity, the members of the claimed group are functionally equivalent. ... Accordingly, if either alternative in the Markush group of step three, i.e., employing a cation resin or a mixed bed resin, is anticipated, the entire claim is anticipated. Demmitt clearly discloses the use of the Houghton process on oxygenated water followed by use of a cation exchange resin. .... Accordingly, ... claim 1 is anticipated by Demmitt." *Ecolochem, Inc. v. Southern California Edison Co.*, 1996 U.S. App. LEXIS 13330 (Fed. Cir., June 5, 1996) (unpublished).[1133]

"with the rubber selected from the group consisting of natural polymers and synthetic high polymers"; "with said rubber particles having an outer surface designed and dimensioned to look like natural mulch selected from the group consisting of pea gravel, wood chips, and tree bark ..."; "said rubber particles are preferably selected from the group consisting of waste rubber buffings and ground tires" — "Like the patent in Abbott Labs., 'the claims do not clearly embrace more than one member of the Markush group.' Therefore, the plain meaning of the claims ... 'limits them to a single [alternative] selected from the recited Markush group.'" *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, et al.*, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).[1134]

"selected technique" — "any analytical method chosen to detect haplotypic patterns." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[1135]

"selectively binds a peptide of human parathyroid hormone (hPTH) selected from the group consisting of peptides having SEQ" — "the district court likely erred by interpreting claim 17 as distinguishing between biologically active and inactive hPTH. ... [W]hile certain claims of Nichols' patent expressly refer to active hPTH, claim 17 does not." *Nichols Institute Diagnostics, Inc. v. Scantibodies Clinical Laboratory, Inc., et al.*, 166 Fed. Appx. 487 (Fed. Cir., Feb. 1, 2006) (unpublished).[1136]

"separating" — "to isolate from a mixture, to divide into constituent parts." *Finnsugar Bioproducts, Inc. v. Amalgamated Sugar Co., et al.*, 1999 U.S. Dist. LEXIS 13271 (N.D. Ill., Aug. 19, 1999).[1137]

"separating layer" — "is a generic term, which includes different species like subcoatings and capsules." *In re Omeprazole Patent Litigation*, 2004 U.S. Dist. LEXIS 9447 (S.D.N.Y., May 19, 2004).[1138]

"regulatory sequence" — "the specification teaches a process requiring one or more of these elements to transform cells with alpha-Gal A DNA, [but] it does not teach that all of them are required. The district court erred in this regard." *Genzyme Corp., et al. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094 (Fed. Cir. 2003).[1139]

"sequentially adding" — "adding one after the other, but in no particular order." *SKW Americas, et al. v. Euclid Chemical Co.*, 231 F. Supp. 2d 626 (N.D. Ohio 2002).[1140]

"serum or plasma" — "Because the ... claim language includes only language about 'serum or plasma,' a test solely on whole blood, without first extracting serum or plasma, would not literally infringe." *Jewish Hospital of St. Louis v. IDEXX Laboratories*, 973 F. Supp. 24 (D. Maine 1997).[1141]

"serum sample" — "may refer to a component of a fluid or a dried blood sample." *PerkinElmer, Inc., et al. v. Intema Ltd.*, 2010 U.S. Dist. LEXIS 66452 (D. Mass., Jul. 2, 2010).[1142]

"set" — "a collection or group." *Affymetrix, Inc. v. Hyseq, Inc.*, 132 F. Supp. 2d 1212 (N.D. Cal. 2001).[1143]

"showing" — "All that 'show' requires is that Glaxo demonstrate with an acceptable degree of certainty, visually or by other appropriate means of data display, that the accused product contains the 29 main peaks." *Glaxo Group Ltd. v. Torpharm, Inc., et al.,* 153 F.3d 1366 (Fed. Cir. 1998).[1144]

"shows" — "requires the display of a PXRD pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display." *Lupin Ltd. v. Abbott Laboratories, et al.*, 484 F. Supp. 2d 448 (E.D. Va. 2007).[1145]

"signalling moiety" — "including, but not limited to, a chemical entity capable of producing a detectable signal." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[1146]

"significant increase in HDL cholesterol" — "an increase in HDL cholesterol that results in a meaningful decrease in an individual's risk of developing cardiovascular disease." *Abbott Laboratories, et al. v. Lupin Ltd., et al.*, 2010 U.S. Dist. LEXIS 60743 (D. Del., Jun. 18, 2010).[1147]

"silica particles" — "particles of SiO_2, which may include other elements, compounds or substances picked up as impurities during the synthesis of silica sols, but not including any elements, compounds or substances that are intentionally added during the synthesis process." *Ondeo Nalco Co. v. Eka Chemicals, Inc.*, 2003 U.S. Dist. LEXIS 4443 (D. Del. 2003).[1148]

"silicone ester wax" — "[a] silicone polymer[] with attached ester groups and waxlike physical properties including linear silicone esters." *Revlon Consumer Products Corp. v. L'Oreal S.A., Cosmair, et al*., 170 F.R.D. 391 (D. Del. 1997).[1149]

"simultaneous actions" [of high temperature, intense mechanical energy, and chemical agent] — "the limitation requires only that the pulp be subjected simultaneously to the three types of energy at some point during dispersal." *Ahlstrom Machinery, Inc. v. Clement*, 13 F. Supp. 2d 45 (D.D.C. 1998).[1150]

"size distribution" — "volume distribution, based on particle size as represented by the diameter of a sphere having the same volume as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis." *Apotex, Inc. v. Cephalon, Inc., et al.*, 2010 U.S. Dist. LEXIS 107344 (E.D. Pa., Oct. 6, 2010).[1151]

"skin" — "the Court sees no reason to offer any additional construction." *Laboratory Skin Care, Inc. v. Limited Brands, Inc., et al.*, 616 F. Supp. 2d 468 (D. Del. 2009).[1152]

"skin cleaning composition for external use on human tissues"; "cleaning composition for use on human skin" — "a composition for removing unwanted non-water soluble substances from the skin." *LP Matthews LLC v. Bath & Body Works, Inc., et al*., 2006 U.S. Dist. LEXIS 76117 (D. Del., Oct. 19, 2006).[1153]

"skin permeable form of fentanyl base" — "fentanyl that is in a form that can pass through the skin, excluding solutions of fentanyl citrate." *Alza Corp., et al. v. Mylan Laboratories, Inc., et al.*, 310 F. Supp. 2d 610 (D. Vt. 2004).[1154] "[W]e agree with the district court's claim construction of 'skin permeable form.'" *Id.*, 391 F.3d 1365 (Fed. Cir. 2004).[1155]

"slope of strain hardening coefficient of greater than or equal to 1.3" — "the slope of strain hardening multiplied by the melt index raised to the 0.25 power must be greater than or equal to 1.3." *Dow Chemical Co. v. Nova Chemicals Corp.*, 629 F. Supp. 2d 397 (D. Del. 2009).[1156]

"softening or melting temperature" — "any temperature at which the viscosity of the binder will be reduced to such a point that the thermally removable layer, or portions thereof, may be removed." *E.I. du Pont de Nemours & Co. v. MacDermid, Inc., et al.*, 2010 U.S. Dist. LEXIS 23750 (D.N.J., Mar. 15, 2010).[1157]

"solid" — "an object having a definite shape that offers resistance to a deforming force." *Rhodia Chimie, et al. v. PPG Industries, Inc.*, 2003 U.S. Dist. LEXIS 18695 (D. Del., Oct. 9, 2003).[1158]

"solid dosage form" — "a dosage form that is neither liquid nor gaseous." *Alza Corp. v. Mylan Laboratories, Inc., et al*., 349 F. Supp. 2d 1002 (N.D. W. Va. 2004).[1159]

"solid integral mass" — "a drug, largely in the form of fine particles absent the presence of free liquid, pressed or squeezed together with the carbohydrate material, without the use of free liquids, into a unitary mass that is not liquid or gaseous." *Cephalon, Inc., et al. v. Barr Laboratories, Inc.*, 389 F. Supp. 2d 602 (D. Del. 2005).[1160]

"solid material" — "something that is not liquid or gas." *Harsco Corp. v. North Star Bluescope Steel, LLC*, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).[1161]

"solid state" — "no construction of this term is necessary ... the plain meaning of the term as understood by someone of ordinary skill shall apply." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[1162]

"soluble $CaSO_4$ anhydride" — "soluble anhydrous $CaSO_4$, or soluble anhydrous calcium sulfate." *Ultimax Cement Manufacturing Corp. v. CTS Cement Manufacturing Corp.*, 587 F.3d 1339 (Fed. Cir. 2009).[1163]

"5% <u>soluble protein loss</u>" — "refer[s] to actual test results on product based on the test methods referenced in the patent." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[1164]

"soluble signal" — "a signal that does not precipitate and is thus detectable by spectrophotometric and/or colormetric assay techniques, such as colormetric, photometric and fluorescent signals." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2006 U.S. Dist. LEXIS 74570 (D. Conn., Oct. 12, 2006).[1165]

"soluble signal" — "a soluble product which generates a detectable signal." *Enzo Biochem, Inc., et al. v. Affymetrix Inc., et al.*, 439 F. Supp. 2d 309 (S.D.N.Y. 2006).[1166]

"solubilizer" — "in the context of the application, 'solubilizer' embraced only surfactants." *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 384 F.3d 1333 (Fed. Cir. 2004).[1167]

"nonionic solubilizer" — "a nonionic compound that increases the solubility of a substance in a particular solvent." *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 221 F. Supp. 2d 535 (E.D. Pa. 2002).[1168] "Mutual's motion for reconsideration of this Court's claim construction for the term 'non-ionic solubilizer' will be denied." *Id.*, 2002 U.S. Dist. LEXIS 20311 (E.D. Pa., Oct. 3, 2002).[1169]

"a solution or dispersion of an effective amount of the active compound"; "dissolving or dispersing an effective amount of the active compound" — "a solution or dispersion is the dispersed or dissolved substance(s) and the medium in which it is dispersed or dissolved." *AstraZeneca AB, et al. v. Mutual Pharmaceutical Co., Inc*., 221 F. Supp. 2d 535 (E.D. Pa. 2002).[1170]

"a solvent selected from acetone, lower alkyl acetate, a mixture of acetone and water and a mixture of lower alkyl acetate and water" — "exclude[s] all bases and solvents other than as particularly claimed, including those that might generally be thought of as equivalent." *Tanabe Seiyaku Co., Ltd., et al. v. United States International Trade Commission, et al.*, 109 F.3d 726 (Fed. Cir. 1997).[1171]

"suitable solvent system"; "solvent system" — "a solvent or mixture of solvents." *Flexsys America LP v. Kumho Tire U.S.A., Inc., et al.*, 2010 U.S. Dist. LEXIS 10761 (N.D. Ohio, Feb. 8, 2010).[1172]

["source and process" limitations] "non-naturally occurring"; "not isolated from human urine"; and "purified from mammalian cells grown in culture" — "we are not convinced that the source limitations in the asserted claims convert the claims into anything other than product claims. ... the 'non-naturally occurring' limitation ... merely prevents Amgen from claiming the human EPO produced in the natural course. ... Similarly, the 'not isolated from human urine' limitation ... simply requires that the claimed EPO, however made, be obtained from a source other than human urine. ... the limitation 'purified from mammalian cells grown in culture' ... only speaks to the source of the EPO and does not limit the process by which the EPO is expressed." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al*., 314 F.3d 1313 (Fed. Cir. 2003).[1173]

"spans" [a non-coding region sequence] — "amplifies, with no further limitation that the region spanned must include a non-conserved intron section." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[1174]

"specific to PCV-2 and not specific to PCV-1" — "an infringing epitope may be common to PCV-2 and some other antigen, as long as it is not also common to PCV-1. Whether one isolates the sequence directly from a PCV-2 virus or engineers a sequence obtained from another source such that it encodes a PCV-2 epitope makes no difference to the proper application of the district court's otherwise correct claim construction." *Intervet Inc. v. Merial Ltd., et al.*, 2010 U.S. App. LEXIS 16104 (Fed. Cir., Aug. 4, 2010).[1175]

"wherein said antigen is stage specific and not lineage dependent, and said antigen is also <u>specifically bound by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-8483</u>" — "any monoclonal antibody that binds only to the CD34 antigen through an antigen-antibody interaction." *The Johns Hopkins University, et al. v. CellPro, Inc., et al.*, 931 F. Supp. 303 (D. Del. 1996);[1176] "the district court's claim construction was not in error." *Id.*, 152 F.3d 1342 (Fed. Cir. 1998).[1177]

"specifically immunoreactive with anti-fillagrin antibodies present in the serum of subject suffering from rheumatoid arthritis" — "the antigen preferentially reacts with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis." *INOVA Diagnostics, Inc. v. Euro-Diagnostica AB, et al.*, 2009 U.S. Dist. LEXIS 74899 (N.D. Cal., Aug. 24, 2009).[1178]

"spheroid" — "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round." *Wyeth v. Mylan Pharmaceuticals, Inc.*, 2009 U.S. Dist. LEXIS 43800 (N.D.W.Va., May 22, 2009).[1179]

"spheroids" — "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round." *Wyeth v. Teva Pharmaceuticals, et al*., 2005 U.S. Dist. LEXIS 20034 (D.N.J., Sept. 6, 2005).[1180]

"spinel" — "The dispute between the parties is whether, when comparing a composition's XRD pattern with the magnesium aluminate spinel reference card, a person of ordinary skill in the art would require fairly strict conformity with the peak intensities on the reference card before identifying a material as spinel or whether that person would recognize a particular composition as containing spinel within the definition of the patent if there was substantial variation in the peak intensities, even though the peak positions generally matched the reference card. ... This Court finds as fact that a person of ordinary skill in the art would not demand strict compliance, or compliance within some arbitrary amount of acceptable deviation, with the relative intensities of the major peaks. This Court does not find that relative intensities are unimportant, however. They are important to an identification of the major peaks, and a greater match with relative intensities would yield greater confidence in a particular phase identification." *W.R. Grace & Co. v. Intercat, Inc., et al*., 7 F. Supp. 2d 425 (D. Del. 1997).[1181]

"sprayable" — "capable of being sprayed." *UV Coatings, Ltd. v. SICO, Inc.*, 2000 U.S. App. LEXIS 16990 (Fed. Cir., Jul. 18, 2000) (unpublished).[1182]

"stable nonagglomerating suspension" — "the district court's construction was not in error. The court's construction requiring that the suspension be stable at the time it is introduced was merely a recognition that the process could be completed at the time of pipeline introduction and did not have to be shipped over long distances." *Conoco, Inc., et al. v. Energy & Environmental International, L.C., et al*., 460 F.3d 1349 (Fed. Cir. 2006).[1183]

"stabilized" — "means resistant to decomposition, particularly the opening of the isothiazolone ring. The backdrop, or explanation, is that shelf-life of the stabilized composition is significantly longer than that for an unstabilized composition under the same storage conditions." *Rohm and Haas Co. v. Lonza Inc., et al.*, 997 F. Supp. 635 (E.D. Pa. 1998).[1184]

"stabilizer" — "any substance that tends to keep a compound, mixture, or solution from changing its physical form or chemical nature." *Penreco v. Hanna's Candle Co.*, 2003 U.S. Dist. LEXIS 27844 (S.D. Tex., Nov. 26, 2003).[1185]

"stabilizer" — "a) an excipient which forms a 'protective colloid' about solid particles of cyclosporin, i.e., completely surrounds the solid particles of cyclosporin; and b) an excipient in which cyclosporin is not soluble." *Novartis Pharmaceuticals Corp., et al. v. Eon Labs Manufacturing, Inc.,* 215 F. Supp. 2d 452 (D. Del. 2002).[1186]

"stabilizing effective amount of a saline or buffer solution" — "the solution contains sufficient chloride or other ions so as to effect some stabilization of the platinum complex against hydrolysis in aqueous solutions." *In re Research Corporation Technologies, Inc.*, 1998 U.S. Dist. LEXIS 23150 (D.N.J., Oct. 16, 1998).[1187]

"stabilizing the level of serum glucose" — "to cause a decrease in the relative fluctuations of a human's blood sugar." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[1188]

"stably" — "the district court correctly discerned that the claims only embrace stable expression of gene sequences integrated into a host's chromosome. However, the specification and prosecution history do not discuss this stability in terms of duration of chromosomal change. Rather, the applicant explicitly described the term 'stably' as referring to the level and duration of gene expression. Therefore, the district court erred in construing this term." *Genzyme Corp., et al. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094 (Fed. Cir. 2003).[1189]

"stainless steel" — "the court declines to construe the term 'stainless steel' in isolation. Instead, the court will pass on to the question of the proper construction of 'stainless steel comprising' specified elements, which is the second term in the '668 patent for which the parties dispute the proper construction." *Ideal Instruments, Inc. v. Rivard Instruments, Inc., et al.*, 498 F. Supp. 2d 1131 (N.D. Iowa 2007).[1190]

"starch" — "starch, whether native or modified by gelatinization or chemical treatment." *MGP Ingredients, Inc. v. Mars, Inc., et al.*, 494 F. Supp. 2d 1231 (D. Kan. 2007).[1191]

"a segment coding for a stable <u>stem and loop structure</u> with a negative ΔG of formation operatively linked down stream of said promoter segment" — "The Court interprets the phrase 'stem and loop structure' to mean a single strand of nucleic acid that folds back onto itself and then hybridizes by forming and collapsing. The Court construes the phrase 'negative ΔG of formation' to mean that the stem and loop structure requires a negative measurement of ΔG to insure that the stem and loop structure is stable. To be 'operably linked,' the nucleic acid segments must function together as they are attached to create the stem and loop construct. Finally, the Court concludes that this Claim requires that the stem and loop segment must be linked downstream of the transcriptional promoter segment identified in element (2)." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1192]

"sterilize" — "to make same free of all viable microorganisms." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[1193]

"stimulate high tissue ingrowth" — "encourage an increased rate or level of tissue growing inward or into the second surface." *Ledergerber Medical Innovations, LLC, et al. v. W.L. Gore & Associates, Inc.*, 2009 U.S. Dist. LEXIS 11556 (N.D. Ill., Feb. 17, 2009).[1194]

"stochastically generated polynucleotide sequences"; "stochastic polynucleotide sequences"; "at least partially stochastic polynucleotide sequences" — "applicants used 'stochastic' to mean containing random variables as opposed to involving the laws of probability." *Applied Molecular Evolution, Inc. v. Morphosys AG, et al.*, 2003 U.S. Dist. LEXIS 27252 (D. Mass., Jan. 3, 2003).[1195]

"storage stability" — "require[s] 90% potency for at least 18 months." *Pharmacia & Upjohn Co. v. Sicor, Inc., et al.*, 447 F. Supp. 2d 363 (D. Del. 2006).[1196]

"strong staining" — "refers to a clear and definite readily detectable signal resulting directly or indirectly from an interaction between an antibody and antigen, for example a color change as determined by light microscopy or a change in fluorescence determined by FACS. 'Strong staining' does not encompass staining that is less than strong, such as weak or moderate staining." *Chiron Corp. v. Genentech, Inc.*, 266 F. Supp. 2d 1172 (E.D. Cal. 2002).[1197]

"structural formula I [depicting an enantiomer]" — "the Court reads structural formula I of the '893 patent to embrace all trans-form isomers, including enantiomeric atorvastatin calcium." *Pfizer, Inc., et al. v. Ranbaxy Laboratories, Ltd., et al.*, 405 F. Supp. 2d 495 (D. Del. 2005);[1198] "claim 1 was correctly construed to include the enantiomeric trans-forms of the compounds of structural formula I." *Id.*, 457 F.3d 1284 (Fed. Cir. 2006).[1199]

"subcoating" — "a layer that is physically on and conforms to the contours of a core and is underneath another layer--the enteric coating. ... [G]elatine capsules are not subcoatings." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002)[1200]; "a layer that is physically on and conforms to the contours of a core and is underneath another layer -- the enteric coating ... [wherein] ... subcoatings and gelatin capsules are different species of the generic term 'separating layer.'" *Astra Aktiebolag, et al. v. Andrx Pharmaceuticals, Inc., et al.* (*In re Omeprazole Patent Litigation*), 2003 U.S. App. LEXIS 24899 (Fed. Cir., Dec. 11, 2003) (unpublished).[1201]

"subject"; "patient" — "the claim terms 'subject' and 'patient' are fairly read to include normal, healthy humans and are not limited to individuals with a nitrogen imbalance or negative nitrogen levels." *Iowa State University Research Foundation, Inc., et al. v. Wiley Organics, Inc.*, 125 Fed. Appx. 291 (Fed. Cir., Mar. 7, 2005) (unpublished).[1202]

"subseries of adjacent selected chromosomal regions" — "a group of chromosomal regions identified by the following process: Chromosomal regions on a DNA strand are selected. The regions need not be adjacent to each other on the DNA strand. The selected regions are then arranged in the order in which they appear on the DNA strand. Regions that are next to one another in this reconfiguration are then selected to comprise a group." *Genetic Technologies Ltd. v. Applera Corp.*, 2004 U.S. Dist. LEXIS 31072 (N.D. Cal., Sept. 15, 2004).[1203]

"substance" — "physical material from which something is made or which has discrete existence." *King Pharmaceuticals, Inc., et al. v. Sandoz, Inc.*, 2010 U.S. Dist. LEXIS 27274 (D.N.J., Mar. 22, 2010).[1204]

"substantial" — "a portion or amount that is considerable in quantity." *ChemFree Corp. v. J. Walter, Inc., et al.*, 2007 U.S. Dist. LEXIS 51677 (N.D. Ga., July 17, 2007).[1205]

"a substantial portion" — "could be up to and including 100%." *Harsco Corp. v. North Star Bluescope Steel, LLC*, 2007 U.S. Dist. LEXIS 55335 (N.D. Ohio, July 31, 2007).[1206]

"not interfering substantially" — "is not indefinite." *Enzo Biochem, Inc., et al. v. Applera Corp., et al.*, 2010 U.S. App. LEXIS 6267 (Fed. Cir., Mar. 26, 2010).[1207]

"substantially above the softening temperature" — "mean[s] sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point-bonds." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[1208]

"substantially above the softening temperature of said binder material" — "the court construes the phrase 'substantially above' to mean a temperature which is sufficiently high both to form a composite and to keep the mixture from solidifying in the extruder." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[1209]

"substantially all [non-ink contaminants]" — "'Substantially all' is accordingly construed to mean 'largely but not wholly that which is specified.'" *Ahlstrom Machinery, Inc. v. Clement*, 13 F. Supp. 2d 45 (D.D.C. 1998).[1210]

"substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer" — "at least 90%, and preferably greater than 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer." *Pozen Inc. v. Par Pharmaceutical, Inc., et al.*, 2010 U.S. Dist. LEXIS 61353 (E.D. Tex., Jun. 18, 2010).[1211]

"substantially 1:1"; "about 1:1" — "mean that the proline and glutamic acid values are within 5% of each other -- that is, the ratio between these values must fall within the range of 0.95:1 to 1." *Evans Medical Ltd., et al. v. American Cyanamid Co., et al.*, 11 F. Supp. 2d 338 (S.D.N.Y. 1998).[1212]

"substantially completed"; "substantially to completion" — "nearly to the end or nearly ended. With respect to where the reaction must be substantially completed, the Court finds that the reaction must be substantially completed in the entire sample." *Roche Diagnostics Corp. v. Inverness Medical Technology Inc., et al.*, 186 F. Supp. 2d 914 (S.D. Ind. 2002).[1213]

"substantially completely wetted" — "largely, but not necessarily wholly, surrounded by resin. In the context of LFRT pellets, it is surrounding the individual filaments by resin to the extent that in articles injection molded from such pellets, the individual filaments are randomly dispersed and at least 50% by weight of the filaments retain a length of 2 millimeters or greater." *LNP Engineering Plastics, Inc., et al. v. Miller Waste Mills, Inc., et al.*, 77 F. Supp. 2d 514 (D. Del. 1999).[1214]

"substantially crystalline form" — "sufficient crystallinity present to permit further optical purification of the enantiomer if required." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[1215]

"substantially different charge" — "the net charge on the product differs from that of the first reagent by an amount sufficient to permit the differential association of the substrate and product with a polyionic compound." *Caliper Technologies Corp. v. Molecular Devices Corp.*, 2003 U.S. Dist. LEXIS 27842 (N.D. Cal., Sept. 3, 2003).[1216]

"substantially equal amounts" — "is sufficiently clear that no additional construction is necessary." *Adco Products, Inc. v. Carlisle Syntec Inc.*, 110 F. Supp. 2D 276 (D. Del. 2000).[1217]

"substantially equivalent to ..." — "not statistically significantly different." *Abbott Laboratories v. Sandoz, Inc.,* 500 F. Supp. 2d 807 (N.D. Ill. 2007).[1218]

"C_{min} substantially equivalent to" — "here, 'substantially equivalent to' means not different than; it does not mean 'bioequivalent as measured by the use of 90% confidence levels' nor does it mean 'not statistically significantly different.'" *Abbott Laboratories v. Sandoz, Inc.,* 2007 U.S. Dist. LEXIS 89403 (N.D. Ill., Dec. 4, 2007).[1219]

"substantially free" — "require[s] a cell suspension of at least 90% purity. In other words, the cell suspension must contain no more than 10% mature lymphoid and myeloid cells." *The Johns Hopkins University, et al. v. CellPro, Inc., et al.*, 931 F. Supp. 303 (D. Del. 1996);[1220] "the district court's construction of the words 'substantially free' was not in error." *Id.*, 152 F.3d 1342 (Fed. Cir. 1998).[1221]

"substantially free" — "free of most, but not all, of the catalyzing material." *ReedHycalog UK, Ltd., et al. v. Baker Hughes Oilfield Operations, Inc., et al.*, 2007 U.S. Dist. LEXIS 67109 (E.D. Tex., Sept. 10, 2007).[1222]

"substantially free [of non-ink contaminants]" — "is construed ... to mean that so nearly all of the non-ink contaminants are screened and cleaned from the first aqueous fibrous suspension that no screening and cleaning is done downstream of the disperser." *Kamyr, Inc. v. Clement*, 952 F. Supp. 12 (D.D.C. 1997).[1223]

"topcoat is substantially free of an elutable material" — "the topcoat is largely or approximately free of an elutable material." *Boston Scientific SciMed, Inc., et al. v. Cordis Corp., et al.*, 2005 U.S. Dist. LEXIS 10735 (D. Del., Jun. 3, 2005).[1224]

"substantially free of nitrosamines or precursors" — "means that the combined content of nitrosamine and nitrosamine precursors is sufficiently low that no appreciable danger to humans or animals will result from contact with the compositions at issue." *Rohm and Haas Co. v. Lonza Inc., et al.*, 997 F. Supp. 635 (E.D. Pa. 1998).[1225]

"said compound or salt being substantially free of other isomers" — "the 'said compound' is largely but not necessarily free of other isomers. In other words, 'substantially free of other isomers' qualifies the compound by indicating that it may not be 100% pure or 100% free of other isomers." *Aventis Pharma Deutschland GMBH, et al. v. Lupin Ltd., et al*., 2006 U.S. Dist. LEXIS 31960 (E.D. Va., May 11, 2006).[1226]

"(S)-[enantiomer] substantially free of R-[enantiomer]" — "essentially free." *UCB Societe Anonyme, et al. v. Mylan Laboratories, Inc., et al*., 2006 U.S. Dist. LEXIS 39393 (N.D. Ga., June 14, 2006).[1227]

"substantially immiscible" — "mean[s] that the granules are largely, but not wholly, incapable of being dissolved into the gel coat." *Safas Corp. v. Etura Premier, L.L.C.*, 293 F. Supp. 2d 436 (D. Del. 2003).[1228]

"said binder particles being substantially incapable of fibrillation under normal conditions into microfibers of less than 10 micrometers diameter at room temperature" — "the binder particles are substantially incapable of forming fibers of less than 10 micrometers diameter by shear and pulling alone without heating or substantial compression." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[1229]

"substantially isopycnic" — "mean[s] that the granules are largely, but not wholly, of equal density with the gel coat." *Safas Corp. v. Etura Premier, L.L.C.*, 293 F. Supp. 2d 436 (D. Del. 2003).[1230]

"the tetracycline compound has substantially no anti-microbial activity" — "the tetracycline compound has been modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect." *Research Foundation of State University of New York, et al. v. Mylan Pharmaceuticals, L.P.*, 2010 U.S. Dist. LEXIS 46791 (D. Del., May 12, 2010).[1231]

"substantially powdered form" — "largely in the form of fine particles absent the presence of free liquid." *Cephalon, Inc., et al. v. Barr Laboratories, Inc.*, 389 F. Supp. 2d 602 (D. Del. 2005).[1232]

"substantially pure" — "does not require construction." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[1233]

"substantially pure DNA ... coding on expression for only a single polypeptide chain" — "refers to a naturally occurring or non-naturally occurring DNA sequence, independent of any plasmid DNA in a host cell, which codes on expression for an immature, fused, and/or incomplete form of a naturally occurring human leukocyte interferon protein, subsequently labeled IFN-α-1." *Schering Corp., et al. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998).[1234]

"substantially pure" and **"substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract"** — "Together, these phrases mean that (1) lutein makes up at least 90% of the total carotenoids that are contained in the lutein composition, and (2) the proportion of non-carotenoid chemical impurities compared to the total carotenoids in the lutein composition is sufficiently small to permit crystallization of the composition." *Kemin Foods, L.C., et al. v. Omniactive Health Technologies, Inc., et al*., 2009 U.S. Dist. LEXIS 88348 (M.D. Fla., Sep. 27, 2009).[1235]

"substantially pure lutein" — "lutein purity ... that is 90% or greater, as measured by UV/visible spectophotometry in conjunction with HPLC, and/or otherwise suitable for human consumption." *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. De C.V.*, 301 F. Supp. 2d 970 (S.D. Iowa 2004).[1236] "[I]t was error for the court to have read the limitation 'suitable for human consumption' into the claims, either as an alternative to the 90% minimum or in conjunction with it. It may well be that all compositions that fall within the scope of claim 1 ... would in fact be suitable for human consumption. However, that is not what the claim requires." *Id.*, 93 Fed. Appx. 225 (Fed. Cir., Mar. 17, 2004) (unpublished).[1237]

"substantially pure regioisomer" — "of greater than 95% purity." *Aventis Pharmaceuticals, Inc., et al. v. Barr Labs., Inc., et al*., 411 F. Supp. 2d 490 (D.N.J. 2006).[1238]

"substantially purified" — "purified to a substantial degree." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[1239]

"substantially purified beta (1,3) glucans"; "purified beta (1,3) glucan" — "glucans comprising predominantly beta (1,3) glycosidic linkages"; "glucans comprising beta (1,3) glycosidic linkages." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1240]

"substantially soluble in the reaction medium" — "the prosecution history demonstrates that the reaction medium consists of the EpB and the DHF only"; "the phrase 'substantially soluble in the reaction medium' excludes the addition of any solubilizer ; and "the phrase 'substantially soluble in the reaction medium' does not exclude gas feed processes. Rather, it only means that the catalysis must occur in a liquid phase." *BASF Corp. v. Eastman Chemical Co.*, 1998 U.S. Dist. LEXIS 23054 (D. Del., Mar. 24, 1998).[1241]

"a nutrient-indicator ... which is substantially the only nutrient in said medium which can be metabolized by [the target microbe] to the extent needed to support continued reproductive growth thereof"; "there being no other nutrients in the medium which are able to support substantial reproductive growth of [the target microbe] in the sample" — "requires only that the nutrient-indicators are the preferred source of reproductive growth of the target microbe, and that the inclusion of other nutrients in the medium does not take the accused product, by virtue of its use of other nutrients, out of the claims." *Environetics, Inc., et al. v. Millipore Corp*., 923 F. Supp. 344 (D. Conn. 1996).[1242]

"substantially uniform" — "largely, but not wholly the same in form." *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358 (Fed. Cir. 2001).[1243]

"a three-dimensional, solid cast, hydrated, substantially uniform alkaline detergent" — "It is clear from the face of the patent that substantially uniform means a level of continuity of the elements from top-to-bottom throughout the cast such that a homogenous cleaning solution is formed over the life of the cast." *Ecolab, Inc., Plaintiff, v. Amerikem Laboratories, Inc., et al.*, 1999 U.S. Dist. LEXIS 23466 (D.N.J., Jan. 8, 1999).[1244]

"substantially uniform mixture"; "substantially uniform particulate mixture" — "a largely--but not wholly--even distribution of particles." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[1245]

"substantially water free" — "a water content below 5%." *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc., et al.*, 249 F.3d 1341 (Fed. Cir. 2001).[1246]

"substituted alkylene" — "a 'substituted' alkylene is limited to alkylenes in which a pendant hydrogen atom has been replaced with one or more similarly pendant non-hydrogen atoms or groups of atoms. 'Substituted' therefore does not include replacements made within the carbon backbone of the alkylene or alkenylene radical." *Penederm, Inc. v. Alzo, Inc.*, 1996 U.S. Dist. LEXIS 18706 (N.D. Cal., Dec. 6, 1996).[1247]

"substrate" — "a material having a rigid or semi-rigid surface." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[1248]

"suffering from" — "having." *Bone Care International, LLC, et al. v. Pentech Pharmaceuticals, Inc., et al.*, 2010 U.S. Dist. LEXIS 54707 (N.D. Ill., Jun. 4, 2010).[1249]

"suffering from or running a risk of depletion of muscle phosphoryl creatine storage" — "having reduced, or potentially reduced, phosphoryl creatine storage in muscle." *Original Creatine Patent Co., Ltd. v. MET-Rx USA, Inc.*, 2009 U.S. Dist. LEXIS 35793 (E.D.N.Y., Apr. 28, 2009).[1250]

"for a period sufficient"; "to increase substantially" — "are not indefinite." *Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371 (Fed. Cir. 2001).[1251]

"sufficient amount"; "effective amount" — "The court would ... decline to limit ... 'effective' or 'sufficient' amount to 150 ppm or greater but for Baxter's second argument, that the prosecution history ... shows a prior sale which must limit the claims of the patent, lest it be invalid under 35 U.S.C. § 102(b). ... The only way to maintain the validity of the '176 patent, then, would be to interpret the terms 'sufficient' or 'effective' amount as requiring at least 131 ppm of water. Therefore, we hold that Abbott disavowed water limits of 131 ppm or less by disclosing the prior sales of sevoflurane and water that were made more than one year before the patent was filed." *Abbott Laboratories, et al. v. Baxter Pharmaceutical Products, Inc., et al.*, 2002 U.S. Dist. LEXIS 26500 (N.D. Ill., March 21, 2002).[1252] "In this case, the district court incorrectly limited the term an 'effective amount' of water to 131 ppm, despite the absence of a clear disavowal of water at lower amounts. Simply disclosing a previous sale of sevoflurane to the USPTO, without saying or doing anything more, does not disavow or relinquish all water concentrations below 131 ppm. As the patent itself discloses, the effective amount of Lewis acid inhibitor depends on the specific storage conditions of the sevoflurane. Moreover, mere submission of an IDS to the USPTO does not constitute the patent applicant's admission that any reference in the IDS is material prior art." *Id.*, 334 F.3d 1274 (Fed. Cir. 2002).[1253]

"sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" — "an amount sufficient to provide a patient with 2.5 to 15 mg of nitroglycerin per day -- that is, 2.5 to 15 mg of nitroglycerin, plus an excess amount to ensure that the desired amount is delivered." *Key Pharmaceuticals, Inc. v. Hercon Laboratories Corp.,* 981 F. Supp. 299 (D. Del. 1997).[1254]

"sufficient quantity" — "a required dosage." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1255]

"a sufficient temperature to soften" — "mean[s] that the vinyl surface covering is softened by heating such that it is receptive of embossment by mechanical means." *Mannington Mills, Inc., et al. v. Armstrong World Industries, Inc., et al.*, 2002 U.S. Dist. LEXIS 18641 (D. Del., Aug. 20, 2002).[1256]

"copper ions in an amount <u>sufficient to degrade</u>" — "enough copper ions to degrade." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 107 F. Supp. 2D 477 (D. Del. 2000).[1257] "[E]nough copper ions to degrade IgG 1 immunoglobulin." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[1258]

"sufficient to permit detection of hybridized labeled nucleic acid containing unique segments" — "sufficient to permit detection of the labeled nucleic acid containing unique segments hybridized to target chromosomal DNA." *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).[1259]

"pressure … <u>sufficient to substantially immediately convert at least a portion of the binder material</u>" — "the pressure must be greater than 400 psi." *KX Industries, L.P., et al. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2D 380 (D. Del. 2000).[1260]

"shear ... <u>sufficient to substantially immediately convert at least a portion of the binder material</u>" — "should be construed according to its plain meaning. … Therefore, the court will adopt the existing language of the claim." *KX Industries, L.P., et al. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2D 380 (D. Del. 2000).[1261]

PUBPAT

"sufficient water" — "means enough water to form a solution of the active ingredient and the nitrate salt." *Rohm and Haas Co. v. Lonza Inc., et al.*, 997 F. Supp. 635 (E.D. Pa. 1998).[1262]

"said matrix material has a <u>sufficiently high viscosity and low solubility in saliva that</u> the matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces" — "mean[s] that at the end of 2 hours there must be a significant amount of dental bleaching agent remaining in the dental tray and that as a result of the remaining bleaching agent's proximity to a patient's teeth, clinically significant bleaching is taking place. This means that a significant amount of the matrix material must remain in the tray at the end of two hours and that the bleaching agent dispersed in the matrix material must remain active so as to provide more than an insubstantial level of bleaching." *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., et al.*, 924 F. Supp. 1101 (D. Utah 1996).[1263]

"conducting a subsequent thermal annealing of the semiconductor material substrate at <u>sufficiently low temperature to substantially limit diffusion of gas from the semiconductor material substrate</u>" — "is not amenable to construction and is, therefore, indefinite as a matter of law." *S.O.I.T.E.C. Silicon on Insulator Technologies, S.A., et al. v. MEMC Electronic Materials, Inc.*, 2010 U.S. Dist. LEXIS 109667 (D. Del., Oct. 13, 2010).[1264]

"said matrix material is <u>sufficiently tacky to retain and hold</u> the dental tray positioned over the patient's teeth for a period greater than about 2 hours without any significant mechanical pressure from the dental tray" — "mean[s] that the matrix material must be sufficiently tacky or sticky as to contribute to the retention of a dental tray over a patient's teeth at the end of two hours, and that whatever dental tray is used not exert 'orthodontic' forces on a patient's teeth such that it would cause discomfort." *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., et al.*, 924 F. Supp. 1101 (D. Utah 1996).[1265]

"sugars" — "hexoses and higher saccharides based on hexoses up to decasaccharides, which are obtained from a refined and consistent source." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[1266]

"a suitable amount" — "an amount sufficient (i.e. effective) of an alkali or alkaline earth metal carbonate to inhibit cyclization to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." *Schwarz Pharma, Inc., et al. v. Paddock Laboratories, Inc.*, 429 F. Supp. 2d 1116 (D. Minn. 2006).[1267]

"a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration" — "an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor is sufficient to treat hypertension or congestive heart failure." *Schwarz Pharma, Inc., et al. v. Paddock Laboratories, Inc.*, 429 F. Supp. 2d 1116 (D. Minn. 2006).[1268]

"a suitable amount ... to inhibit cyclization and discoloration" — "a sufficient (i.e. effective) amount of an alkali or alkaline earth metal carbonate to reduce cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." *Schwarz Pharma, Inc., et al. v. Paddock Laboratories, Inc.*, 429 F. Supp. 2d 1116 (D. Minn. 2006).[1269]

"a suitable amount ... to inhibit hydrolysis" — "a sufficient (i.e., effective) amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." *Schwarz Pharma, Inc., et al. v. Paddock Laboratories, Inc.*, 429 F. Supp. 2d 1116 (D. Minn. 2006).[1270]

"an unleaded gasoline <u>suitable for combustion in an automotive engine</u>"; "an unleaded gasoline fuel suitable for combustion in a spark ignition automotive engine" — "cover fuels that will regularly be used in autos, not that conceivably could be." *Union Oil Co. of California v. Atlantic Richfield Co., et al.*, 208 F.3d 989 (Fed. Cir. 2000).[1271]

"suitable for oral administration" — "simply [means] that animals and/or humans can ingest the solution orally. ... a solution would not be 'suitable' for oral administration only 'if it would lead to certain death or debilitating harm or, perhaps, contained ingredients humans are incapable of digesting and eliminating.'" *Medeva Pharmaceuticals Manufacturing, Inc., et al. v. Morton Grove Pharmaceuticals, Inc*., 174 F. Supp. 2d 802 (N.D. Ill. 2001).[1272]

"suitable for therapeutic administration" — "[w]e do not agree that a complex 'suitable for therapeutic administration' requires a degree of purity greater than that already required by the claims of the method patents. ... One of ordinary skill in the art would have employed the same purity standards for both the earlier claimed method and the instantly claimed composition." *Research Corporation Technologies, Inc., et al. v. Gensia Laboratories, Inc., et al.*, 2001 U.S. App. LEXIS 4444 (Fed. Cir., March 23, 2001) (unpublished).[1273]

"suitable for therapeutic administration by injection in solution therefor" — "a tumor reducing platinum complex that is capable of being placed into solution or other nonharmful media for parenteral administration." *In re Research Corporation Technologies, Inc.*, 1998 U.S. Dist. LEXIS 23150 (D.N.J., Oct. 16, 1998).[1274]

"suitable for use in a biosensor" — "does not merely state a purpose or intended use for the claimed structure. Rather, the phrase informs the construction of the remainder of the claims by defining the matrix coating. The body of the claims is directed to an article that cannot be divorced from the intended field of use. It is only under the conditions imposed by the phrase 'suitable for use in a biosensor' that the elements of the claims perform the functions by which they are defined." *Biacore, AB, et al. v. Thermo Bioanalysis Corp.*, 79 F. Supp. 2d 422 (D. Del. 1999).[1275]

"super-purifying said smoke to reduce taste imparting components below thresholds for imparting smoke odor and taste" — "will not be numerically limited by the Court." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[1276]

"surface active material" — "means lung surfactant extract material before it is combined with a pharmaceutical carrier such as physiological saline." *Forest Laboratories, Inc., et al. v. Abbott Laboratories, et al.*, 1998 U.S. Dist. LEXIS 23171 (W.D.N.Y., Aug. 3, 1998).[1277] "The Court notes that even if it were not bound to follow Judge Arcara's ruling, it would nonetheless apply the same claim construction--at least with respect to the meaning of the phrases 'surface active material' and 'based on the dry weight of the material.'" *Abbott Laboratories, et al. v. Dey, L.P., et al.*, 110 F. Supp. 2d 667 (N.D. Ill. 2000).[1278] "We conclude that the district court properly decided that the term 'surface active material' means the material containing the prescribed materials in the prescribed percentages, when measured in the dry state, i.e., before being combined with the pharmaceutical carrier." *Forest Laboratories, Inc., et al. v. Abbott Laboratories, et al.*, 239 F.3d 1305 (Fed. Cir. 2001).[1279]

"surface pasteurizing" — "using heat for destroying bacteria on the surface." *Unitherm Food Systems, Inc. v. V.H. Cooper & Co., Inc.*, 2010 U.S. Dist. LEXIS 55911 (N.D. Okla., Jun. 4, 2010).[1280]

"surfactant" — "encompass[es] both hydrophilic surfactants and lipophilic surfactants." *Novartis Pharmaceuticals Corp., et al. v. Abbott Laboratories*, 294 F. Supp. 2d 552 (D. Del. 2002).[1281]

"surfactant" — "a substance that, when introduced into a liquid solution at comparatively low concentrations, dramatically reduces the surface tension of that solution or the interfacial tension between the solution and another surface. Typically, though not necessarily, surfactants have an amphipathic structure - that is, a hydrophobic tail and a hydrophilic head - and, at equilibrium, the concentration of the surfactant at a phase interface is greater than its concentration in the bulk of the solution. By way of example, when introduced at concentrations of less than one percent, 'surfactants,' as that term is used in the 859 patent, will reduce the surface tension of pure water (at room temperature) to at least 45 dynes/cm or less." *Polyclad Laminates, Inc., et al. v. MacDermid, Inc.*, 2001 U.S. Dist. LEXIS 17421 (D.N.H., Sept. 12, 2001).[1282]

"surfactant-based" — "a cleaning fluid whose active cleaning agent is one or more surfactants." *ChemFree Corp. v. J. Walter, Inc., et al*., 2007 U.S. Dist. LEXIS 51677 (N.D. Ga., July 17, 2007).[1283]

"surrounded by" — "encircle[d] on all sides" or "confined on all sides." *Sud-Chemie, Inc. v. Multisorb Technologies, Inc.*, 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).[1284]

"a plant ... which is <u>susceptible to infection and transformation by Agrobacterium and capable of generation thereafter</u>" — "as of the filing date of the 236 patent no methodology existed by which monocots could be infected and transformed by Agrobacterium to produce plants capable of regeneration. A person skilled in the art would have been aware of this limitation ... and would understand the wording of the plant and seed claims to mean that they did not cover monocots such as corn." *Plant Genetic Systems N.V., et al. v. Dekalb Genetics Corp.*, 175 F. Supp. 2d 246 (D. Conn. 2001).[1285]

"sustained release" — "refers to a dosage that is distinguished from immediate release in that it releases metoprolol succinate over a controlled or extended period of time close to or within the colon." *In re Metoprolol Succinate Patent Litigation*, 2006 U.S. Dist. LEXIS 1328 (E.D. Mo., Jan. 17, 2006).[1286]

"[*addition of the term*] 'sustained release'" — "does not alter the meaning of claim 1 ... The addition of the term 'sustained release' simply emphasizes a feature inherent in the composition." *Ultradent Products, Inc. v. Life-Like Cosmetics, Inc., et al.*, 924 F. Supp. 1101 (D. Utah 1996).[1287]

"swine infertility and respiratory syndrome virus, ATCC-VR2332" — "the preamble language, 'swine infertility and respiratory syndrome virus, ATCC-VR2332' limits the claim to the PRRS strain deposited, but not to any level of virulence." *Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp.*, 984 F. Supp. 239 (D.N.J. 1997).[1288] "We conclude that the district court again correctly chose the middle ground between the parties' contentions." *Id.*, 320 F.3d 1339 (Fed. Cir. 2003).[1289]

"said composition exhibiting <u>synergistic anti-proliferative activity against at least one form of cancer</u>" — "said combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances." *SourceOne Global Partners, LLC, Plaintiff, v. KGK Synergize, Inc.*, 2010 U.S. Dist. LEXIS 55015 (N.D. Ill., Jun. 3, 2010).[1290]

"synergistically effective amount" — "any amount that is synergistic against any bacteria. The fact that the same dosage amount does not yield synergy under other circumstances is irrelevant; once a particular amount yields synergy under any circumstance, that amount is 'synergistically effective.'" *Geneva Pharmaceuticals, Inc., et al. v. GlaxoSmithkline PLC, et al.*, 349 F.3d 1373 (Fed. Cir. 2003).[1291]

"systemic administration to the mammal of an effective but non-toxic anxiolytic dose of the 6-hydroxy-metabolite" — "refers to the administration of an externally-measured quantity of the metabolite into the body, and not to the administration of a dose of *buspirone* into the body, which, in turn, produces variable and changing levels (not doses) of the metabolite in the bloodstream." *In re: Buspirone Patent Litigation*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002).[1292]

"synthetic" — "outside a cell body." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[1293]

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"tablet" — "an oral dosage form consisting of a small mass of medication." *Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 2005 U.S. Dist. LEXIS 6894 (D. Del., April 22, 2005).[1294]

"tack modifier" — "shall include antioxidants only when each is used in an amount greater than three percent of the total weight of the product." *Edizone, LC v. Cloud Nine, LLC, et al.*,2006 U.S. Dist. LEXIS 68069 (D. Utah, Sept. 21, 2006).[1295]

"a compatible <u>tackifier</u>" — "a substance that gives the composition its softness and high initial adhesivity and is compatible with the other constituents in the adhesive composition." *Adco Products, Inc. v. Carlisle Syntec Inc.*, 110 F. Supp. 2D 276 (D. Del. 2000).[1296]

"target nucleic acids" — "nucleic acids that are deliberately exposed to the nucleic acids attached to the substrate." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[1297]

"target protein" — "a peptide, polypeptide, protein, or protein complex for which identification of a ligand or binding partner is desired." *Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc.*, 79 F. Supp. 2d 409 (D. Del. 1999).[1298]

"target specific sequence" — "a known polymer sequence that has affinity for another sequence." *Affymetrix, Inc. v. Illumina, Inc.*, 446 F. Supp. 2d 277 (D. Del. 2006).[1299]

"tartaric acid" — "not only includes tartaric acid (3-OH-malic) but also tartaric, tartarate, tartrate, 2-3-dihydroxybutanedioic acid, and meso-tartaric acid." *Great Plains Laboratory, Inc. v. Metametrix Clinical Laboratory, et al.*, 2006 U.S. Dist. LEXIS 66501 (D. Kan., Sept. 15, 2006).[1300]

"template" — "a cloning vector." *Promega Corp. v. Applera Corp.*, 2002 U.S. Dist. LEXIS 26927 (W.D. Wis., Jan. 2, 2002).[1301]

"a transcription <u>termination segment</u>" — "mean[s] a configuration of bases on the fragment of the DNA construct, which must signal the end point of the RNA molecule." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1302]

"test ligand" — "an agent which is a compound, molecule, or complex that is being tested for its ability to bind to a target protein." *Scriptgen Pharmaceuticals, Inc. v. 3-Dimensional Pharmaceuticals, Inc.*, 79 F. Supp. 2d 409 (D. Del. 1999).[1303]

"tetracycline compound" — "a compound within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure." *Research Foundation of State University of New York, et al. v. Mylan Pharmaceuticals, L.P.*, 2010 U.S. Dist. LEXIS 46791 (D. Del., May 12, 2010).[1304]

"tetrafluoroethylene" — "a repeating molecular unit (monomer) comprised of two carbon atoms and four fluorine atoms, also known as C_2F_4." *Greene, Tweed of Delaware, Inc. v. Dupont Dow Elastomers, L.L.C., et al.*, 2002 U.S. Dist. LEXIS 23554 (E.D. Pa., Nov. 18, 2002).[1305]

"<u>the</u> amplification reaction" — "an amplification reaction comprising multiple thermal cycles." *Applera Corp. v. Stratagene Corp.*, 2007 U.S. Dist. LEXIS 17154 (D. Conn., Mar. 9, 2007).[1306]

"<u>the</u> salt" — "refers to 'salt (III),' the product of step (a)." *Eastman Chemical Co., et al. v. BASF Aktiengesellschaft, et al.*, 47 Fed. Appx. 566 (Fed. Cir., Sept. 17, 2002) (unpublished).[1307]

"therapeutic agent" — "a tissue ingrowth promoter or antibiotic." *Marctec, LLC v. Johnson & Johnson, et al.*, 2009 U.S. Dist. LEXIS 27011 (N.D. Ill., Mar. 31, 2009).[1308]

"therapeutic composition" — "a composition that is useful for the treatment or prevention of diseases or disorders." *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, 2003 U.S. Dist. LEXIS 877 (D. Del., Jan. 13, 2003).[1309]

"therapeutic dose" — "claims 11, 13, and 14 contain neither means-plus-function limitations nor step-plus-function limitations." *Alza Corp. v. Mylan Laboratories, Inc., et al.*, 349 F. Supp. 2d 1002 (N.D. W. Va. 2004).[1310]

"therapeutic level" — "a level that is above the baseline level in the body and is sufficient to obtain the desired therapeutic result." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[1311]

"therapeutically effective" — "[an] amount ... that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22: stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 457 F.3d 1293 (Fed. Cir. 2006);[1312] "I must conclude that the district court's construction of the 'therapeutically effective' limitation comports with the patentee's own repeated descriptions of the claimed invention. It is exactly the way a skilled artisan would interpret the patent, as the district court held." Id. (Michel, C.J., dissenting).[1313]

"therapeutically effective"; "therapeutically ineffective" — "no construction is necessary." *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., et al.*, 528 F. Supp. 2d 967 (N.D. Cal. 2007).[1314]

"therapeutically effective"; "effective in treating" — "describe treatment with CHO-glycosylated antibodies, not previous therapy with antibodies derived from non-CHO cell lines." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[1315]

"therapeutically effective amount" — "The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply." *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, 2010 U.S. Dist. LEXIS 48844 (D.N.J., May 17, 2010).[1316]

"therapeutically effective amount" — "it is unnecessary for the Court construe the term 'therapeutically effective amount.' The tablet envisioned by Perrigo's ANDA would ... infringe [] even if the Court were to adopt Defendants' proposed construction." *McNeil-PPC, Inc., et al. v. Perrigo Co., et al*., 443 F. Supp. 2d 492 (S.D.N.Y. 2006).[1317]

"a therapeutically effective amount" — "an amount sufficient to produce a desired therapeutic effect." *Novartis Pharmaceuticals Corp., et al. v. Apotex Corp., et al*., 2006 U.S. Dist. LEXIS 10130 (S.D.N.Y., March 13, 2006).[1318]

"therapeutically effective amount" — "A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals." *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd., et al*., 494 F. Supp. 2d 54 (D. Mass. 2007).[1319]

"a therapeutically effective amount of a beta adrenergic stimulator" — "an amount of a beta adrenergic stimulator, therapeutically effective for weight loss, alone, without the inclusion of any other ingredient to improve or change its function." *American Phytotherapy Research Laboratory, Inc., et al. v. Impact Nutrition, Inc., et al.*, 201 F. Supp. 2d 1145 (D. Utah 2002).[1320]

"therapeutically effective period of time" — "does not require construction." *Medical Research Institute v. Bio-Engineered Supplements & Nutrition, Inc., et al.*, 2007 U.S. Dist. LEXIS 3576 (E.D. Tex., Jan. 12, 2007).[1321]

"administering ... a first composition ... and thereafter [] administering ..." — "Because Defendant's product does not administer an estrogenic compound in the first-stage and progestin in the second-stage, it does not contain all elements and limitations of the claim and, therefore, does not literally infringe claim 1." *Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc.*, 174 F. Supp. 2d 229 (D.N.J. 2001).[1322] "The district court correctly understood claim 1 to require administration of an estrogenic compound during certain designated days early in the woman's menstrual cycle, followed by administration of progestin for the last 21 days of the cycle." *Id.*, 325 F.3d 1356 (Fed. Cir. 2003).[1323]

"and therebetween, a DNA segment" — "this element to require[s] that the nonnative DNA construct must contain a DNA segment between the transcriptional promoter segment and the transcription termination segment." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1324]

"thermal cycler" — "an instrument for use in a nucleic acid amplification reaction comprising multiple thermal cycles for alternately heating or cooling samples." *Applera Corp. v. Stratagene Corp.*, 2007 U.S. Dist. LEXIS 17154 (D. Conn., Mar. 9, 2007).[1325]

"thermogenically effective amount"— "an amount which results in an increase in total energy expenditure or fat burning." *Iovate Health Sciences, Inc., et al. v. Allmax Nutrition, Inc., et al.*, 639 F. Supp. 2d 115 (D. Mass. 2009).[1326]

"thermoplastic" — "capable of softening or fusing when heated and of hardening again when cooled." *3M Innovative Properties Co., et al. v. Dupont Dow Elastomers LLC*, 361 F. Supp. 2d 958 (D. Minn. 2005).[1327]

"thermoplastic elastomeric block copolymer" — "a class of polymeric materials composed of two or more comonomeric units in extended segments having hard and soft blocks." *E.I. du Pont de Nemours & Co. v. MacDermid, Inc., et al.*, 2010 U.S. Dist. LEXIS 23750 (D.N.J., Mar. 15, 2010).[1328]

"thickener" — "a substance or material, whether inherent in or separately added to a composition, separate from the low molecular weight carbohydrate and chloride salt, which consists of either 1) a cellulose derivative with molecular weights of about 60,000 to 1,000,000 or 2) a carbohydrate with molecular weights of about 10,000 to 50,000, which causes an increase in the composition's viscosity." *Sears Petroleum & Transport Corp., et al. v. Archer Daniels Midland Co., et al.*, 2007 U.S. Dist. LEXIS 53576 (N.D.N.Y., July 24, 2007).[1329]

"thickener" — "a substance or material, whether inherent in or separately added to a composition, which causes an increase in the composition's viscosity." *Cargill, Inc. v. Sears Petroleum & Transport Corp., et al.*, 334 F. Supp. 2d 197 (N.D.N.Y. 2004).[1330]

"three-dimensional in vivo morphology" — "refers to the shape of the cells from which the glucans are derived." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1331]

"through a computer-controlled printing device" — "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides." *Oxford Gene Technology Ltd. v. Mergen Ltd., et al.*, 2004 U.S. Dist. LEXIS 19818 (D. Del., Sept. 29, 2004).[1332]

"substantially uniformly dispersed throughout said coating" — "the term 'throughout' is unambiguous and thus, the ordinary meaning must prevail. The ordinary meaning of 'throughout' is 'in or through every part' or 'everywhere.'" *Nichols, et al. v. Strike King Lure Co., et al.*, 2000 U.S. Dist. LEXIS 15781 (N.D. Tex., Oct. 25, 2000).[1333]

"tissue ingrowth promoter" — "a therapeutic agent used to increase tissue growth." *Marctec, LLC v. Johnson & Johnson, et al.*, 2009 U.S. Dist. LEXIS 27011 (N.D. Ill., Mar. 31, 2009).[1334]

"tissue plasminogen activator" — "mean[s] native human t-PA, whether produced from natural source extraction or recombinant cell culture systems described in the extraction or recombinant cell culture systems described in the patent, as well as certain described biologically active human tissue plasminogen activator equivalents which (i) are capable of catalyzing the conversion of plasminogen to plasmin; (ii) bind to fibrin, and; (iii) share basic immunological properties of native t-PA." *Genentech, Inc. v. Boehringer Mannheim GmbH, et al*., 989 F. Supp. 359 (D. Mass. 1997).[1335]

"tissue specific mammalian cellular enhancer" — "a DNA sequence in a mammalian cell that functions to greatly increase transcription in a specific tissue-type or cell-type, but which barely works in other tissue or cell-types, or does not work at all." *Massachusetts Institute of Technology v. Imclone Systems, Inc.*, 498 F. Supp. 2d 435 (D. Mass. 2007).[1336]

"titanium nitride" — "a compound with a one-to-one ratio of titanium atoms to nitrogen atoms." *OKI Electric Industry Co., Ltd. v. LG Semicon Co., Ltd., et al.*, 1999 U.S. Dist. LEXIS 22625 (N.D. Cal., Jul. 19, 1999).[1337]

"topcoat" — "the component of a dosage form that provides for the altered release additionally has an outmost coating comprising galantamine and water-soluble polymer." *Janssen, L.P., et al. v. Barr laboratories, Inc., et al.*, 2009 U.S. Dist. LEXIS 12676 (D.N.J., Feb. 19, 2009).[1338]

"treating or preventing ... [by administering] ... to a human in need thereof" — "administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. Thus, the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B_{12} must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia." *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Cir. 2003).[1339]

"treatment of PHN" — "achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment." *Novartis Pharmaceuticals Corp., et al. v. Roxane Laboratories, Inc.*, 2010 U.S. Dist. LEXIS 97610 (D.N.J., Sep. 17, 2010).[1340]

"heating ... to a temperature substantially above the softening temperature of said binder material" — "heating to a temperature sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point bonds." *KX Industries, L.P., et al. v. PUR Water Purification Products, Inc.*, 108 F. Supp. 2D 380 (D. Del. 2000).[1341]

"passing the produced smoke through a filter <u>to remove mainly the tar therefrom</u>" — "the Yamaoka Patent claims a process for filtering smoke to the extent that the smoke produced by the filtration is still able to impart a noticeable and "agreeable" taste and smell to the fish. The Yamaoka Patent does not claim a process specifically intended to filter flavor-giving particles out of the smoke." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[1342]

"applying an effective dosage of zinc gluconate <u>to the oral mucosa of a human in need of treatment</u>" — "[is] restricted to applications of zinc gluconate to the lining of the mouth, tongue, and throat, [but] ... extend[s] to any method of delivery to the lining of the mouth, tongue, and throat, and in particular to a method of delivery to the oral mucosa that involves pumping the zinc gluconate through the nose." *Quigley Corp. v. GumTech, Inc., et al.*, 2000 U.S. Dist. LEXIS 2486 (E.D. Pa., Mar. 9, 2000).[1343] "There is one additional term that we have not yet explicitly interpreted in the claims that is disputed by the parties, and that is the term 'applying'. ... we cannot limit 'applying' to mean only the situs of the initial introduction of the substance to the body, and instead must take it to allow any means by which the zinc gluconate gets to the mucosa in question." *Id.*, 2000 U.S. Dist. LEXIS 4957 (E.D. Pa., Apr. 19, 2000).[1344]

"whereby <u>transcription of the DNA segment produces a ribonucleotide sequence</u>" — "during transcription of the nonnative DNA segment, its double helix must separate and the RNA polymerase must produce an mRNA. This mRNA must be a single stranded ribonucleotide sequence complementary to the DNA from which it was produced." *Enzo Biochem, Inc. v. Calgene, Inc.*, 14 F. Supp. 2d 536 (D. Del. 1998).[1345]

"transfected mouse cell"; "IL-2R γ deficient mouse cell"; "transgenic mouse cell" — "the court construes these terms as limited to genetically engineered cells." *Central Institute for Experimental Animals v. Jackson Laboratory*, 2010 U.S. Dist. LEXIS 10548 (N.D. Cal., Feb. 8, 2010).[1346]

"transfer resistance" — "the tendency of a cosmetic not to transfer to other surfaces, including skin, clothing, glassware and silverware." *Revlon Consumer Products Corp. v. L'Oreal S.A., Cosmair, et al.*, 170 F.R.D. 391 (D. Del. 1997).[1347]

[i] "transforming"; [ii] "transformed eucaryotic cell" — [i] "process for changing the genotype of a recipient cell mediated by the introduction of dna"; [ii] "a eucaryotic cell which has undergone a genotypic change as a result of the introduction of DNA into the cell." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[1348]

"providing <u>a treating flow of said hydrogen peroxide solution from one or more of said wells</u>" — "the term 'treating flow' ... is read to have no pressure limitation associated with it and to be limited to 'chemical remediation.'" *Cleanox Environmental Services, Inc. v. Hudson Environmental Services, Inc., et al.*, 14 F. Supp. 2d 601 (D.N.J. 1998).[1349]

"treatment of cerebral ischemia" — "an antagonistic intervention with regard to the N-methyl-D-aspartate (NMDA) receptor channels." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[1350]

"treatment of an imbalance of neuronal stimulation" — "an antagonistic intervention with regard to the excessive inflow of calcium through N-methyl-D-aspartate (NMDA) receptor channels." *Forest Laboratories Inc., et al. v. Cobalt Laboratories Inc., et al.*, 2009 U.S. Dist. LEXIS 56368 (D. Del., Jul. 2, 2009).[1351]

"triple helix conformation" — "has a readily understood meaning such that no construction is necessary." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1352]

"truncated Factor VIII protein which is an active procoagulant" — "a Factor VIII protein that promotes blood coagulation and lacks a portion of the amino acid sequence of the human Factor VIII protein." *Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 2010 U.S. Dist. LEXIS 16150 (D. Del., Feb. 24, 2010).[1353]

"[a process for] curing raw <u>tuna meat</u>" — "claims only a process for curing tuna, and not any other kind of fish or meat." *Tuna Processors, Inc. v. Hawaii International Seafood, Inc., et al.*, 2007 U.S. Dist. LEXIS 77396 (D. Haw., Oct. 17, 2007).[1354]

"turbidity" — "deficient in clarity; turbidity is an expression of the optical property that causes light to be scattered and absorbed rather than transmitted with no change in direction or flux level through the water sample. In precision, sensitivity, and applicability over a wide turbidity range, the nephelometric method is preferable to visual methods. Nephelometric measurement results are reported as nephelometric units (NTUs)." *Clearvalue, Inc., et al. v. Pearl River Polymers, Inc., et al.,* 2006 U.S. Dist. LEXIS 48473 (E.D. Tex., July 17, 2006).[1355]

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"ultrapasteurization" — "to decrease the number of spoilage organisms beyond that obtained with conventional pasteurization without sacrificing functional performance." *Sunny Fresh Foods, Inc. v. Michael Foods, Inc., et al.*, 205 F. Supp. 2d 1077 (D. Minn. 2002).[1356]

"express a gene for human growth hormone <u>unaccompanied by</u> the leader sequence of human growth hormone or other extraneous protein bound thereto" — "only requires that the expression product be 'unaccompanied' by uncleavable protein." *Novo Nordisk of North America, Inc., et al. v. Genentech, Inc.,* 1995 U.S. Dist. LEXIS 12588 (S.D.N.Y., June 28, 1995).[1357]

"uncoated" — "uncoated with an adhesive." *Sud-Chemie, Inc. v. Multisorb Technologies, Inc.*, 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).[1358]

"uncured" — "refer[s] to an elastomeric compound which has not undergone any curing or vulcanization process." *Canton Bio-Medical, Inc. v. Integrated Liner Technologies, Inc.*, 19 F. Supp. 2d 22 (N.D.N.Y. 1998).[1359]

"underivatized" — "not derivatized. Derivatized is a term well recognized by those skilled in the art as a chemical modification made to the glucan moiety, such as methylethers, carboxymethylethers, acetylesters, sulfonylester and phosphoric acid esters." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1360]

"undesirable" — "does not need to be construed." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[1361]

"undesirable low level of blood serum HDL-cholesterol" — "does not need to be construed." *Nutrition 21, LLC v. General Nutrition Corp.*, 2006 U.S. Dist. LEXIS 58002 (E.D. Tex., April 17, 2006).[1362]

[*undisputed claim limitations*] — "Although the construction of the claim is independent of the device charged with infringement, it is convenient for the court to concentrate on those aspects of the claim whose relation to the accused device is in dispute." *Pall Corp. v. Hemasure, Inc.*, 181 F.3d 1305, 1308-09 (Fed. Cir. 1999).[1363] "[W]e are reviewing only certain disputed terms of the claim construction and lack the power to construe other terms not disputed by the parties." *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323 (Fed. Cir. 2007).[1364]

"allowing the resultant assembly to set and dry such that the calcined gypsum forms set gypsum having voids <u>uniformly dispersed therein</u>" — "The only part of the resultant assembly that need have uniformly dispersed voids is the deposited dispersion described in claim 25." *United States Gypsum Co., et al. v. LaFarge North America, Inc., et al.*, 508 F. Supp. 2d 601 (N.D. Ill. 2007).[1365]

"containing <u>uniformly dispersed therein</u> a static-reducing amount of electrically conductive particulate material" — "The written description of the '040 patent thus shows that the 'uniformly dispersed' limitation requires the distribution of conductive particles across the length and width of the conductive layer but does not require uniform dispersion of the particles across the thickness of the layer." *Charleswater Products, Inc. v. Nevamar Corp.*, 1998 U.S. App. LEXIS 31011 (Fed. Cir., Dec. 10, 1998) (unpublished).[1366]

"uniformly dispersing the foam"; "voids <u>uniformly dispersed therein</u>" — "needs no construction." *United States Gypsum Co. v. LaFarge North America, Inc., et al.*, 2009 U.S. Dist. LEXIS 101603 (N.D. Ill., Nov. 2, 2009).[1367]

"unique segments"; "unique sequence"; "repetitive sequence" — "The court [] construes the word 'segment' to mean 'a stretch of nucleic acid'"; "The court [] construes the term 'sequence' to mean 'an ordering of nucleotide bases'"; "the specification of the '841 patent includes an express definition of 'repetitive': ... (see Hood et al., Molecular Biology of Eucaryotic Cells ... for an explanation of repetitive sequences)"; "The court [] construes 'unique' to mean 'occurring fewer than 10 times per haploid genome.'" *Regents of the University of California, et al. v. Dako North America, Inc., et al.*, 2006 U.S. Dist. LEXIS 45579 (N.D. Cal., July 3, 2006).[1368]

"units" — "the structural monomeric units or the number of atoms, including those as part of an overall copolymeric structures." *Rembrandt Vision Technologies, L.P. v. Bausch & Lomb, Inc., et al.*, 2007 U.S. Dist. LEXIS 36919 (E.D. Tex., May 21, 2007).[1369]

"unlinked" — "not physically or chemically linked on the same piece of contiguous DNA." *Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000).[1370]

"*[unspecified enantiomeric purity]*" — "The claims do not expressly refer to a specific minimum optical purity or percentage of the detrorotatory enantiomer. ... Because of the nature of enantiomeric separation at the time, one of ordinary skill in the art would not have read a claim to an enantiomer of ofloxacin as requiring 100 percent purity. ... Thus, although one of ordinary skill in the art would have understood the claim to the compound levofloxacin to be substantially pure levofloxacin, the realities of science would have led such a skilled artisan to conclude that the purity was not 100 percent." *Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al*., 348 F. Supp. 2d 713 (N.D. Va. 2004).[1371]

"*[unspecified testing method for measuring release rate]*" — "the Court refuses to apply any claim limitation that mandates certain testing procedures or conditions." *Alza Corp. v. Mylan Laboratories, Inc., et al*., 349 F. Supp. 2d 1002 (N.D. W. Va. 2004).[1372]

"unstable" — "we agree with the Commission that the specification requires ... that the claim term 'unstable' refers to ions that are unstable from the perspective of the disclosed Mathieu stability diagram." *Finnigan Corp. v. United States International Trade Commission, et al.*, 180 F.3d 1354 (Fed. Cir. 1999).[1373]

"incubating <u>until</u> CPE is observed" — "In its construction of the claim language, this court contemplates that incubation will be halted after the observation of some degree of CPE and rejects any wholesale adoption of Boehringer's position. ... the court's construction contemplates that the process focuses on CPE and that there is some stopping point. That point is not when minimal CPE is observed, but when there is a significant degree of CPE." *Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp*., 984 F. Supp. 239 (D.N.J. 1997).[1374] "We hold that this limitation merely defines the minimum period for incubation of the inoculated cell sheet." *Id.*, 320 F.3d 1339 (Fed. Cir. 2003).[1375]

"continuing the said administration of HMB <u>until</u> the amount of nitrogen in the patient's urine has substantially decreased" — "mean[s] that the administration of HMB must continue up to the time that a patient's urinary nitrogen levels have been reduced by a substantial amount." *Iowa State University Research Foundation, Inc., et al. v. Wiley Organics, Inc.*, 2005 U.S. App. LEXIS 3694 (Fed. Cir., May 7, 2005) (unpublished).[1376]

"up to about 10%" — "the ordinary meaning of the phrase 'up to about 10%' includes the 'about 10%' endpoint." *AK Steel Corp. v. Sollac, et al.*, 344 F.3d 1234 (Fed. Cir. 2003).[1377]

"urinary bladder submucosa" — "urinary bladder submucosa delaminated from the abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue." *Cook Biotech, Inc., et al. v. Acell, Inc., et al.*, 460 F.3d 1365 (Fed. Cir. 2006).[1378]

"thermoplastic <u>urethane</u>" — "a material that softens when heated and hardens when cooled, is formed from the reaction of isocyanates and polyols, and exhibits the functions of the coating layer including traction, wear, transmission of traction loads to the cords, and resistance to environmental factors." *Schindler Elevator Corp. v. Otis Elevator Co.*, 2010 U.S. Dist. LEXIS 2463 (D.N.J., Jan. 13, 2010).[1379]

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"moisture vapor permeable" — "is essentially synonymous with 'breathable.'" *Herman v. William Brooks Shoe Co., et al.*, 1999 U.S. Dist. LEXIS 18888 (S.D.N.Y., Dec. 6, 1999).[1380]

"no vaporization" — "no conversion to a gaseous state." *Smith & Nephew, Inc. v. Arthrocare Corp.*, 2004 U.S. Dist. LEXIS 31057 (W.D. Tenn. 2004).[1381]

"vector" — "a DNA agent (usually a virus or plasmid) generally used in a cloning process or to transmit genetic material to a cell or organism. Vectors do not continue to exist after they have been used in a cell or organism." *Central Institute for Experimental Animals v. Jackson Laboratory*, 2010 U.S. Dist. LEXIS 10548 (N.D. Cal., Feb. 8, 2010).[1382]

"vertebrate" — "is widely known and understood to cover anything with a segmented bony or cartilaginous spinal cord which obviously includes humans." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 314 F.3d 1313 (Fed. Cir. 2003).[1383]

"vertebrate cells" — "cells from an animal having a backbone." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[1384]

"VISICHROME" — "a water-based acrylic colorant system used to color rubber particles." *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, et al.*, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).[1385]

"method for using vulcanized rubber" — "the process of treating crude or synthetic rubber ... to give it useful properties." *Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC, et al.*, 2007 U.S. Dist. LEXIS 38799 (E.D. Mo., May 29, 2007).[1386]

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"water" — "purified water (per the USP)." *UCB, Inc., et al. v. KV Pharmaceutical Co.*, 2009 U.S. Dist. LEXIS 72764 (D. Del., Aug. 18, 2009).[1387]

"water-alcohol mixture" — "EEI asserts that the district court misconstrued the term 'water-alcohol mixture' because it did not limit the term composition to at least 30 percent water as described in the specification. ... the patentee did not limit the claim term as EEI suggests, and the district court did not err in its claim construction." *Conoco, Inc., et al. v. Energy & Environmental International, L.C., et al.*, 460 F.3d 1349 (Fed. Cir. 2006).[1388]

"water-balance" — "indicates that the aqueous solution is closed to unrecited components except for incidental impurities found in the recited components." *Sears Ecological Applications Co., LLC v. MLI Associates, LLC*, 2009 U.S. Dist. LEXIS 78281 (N.D.N.Y., Sep. 1, 2009).[1389]

"water content" — "is not an ambiguous term. It simply means the amount of water in a given thing." *In re Omeprazole Patent Litigation*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002).[1390]

"a water soluble salt" — "The district court correctly discerned that this language permits the inclusion of talc." *In re Omeprazole Patent Litigation*, 483 F.3d 1364 (Fed. Cir. 2007).[1391]

"water-soluble polydextrose" — "We discern no error in the district court's construction of the claims as including the definition of 'water-soluble polydextrose' in the specification. Having explicitly defined this term as limited to that prepared with a citric acid catalyst, this effected a disclaimer of the other prior art acids." *Cultor Corp., et al. v. A.E. Staley Manufacturing Co.*, 224 F.3d 1328 (Fed. Cir. 2000).[1392]

"water vapor impermeable polymer layer" — "a polymer layer that is substantially impermeable to water vapor. Substantially impermeable means that some amount of water vapor may pass through the polymer layer, provided that the polymer/absorbent layer combination constitutes the mechanism for avoiding water vapor caused sogginess in the foodstuff and such passage is minimized so as to reduce resulting heat loss during the holding period." *Fort James Corp. v. J.H. McNairn, Ltd.*, 2006 U.S. Dist. LEXIS 36528 (N.D. Ga., April 4, 2006).[1393]

"water vapor permeable" — "allowing water vapor to pass through." *Sud-Chemie, Inc. v. Multisorb Technologies, Inc.*, 2006 U.S. Dist. LEXIS 77235 (W.D. Ky., Oct. 19, 2006).[1394]

"wetting agent" — "any of a group of surface-active agents which, when added to a liquid, reduce the contact angle and cause the liquid to spread more easily over, or penetrate into, a solid surface." *Biovail Laboratories, Inc. v. Torpharm, Inc.,* 326 F. Supp. 2d 605 (E.D. Pa. 2004).[1395]

"wetting agent" — "any of a group of surface active agents which, when added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface." *Biovail Corp. International, et al. v. Andrx Pharmaceuticals, Inc.*, 158 F. Supp. 2d 1318 (S.D. Fla. 2000).[1396]

"whereby intimate diffusional contact with skin of the patient is maintained for a period of at least about 24 hours without destruction of the physical integrity thereof" — "does not require that the adhesive transdermal layer maintain contact with the skin of a patient for at least about 24 hours, but rather only that the layer be capable of maintaining contact with the skin of a patient for that amount of time." *Key Pharmaceuticals, Inc. v. Hercon Laboratories Corp.,* 981 F. Supp. 299 (D. Del. 1997).[1397]

"selecting a set of at least four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, <u>wherein at least four of the loci in the set are selected from the group of loci consisting of ...</u>" — "covers only sets of short tandem repeat loci in which all the loci in the reaction, whether four or more, are selected from the group of loci listed in step (b)." *Promega Corp. v. Applera Corp.*, 2002 U.S. Dist. LEXIS 26927 (W.D. Wis., Jan. 2, 2002).[1398]

"wherein said food acid slows down oxidation of ascorbic acid" — "the food acid functions to slow down the oxidation of ascorbic acid." *Yoon Ja Kim v. Dawn Food Products, Inc.*, 2004 U.S. Dist. LEXIS 20837 (N.D. Ill., Oct. 12, 2004).[1399]

"wherein said phosphorous-containing acid or salt thereof is present in an amount of about 30 to about 40 weight percent" — "the trial court correctly construed the claim to require an aggregate amount of such acids or salts to be between about 30 and about 40 weight percent." *Biagro Western Sales, Inc., et al. v. Grow More, Inc.,* 423 F.3d 1296 (Fed. Cir. 2005).[1400]

"whereby said substantially uniform particulate mixture is deformed, consolidated into a desired form and solidified in the extrusion die and is extruded from said die cavity as a solid composite porous article" — "means that, as a necessary result of the above steps, the 'substantially uniform particulate mixture' changes form due to softening, is shaped under pressure, and is solidified, all within the extrusion die, and the resulting product is extruded from the die as a solid composite article having pores." *KX Industries, L.P., et al. v. Culligan Water Technologies, Inc., et al.*, 90 F. Supp. 2d 461 (D. Del. 1999).[1401]

"DNA sequences ... which code on expression for a polypeptide of the IFN-α type"; "DNA sequences which code on expression for a polypeptide of the IFN-α type coded for on expression by any of the foregoing DNA sequences and inserts" — "refer to both naturally occurring and non-naturally occurring DNA sequences which bear the genetic code for expressing the polypeptide; actual expression and detection of the protein, however, is not required." *Schering Corp., et al. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998).[1402]

"a method for simultaneously desizing and decolorizing a dyed fabric ... which comprises ..." — "the district court's single-step process limitation is unsupported by the claim language and the written description, and we see no disclaimer of multi-step processes in the prosecution history." *Wasinger v. Levi Strauss & Co.*, 106 Fed. Appx. 34 (Fed. Cir., Jul. 8, 2004) (unpublished).[1403] "Because I think that the applicants' statements in the prosecution history, coupled with those of the examiner, rise to the level of a clear disclaimer of a process including a subsequent oxidation step, I respectfully dissent." *Id.* (Dyk, J., dissenting).[1404]

"glycosylation which differs" — "Glycosylation as to which there is a detectable difference based upon what was known in 1983-1984 from that of human urinary erythropoietin, having in mind that the patent holder, Amgen, taught the use of this Western blot, SDS-PAGE and monosaccharide test." *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 126 F. Supp. 2d 69, 89 (D. Mass. 2001).[1405]

"DNA sequences which hybridize to any of the foregoing DNA inserts" — "refers to DNA segments, which under conditions as least as stringent as those set forth in the specification of the '901 Patent, are able to bind and form a double-stranded structure with those DNA inserts specified in the patent and deposited at the DSM." *Schering Corp., et al. v. Amgen Inc.*, 18 F. Supp. 2d 372 (D. Del. 1998).[1406]

"which is bound"; "activated to contain" — "reflect structural limitations not the process by which the claimed invention is obtained." *Biacore, AB, et al. v. Thermo Bioanalysis Corp.*, 79 F. Supp. 2d 422 (D. Del. 1999).[1407]

"orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which upon administration provides a time to maximum plasma concentration (T_{max}) of ..." — "the claims explicitly state that the treatment methods are accomplished by administering a sustained-release oral, opioid dosage form to 'a human patient' and achieving the specified PK and efficacy results in 'the patient.' The Court finds that such phrases, taken in their ordinary and plain meaning, unambiguously refer to an individual patient, rather than patients on average." *Purdue Pharma, L.P., et al. v. F.H. Faulding and Co., et al.*, 48 F. Supp. 2d 420 (D. Del. 1999).[1408]

"while the amplification reaction is in progress" — "during the amplification reaction." *Applera Corp. v. Stratagene Corp.*, 2007 U.S. Dist. LEXIS 17154 (D. Conn., Mar. 9, 2007).[1409]

"whole glucan particles"; "whole β-glucan particles" — "a glucan derived from a glucan-containing cell that retains the intact cell wall structure of the cell in vivo." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1410]

"whole β-glucans"; "whole yeast β-glucans" — "glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived"; "glucans which maintain the intact, three-dimensional in vivo morphology of the yeast cells from which they are derived." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1411]

"whole glycosylated recombinant human, chimeric, CDR-grafted or bispecific antibody" — "describe[s] a whole recombinant human, chimeric, CDR-grafted or bispecific antibody that is glycosylated." *Glaxo Wellcome Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316 (D. Del. 2001).[1412]

"whole yeast β-glucan" — "glucans which maintain the intact, the three-dimensional in vivo morphology of the yeast cells from which they are derived." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1413]

"with diminished incidence(s) of nausea and emesis" — "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day." *Wyeth v. Teva Pharmaceuticals, et al*., 2005 U.S. Dist. LEXIS 20034 (D.N.J., Sept. 6, 2005).[1414]

"without a prior disruption step" — "before extracting alkali-insoluble components from glucan-containing cell walls, no step is performed that would disrupt the cell walls." *Biopolymer Engineering, Inc., et al. v. Immunocorp, et al.*, 2007 U.S. Dist. LEXIS 94207 (D. Minn., Dec. 21, 2007).[1415]

"without adding undesired sensory properties to the food" — "is unambiguous and refers to undesired properties of the food, not the casing." *Red Arrow Products Co. LLC v. Resource Transforms International, Ltd., et al*., 2006 U.S. Dist. LEXIS 18828 (W.D. Tex., April 4, 2006).[1416]

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"yeast food" — "any commercially available mineral yeast food that includes a combination of such ingredients as calcium sulfate, ammonium sulfate, starch, etc." *Yoon Ja Kim v. Dawn Food Products, Inc.*, 2004 U.S. Dist. LEXIS 20837 (N.D. Ill., Oct. 12, 2004).[1417]

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"zinc alloy" — "the zinc-nickel plating disclosed in the Hsu 871 patent, which is a zinc-nickel alloy comprising about 80-94% by weight zinc." *Timken Co., et al. v. SKF U.S.A., Inc.*, 193 F. Supp. 2d 813 (E.D. Pa. 2002).[1418]

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3. A Concentration Level

The construction of the phrase "a concentration level"is in dispute. This language appears in the following contexts: "directing a recirculating spray of concentrated detergent solution having a concentration level in the range of 0.5 to 12% detergent by weight onto said fabric for a first period of time as said fabric is tumbling in said wash chamber"; "directing a recirculating spray of said lesser concentrated detergent solution onto said fabric for a second period of time"; and "a concentrated detergent solution." ('370 patent, claims 1, 8, 15; '718 patent, claim 1.)

Whirlpool argues that the wording "having a concentration level in the range of 0.5 to 12% detergent by weight" should be construed as follows: "This claim limitation means that the detergent solution may have a varying concentration level, i.e., in the range of 0.5 to 12% by weight, during the first time period. The concentration level of the detergent solution may also, but is not required to, remain at a fixed level." Further, the phrase "said lesser concentrated detergent solution" should be construed to mean: "The detergent concentration level may vary or remain at a fixed level during the second period of time, but must remain no less than 0.28 % detergent by weight."

LG argues for the following construction: "Concentrated detergent having a fixed concentration level in the range of 0.5 to 12% by weight" and "concentrated detergent solution having a fixed, lesser detergent concentration level."

The dispute pertains to whether the indefinite article "a" modifying "concentration level" means the solution concentration must be at a fixed level, or whether it may vary within the stated boundaries. Whirlpool contends that construing "a" as non-limiting and permitting a range of concentration levels accords with the ordinary meaning of the word, simple English sentence structure, and applicable precedent. According to the Federal Circuit: "'This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.' Unless the claim is specific as to the number of elements, the article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article.'" Scanner Techs. Corp. v. ICOS Vision Sys. Corp., 365 F.3d 1299, 1304 (Fed. Cir. 2004) (quoting KCJ Corp v. Kinetic Concepts. Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000)). The preamble to the claim in which this disputed phrase appears contains the open ended word "comprising," but the phrase itself uses the word "having" (i.e., "having a concentration level"). The Federal Circuit has held that "having" may at times be construed as an open ended term as well. See, e.g., Lampi Corp. v. Am. Power Prods. Inc., 228 F.3d 1365, 1376 (Fed. Cir. 2000); Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1573 (Fed. Cir. 1997); Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001) (explaining that the transition word "having" can make a claim open, although the term does not convey the open-ended meaning as strongly as "comprising" and thus should be considered in context). Nothing in the '370 patent, Whirlpool argues, evinces an intent to limit "a" to a singular interpretation. Whirlpool also notes that the specification discusses adding fresh water to the detergent solution during a wash cycle, ('370 patent, col. 6, lines 58-64: "Once the mixing tank 80 is emptied, fresh water is added through the detergent water valve 40, 42 and 76 as required by the water level sensor 140"), which necessarily means that the detergent concentration level varies.

LG counters that the indefinite article "a" should be construed to refer to detergent solutions with some fixed concentration level. The intrinsic evidence, LG contends, requires restricting this claim term to a single level. See KCJ Corp. v. Kinetic Concepts. Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000) ("When claim language or context suggest an ambiguity in application of the general meaning of an article, this court undertakes an examination of the written description and the prosecution history to ascertain whether to limit the meaning of 'a' or 'an.'"). The Federal Circuit looked to the claim language, specification, and prosecution to determine that the term "a metallic gas-confining chamber" had to be construed as limited to a single chamber in AbTox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023-24 (Fed. Cir. 1997), modified in part, 131 F.3d 1009, 1010 (Fed. Cir. 1997). The court relied on the fact that the specification contained repeated references to "said chamber." LG points out that in this case, the claim at various points discusses "said concentrated detergent solution" and "said lesser concentrated detergent solution. " Based on AbTox, LG contends, the use of the word "said" in this case requires construing the claim to mean a single, fixed concentration level. The Court rejects this reasoning because "said" clearly modifies the term "solution," not "concentration level." In fact, the claims no where use the phrase "said concentration level."

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LG next argues although "a" can mean "one or more," it can also receive a singular interpretation when the patentee evinces a clear intent to so limit the article. Scanner Techs. Corp. v. ICOS Vision Sys. Corp., 365 F.3d 1299, 1304 (Fed. Cir. 2004). The public record in this case, LG contends, reflects such an intent. LG says that the disclosed preferred embodiment uses only single, fixed concentration levels. However, the mixing tank embodiment is merely one embodiment, and the Court may not read a limitation onto the claim from the written description. RF Delaware, Inc. v. Pacific Keystone Techs., Inc., 326 F.3d 1255, 1263 (Fed. Cir. 2003); see also Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (claims will not be limited to the preferred embodiment absent "words or expressions of manifest exclusion or restriction" representing a clear intent to disavow claim scope). Moreover, as discussed above, the patent in fact appears to embrace varying concentration levels through the addition of fresh water.

LG goes on to point out that Whirlpool's communications with the patent office recited "a" concentrated solution, which again LG says means a fixed concentration level. The Court has already rejected this limited construction of the word "a." Finally, LG maintains that Whirlpool could have drafted the claims with words such as "variable" or "varying" but did not because it meant for the claim to cover only fixed concentration levels. Once again, this misses the point; the claim is drafted with open-ended language in order to allow for a range of concentration levels. Cf. Insituform Techs., Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1106 (Fed. Cir. 1996) (restricting "a" to a singular interpretation because "the claim is specific as to the number of elements (one cup) and adding elements eliminates an inherent feature (discontinuous vacuum) of the claim").

Accordingly, the Court adopts Whirlpool's construction of the phrase "a concentration level" as permitting varying concentration levels because there is no evidence of clear intent to limit the article.
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The primary dispute in this case concerns the meaning of the final phrase of step (b) of claim 1, which reads:

and wherein the chromosomal DNA is present in a morphologically identifiable chromosome or cell nucleus during the in situ hybridization.

'841 patent, col 17, lines 22-25 (emphasis added). The University argues that this phrase is limited to the singular and means that the '841 patent permits researchers to detect unique DNA sequences on a single chromosome or cell nucleus. Oncor contends that the phrase merely clarifies that the target chromosomal DNA are present in intact chromosomes or cell nuclei, but does not limit the number of these structures.

A

An examination of the disputed text does not reveal a single ordinary English meaning. Oncor contends that use of the indefinite article "a" or "an" in a patent claim means "one or more." Reply at 2. In support of this contention, Oncor notes that a renowned patent treatise defines "a" or "an" as connoting one or more when used in a claim." Id. See Robert G. Faber, Landis on Mechanics of Patent Claim Drafting 531 (3d ed 1990). Moreover, in the context of statutory interpretation, several courts have interpreted the article "a" as referring to the plural. See, e.g., People v Carter, 75 Cal. App. 3d 865, 142 Cal. Rptr. 517, 520 (Cal Ct App 1977); Application of Hotel St. George Corp, 207 N.Y.S.2d 529, 531, 532 (NY Sup 1960).

On the other hand, many regard the standard English meaning of "a" or "an" to be singular. The Webster's Ninth New Collegiate Dictionary states that "a" is "used as a function word before singular nouns." Id at 43. When used in patent law, at least one court has interpreted the article "a" as referring to only one. See, e.g., Application of Zickendraht, 50 C.C.P.A. 1529, 319 F.2d 225, 231 (Cust & Pat App 1963) (Rich, J, concurring); Hastings v Brown, 1 El & Bl 450, 454, 118 Eng Rep 505 (KB 1853). Other courts have construed "a" as limited to the singular in the context of statutory interpretation. See, e.g., Savin Rock Arcade, Inc v Fitzpatrick, 160 F. Supp. 775, 776 (D Conn), aff'd, 259 F.2d 904 (1958); Harward v Commonwealth, 229 Va. 363, 330 S.E.2d 89, 91 (Va 1985). Thus, while the article "a" can mean "one or more," the court must look to the patent specification and history to determine whether the "inventors here intended it to have other than its normal singular meaning." See North American Vaccine, Inc v American Cyanamid Co, 7 F.3d 1571, 1575-76 (Fed Cir 1993).

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B

Several references in the patent specification suggest that the method described in the '841 patent permits detection of unique DNA sequences on a single chromosome or cell nucleus. Although the patent describes in situ hybridization generally as involving multiple chromosomes or cell nuclei, see '841 patent, col 3, lines 13-17, the method described in claim 1 is limited to "a * * * chromosome or cell nucleus." Id at col 17, lines 23-24. The target "chromosomal DNA is present" in this morphologically identifiable structure. Id at col 17, line 23 (emphasis added). Moreover, the patent lists as its preferred embodiment "selecting from the clones hybridization probes to unique sequence regions of a particular chromosome." Id at col 5, lines 58-63 (emphasis added). The example depicted in the patent is one that involves only a single chromosome. Id at Fig 1C. Most importantly, the patent specification states that the invention "can be viewed as a large collection of hybridization probes to unique sequence regions of a specific chromosome." Id at col 5, lines 56-58 (emphasis added). This indicates that the phrase "a morphologically identifiable chromosome or cell nucleus" should be read in the singular.

1

In response, Oncor correctly points out that much of the evidence relied on by the University consists of specific embodiments of the invention which cannot serve as claim limitations. See, e.g., Constant v Advanced Micro-Devices, 848 F.2d 1560, 1571 (Fed Cir 1988); Laitram Corp v Cambridge Wire Cloth Co, 863 F.2d 855, 865 (Fed Cir 1988); Loctite Corp v Ultraseal Ltd, 781 F.2d 861, 867 (Fed Cir 1985). This, however, is not a case in which the claim language is completely silent with respect to the limitation proposed by the plaintiff and the plaintiff is attempting to add extraneous limitations that appear in the specification but not in the claim. Compare Intervet America, Inc v Kee-Vet Laboratories, Inc, 887 F.2d 1050, 1053 (Fed Cir 1989). Nor is this a case where the ordinary English meaning of the claim language clearly suggests one interpretation and the plaintiff argues for a contrary interpretation based on examples in the patent specification. Compare Constant v Advanced Micro-Devices Inc, 848 F.2d 1560, 1571 (Fed Cir 1988). Instead, this case involves a situation in which the language of the claim is susceptible to two alternative interpretations, and the court must determine what is meant by this language by referring to the patent specification and its history. See Vitronics, 90 F.3d at 1582. The examples and preferred embodiments of the patent, therefore, may shed some light on the meaning of the disputed phrase.

2

Next, Oncor argues that several exchanges in the prosecution history suggest that the last phrase of step (b) was added to clarify the form of the target DNA, rather than their number. This evidence consists, in part, of statements by the applicant that the amended language was added to address the examiner's concern that the chromosomal DNA could have been processed prior to hybridization, Willard Decl, Exhibit 9, at 4, and makes clear that the chromosomal DNA retain their morphological detail, id at 5.

This evidence, however, does not resolve the issue currently before the court. Oncor cannot succeed on its claim merely by focusing on the intent of the parties to the prosecution of the '841 patent. The Federal Circuit made clear in Markman v Westview Instruments, Inc, 52 F.3d 967, 986 (Fed Cir 1995), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), that:

the focus in construing disputed terms in claim language is not the subjective intent of the parties to the patent contract when they used a particular term. Rather the focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.

Taken in its most favorable light, the evidence presented by Oncor merely suggests that the applicants were not contemplating the number of chromosomes or cell nuclei that contain the target chromosomal DNA when they added the last phrase of claim 1; it does not suggest that the phrase was intended to refer to multiple chromosomes or cell nuclei. Such evidence cannot change the plain meaning of a "specific chromosome" to something other than the singular.

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The above discussion reveals that it is at least equally plausible that the phrase "a morphologically identifiable chromosome or cell nucleus" refers to a single chromosome or cell nucleus, as opposed to multiple chromosomes or cell nuclei. The Federal Circuit has set forth the following rule of construction for such situations:

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Where there is an equal choice between a broader and narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.

Athletic Alternatives, Inc v Prince Mfg, Inc, 73 F.3d 1573, 1581 (Fed Cir 1996); see also Ethicon Endo-Surgery, Inc v United States Surgical Corp, 93 F.3d 1572, 1581 (Fed Cir 1996) ("To the extent that the claim is ambiguous, a narrow reading which excludes the ambiguously covered subject matter must be adopted."). Since the patent specification and history indicate that the narrower construction of the last phrase of step (b) of claim 1 is at least as plausible as the broader construction, the court concludes that it refers to a single chromosome or cell nucleus.
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3

The patent in suit, U.S. Pat. No. 6,002,065 ("the '065 patent"), is owned by appellant Norian Corporation. As the district court explained, the patent is directed to kits "for preparing rapidly setting calcium phosphate compositions to be used as 'bone cements' in medical or dental procedures." The asserted claims of the '065 patent are claims 8-10. Claim 8 provides as follows:

A kit for preparing a calcium phosphate mineral, said kit consisting of:

at least one calcium source and at least one phosphoric acid source free of uncombined water as dry ingredients; and

a solution consisting of water and a sodium phosphate, where the concentration of said sodium phosphate in said water ranges from 0.01 to 2.0 M and said solution has a pH in the range of about 6 to 11.

Dependent claim 9 recites the kit of claim 8 wherein the sodium phosphate is present in the water at a concentration ranging from about 0.05 to 0.5 M. Dependent claim 10 recites the kit of claim 8 wherein the solution has a pH in the range from about 7 to 9.

The issue before the district court was very narrow. It was undisputed that the accused kit sold by Stryker consisted of a vial of powdered material containing sources of calcium and phosphoric acid, a spatula, and a syringe filled with a 0.25 M sodium phosphate solution. The solution was made from two different sodium phosphates: monobasic sodium phosphate monohydrate and dibasic sodium phosphate heptahydrate. The question posed to the district court was whether Stryker's sodium phosphate solution was "a solution consisting of water and a sodium phosphate" within the meaning of that portion of claim 8. That question turned on whether the district court construed the claim term "a sodium phosphate" to include a solution prepared from one or more sodium phosphates, or whether the term was limited to a solution prepared from only a single sodium phosphate. The district court concluded that the claim term required that the solution be made from only a single sodium phosphate. Because it was undisputed that Stryker's solution was made from more than one sodium phosphate, the court ruled that Stryker's solution did not infringe Norian's patent. Norian appeals, contending that the district court's claim construction was too narrow, and that the term "solution consisting of water and a sodium phosphate" should be construed to include solutions made from multiple sodium phosphates and should not be limited to solutions made from only a single sodium phosphate.

II

It is undisputed that there are multiple types of sodium phosphates. The '065 patent refers to several of them: monobasic sodium phosphate, which contains one sodium atom, two hydrogen atoms, and one phosphate group; dibasic sodium phosphate, which contains two sodium atoms, one hydrogen atom, and one phosphate group; and trisodium phosphate, which contains three sodium atoms and one phosphate group. Each of the sodium phosphates can be associated with different numbers of water molecules.

Norian argues that its claims read on any solution made from a single sodium phosphate as well as any solution made from a combination of different sodium phosphates. The claim term "a sodium phosphate," according to Norian, should be understood to embrace a mixture of multiple types of sodium phosphates as well as a single sodium phosphate. That

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construction makes sense, according to Norian, because once the various sodium phosphates are put into a water solution, they dissociate into ions, and the same ions are present in the resulting solution regardless of which type or types of sodium phosphates were used as the starting materials.

The district court rejected Norian's argument on several grounds. First, the court noted that the asserted claims use the restrictive term "consisting of" to define the contents of the claimed solution. In that context, the court explained, the term "a" must be interpreted to mean that the solution consists of water and only a single solute, i.e., a single type of sodium phosphate, not a mixture of different sodium phosphates. The court found support for that interpretation in the specification, which contains repeated references to solutions made from a single sodium phosphate, but contains no reference to making the solution from more than one sodium phosphate. In addition, the court noted that claim 8 uses the phrase "at least one" in the first limitation, which refers to sources of calcium or phosphoric acid, but does not use that phrase in the second limitation, which refers to the ingredients of the solution. The court pointed to the use of the term "a" rather than the phrase "at least one" as indicating that only a single type of sodium phosphate is used in the claimed solution. Finally, the court ruled that the prosecution history of the '065 patent shows that the patentee surrendered the claim scope that was encompassed by the phrase "a sodium phosphate solution" in the predecessor to claim 8 when the patentee amended that language to read "a solution consisting of water and a sodium phosphate."

We agree with the district court's construction of the claim language. The patent contains multiple references to various different sodium phosphates. In that context, the reference in the claim to "a sodium phosphate" is most naturally understood as a reference to one of the different sodium phosphates. As the district court pointed out, the language used to claim the solution in claim 8 is different from the formulation used in the same claim to describe the sources of calcium and phosphoric acid, where the claim refers to "at least one calcium source and at least one phosphoric acid source." If the patentee had meant to claim the use of at least one type of sodium phosphate in the recited solution, it would have been simple to use the same language in the second portion of the claim that was used in the first.

Even aside from the departure from the "at least one" phrase used in the first limitation, the word "a" is conspicuous in the phrase "a sodium phosphate." Although the word "a" generally means "one or more" in open-ended claims containing the transitional phrase "comprising," KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000), that general rule does not apply when the specification or the prosecution history shows that the term was used in its singular sense. See, e.g., Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 977-79 (Fed. Cir. 1999) (noting that "our cases emphasize that 'a' or 'an' can mean 'one' or 'more than one,' depending on the context in which the article is used," and holding that the phrase "comprising . . . an upstanding feed tube" is limited to a single such feed tube based on the prosecution history); AbTox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023-27 (Fed. Cir. 1997) (limiting the phrase "comprising . . . a metallic gas-confining chamber" to a single such chamber based on context gleaned from the specification). In particular, this court has interpreted the word "a" in its singular sense when, as in this case, it has been used in conjunction with the closed transitional phrase "consisting of." See Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1281 (Fed. Cir. 2003) ("Although 'a' without more generally could mean one or more in an open-ended patent claim, 'a' with 'consisting of' in this case indicates only one member of a Markush group."). Thus, the claim language "consisting of . . . a sodium phosphate," on its own, suggests the use of a single sodium phosphate.

That interpretation is consistent with the specification, as the district court ruled. In particular, example 3 of the specification includes a chart listing the different setting times that are associated with different solutions. Each of the listed solutions contains a single solute, which is either a type of sodium phosphate or a type of sodium carbonate. While the scope of a claim is not necessarily limited to the examples disclosed in the specification, nothing in the '065 patent specification points away from the district court's construction limiting claim 8 to single-solute solutions. Rather, each of the solutions described in the specification uses only a single solute, and the specification makes no reference to using a mixture of multiple solutes in a single solution.

Norian has argued that the specification contains references to solutions made from multiple types of sodium phosphates. In reissue proceedings before the Patent and Trademark Office, Norian argued that example 3 mentions a solution made from a mixture of trisodium phosphate dodecahydrate and dibasic sodium phosphate heptahydrate. '065 patent col. 10, ll. 46-50. However, as the PTO pointed out, that solution is not the solution recited in claim 8, but instead is a "colloid control" used in connection with the claimed solutions described in example 3. Norian also argues that example 2 supports its claim construction through its reference to "Sigma Diagnostics 1.0 M Phosphate Buffer," an "off the shelf" buffer solution. '065 patent, col. 9, ll. 52-59. Norian contends that off-the-shelf buffer solutions are made from mixtures of multiple types of

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sodium phosphates. However, the trial court concluded based on the evidence of record that Sigma's phosphate buffer solution was made from potassium phosphates, not sodium phosphates, and that the use of the term "phosphate buffer" does not imply that the buffer solution was made from multiple forms of sodium phosphates, or even any sodium phosphates at all. Thus, nowhere in the specification does the patentee refer, either explicitly or implicitly, to making the claimed solution from a mixture of multiple sodium phosphates.

The district court was also correct to rely on the prosecution history, which reflects a series of patentability rejections, followed by narrowing amendments and clarifying explanations from the prosecuting attorney. The prosecution history shows that through the series of amendments, Norian surrendered significant scope for what became claim 8. In response to one series of rejections, Norian narrowed the claim by changing the transitional phrase in the claim's preamble from "comprising" to "consisting essentially of" and then ultimately to "consisting of." In response to another rejection, Norian amended the critical claim language by replacing the words "a sodium phosphate solution" with the words "a solution consisting of water and a sodium phosphate." The prosecuting attorney advised the examiner that the amendment "limited the claimed kit to one in which the solution is made of water and a single solute, where the solute is either a sodium phosphate or a sodium carbonate, which solute is completely dissolved in the water" (emphasis added).

If there were any doubt that the reference to "a sodium phosphate" meant a single type of sodium phosphate, the prosecuting attorney directed the examiner to the specification's tables for examples of the single-solute solutions to which the amended claim was limited. As the prosecuting attorney noted, the tables disclose "solutions of different sodium phosphates": one solution is made from monobasic sodium phosphate, another from dibasic sodium phosphate, and a third from trisodium phosphate. But none of the solutions is made from a mixture of different sodium phosphates. In other words, the specification contemplates the use of various forms of sodium phosphate, but used individually, not simultaneously in the same solution. As the prosecuting attorney explained, the claim was limited "with the incorporation of the additional limitation limiting the solution to one that consists of water and a sodium phosphate."

Other references in the prosecution history underscore the restrictive scope that was accorded to the claim language. Thus, the prosecuting attorney explained that "the solution is limited to one that is made of water and a solute selected from a sodium phosphate or sodium carbonate," and that "the claimed kits of the present application are limited to kits in which the setting liquid is a solution of water and a solute, where the solute is either a sodium phosphate or a sodium carbonate." The district court properly construed that language to limit the scope of the claim at issue in this case to a single solute in the water solution, i.e., to a single type of sodium phosphate.

Norian makes essentially three arguments in response to the district court's claim construction. First, Norian argues that after any sodium phosphate salt goes into solution, it does not maintain its solid, compound form, and thus it ceases to be identifiable as, for example, monobasic sodium phosphate monohydrate or dibasic sodium phosphate heptahydrate. Instead, it dissolves into dissociated sodium ions and phosphate ions in water. Therefore, according to Norian, the reference to "a sodium phosphate" in a water solution can only mean a solution containing sodium ions and phosphate ions, which solution will be produced when any one or more types of sodium phosphates are added to water.

The problem with that argument is that it runs afoul of the language and the prosecution history of the '065 patent. In the claim language, the specification, and the prosecution history, the patentee described the claimed solution by reference to the substances used to make it-solutes that include a variety of different types of sodium phosphates. The patentee could have chosen to claim the solution as "a sodium phosphate solution," as was recited in an earlier version of the claims, or as a solution consisting of "at least one sodium phosphate," which would have tracked the language used in the first limitation of claim 8. Instead, the patentee departed from those formulations and chose to recite a solution consisting of water and "a sodium phosphate." In context, that language denotes a solution made from water and a single solute drawn from among the various types of sodium phosphates.

Norian's second argument is that the prosecution history cannot be read as broadly as the district court read it. Norian explains that the amendment in question (i.e., amending the language from "a sodium phosphate solution" to "a solution consisting of water and a sodium phosphate") was made in response to a prior art patent to Iwamoto, which disclosed a colloidal setting solution, rather than a pure solution containing no suspended particles. Because the sole purpose of the amendment was to avoid the effect of the Iwamoto reference, Norian argues, the prosecution history should not be interpreted as disclaiming pure solutions that are made from more than a single solute.

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The problem with that argument is that there is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner's rejection. To the contrary, it frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to. See, e.g., Fantasy Sports Props., Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1114-15 (Fed. Cir. 2002) (patentee "cannot now be heard to argue" a broad construction of the term "bonus points" because patentee acquiesced in the examiner's narrow interpretation to distinguish the claims from prior art, even though under the broad construction the invention may have been patentably distinct from the prior art); Elkay Mfg. Co., 192 F.3d at 979 (patentee relinquished a construction of claim language that could include separate air and liquid feed tubes, because patentee distinguished a prior art reference by arguing that the reference taught the use of separate liquid and air feed tubes; court found it "irrelevant . . . whether [patentee] had to relinquish an interpretation of the feed tube limitation that could cover more than one flow path for liquid and air"). Here, in the course of amending, the patentee expressly spoke to the meaning of the amended claim, noting that it was limited to a single solute. We therefore agree with the district court that Norian surrendered all sodium phosphate solutions made from more than a single solute, i.e., a single type of sodium phosphate.

Norian's third argument is that by defining the solution of the asserted claims in terms of the ingredients used to make the solution, rather than in terms of the ions found in the solution after it was made, the court has improperly converted what was meant to be a product claim into a product-by-process claim, without applying the legal principles applicable to such claims. We disagree. All that the district court has done is to conclude that the patentee characterized the solution in terms of the components put into it, which the evidence before the court (including the specification) showed to be a conventional means of describing a solution. Because the patentee chose to describe the solution in that fashion, the claims remained product claims, but their scope was limited to the designated ingredients from which the claimed solution was made.

Ultimately, Norian's arguments distill to the basic contention that a person of skill in the art would understand that any "sodium phosphate solution" will contain sodium ions and phosphate ions, no matter whether it is made from one type or multiple types of sodium phosphate. While that may be so, it does not change the clear effect of the prosecution history, the specification, and the claim language. Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1320-21 (Fed. Cir. 2002) (holding that the term "calcium orthophosphate," as used in the claim and in light of the prosecution history, did not cover monocalcium orthophosphate, even though a person of skill in the art would recognize that the term generally refers to a family of compounds that includes monocalcium orthophosphate). Norian did not simply claim a "sodium phosphate solution"; nor did Norian broadly claim a solution containing sodium and phosphate ions. Instead, Norian limited the solution in claim 8 to one using a single type of sodium phosphate. Although Norian might have claimed the solution more broadly, it did not, and we are not now free to interpret the claim in a way that is at odds with the claim language and other intrinsic evidence.

Finally, Norian argues that even if the district court was correct in its claim construction and literal infringement was not established, the court still should not have foreclosed its effort to prove infringement under the doctrine of equivalents. Norian, however, amended the pertinent claim language in a way that, as the district court construed it, disclaimed solutions made from multiple types of sodium phosphates. If the district court was correct in that characterization of the prosecution history--and we believe that it was--Norian is not entitled to prevail on a doctrine of equivalents theory. Instead, under the doctrine of prosecution history estoppel, a narrowing of claim scope during prosecution creates a presumption that the patentee has surrendered, for purposes of the doctrine of equivalents, all subject matter falling between the scope of the original claim and the scope of the claim as amended. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 741, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002).

Norian does not suggest that this case falls within one of the exceptions to the rule of prosecution history estoppel set forth by the Supreme Court in Festo. See Festo, 535 U.S. at 740-41. Instead, Norian's argument is that Festo is inapplicable altogether because Norian never surrendered the subject matter in dispute. As indicated above, we have rejected Norian's interpretation of the prosecution history, and we have concluded, contrary to Norian's argument, that the patentee disclaimed solutions made from more than one form of sodium phosphate. As such, Festo is applicable to Norian's argument under the doctrine of equivalents, and in the absence of any suggestion of why the principles of Festo do not bar Norian from recourse to that doctrine to establish infringement, we hold that Norian cannot avoid summary judgment of noninfringement on that ground. Accordingly, we uphold the district court's judgment in all respects.

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I. Claim Terms Using The Word "About"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"less than about 5 seconds"	Less than 6 seconds.	No construction necessary.
"less than about 8 seconds"	Less than 9 seconds.	No construction necessary.
"about 4 seconds"	Between 3 and 5 seconds.	No construction necessary.
"about 3.5 to 8 seconds"	Between 3 and 9 seconds.	No construction necessary.
"about 1.0 [mu] L of the blood sample"	Less than 1.1 [mu] L of blood sample.	No construction necessary.
"between about 0.1 [mu] L and about 1.0 [mu] L of the blood sample"	Between 0.09 [mu] L and about 1.1 [mu] L of blood sample.	No construction necessary.

With respect to claim terms using the word "about" that refer to the volume of the blood sample, Plaintiffs contend that "nothing in the intrinsic evidence suggests either a particularly broad or a particularly narrow construction of the term 'about'". Plaintiffs further contend that "[t]he only real guidance within the specification or claims for any particular range of values for the volumes comes from the structure of the claims themselves and the number places to which the volume is given." (D.I. 357 at 20.) Thus, as an example, Plaintiffs suggest that it is "reasonable" to extend a claimed range of "about" 0.1 to 1.0 [mu] L to 0.09 to 1.1 [mu] L. (See, id.) Plaintiffs do not appear to cite any cases in which either the Federal Circuit or a district court has adopted this mode of analysis to construe the term "about." With regard to the claim terms using the word about that refer to test times, Plaintiffs make similar arguments. (See, id. at 34-36.)

In passing, Plaintiffs do direct the Court to the Federal Circuit decision Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1327-28 (Fed. Cir. 2007). There the Federal Circuit affirmed a district court that, based in part on the statistical analysis of an expert, construed the claim term "about" to a specific numerical range. However, in the Court's view, Ortho-McNeil is not helpful here, mainly because Plaintiffs do not provide the Court with the type of expert witness testimony that was significant in Ortho-McNeil. Furthermore, in Ortho-McNeil, the Federal Circuit engaged in a careful analysis of the specification and a comparison of multiple claims, which bolstered the construction suggested by the extrinsic evidence. See, Ortho-McNeil, 476 F.3d at 1327-28. Here, Plaintiffs have provided no such analysis, but instead, as explained above, appear to suggest that such an analysis would be futile due to a lack of probative evidence in the internal record. (See, D.I. 357 at 20.)

In these circumstances, the Court concludes that the term "about" should simply be given its ordinary and accepted meaning of "approximately." See, Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (where, inter alia, "the patentee did not clearly redefine 'about' in the specification," holding "that the term 'about' should be given its ordinary and accepted meaning of 'approximately.'"); Unigene Labs., Inc. v. Apotex Inc., No. 06 CV. 5571 (RPP), 2008 U.S. Dist. LEXIS 66005, at *26-*27 (S.D.N.Y. Aug. 28, 2008) ("Without evidence, either intrinsic or extrinsic, that would provide a basis for construing the numerical limits of the term 'about 20 mM citric acid' in claim 19 of the '392 patent, the Court gives the word 'about' its ordinary meaning of 'approximately' and construes the claim term no further.").
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B. Claim Construction

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In finding that Merck acted as its own lexicographer, the district court relied on the following passage from the specification:

Because of the mixed nomenclature currently in use by those or [sic] ordinary skill in the art, reference to a specific weight or percentage of bisphosphonate compound in the present invention is on an active weight basis unless otherwise indicated herein. For example the phrase "about 70 mg of bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof and mixtures thereof, on an alendronic acid weight basis" means that the amount of bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

'329 patent, col. 10, l. 65 - col. 11, l. 8 (emphasis added). According to the district court's opinion, the patentee uses the phrase "about 35 [or 70] mg" to account for variations in the molecular weight of the different derivatives of alendronic acid and to deliver exactly 35 (or 70) mg of alendronic acid. Merck, 288 F. Supp. 2d at 613. For example, the court noted that alendronate monosodium trihydrate, which is used in Fosamax, requires an atom of sodium for each molecule. Id. at 613-14. If a heavier metal were chosen, such as potassium, the weight of the derivative compound would have to increase to deliver exactly the same number of molecules of the active alendronate compound found in 35 [or 70] mg of alendronic acid. Id. at 614. The district court thus construed the term "about 35 [or 70] mg" to mean the amount of the derivative compound that gives exactly 35 [or 70] mg of the active compound.

We reverse the district court's construction of "about" and hold that such term should be given its ordinary meaning of "approximately." n7 To properly construe a claim term, a court first considers the intrinsic evidence, starting with the language of the claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally claim terms should be construed consistently with their ordinary and customary meanings, as determined by those of ordinary skill in the art. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). While in some cases there is a presumption that favors the ordinary meaning of a term, Tex. Digital Sys. v. Telegenix Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002), the court must first examine the specification to determine whether the patentee acted as his own lexicographer of a term that already has an ordinary meaning to a person of skill in the art. See, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1988); Brookhill-Wilk, 334 F.3d at 1299.

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n7 The dissent frames the dispute in terms of the entire phrase "about 70 [35] mg of alendronate monosodium trihydrate, on an alendronic acid basis." Post at 2: 22-3: 2. Notwithstanding this contention, the district court identified the "disputed claim terms" as "about 70/35 mg." Merck, 288 F. Supp. 2d at 616. In its brief to this court, Merck likewise stated the issue as whether the district court properly construed the aforementioned limitation (not disputed term) on grounds that the '329 patent expressly defined "about 70 mg" as calculated "based on 70 mg of alendronic acid." See Appellee Br. at 3 (statement of issues). We agree with Merck, and the district court, that the dispute concerns the proper meaning of "about." We thus understand the dissent to argue that meaning is fixed by the context of the claim and the language of the written description.

It is correct to look first to those sources for the meaning at issue. See Vitronics, 90 F.3d at 1582. However, as is noted above when the intrinsic evidence does not clearly establish its own lexicography, it is proper to determine the ordinary meaning of the term. For that reason we ascribe "about" its ordinary meaning here.

Moreover, the dissent pursues a philosophical argument as to the deference which should be given to the trial court. Claim construction being a legal matter it is reviewed de novo and this is still the law notwithstanding the desire of some members of this court to consider creating an exception to that rule. See Cybor, 138 F.3d at 1462-63 (Plager, J., concurring); id. at 1463-66 (Mayer, C.J., concurring in judgment); id. at 1473-75 (Rader, J., dissenting). Therefore, if we apply proper legal precedent as the majority has done in this case, the result is clear and obvious.

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When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description. See, e.g., Bell Atl. Network Servs. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). We have repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term. Id.; see also Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000)

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("Absent an express in tent to impart a novel meaning, claim terms take on their ordinary meaning."); Renishaw, 158 F.3d at 1249 ("The patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim.") (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)); Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1177-78 (Fed. Cir. 2002) (stating that the "presumption in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence"). In the present case, the passage cited by the district court from the specification for Merck's definition of "about" is ambiguous. It fails to redefine "about" to mean "exactly" in clear enough terms to justify such a counterintuitive definition of "about."

The phrase's ambiguity arises from the fact that it can easily be read as Teva does - as a way of explaining what is meant by the use of the phrase "alendronate acid active basis" rather than as a way of radically redefining what is meant by "about." The district court construed the phrase "about 70 [or 35] mg" to mean that one should administer approximately 70 (or 35) mg of the derivative compound, such that the end result is that the patient is administered exactly 70 (or 35) mg of alendronic acid. In other words, the district court determined that the quantity specified in the claims (35 or 70 mg) modifies the amount of the derivative compound rather than the active compound. Under such a construction, the term "about" informs one of ordinary skill in the art to select whatever quantity of the derivative compound necessary to give exactly 35 (or 70) mg of alendronic acid; for alendronate monosodium trihydrate, the word "about" thus meant that 45.68 mg (or 91.35 mg) of that compounds could be delivered - the amount necessary to give exactly 35 (or 70) mg of alendronic acid.

Unlike the limiting definition of "about" adopted by the district court, Teva's interpretation of the paragraph in question would mean that "70 [or 35] mg" refers to the amount of the active compound to be administered rather than the amount of the derivative compound. The term "about" in the claims would then serve to modify the quantity of the active compound in a way consistent with its normal definition of "approximately." Under this construction, the modifying phrase "about 70 [or 35] mg" would refer to approximately 70 (or 35) mg of alendronic acid. n8

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n8 Merck argues that the district court's construction is supported by the fact that "about" was not used twice in the underlined sentence cited by Merck, i.e., that the specification does not state that "the amount of bisphosphonate compound selected is calculated based on about 70 mg of alendronic acid." (emphasis added). While Merck's grammatical savvy is noted, we believe that the omission of a second "about" is likely an inadvertent error rather than the product of meticulous drafting.

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The claim construction urged by Merck and adopted by the district court reads the sentence of the passage underlined above out of context. In the sentence before the highlighted sentence, the patentee informs those of ordinary skill in the art that, when the patent refers to a certain amount of a bisphosphonate compound, it is actually instructing them to administer a certain amount of the active component of the compound rather than the compound itself, i.e., that one should calculate the amount dispensed on an "active weight basis." This preceding sentence thus acts to specify a common denominator to be used for all derivatives of alendronic acid. The underlined sentence merely gives a specific example - that of an alendronate derivative - to show what is meant by using the phrase "active weight basis."

Given that the passage that Merck relies on is amenable to a second (and more reasonable) interpretation, we hold Merck did not clearly set out its own definition of "about" with "reasonable clarity, deliberateness, and precision," and thus failed to act as its own lexicographer. In re Paulsen, 30 F.3d at 1480.

As further support for this conclusion, we note that other parts of the specification also suggest that "about" should be given its ordinary meaning of "approximately." The specification repeatedly describes a range of acceptable dosage amounts, with the patentee emphasizing that unit dosages will vary. For example, the specification suggests that a once-weekly dosage amount could contain anywhere from about 17.5 mg to about 70 mg of any alendronate compound on an alendronate acid active basis, with about 35 mg and about 70 mg being only two examples of a unit dosage:

For once-weekly dosing, an oral unit dosage comprises from about 17.5 mg to about 70 mg of the alendronate compound, on an alendronic acid active weight basis. Examples of weekly oral dosages include a unit dosage which is useful for

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osteoporosis prevention comprising about 35 mg of the alendronate compound, and a unit dosage which is useful for treating osteoporosis comprising about 70 mg of the alendronate compound.

'329 patent, col. 12, ll. 56-63 (emphasis added). In addition to the above passage, at another point in the specification the range for the normal unit dosage is further widened to "about 8.75 to about 140 mg." '329 patent, col. 12, ll. 52-55 (stating that "a unit dosage typically comprises from about 8.75 mg to about 140 mg of an alendronate compound on an alendronic acid active weight basis"). The specification thus suggests the patentee contemplated a range of dosages, further compromising Merck's proposition that it acted as its own lexicographer in defining "about" to mean "exactly." n9

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n9 We also note that Examples 7 and 8 in the '329 patent do not contradict the construction we adopt on appeal because they are only examples of the tablets that could be prepared according to the patent. Neither example clearly states that the only embodiment of the claims would be the exact formulations described therein.

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Finally, our construction of "about" eliminates the problem pointed out by Teva that the district court's construction of the term "about" renders other parts of the claim superfluous. As Teva notes, the specification uses both the term "about" and "on an alendronic acid basis" at least 15 times to describe a dosage strength. If, as Merck urges, "about 35 [or 70] mg" means exactly 35 (or 70) mg of alendronic acid, then the oft-repeated phrase "on an alendronic acid active basis" would be unnecessary since such an understanding would be clear simply by using the term "about." A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so. Elekta, 214 F.3d at 1307 (construing claim to avoid rendering the 30 degree claim limitation superfluous); Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed. Cir. 1996) (rejecting the district court's claim construction because it rendered superfluous the claim requirement for openings adjacent to the end walls). By construing "about" to mean its accepted and ordinary meaning of "approximately," the phrase "alendronic acid basis" is no longer excess verbiage, but is instead necessary because it is the noun that "about 35 [or 70] mg" modifies.

Because the patentee did not clearly redefine "about" in the specification, and because the district court construed the claim term in a manner inconsistent with the specification, we reverse the district court's claim construction. We thus hold that the term "about" should be given its ordinary and accepted meaning of "approximately."
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This case shows the consequences of paying only lip service to the often-cited, but rarely-followed lexicographer rule and the basic jurisprudential principle of according trial courts proper deference.

Elect the Lexicographer Option at Your Own Risk

With this court's claim constructions wavering between the plain meaning rule (often a subtle way for judges to impose their own semantic subjectivity on claim terms, see, e.g., K-2 Corp. v. Salomon S.A., 191 F.3d 1356 (Fed. Cir. 1999) ("permanent" affixation of the wheels to the skate boot in the context of in-line skates did not include a bolt that could only be reached by tearing apart the shoe)) and the "specification uber alles" rule (often a way for judges to import limitations not included in the claim, see, e.g., Phillips v. AWH Corp., 363 F.3d 1207, 1213-14 (Fed. Cir. 2004), vacated, reh'g en banc granted, 376 F.3d 1382 (Fed. Cir. July 21, 2004)), a patent applicant might suppose that the best option to define the scope of the claim language might be the lexicographer rule. Under the lexicographer rule, an inventor acts as an independent lexicographer and can even give claim terms a meaning "inconsistent with its ordinary meaning." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325-26 (Fed. Cir. 2002)); see also Teleflex, 299 F.3d at 1325 ("An inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.'" (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994))). Indeed, this court often acknowledges that an applicant, acting as a lexicographer, may define "black" as "white." See Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (Fed. Cir. 1990) ("It is a well-established axiom in patent law that a patentee is free to be his or her

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own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings."); see also, e.g., Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1373 (Fed. Cir. 2004) (patentee defining "annular," which ordinarily means in the shape of a ring, to describe structures that are not circular or curved, but polygonal). In this case, the patentee used the lexicographer rule to define a lengthy phrase. In its definition, the patentee defined the phrase with precise values. The patentee's definition, however, fell five letters short of success because the phrase included the word "about." This court seized on that word, gave it an ordinary meaning, and cast aside the lexicographer rule without a convincing explanation. Moreover, this court overturned the result of a lengthy district court trial for the sole reason that the trial court applied this court's lexicographer rule. I find it hard to explain to the district court how it erred by following this court's rules.

The disputed term in claim 23 of the '329 patent is the phrase "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis." Similarly, the disputed term in claim 37 is the phrase "about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis." Teva contends that this court should parse out one word in that phrase, "about," and accord that single word its ordinary meaning of "approximately." Merck, on the other hand, contends that the term "about" is inseparable from the entire phrase, which it defines under the lexicographer rule to account for the variability in the active ingredient weight that would result from the use of a salt of alendronic acid.

The specification shows the proper interpretation of the disputed phrase. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). In the specification of the '329 patent, the patentee exercised the lexicographer option and defined the disputed phrase as follows:

Because of the mixed nomenclature currently in use by those of ordinary skill in the art, reference to a specific weight or percentage of a bisphosphonate compound in the present invention is on an acid active weight basis, unless otherwise indicated herein. For example, the phrase "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis" means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

'329 patent, col. 10, l. 65 - col. 11, l. 8.

In a passage that classically invokes this court's lexicographer doctrine, the patentee clearly, deliberately, and precisely defined the phrase "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis." The patentee set forth that entire term with quotations, including the word "about" and then stated unambiguously that the "phrase ...means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid." '329 patent, col. 11, ll. 2 - 8 (emphases added). The choice of the words "phrase" and "means," combined with the use of quotation marks to set the phrase off from the rest of the sentence, unmistakably notify a reader of the patent that the patentee exercised the option to define the entire phrase without respect to its ordinary meaning as understood by one of ordinary skill in the art at the time of the invention. See Multiform Dessicants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

To underscore the choice to define the phrase as a lexicographer, the patentee explains the reason that this phrase needs definition - "because of the mixed nomenclature currently in use by those of ordinary skill in the art." '329 patent, col. 10, ll. 65-66. Therefore, even a casual reader, let alone one with skill in this art, would immediately recognize that the patentee intended to avoid any ambiguity inherent in "mixed nomenclature" by explicitly defining the entire phrase. See Paulsen, 30 F.3d at 1480 ("'Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change." (quoting Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388 (Fed. Cir. 1992))).

The language of this definition explains further the scientific reason that an express definition is necessary. Alendronate monosodium trihydrate is a bisphosphonate selected from the group consisting of alendronic acid, pharmaceutically acceptable salts thereof, and mixtures thereof. A salt or a mixture may require a different weight to achieve the same number of bisphosphonate molecules present in 70 mg of alendronate.

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The patentee did not leave this difference vague, however, but instructed that the precise dose in claim 23 - "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis" - means that the amount of alendronate monosodium trihydrate is calculated based on 70 mg of alendronic acid. Similarly, the disputed language of claim 37 - "about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis" - means that the amount of alendronate monosodium trihydrate is calculated based on 35 mg of alendronic acid. The word "about" in the defined phrase takes into account the variability of the weight of the active ingredient that would result from using different salts of alendronic acid in the tablets, instead of the acid itself. In other words, a heavier salt would require more by weight to achieve the same number of alendronate molecules. For example, about 70 mg of alendronate sodium, on an alendronic acid active basis, contains the same number of molecules of alendronate as 70 mg of alendronic acid, regardless of the actual weight of the alendronate sodium in the tablet.

With respect to the word "about," the patentee included that word in the entire phrase expressly defined in the specification and set off by quotation marks. Therefore, this court cannot, without disturbing the patentee's express definition of the entire phrase, abstract that term out of its context and supply an ordinary meaning. Thus, by abstracting "about" out of the patentee's express definition, this court's opinion defeats the patentee's choice of words, punctuation, and phraseology and instead extracts a single word from its context in the phrase. Accordingly, the majority rewrites the express definition either by moving the word "about" outside of the quotation marks of the defined phrase or by inserting the word "about" into the definitional portion of the sentence so that it would read "the amount of the bisphosphonate compound is calculated based on about 70 mg of alendronic acid." If the patentee had chosen either of those two phraseologies, the majority opinion might be correct in its analysis. But because the patentee did not, this court cannot give any principled reason that the district court erred in applying the lexicographer rule. Contrary to this court's rules, this opinion rewrites the specification and substitutes language not chosen by the patentee. See, e.g., Chef Am., Inc. v. Lamb Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) (repeating the well-established rule that "courts may not redraft claims").

Throughout the patent, the applicant remained faithful to the disputed phrases in claims 23 and 37 consistent with the specified lexicography, thus completely dispelling any notion of ambiguity in the term "about." In particular, Examples 7 and 8 corroborate the express definition. Example 7 states that "tablets containing about 35 mg of alendronate, on an alendronic acid active basis, are prepared using the following weights of ingredients" and lists alendronate monosodium trihydrate requiring a mass of 45.68 mg. See '329 patent, col. 19, ll. 14 - 21. Similarly, example 8 states that "[a] liquid formulation containing about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis, per about 75 mL of liquid is prepared using the following weights of ingredients" and lists alendronate monosodium trihydrate having a mass of 91.35 mg. Id. at col. 19, ll. 44 - 52. In these examples, the applicant supplied an exact weight that equates with "about 70 mg of alendronate ...on an alendronic acid active basis." Accordingly, the district court did not err in construing "the disputed claim terms 'about 70/35 mg' to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories." Merck, 288 F. Supp. 2d at 616. The district court followed this court's rules.

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As the district court correctly stated, the claim language "indicates that the invention's chemical components should be limited to the precise ranges set forth therein." Jeneric, 1999 U.S. Dist. LEXIS 6990, at *28, 1999 WL 66537, at *10. The district court's claim interpretation finds support in claim construction principles enunciated by this court in other cases. In general, "[a] term such as 'about' is not subject to [] a precise construction . . . but is dependent on the factual situation presented." W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1280, 6 U.S.P.Q.2D (BNA) 1277, 1282 (Fed. Cir. 1988). Without broadening words that ordinarily receive some leeway, see Modine Manufacturing Co. v. United States International Trade Commission, 75 F.3d 1545, 1554, 37 U.S.P.Q.2D (BNA) 1609, 1615 (Fed. Cir. 1996), the precise weight ranges of claim 1 do not "avoid[] a strict numerical boundary to the specified parameter," Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217, 36 U.S.P.Q.2D (BNA) 1225, 1229 (Fed. Cir. 1995).

This construction, assigning numerical precision to composition ranges, is particularly appropriate when other variables in the same claims explicitly use qualifying language. See Modine Mfg., 75 F.3d at 1551. Claim 1 contains a mixture of imprecise and precise claim limitations. Specifically, claim 1 uses the word "about" to qualify the values of many variables: the range of the maturing temperature, the coefficient of thermal expansion, the leucite crystallite sizes, and the weight percentage of leucite crystals. In contrast, the claim recites precise ranges for the weight of dental compositions. Under

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these circumstances, the district court correctly limited the weight ranges to those recited precisely in the table of claim 1.

This reading finds additional support in the written description of the '791 patent. As illustrated below, columns 2 and 3 of a table in the '791 patent disclose the outermost and preferred ranges of dental compositions, respectively:

Oxide	Range	Preferred	Example 1	Example 2
SiO<2>	57-66	58-65	62.1	58.0
Al<2>O<3>	7-15	8-14	9.8	14.0
K<2>O	7-15	11-15	14.2	15
Na<2>O	7-12	7.5-11	7.6	8.1
Li<2>O	0.5-3	0.7-1.5	1.1	1.5
CaO	0-3	0-1.5	1.0	1.0
MgO	0-7	0-5	1.9	1.0
F	0-4	0-3	1.9	1.0
CeO<2>	0.1	0-0.5	0.4	0.4
Coefficient of thermal expansion (RT to 450 degrees C.) (x 10<-6/degree C.)	12-17.5	12-17.5	15.0	17.4
Maturing Temperature (degree C.)	790-1050	800-1000	815	850
Maturing Temperature (degree F.)	1318-1922	1472-1832	1500	1562

'791 patent, col. 3, ll. 10-26. Claim 1 covers the outermost ranges listed in column 2 of the table while independent claim 6, not asserted in the present action, covers the preferred ranges listed in column 3. Under the correct reading of the claims, the porcelain composition ranges represent the outermost bounds of the disclosed embodiments. The specification's teachings are consistent with this claim construction.

The district court also found that "evidence shows that claim 1 needed to be written narrowly to avoid being anticipated or rendered obvious by Jeneric's United States Patent No. 4,798,536 ('536 patent)." Jeneric, 1999 U.S. Dist. LEXIS 6990, at *30, 1999 WL 66537, at *10. In fact, the '791 patent incorporates by reference the '536 patent, which issued over six years before the filing date of the '791 patent. The '536 patent teaches use of dental compositions nearly identical or overlapping with the ranges recited in claim 1 of the '791 patent. "When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1346, 51 U.S.P.Q.2D (BNA) 1943, 1946 (Fed. Cir. 1999). Thus, Jeneric may not rely on the precise ranges of the claims to distinguish itself from prior art during prosecution and then later construe the ranges more broadly during an infringement action. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1677 (Fed. Cir. 1995). The district court properly acknowledged this principle. In sum, this court agrees with the district court that claim 1 limited the compositions to the ranges listed in the table.
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F. "About" 27

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27 An example for each type of "about" term is provided. See D.I. 55 at 46 for the comprehensive list.

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i.The Parties' Positions

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The central dispute regarding the "about" claim terms in the CIP patents is whether a person ordinarily skilled in the art would read those terms in reference to the United States Pharmacopeia ("USP"), a "non-governmental, official public standards-setting authority, which sets and publishes quality . . . and consistency standards, as well as verification standards for … prescription and over-the-counter medicines, other health care products, food ingredients, and dietary supplements." (D.I. 58 at 36-37 & n.18) (internal citation omitted)

Abbott contends that nowhere in the claims or specification is there an indication that the inventor intended to depart from the general principle that "about" avoids a strict numerical limitation. (D.I. 55 at 47-48 (citing Cohesive Techs., 543 F.3d at 1368; Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120 (Fed. Cir. 2002))) Abbott argues that where, as here, the patentee did not clearly redefine the word, "about" should be given its ordinary and customary meaning of "approximately." (Id. at 47-48 (citing Merck & Co. v. Teva Pharms., Inc., 395 F.3d 1364, 1369-72 (Fed. Cir. 2005); UCB, Inc. v. KV Pharm. Co., 2009 U.S. Dist. LEXIS 72764, at *15 (D. Del. Aug. 18, 2009);Unigene Labs., Inc. v. Apotex Inc., 2008 U.S. Dist. LEXIS 66005, at *26-27 (S.D.N.Y. Aug. 28, 2008))) Additionally, according to Abbott, a person ordinarily skilled in the art would understand that "about" means "approximately," because the term "about" "reflects the inherent uncertainty in any scientific measurement -- i.e., repeated measurements of the same property will not yield exactly the same result due to the limitations of accuracy and precision associated with measurement and testing techniques." (Id. at 49 (citing D.I. 56, AA Ex. A. ("Foster Decl.") P 56 and McGinity Decl. PP 63-66))

With respect to whether an ordinarily skilled artisan would refer to the USP to define the "about" terms in the CIP patent claims, Abbott argues that she would do so only for the particular purpose specified in the CIP patents. (D.I. 58 at 37-39 & n.19) The CIP patents' specifications all include a single reference to the USP:

Each nicotinic acid formulation of the instant invention will typically exhibit the following dissolution profile in U.S.P. XXIII, Apparatus I, 900 mls of deionized water at 37[degrees]C., baskets at 100 RPM, as indicated in Table 3.

(E.g., '229 patent, col. 9 lines 13-16)The claims of the '691 and '967 patents also reference the USP in connection with this same "type I dissolution apparatus." ('691 patent, claims 1, 13 (referring to "a type I dissolution apparatus (basket) according to [USP XXII]"); '967 patent, claims 1, 16 (same)) According to Abbott, there is no reference to the USP in connection with any other aspect of the CIP claims. (D.I. 58 at 38) Thus, an ordinarily skilled artisan would know that the USP should be consulted to determine the parameters of the "about" claims in the '691 and '967 patents because those particularly refer to measuring an in vitro (i.e., laboratory testing) dissolution profile. (Id. at 38 n.19)

Relying on the USP for other uses, Abbott continues, would be inappropriate because most of the contexts in which "about" appears are related to parameters that the USP does not govern. (Id. (citing D.I. 56 AA Ex. E, Supplemental Foster Decl. ("Supp. Foster Decl.") PP 16-28)) The USP sets performance standards for in vitro parameters of drug quality, purity, and consistency between batches. (Supp. Foster Decl. PP 8, 10) The USP does not, as Lupin suggests, set standards for in vivo (i.e., biological) parameters, such as pharmacokineticsor bioequivalence. (Id. P 10) Thus, a person ordinarily skilled in the art would not have looked to the USP in the context of in vivo measurements, such as the plasma concentration parameters of the '229 patent or the urinary metabolic profile parameters of the '715 patent. (Id. PP 24-28) In Abbott's view, a person ordinarily skilled in the art would not even have looked to the USP for guidance regarding in vitro parameters, other than the specific parameter for the "type I dissolution apparatus" disclosed in the '691 and '967 patents, because she would have understood "about" to mean "approximately." (Id. at 39-40 (citing Supp. Foster Decl. PP 14-23))

Lupin, by contrast, argues that the "technological and stylistic context" of the "about" terms dictates that the USP parameters be consulted. (D.I. 54 at 28-29 (citing Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995))) The CIP patents concern the fields of pharmaceutics (creating an appropriate dosage form for a drug) and biopharmaceutics. (Id. (citing '229 patent, col. 7 line 50 to col. 16 lines 1-27)) Lupin acknowledges that absolute precision in measuring active ingredient weights and concentrations in bloodplasma and urine is not possible in these fields. (Id. at 29) However, boundaries of weights and in vivo concentrations can still be set, and are necessary to distinguish the CIP dosage forms from priorart SR dosage forms. (Id. (citing D.I. 56, LA000683-84, Taft Declaration (hereinafter "Taft Decl.") PP 10-11))

Lupin's expert, Dr. Taft, declares that in the fields of pharmaceutics and biopharmaceutics, using "about" to modify a numerical range is understood to refer to a deviation acceptable around a particular data point. (Taft Decl. PP 10-12; see also D.I. 60 at 34-38 (discussing general agreement among Dr. Cefali, an inventor of most of the CIP patents, David Bova,

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Lupin's expert, Dr. Taft, and Abbott's experts, Drs. McGinity and Foster, that there is "inherent variability" in the manufacturing process based on the particular equipment used and/or accuracy of assay method).) Lupin argues that the numerical ranges in almost all of its proposed constructions represent the accepted variance percentages found in the USP XXII and USP XXIII, which were in effect at the time of the invention. (D.I. 60 at 32-38)

According to Lupin, the only numerical ranges that are not derived from a versionof the USP are with respect to claim 13 of the '691 patent and claim 16 of the '967 patent, both of which require a particular "fit factor F[2]" for comparing a test dissolution profile to a reference dissolution profile. (D.I. 54 at 41-43) Lupin proposes that a "fit factor F[2]" of "about 44" should be construed as "no less than 43.5" because numbers between 43.5 and 43.9 round to the nearest whole number, which is 44. (Id. at 42 (citing San Huan New Materials High Tech., Inc. v. Int'l Trade Comm'n, 161 F.3d 1347, 1361 (Fed. Cir. 1998)) According to Lupin, nothing in the '691 or '967 patents' specifications or prosecution histories warrants departing from this "standard scientific convention." (Id. (citing Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1320-21 (Fed. Cir. 2001))

ii. Recommended Construction

I recommend different constructions for each set of "about" claims in dispute, as follows.

a. Claims regarding "dose-amount limitations" in the '229, '715, and '967 patents

I recommend that the Court adopt Lupin's proposed construction of "about" for the doseamount limitations claims in the '229, '715, and '967 patents. The "dose-amount" limitations claims are claims 17 and 25 ofthe '229 patent; claims 1, 3, 5, 7, and 9 of the '715 patent; and claim 16 of the '967 patent. (D.I. 54 at 29-30) Both parties agree that a person ordinarily skilled in the art would look to the USP for guidance on these issues, and the patent's inventors and all the experts agree that "about" in these claims essentially means within the range of scientifically acceptable error. Given that the USP edition in effect at the time of the invention set the standards for such scientifically acceptable manufacturing errors in pharmaceutical preparations, a person ordinarily skilled in the art would have consulted the USP to determine the meaning of "about." Abbott, however, objects that the USP XXIV -- which is not the one in effect at the time of the invention -- has a specific tablet strength tolerance for niacin compositions, which is +/-10%, rather than the "general" tolerance of +/- 15%. (D.I. 58 at 39 n.21) There is nothing in the record as to whether the USP XXII and XXIII -- the versions of the USP that were in effect at the time the patents were being prosecuted -- also had a specific tolerance for niacin compositions. In the absence of such evidence, I recommend that the Court construethe "dose-amount limitations" in accordance with Lupin's proposed construction (i.e., +/- 15%).

b. Claims regarding Blood Plasma Concentration limitations and Urinary-Metabolite-Profile limitations in the '229 and '715 patents

With respect to the blood plasma concentration limitations and Urinary-Metabolite-Profile limitations in the '229 and '715 patents, I recommend that the Court adopt Abbott's construction of "about" in claims 17 and 25 of the '229 patent and claims 1, 5, and 9 of the '715 patent. Abbott's assertion that the USP standards are not designed to apply to in vivo parameters, such as blood plasma concentrations and urinary metabolite profiles, appears to be supported by Lupin's expert, Dr. Taft. (D.I. 61, LA000971-981, Supplemental Taft Declaration ("Supp. Taft Decl.") PP 6-8) Although agreeing with Abbott's expert that repeated measurements of blood plasma concentrations may not yield the same results, Dr. Taft states that "the results should be reproducible to within an acceptable degree of error. In my opinion, an acceptable degree of error is +/- 10%." (Supp. Taft Decl. P 6) He goes on to state that the USP provides guidance for "performance characteristics" of theanalytical methods used to measure "drug and, in some cases, metabolite(s) in plasma and/or urine." (Id. P 7) However, "the USP does not specify an acceptable limit of variability in these performance characteristics," which themselves are but one aspect of verifying that a test for blood plasma concentration or urinary metabolites is accurate. (Id. PP 6, 8) Dr. Taft notes that "+/- 10% is supported by the scientific literature, specifically for published methods used to measure niacin," and cites the results of two studies that described their variation in reproducability results as at or below 10%. (Id. P 8 (emphasis added))

Thus, it seems that not even Lupin's own expert believes that the USP provides the proper guidelines for measuring blood plasma concentrations and urinary metabolite profiles. In fact, Dr. Taft's reliance on "scientific literature" and other studies indicates that what he is really basing his opinion on is what a person ordinarily skilled in the art would rely upon - namely, the body of available published literature and conventions in the art. In these circumstances, Abbott's construction of

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"about" as "approximately" reflects the ordinary and customary meaningof the term as understood by a person ordinarily skilled in the art and is more appropriate than Lupin's more specific numerical range.

c. Dissolution profile claims in the '691 and '967 patents

Both parties recognize that claim 13 of the '691 patent and claim 16 of the '967 patent expressly reference USP standards for measuring an in vitro dissolution profile. (D.I. 58 at 38 n.19; D.I. 54 at 40) Although "about" generally avoids a "strict numerical boundary to the specified parameter," it must still be interpreted according to the patent's field and specification, and can be narrowed where the specification allows it. Cohesive Techs., 543 F.3d at 1368-69.

In Cohesive Techs., 543 F.3d at 1368-69, the Federal Circuit construed "about 30 [mu] m" as "between 25.434 [mu] m and 34.566 [mu] m" because the specification provided the precise means of doing so. Specifically, another part of the specification treated "about 50 [mu] m" as if it were the same as "42.39 [mu] m." Id. This deviation from the exact number 50 represented an "acceptable variance of at least 15.22%." Id. Therefore, the court applied a 15.22% variance to the "about 30 [mu] m" term and decided it should encompass "at least25.434 [mu] m but not more than 34.566 [mu] m." Id.

Similarly, here, before reciting a litany of percentage ranges using the term "about," the '691 and '967 patents teach that the in vitro dissolution profile to be used in the invention should be measured according to USP XXII's standards. ('691 patent, col. 30 lines 13-33; '967 patent, col. 30 lines 43-62) The claims of the '691 and '967 patents also reference the USP in connection with this same "type I dissolution apparatus." ('691 patent, claims 1, 13; '967 patent, claims 1, 16) Therefore, I recommend that the Court adopt Lupin's proposed construction of "about" in claim 13 of the '691 patent and claim 16 of the '967 patent, because it comports with express claim language and would be understood by a person ordinarily skilled in the art to require consultation of the USP XXII standards for dissolution profiles.

d. "Fit factor F[2]" claims in the '691 and '967 patents

With respect to the meaning of "about" in the "fit factor F[2]" claims -- claim 13 of the '691 patent and claim 16 of the '967 patent -- I recommend that the Court adopt Lupin's proposed constructions. In Viskase Corp., 261 F.3d at 1321, the Federal Circuit reversed adistrict court that construed the term "about 0.91 g/cm3" to mean densities between 0.905 and 0.914 based on the reasoning that numbers in that range would be rounded to 0.91. Although the Federal Circuit agreed that this practice "is a standard scientific convention when a number has not been carried to the next mathematically significant figure," it construed the term "below about 0.91 g/cm3" as "below about 0.910 g/cm3." Id. at 1322. It did so in large part because the inventor had used the density figure "0.910" during prosecution to distinguish prior art, even though the claims themselves only recited "0.91." Id. at 1321-22. In this way the inventor had signaled that it was important to describe the numbers out to three decimal places.

Here, the '691 and '967 patents' specifications explain that the range of potential "fit factor F[2][s]" will be a "number between 0 and 100." ('691 patent, col. 11 lines 17-62; '967 patent, col. 11 lines 35-63) However, the patents list recommended fit factor F[2] values (for both Niaspan(R) and competitor products) using numbers described to the first decimal place, e.g. "+/- 79.0" for Niaspan(R), and "54.3" for a competitor's product. This indicatesthat the inventors intended that the fit factor F[2] values be described to the first decimal place. Lupin's construction accommodates that intention.

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9. About

The parties further quarrel over the term "about", despite its relatively benign nature and acceptance in common parlance. Ordinarily, as Sears notes, the term would simply mean "approximately", and would not require further construction. Defendants argue, however, that the term should not be construed to permit expansion of the specified molecular weight ranges to cover decasaccharides outside of the specified Markush group comprised of "glucose, fructose, higher saccharides based on glucose and fructose and mixtures thereof." 16

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16 As the Federal Circuit has recognized,

[a] Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C.

Abbott Laboratories v. Baxter Pharm. Products, Inc., 334 F.3d 1274, 1280 (Fed. Cir. 2003). Markush group listing is generally considered to signify a closed category; "[i]f a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim" such as occurred in this action. See id. at 1281.

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While stressing the importance of intrinsic source guidance for patent claim terms, the Federal Circuit has not altogether abandoned other, previously well-accepted sources, including dictionaries, to assist in the claim construction exercise. That court confirmed the continued availability of such sources in Phillips, stating that

[a]s we have noted above, however, we do not intend to preclude the appropriate use of dictionaries. Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation.

Phillips, 415 F.3d at 1322 (citations omitted).

In this case the term "about" is defined in one as meaning "reasonably close to", "almost", or "in the vicinity." Merriam Webster's Collegiate Dictionary (10th ed. 1995). The need for the use of the term "about" was explained by Professor Nauman in his declaration, to address the common practice of those of ordinary skill in the art to attribute whole numbers for atomic weights of hydrogen, carbon and oxygen despite the fact that such weight would actually vary depending upon the specific isotopes within those molecules. See Nauman Second Decl. (Dkt. No. 183-2) PP 18-19. Accordingly, while it is true that the term "about" lacks universal meaning in patent claim jargon, depending upon the particular facts of the case, see Pall Corp. v. Micron Separations, 66 F.3d 1211, 1217 (Fed. Cir. 1995), I will define it in this case based upon its plain and ordinary meaning to be "approximately the value as stated." See Novartis Pharms. Corp. v. Apotex Corp., 02 Civ. 8917, 2006 U.S. Dist. LEXIS 10130, 2006 WL 626058, at *9-10 (S.D.N.Y. Mar. 13, 2006). While I find no need to define about, which is understandable and intended to mean approximately, giving a margin for testing error, I agree with the defendants -- and Sears does not appear to argue otherwise -- that it should not be utilized so loosely as to permit expansion to encompass, for example, where 1500 is specified as an outer limit, to include decasaccharides with the molecular weight of 1638 with regard to the '793 patent. 17

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17 The significance of the disagreement over the term "about" relates to whether Sears could potentially claim that low molecular weight carbohydrates or sugars extending above the specified molecular weight ranges are intended to be encompassed within the purview of patent claims. During the Markman hearing Sears disavowed any such intention, specifically stating, for example, that decasaccharides, with a molecular weight of approximately 1638, would fall outside of claim one of the '793 patent, which specifies 1500 as an upper limit. With that assurance, the disagreement over the meaning of the term "about" takes on markedly decreased significance.

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C. "About"

The parties have focused relatively little attention on the term "about," but disagree about its meaning nevertheless. The term "about" is important because it modifies the PXRD angles listed in Claim 1. '507 Patent col.16 ll.21-27. Therefore, a

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crystalline cefdinir product falls within the scope of Claim 1 even if it only exhibits peaks at "about" the PXRD angles listed in Claim 1. Lupin suggests that "about" simply allows for "some range of error intrinsic to the [PXRD] measurement itself." (Lupin Br. at 14.) Abbott and Astellas, on the other hand, urge that "about" be given its ordinary dictionary meaning, which is "approximately." (Abbott and Astellas Br. at 20.)

"About" is not defined anywhere in the patent or in the prosecution history, but its use in the specification offers some indication of its meaning. The PXRD angles listed in column 1, like the angles listed in Claim 1, are modified by the word "about." '507 Patent col. 1 ll.56-26. Those angles are associated with Crystal A, and the peaks present at those angles are displayed in Figure 1. The specification notes, however, that Figure 1's "diffraction pattern is given only for reference and any crystal of the compound (I) which shows substantially the same diffraction pattern is identified as Crystal A of the compound (I)." Id. col.1 l.67-col.2 l.2. Because any form of crystalline cefdinir showing "substantially the same" PXRD pattern would be identified as Crystal A, the patent strongly indicates that the word "about" refers only to minor deviations from a PXRD angle.

Moreover, the parties' experts seem to agree that a person of ordinary skill in the art would also construe "about" fairly narrowly in the context of PXRD testing. See Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995) (noting that the word "about" does not have a universal meaning in patent claims, and must be construed in its "technological and stylistic context"). Dr. Atwood says that "'about' is intended to recognize that insignificant differences arise due to, among other factors, the type of equipment used to make the [PXRD] measurement, the care taken in making the measurement, and the number of samples measured." (Atwood Decl. P 9.) Similarly, Dr. Trevor Laird, one of Lupin's experts, explains that "about" refers to "inherent and minor measurement variations associated with the performance of the x-ray diffraction test itself." (Laird Decl. P 39.)

Considering the text of the specification and the views of both experts, the Court concludes that "about" encompasses only measurement errors inherently associated with PXRD testing.
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"About"

Neither party addressed this term in its briefs. In the parties' Patent Rule 4-5(d) Joint Claim Construction Chart, GNC identified "about" as a distinct term in certain claims from all the patents-in-suit and stated that to the extent that the term requires a definition, the Court should construe the term to mean "almost." Nutrition 21 does not ask the Court to construe the term and does not contend the term has a special meaning in the art. Because "about" is a lay term that does not require construction, the Court will not construe the term for any of the patents-in-suit.
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3. "About"

The final claim term in issue is "about" as it is used in Claims 2 and 3 of the '569 patent and Claims 1, 17 and 18 of the '565 patent. n4 Plaintiffs contend that "about" should mean "approximately" (Pl. Memo. at 14); defendants contend it should mean "limited to the precise lower and upper limits of the recited range" (Def. Memo. at 22-23). n5

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n4 The relevant language in the '569 Patent is in Claim 2: "[a] composition according to claim 1 having a pH of from about 3 to about 5" (emphasis added); and Claim 3: "[a] composition according to claim 2, having a pH of from about 3.5 to 4.5" (emphasis added). The relevant language in the '565 Patent is in Claim 1: "about 0.002% to about 0.02% on a weight per volume basis of a benzalkonium chloride" (emphasis added); Claim 17: "[a] composition according to claim 1 having a pH of from about 3 to about 5" (emphasis added); and Claim 18: "[a] composition according to claim 17 having a pH from about 3.5 to 4.5" (emphasis added).

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n5 Plaintiffs argue there is no need to construct this term because defendants have already admitted their composition is within the ranges plaintiffs' patents claim under either proposed constructions for all claims in which construction of the term "about" is disputed (Pl. Resp. at 7-8). Despite these admissions, in the interest of completeness, at this stage of the suit I find it is more prudent to construct each of the disputed claim terms.

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The plain and ordinary meaning of "about," and how it would be read by one skilled in the art, is "approximately." Defendants point to no language in the specifications or prosecution history that suggests the inventors redefined "about" in a manner contrary to its plain and ordinary meaning.

Construing "about" to mean "approximately" is consistent with another claim in the patent in suit that states a range but has no qualifying term preceding it (see '565 Patent Claim 14 ("A composition according to claim 13 comprising a polyoxyethylene cholesteryl ether in which the number of repeating units in the polyoxyethylene moiety is from 16 to 26."). This range is limited to the precise upper and lower numbers cited. If "about" were construed as limiting ranges to their precise upper and lower limits, the use of "about" would be superfluous when contrasted with a range that has no preceding qualifying language. Because, as noted above, "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so," I find defendants' proposed construction must be rejected because it would render the term "about" meaningless. Merck & Co. v. Teva Pharm. USA, Inc., supra, 395 F.3d at 1372

Defendants argue that if "about" is construed to mean "approximately," it will be impossible to determine the precise bounds of the claims' ranges for purposes of invalidity and infringement (Def. Memo. at 23). This reasoning is flawed. A patent is not invalid merely because claims approximate certain values within it. See Merck & Co. v. Teva Pharm. USA, Inc., supra, 395 F.3d at 1369-72 (constructing term "about" that preceded numeric value to mean "approximately"); Jeneric/Pentron, Inc. v. Dillon Co., supra, 205 F.3d 1377, 1381 (Fed. Cir. 2000) (ranges in claim preceded by "about" were approximations and claims not preceded by "about" or a similar qualification were precise figures). The inventors are permitted to patent approximate measurements for their composition and, thus, construing the term "about" to mean "approximately" is also permissible.

For these reasons, I find that the term "about" should be construed to mean "approximately."
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D. About

Several of the claims discuss shelf life in terms of time limits. The dispute between the parties about the interpretation of those time limits centers on the word "about." Sunny Fresh claims that the word "about" means "not less than" (Kempf Aff., Ex. 26), while Michael Foods claims that "about" means approximately, (Kempf Aff., Ex. 27). The term "about" therefore requires construction.

The relevant claim language includes: "refrigerated shelf life of about four weeks to about 36 weeks," "a preselected shelf life of about eight weeks to about 36 weeks," "shelf life of about 16 to 36 weeks under refrigerated conditions," "shelf life of about 16 weeks," "shelf life of about 16 weeks to 36 weeks under refrigerated conditions," and "characterized by a refrigerated shelf life of about four weeks to 36 weeks." (Kempf Aff., Ex. 23.)

As discussed, the words of a claim will be given their ordinary and accustomed meaning unless it appears that the inventor used them differently. Vitronics, 90 F.3d at 1582. According to the Federal Circuit, the ordinary and accustomed meaning of "about" is approximately. See Conopco, Inc. v. May Dept. Stores Co., 46 F.3d 1556, 1561 n.2 (Fed. Cir. 1994)(quoting Webster's Third New International Dictionary (1986)); see also Blacks Law Dictionary (7th ed. 1999)(defining about as "approximately"). The inventors in this case gave no indication in the claim language, specification or prosecution history that the word "about" means anything other than its ordinary and accustomed meaning. The court therefore construes the term "about" to mean "approximately." 10

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10 The exact boundaries of "about" in this case are a question fact for the trial court. As the Federal Circuit explained:

Such broadening usages as "about" must be given reasonable scope; they must be viewed by the decisionmaker as they would be understood by persons experienced in the field of the invention. Although it is rarely feasible to attach a precise limit to "about," the usage can usually be understood in light of the technology embodied in the invention. When the claims are applied to an accused device, it is a question of technological fact whether the accused device meets a reasonable meeting of "about" in the particular circumstances.

Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed. Cir. 1996)(citations omitted).

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Sunny Fresh's definition of "about" ignores the ordinary and accustomed meaning of the term. Moreover, Sunny Fresh's definition of the term "about" renders language in the patent redundant and thus meaningless. For instance, Sunny Fresh claims that "about 8 weeks to about 36 weeks" means "a refrigerated shelf life of not less than 8 weeks to not less than 36 weeks." If a product has a shelf life of 12 weeks, it would meet the lower limitation - a shelf life of not less than 8 weeks - but would not meet the upper limitation - a shelf life of not less than 36 weeks. Because the only product that would meet Sunny Fresh's definition would be one with a greater than 36-week shelf life, the words "about 8 weeks" in the phrase "about 8 weeks to about 36 weeks" become meaningless. The court rejects such a definition. See, e.g., Biagro Western Sales, Inc. v. Helena Chemical Co., 160 F. Supp. 2d 1112, 2001 WL 980961 (E.D. Cal. 2001)(stating that a patent claim should not be construed to render a language in patent meaningless). Moreover, if the inventors had intended such a result, surely the inventors simply would have excluded the language "about 8 weeks to" and succinctly provided for "a shelf life of about 36 weeks."

Accordingly, based upon clear intrinsic evidence, the court interprets the term "about" to mean "approximately" and, based upon that interpretation, construes the disputed elements as follows: "Shelf life of from about 16 to 36 weeks under refrigerated conditions" means shelf life of from approximately 16 to 36 weeks under refrigerated conditions, "Shelf life of about eight weeks to about 36 weeks" means shelf life of approximately eight weeks to approximately 36 weeks, "shelf life of about four weeks to about 36 weeks" means shelf life of approximately four weeks to approximately 36 weeks, "shelf life of about 16 weeks" means shelf life of approximately 16 weeks, "shelf life of about 16 weeks to 36 weeks under refrigerated conditions" means shelf life of approximately 16 weeks to 36 weeks under refrigerated conditions and "characterized by a refrigerated shelf of about four to 36 weeks" means characterized by a refrigerated shelf of approximately four to 36 weeks.
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2. "About 0.001 To 0.03 Parts Ascorbic Acid" (Claims 5, 6-8, 10)

Kim argues that the word "'about' is used because fruit juices are a mixture of food acids." Kim cites generally to the prosecution history in support of her construction.

A heavy presumption exists, however, that the ordinary meaning of a word in a claim applies. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). The Court may consult dictionaries to determine the ordinary meaning of a word. Texas Digital, 308 F.3d at 1202-03. "As a general rule, the construing court interprets words in a claim as one of skill in the art at the time of the invention would understand them." Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1555 (Fed. Cir. 1997). The '355 patent issued on October 26, 1999. Accordingly, the Court consults Random House Webster's College Dictionary (Random House, Inc. 1998).

That dictionary defines the word "about" as "approximately; near; close to." Random House Webster's College Dict. at 4. There is nothing in the claim language, the specification 7, or the prosecution history that compels a deviation from this ordinary meaning. In the absence of an express intent by the patentee to impart a novel meaning to a claim term, the words are presumed to take on the ordinary and customary meaning attributed to them by those of ordinary skill in the art. Teleflex, 299 F.3d at 1325.

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7 The specification does not require a different construction. See '355 patent, col. 5, lns. 36-39 ("Ascorbic acid incorporated into a yeast-leavened product mix formula ranges from about 10 ppm, to 300 ppm, preferably about 15 ppm to 250 ppm by weight of flour."); '355 patent, col. 5, lns. 46-49 ("Food acid ranging from about 0.015 to 0.20 parts, preferably about 0.2 to 0.15 parts per 100 parts flour is added to the yeast-leavened product mix formula.").

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Accordingly, the Court construes the term "about 0.001 to 0.03 parts ascorbic acid" to mean "approximately 0.001 to 0.03 parts ascorbic acid."
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4. About 0.20 mg to about 1.0 mg of said supplement

The term "about 0.20 mg to about 1.0 mg of said supplement" appears in claims 2 and 10 of the '015 Patent. Claim 2 provides an example of the term's use: "The method of claim 1, wherein said effective amount is from about 0.20 mg to about 1.0 mg of said supplement per 1.0 kg of body weight." Plaintiffs offer this construction: "A yeast cell wall extract in an amount of about 0.20 mg to about 1.0 mg of the nutritional supplement." Immudyne construes the term as "0.15 mg to 1.4 mg of said supplement." There is no evidence that would permit the Court to specify a permissible deviation from 0.20 mg or 1.0 mg. The Court declines to arbitrarily construe "about" through use of rounding principles. Instead, the Court gives the term "about" its ordinary meaning of "approximately." See Merck, 395 F.3d at 1369-72 & n.7. The Court therefore construes "about 0.20 mg to about 1.0 mg of said supplement" as "approximately 0.20 mg to approximately 1.0 mg of said supplement."
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Claim Interpretations

I held a hearing pursuant to Markman v. Westview, U.S. , 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), at which the parties presented evidence, including the testimony of their experts, on the proper interpretation of terms in the claim language of the various patents in suit, where such terms are disputed. Having heard the evidence, I reach the following conclusions.

The term "about" as used in the phrase "a density below about 0.91 g/cm3" means a number between 0.905 and 0.914. I reach this conclusion for the following reasons: First, the ordinary dictionary definition of "about" means "reasonably close to," "near" or "around." WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY (1983), p.45. Thus, as one of the experts testified, a person skilled in the art of the invention, reading this language, would assume the term included numbers slightly above and slightly below 0.91 g/cm3. Accord, e.g., Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed. Cir. 1995) ("about" means "approximate"); Conopco, Inc. v. May Dept. Stores Co., 46 F.3d 1556, 1561 and n.2 (Fed. Cir. 1994), cert. denied, 131 L. Ed. 2d 582, 115 S. Ct. 1724 (1995).

Second, as experts on both sides in this case agreed, persons skilled in the art understand that ordinarily numbers defined with two decimal places encompass any three decimal place number within a .005 range of the two decimal place number. That is, 0.91 encompasses 0.905 to 0.914, because either of these numbers would be rounded off to 0.91 if the third decimal place is removed. An exception to this rule lies in cases in which a patentee has itself limited the interpretation ordinarily given a two decimal place number. E.J. DuPont de Nemours & Co. v. Phillips Petroleum Co., 711 F. Supp. 1205, 1222 (D.Del. 1989).

In the present case, Viskase consistently used two digit numbers in its specifications. ANC argues that Viskase is limited to

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0.910 as a result of statements made to the patent examiner during the prosecution of U.S. Pat. 4,863,769. I disagree. ANC relies, first, on the fact that the original patent application (Serial No. 745,236) did not have a density limitation. After its rejection in February, 1986, Viskase filed the continuation application that became the '769 patent. In that continuation application, Viskase narrowed its claims by adding language stating "below about 0.91 g/cm3." ANC's patent expert testified that this history precluded a broad range of interpretation. But he ignores the word "about." "Below about 0.91" is, for the reasons stated, different from "below 0.91."

ANC's second argument is that Viskase's actions with respect to two additional claims in the continuation application which as submitted stated that the copolymer had a density "above 0.91 g/cm3", and which were subsequently changed to "below" rather than "above," limit all of the claims to densities below 0.91 g/cm3. The examiner rejected these claims as originally filed, stating that there was no support in the specification for a VLDPE of above 0.91. But he also noted that "clearly applicant intended to claim below 0.91." (Viskase Trial Ex. 3, p. 253) Furthermore, in the same paragraph the examiner held that the disclosure for other claims, correctly stating the density limitation as below rather than above 0.91 g/cm3, was "enabling for claims limited to the VLDPE having a density of from about 0.86 to about 0.91." As the examiner concluded, the use of "above" was obviously just an error, although a careless one, which was corrected. It carried no meaning that would limit the interpretation of these claims to exactly 0.910. That the examiner understood that the claims encompassed some inexactness that could go beyond 0.910 is shown by his own repetition of the word "about" in the same paragraph in discussing the claims, as well, of course, by his allowance of the claims with the inclusion of the word "about" as modifying 0.91.

ANC next argues that one of the patents relied on by the examiner in initially rejecting the application that became the '769 patent, Nishimoto, U.S. Patent No. 4,456,646 encompassed a density between 0.900 to 0.950 g/cm3. ANC argues that Viskase's argument against this patent was that it described linear low density polyethylene (LLDPE) rather than VLDPE, and thus necessarily agreed that LLDPE densities went as low as 0.900 (or at least stopped at 0.91 g/cm3). But ANC has misconstrued Viskase's argument before the examiner. Viskase did say that Nishimoto described its own copolymer as LLDPE, but the point of that was that LLDPE's are different from VLDPE's. Viskase went on to attach various articles discussing the newly discovered VLDPE's and the differences between them and LLDPE's. Viskase also distinguished Nishimoto on the ground that the 0.90 density lower limit in that patent was hypothetical and that the copolymers disclosed in Nishimoto are made using different catalysts and are incompatible with the VLDPE copolymers. The examiner in response agreed that Nishimoto did not anticipate the claims in the '769 patent.

ANC also argues that a statement made by Viskase in a disclosure made after the notice of allowance limits Viskase's claims to copolymers with a density below 0.910 g/cm3. The notice of allowance was dated November 6, 1988. On November 23, 1988, Viskase notified the Patent Office, pursuant to its duty of disclosure under 37 C.F.R. 1.56, of the existence of Shibata U.S. Patent No. 4,429,079, which issued January 31, 1985, and which Viskase stated that it had recently learned. Viskase described Shibata as describing two ethylene/alpha-olefin copolymers designated as "A" and "B." The "A" copolymer is the one of concern in this suit. Viskase stated that the Shibata "A" copolymer was different from its claimed invention because "the present application … does not have a density below about 0.910 g/cm3 as defined in all pending claims." Shibata describes a copolymer with a density of 0.910 to 0.940 g/cm3. Viskase says the use of the third decimal point was an obvious error. Whether or not it was intentional, I agree that in no other place in the prosecution history did Viskase use a third decimal point. As Viskase argues also, the same letter distinguished Shibata on the ground that the Viskase patent claims did not have densities below "about" the 0.910 g/cm3 range. I conclude that Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989), controls. In that case, the Federal Circuit held that remarks made by an attorney during the prosecution history that claims were restricted to a certain vaccination scheme, although some claims were not so limited, did not alter the claim language, and that the claim language controlled. In this case, the examiner certainly knew that the claims themselves included broader language than the limitation of 0.910. He did not require an amendment. The language, accordingly, is not so limited.

Finally, ANC argues that "about 0.91 g/cm3" cannot include a range of 0.912 g/cm3 because of the further language in the relevant claims stating that the film has "a 1% secant modulus below about 140,000 kPa." ANC says such a film necessarily has a secant modulus in the 165,000 or 170,000 range. In support of this conclusion, ANC introduced the testimony of its expert, Dr. Quirk. Dr.Quirk relied upon a measurement taken from an illustration in an article cited to the Patent Office by Viskase and the Karol patent, which Dr. Quirk testified discussed the relationship between density and secant modulus. On cross examination, however, Dr. Quirk agreed that the secant modulus measurement will vary depending upon the method used to make the film. He did not explain his reference to the Karol patent. ANC has failed to show that the limitation of "a

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1% secand modulus below about 140,000 kPa" requires that "about 0.91 g/cm3" be limited to 0.910 g/cm3.
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"Density" - The First Family

The district court construed the density term "about 0.91 g/cm3" to mean densities between 0.905 and 0.914, based on the reasoning that numbers in this range would be rounded to 0.91. We agree that this is a standard scientific convention when a number has not been carried to the next mathematically significant figure. However, ANC disputes the applicability of this convention to the facts of this case.

ANC argues that the specification and prosecution history make clear that "below about 0.91 g/cm3" is not entitled to broader scope than "below about 0.910 g/cm3", citing conventional descriptions of the densities of various classes of polyethylenes. ANC states that 0.91 g/cm3 is a generally accepted dividing line between "very low" and "low" density polyethylenes, and that a density range of the breadth adopted by the district court is contrary to this accepted usage, for it takes "very low density" into the range of "linear low density." ANC points out that during prosecution of the first family patents Viskase used 0.91 with a zero in the third decimal place. ANC also cites Viskase's incorporation into the first family patents of the process descriptions in commonly owned United States Patent No. 4,302,566 (Karol), which designated 0.91 g/cm3 as the upper boundary for very low density polyethylenes. The first family '769 patent states that Karol teaches that:

In order to produce ethylene copolymers having a density below 0.91 g/cm3 by means of a fluid bed process, it is necessary to employ gaseous reaction mixtures containing higher amounts of higher alpha olefin comonomer vis-a-vis the amount of ethylene employed, than are employed to produce copolymers having a density of greater than 0.91 g/cm3.

'769 patent, col. 2, lines 53-59. Another patent referenced in the first family specifications, United States Patent No. 4,302,565 (Goeke), contains a similar process description. ANC argues that these usages of "below 0.91" and "greater than 0.91" are meaningless if 0.91 g/cm3 were intended to have a range as high as the 0.914 g/cm3 holding of the district court. Thus ANC argues that a scope significantly higher than 0.910 g/cm3 is not a reasonable construction of the usage "below about 0.91" in the claims of the first family.

Viskase disagrees, and points out that the second family '784 patent, filed one month after filing of the '769 application, defines "very low density" as reaching to "about 0.915 g/cm3":

Those copolymers having a density in the range of from about 0.86 to about 0.915 grams per cubic centimeter are commonly referred to as a very low density polyethylene, while those having a density greater than about 0.915 grams per cubic centimeter are commonly referred to as linear low density polyethylene.

'784 patent, col. 9, lines 14-20. Viskase states that the scientific literature accepts this higher figure, and that in all events the inventors made clear the definition they intended. ANC responds with other sources that draw a line at 0.910, citing Ferguson Patent No. 4,640,856, filed in 1985, which defines very low density polyethylenes as having a density "of less than 0.910 [while] conventional polyethylenes and LLDPEs [linear low density polyethylenes] have densities as low as 0.912."

ANC stresses that during prosecution of the first family, Viskase itself treated 0.91 as if it were 0.910. In discussing Shibata United States Patent No. 4,429,079 when Viskase cited this reference to the patent examiner, Viskase recognized that Shibata describes a multilayer heat-shrinkable composition using a linear low density polyethylene copolymer (Shibata's "A" copolymer) having a density range of "0.910 to 0.940 g/cm3." Viskase distinguished its products from Shibata by stating:

The "A" copolymer is clearly not pertinent to the present application in that it does not have a density below about 0.910 g/cm3 as defined in all pending claims.

We agree with ANC that this statement is highly relevant, for it relies on the third significant figure of the 0.910 g/cm3 density to distinguish the first family densities, claimed as "below about 0.91 g/cm3," from the prior art densities of 0.910 to

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0.940 g/cm3.

Viskase states that its use of 0.910 in distinguishing the first family from the Shibata product was an error by its patent attorney, and points out that 0.910 does not appear in any of the first family specifications or claims or elsewhere in the prosecution history. An asserted error in the prosecution record must be viewed as are errors in documents in general; that is, would it have been apparent to a person experienced in this technology that an error was made, or at least that the information should not be relied upon. See Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc., 249 F.3d 1341, 1348, 58 U.S.P.Q.2D (BNA) 1737, 1742-43 (Fed. Cir. 2001). The district court agreed with Viskase, and ruled that this isolated usage of the density figure 0.910 did not outweigh the extensive usages of 0.91 in the first family patents. The court declined to construe "below about 0.91 g/cm3" as meaning below 0.910 g/cm3 or below about 0.910 g/cm3.

We do not share the district court's conclusion. It is clear that the prosecution argument to distinguish Shibata was presented as necessary to draw a line in this crowded field of technology, and that Viskase drew the line between "very low density" and other polyethylenes at 0.910 g/cm3. Although we agree that this line is not used in all cases, for example in the second family patents, it is reflected in several cited references including the Goeke and Karol patents of common ownership. In addition, the first family specifications illustrate use of the third decimal place for the densities of other classes of polyethylenes, as shown in Table 3 in the '769 patent:

Resin Type	Density
VLDPE	0.90
LDPE	0.917
LLDPE	0.918
EVA-13	0.940
EVA-5	0.920
IONOMER	0.950

'769 patent, col. 12, lines 15-25.

Although Viskase argues that the evidence does not establish a dividing line between VLDPE and LDPE at precisely 0.910 g/cm3, we conclude that Viskase itself set the boundary at 0.910 g/cm3 for the first family patents. A person experienced in this field could reasonably be expected to rely on this specificity in the prosecution record, in view of the other references that use 0.910 to distinguish very low from linear low density polyethylenes, and considering Ferguson's statement that 0.912 is the density of linear low density, not very low density, polyethylenes. At a minimum, we conclude that a person knowledgeable in the field of polyethylene copolymers, reading the first family specifications and prosecution histories, would not view "below about 0.91" as extending to an upper limit of 0.914. Thus, we hold that the correct construction of the claims of the first family patents is that "below about 0.91 g/cm3" means "below about 0.910 g/cm3." We need not decide what range is reasonably encompassed in the "about" in "about 0.910," for in all events it can not reach films having a density of 0.912, a product at issue in this suit.
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1. Less than about one percent, by weight, protein

The term "less than about one percent, by weight, protein" appears in claims 6, 8, and 9 of the '540 Patent and claim 5 of the '972 Patent. Claim 8 of the '540 Patent provides an example of the term's use: "Whole glucan particles derived from yeast cells and having substantially the in vivo glucan morphology, said glucan particles containing less than about one percent, by weight, protein and being spherical in shape with an average particle size of from about 2 to about 10 microns." Plaintiffs assert that the term should be construed as "glucan particles containing less than about one percent, by weight, protein." Immudyne contends that the Court should construe the limitation as "1.4% or less, by weight, protein."

The Federal Circuit has repeatedly stated that use of a term such as "about" avoids a "strict numerical boundary to the specified parameter" and that the range "must be interpreted in its technological and stylistic context." Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1355-56 (Fed. Cir.), cert. denied, 2007 U.S. LEXIS 12376, 76 U.S.L.W. 3274 (2007); Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326-28

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(Fed. Cir. 2007); Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217-18 (Fed. Cir. 1995). Neither the claims nor the specifications illuminate the limit that "about" imparts to "one percent, by weight, protein." 2 No variation from the limitation "less than about one percent, by weight, protein" appears in the '972 Patent's and the '540 Patent's claims. Cf. Ortho-McNeil Pharm., 476 F.3d at 1327. The specifications do not provide a basis to precisely determine the permissible upward deviation from one percent, though they indicate that it is small. Protein is characterized as an "undesirable contaminant[] which affect[s] the biological and hydrodynamic properties of the whole glucan particles." '540 Patent, col. 4, l. 67 to col. 5, l. 2; '972 Patent, col. 4, ll. 65-68. The preferred practice is to remove substantially all protein:

Preferably, the aqueous hydroxide digestion step is carried out by a series of contacting steps so that the amount of residual contaminants such as proteins are less than if only one contacting step is utilized. In other words, it is desirable to remove substantially all of the protein material from the cell. Preferably such removal is carried out to such an extent that less than one percent of the protein remains with the insoluble cell wall glucan particles. . . . The digested glucan particles can be, if necessary, subjected to further washings and extraction to reduce the protein and contaminant level to the preferred amounts hereinbefore indicated.

'540 Patent, col. 5, l. 52 to col. 6, l. 2; '972 Patent, col. 5 ll. 50-68. Highlighting the purity of the glucan, the specifications later reiterate the claim term:

The whole glucan particles obtained from the present process are comprised of highly pure glucan, which consists essentially of [beta] (1-6) and [beta] (1-3) linked glucan. The whole glucan particles contain very little contamination from protein and glycogen. Preferably, the whole glucan particles . . . contain . . . approximately 1% by weight protein . . . .

'540 Patent, col. 6, ll. 28-36; '972 Patent, col. 6, ll. 26-34.

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2 In their reply memorandum, Plaintiffs state: "Nothing in the intrinsic evidence of the '540 and '972 Patents imparts limited meaning to ['about']." Immudyne's reply memorandum, states that "[t]he intrinsic evidence does not compel a non-scientific meaning of 'about.'"

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Discerning no precise clarification of the meaning "about" in the intrinsic evidence, Immudyne asserts that the Court should apply general rounding principles to construe "about one percent." Immudyne contends that Plaintiffs "should be held to a clearly-defined range of protein" because they "pursu[ed] patent rights" and that Immudyne has "a right to know that the words used in a patent have some meaning." The Court declines to arbitrarily construe the term in the manner proposed by Immudyne:

Claims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention," that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

PPG Indus., 156 F.3d at 1355 (citation omitted); see Acumed LLC v. Stryker Corp., 483 F.3d 800, 806 (Fed. Cir.) ("[A] sound claim construction need not always purge every shred of ambiguity."), cert. denied, 169 L. Ed. 2d 393, 76 U.S.L.W. 3253 (2007). Without evidence that would provide a basis to specify the permissible deviation from one percent, the Court gives the term "about" its ordinary meaning of "approximately." See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1369-72 & n.7 (Fed. Cir. 2005). Thus, the Court construes "less than about one percent, by weight, protein" as "less than approximately one percent, by weight, protein."

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3. Particle size of about 1.0 micron or less

The parties dispute the construction of limitations regarding particle size that appear in claims 1 and 9 of the '015 Patent and claims 1 and 2 of the '719 Patent. Claim 1 of the '015 Patent is:

A method for improving the growth and survival of animals comprising:

administering an effective amount of a nutritional supplement to an animal, said nutritional supplement comprising water-insoluble yeast cell wall extract comprising purified beta (1,3) glucan having a particle size of about 1.0 micron or less.

Claim 9 of the '015 Patent claims "[t]he method of claim 1, wherein said particle size is about 0.20 microns or less." Claim 1 of the '719 Patent is "[a] composition suitable for nutritional supplementation comprising a water- insoluble yeast cell wall extract comprising substantially purified beta (1,3) glucans having a particle size of about 1.0 microns or less." Claim 2 of the '719 Patent claims "[t]he composition of claim 1 having a particle size of about 0.2 microns or less." Plaintiffs contend that the particle size limitations in claim 1 of the '719 Patent and claim 1 of the '015 Patent should be construed as: "The yeast cell wall extract includes beta (1,3) glucan particles that have a particle size of about 1 micron or less." Immunocorp and Biotec propose this construction: "The particles of the cell wall extract are ground to a fine size of about 1.0 microns or less." Immudyne asserts that the proper construction is "particle size of 1.4 microns or less." Plaintiffs propose this construction for claim 9 of the '015 Patent and claim 2 of the '719 Patent: "The yeast cell wall extract includes beta (1,3) glucan particles that have a particle size of about 0.20 microns or less." Immudyne offers "particle size of 0.24 microns or less."

The intrinsic evidence suggests a narrow construction of "about." The patents' claims include two distinct limitations regarding particle size. Noting that "beta (1,3) glucan may be isolated from yeast cell walls by conventional methods known by those of ordinary skill in the art," the specifications assert that "[a]n improved glucan product is obtained when the average particle size is preferably about 1.0 microns or less, and more preferably about 0.20 microns or less." '015 Patent, col. 2, ll. 25-32; '719 Patent, col. 2, ll. 26-33. The specifications later reiterate the size limitations that appear in the patent claims. Although the Court discerns that "about" has a narrow construction from the intrinsic evidence, there is no evidence that would permit the Court to specify a permissible deviation. Accordingly, the Court declines to arbitrarily construe "about" through use of rounding principles. Instead, the Court gives the term "about" its ordinary meaning of "approximately." See Merck, 395 F.3d at 1369-72 & n.7.

As to the proposal of Immunocorp and Biotec regarding grinding, the disputed terms do not explicitly contain a grinding limitation. Accordingly, Immunocorp and Biotec rely on the specifications and prosecution histories to support their proposal. In construing claims, a court must not import limitations from a patent's specification. In re Trans Tex. Holdings Corp., 498 F.3d 1290, 1299 (Fed. Cir. 2007); Phillips, 415 F.3d at 1323. In general, methods of manufacture disclosed in a specification do not limit product claims:

It is generally true . . . that product claims are not limited to the methods of manufacture disclosed in the specification and that "[t]he method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. . . . A novel product that meets the criteria of patentability is not limited to the process by which it was made." However, process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention.

Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1375 (Fed. Cir. 2007) (citation omitted). Immunocorp and Biotec contend that grinding is critical to the inventions.

Although the specifications of the '015 Patent and the '719 Patent repeatedly refer to "finely ground" or "fine grind" glucan, the specifications reveal that particle size rather than the process of grinding is essential. For instance, the Detailed Description of the Preferred Embodiment(s) states: "To obtain the desired smaller particle size, the mixture comprising the beta (1,3) glucan product is ground down using a blender or ball mill, for example." '015 Patent, col. 2, ll. 33-35; '719 Patent, col. 2, ll. 34-36. Under the subheading "Nutritional Supplementation," the detailed description reveals the benefits of

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a smaller particle size:

Both the fine grind and non- ground substantially purified beta (1,3) glucan, more preferably the fine grind glucan described herein, may be administered orally. Finely ground glucan may be administered parenterally. It is believed that upon oral administration, the smaller or finer particle sized glucan is more quickly dissolved in the gastrointestinal tract, and consequently more readily absorbed, as compared to a non- ground glucan product which comprises larger sized glucan particles. Toxic effects have not been detected. It is believed that a fine grind glucan is even more systematically effective than a soluble version. The preferred particle size of the fine grind glucan product is about 1.0 micron or less, and more preferably, 0.20 microns or less.

'015 Patent, col. 2, l. 64 to col. 3, l. 9; '719 Patent, col. 2, l. 65 to col. 3, l. 11.

During the prosecution of the '015 Patent, the examiner rejected claims "as being unpatentable over Schoenherr et al. (MacroGard Publication)":

Schoenherr et al. disclose the use of Beta 1,3 glucans as a nutritional supplement. The supplement is used as feed an various animals, and includes a teaching of its use on pigs and fish. The feed may be administered either orally or parenterally by injection . . . . Those of ordinary skill would have found it well within their skill to use such an additive on any number of animals given the animal models taught therein. However, Schoenherr et al. differs in that the particle size of the Beta 1,3 glucan is not taught.

However, given the general teaching of its art accepted use for the same method of nutritional supplementation, it would have been well within the skill of the ordinary practitioner to claim the instant formulation for its instantly claimed method of nutritional supplementation as taught by Schoenherr et al. Indeed, there are no unusual and/or unexpected results which would rebut the instant prima facie obviousness. It is therefore deemed that it would have been obvious to claim the instant method given the clear teaching of Schoenherr et al. to use beta 1,3-glucans as a nutritional supplement.

(Citations omitted.) The applicant first responded by distinguishing the particle size taught in the MacroGuard publication: "Clearly, the MacroGuard article teaches away from Applicant's invention. The MacroGuard articles teaches a particle size over a thousand times larger than the particle size claimed in the instant application." Summarizing the specification, the applicant next asserted that the application taught finely ground glucan particles, i.e., glucans having a fine particle size. The applicant continued by noting that the prior art does not teach use of particles of such a small size or grinding particles to such a small size. The applicant concluded by highlighting the advantages of use of the smaller particles. The examiner withdrew the obviousness rejection.

During the '719 Patent's prosecution, the examiner rejected claims "as being unpatentable over Jamas et al.":

Jamas et al. differs in that there is no disclosure of the claimed particle size. However, given the broad disclosure of the glucan particles derived from the yeast cell walls, and administration by the same art recognized routes as disclosed in Jamas et al., those of ordinary skill would have found it within their skill to modify the composition in any art recognized manner which would result in the similar therapeutic effects.

The applicant responded:

Jamas teaches what has long been believed in the industry, the necessity for a soluble glucan to avoid toxic effects. Jamas repeats the belief of the toxic effects of insoluble glucan products in his specification. Jamas does not teach, disclose or suggest the use of insoluble glucans, of any particle size, for nutritional purposes. Jamas did not solve and did not claim to solve the problem of presenting the insoluble molecule effectively in the digestive tract in order to be useful. The industry has long sought solubilizing solutions. Applicant, in contrast, has disclosed uses for a "fine grind" insoluble product that are surprising by their general beneficial effect.

The subject application is the first to teach that there is a particle size such that the insoluble glucan may be used advantageously and beneficially for nutritional purposes. . . .

In conclusion, Jamas does not teach or suggest use of insoluble glucans for nutritional purposes. This is true because

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Jamas did not appreciate that the insoluble glucan particle size could be limited so as to achieve significant performance in a valuable field where it was otherwise lacking.

The examiner agreed that the applicant's response overcame the rejection.

The Court's review of the specifications and prosecution histories reveals that the particle size itself, not the process of grinding, is essential to the inventions claimed in the '015 Patent and the '719 Patent. Although the specifications do not disclose methods other than grinding to obtain the small particle sizes, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Phillips, 415 F.3d at 1323. Accordingly, the Court declines to read grinding into the construction of the disputed terms.

For these reasons, the Court construes "a particle size of about 1.0 micron or less" in claim 1 of the '015 Patent and "a particle size of about 1.0 microns or less" in claim 1 of the '719 Patent as "a particle size of approximately 1.0 micron or less." The Court construes "said particle size is about 0.20 microns or less" in claim 9 of the '015 Patent as "a particle size of approximately 0.20 microns or less." The Court construes "a particle size of about 0.2 microns or less" in claim 2 of the '719 Patent as "a particle size of approximately 0.2 microns or less."
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A. "The Total Amount of Methylphenidate Hydrochloride Present Is About 10 To 40 mg"

Plaintiffs' Construction	Defendant's Construction
The term "about" should be given its ordinary and customary meaning of "approximately."	The total amount of methylphenidate hydrochloride present is very close to 10 to 40 mg (due to rounding or within measurement error).

The parties dispute the level of precision that the Court should impute to the word "about." Plaintiffs contends that the term "about" should be defined simply as "approximately," while Defendant contends that it should be understood more stringently as requiring precision within "rounding" or "measurement error."

Although the specification explains that "[a] typical dose is expected to be from about 10 to 40 mg of active drug," ('215 patent at 2:60-61), Defendant acknowledges that "nowhere else in the specification is the term 'about' used in conjunction with the amount of drug." (D.I. 40 at 13.) Thus, in support of their proposed construction, Defendant contends that "every description of the total dose of methylphenidate hydrochloride is from 10 mg to 40 mg and stated in 5 mg or 10 mg increments," which, according to Defendant, "shows that the variance permitted by the word 'about' must be less than the 5 mg increments in dosages shown in the specification." This, Defendant contends, further confirms that "the total amount of methylphenidate hydrochloride in the claimed capsule is limited to being very close to 10 to 40 mg with the variations outside that range due to rounding or within measurement error." (D.I. 40 at 13-14.) In addition, Defendant notes that although Plaintiff UCB listed the '215 patent in the Orange Book for 10, 20, 30, and 40 mg dosage forms, 1 it did not do so for the 50 and 60 mg dosage forms. This, Defendant contends, demonstrates that "a claim of patent infringement cannot reasonably be asserted against the 50 and 60 mg dosage strengths" and, as such, that the Court should adopt Defendant's proposed construction to preclude Plaintiffs from making such an infringement allegation. Defendant further notes that the "about 10 to 40 mg" limitation was added during prosecution in response to an examiner rejection, and that this also confirms that the claims cannot be understood to reach a 50 mg dosage form.

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1 Under the Hatch-Waxman statutory scheme for the approval of new and generic drugs, a pioneer drug manufacturer that has had its drug approved by the FDA must notify the FDA of all patents it owns "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). These patents are listed in an FDA publication commonly referred to as the "Orange

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Book."

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Plaintiff responds that the plain and ordinary meaning of the word "about" is "approximately" and that there is nothing in the specification that would alter this understanding. With regard to Defendant's position that the specification, by providing examples of dosage strengths separated by only 5 mg, distinguishes dosage forms that differ in strengths by 5 mg, Plaintiffs contend that the exemplary dosage strengths in the patent "provide no support for [Defendant's] position that "about 10 to 40 mg" must be defined to mean "very close to 10 to 40 mg with variations outside that range due to rounding or within measurement error." (D.I. 50 at 6.) As to Defendant's reliance on the prosecution history, Plaintiff contends that during prosecution there was no discussion of the word "about" and that, in these circumstances, there was no "clear and unmistakable" disavowal of claim scope or intention to otherwise limit the meaning of the word "about." (Id. at 4-5.) Finally, with regard to the fact that Plaintiff UCB declined to list the '215 patent in the Orange Book for the 50 and 60 mg dosage forms, Plaintiffs note that the failure to list a patent in the Orange Book does not foreclose its assertion against a generic and that, in any event, this is extrinsic evidence that has little bearing on how the term "about" should be construed.

"The word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular case." Pall Corp. v. Micron Separations, 66 F.3d 1211, 1217 (Fed. Cir. 1995). "The use of the word 'about,' avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context." Id. Courts should "thus consider how the term . . . was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter, and may be received from the inventor and others skilled in the field of the invention." Id.

Instructive here is the recent Federal Circuit decision Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1327-28 (Fed. Cir. 2007). In Ortho-McNeil, the Federal Circuit affirmed a district court's "narrow" construction of the term "about 1:5" as encompassing a range of ratios "no greater than 1:3.6 to 1:7.1." In so doing, the Federal Circuit noted a number of evidentiary hallmarks that supported the narrow construction, including (1) a "dichotomy" between the claimed ratio and broader ratios in other claims, (2) passages in the specification suggesting a narrow interpretation of "about" so as to avoid rendering similar ratios in other claims meaningless (3) language in the specification referring to ratios similar to the claimed ratio, and (4) expert witness testimony regarding statistical data in the patent that supported the narrow construction. Id.

The type of evidentiary hallmarks that supported a narrow construction of "about" in Ortho-Mcneil do not appear to be prevalent here. For instance, only one claim in the '215 patent refers to the claimed dosage range of "about 10 to 40 mg" of methylphenidate. Thus, there are no differences among claims that suggest a narrow interpretation of the word "about," and, similarly, there is no danger of rendering claim limitations meaningless through a broad construction of "about."

With regard to the specification, as the parties note, the 10 to 40 mg methylphenidate dosage range is referred to only once, and there is no discussion of alternative dosage ranges to suggest that the 10 to 40 mg dosage range should be understood narrowly. Although, as Defendant notes, the specification describes various exemplary dosage strengths within the 10 to 40 mg dosage range (i.e., 10 mg, 20 mg, 25 mg, and 30 mg), the Court sees nothing about these particular examples suggesting that the endpoints of the 10 to 40 mg dosage range should be limited in terms of "measurement error" or "rounding error," as Defendant requests. To the extent this evidence suggests a distinction among dosage forms that differ in strength by 5 mg, Defendant has not proposed a construction that meaningfully incorporates this concept. Defendant has not, for instance, proposed that the end points of the claimed dosage range have error bars of +/-2.5 mg. Likewise, with regard to extrinsic evidence, though Defendant notes that Plaintiff UCB declined to list the '215 patent in the Orange Book for the 50 and 60 mg dosage forms, Defendant fails to specifically explain how this supports their proposal to define the term "about" as referring to "measurement error." At most, this evidence perhaps suggests that the term "about 10 to 40 mg" should not be understood to encompass 50 and 60 mg, which may, in turn, suggest an error bar of +/-5 mg. But Defendant does not propose a construction along these lines either. Similarly, although the limitation "about 10 to 40 mg" was added to the claims during prosecution in response to a rejection, Defendant has not meaningfully explained how this calls for construing the term "about" in terms of "measurement error." In short, in the Court's view, there is a significant disconnect between the evidence relied upon by Defendant and its proposed construction.

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Although, in circumstances such as these, the Court may reject the parties' proposed constructions and formulate its own construction, the Court concludes that it would not be responsible to do so here. Because Defendant has not proposed constructions that genuinely reflect the evidence it relies upon, the parties have not, through their claim construction arguments, provided the Court with the necessary "technological facts" and "technologic and stylistic context" to confidently adopt any alternative construction of "about," including, for instance, constructions with specific numerical error bars. See Pall Corp., 66 F.3d at 1217. For instance, the factual record regarding Plaintiff's decision not to list the '215 patent in the Orange Book for the 50 and 60 mg dosage remains almost entirely undeveloped. Likewise, unlike Ortho-McNeil, where expert interpretation of statistical data in the specification bolstered a narrow construction of "about," Defendant provides no such expert witness testimony explaining how one of skill in the art would understand the specification's description of 10 mg, 20 mg, 25 mg, and 30 mg dosage strengths may limit the claims, if at all.

In these circumstances, the Court concludes that, in the claim term "about 10 to 40 mg," the word "about" should simply be construed to mean "approximately." See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (where, inter alia, "the patentee did not clearly redefine 'about' in the specification," holding "that the term 'about' should be given its ordinary and accepted meaning of 'approximately.'"); Unigene Labs., Inc. v. Apotex Inc., No. 06 CV. 5571 (RPP), 2008 U.S. Dist. LEXIS 66005, at *26-*27 (S.D.N.Y. Aug. 28, 2008) ("Without evidence, either intrinsic or extrinsic, that would provide a basis for construing the numerical limits of the term 'about 20 mM citric acid' in claim 19 of the '392 patent, the Court gives the word 'about' its ordinary meaning of 'approximately' and construes the claim term no further."). Accordingly, the Court will construe the claim term "the total amount of methylphenidate hydrochloride present is about 10 to 40 mg" to mean, as Plaintiffs contend, "the total amount of methylphenidate hydrochloride present is approximately 10 to 40 mg."

Noting that the word "approximately" is a claim term, Defendant, citing Helmsderfer v. Bobrick Washroom Equipment, Inc., 527 F.3d 1379, 1382 (Fed. Cir. 2008), contends that this construction is inappropriate because it improperly gives two different claim terms (i.e., "about" and "approximately") the same meaning. See Helmsderfer, 527 F.3d at 1382 ("[P]recedent instructs that different claim terms are presumed to have different meanings . . . ."). However, notwithstanding this consideration, without a more concrete basis for either Defendant's construction or some alternative construction of "about," the most appropriate construction of "about" is simply "its ordinary and accepted meaning of 'approximately'." Merck, 395 F.3d at 1372.
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F. About 100 IU

Aventis and Teva request construction of "about 100 IU" in claim 28 of the 618 patent 618 patent, 11 50-51. Aventis urges that the court not limit the phrase to a precise construction Teva posits that the phrase should be construed to encompass range values from 90 IU to 122 IU, the lowest and highest values reported in the examples contained in the 618 patent.

"About" is defined as "approximately" or "near" Webster's II New Riverside University Dictionary (1994). It has been interpreted as meaning "reasonably close to" CellNet Data Systems, Inc v Itron, Inc, 17 F Supp 2d 1100, 1114 (N D Cal 1998). Based on this plain and ordinary meaning, the court declines to limit the phrase "about" to a precise construction. Taking limitations from patent examples and importing them as claim limitations is in direct contravention to Federal Circuit precedent. See Unitherm Food Sys v Swift-Ecknch, Inc, 375 F.3d 1341, 1351 (Fed Cir 2004), Jeneric, 205 F.3d at 1381. The court does agree with Teva that it would be inappropriate to construe "about 100 IUs" to recognize only variability above 100 IU and ignore the variability below that value. Thus, the court construes "about 100 IU" as follows from some reasonably close number below 100 IU to some reasonably close number above 100 IU.
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C. The Meaning Of The Phrase "Weight Ratio Of Cyclosporin To Water Of About 1:300 To About 1:1500"

Novartis contends that the phrase "weight ratio of cyclosporin to water of about 1:300 to about 1:1500" should be construed

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to mean a "weight ratio of solid cyclosporin particles to water of 1:255 to 1:1725." (D.I. 298 at 2). According to Novartis, the term "about" in the disputed phrase allows for an actual range of plus or minus fifteen percent at each listed value. (D.I. 298 at 9). Specifically, Novartis contends that a person of ordinary skill in the art would use this figure because it is listed in the United States Pharmacopeia (hereinafter "USP"), a standard-setting body in the field of pharmacology. (D.I. 298 at 12).

Eon contends that the disputed phrase should be construed to mean a weight ratio of cyclosporin to water of 1:250 to 1:1549. (D.I. 302 at 4). Specifically, Eon contends that since the specification and prosecution history of the '382 Patent do not provide a specialized definition, the term "about" should be given its ordinary meaning in a mathematical context, whereby decimals are rounded up or down to the nearest integer according to numeric value. (D.I. 302 at 33). Furthermore, because the applicants' added the disputed phrase to Claim 1 in response to the Examiner's request for elaboration, Eon contends that Novartis is estopped from claiming a broader range of ratios than will approach exactness in quantity. (D.I. 302 at 35).

In construing the phrase "weight ratio of cyclosporin to water of about 1:300 to about 1:1500," the Court has considered the claim language, specification, and prosecution history of the '382 Patent. (D.I. 303, '382 Patent, A4, col. 4, lns. 54-57, A7, col. 9, lns. 21-28; D.I. 299 at PP3, 29; D.I. 303 at A262-63, A265). Based upon this review, the Court concludes that there is support for Eon's position. Although the drug monographs listed in the USP commonly include values in the fifteen percent range, this figure is not exclusive, as Novartis has recognized in its briefing. (See D. I. 298 at 12). Moreover, in response to an Office Action, which required the applicants to "provide more definite claim wording so as to clearly distinguish the present claims from that of the prior art" and to limit the claims to the invention for which "the disclosure is enabling," the applicants amended Claim 1 by adding the disputed phrase. (D.I. 303 at A 258-265). In view of these circumstances, the Court concludes that the term "about" in the disputed phrase must be given a more limited construction. Accordingly, the Court will construe the phrase "weight ratio of cyclosporin to water of about 1:300 to about 1:1500" to mean a weight ratio of cyclosporin to water of 1:250 to 1:1549

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1. "About 1:5"

a. The Parties' Positions

It is undisputed that, at a minimum, "about 1:5" is equivalent to "approximately 1:5," and therefore permits some amount of deviation from exactly 1:5. The parties' positions diverge, however, as to the amount of deviation "about" permits. Ortho-McNeil argues that "about 1:5" should encompass at least 1:3.6 to 1:7.1, because, in terms of efficacy, the ratios in this range are statistically equivalent to 1:5. Kali and Teva/Barr counter that "about" should only encompass minor deviations from 1:5 resulting from "measurement error," and that this range should span, at most, from 1:4.9 to 1:5.1. Before the Court examines the intrinsic and extrinsic evidence, two preliminary issues must first be addressed.

b. The Effect of the Federal Circuit's Decision in Ortho-McNeil v. Caraco

On January 19, 2007, the Court of Appeals for the Federal Circuit issued a decision construing the "about 1:5" limitation in Claim 6 of the '691 patent in a nearly identical Hatch-Waxman Act infringement case brought by Ortho-McNeil against another generic drug manufacturer. See Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs, Ltd., 476 F.3d 1321, 2007 U.S. App. LEXIS 1133 (Fed. Cir. Jan. 19, 2007). There, the Federal Circuit held that the District Court for the Eastern District of Michigan properly interpreted "about 1:5" to mean "approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1." Id. at *18-19.

Ortho-McNeil argues that this holding settles the claim construction dispute in this case, and definitively sets "about 1:5" as equal to 1:3.6 to 1:7.1. The Court disagrees. The facts and analysis of Caraco make clear that the Federal Circuit was not deciding the exact parameters of "about 1:5," but instead was only placing a ceiling on what range of ratios "about" could possibly represent. In Caraco, the defendant generic manufacturer's ANDA would have permitted it to sell a generic Ultracet with a weight ratio of 1:8.67; however, the ANDA also included a manufacturing variance that would have allowed the defendant to legally sell its generic with a weight ratio ranging as low n11 as 1:6.41. See Ortho-McNeil Pharm. Inc. v. Caraco Pharm. Labs., Ltd., No. 04-CV-73698, 2005 U.S. Dist. LEXIS 24998, at *2 (E.D. Mich. Oct. 19, 2005). Ortho-

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McNeil argued there, as it does here, that "about 1:5" encompasses at least 1:3.6 to 1:7.1, the range of ratios representing the statistical variation in efficacy of 1:5. Id. at *7-8. However, during the litigation, the defendant amended its ANDA to "cut its authorized manufacturing variability in half to a minimum of 1:7.5." Id. at *2-3. Thus, under the facts presented in Caraco, the Federal Circuit only needed to decide whether "about 1:5" could extend higher than 1:7.1, as urged in that case by Ortho-McNeil, n12 in order to determine whether there was literal infringement. Absent language in Caraco to the contrary, this Court will not assume that the Federal Circuit decided more. See NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1311 (Fed Cir. 2005) (stating that a court need only construe a claim term "to the extent necessary to resolve the controversy") (quoting Vivd Techs., Inc., 200 F.3d at 803); see also Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1219 (Fed. Cir. 1995) (construing "about 5:1" to "not include the [allegedly infringing] ratio of 4:1," without determining exactly how far "about" expands 5:1).

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n11 As the Federal Circuit did in Caraco, the Court here will use terminology that compares different ratios in terms of their second number. For example, even though the fraction 1:6.41 is greater than 1:8.67, the Court will call it "lesser" or "lower," because 6.41 is less than 8.67.

n12 See Caraco, 2005 U.S. Dist. LEXIS 24998, at *8 (describing how Ortho-McNeil argued before the District Court that the scope of "'about 1:5' necessarily extends somewhat beyond" 1:3.6 to 1.7.1, in an apparent attempt to encompass the 1:7.5 floor set by the defendant's amended ANDA).

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The Federal Circuit's analysis also indicates that it only decided whether the scope of "about 1:5" was broader, not equal to or narrower, than 1:3.6 to 1:7.1. First, Caraco simply held that "about 1:5" was "no greater" than 1:3.6 to 1:7.1, rather than using language indicating an equivalence to this range, such as "extends to" or "no greater and no lesser than." Second, Caraco's claim construction stressed that "the qualifier 'about' is narrow," and that it "was meant to encompass compositions very close to" 1:5, Caraco, 2007 U.S. App. LEXIS 1133, at *16-17 (emphases added), thus indicating that the Court was only concerned with whether the scope of "about 1:5" was broader than 1:3.6 to 1:7.1. Third, the Federal Circuit in Caraco never considered the defendant's argument there (and Defendants' argument in this case) that "about 1:5" should be construed more narrowly than 1:3.6 to 1:7.1 using measurement error. See Caraco, 2007 U.S. App. LEXIS 1133, at *5.

Finally, although the Caraco Court did rely in part on the opinion of Ortho-McNeil's expert, Donald R. Stanski, M.D., that "'about 1:5' . . . includes a ratio up to and including 1:7.1," Caraco, 2007 U.S. App. LEXIS 1133, at *18-19 (emphasis added), it did so only to undercut Ortho-McNeil's argument that "about 1:5" extends beyond 1:7.1, not to definitively state that "about 1:5" is equivalent to the full scope of 1:3.6 to 1:7.1. This is clearly how the District Court used Dr. Stanski's testimony in its analysis, when it explained that the "'[u]p to' 1:7.1," language Dr. Stanski used "would put an upper limit on the range, while [Ortho-McNeil's argument for] 'at least' 1:3.6 to 1:7.1 has no upper limit," and would "result[] in a meaningless and boundless construction." Caraco, 2005, U.S. Dist. LEXIS 24998, at *8-9. The Federal Circuit said that it "s[aw] no error in the district court's construction," and cited it approvingly. Caraco, 2007 U.S. App. LEXIS 1133, at *18.

The Court concludes that Caraco's holding that "about 1:5" extends "no greater than 1:3.6 to 1:7.1" did not answer whether the scope of "about 1:5" extends to a range narrower than 1:3.6 to 1:7.1. As a result Caraco does not settle the infringement issue here since Defendants' ANDAs would also permit them to legally sell their generic drug with a weight ratio as low as 1:6.41, and Defendants' have not voluntarily amended their ANDAs to limit this range. Thus, the Court must decide whether the meaning of "about 1:5" encompasses 1:6.41. This is the question the Court will address below.

c. Construing the Term "About"

The second preliminary issue the Court must address is Kali and Teva/Barr's suggestion that courts unvaryingly "interpret 'about' based on the imprecision inherent in measurement of the claimed element in question," (see, e.g., Kali Reply Br. at 7), and that therefore, this Court should do the same.

Not surprisingly, the proper interpretation of the word "about," when used in front of a numerical measurement in a patent claim, has been the subject of relatively frequent litigation before the Courts. See, e.g., Caraco, 2007 U.S. LEXIS 1133, at

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*18-19 (construing "about 1:5"); Merck, 395 F.3d at 1370 (interpreting "about 70 mg"); Pall, 66 F.3d at 1217-18 (interpreting "about 5:1 to about 7:1"); Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1455-56 (Fed Cir. 1988) (construing "about 10<8> liters/mole"); W.L. Gore & Assoc. Inc. v. Garlock, Inc., 842 F.2d 1275, 1280 (Fed. Cir. 1988) (construing "about 100% per second"). In support of their position, Kali and Teva/Barr cite Hybritech Inc. v. Abbott Laboratories, where the Federal Circuit, with little elaboration, affirmed a district court's construction of a claim requiring antibodies with an affinity of "at least about 10<8> liters/mole," as encompassing "two- to three-fold measurement errors inherent in affinity measurements." 849 F.2d at 1455.

The Federal Circuit has explained that "'the word 'about' does not have a universal meaning in patent claims, [and instead,] the meaning depends on the technological facts of the particular case.'" Caraco, 2007 U.S. App. LEXIS 1133, at *13 (quoting Pall, 66 F.3d at 1217). Therefore, the limitation "about" is not exempt from the Federal Circuit's instruction that the meaning of a claim limitation must be that which would be usual and customary to the person of ordinary skill in the particular art at the time of the particular invention. See Phillips, 415 F.3d at 1312-13. Presumably, the Federal Circuit used this same context-specific approach in Hybritech, and, on the basis of intrinsic and extrinsic evidence relevant to that particular invention, concluded that measurement error was the appropriate benchmark for defining "about." See Hybritech, 849 F.2d at 1455. In other cases, involving different technologies, claims, and specifications, "about" may mean something different. For instance, in Pall, the Federal Circuit construed "about 5:1" not to encompass a ratio of 4:1 because test data in the patent specification and testimony of the inventor showed that a nylon resin membrane with a methylene to amide ratio of 4:1 lacked the desirable properties present in the claimed 5:1 ratio. Id. at 1217-18. In other words, the extent of "about" was limited by what worked as well as 5:1. Thus, the Court rejects Defendants' suggestion that Hybritech created a per se rule that "about" is always consistent with "measurement error." The meaning of "about 1:5" is dictated primarily by the intrinsic evidence in this case, to which the Court now turns.

d. The Intrinsic Evidence

i. The '691 Patent Claims

The claims of the '691 patent provide the starting point for an examination of the intrinsic evidence. See Phillips, 415 F.3d at 1314. Those claims make clear that "about 1:5" was intended to be relatively narrow in scope because it is "distinctly claimed and distinguished from other broader weight ratio ranges in the patent," such as Claim 1 which contains the limitation: "a weight ratio from about 1:1 to about 1:1600." Caraco, 2007 U.S. App. LEXIS 1133, at *14-15. Besides Claim 6, only Claim 4, which claims "about 1:1," distinctly claims a single ratio as opposed to a range. Noting this, the Federal Circuit observed in Caraco that this is further evidence that "about" must be "narrow" because otherwise the scope of "about 1:5" would "encompass a range of ratios that could potentially render meaningless" the "about 1:1" limitation. Id. at *16-17.

Kali and Teva/Barr argue that the words of the claims support their measurement-error theory of claim construction. Defendants' position is that because the word "about" in the claim describes a weight ratio, "about" must be referring to imprecision in the measurement of the weights of tramadol and acetaminophen. Defendants argue further that, in contrast, Ortho-McNeil's claim construction theory (explained in detail below) is not supported by the words of the claims because it is based on animal testing data that does not appear in the claims.

Defendants are correct that the words of the claims do not refer to the test data, found in the specification, upon which Ortho-McNeil relies. But the claims also do not refer to errors in the measurement of the weights of tramadol and/or acetaminophen. There are two gaps in Defendants' position. First, the fact that "about" modifies weight ratios only informs the reader that some degree of variation in those ratios is permitted. The language says nothing about what standard shall determine the correct degree of that variation, and therefore makes it no more likely that the inventors intended that variation to reflect errors in measuring the weight of tramadol or acetaminophen as opposed to the statistical imprecision inherent in the method of using the specification's test data to find efficacy at that ratio, as urged by Ortho-McNeil. Both could cause variation in the weight ratios, and the words of the claims are silent as to both.

Second, imprecision in a weight ratio is not the same thing as imprecision in a measurement of the weight of the drugs that constitute that ratio. A measuring error will not always cause imprecision or variation in the corresponding weight ratio. If a scientist intended to create a drug with a 1:5 weight ratio containing 25 mg of tramadol and 125 mg of acetaminophen, but mistakenly measured 30 mg of tramadol and 150 mg of acetaminophen, the scientist still would have created a drug with precisely a 1:5 weight ratio. While such an error may be unlikely, its possibility illustrates that using "about" to describe a

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weight ratio does not necessarily refer to errors in measuring the weights of the drugs constituting that ratio.

In sum, the fact that "about" modifies weight ratios does not support Defendants' measurement error argument. It simply begs the question: what standard shall give meaning to the word "about"? Because the words of the claims do not answer this question, the Court will move on and examine the patent specification.

ii. The Specification

The Federal Circuit has described the patent specification as "the single best guide to the meaning of a disputed term." See Vitronics, 90 F.3d at 1582. It "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. (citing Markman, 52 F.3d at 979). The '691 patent specification does not explicitly define "about." Implicitly, however, the specification (1) supports a definition of "about" that encompasses the full extent of the variation inherent in the statistical method of determining whether tramadol/acetaminophen doses in certain weight ratios demonstrate efficacy, and (2) is wholly lacking in support for a definition linked to measurement error.

(a) Statistical Variation in Efficacy

According to the specification, the inventors only claimed weight ratios of tramadol and acetaminophen that demonstrated synergistic effects when administered to test mice. '691 patent, col. 2, ll. 55-67; col. 3, l. 63-col. 4, l. 6; col 8 ll. 38-68. The specification also explains how the testing was performed and charts the resulting data. The mice were administered precise doses of tramadol and acetaminophen in each weight ratio tested, for example, 1000:1, 1:1, 1:5, and 1:5.7. Each weight ratio was tested using different dosages of the drugs. For example, the mice received the drugs at a 1:5 weight ratio in three ways: (1) 2.5 mg of tramadol and 12.5 mg of acetaminophen; (2) 5 mg of tramadol and 20 mg of acetaminophen; and (3) 10 mg of tramadol and 50 mg of acetaminophen. At each dosage, the inventors recorded what number out of 30 test mice experienced pain relief. See '691 patent, cols. 9-10.

Using the resulting data, the inventors then statistically estimated how many milligrams of tramadol and acetaminophen must be administered in order for 50 percent of the 30 test mice to experience pain relief at each particular weight ratio. The resulting value is called the "median effective dose" of the weight ratio, or "ED50" for short. See '691 patent, col. 8 ll. 29-30 (explaining that the "ED50 [value] was estimated from the dose-response curve for a specific fixed-ratio" (emphasis added)); (Smith Inf. Rep., at pp. 8-9, PP 1-5.). n13 To illustrate, at 1:5, the test data found that 2.5 mg of tramadol and 12.5 mg of acetaminophen caused seven of 30 mice to experience pain relief; at 5 mg/25 mg, 18 n14 of 30 mice experienced pain relief; and at 10 mg/50 mg, all 30 mice experienced pain relief. '691 patent, cols. 9-10, Table 1. Using that data, the inventors "estimated" that in order for 50 percent of 30 test mice to experience pain relief, it would be necessary to administer 4 mg of tramadol and 19.8 mg of acetaminophen. See '691 patent, col. 8 ll. 29-30; cols. 9-10. Therefore, 4 mg/19.8 mg is the ED50 for tramadol/acetaminophen at a 1:5 weight ratio. The ED50 data points for each weight ratio tested by the inventors are plotted in a graph found at Figure 1 of the specification.

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n13 The Court finds the expert opinions of Dr. Stanski and Dr. Eric Smith helpful and persuasive in explaining some of the principles and terms of art appearing in the specification, and will rely on those opinions during its evaluation of the intrinsic evidence herein. See Markman, 52 F.3d at 980.

n14 Although the specification states that only 8 out of the 30 mice experienced pain relief at this level, Dr. Stanski's and Dr. Smith's expert reports state that this number should be 18 based on their calculations, and based on the calculations the inventors performed for each of the other ratios. They therefore conclude that the "8" must be a typographical error. (See Stanski Inf. Rep., at p. 6, P 8; Smith Inf. Rep., at p. 7, P 10.)

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Importantly, each ED50 value is only a statistical estimate, based upon the experimental data, of what the true ED50 value would be if it were possible to test an infinite number of animals at a particular dose. (See Smith Inf. Rep., at pp. 4-5, PP 2-4.) Obviously, only a finite number of mice can be tested, here 30. If further experiments were conducted, the result would be "a slightly different proportion of animals testing 'positive' or 'negative,'" for pain relief, and thus, the ED50 value

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estimated from those results would also vary. (See id., at p. 5, P 4.) To represent this uncertainty, Table 1 lists, and Figure 1 plots, the "95 percent confidence interval" of each weight ratio's ED50 values. '691 patent, Figure 1; col. 8, ll. 61-64; Table 1, cols. 9-10. "A confidence interval describes the variation in the estimate by using upper and lower values that represent a possible range of values that could be obtained from repeated experiments." (Smith Inf. Rep., at p. 5, P 4.) Therefore, a 95 percent confidence interval means that if the inventors' mice experiment was repeated 100 times, roughly 95 percent of results would fall within the 95 percent confidence interval ranges. (Id. at p. 5, P 4.)

The 95 percent confidence intervals for the 1:5 weight ratio's ED50 value (4.0 mg tramadol/19.8 mg acetaminophen) are 3.3 mg to 4.7 mg of tramadol, and 16.7 mg to 23.4 mg of acetaminophen. According to Ortho-McNeil's experts, Dr. Stanski, and Eric Smith, PhD., a range of weight ratios that are "statistically indistinguishable" from 1:5 can be discerned from these 95 percent confidence interval figures. (Smith Inf. Rep., at pp. 24-25, PP 1-3; Stanski Inf. Rep., at pp. 5-7, PP 7, 10, 12.) The low end of the ratio range is determined by combining the lowest acetaminophen weight, 16.7 mg, with the highest tramadol weight, 4.7 mg. This combination results in a weight ratio of 1:3.6. The high end is then determined by combining the highest acetaminophen weight, 23.4 mg, with the lowest tramadol weight, 3.3 mg. This results in a weight ratio of 1:7.1. Thus, in Dr. Stanski's and Dr. Smith's opinions, the data in the specification demonstrates that a 1:5 weight ratio is statistically indistinguishable from a range of 1:3.6 to 1:7.1. (Smith Inf. Rep., at p. 24, P 1 n15; Stanski Inf. Rep., at p. 6, P 7; p. 7, P 10, 12.) A person of skill in the art of analgesic drugs reading this data would find, Dr. Stanski concludes, that "about" encompasses this "statistical variation in efficacy" of the 1:5 weight ratio, and therefore, "'about 1:5' would not be statistically different from a ratio up to and including 1:7.1 and a ratio down to and including 1:3.6." (Stanski Inf. Rep., at p. 6, P 7; p. 7, P 12 (emphases added).)

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n15 Dr. Smith's report actually claims that 1:3.55 to 1:7.09 is encompassed by "about 1:5." Dr. Stanski explained in his report that this only differs from his own 1:3.6 to 1:7.1 range because he chose to round to the first decimal place.

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Defendants seek to discredit Ortho-McNeil's theory of claim construction as mere manufactured "statistical machinations" (Kali Supp. Br. at p. 10.), and "statistical gymnastics," (Teva/Barr Reply Br. at p. 2.). However, Ortho-McNeil's expert states that the methodology used by the inventors is not novel in the pharmaceutical industry. (Smith Inf. Rep., at p. 8, P 3.) Defendants do not offer extrinsic evidence to the contrary, and as explained further below, do not offer a more persuasive reading of the intrinsic evidence. Despite the use of data and statistics, Plaintiff's claim construction theory is not as complicated as Defendants would have it seem: the patent teaches that the inventors claimed 1:5 because it demonstrated efficacy, and, according to Plaintiff's experts, the patent data proving 1:5's efficacy also shows that the ratios 1:3.6 through 1:7.1 would, statistically speaking, demonstrate the same efficacy as 1:5. Thus, the Court concludes that this range of ratios offers a sound basis, grounded in the patent specification, for measuring the full breadth of "about 1:5." In contrast, Defendants have failed to show any reason, supported by the patent specification or otherwise, why "about" was intended to represent variation caused by measurement error.

(b) Measurement Error

Measurement error is not mentioned in any manner in the specification. This omission is significant, in light of the fact that the specification carefully details how the inventors prepared the tramadol/acetaminophen combinations administered to mice for testing. See '691 patent, col. 5, ll. 39-61; col. 6, ll. 32-52. If the occurrence of measurement errors were important enough, or common enough, that the inventors felt the need to represent the variation created by such errors with the word "about" in the patent claims, one would think such errors would be accounted for in the specification's description of how the drug is prepared and measured for administration. Instead, the specification's description uses precise measurements. For example, in describing how the drugs at a 1:50 ratio were prepared, the specification states that

400 mg of [acetaminophen] as the free base is suspended with 10 mL of the 8 mg tramadol solution and 2 drops of TWEEN 80, a pharmacological dispersant, manufactured by Fisher Scientific Company, to yield the 1:50 ratio, i.e., (8 mg: 400 mg) combination per 10 mL of water.

'691 patent, col. 5, ll. 54-59. There is no mention of any variation in the amounts of tramadol or acetaminophen

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administered to the mice, with the word "about" or otherwise. Indeed, as Kali and Teva/Barr point out, the specification demonstrates that the inventors were capable of measuring the weight of the drugs with accuracy up to at least a hundred-thousandth of a milligram. See '691 patent, cols. 9-10 (stating that, at a weight ratio of 1:800, the inventors administered 0.03125 mg of tramadol to the test mice). Defendants argue that this precision proves that "about" should at most represent a one-tenth of decimal point variation from 1:5, i.e., 1:4.9 to 1:5.1. However, this argument prematurely assumes that measurement error has already been established as the guidepost for measuring the variation represented by "about." It has not. Moreover, it also assumes that measurement errors are made. Simply because the data shows that the inventors could accurately measure tramadol to the fifth decimal place, in no way suggests that the inventors could not also do so to the sixth, seventh, or twentieth decimal places. Instead of proving that minute measurement errors should guide the meaning of "about," the precision measurements shown in the specification suggest that there were no imprecisions at all in weights of the drugs administered to the test rats. Even if measurement errors are made, the absence of any reference to them in the specification suggests that such errors were not contemplated by the inventors. As a result, a person of ordinary skill reading the patent would not contemplate that "about 1:5" refers to imprecision resulting from measurement errors.

Kali and Teva/Barr point out that the specification states that, in addition to testing tramadol and acetaminophen at a 1:5 weight ratio, the inventors also tested a 1:5.7 weight ratio. From this, Defendants argue that "about 1:5" cannot extend to 1:5.7 because the inventors recognized 1:5.7 and 1:5 as distinct ratios. This argument overlooks that, unlike the '691 patent's claims, the specification's test data does not use the word "about" before its tested ratios. Therefore, the specification does not show that "about 1:5" in Claim 6 does not encompass 1:5.7; it only shows that the inventors considered exactly 1:5 to be distinct from exactly 1:5.7 for testing purposes. Furthermore, the fact that 1:5.7 was tested and ultimately not claimed, if anything, could suggest that the inventors thought that "about 1:5" already encompassed 1:5.7, and that therefore it was unnecessary to separately claim this data point. This is especially so in light of the test data, which shows that the 95 percent confidence intervals for the ED50 values of 1:5 (3.3-4.7 mg tramadol / 16.7-23.4 mg acetaminophen) encompass the ED50 values for 1:5.7 (4.1 mg tramadol / 23.3 mg acetaminophen). '691 patent, cols. 9-10, Table 1. Thus, Defendants' argument based on testing at a ratio of 1:5.7 further supports Ortho-McNeil's construction of "about 1:5."

In conclusion, the Court finds no basis in the intrinsic n16 or extrinsic evidence for using measurement error as a guide for construing the scope of "about 1:5." In contrast, the Court finds that the statistical variation in efficacy provides an appropriate benchmark. As explained above, the Federal Circuit in Caraco used this standard to set a ceiling for "about 1:5." This Court finds that it provides a floor as well, and holds that "about 1:5" encompasses ratios up to and including 1:7.1 and ratios down to and including 1:3.6.

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n16 Neither party argues that the prosecution history of the '691 patent sheds light on the proper interpretation of "about 1:5."

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I. Construction of Claim 6

Claim 6 includes four limitations: (1) "pharmaceutical composition"; (2) "a tramadol material"; (3) "acetaminophen"; and (4) a "weight ratio of the tramadol material to acetaminophen" of "about 1:5." Caraco does not contest the first three limitations of Claim 6, therefore the fourth limitation is the only issue for purposes of summary judgment.

To interpret a claim limitation, the Court uses the perspective of "a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). The claims are of primary importance, and "the words of a claim are generally given their ordinary and customary meaning." Id. at 1312. The specification is the best guide to the meaning of a disputed term, though extrinsic evidence in the form of expert testimony can be useful to provide background on the technology at issue or to establish that a term has a particular meaning in the pertinent field. Id. at 1315, 1318.

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The term "about" is commonly used in patent claims to broaden numerical limitations and must be construed in the light of the specific facts of each case. E.g., Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of the word 'about,' avoids a strict numerical boundary to the specified parameter."). The term "about" is defined as meaning "approximately" in the Oxford English Dictionary, and this meaning has also been used in some cases by the Federal Circuit Court. See, Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1369-70 (Fed. Cir. 2005).

Ortho's position is that a person of skill in the art would evaluate the animal testing data in the patent to ascertain the degree of variability associated with the term "about". Table 1 and Figure 1 of the '691 patent display ED50 values that show the amount of a combined dose of tramadol and acetaminophen needed to provide pain relief in 50% of the test subjects (i.e., mice). Ortho's experts read Table 1 and Figure 1 to reveal that combinations containing between 3.3 and 4.7 mg/kg of tramadol and between 16.7 and 23.4 mg/kg of acetaminophen (i.e., ratios of 1:3.6 to 1:7.1) are statistically indistinguishable from the tested combination at a ratio of 1:5 in yielding pain relief in 50% of the test subjects. According to Ortho's experts, one of ordinary skill in the art would conclude that "about 1:5" includes a range of ratios that "extends up to and includes 1:7.1." This opinion is given by Donald R. Stanski, M.D. and is confirmed by Eric Smith, PhD. (Stanski Inf. Rep., p. 2, p. 7, P 12; Smith Inf. Rep. p. 25). These ranges are termed 95% confidence levels, indicating the range within which the tested ED50 value would fall 95% of the time if the mouse tests were repeated. Therefore, Ortho concludes that the scope of the limitation "about 1:5" necessarily extends somewhat beyond the range described.

Each of the claims of the '691 Patent that claim a weight ratio use the term "about" preceding the ratio. While many of these ratios are stated as ranges, Claim 6 is not. Obviously the drafters of the patent were able to state weight ratios as ranges when they wanted to. Furthermore, the repeated use of the term "about" indicates contemplation of minor measuring errors. This conclusion is further supported by the fact that the phrase "about 1:5" describes weight ratios and nowhere specifies confidence level ratios or statistically equivalent ratios.

In patent infringement litigation taking place in New Jersey, Ortho has contended that a weight ratio of about 1:5 constitutes a ratio range of "at least" 1:3.6 to 1:7.1. The words "at least" preceding a range of numbers defining the term "about 1:5" results in a meaningless and boundless construction. Such a construction would clearly run into the prior art because the Flick patent's 1:10 ratio is "at least" 1:7.1. In addition, Ortho's expert Dr. Stanski stated that a person skilled in the art would interpret the ratio of "about 1:5" to include compositions where the ratio "extends up to and includes 1:7.1." (Stanski Infringement Rep. at P 12). "Up to" 1:7.1 would put an upper limit on the range, while "at least" 1:3.6 to 1:7.1 has no upper limit.

The Federal Circuit opines that expert testimony, which is "generated at the time of and for the purpose of litigation," is "less reliable" than the patent itself in defining claim terms. Phillips, 415 F.3d at 1318. Expert testimony should be rejected when it "is clearly at odds with the claim construction mandated by the claims themselves . . . ." Id. Claim 6 refers to a "weight ratio of about 1:5", yet Dr. Stanski argues that defining "about 1:5" requires a statistical comparison of the pharmacological effect of various drug ratios in mice. First, Claim 6 does not refer to dosage combinations with "about" the same pharmacological profile as a weight ratio of 1:5. Second, nothing in the patent's specification suggests that defining "about 1:5" requires a statistical analysis of data concerning analgesic effect in mice. The patent repeatedly uses the term "about" to refer to weight measurements. ('691 Patent, col. 5, II. 5-11) (referring to "dosages" of "about 800mg/kg," "about . 3 to 200 mg/kg," and "about 10 to 6000 mg/kg/day"). Third, the patent distinguishes between weight ratios as close as 1:5 and 1:5.7 (id. at Figure 1), which contradicts Dr. Stanski's opinion that all ratios between 1:3.6 to 1:7.1 are the same as 1:5.

Taking into consideration all of the arguments contained in the parties' briefs, the Court construes the term "about 1:5" in Claim 6 to mean a weight ratio of approximately 1:5, encompassing a range of ratios of no greater than 1:3.6 to 1:7.1.
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B. Claim Construction

The central question in this case is the proper construction of the disputed claim limitation, "about 1:5." Although both the parties and the district court seem to agree that the term "about" means "approximately," the parties and the district court disagree over the numerical limits that that term imparts to the limitation "1:5" in this case.

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This court has looked at the meaning of the term "about," and similar qualifying words or phrases, in other cases and has developed an approach to the interpretation of such terms:

[T]he word "about" does not have a universal meaning in patent claims, . . . the meaning depends upon the technological facts of the particular case.

* * *

The use of the word "about," avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term . . . was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter . . . .

Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995) (citations omitted). See also Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed. Cir. 1996) (stating that "the usage [of the term 'about'] can usually be understood in light of the technology embodied by the invention"); Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556 (Fed. Cir. 1994) (discussing the criticality of the claimed ratio to the invention and whether or not one of ordinary skill in the art would have read the modifier "about" expansively in light of the intrinsic evidence).

We must focus, then, on the criticality of the 1:5 ratio to the invention in claim 6 of the '691 patent. The intrinsic evidence points to a meaning for the term "about 1:5" that is narrow because the 1:5 weight ratio, along with the 1:1 weight ratio, is distinctly claimed and distinguished from other broader weight ratio ranges in the patent. There are fifteen claims in the '691 patent, all of which use the term "about" to modify the weight ratio or weight ratio ranges of tramadol to acetaminophen. n4 '691 Patent, cols.11-12. There are two claims, claim 4 and disputed claim 6, that claim a single weight ratio; the other claims distinctly point out ranges of weight ratios. For example, independent claim 1 reads: "A pharmaceutical composition comprising a tramadol material and acetaminophen, wherein the ratio of the tramadol material to acetaminophen is a weight ratio from about 1:1 to about 1:1600." Id. col.11 ll.19-22. This leads to a conclusion that one of ordinary skill in the art would understand the inventors intended a range when they claimed one and something more precise when they did not.

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N4 This is identical to the treatment of weight ratios and weight ratio ranges in the '221 reissue patent. Both specific weight ratios and weight ratios in ranges are modified by the term "about." '221 Reissue Patent, cols.11-14.

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The criticality of the "about 1:5" parameter to the claimed invention is also supported by other intrinsic evidence. As noted, in the specification, the inventors disclose the following:
The [acetaminophen] and the tramadol material are generally present in a weight ratio of tramadol material to[acetaminophen] from about 1:1 to 1:1600. Certain ratios result in a composition which exhibits synergistic analgesic effects. For example, in a composition comprising a tramadol material and [acetaminophen], the ratio of tramadol material: [acetaminophen] is preferably from about 1:5 to 1:1600; and more preferably, from about 1:19 to 1:800.

The most preferred ratios are from about 1:19 to 1:50. Compositions of tramadol material and [acetaminophen] within these weight ratios have been shown to exhibit synergistic analgesic effects. In addition, the particular compositions wherein the ratio of the components are [sic] about 1:1 and about 1:5 are encompassed by the present invention.

Id. col.3 l.63 to col.4 l.8. These paragraphs suggest that the qualifier "about" is narrow because to find otherwise would allow the scope of the more specifically identified ratio, 1:5, to encompass a range of ratios that could potentially render meaningless another claim's limitation, namely the 1:1 limitation.

Furthermore, the data points from the experiments described in the specification support a conclusion that the more specifically identified ratio of 1:5 was meant to encompass compositions very close to that ratio. The experiments disclosed in the specification show data points for ratios of tramadol to acetaminophen in the lower ratio quadrant of 1:1, 1:3, 1:5,

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1:5.7, and 1:15. '691 Patent, col.7 l.49 to col.8 l.68; id. Fig. 1 & Table 1. Yet, the patentees chose to specifically claim ratios of 1:1 and 1:5. If the data suggested to the inventors that a range of ratios in this lower ratio quadrant was desirable, they could easily have claimed a ratio range of "about 1:1 to about 1:5," or even a ratio range of "about 1:3 to about 1:5," but they did not. Instead, they chose a specific data point for claim 6 of precisely 1:5. Moreover, the identification of the 1:5 ratio in both claim 6 and the specification is especially important when the only other specifically identified ratio is close to it, 1:1, and the other claims point to a broad range of ratios. This dichotomy between the specific ratio of 1:5 and the broader ratio ranges of the other claims points to a narrow scope for the "about 1:5" limitation.

As discussed above, the district court relied in part upon Ortho's expert evidence to arrive at its claim construction. Ortho's expert, Dr. Stanski, noted that the data in the patent shows a synergistic analgesic effect for many ratios tested. In addition, he noted that the patent discloses statistical variability in the measured responses for each ratio. Dr. Stanski stated that "[b]ased on that statistical variability and [his] expertise,[he] can use statistical analyses to determine confidence bounds for the data in the patent, and [is] thus able to determine an upper bound and lower bound for the 1:5 weight ratio." Dr. Stanski concluded that "the ratio of 'about 1:5' would not be statistically different from a ratio up to and including 1:7.1 and a ratio down to and including 1:3.6." In other words, Dr. Stanski opined that "about 1:5" means "about 1:5, which includes a ratio up to and including 1:7.1."

Considering the intrinsic and extrinsic evidence in this case, we see no error in the district court's construction of the term "about 1:5" to mean "approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1."
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2. "About 2 to about 4 minutes" and "about 190 [degrees] F. to about 205 [degrees] F."

Schreiber argues the time and temperature limitations separately, but we agree with Saputo that these claim terms are interdependent. At base, we are construing a recipe. Logic dictates that higher temperatures allow shorter cooking times while lower temperatures require longer in the oven; in other words, the two measurements are related. This, however, is as far as we follow Saputo's argument; based on the public record, we must construe the time and temperature ranges as Schreiber advocates.

Starting with the claim language, every single claim in Patent 728 teaches a cooking temperature of "about 190 [degrees] F. to about 205 [degrees] F." for either "about 3 minutes" or "about 2 minutes to about 4 minutes." The specification, however, consistently discloses "a temperature of about 150 [degrees] F. to about 300 [degrees]F., preferably at about 190 [degrees] F. to about 205 [degrees] F. . . . [for] about 30 seconds to about 10 minutes, preferably about 2 minutes to about 4 minutes." (Patent 728, col. 2, ll. 54-59; see also id. at col. 6, ll. 5-11.) Example 4 illustrates a recipe cooked "at about 170 [degrees] F. to about 180 [degrees] F.," but no example reveals a cooking time greater than "about three minutes."

The prosecution history is entirely unenlightening on the issue. Saputo does not point to any prior art that would limit the ranges to those stated in the claims, as opposed to those taught in the specification. Although Schreiber apparently attempted initially to include the broad time range in its claims, the record does not reveal why the attempt was abandoned. Finally, Patent 728 does not identify the time and temperature as "important factors" of the invention. (Patent 728, col. 2, ll. 19-63 (Summary of the Invention).)

Saputo's invocation of "common sense" is appealing at some level: when a recipe dictates two to four minutes, one does not expect to cook the batter for ten. Likewise, when the recipe states a cooking temperature of 190 [degrees] F. to 205 [degrees] F, setting the oven for 150 [degrees] or 300 [degrees] would be silly. But the recipe here is not strictly limited to the small ranges and, in fact, consistently teaches the broad ranges throughout the narrative description. Saputo refers to nothing in the public record supporting its contention that we should ignore the specification. Therefore, we construe "about 2 minutes to about 4 minute" to encompass a range of 30 seconds to ten minutes; "about 190 [degrees] F. to about 205 [degrees] F." includes 150 [degrees] F. to 300 [degrees] F. 7

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7 The parties agree that "about 3 minutes" includes two minutes and four minutes.

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B. "About" Claims

The word "about" is at the core of the debate over the next three disputed claim terms. Although the use of "about" in a patent claim obviously demonstrates a patentee's intent to avoid strict numerical boundaries, the parties clash about the breadth imposed on the specified ranges by its inclusion in Patent 728. Schreiber believes "about" must be read expansively; Saputo disagrees.

The Federal Circuit has provided guidance on the impact of "about" on claim construction. See, e.g., Modine Mfg. Co. v. International Trade Comm'n, 75 F.3d 1545, 1554 (Fed. Cir. 1996); Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995); Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1561 (Fed. Cir. 1994). "About" means "with some approach to exactness in quantity, number, or time: Approximately," Conopco, 46 F.3d at 1561 n.2 (quotation omitted); "approximately" means "reasonably close to," Quantum Corp. v. Rodime, Plc., 65 F.3d 1577, 1581 (Fed. Cir. 1995). On the other hand, "'about' must be given reasonable scope . . . . [and must] be understood in light of the technology embodied in the invention." Modine Mfg., 75 F.3d at 1554. In the end, the Federal Circuit appears to construe "about" much as it does other patent language -- by resort to the patent itself and the prosecution history. See Pall Corp., 66 F.3d at 1217 ("We thus consider how the term 'about 5:1 to about 7:1' was used in the patent specification, the prosecution history, and other claims."); Conopco, 46 F.3d at 1561 ("The '179 specification and prosecution history do not support the argument that the inventors used this term ['about'] differently from its ordinary meaning.").

1. "About 25%"

Schreiber concedes that the phrase "at least 25%," present in asserted Claims 32 and 44, constitutes an absolute floor of 25%. It insists, however, that "about 25%," as used in asserted Claims 10, 12-13, 16-17, 30-31, 33, 36, 38-39, and 42-43, means "greater than about 20%." Aside from the difficulty of including an ambiguous descriptor in a definition intended to provide a limit on an already ambiguous phrase, the public record prohibits such a broad interpretation of "about 25%."

Schreiber initially sought to patent an imitation cheese "containing at least about 20% by weight of dry, particulate rennet casein." (Saputo Ex. F, Serial No. 772, 567 Tab 1, Patent Application of Feb. 28, 1977, at 1 (Abstract of the Disclosure).) In its 1978 application, however, Schreiber not only described a German patent covering a cheese product "containing up to 20 weight percent of rennet casein," but also abandoned its claim to "about 20%" in favor of "at least about 25%." (Saputo Ex. F, Serial No. 877,071 Tab 1, Patent Application of Feb. 14, 1978, at 3-4.) The description of the German patent and use of "at least about 25%" survived the next 19 years to be included in Patent 728. (Patent 728, col. 1, l. 66 - col. 2, l. 2 (German patent description); id. col. 2, l. 23 ("about 25%").) Clearly Schreiber changed its position to avoid prior art.

Furthermore, after the patent examiner rejected the 1978 Patent Application, Schreiber answered the examiner's other prior art concerns:

> The Examiner's attention is courteously invited to the teachings of U.S. Patents No. 4,055,555 and No. 4,096,586 [Badertscher Patents] that expressly teach that . . . about 21.25 weight percent represents the theoretical upper limit for solvation. Inasmuch as the present invention contemplates at least about 25 weight percent . . . and prefers about 30 to about 45 percent by weight there can be no question whatever that the present invention is unobvious.

(Saputo Ex. F, Serial No. 877,071 Tab 3, Amendment of Apr. 17, 1979, at 4-5.) Again, Schreiber expressly disowned any claim to 21.25% and below for the purpose of making its invention "unobvious" in light of the Badertscher.

Schreiber now maintains that Badertscher's "theoretical" 21.25% could not actually have constituted prior art because hypothetical limits do not enable one skilled in the art to reproduce the product. Schreiber's argument, however, is to the wrong tribunal at the wrong time. If it was unhappy that the examiner considered the Badertscher patents prior art, it should have addressed the issue during the prosecution of Patents 800 and 728. Our task is not to correct alleged errors during the

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patent process; rather, we are interested in Schreiber's understanding of the claim terms as demonstrated by the patent process. Here, instead of arguing that the Badertscher patents were not prior art, Schreiber chose to distinguish them on the ground that "about 25%" does not mean "21.25%." Schreiber must live with that choice.

At this point Saputo argues only that Schreiber cannot recapture concentrations below 21.25%. We agree based on the prosecution history, but decline to delineate any more specific boundaries for "about 25%."
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The Competing Constructions

(a) "from about 4 to about 12 [nucleotide triplets] [L-amino acid residues]"

Plaintiffs construe this limitation, which is common to both claims, as encompassing lengths of from 3 to 13 random triplets. 3 Plaintiffs' argument focuses on the word "about" and its "clear warning" that exactitude is not being claimed. Plaintiffs' Response, at 5. Dyax's counter-construction centers on the consistent use by the patentee of the definite integers 4 and 12. "Nowhere in the specification did the patentee say that any integer within the range should be afforded anything other than its ordinary accustomed meaning. Indeed, in the specification, when the patentee wished to refer to an amino acid sequence of length 12, he used the number 12; when he wished to refer to a length of 7 amino acids he used the number 7; and when he wished to refer to a 5 amino acid sequence, he used the number 5." Dyax Brief, at 19. Thus, according to Dyax, "from about 4 to about 12" means from 4 to 12. 4

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3 Dyax disputes any requirement that the triplets be random. The limitation that the oligonucleotide sequences (or the corresponding peptide sequences) be "random" appears nowhere in the language of the disputed claims, although it does appear in a number of other claims of the patent. As plaintiffs acknowledge, courts should normally not introduce into a claim by interpretation "limitations that are explicitly contained in other claims." Caterpillar Tractor Co. v. Berco, S.p.A., 714 F.2d 1110, 1116 (Fed. Cir. 1983).

4 Dyax does not address the significance of the term "about" because of what I believe is a mistaken premise that the meaning of words of qualification has no relevance to a "literal" Markman construction, but "is more properly an issue relating to the availability or nonavailability of the doctrine of equivalents." Dyax Brief, at 25-26 n.**. On this point, plaintiffs are correct that "all the limitations of a claim must be considered meaningful," Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991), a principle of claims construction that Dyax elsewhere acknowledges in its brief.

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(b) "and wherein the sum of [corresponding peptide sequences] [claim 24] [said corresponding epitopic peptide sequences] [claim 34] [encoded by said oligonucleotide population] [claim 24] represents at least about 10% of all possible peptide sequences of said length"

While written slightly differently in the two claims, this limitation refers to the size of the peptide library needed to make the invention work. Plaintiffs offer no consistent construction of what is meant by "about 10% of all possible peptide sequences," but suggest that "10%" can consist of: (1) 300,000 (or perhaps 30,000) distinct members for any coded library of random peptides with a length in the range of 5 to 13 amino acid residues; (2) 16,000 (or perhaps 1,600) distinct members for any coded library of random peptides with a length of 4 amino acid residues; and (3) 80 (or perhaps 800) distinct members for any coded library of random peptides with a length of 3 amino acid residues. 5 Plaintiffs' Brief, at 11, 16. The limitation "all possible peptide sequences of said length" plaintiffs construe to mean "the complete range of possible epitopic peptide sequences … within the range of 3 to 13 L-amino acid residues consistent with the means by which the 'oligonucleotide population' was generated." Id., at 11.

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5 The suggested population figure of 80 tripeptides may be a mathematical error. It is possible that plaintiffs meant 800 rather than 80 as 20<3>/10 = 800. Plaintiffs' calculations for populations of tetrapeptides and pentapeptides are largely faithful to the formula 0.10 x L = 20<L>/10), reporting the accurate result of 20<4>/10 = 16,000 for tetrapeptides, and the approximately accurate result of 20<5>/10 = 300,000 for pentapeptides. Nonetheless, the parentheticals following the two calculations (suggesting the figures of 1,600 and 30,000 respectively) are consistent with the assertion that 10% in fact means 1%.

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According to Dyax, the 10% limitation requires that the total of the peptide sequences encoded by the oligonucleotide population encompass at least 10% of the possible peptide sequences of a single given length within the range of from 4 to 12 L-amino acids. "All possible peptide sequences of said length," Dyax construes to mean the number of sequences derived by the formula L = 20<L> where <L> represents the given length within the specified range of L-amino acid residues and 20 signifies the number of genetically encodeable amino acids. Thus, if L is 12, the possible number of sequences is 20<12> or 4.096 x 10<15>, which when divided by 10 yields a library of 4.096 x 10<14> members. Dyax Brief, at 13-14.

Analysis

The parties' dispute boils down to a basic difference in interpretation that plaintiffs accurately summarize as follows: "Dyax argues that [infringement] should be determined from the perspective of the size of the peptide library made, whereas plaintiffs' position is that infringement is determined by the size of the peptide library necessary to bind the desired target." Plaintiffs' Response, at 2. Plaintiffs, in other words, maintain that as Dr. Pieczenik refined his invention, he realized that "five amino acids [the pentapeptide] is a representative length of peptide sequences which can bind with differential specificity to an antibody." Plaintiffs' Brief, at 14 (emphasis in original). Moreover, "antibodies are now known to have specificities which can be competed by peptides in the range of 5-7 amino acids, with a mean in the range of around 5 amino acids." Plaintiffs' Response, at 10 (emphasis added). Thus, "the entire universe of antibodies is equivalent to the entire universe of epitopic peptides that are 5 amino acids long on average or 3.2 x 10<6> possible antibodies." Plaintiffs' Brief, at 15. Because "many of the encoded peptides will present sufficiently similar binding surfaces that a single antibody will react with any of them …. it is not necessary to have all, or even most, of the possible coding sequences represented." Id., at 15 (quoting from File History, at 202). In fact, "all possible antibodies will be found to bind specifically with one of the mixture of random peptides provided a) the peptides are 5-7 amino acid residues in length, and b) the mixture contains at least about 10% of all possible peptide sequences." Id. (quoting File History, at 200). Therefore a library of "about" 300,000 members is all that is required to identify the "universe" of possible antibody binding sites. Id.

This assertion is the crux of the dispute about the necessary size of the specified library because, as a matter of undisputed scientific fact, there are 20 naturally occurring amino acids. Thus, where the peptide length consists of 5 amino acid residues, the possible number of peptides is 20<5>, or more conventionally stated, 3.2 x 10<6>. Where, however, the length is 12 amino acid residues, the possible number of peptides is 20<12> or 4.096 x 10<15>. It follows that a library containing 10% of all possible peptide sequences where the length is 12 would contain 4.096 x 10<14> members, as Dr. Pieczenik himself pointed out to the PTO in correcting the examiner's assumption that the correct formula for calculating the possible number of peptide sequences where L is 12 is the inverse of 20<12>, or 12<20>. In traversing the examiner's rejection, Dr. Pieczenik gave the following example. "For a peptide having a sequence length of 12 (L = 12), each position having an equal probability of being one of the 20 natural amino acids (N = 20), the number of possible sequences is N<L> = 20<12>, which can be converted to 4.1 x 10<15>." Dyax Brief, at 21 (quoting File History, at 734). He went on to point out that the examiner's method resulted in a million-fold error on the high side. Id. (quoting File History, at 735). 6 The point is crucial because, as Dyax points out, "the peptides in [its] libraries are longer than 12 amino acids -- indeed, some are longer than 60 amino acids. And, Dyax's phage display libraries include far fewer than 10% of the possible peptide sequences for a selected peptide length." Dyax Brief, at 9. A library of 300,000 members would represent but 0.0000000073% of the possible number of sequences where L is 12, when the formula advocated by Dyax and used by Dr. Pieczenik in his illustration to the PTO is applied. See Table, Dyax Reply, at 5. None of the corresponding percentages for lengths 6 to 13, which range from 0.47% (6) to 0.00000000037% (13), could ever reasonably thought to be "about 10%," no matter how flexibly the limitation is to be read. It is therefore critical to an understanding of plaintiffs' position to trace the elements of the argument that the "said" in the phrase "all possible peptide sequences of said length," refers to pentapeptides.

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6 Plaintiffs maintain that Dr. Pieczenik was taken out of context and was referring to the correct method of calculating the number of theoretically possible sequences and not the number of sequences that are biochemically possible. Plaintiffs' Response, at 13-14. This distinction, however, appears nowhere in the exchange with the examiner.

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To the extent that plaintiffs' argument is based on the actual language of claims 24 and 34, it rests on the supposed difference between the meaning of "selected length" (the term used in the antecedent application) and the term "said length" (the term ultimately chosen). "Whereas selected refers to the random length selected a priori, said refers to the length of the random peptide sequence that, for example, binds to an antibody." 7 Plaintiffs' Response, at 8 (emphasis in original). This semantic change, plaintiffs argue, would have alerted an attentive reader of ordinary skill in the art, familiar with the "scientific presumption" that "antibodies are now known to have specificities which can be competed by peptides in the range of 5-7 amino acids, with a mean in the range of around 5 amino acids," to the fact that a pentapeptide library is sufficient to define all peptide sequences with lengths from 6 to 13 amino acid residues. Id., at 10. In other words, a library of 300,000 distinct figures (roughly 10% of 3.2 x 10<6>) would completely satisfy the 10% limitation in the claims. "Said" is a term used by patent drafters who (like many lawyers) are unexplainably uncomfortable with using the more colloquial "the" when referring back to previously recited claim elements. See Landis on Mechanics of Patent Claim Drafting (2001) § 23. Neither claim 24 nor claim 34 makes any antecedent reference to pentapeptides as the sequence defining the "said" length. The element referenced is rather "a length from about 4 to about 12 nucleotide triplets," that is, one of 9 (or 10) designated lengths with its corresponding peptide sequence. Pentapeptides are certainly one of these lengths, but not the only length referenced. The claims language, in other words, simply will not support the load bearing weight plaintiffs attempt to assign to the word "said."

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7 As Dyax points out, this assertion contradicts the specification of the patent, which teaches that "the invention features a discrete recombinant vector population of substantially identical autonomously replicating nucleic acid sequences including a structural gene and a population of oligonucleotide inserts therein, each insert containing a uniform length selected from between about 4 to about 12 nucleic acid coding triplets, preferably between 4 and 7, and most preferably five. '393 patent, Col. 4, Ins. 19-27 (emphasis added).

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Plaintiffs' prosecution file history and prior art arguments fare no better. Much emphasis is placed on the qualified disclosure in the original 1985 application that

> the size of the antibody recognition site corresponds to a peptide sequence in the range of between about 4 and about 12 amino acid residues … [and that] there are about three million (20<5>) different possible sequences of the twenty amino acid residues taken five at a time and about sixty million if the amino acid residues are taken six at a time. This finite number of peptide sequences may represent the full range of possible antibody recognition sites. Production and maintenance of a representative sample of the peptide sequences of the appropriate length provides the means (1) to screen any antibody of interest in order to determine the precise peptide sequence it binds to ….

Plaintiffs' Brief, at 12 (quoting File History, at 14-15). 8 From this, plaintiffs deduce that it would have been "clear" to one skilled in the art that the inventor had "recognized that random pentapeptides can adequately represent any random 12 amino acid sequence in terms of competitive binding to antibodies." Id., at 12-13. Why this is so is not explained in any meaningful way, other than by random citations to the discussion of the prior art in the original 1985 patent application, which when read in context, offer no support for plaintiffs' late blooming theory that the '363 patent teaches a universe of antibody binding sites bounded by pentapeptides. The citation to Geyson, et al., in the file history is a good example. It is clear in context that Geyson was cited to explain to the PTO why degeneracy (the phenomenon by which an antibody may recognize more than one peptide sequence) made it possible to construct a working population consisting of only 10% of the peptides of a given length rather than, as the examiner thought would be necessary, the entire peptide population associated with that length. It does not follow from the discussion of Geyson (or Dame, et al., the other principal prior art source cited) that the "prosecution file history make[s] clear to one skilled in the art that any coded library of random peptides with [a]

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length in the range of 5-13 amino acid residues and containing at least about 300,000 (e.g. 30,000 = 1%) distinct members is understood to mean an oligonucleotides population that represents at least about 10% of all possible peptide sequences of said length." Plaintiffs' Brief, at 15-16 (emphasis in original).

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8 As Dyax argues, the assertion that the range of 3 to 60 million peptides represents the universe of possible antibody recognition sites ignores antibodies that bind conformationally dependent epitopes "for which pentapeptides and hexapeptides cannot successfully compete in many circumstances." Dyax Brief, at 25 n*. According to Dyax, when these are considered the number of possible antibody recognition sites "far exceeds" the 3 to million figure posited by Dr. Pieczenik. Even if the 3 to 60 million figure is correct, plaintiffs do not explain why the absolute bottom of that range represents the operative number of desired peptides.

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Conclusion

The limitation establishing a library of peptide sequences representing "at least about 10% of all possible peptide sequences" of "from about 4 to about 12 L-amino acid residues" has one definite term -- "all possible" -- and two indefinite terms -- "at least about 10%" and "from about 4 to about 12." There is no indication in the patent specification that Dr. Pieczenik intended these phrases to convey any meaning other than their ordinary English connotation. Thus, "all possible" can only be understood to mean the universe of peptide sequences associated with L-amino acid lengths of "from about 4 to about 12." While I agree with plaintiffs that the term "about" is a term of deliberate imprecision that might fairly capture the integers 3 and 13 at the boundaries of "from about 4 to about 12," the term "all possible" can only mean in context the entire universe of what could occur, that is, the total number of naturally occurring sequences that can possibly be associated with the selected length, whether 20<3> or 20<13> or some other specified length within the asserted range of 3 to 13 amino acid residues.

* * *

ORDER

For the foregoing reasons, the court for Markman purposes will construe the disputed terms as follows. The limitation "from about 4 to about 12 nucleotide triplets," as used in claims 24 and 34 of the '363 patent, is sufficiently indefinite to include a range whose boundaries are delimited by 3 and 13. Similarly, the limitation "from about 4 to about 12 L-amino acid residues" means a range of from 3 to 13 of such residues. The limitation "represents at least about 10% of all possible peptide sequences" means approximately 10% or more of the possible peptide sequences of a given length within the range of 3 to 13 L-amino acids where the number of possible peptide sequences is equal to 20<L>. "Oligonucleotide" means a compound created by the condensation of typically fewer than 20 nucleotides.
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Nylon 46 Membranes

Three years after Pall filed this suit, MSI converted most of its membrane manufacture from nylon 66 to nylon 46. Nylon 46 is made not from hexamethylenediamine and adipic acid, but from tetramethylenediamine and adipic acid. Claim 34, quoted supra, does not name polytetramethylene adipamide (nylon 46). However, claim 116 of the Pall patent describes the polyamide resins in terms of their methylene to amide ratio:

116. A hydrophilic skinless alcohol-insoluble polyamide resin membrane sheet of alcohol-insoluble hydrophobic polyamide resin having a ratio CH2:NHCO of methylene CH2 to amide NHCO groups within the range of about 5:1 to about 7:1; capable when completely immersed in water of being wetted through within no more than one second, and reverting when heated to a temperature just below the softening temperature of the membrane to a hydrophobic material which is no longer wetted by water. [Emphasis added.]

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Nylon 66 has a ratio of methylene to amide groups of 5:1. Nylon 46 has a ratio of 4:1. Pall asserts that the term "about 5:1 to about 7:1" is infringed by the ratio of 4:1, either literally or by the doctrine of equivalents.

A. Literal Infringement

The district court, construing the term "about 5:1 to about 7:1," observed that the word "about" does not have a universal meaning in patent claims, and that the meaning depends on the technological facts of the particular case. We have so held. E.g., Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 821-22, 6 U.S.P.Q.2D (BNA) 2010, 2013 (Fed. Cir.), cert. denied, 488 U.S. 927, 102 L. Ed. 2d 330, 109 S. Ct. 312 (1988); W.L. Gore & Assoc. Inc. v. Garlock, Inc., 842 F.2d 1275, 1280, 6 U.S.P.Q.2D (BNA) 1277, 1282 (Fed. Cir. 1988).

The determination of whether the literal meaning or scope of "about 5:1 to about 7:1" includes 4:1 is a matter of claim construction, a question of law for decision de novo by this court. The use of the word "about," avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context. We thus consider how the term "about 5:1 to about 7:1" was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter, and may be received from the inventor and others skilled in the field of the invention. See Markman, 52 F.3d at 980, 34 U.S.P.Q.2D (BNA) at 1330 ("The court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent.") (quoting Seymour v. Osborne, 78 U.S. 516, 546, 20 L. Ed. 33, (1871)).

Dr. Pall, the inventor, explained his usage of "about 5:1 to about 7:1" as deriving from his tests of the performance of various nylon resin membranes. He explained that the ratios change in half integers, e.g., 7:1, 6.5:1, 6:1, etc., depending on the total number of methylene groups in the acid and amine components of the polymer. For example, each recurring unit of nylon 66 contains 10 methylene groups and 2 amide groups, for a ratio of 10:2, which reduces to 5:1. Each recurring unit of nylon 46 contains 8 methylene groups and 2 amide groups, for a ratio of 4:1. The Pall patent also illustrated a mixture having the ratio of 5.3:1.

Dr. Pall testified that he conducted experiments with several commercially available nylon resins. He found that a nylon resin having a methylene:amide ratio higher than 7:1 produced membranes that were less readily wettable, such that use of a wetting agent was required for optimum results. He therefore placed the upper limit of "about 7:1" in the claims. Dr. Pall stated that the only commercially available nylon resin with a ratio lower than 5:1 was a nylon with the ratio of 3:1, and that he made a membrane of the 3:1 nylon and found it to be soluble in alcohol and therefore unacceptable. No experiments were conducted with a nylon between 3:1 and 5:1, he testified, because none was commercially available. He placed the lower limit at "about 5:1." The reasons for these claim limitations also appear in the patent specification.

The district court found that Dr. Pall's use of the word "about" was "appropriate." We agree that the evidence showed that an exact limitation would have been inappropriate. However, the evidence showed that while a ratio of 7:1 was satisfactory, higher ratios were not, suggesting that the upper limit was close to 7:1, and did not extend to, for example, 8:1. At the lower ratios, although Dr. Pall conducted no tests with resins between 3:1 and 5:1, the 3:1 resin was clearly unsatisfactory. Reviewing all the evidence, the district court held that a literal reading of "about 5:1 to about 7:1" did not include the ratio of 4:1. On plenary review we reach the same conclusion.

Since the claim is construed more narrowly than would literally encompass the ratio of 4:1, the district court's finding that MSI's nylon 46 membranes do not literally infringe the Pall patent is affirmed.
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(2) "About"

Abbott and Ranbaxy dispute the meaning of "about 5 to about 50% by weight" in claims 4 and 7. Abbott contends that the use of the word "about" signals that the range of polymer weight is intended to permit some flexibility. Dr. Gilbert Banker,

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Abbott's pharmaceutical formulation expert, states that because the claim asserted whole numbers, rather than significant figures of less than a whole integer, n12 someone skilled in the art would understand the term "about" to include one integer on either side of the claimed range. Thus, the range would actually comprise from 4 to 51% by weight of pharmaceutically acceptable polymer. Ranbaxy argues that Abbott's "integer" approach is arbitrary and invalid because it stretches the claimed range too much. At the low end, a shift from "5% by weight" to "4% by weight" represents a 20% difference. Ranbaxy's second formulation expert, Dr. Robert Haluska, contends that a person of ordinary skill in the art would deem such a difference a material change. As support, Ranbaxy cites FDA guidelines for extended release formulations that state that varying the amount of release controlling excipient, such as a pharmaceutically acceptable polymer like HPMC, by more than 5% could have a "significant impact" on formulation quality and performance. Center for Drug Evaluation and Research, FDA, SUPAC-MR: Modified Release Solid Oral Dosage Forms 9-11 (Sept. 1997). Thus, Ranbaxy contends that "about" should mean no more than 5% variation in the claimed range. A 5% deviation from the lower end of the claimed range would result in a lower bound of 4.75%. Even if "about" were construed to allow the recited values to deviate by a significant figure, the resulting range would be only "4.5 to 50.5." Ranbaxy cites Abbott's expert's declaration for this proposition. Dr. Banker stated, "Importantly, claim 1 uses the number "5," rather than a more precise number such as 5.0 or 5.00. By providing only one significant figure, the patentees indicated that the value "5" -- even without the qualifier "about" -- could be as low as 4.5, since 4.5 rounds to 5." Banker Decl. P 68. But in the next paragraph of his declaration, Dr. Banker states that Abbott's use of "about" "indicated an intent to introduce an additional level of tolerance into the lower value of the range." Id. P 69. Thus, given the large percentage range defined by the claim, "'wiggle room' of 1% at each end of the range (i.e., 4 to 51%) is entirely reasonable." Id. Abbott asserts that the FDA regulations are irrelevant to patent claims but rather relate to permissible modifications to a specific FDA-approved drug. The patent claims, by contrast, are intended to encompass a large range of potential formulations.

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n12 "Significant figures are digits which have practical meaning. In some instances zeros are significant; in other instances they merely indicate the order of magnitude of the other digits by locating the decimal point... In any result the last significant figure is only approximate, but all preceding figures are accurate. When 473 mL is recorded, it is understood that the measurement had been made within +/- 0.5mL or somewhere between 472.5 and 473.5 mL." Remington: The Science and Practice of Pharmacy 75 (1995).

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The Federal Circuit has tangled with "about" before and stated that such a term "is not subject to... a precise construction," but rather "is dependent on the factual situation presented." W.L. Gore & Assocs. v. Garlock, Inc., 842 F.2d 1275, 1280 (Fed. Cir. 1988); see also Jeneric/Pentron, 205 F.3d at 1381. It is not clear to this Court from the evidence submitted that significant figures applies to percentages, such as the range in claims 4 and 7; rather significant figures appears to apply to figures such as measurements of mass and volume and serves to ensure an acceptable range of error in duplicating such measurements. The patent covers a pharmaceutical for use in humans, as the in vivo data disclosed from the pilot study makes clear. Such use requires FDA approval. The FDA regulations on which Ranbaxy relies were in effect in 1997, when the application for the '718 patent was filed; they would have been known to a person of ordinary skill in the art. This Court finds the reasoning behind the FDA regulations persuasive, although noting that the regulations themselves are addressed to post-approval products. Thus, this Court finds that the claim properly reads "[a] pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and from 4.75% to 52.5% by weight of pharmaceutically acceptable polymer."

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D. "About"

Finally, the parties dispute the meaning of the term "about," which is used by the '152 Patent to modify ingredient range limitations ("about" 5-75% starch) and temperature limitations (heating said formulation to a maximum temperature of "up to about 80 [degrees]"). Defendants ask the court to construe the term from "about" 5-75% starch to mean from 4.75% starch to 78.75% starch and to construe the 80 [degrees] limitation to mean a temperature that may approach, but not exceed, a maximum of 80 [degrees] C. MGPI, on the other hand, contends that the starch limitation should be construed to

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mean 2-80% by weight starch and that "to a maximum temperature of up to about 80 [degrees]" limitation should be read out of step [ii] altogether such that the formulation is heated so as to render the formulation homogeneous and flowable while avoiding heat denaturation of said grain protein.

a. "About 5-75% by Weight Starch"

Defendants contend that the "about" 5-75% starch limitation should be construed by taking 5% of the end-points, which equals 4.75% to 78.75% starch. In support of this argument, they cite Dr. Foegeding's testimony that a person of ordinary skill in the art would view the fact that a range has already been specified as including the essential levels of tolerance, and that "about" would be viewed by a person of ordinary skill to be in line with a 5% "rule of thumb" that is used in the normal course of practice by such a person and viewed as acceptable in an industrial situation.

MGPI contends that the court should disregard Dr. Foegeding's opinion as to the meaning of "about" because it is merely a number he pulled out of thin air with no relation to the technology at issue. According to MGPI, defendants are improperly fixated on providing a precise numerical range. MGPI argues that "about" qualifies a range which depends on the formulation and other factors so long as the prime functional goal--a formulation homogeneous and flowable without substantial heat denaturation of the protein--is met. MGPI contends that the lower limit (5%) of the range would lie in the range of 2% to 3% principally because it is advantageous at times to operate in that zone, and one skilled in the art of extrusion would expect the '152 Patent claims to cover that lower range.

The word "about" does not have a universal meaning in patent claims, as its meaning depends upon the technological facts of the case. Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007). The use of the word "about" avoids a strict numerical boundary, and requires the court to interpret the range in its technological and stylistic context. Central Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1354 (Fed. Cir. 2007). The court considers how the term was used in the patent specification, the prosecution history, and other claims. Id. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Id. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter. Id.

The intrinsic evidence points to a broad meaning of the term "about" in the "about 5-75% by weight starch" limitation. The claims themselves set forth broad ranges for the various components of the formulation. The formulation must include 20-85% grain protein, 5-75% starch, and 10-40% plasticizer. These amounts are set forth in essentially rounded numbers at 5% increments. This stands in stark contrast to the "at least about 0.01%" reducing agent, which indicates that the inventors deliberately chose not to be so precise about the relative quantity of the grain protein, starch, and plasticizer ingredients.

The specification also discusses the relative amounts of grain protein, starch, and plasticizer in 5% increments, and every one of those increments is qualified by the word "about." See generally '152 Patent, col. 2-3. For example, the specification refers to about 20-85% grain protein, and states that the formulation will "more preferably" include "from about 30-70% by weight grain protein." Id. col. 2, ll. 49-50. It explains that the grain would normally be provided as a mixture, and when such mixtures are used, typically they would comprise "at least about 50% by weight of the desired grain protein, and more preferably at least about 75% by weight thereof." Id. col. 2, ll. 60-62. As for starch, the specification states that the formulation should include "about 5-75% by weight starch, and more preferably from about 10-70% by weight thereof." Id. col. 2, ll. 65-66. The fact that the preferred 10-70% range is stated more narrowly than the claimed range of about 5-75% indicates that the claimed range truly represents the outer range of the parameter.

Focusing on the principle that "the claims themselves provide substantial guidance as to the meaning of particular claim terms," Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc), cert. denied, 546 U.S. 1170, 126 S. Ct. 1332, 164 L. Ed. 2d 49 (2006), the court returns to the fact that the relative quantities of ingredients are stated in 5% increments. In order to give meaning to these chosen claim terms and their relative degree of precision, the word "about" should not be read to extend the range of the claim downward such that the stated percentage is closer to 0% than it is to 5%, nor should it be extended upward such that the stated percentage is closer to 80% than it is to 75%. The criticality of the claimed range to the invention requires that the claim not be construed so broadly. Accordingly, the court construes the claim term "about 5-75% by weight starch" to mean approximately 5 5-75% by weight starch, but not less than 2.5% by weight starch nor more than 77.5% by weight starch.

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5 "About" is synonymous with "approximately." See Webster's Third New International Dictionary, Unabridged 5 (1986); Roget's II, The New Thesaurus 4 (1988); see, e.g., Ortho-McNeil Pharm., Inc., 476 F.3d at 1328 (finding no error in the district court's construction of the term "about 1:5" to mean "approximately 1:5, encompassing a range of ratios no greater than 1:3.6 to 1:7.1").

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In reaching this conclusion, the court notes that it finds both parties' expert opinions to be unhelpful in determining the criticality of the parameter. Dr. Foegeding explains that "about" implies a certain limited amount of tolerance of variance for the upper and lower points of the range, generally 5% or less of the endpoints. Thus, his 5% end-point rationale would require the court to construe the claim term to mean 4.75% starch to 78.75% starch. His rationale is that this 5% tolerance is "acceptable in an industrial situation." Dr. Foegeding does not, however, explain how this 5% end-point sets forth a critical parameter given the relevant technology which is at issue in the '152 Patent. The opinion of plaintiff's expert and the inventor, Dr. Bassi, is equally unhelpful. He proposes a tolerance of "very roughly 10-15% of the overall range." But, this would not work because it would put the low end of the starch range close to zero. He proposes to remedy this by simply using half of the low end of the tolerance computation, which would make the outer limit of the low end 2%. Ultimately, it appears to the court that the experts have picked rather arbitrary numbers without assisting the court with understanding how a person of ordinary skill in the art would understand the criticality of the stated parameters. Accordingly, the court construes this claim term, as stated above, based solely on the intrinsic evidence.

b. Heating . . . to a Maximum Temperature of Up To About 80 [degrees]

Defendants contend that the heating in subparagraphs [ii] of claims 1 and 24 of the '152 Patent should be construed to mean the temperature may approach, but not exceed, a maximum of 80 [degrees] Celsius. MGPI, on the other hand, argues that the "up to about 80 [degrees]" limitation should be broadly construed in light of the claim language that the formulation is to be heated so as to render the formulation homogeneous and flowable while avoiding heat denaturation of the grain protein. MGPI's argument is, essentially, that the court should disregard the 80 [degrees] limitation entirely so long as this stated purpose of the heating step is accomplished.

Once again, the court begins with the claim language. Step [ii] of claims 1 and 24 require heating the formulation to a maximum temperature of up to about 80 [degrees] "in order to render the formulation substantially homogeneous and flowable," avoiding "any substantial heat denaturation of said grain protein." '152 Patent, col. 5, ll. 64-66 & col. 7, ll. 34-36. The specification further explains as follows:

[I]t is important to maintain the temperature of the material within the extruder barrel below about 80 [degrees] C. to avoid heat denaturation of the protein content of the formulation. . . .

. . . As in the case of extrusion processing, the melt temperature inside the barrel of the injection molder should be maintained to a level of up to about 80 [degrees] C., and more preferably up to about 65 [degrees] C. (indeed, it is preferred that the initial formulation and forming steps be carried out so that the formulation experiences a maximum temperature of about 65 [degrees] C.).

'152 Patent, Col. 4, ll. 9-13, 16-22 (emphasis added).

The language underlined above was added during patent prosecution in order to distinguish Mullen. The remarks to that amendment explain that "in the extrusion process of the present invention [i.e., step [ii] of the claimed method], time and temperature conditions are carefully maintained so as to avoid any substantial heat denaturation of the grain protein." The temperature conditions disclosed in Mullen, however, are more predominantly concerned with the minimum temperatures for decomposing the protein which would seem to be more analogous with substantially denaturing the grain protein in step [iii] of the claimed method in the '152 Patent. For example, claim 1 of Mullen sets forth a process which includes, among other things, heating the composition to temperatures "of at least about 70 [degrees] C." '715 Patent, col. 9, ll. 9. Claim 13 discloses a process wherein "the plastic mass is heated to temperatures in the range of about 70 [degrees] to 190 [degrees] C." Id. col. 10, ll. 10-11. The specification discusses the same temperatures, id. col. 7, ll. 2-3, and the preferred embodiments of the invention set forth temperatures within these parameters, see generally id. col. 8 (setting forth

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temperatures in the three zones of the extruder ranging from 90 [degrees] in Zone 1 in each of the preferred embodiments, to 110 [degrees]-125 [degrees] in Zone II, to 143 [degrees]-161 [degrees] in Zone III). Thus, largely because the relevant temperatures disclosed in Mullen are more predominantly concerned with minimum temperatures for denaturing the protein in the extruder, referring to the temperatures set forth in Mullen is really not that helpful in determining a more precise parameter for the "up to about 80 [degrees]" maximum parameter set forth in the '152 Patent.

Dr. Bassi testified in his deposition that denaturation may start at about 75 [degrees] Celsius. He explained that as the temperature increases, the amount of denaturation is not linear, but rather is "logarithmic like an F16, just goes way up right away." Bassi Depo. at 162:19-21. He further explained that complete denaturation would occur at at least 120 [degrees] Celsius. At 88 [degrees] Celsius, the protein would not be substantially denatured, but the denaturation would be substantial enough "to make a difference in the flow characteristics and its -- and it being not very homogeneous." Id. at 164:7-9. He explained that 80 [degrees] is a guide, but "the most important part is also watching the characteristics of the extrudate." Id. at 169:1-2.

An excerpt from the book Food Chemistry further explains the impact of temperature on denaturation of protein:

Thermal denaturation of monomeric globular proteins is mostly reversible. For example, when many monomeric enzymes are heated above their denaturation temperatures, or even briefly held at 100 [degrees] C, and then are immediately cooled to room temperature, they fully regain their activities . . . . However, thermal denaturation can become irreversible when the protein is heated at 90-100 [degrees] C for a prolonged period even at a neutral pH.

Food Chemistry, supra, at 359.

This evidence clearly does not support defendants' argument that the court should construe the claim term to impose an 80 [degrees] cap. Their only evidence in support of that claim construction is Dr. Foegeding's opinion that a person of ordinary skill in the art would understand that it is critical that the temperature not exceed 80 [degrees] Celsius in order to maintain the grain protein of the formulation in substantially undenatured form. The court discounts Dr. Foegeding's proposed 80 [degrees] cap primarily because his opinion on this issue is too conclusory and unsupported to assist the court in understanding the relevant technology or educate the court about the nature of the invention.

Viewing the "up to about 80 [degrees]" limitation in light of the relevant technology, the criticality of this temperature parameter is to heat the formulation so that it is substantially homogeneous and flowable, while avoiding substantial heat denaturation of said protein. Mindful that various other factors can impact the rate and degree of denaturation as well as flow characteristics, the court believes that the claim term "up to about 80 [degrees]" must be construed with some degree of flexibility. But, at the same time, this limitation must be given some force because the specification explains that the formulation should more preferably be heated to a lower temperature of only up to about 65 [degrees]. The evidence indicates that heat denaturation can begin to occur as low as 75 [degrees] and that the amount of denaturation goes up logarithmically thereafter, and that the protein would be denatured enough to make a difference in the composition of the extrudate at 88 [degrees]. This suggests that the temperature of the formulation most certainly should not reach 88 [degrees]. This temperature is consistent with other evidence which indicates that denaturation can become irreversible when the protein is heated at 90-100 [degrees] for a prolonged period, and that the preferred embodiments set forth in Mullen disclose a low-end temperature of 90 [degrees] in the first zone of the extruder. Thus, it appears that a person of ordinary skill in the art would likely recognize the temperature of 88 [degrees] to be below the generally accepted temperatures where denaturation becomes substantial. In light of this record, then, the court believes that one of ordinary skill in the art would understand that the temperature of the formulation in step [ii] of the claimed method should not reach 88 [degrees]. The court wishes to emphasize that this temperature, of course, continues to be qualified by the remainder of the claim language that the formulation is heated so as to render it substantially homogeneous and flowable while avoiding substantial heat denaturation. Thus, the formulation could be heated beyond this point at a lower temperature. The court is only construing the claim limitation concerning the maximum temperature for heating the formulation in step [ii] of the claimed method. Accordingly, the court construes the claim term "up to about 80 [degrees]" to mean up to approximately 80 [degrees] but not to reach 88 [degrees].

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About 50-70%

The Court agrees with MRI that this term does not require construction. n2 BSN argues that the term should be restricted at two significant digits (i.e. 49.5-70.5%) for two reasons: (1) 50 and 70 each have either one or two significant digits and (2) the specification stated a preferred range of 55-65% and these numbers have two significant digits. See Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed Cir. 1996) (adopting the narrower construction of a term that had conflicting but equally plausible meanings). However, there are no contradictory interpretations of this term that would require a narrow interpretation. See id. Furthermore, BSN's proposed construction improperly imports a claim limitation from the specification. See Phillips, 415 F.3d at 1323.

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n2 While the parties dispute--without detailed briefing--the level of ordinary skill in the art for the '707 patent, the Court's construction is not affected because the disputed terms are either defined in the patent or are ordinary words not specific to the art to be construed according to their customary meaning.

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The sole remaining issue to be decided by the Court is presented as one of claim construction. Claim 1 of the 907 patent is reproduced below, with the disputed phrase italicized.

1. A method of treatment of a patient having an endo-bronchial infection comprising administering to the patient for inhalation a nebulized unit dose of 4.0 ml or less of an aqueous solution comprising from about 60 to about 200 mg/ml of tobramycin in a physiologically acceptable carrier for a duration of nebulization less than about 10 minutes, using an inhalation device having a rate of aerosol output of not less than about 4 [mu] l/sec, that releases at least about 75% of the loaded dose, and that produces aerosol particles having particle sizes between about 1 [mu] m to about 5 [mu] m.

Specifically, defendants ask the Court to find that an aqueous solution of 50 mg/ml of tobramycin in a physiologically acceptable carrier would be excluded from the range "about 60 to about 200 mg/ml." In the alternative, it argues that if plaintiff cannot precisely determine the range of tobramycin concentrations that would infringe, then the 907 patent should be deemed invalid as indefinite.

Plaintiff contends that "about 60 to about 200 mg/ml" should be construed as "approximately 60 to approximately 200 mg/ml." Plaintiff asserts that any further definition of the outer limits of this range would be inappropriate because it would be up to a jury to decide the factual issue of whether 50 mg/ml (or any other amount) reads on the phrase "about 60 to about 200 mg/ml" either literally or under the doctrine of equivalents. It also argues that defendants do not currently make or sell any product containing 50 mg/ml of tobramycin and improperly seek an advisory opinion.

Although the issue has been framed as a pure question of claim construction, defendants essentially seek a declaratory-judgment that a 50 mg/ml tobramycin solution would not infringe the 907 patent. It is true that without an actual controversy, the Court would lack subject-matter jurisdiction to decide that question. 28 U.S.C. 2201. Yet, despite plaintiff's assertions to the contrary, there is an actual controversy in this case because at least one defendant has sold a 50 mg/ml dosage (Birdsong Decl. P 12).

As for the proper construction of "about 60 to about 200 mg/ml," defendants argue that this range excludes any concentration less than 60 mg/ml. In short, they seek to limit this phrase to mean "between exactly 60 and about 200 mg/ml." That interpretation is rejected. Defendants attempt to improperly read in limitations from the patentee's examples in the specification. The arguments about what was or was not described as the "minimal yet efficacious" concentration of tobramycin in the prior art are also unpersuasive, at least for claim construction purposes, because "minimal yet efficacious" does not appear in the claims.

Nowhere did the inventor expressly define "about 60 mg/ml" to mean "at least 60 mg/ml" or "exactly 60 mg/ml" or anything

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other than the ordinary and customary meaning as understood by a person of ordinary skill in the art. Here, claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed.Cir. 2005) (en banc). The Federal Circuit has held that the word "about" should be given its ordinary meaning of "approximately." Merck & Co v. Teva Pharms. USA, 395 F.3d 1364, 1369 (Fed. Cir. 2005). Accordingly, this order finds that the proper construction of this phrase is "approximately 60 to approximately 200 mg/ml."
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A detailed description of the technology has been set forth in the Court's claim construction ruling of October 30, 2005 and is incorporated herein. The asserted claims of the Patents are directed to the therapeutic use of an antibody to a substance the patents define as "about 70 kDa mediator substance." This Court construed the "about 70 kDa mediator substance" to mean "biologically active TNFa." This construction would necessarily cover antibodies to TNF from any species, including humans. Defendant Abbott moves for summary judgment under Noelle because the Patents allegedly violate 35 U.S.C. § 112 for failing to disclose a human protein when all that is described in the specification is a mouse protein.
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Claim terms in claims 23 and 37 of the '329 Patent are disputed in this case. Accordingly, the Court will focus its discussion on these claims

In full, claim 23 of the '329 Patent provides, "[a] method according to claim 22 wherein said unit dosage of said bisphosphonate comprises about 70 mg of alendronate monosodium trihydrate on an alendronic acid active basis." (PTX 1, '329 Patent at col. 21, lines 24-27) (emphasis added).

In full, claim 37 of the '329 Patent provides, "[a] method according to claim 36 wherein said bisphosphonate unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis." (PTX 1, '329 Patent at col. 22, lines 24-26) (emphasis added).

Teva contends that the term "about" in claims 23 and 37 should be construed according to its ordinary meaning of "approximately." (D.I. 147 at 3). Merck contends that the patentee in this case acted as his own lexicographer and set out the meaning of "about" in the specification where the specification explains that the term "about" accounts for the variability of weight of the active ingredient that would result from the use of different salts of alendronic acids. (D.I. 141 at 42). Thus, Merck contends that the phrase "about 70 mg" as used in claim 23 and "about 35 mg" as used in claim 37 means 70 and 35 mg respectively of the active ingredient on an alendronic acid active basis. Id. at 43. In other words, Merck contends that, regardless of the final weight of the actual active ingredient in the tablet, it contains the same number of alendronate core molecules as 70/35 mg of alendronic acid.

In rebuttal, Teva contends that Merck's proffered construction makes no sense. Teva points out that according to Merck, the word "about" is used to account for the fact that different alendronate salts have different molecular weights, and that to deliver the same amount of physiologically active compound to the bone they must be delivered at slightly different dosage strengths. (D.I. 147 at 4). Teva contends that Merck's interpretation is nonsensical because the claim itself accounts for this phenomenon by directing that the compound be administered on the basis of a common denominator, i.e., "on an alendronic active basis." Id. In other words, Teva contends that the claims require that the amount "alendronate sodium trihydrate" be sufficient to deliver the same amount of active material as "about 70/35 mg" of alendronic acid. Id. As a result, Teva contends, the term "about" does not perform the function which Merck assigns to it, and must be in the claim for another purpose, that is, to have its ordinary meaning of "approximately."

After reviewing the claim terms and the specification, the Court concludes that the patentee explicitly and with reasonable clarity and precision defined the term "about 70 mg" in claim 23 and "about 35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories. Simply put, no matter what the final weight of the actual active ingredient in the tablet is, it contains the same number of alendronate

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core molecules as 70/35 mg of alendronic acid.

The relevant portion of the '329 Patent specification provides:

Because of the mixed nomenclature currently in use by those or [sic] ordinary skill in the art, reference to a specific weight or percentage of bisphosphonate compound in the present invention is on an active weight basis unless otherwise indicated herein. For example the phrase "about 70 mg of bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof and mixtures thereof, on an alendronic acid weight basis" means that the amount of bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

PTX 1, the '329 Patent, col. 10, 65-col. 11, line 8. (emphasis added). The Court concludes that the specification clearly indicates that the terms "about 70 mg" and "about 35 mg" refer to the fact that depending on the derivative of the alendronic acid that could be used in the oral formulation, different weights will be needed in order to get the same effect as 70 or 35 mg of the seminal compound, alendronic acid. As Merck points out, the alendronate sodium in Fosamax includes an atom of sodium metal for each molecule of alendronate sodium. (D.I. 138 at 24). If a formulator was to select a different salt which includes a metal atom that is heavier than salt, e.g., a potassium or barium atom, the total amount of material in each tablet would have to increase if the amount of alendronic acid were to remain the same. By conforming the weight of the alendronate derivative in the claim of the '329 Patent to the equivalent weight of the alendronic acid, a formulator can consistently know how many basic units (alendronic acid units) are to be used, even though the final total weight may be different. Examples 7 and 8 of the '329 Patent reinforce this conclusion. They provide for oral formulations "containing about 35 mg" and "about 70 mg" of alendronate "on an alendronic acid active basis." The claims at issue use the same phraseology and the ingredient tables in the examples are consistent with the premise that "about" accounts for the fact that alendronate derivatives have accessories that add to the weight of the molecules. Thus, in the examples "about 35 mg" turns out to be 45.68 mg of alendronate monosodium trihydrate and the "about 70 mg" turns out to be 91.35 mg of alendronate monosodium trihydrate. See PTX 1, the '329 Patent col. 19 lines 13-15, col. 19, lines 44-46, col. 19 lines 20-21, col. 19 lines 51-52.

Although the Court finds that Dr. Russell, is competent in the area of bisphosphonates, it does not find his opinion as to the definition of the phrases "about 70/35 mg" in the '329 Patent persuasive. During cross examination on this issue, Dr. Russell testified as follows:

Q. Now is it true that when you deal with the claims in this case, the claims recite 70 and 35; correct? That is 70 mg a week and 35?

A. The claims say about 70 and about ….

Q. And what does "about' mean to you?

A. Well about to me depends how precise a definition we want. But for purposes of how close the 40 and 80 are to about 35 and 70, I've given you my opinion on that, that for practical purposes, those would be the same, they would be indistinguishable in their effects, given everything else we know about the properties of these drugs.

Q. But the claim itself, what the claim really means, is 70, not 80; correct?

A. It says about 70 and about 35.

Q. Did you read the patent, Dr. Russell, the entire body of the patent?

A. Yes, I have.

Q. So in the patent, does it tell you what about 70 means?

A. There is a reference somewhere to about in the patent as I recall, but I'd need to be directed to where it was.

Q. Why don't you go to the first, in the patent, which is Defendant's Exhibit 1 and Plaintiff's Exhibit 1, at column 11,

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lines-about 1 through 9. It says here in the definitional context exactly what about 70 milligrams means; correct?

A. It- well, there's almost an intrinsic contradiction in this, because the definition here is talking about 70, and then referring to whatever salt form is used being referenced to the alendronic acid itself, yes.

Q. But in the patent it gives you a precise reference and says when we say about 70 milligrams of a bone resorption inhibiting bisphosphonate, what we mean is that amount of a bisphosphonate that will deliver an equivalent amount, the equivalent of 70 milligrams of alendronic acid; correct?

A. Yes. I have difficulty with this statement because the reason if it's that precise at 70, why does it use the phrase about?

Q. But they gave you that exact definition; correct?

A. It's a curious use of the English language.

Q. I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated in this?

A. Possibly.

Q. But that's what the definition says; right?

A. That is the definition as it's described in the patent.

Russell at 337-339. (emphasis added). Although Dr. Russell opined that the explicit definition of the disputed claim terms in the specification was "a curious use of the English Language," he testified that Merck's proffered construction is the definition as it is described in the patent. The Court finds Dr. Russell's interpretation unpersuasive, especially in light of the fact that patentees may give special meanings to claim terms either explicitly or implicitly in patent specifications. Further, with regard to Teva's claim that there is no function to Merck's proffered construction, the Court finds this argument unpersuasive given the clear directive in the specification to construe the term "about 70/35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives and the fact that depending on the derivative of alendronic acid used in the oral formulation, different weights will be needed in order to get the same effect as 70 or 35 mg of alendronic acid. See Bell Atl. Network Servs., 262 F.3d at 1268 (noting that the specification must express a clear intent to redefine a claim term). Accordingly, the Court will accept Merck's proffered construction and construe the disputed claim terms "about 70/35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories.
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1. Disputed claim terms "about 95% of the cumulative total of modafinil particles in said composition" mean: approximately 95% of the aggregate of the individual percent values for all measurable particles in the composition based on a volume distribution.
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Claim Interpretation

2. The formula set out in claim one of each of the patents describes the same hydroxy-terminated urethane compound, with two components identified as "R" and "R<1>." The patents are distinguished primarily by the different applications for which the urethane compound is claimed. In addition, the '260 patent claims a method for using the patented compound in a topical composition.

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3. Claim interpretation is a matter of law, solely within the province of the Court. Markman v. Westview Instruments, 52 F.3d 967, 978 (Fed. Cir.), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The Court interprets the meaning of the claim terms as would one skilled in the art. Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 867 (Fed. Cir. 1985). Because the inventor may be his or her own lexicographer, Autogiro Co. of American v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 397 (Ct. Cl. 1967), the Court may also determine whether a word or term used in the claims was intended to have a meaning which differs from the meaning used in the art.

4. Where there is question about the meaning that those skilled in an art give a term used in the claim, the specification and prosecution history (which contains the patent application as filed and the official record of the proceedings before the Patent and Trademark Office ("PTO")) can provide relevant information about the scope and meaning of the claim. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988). To ascertain the meaning of the claims, the Court considers these three sources: the claims, the specification, and the prosecution history. Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991). The patent specification, in particular, is the principal source for determining the meaning of ambiguous terms used in a patent claim. Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452-53 (Fed. Cir. 1985); see also Specialty Composites, 845 F.2d at 987.

5. It is inappropriate to read limitations into the claims from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim. E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir.), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).

6. Because the terms "linear" and "branched" do not appear in, nor are they required by, the language of the claims-in-suit, the claims do not contain any limitation based on the "linear" or "branched" nature of the claimed composition, or of its ingredients.
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2. What is the Proper Construction for the Phrase "heating . . . in the absence of pressure or shear" in the '311 Patent?

Claim 1 and claim 94 of the '311 patent include the phrase: "heating said substantially uniform mixture, in the absence of pressure or shear sufficient to convert the binder particles. . . ." KXI contends the phrase "in the absence of pressure or shear sufficient to convert the binder particles" means that any pressure and shear applied to the "substantially uniform mixture" during heating should not be sufficient to convert the binder particles to a continuous web matrix or forced point-bonds. KXI also contends this phrase does not require that all of the mixture be heated prior to the application of sufficient pressure and shear to convert the binder particles. Culligan contends "in the absence of pressure or shear sufficient to convert the binder particles" means subjecting the mixture to "as little pressure and shear as possible during the entire heating process." Culligan contends at a given location along the extruder, the entire mixture must be fully heated before sufficient pressure and shear are applied to the mixture to convert the binder.

According to KXI, some pressure or shear is permitted while the mixture is being heated, so long as there is not enough pressure or shear to convert the mixture into a continuous web matrix or forced point-bonds. KXI cites passages from the '311 patent specification that disclose the presence of some pressure or shear before the "substantially uniform mixture" has been heated to a temperature above the binder's softening temperature. See U.S. Patent No. 5,019,311, column 19, lines 35-48; column 19, lines 39-42; column 12, lines 61-66.

Culligan argues that the prosecution history of the '722 patent supports its interpretation. The application which led to the '722 patent was originally filed as a subsequent, divisional application of the co-pending application which led to the '311 patent, and was prosecuted after the '311 patent issued. The court will not rely on the prosecution history of the '722 patent here in interpreting the claims of the '311 patent.

Culligan cites passages from the '311 patent's specification stating that no pressure should be applied after heating. Culligan cites column 18, line 67 to column 19, line 2. This states "during heating, no pressure is applied and no effort is made to consolidate the powder. The powder must be at the desired temperature before pressure and shear are applied." The court notes, however, that the statement was made in the context of a discussion of compression molding, one method offered for producing the composite material. Culligan also cites passages from the '311 patent's specification stating that the mixture

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should be heated "in the absence of any significant pressure or shear." U.S. Patent No. 5,019,311, column 5, lines 3-15; column 12, lines 33-41.

The court agrees with KXI that the '311 patent's specification permits some pressure or shear to occur before the particulate mixture has been heated to a temperature "substantially above the binder's softening temperature." The court construes the contested phrase according to the plain language of the words of the claim. Accordingly, the court construes the phrase "in the absence of pressure or shear sufficient to convert the binder particles" as follows: any pressure and shear applied to the mixture must not be sufficient to convert the mixture to a continuous web matrix or forced point-bonds until the mixture has been heated to a temperature substantially above the softening temperature of the binder.

KXI contends the claims of the '311 patent do not require all the mixture to be heated prior to the application of sufficient pressure and shear to convert the binder. Culligan contends that all of the mixture at a given axial location must be fully heated before pressure and shear are applied to convert the binder. The court finds no reason to read either of these interpretations into the definition of the contested phrase.
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1. "heating . . . in the absence of pressure or shear sufficient to convert the binder particles"

KXI contends that the phrase "heating . . . in the absence of pressure or shear sufficient to convert the binder particles" allows the application of some pressure or shear while the mixture is being heated. Therefore, according to KXI, pressure or shear can be applied to the mixture during heating. KXI argues that the only limitation of the phrase is that any pressure or shear applied during heating must not be sufficient to convert the binder particles into the continuous web matrix or forced point-bonds. KXI states that the court adopted its proposed construction of this phrase in Culligan.

For the most part, PUR appears to agree with KXI that the phrase "heating . . . in the absence of pressure or shear sufficient to convert the binder particles" allows the application of some pressure or shear during heating. In a compression molding process, however, PUR contends that no pressure or shear is applied during the heating step. In describing how the invention is used in compression molding, the specification states that "during heating, no pressure is applied and no effort is made to consolidate the powder. The powder must be at the desired temperature before pressure and shear are applied."

In Culligan, the court found that "heating . . . in the absence of pressure or shear sufficient to convert the binder particles" allows some pressure or shear to occur during the heating step. In that case, however, it was not necessary for this court to decide whether Koslow disclaimed applying pressure or shear during heating in compression molding because both KXI and Culligan used extrusion processes. Thus, in its claim construction in Culligan, the court did not rely on the statement in the specification cited by PUR in this case because that statement was made in the context of a discussion of compression molding.

The court finds, as it did in Culligan, that "heating . . . in the absence of pressure or shear sufficient to convert the binder particles" allows some pressure or shear to occur during the heating step. Accordingly, the court construes the phrase to mean that any pressure or shear applied to the mixture during heating must not be sufficient to convert the mixture into a continuous webbing structure or forced point bonds. In compression molding, however, the court agrees with PUR that Koslow disclaimed applying any level of pressure or shear during heating. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").
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5. "Said Additive Being Present in an Amount Sufficient to Accelerate the Rate of Hardening of Said Hydraulic Cement Mix and to Increase its Compressive Strength after Hardening"

All three claims contain an identical function clause, which states that addition of the admixture will "accelerate the rate of

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hardening [of the cement mix and] increase its compressive strength after hardening." 9 Again, Euclid argues this clause begs two questions: accelerate the rate of hardening relative to what, and increase its compressive strength relative to what? To answer these questions, Euclid asserts the Court should construe this phrase to mean that addition of the admixture will "(1) accelerate the rate of hardening of the hydraulic cement mix relative to a plain mix at initial set and final set; and (2) increase the compressive strength of the hydraulic cement mix relative to a plain mix at any age of the hydraulic cement mix after it hardens." MBT concedes that the claim language needs clarification, but objects that Euclid's proposed construction is too complex and also imports limitations into the claims which simply should not be there. Instead, MBT asserts the Court should construe the phrase to mean that addition of the additive will "decrease the amount of time of set of the cement and … increase the compressive strength of the cement relative to plain mix (with no admixture)." The Court resolves this dispute by breaking the functional clause in question into two parts, and examining each part separately.

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9 Actually, the functional clause of claims 1 and 20 refer to an "additive," while claim 38 refers to an "admixture." In their written briefs, the parties disputed the meaning of the word "additive." At oral argument, however, the parties largely agreed (and, in any case, the Court concludes that one skilled in the art would understand) that the two terms are synonymous.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

a. "Accelerate the Rate of Hardening"

The functional clause first states that addition of the admixture will "accelerate the rate of hardening of [the] hydraulic cement mix." Euclid argues the Court should construe this language to mean "accelerate the rate of hardening of the hydraulic cement mix relative to a plain mix at initial set and final set" (emphasis added). MBT agrees that the acceleration is "relative to a plain mix," but MBT does not agree to the references to initial set and final set: "one of ordinary skill in the art would have read this claim language as calling for a general acceleration of hardening, and not as calling for acceleration of hardening at two particular times, as [Euclid] contends." MBT's claim construction brief at 14. MBT insists there is "no basis for the assertion that acceleration of the rate of hardening must be evinced at initial set, final set, or both of these points." Id. at 15. MBT does concede, however, that to "accelerate the rate of hardening" is to "decrease the amount of time of set." Joint claims chart at 5. It is unclear precisely what MBT means by "time of set."

The critical question raised by the parties is: how do you determine whether, in fact, the admixture has "accelerated the rate of hardening" of a cement mix? Euclid says the rate of hardening was "accelerated," as claimed by MBT, only if the time to reach both initial set and final set has decreased. MBT objects, saying the claim language "calls for a general acceleration of hardening, and not as calling for acceleration of hardening at two particular times." Construction brief at 14. The problem with MBT's objection, however, is that whether acceleration has occurred must be measured at some point in time. In all of the three cases shown below, for example, acceleration in the rate of hardening arguably did occur, but the point in time of acceleration varies. Does the patent cover only the admixture shown in scenario one, where both the time to initial set and final set are decreased, or does it also cover the admixtures shown in scenarios two and three, where only one of these benchmarks times is decreased?

[SEE Stiffness of Cement Over Time IN ORIGINALS]

Scenario 1: The additive immediately causes the cement to stiffen quicker, and the cement continues to stiffen quicker. Comparing a cement mix with the additive to a cement mix without the additive, the time to initial set and final set is shorter.

[SEE Stiffness of Cement Over Time IN ORIGINALS]

Scenario 2: The additive initially has no effect on the cement, but later causes it to stiffen quicker. Comparing a cement mix with the additive to a cement mix without the additive, the time to initial set is the same, but the time to final set is shorter.

[SEE Stiffness of Cement Over Time IN ORIGINALS]

Scenario 3: The additive initially causes the cement to stiffen quicker, but this effect wears off. Comparing a cement mix

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with the additive to a cement mix without the additive, the time to initial set is shorter, but the time to final set is the same.

Importantly, the claim language, itself, does not refer to "initial set" or "final set;" indeed, the '194 patent does not claim anywhere that the admixture will affect the rate of setting. Rather, the claim language only asserts the admixture will accelerate the rate of hardening. This distinction is critical because, while "setting" and "hardening" are related, it is clear that a person skilled in the art accords different meanings to the terms. Indeed, the same is true of a layman.

In the context of concrete, the ordinary and customary meaning of the term "hardened," to a layman, refers to the point in time when the cement is completely stiff -- it is no longer wet or malleable. Put simply, once the cement has hardened, a child cannot scratch his initials into the sidewalk with a stick. In contrast, if concrete is still "setting," it remains malleable, to some degree; perhaps it is soupy, perhaps it is mucky, perhaps it is like dried mud, but concrete that is still "setting" is not "hardened." Similarly, to a layman, the ordinary and customary meaning of the term "accelerate the rate of hardening" means that it will take less time for a concrete mix to reach a state of hardness. The speed of hardening is quicker; the time to reach hardness is less. A layman, however, would not necessarily believe that, if a wet concrete mix takes less time to become "hard," it will also take less time to become mucky. Maybe; maybe not.

In this case, the layman's understanding completely parallels that of one skilled in the art, and is borne out by other language in the patent, including the patent specification, as well as extrinsic evidence. 10 In several places, the patent distinguishes between "setting" and "hardening." In the "background of the invention" section, the patent describes the principal benefit of the invention as being "acceleration of rate of hardening and setting." '194 patent, col. 1, lines 14-16 (emphasis added). Similarly, in the "summary of the invention" section, the patent states that "it is another object of this invention to provide hydraulic cement mixes … which include an admixture which will advantageously accelerate the rate of hardening and setting of the cement mix." Id. at col 3., lines1-7 (emphasis added). This language highlights the patent drafter's choice to claim only that the invention "accelerates the rate of hardening." The drafter did not claim that the invention also accelerated the rate of setting, even though the drafter earlier noted that this was one of the objects of the invention. It is significant that the drafter did not use the term "setting" of concrete in the claims language, only "hardening," and that the drafter did not specify any particular point (or points) in time, before final hardening, at which or by which the claimed acceleration must occur. In other words, there is negative support in the patent background and patent summary for Euclid's argument that an accelerated rate of hardening must be measured with reference to initial set and final set.

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10 The prosecution history and prior cited art do not shed light on the appropriate construction of the phrase "accelerate the rate of hardening."

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Euclid does point to the patent's "description of the preferred embodiments," which is replete with examples of the temporal decrease that different formulations of the patented admixtures caused various types of cement mixes to reach "initial set," "final set" or both. In particular, the specification lists 72 examples of cement mixes to which were added various admixture formulations. See patent Tables I-XX. 11 These Tables generally show that the three-component admixtures claimed in the patent, when added to a plain cement mix: (1) decrease time to initial and final set, and increase compressive strength; and (2) are superior in these areas to one-and two-component admixtures. The Tables "prove" that the admixtures accelerate hardening by showing the decrease in time it took for the cement mix to reach initial set and final set, when the admixture was added. As an example, Table XIII, mix 62 shows that addition of a particular formulation of the three-component admixture decreased the time to initial set by 3 3/8 hours, and decreased the time to final set by 41/2 hours. Euclid argues that MBT's continued references to initial set and final set in the patent specification show that one skilled in the art would measure acceleration of hardness by measuring time to both initial and final set. 12

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11 The Tables include a total of 74 cement mixes. Mixes 1 and 6 include no admixture. The other mixes contain admixtures, but only some of these admixtures include all three of the components claimed by the patent; the other admixtures contain only 1 or 2 of the 3 components, and are presented for the sake of comparison. See, for example, Table XI, mix 37 (the admixture contains all three components, being the thiocyanate, the alkanolamine, and the nitrate); Table XI, mix 36 (the

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admixture contains only the thiocyanate and the nitrate); Table XI, mix 35 (the admixture contains only the nitrate); Table XI, mix 34 (the admixture contains only the thiocyanate); and Table IV, mix 12 (the admixture contains only the alkanolamine and the nitrate). Of the 74 mixes listed, only about half of them contain the patented three-component admixture.

12 MBT responds to this argument, in part, by noting that some of the tables list data only for final set, and do not address initial set. Tables XIX and XX, for example, show only the decrease in time to final set. MBT asserts this shows that time to initial set is not relevant to measuring whether the admixture accelerated hardness. The eight admixtures in these two tables, however, contain only one of the three components recited by the patent -- that is, the admixtures in these tables include only the alkanolamine, and not the thiocyanate or the nitrate. The data in these Tables (and in others) are apparently presented to "separate out" the effect of one of the three specific components of the patented invention, and to show how the three components have a "surprising" beneficial interactive effect. For every cement mix containing the patented, three-component admixture, the Tables present data showing a decrease in time to both initial and final set. Thus, while the Court ultimately agrees with MBT that the '194 patent does not claim the admixture will accelerate the rate of initial set, Tables XIX and XX do not support MBT's position.

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It is hornbook law, however, that the scope of a claim should not be limited to the preferred embodiment or specific examples disclosed in the specification. Vitronics., 90 F.3d at 1582; Ekchian, 104 F.3d at 1303. While the preferred embodiments may prove that MBT's invention achieves its "objective" of "advantageously accelerating the rate of hardening and setting of the cement mix," MBT chose to claim only that the admixture would accelerate the rate of hardening.

Extrinsic evidence also strongly supports this conclusion. The evidence was clear, and the parties do not dispute, that, to a person reasonably skilled in the art, there are two critical points in time regarding the stiffness of a cement mix -- when it reaches initial set, and when it reaches final set. This is because, as noted above, the time of initial set is when the concrete should no longer be worked, and the time of final set is when the forms into which the concrete was poured can be removed. These benchmarks are so important that there are several different, accepted tests for determining when "initial set" and "final set" occur, and these tests do not necessarily agree with each other. See footnote 4, above (describing three different penetrometer tests and the "slump test," all of which are standardized ASTM tests); see also ASTM C 125 at 3 (defining the terms "time of setting," "time of final setting," and "time of initial setting," and noting that "development of rigidity during setting is a gradual and continuous process, and the time of setting is defined arbitrarily in terms of a given test method") (emphasis added); ASTM C 403/C at P5.1 ("since the setting of concrete is a gradual process, any definition of time of setting must necessarily be arbitrary"). 13 Indeed, in the "description of preferred embodiments" section, MBT states it measured these beneficial effects "in accordance with current applicable ASTM standards." '194 patent, col. 4, lines 31-32.

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13 While MBT used the "slump test" (ASTM C 143) to measure initial and final set in Tables I-XX, a person reasonably skilled in the art would understand that the results would have been essentially the same using the other tests, as well.

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This extrinsic evidence confirms, however, that it is only when the cement has stiffened to the point that it has reached "final set" that the cement is described as "hard." ASTM C125, which recites the "standard terminology relating to concrete," explains that admixtures are used to modify the properties of a cement mix that is "freshly mixed, setting, or hardened." ASTM C 125 at 1 (defining "admixture") (emphasis added). The use of the disjunctive suggests that an admixture can modify the setting properties of cement without modifying hardening, and vice versa. One skilled in the art, then, would surely understand and adopt the following explanation of the difference and relation between "setting" and "hardness," taken from a leading treatise in the field:

The stiffening times of cement paste or mortar fraction are determined by setting times. The setting characteristics are assessed by "initial set" and "final set." When the concrete attains the stage of initial set it can no longer be properly handled and placed. The final set corresponds to the stage at which hardening begins."

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Concrete Admixtures Handbook: Properties, Science, and Technology, § 1.7 ("Cement Science, Setting") at 15 (V.S. Ramachandran ed. 1984). This same treatise makes clear that setting and hardening are related but separate concepts: "accelerating admixtures slightly accelerate or do not modify setting times, therefore the word 'accelerating' should be employed to indicate early strength development, in place of 'setting times.'" Id. § 3.1.1 at 120.

In sum, a person skilled in the art would understand that the term "accelerate the rate of hardness" must be construed with reference only to final set, for the simple reason that the time it takes cement to "harden" is only passingly related to the time it takes for the cement to reach initial set. Thus, Euclid's suggested construction is inaccurate by virtue of requiring too much. MBT's suggested construction, however, is inaccurate by virtue of requiring too little. As noted above, the question of whether acceleration has occurred must be measured at some point in time, and MBT suggests, vaguely, only that the measurement be a "decrease [in] the amount of time of set of the cement." The rate of hardening must be measured relative to final set.

The ordinary and customary meaning, to a person skilled in the art, of the term "hardened," refers, at the earliest, to the point in time that the cement reaches final set. It is at this juncture that the cement is first classified as "hardened" by persons skilled in the art. Indeed, only after cement has reached final set can it reasonably be strength-tested -- it would be impossible to attempt to fracture a cube-shaped piece of cement if the cement mix still has a slump. Once the cement reaches final set, it may become still harder and stronger, but the point in time of final set is when it becomes "hardened." To accelerate the rate of hardening of cement, then, must mean, to one skilled in the art, to decrease the time it takes for the cement to reach final set.

Ultimately, then, the Court concludes that, when MBT claimed invention of an additive that will "accelerate the rate of hardening of [the] hydraulic cement mix," it claimed invention of an admixture that will "decrease the amount of time it will take for an hydraulic cement mix to reach final set, relative to a plain mix." The Court construes the claim language accordingly.

b. "Increase Compressive Strength after Hardening"

The second function described in the functional clause of claims 1, 20, and 38 is that the admixture will "increase [the] compressive strength [of the hydraulic cement mix] after hardening." Euclid asserts the Court should construe this phrase to mean that addition of the admixture will "increase the compressive strength of the hydraulic cement mix relative to a plain mix at any age of the hydraulic cement mix after it hardens." 14 MBT, while conceding that the claim language needs clarification, objects especially to inclusion of the phrase "at any age." MBT first proposed, instead, that the Court should construe the phrase to mean that addition of the additive will "increase the compressive strength of the cement relative to plain mix (with no admixture)." Joint claim construction chart at 5. Over the course of briefing MBT modified its position somewhat, stating it claimed that cement to which its patented admixture was added, "after hardening, must exhibit a compressive strength greater than that of a like, but plain, cement mix (absent the additive/ admixture) at a like time interval after mixing." Answering brief at 11. With this change, the difference between MBT's and Euclid's suggested constructions appears slight.

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14 Notably, this proposed construction supports the Court's construction of the term "accelerate the rate of hardening." Euclid's reference to the strength of cement "after it hardens" confirms that hardening occurs at a specific juncture, so that measurement of the rate of hardening with reference to more than one point in time is inappropriate.

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To begin with, as noted above, the phrase "after hardening" clearly refers to, at the earliest, a point in time after final set has occurred. The question raised by the parties is whether the claimed increase in compressive strength must appear at every time of measurement thereafter, or only at some point(s) thereafter. Put differently, does the patent cover only the admixture shown in scenario four, below, where the compressive strength of the concrete with the admixture is superior at all times after hardening, or does it also cover the admixtures shown in scenarios five and six, where compressive strength is superior only early or late in the life of the hardened concrete?

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[SEE Strength of Cement Over Time IN ORIGINALS]

Scenario 4: The additive gives the cement greater strength at initial hardening and at all times subsequent.

[SEE Strength of Cement Over Time IN ORIGINALS]

Scenario 5: The additive does not increase the strength of the cement at initial hardening or for some period thereafter, but eventually gives the cement greater strength.

[SEE Strength of Cement Over Time IN ORIGINALS]

Scenario 6: The additive gives the cement greater strength at initial hardening and for some period thereafter, but eventually a "plain mix" obtains equal strength.

The Court concludes that the claim language, the patent specification, the prior cited art, and the extrinsic evidence all point to the same conclusion: the '194 patent claims that the admixture will "increase the compressive strength of the hydraulic cement mix, relative to a plain mix, when measured at a like time interval after hardening."

First, the plain language of the claim states simply that, when the admixture is added to an hydraulic cement mix, it will "increase its compressive strength after hardening." Put simply, the ordinary and customary meaning of this phrase is that, once the cement is hardened, it will be stronger. The plain language does not suggest that the cement will be stronger for a while, but then only equally strong as a cement without the admixture; nor does the plain language suggest that the cement will only become stronger some time long after it has hardened. MBT adopts this position itself when it states that the claim language "is neither limited to early compressive strength, nor to ultimate compressive strength, nor to the strength at any other particular time." Answering brief at 11. Rather, a layman would understand the ordinary and customary meaning of the claim language to assert that, if you compare two cement mixes after they have hardened -- one with and one without the admixture -- the one with the admixture would be stronger. Furthermore, a layman would understand that the strength of the two cement mixes must be measured at similar points in time -- the patent is not claiming that a 5-day-old cement mix with the additive will be stronger than a 25-day-old plain cement mix. Rather, if you compare two hardened cement mixes of equal age, the one containing the admixture will have higher compressive strength.

The patent specification language supports this conclusion. The "background of the invention" section of the patent notes that the "invention relates to admixture compositions for incorporation into hydraulic cement mixes … to provide … compressive strength at all ages." '194 patent, col. 1, lines 14-16 (emphasis added). In the "summary of the invention" section, MBT explains that the admixture "yields beneficial effects … on early and ultimate compressive strength [of cementitious mixes] after hardening." Id. at col. 2, lines 59-61 (emphasis added). 15 The data presented by MBT in the patent specification then confirms that the patent is referring to a comparison between (1) cements with and without the admixture (2) when measured at any similar period of time after hardening. In the "description of preferred embodiments," MBT provides extensive data showing the increases that different formulations of the patented admixtures have on the compressive strength of cement mixes. As noted earlier, the specification lists 72 examples of cement mixes to which were added various admixture formulations. These Tables generally show that the 1-day, 3-day, 7-day, and 28-day compressive strength measurements for cement mixes to which were added the patented three-component admixtures are stronger than the same mixes without the admixture. Thus, for example, Table X, mix 29 shows that the admixture increased 1-day compressive strength by 45% and 3-day compressive strength by 12%. Some of the Tables present compressive strength data for only the 1-day time period (e.g., Table V), some for the 1-day and 3-day time periods (e.g., Table X), and some for the 1-day, 7-day, and 28-day time periods (e.g., Table XII). While the scope of the claims should not be limited to the preferred embodiment or specific examples, the claims should be read in view of their specification. Vitronics, 90 F.3d at 1582. Here, the specification is completely parallel with the Court's understanding of the ordinary and customary meaning of the claim language.

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15 In describing the "object[s] of the invention," however, MBT does not address "ultimate" compressive strength, stating only that one objective is to "increase the early compressive strength." '194 patent, col. 3, lines 1-7 (emphasis added).

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The prior art cited by MBT in its '194 patent also supports the conclusion that the claim language "increase compressive strength after hardening" is not limited to a period of time shortly after hardening, or any other period. MBT cites the "Burge Patent" (no. 3,782,991) and the "Rosskopf patent" (no. 4,373,956). The Burge patent is directed at a cement admixture with the "significant object" of providing "early strength." '991 patent at col. 2, lines 9-12 (emphasis added). The compressive strength measurements presented in the '991 patent specification cover only the first 48 hours after final set. Id. at col. 6, lines 42-53. The specification then makes special mention of the fact that the "rapid development of early strength, that is to say, 9 to 15 hours after preparation, can be clearly recognized." Id. at col. 6, lines 59-61 (emphasis added). In other words, the Burge patent uses the term "early strength" to mean the first two days after final set; after this time, the compressive strength is no longer referred to as "early," so that early strength does not mean, say, the first 28 days after final set.

In contrast, the Rosskopf patent (which, itself, cites Burge) is directed at increasing "the compressive strength" of cement mixes, not just the "early" compressive strength. '956 patent, col. 2, lines 65-68 (use of this additive … results in an increase in compressive strength"). The Rosskopf patent specification, like MBT's '194 patent, then presents compressive strength data for the 1-day, 7-day, and 28-day periods after final set. See, e.g., id. at col. 16, Table V. Further, the Rosskopf patent specification makes special mention of "the early (one day) compressive strength" data. Id. at col. 6, line 56 (emphasis added). This suggests that the two phrases used by MBT in the '194 patent specification -- "early and ultimate compressive strength," and "compressive strength at all ages" -- would be understood by a person reasonably skilled in the art as meaning the compressive strength during the entirety of the period following hardening, or final set.

Finally, the expert testimony at the Markman hearing made clear that: (1) the compressive strength of concrete normally increases with time over the first 28 days, and then levels off; and (2) measurements of compressive strength are commonly measured at the end of 16 hours, and then at the end of 1, 3, 7, 28, 60, and 365 days. (Generally, the latter two measurements merely confirm that any changes in compressive strength after 28 days are slight.) Given that compressive strength of concrete is commonly measured by those skilled in the art for such a long period of time, and given that the '194 patent claim language (as opposed to the patent specification) does not limit itself to "early" or "ultimate" compressive strength, the Court concludes MBT has claimed that its additive will make cement stronger after hardening, regardless of when after hardening the strength of the cement is measured. It appears that MBT's position, at least as stated in its answering brief, is the same.

Accordingly, the Court construes the functional clause of claims 1, 20, and 38 of the '194 patents as follows: "said admixture being present in an amount sufficient to: (1) decrease the amount of time it will take for an hydraulic cement mix to reach final set, relative to a plain mix; and (2) increase the compressive strength of the hydraulic cement mix, relative to a plain mix, when measured at a like time interval after hardening."
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Last is the phrase "accelerated rate of healing and accelerated rate of symptom relief", which Astra asks the Court to construe as "a faster resolution of symptoms or effects of a disease, compared to omeprazole." In support of its proposed construction Astra relies upon the language of the claim itself as well as the specification. In particular, the specification explains that the higher anti-secretory effect of (-)-omeprazole as compared to omeprazole gave rise to the expectation that healing and symptom relief would be faster for patients administered (-)-omeprazole:

Therefore, the anti-secretory effect, which is directly correlated to the AUC irrespective of compound, was higher for (-)-omeprazole than for omeprazole racemate following administration of identical doses. This is expected to give a clinical advantage for (-)-omeprazole, since the number of patients healed from the acid-related disease is expected to be higher, and healing is also expected to be achieved within a shorter time frame. It might also be expected that a more rapid symptom relief will be obtained.

'192 patent, col. 6, line 61 to col. 7, line 2. Thus, the Court finds that one skilled in the art would understand the term "faster" in the disputed phrase to be referring to a comparison of (-)-omeprazole to omeprazole. Accordingly, the Court shall

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construe the phrase "accelerated rate of healing and accelerated rate of symptom relief" consistent with Astra's proposed construction, namely, as "a faster resolution of symptoms or effects of a disease, compared to omeprazole."
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2. Accelerated Release

The next term at issue is the preamble term "accelerated release." In this regard, AVI mounts a two-tiered attack. As an initial matter, it argues that construction of the preamble claim term accelerated release is unnecessary because it should not be read to limit the claims as it relates to only the purpose of the patent rather than a structural limitation. Alternatively, it asserts that accelerated release means that the rate of release of the blowing agent occurs more quickly than what the rate of release would be without channels perforating the foam. Oddly, Dow skips over AVI's first tier of argument and proceeds to the second, to which it counters that accelerated release means that the rate or release of the blowing agent over time, after perforating, is increased so that the time required to cure the foam is substantially reduced relative to the time required to cure the foam without perforation.

As to AVI's first point that the preamble term accelerated release is not a claim limitation, I disagree. As previously explained, a preamble is a claim limitation if it is necessary to provide meaning to the claimed invention. Rowe, 112 F.3d at 478-79; In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). Conversely, it is not a limitation if the claimed invention is complete and the preamble only states a purpose or intended use of the invention. Rowe, 112 F.3d at 478-70. Here, the preamble states as follows: "A method for providing accelerated release of a blowing agent from an extruded plastic foam . . . ." Accelerated release is thus more than just a mere statement of the purpose of the perforation patents; it is essential to breath life, meaning, and vitality to the claims. See In re Paulsen, 30 F.3d at 1479; Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995); Porter v. Farmers Supply Serv., Inc., 790 F.2d 882, 885 (Fed. Cir. 1986) (stating that preamble "gives meaning to other elements of the claimed invention"); see generally 2 DONALD S. CHISUM, PATENTS § 8.06[1][d] (1998). Further, in light of the specification and prosecution histories, it is plain that the claims require accelerated release. See Rowe, 112 F.3d at 478-80.

Turning to the construction of that term, I agree with AVI that it means that the rate of release of the blowing agent occurs more quickly than what the rate of release would be without channels perforating the foam. Interpretation begins with the words in a claim, which should generally be ascribed their ordinary and customary meaning. See, e.g., Bell Communications Research, Inc., 55 F.3d at 620. The ordinary meaning of the word accelerated is to increase over what would otherwise be the case. This comports with AVI's construction.

In addition to examining ordinary meaning, "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at 979); Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (Fed. Cir. 1990) ("[A] patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings.").

In the case at bar, the specification defines the term to mean that "the blowing agent permeates from the foam into channels to accelerate the release of blowing agent from what the rate would be without channels. See the '016 patent, at 3:20-24 (emphasis added). Again, this comports with AVI's construction. See Vitronics, 90 F.3d at 1582 (espousing that specification is generally dispositive and "is the single best guide to the meaning of a disputed claim term"). Conversely, noticeably absent from this specification definition is any adjective like "substantially" to support Dow's construction. Nor is there any rate or quantity of release of blowing agent from the foam after perforation is set forth, other than a rate a release greater than a foam with no channels.

For these reasons, I agree with AVI's construction of accelerated release.
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5. "an accelerator/cure package for said rubbery polymer"

Carlisle proposes that the term "an accelerator/cure package for said rubbery polymer" should be construed to mean "a sulfur containing vulcanization type curative which is just for the rubbery polymer blend and not the tackifier component." Adco argues that the plain meaning of the term should apply, or that it should be construed to mean "a package that includes a compound to cross-link the polymer chains of the rubbery polymer, and for reducing the time needed to complete such cross-linking."

The patent specification states that the rubbery composition "may be cured using any of several well-known curing systems including sulfur and sulfur-containing systems." The specification does not limit the claimed invention to sulfur-based curing systems. Accordingly, the court finds that it would be improper to limit the claim language to sulfur-based systems. Because the meaning of this term is likely outside the understanding of the prospective jurors, the parties should include a definition of this term in the jury materials. The court finds that the definition proposed by Adco is suitable: "a package that includes a compound to cross-link the polymer chains of the rubbery polymer, and for reducing the time needed to complete such cross-linking."
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"acceptable level suitable for intravenous administration"

The thrust of Baxter's argument is that the patent fails to define "acceptable level suitable for intravenous administration," and no objective measure or numeric cutoff point for "acceptability" is provided in the patent's specification. As evidence of this point, Baxter points to the inability of the Patent Office examiner, inventor, prosecuting patent attorney, and experts to define this claim term. Baxter thus concludes that, "[w]ithout clear boundaries, potential infringers cannot determine whether or not they infringe the ' 191 patent."

During the prosecution of the '191 patent, the examiner did in fact initially reject Claim 1 on the ground that the phrase "an acceptable level" of anticomplement activity was indefinite because "[t]he metes and bounds of what is defined by . . . an 'acceptable level' cannot be determined." (D.I. 161, Joint Appendix 35.) Bayer responded to the examiner's rejection by explaining that the acceptable level of ACA generally depends on the concentration of the IGIV. Id. Bayer pointed to the example in the specification for 5 and 10% IGIV solutions. Id. (citing the '191 patent, 5:57-64.) Based on Bayer's explanation, the examiner withdrew the rejection, acknowledging that '"an acceptable level' is not vague because it depends on the concentration of IGIV." (D.I. 161, Joint Appendix 83.)

Baxter also highlights the deposition testimony of the inventor and prosecuting attorney of the '191 patent, and Talecris's experts, as support for its contention that the claim term "acceptable level" renders the claims of the '191 indefinite. In summary, the deposition testimony of these witnesses reveals to the court a reluctance to assign any specific definition of "acceptable level" of ACA because acceptability is dependent upon a number of variables, which may include the assay used to measure ACA, the properties of a given IGIV solution, and the individual characteristics of the patient. (See, e.g., D.I. 231 at 14.)

Baxter argues that "the variety of methods available to measure ACA, but which have not been defined by the patentee, can result in infringement or non-infringement depending on which method is chosen." (D.I. 23 at 19.) The defendants consequently view this uncertainty and lack of boundaries in the '191 patent as grounds for a finding of indefiniteness. Baxter principally relies on two cases from the Federal Circuit Court of Appeals, and one case from the Eastern District of Texas, as the legal foundation for its argument.

In Honeywell Int'l, Inc. v. Int'l Trade Comm'n, the Federal Circuit affirmed a decision of the United States International Trade Commission that invalidated a patent due to indefiniteness. 341 F.3d 1332, 1338 (Fed. Cir. 2003). The patent in Honeywell concerned the production of synthetic yarn. The claim term at issue recited "thereby obtaining a drawn yarn with

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a terminal modulus of at least 20 g/d and a melting point elevation [MPE] of 10 C. to 14 C." The claims did not recite the method used for measuring MPE or preparing samples. The Federal Circuit held the claim "insolubly ambiguous, and hence indefinite … [in that] the claims, the written description, and the prosecution history fail to give [the Court], as the interpreter of the claim term, any guidance as to what one of ordinary skill in the art would interpret the claim to require."

In Datamize, LLC v. Plumtree Software, Inc., the Federal Circuit considered the claim term "aesthetically pleasing," which the district court had found to be "hopelessly indefinite" in a utility patent claiming a software program. 417 F.3d 1342, 1347 (Fed. Cir. 2005). Affirming the district court, the Federal Circuit stated that "the scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention. … Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention." Id. at 1350.

In Halliburton Energy Servs, Inc. v. MI, LLC., the district court considered a patented invention directed to using drilling fluids that contain "fragile gels" or exhibit "fragile gel behavior" in drilling operations. 456 F. Supp. 2d 811 (E.D. Tex. 2006). The court determined that any possible construction of "fragile gel" would include subjective terms that render the claims indefinite. Id. at 816. The court opined that neither the specification nor any other evidence provided an objective standard for determining the scope of the amorphous terms. Id. at 817.

In view of these cases, Baxter argues that 1) as in Honeywell, neither the method of measuring ACA nor the level of ACA that is "acceptable" is taught by the '191 patent; 2) as in Datamize, the '191 patent provides no standard by which to measure "acceptability;" and 3) as in Halliburton, no objective measure or numeric cutoff point for "acceptability" is provided in the '191 patent. (D.I. 231 at 9.) Talecris distinguishes the claim at issue in Honeywell from Claim 1 of the '191 patent, stating that "the Honeywell claim contained a specific numeric range and it therefore required a specific test method to yield a precise numeric value." Conversely, Claim 1 of the '191 patent does not contain a numeric range; rather, it requires the measurement of ACA to determine relative ACA levels--an increase followed by a reduction. As such, Talecris argues that it is not necessary for Claim 1 to recite numeric limits of acceptability based on a particular test for a particular product as it would unfairly and unnecessarily limit Claim 1. The court agrees.

Talecris distinguishes Datamize and Halliburton from this case by pointing out that those cases involved the purely subjective terms "aesthetically pleasing" and "fragile gel," respectively. In both instances, the claim terms were judged as lacking an "objective anchor" that identified the bounds of the claims for one skilled in the art. Datamize, 417 F.3d at 1350; Halliburton, 456 F. Supp. 2d at 817. Here, the court is persuaded that "acceptable level suitable for intravenous administration" is not purely subjective, and therefore not analogous to Datamize and Halliburton. To the contrary, the record reflects that the phrase has meaning to those of ordinary skill in the art, albeit the determination of that meaning may depend on a number of variables, and the ultimate determination of acceptability may be temporally distant from the time in which the inventive steps of the claim are performed. (See, e.g., D.I. 239, Ex. 7 at 135 (relating the testimony of Baxter's infringement expert, Dr. Snape, in which he admits that the FDA release limits are indicative of what the regulatory authority and manufacturer have agreed are acceptable to give a human patient, for release of a particular product, and that everyone in his field would know as much).)

The court finds the Federal Circuit's guidance in SmithKline Beecham Corp. v. Apotex Corp. to be instructive here. 403 F.3d 1331 (Fed. Cir. 2005.) The Court explained that "[t]he test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." Id. at 1341 (emphasis added). What the Federal Circuit observed in SmithKline, the court finds especially applicable here: "[b]readth is not indefiniteness." Id. (citing In re Gardner, 427 F.2d 786, 788, 57 C.C.P.A. 1207 (C.C.P.A. 1970).

"increased level of anticomplement activity," "then incubating the solution of step a)" and "increased anticomplement activity of the solution"

The court has reviewed and considered Baxter's arguments that the claim terms "increased level of anticomplement activity," "then incubating the solution of step a)," and "increased anticomplement activity of the solution" are indefinite because they are ambiguous or "nonsensical" under the court's claim construction. Applying the legal principles discussed above, the court finds no issue of indefiniteness with these claim terms. Baxter's arguments are essentially reargument of claim construction with a view towards its non-infringement defense. The plain and ordinary meaning of these claim terms

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are sufficiently definite such that one skilled in the art would understand the bounds of the claim when read in light of the specification.
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11. "acetylation"

Plaintiff's proposed construction of "acetylation" is: "a chemical reaction that introduces an acetyl functional group onto a molecule." Defendant argues the term is indefinite as a matter of law, because the term does not appear in the specification or the file history.

Plaintiff argues a person of ordinary skill in the art would understand the term "acetylation" to have the same meaning, with simply a different tense, as the term "acetylated," which is used in the specification. Defendant did not dispute this. Plaintiff's proposed construction will be adopted.
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1. "4-amino-1-hydroxybutane-1, 1-biphosphonic acid"

Both parties agree that neither the patent claim nor the specification expressly defines the term "4-amino-1-hydroxybutane-1, 1-biphosphonic acid". Defendants argue that "4-amino-1-hydroxybutane-1, 1-biphosphonic acid" in claim 1 should be construed to encompass only the free acid form. (D.I. 107 at 11-17.). According to Defendants, claim 1 of the '077 Patent expressly recites the administration of "4-amino-1-hydroxybutane-1, 1-biphosphonic acid" (which is now known as alendronic acid), and this chemical name in claim 1 is unambiguous and refers to a single compound. (D.I. 107 at 12). Defendants maintain that the specification distinguishes between salts and acids, therefore strengthening their position that claim 1 refers only to a single acid compound. (D.I. 107 at 13).

In support of their proposed construction, Defendants direct the Court to Table 6 of the '077 Patent specification, which lists typical pharmaceutical formulations of amino-butan diphosphonic acid. For example, Defendants point out that Table 6 distinguishes between formulations containing "4-amino-1-hydroxybutan-1, 1-biphosphonic acid" and those containing "4-amino-1-hydroxybutan-1, 1-biphosphonic acid, sodium salt." (D.I. 107 at 13; '077 Patent col. 13 lines 5-18). Additionally, Defendants direct the Court to the examples in the patent specification. For example, Defendants point out that examples 1 through 4 describe the manufacture of acids, whereas, the manufacture of salts is described separately in examples 5 through 8. (D.I. 107 at 13; '077 Patent col. 3 lines 31-68, col. 4 lines 1-68, col. 5 lines 1-68, col. 6 lines 1-68). Additionally, according to Defendants, Merck's expert, Dr. Recker supports their proposed construction. Specifically, Defendants point to Dr. Recker's testimony where he conceded that the '077 Patent specification distinguishes between acids and salts. (Recker Tr. 481:1-21).

In addition to the tables and language of the specification Defendants also direct the Court to the prosecution history of the '077 Patent. According to Defendants, the patentee disclaimed the coverage of salts through claim amendments made during the prosecution history. (D.I. 107 at 14). Finally, in support of their contention that acid and sodium are not used interchangeably, Defendants point to affidavits of Merck scientists, Dr. Brenner and Dr. Rodan, which describe differences between the effects of alendronic acid and alendronate sodium. (D.I. 113 at 14; DTX 14, P 11; DTX 65, P 22).

In response to Defendants' proffered interpretation of claim 1, Merck contends that claim 1 of the '077 Patent includes both the acid and sodium salt forms of "4-amino-1-hydroxybutane-1, 1-biphosphonic acid". Merck asserts that those of ordinary skill in the art, at the time of the '077 Patent filing, understood that the acid and sodium salt forms have identical therapeutic properties in regard to bone disease, and that they are chemically indistinguishable after being dissolved in bodily fluids. (D.I. 106 at 9). Additionally, in support of its position, Merck directs the Court to Table 6 of the specification. Table 6 lists typical pharmaceutical formulations containing amino-butan-diphosphonic acid. The first entry under the heading "Opercolated Capsules" lists 4-amino-1-hydroxybutan-1, 1-biphosphonic acid, sodium salt as the first referenced acid. ('077 Patent col. 13 lines 3-9). Thus, Merck contends, the specification clearly and implicitly defines "4-amino-1-hydroxybutane-

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1, 1-biphosphonic acid" as encompassing its sodium salt forms. (D.I. 106 at 10).

In addition, Merck again points to Table 6 of the specification, where two other formulations are disclosed which are effervescent granules and formulations suitable for injection. ('077 Patent col. 13 lines 15-32). Merck contends that although these formulations are listed as containing 4-amino-1-hydroxybutan-1, 1-biphosphonic acid, both formulations are a sodium salt solution. (D.I. 106 at 10-11). Merck asserts that, although actually administering a sodium salt solution, the specification defines these formulations as containing alendronic acid, which demonstrates the contextual usage of the term acid as adopted by the '077 Patent specification. (D.I. 106 at 11). Additionally, Merck directs the Court to Tables 7 and 8 of the specification. ('077 Patent col. 14, lines 40-67, col. 15, lines 1-48, col. 16, lines 1-47). Tables 7 and 8 depict results obtained by administering different bisphosphonates to rats. Id. However, the text does not specify whether the free acid or sodium salt forms were administered. Id. Merck argues that this demonstrates that those of skill in the art recognize that the administration of free acid versus sodium salt is immaterial to the compounds efficacy in inhibiting bone reabsorption. (D.I. 106 at 12).

In response to Defendants' argument that the specification differentiates between the free acid and sodium salt forms, Merck also contends that the '077 Patent specification contains two distinct sections with different purposes. (D.I. 106 at 12). The first section, Merck argues, is a chemistry section setting out methods for making certain pharmaceutically active bisphosphonates and is merely background and not related to claim 1 of the '077 patent. (D.I. 106 at 12). However, the second section, (which starts at column 6 line 45 of the '077 Patent) Merck contends, could be classified as the biological section, which deals with pharmacological effects of bisphosphonates and supports the claim in issue. (D.I. 106 at 12).

Merck also directs the Court to Novo Nordisk v. Genentech, Inc., 77 F.3d 1364 (Fed. Cir. 1996). In Novo Nordisk, the Federal Circuit, bypassing an ordinary meaning analysis, determined that a term was implicitly disclosed in the specification as encompassing both forms of human growth hormone. See Novo Nordisk, 77 F.3d at 1368; (D.I. 106 at 15). Merck contends that Novo Nordisk is highly analogous to the case at bar and urges the Court to adopt its reasoning in reference to its interpretation of claim 1. (D.I. 106 at 15).

Merck also asserts that the PTO, in a Notice of Final Determination in 1995, specifically found that the '077 Patent claims 4-amino-1-hydroxybutane-1, 1-biphosphonic acid monosodium salt trihydrate (alendronate sodium), the active ingredient in Fosomax(R) and the Defendants' accused products, and argues that this determination should be given deference. (D.I. 106 at 17). Finally, Merck maintains that the amendments made during the prosecution of the patent are irrelevant in this case because the first claims that were submitted were composition claims, whereas, the approved claim was a method of use claim and therefore the amendments did not result in a narrowing of coverage. (D.I. 114 at 23).

The starting point for a claim construction analysis is the language of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). While the court may consider the patent specification and prosecution history as relevant intrinsic evidence in its analysis, the court need not accord this evidence the same weight as the claims themselves. CCPI v. American Premier, Inc., 966 F. Supp. 276, 278 (D. Del. 1997). Rather, "the claim language itself is of paramount importance," and therefore the specification and prosecution history need only be consulted to give the necessary context to the claim language. Id. Additionally, a court may consider extrinsic evidence, including expert and inventor testimony, dictionaries and learned treatises in order to assist it in construing the true meaning of the language used in the Patent. Markman, 52 F.3d at 979-80. Thus, the specification and other evidence may assist in determining the meaning of a claim, but it may not be used to impose limitations on a claim not found in the words of the claim itself. Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994).

After reviewing the claim language, specification, and prosecution history of the '077 Patent, in addition to considering the expert testimony, the Court agrees with Merck's interpretation of this language. The phrase "4-amino-1-hydroxybutane-1, 1-biphosphonic acid" is not explicitly defined in the patent. However, in the Court's view, the specification defines the term by implication. Specifically, the Court concludes that in claim 1 of the '077 Patent "4-amino-1-hydroxybutane-1, 1-biphosphonic acid" includes both its free acid and sodium salt forms.

The starting point of this claim construction analysis is that claim 1 of the '077 Patent is a method of use claim as opposed to a composition claim, as it was initially filed. (PTX 25 at 143). Following from this, the Court finds that Merck's separation of the specification into chemistry and biological sections is correct. If claim 1 were still a composition claim the chemistry section would be highly instructive. However, claim 1 of the '077 Patent is a method of use claim i.e. it discloses a method

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for treating urolithiasis and inhibiting bone reabsorption. Therefore, pharmacological effects described in the biological section are more pertinent to the claim.

The Court also finds that in terms of their effectiveness for treating bone reabsorption, there is no difference between the free acid and sodium salt forms as used in the '077 patent specification. First, the Court is persuaded by Dr. Recker, Merck's expert, who testified that in the biological part of the '077 Patent specification, sodium salt is used interchangeably with the acid form. (Recker Tr. 448:8-25). Further, as Dr. Recker testified, there are no distinctions between the free acid and sodium salt forms in reference to the measurement of toxicity and biological effects. (Recker Tr. 450:5-10). Additionally, Defendants assert that Dr. Recker admitted that there were distinctions made between the free acid and sodium salt forms in the '077 Patent. (Recker Tr. 481:1-21). However, this excerpt of Dr. Recker's testimony was taken out of context. After the portion of Dr. Recker's testimony that Defendants cite, Dr Recker testified as follows:

Q. That's right. He doesn't use the word acid, he uses the word salt. When he means salt, he said salt, doesn't he?

A. I don't know what he means but I know what's written down here is salt.

Q. But when he talked about the acid, 4-amino-1-hydroxybutane acid you refer he's not talking about a salt there, don't you

A. Yes but again it's--this is in the context of biology and he uses salt later. And so I-even though he said salt here, in my view and in the view of an ordinary clinical scientist, he would be referring to a sodium salt as well, particularly when you look at the context of this whole section of the-Patent.

(Recker Tr. 481:21-482:10).

Further, the tables and examples listed in the '077 Patent specification also support Merck's proposed claim construction. Specifically, the sentence before Table 6 of the '077 Patent specification (at column 13) states that "some typical pharmaceutical formulations containing amino-butan-diphosphonic acid are shown here below." ('077 Patent col. 13, lines 3-4). In Table 6, under the section titled Opercolated Capsules, 4-amino-hydroxybutane-1, 1-biphosphonic acid, sodium is listed. Additionally, Dr. Hanzlik, Defendants' expert, in reference to the Effervescent Granules Section of Table 6, conceded that there might be an opportunity for sodium salt. (Hanzlik Tr. 293:3-5).

The Court finds Dr. Hanzlik's testimony concerning the distinctions made between the free acid form and sodium salt form in the specification unpersuasive. Dr. Hanzlik testified that Tables 7 and 8, which depict results obtained by administering different bisphosphonates to rats, would be useless to a scientist because they do not list which form was used i.e. acid or sodium salt. (Hanzlik Tr. 297:16-298:1-17). The Court finds that this ambiguity in Tables 7 and 8 supports Merck's contention that there is no difference between the free acid and sodium salt forms in terms of bone disease treatment. Additionally, the '077 Patent is a method of use patent which claims a method for the treatment of urolithiasis and bone reabsorption. Dr. Hanzlik is admittedly not a clinician. (Hanzlik Tr. 281:1-3). Further, he has no education or research experience specific to bisphosphonates. (Hanzlik Tr. 275:16-24, Tr. 276:12-24, Tr. 277:12-22, Tr. 280:18-20).

In addition, the Court finds this issue to be analogous to the issue before the Federal Circuit in Novo Nordisk v. Genentech, Inc., 77 F.3d 1364 (Fed. Cir. 1996). In Novo Nordisk, the parties disputed the term "human growth hormone." Id. at 1368. The patentee asserted that the term encompassed both the human growth hormone ("hGH") and "met hGH" which contained an extra molecule. Id. at 1366, 1368. The Federal Circuit held that the term was implicitly defined in the specification and encompassed both forms. Id. at 1368. Similarly, in the case at bar the specification, especially in Tables 7 and 8, implicitly defines "4-amino-1-hydroxybutane-1, 1-biphosphonic acid" to encompass both the sodium salt and free acid forms.

The Court also finds the PTO's determination that claim 1 of the '077 Patent claims alendronate sodium, the active ingredient in Fosomax(R), instructive. Although claim interpretation is a question of law and the Court should be the final arbiter, the Court finds that the PTO's determination should be given weight in this case. See e.g. Purdue L.P. v. Faulding Inc., 230 F.3d 1320 (Fed. Cir. 2000) (citing Quad Envtl. Technologies Corp. v. Union Sanitary Dist., 946 F.2d 870, 875-76 (Fed. Cir. 1991) for the proposition that although the PTO should be accorded some deference, the Court is the final arbiter on questions of law).

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Lastly, Defendants contend that the patentee disclaimed the use of salts during the prosecution of the '077 Patent. (D.I. 107 at 14-15). The Court disagrees with Defendants' contention and finds that there was no disclaimer of salts during the prosecution of the '077 Patent. Under the doctrine of prosecution history estoppel, the burden is on the patentee to prove that he did not surrender an equivalent during the prosecution of the patent. However, the analysis is different when the court is construing the claim language. See Gentile v. Franklin Sports, Inc., 211 F. Supp. 2d 334, 337 (D. Mass. 2002). The Federal Circuit has recognized the distinction in the analysis of prosecution history in claim construction and under the doctrine of equivalents and has stated:

Claim interpretation in view of the prosecution is a preliminary step in determining literal infringement, while prosecution history estoppel applies as a limitation on the range of equivalents if, after the claims have been properly interpreted, no literal infringement has been found. The limit on the range of equivalents that may be accorded a claim due to prosecution history estoppel is simply irrelevant to the interpretation of those claims.

Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995). The distinction between the two stages of analysis is the burden of proof. In order to prove that a patentee has disclaimed a meaning to a term during the prosecution history, for purposes of claim construction, the challenger "must prove that the patentee made clear representations during the prosecution history which limit the scope of his claim." Gentile, 211 F. Supp. 2d at 337.

In this case, the Defendants can point to no specific evidence in the prosecution history that the patentee "made clear representations during the prosecution history which limit the scope of his claim." Id. The Court finds that the fact that the patentee amended a composition claim to a method claim does not amount to a clear representation that the patentee limited the scope of his claim to the free acid form of 4-amino-1-hydroxybutane-1, 1-biphosphonic acid. Therefore for the aforementioned reasons, the Court construes the term 4-amino-1-hydroxybutane-1, 1-biphosphonic acid, to include both free acid and sodium salt forms.

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INFRINGEMENT

The district court ruled that the claim is infringed by Teva's product. The court found that the claimed method whereby 4-amino-1-hydroxybutane-1,1-biphosphonic acid is used to treat urolithiasis and bone reabsorption disorders (such as osteoporosis) is infringed by administration of the acid salt. The therapeutic agent of the claim is 4-amino-1-hydroxybutane-1,1-biphosphonic acid, whose application is exemplified in the specification in formulations that include the salt and admixtures of the biphosphonic acid with a salt-forming material. The patent refers to formulation of various biphosphonic acids for administration "as the sodium salt," "in the salt form," "in the form of Na salt," and as "4-amino-1-hydroxybutan-1,1-biphosphonic acid, sodium salt."

Specification Table 6 is headed: "Some typical pharmaceutical formulations containing amino-butan-diphosphonic acid," and shows the diphosphonic acid formulated in three ways: (1) as "opercolated capsules" containing "4-amino-1-hydroxybutan-1,1-biphosphonic acid, sodium salt"; (2) as "effervescent granulates" where the formulation includes 4-amino-1-hydroxybutan-1,1- biphosphonic acid, sodium carbonate, and sodium bicarbonate; and (3) "formulations suitable for injection" where the ingredients include 4-amino-1-hydroxybutan-1,1-biphosphonic acid and sodium hydroxide. The witnesses qualified in the field of the invention testified that a pharmacologist of ordinary skill in the field would understand that the active agent is 4-amino-1-hydroxybutane-1,1- biphosphonic acid, and that the method of treatment of bone disorders includes use of the active agent in the form of the salt.

This usage is clearly presented in the specification. In addition to the formulations in Table 6, patent Tables 7 and 8 compare the potency of various biphosphonates that are listed as the acids "in the form of" the salt, and the specification describes various biphosphonic acids "in the form of" the salt; e.g.:

difluoromethanebiphosphonic acid in the form of the Na salt dichloromethanebiphosphonic acid in the form of the sodium salt

'077 patent, col. 9, lines 26-51. The specification describes the unusually high activity of 4-amino-1- hydroxybutane-1,1-

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biphosphonic acid in an in vivo rat model for inhibition of bone resorption, exemplified in application as the salt. The footer in Table 7 refers to the compounds as "various aminobiphosphates" and includes the compound "AHBuBP," which is defined as the biphosphonic acid here at issue, although the "phosphate" terminology generally refers to salts. Thus throughout the specification the inventors described the acid active agent as encompassing the acid and its salt forms.

In evidence were several technical publications that describe treatment with biphosphonic acids in terms that include treatment using the salt form. In an article entitled "Alendronate: A New Biphosphonate for the Treatment of Osteoporosis," the caption names the product "4-amino-1- hydroxybutylidene-1,1-bisphosphonic acid" and Figure 1 depicts the sodium salt. In an article entitled "Rationale for the Use of Alendronate in Osteoporosis," a diagram of the structure of the sodium salt is labeled both as "Alendronate" and as "4-amino-1-hydroxybutylidene-1,1- bisphosphonic acid." An article entitled "Advances in the Management of Paget's Disease of Bone" refers to three different diphosphonates by their common names, using a description encompassing the acid and salt forms: "eudronic acid (disodium eudronate)," "clodronic acid (clodronate)," and "pamidronic acid (pamidronate)." These are the same usages employed in the '077 specification.

In construing patent claims, the court must apply the same understanding as that of persons knowledgeable in the field of the invention. "Patents are written not for laymen, but for and by persons experienced in the field of the invention." Voice Techs. Group, Inc. v. VMC Sys., Inc., 164 F.3d 605, 615 (Fed. Cir. 1999). See Hoechst Celanese Corp. v. B.P. Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning.").

The district court found that a person skilled in the treatment of osteoporosis and urolithiasis would have a medical degree, knowledge of the methods of treatment of patients with these disorders, and knowledge of the pharmacology and usage of biphosphonates. The court determined how such persons would understand the claim in light of the specification, its prosecution history, and customary usage in the field of the invention. See Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999).

A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267-68 (Fed. Cir. 2001); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998). Thus claims must be construed so as to be consistent with the specification, of which they are a part. Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed. Cir. 1996); Slimfold Mfg. Co. v. Kinkead Indus. Inc., 810 F.2d 1113, 1117 (Fed. Cir. 1987).

The claim herein is directed to a method of treatment of urolithiasis and inhibiting bone reabsorption, by administering an effective amount of the specified biphosphonic acid. The evidence of all the qualified witnesses was that persons in this field would understand that the acid is the active agent and that the acid is administered when it is in the form of the salt. There was no evidence that the claimed method of treatment is not achieved by the acid salt. The record shows that Teva and Zenith, as well as Merck, label their products with the "free acid equivalent."

The record contains extensive evidence that persons experienced in this field use the same lexicography as did the inventors in referring to the active ingredient "in the form of" the salt. See Multiform Desiccants, 133 F.3d at 1477 (the inventor's words "must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology"). Dr. Recker, an expert on behalf of Merck, testified that the '077 patent uses the word "acid" to encompass the sodium salt, and that to a pharmacologist this usage is well understood. The cited articles match this usage. The Director of the Patent and Trademark Office also so recognized, in informing the Food and Drug Administration that the patent covers the federally registered product.

The only contrary evidence was provided by a Teva witness who was a chemist and who conceded that he was not qualified in pharmacology. He testified that an acid is not a salt. The district court discounted this testimony, recognizing the absence of qualification of the witness in the field of the invention. The specification shows that the inventors knew the chemical difference between an acid and a salt, for they described the pharmacologic use of the acid "as the salt," and referred to the "biphosphonic acid, sodium salt." The district court placed weight on the evidence of persons qualified in the field of the invention, as against the simplified answer of a witness who, although qualified as a chemist, was notable for his distance from the field of pharmacology.

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The question is not whether a general chemist would know the difference between an acid and a salt. The question is whether a person experienced in the field of the invention and familiar with the usages of pharmacology and the prior art, reading the patent specification, would know that for the treatment of urolithiasis and to inhibit bone reabsorption, the statement that 4-amino-1- hydroxybutane-1,1-biphosphonic acid is administered to treat these diseases, encompasses administration as the acid salt. All of the pharmacologist witnesses agreed that this was the correct reading.

Teva argues that it is improper to go outside of the prosecution record to explain the meaning of terms used in a patent claim. It is well established that evidence extrinsic to the patent documents cannot change the meaning of a term as used in the claim from the meaning with which it is used in the specification. However, it is not prohibited to provide the opinions and advice of experts to explain the meaning of terms as they are used in patents and as they would be perceived and understood in the field of an invention. See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314 (Fed. Cir. 2003); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309, (Fed. Cir. 1999). We conclude that there was not reversible error in the court's crediting of the pharmacologists' testimony, buttressed by publications, the usages in the specification, and the view of the PTO, as against the testimony of a chemist without experience in the specific field of the invention.

The prosecution history is not contrary to this conclusion, for the cancellation of the composition claims was not a disclaimer of the specific method described in the '077 patent. The method claim was entered and allowed upon the examiner's rejection of the composition claims. The new use of a known composition is claimed as a method. See 35 U.S.C. § 100(b) (Eligible methods include "a new use of a known process, machine, manufacture, composition of matter, or material."); Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 875 (Fed. Cir. 1985). The specification shows that the active ingredient in the claimed method is the biphosphonic acid; there was no rejection of the method claim during prosecution, and no departure from the meaning of the terms as used in the specification.

We affirm the district court's holding that the claimed method of treatment by administration of the biphosphonic acid is infringed whether administered as the pure acid or in the form of the acid salt.
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MAYER, Chief Judge, dissenting.

I agree with the court to the extent that it upholds the validity of '077 patent; however, because I believe that the district court erred in its claim construction by concluding that the term "acid" as used in the claim should be construed to encompass both acids and salts, I dissent. Such construction does not accord with a plain reading of the claim or the claim in light of the specification.

In a few instances in the specification of the '077 patent, alendronic acid is named when actually referring to the salt. But in the vast majority of instances, the specification distinguishes between the two. For example: the specification lists as the preferred embodiments, inter alia, 4-amino-1-hydroxybutane-1,1-biphosphonic acid and its sodium, aniline, and lysine salts, '077 patent, col. 3, ll. 20-26; in the "Toxicology Study" section of the specification, tests were conducted for the acid and the salt, listing them as separate compounds, id. at col. 6, ll. 48-49; and in a discussion of the bone reabsorption and in vivo calcification experiments, the acid is juxtaposed with the name of another compound that is characterized as the sodium salt, id. at col. 9, ll. 45-51. These examples, and there are others, evidence that the acid and the salt are distinct compounds and that the patentee is able to distinguish between the two when he so chooses.

Further support for the proposition that the two are distinct compounds can be found in the testimony of the parties' expert witnesses. Three expert witnesses, two provided by Merck, one by Teva, all possessing ordinary skill in the art of chemistry and pharmacology, testified that acid--as that word is ordinarily and customarily used in the relevant art--is distinct in its chemical composition from salt. The term "acid," then, as it is used here, cannot be read to mean "acid and its salts"; the literal scope of the claim can extend only to the acid itself. Because Teva's proposed products are not acids, there can be no literal infringement of the '077 patent.
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This Court previously construed 'acid labile pharmaceutically active substance,' found in claim 1 of the '230 Patent, as "those that are transformed into biologically active compounds by a rapid degradation or transformation in acid media." Id. at 483. The Court also determined that the claim language, specification, and '230 Patent file history all support a reading which includes omeprazole. Id. at 483-85. The Court confirmed its construction again in its order denying Eon and Mylan/Esteve's summary judgment motion arguing for its exclusion (Jan. 12, 2006 Order at 15-17) and now incorporates that construction here. However, Apotex's invalidity challenge raises the new issue of whether the term "acid labile pharmaceutically active substance" includes all acid sensitive materials, regardless of whether they are labile (degrade) in alkaline media. Accordingly, the Court now expands upon its prior claim construction of "acid labile pharmaceutically active substance."

When previously construing "acid labile pharmaceutically active substance," the Court read claim 1 of the '230 Patent in light of the background specifications, specifically column 1, lines 14-27. Astra v. Andrx, 222 F. Supp. 2d at 484; see Markman, 52 F.3d at 978-79 A court must construe the terms of the claims in light of the language in the specification, because the claims are part of "a fully integrated written instrument" and "must be read in view of the specification, of which they are a part."). That part of the specifications specifically states that the '230 Patent is directed to "substances that are labile in acid media, but have better stability in neutral to alkaline media." (PSWTX 2A 1:23-25.) Therefore, the Court finds that the phrase "acid labile pharmaceutically active substance" (or "acid labile compound") refers to a compound that is sensitive to acid but has better stability in alkaline conditions. 10

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10 This claim construction is consistent with the extrinsic evidence considered by the Court. For example, Plaintiffs' expert Dr. Langer, focusing on the same portion of the '230 patent specification (PSWTX 2A 1:23-27), testified that the '230 patent requires that the claimed acid labile compounds be stable in a base. (Langer Tr. 7143:8-11, 7144:5-10.)

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B. "actinic radiation"

MacDermid proposes to construe "actinic radiation" as "radiation that is capable of cross-linking (curing) the photocurable materials of the invention." (MacDermid Opening Br. at 8.) DuPont proposes the construction "radiation capable of effecting a chemical change in an exposed moiety." (Tr. at 29.)

DuPont derives its construction from the specification. (Id. at 123.) DuPont contends that the specification defines actinic radiation, and this definition should be used. (Id.) The specification dictates that "actinic radiation is radiation capable of effecting a chemical change in an exposed moiety." (Id.; '835 Patent, col. 5, lines 13-16.) DuPont states that this is the unequivocal definition of actinic radiation and should thus be used in its construction.

DuPont further criticizes MacDermid's construction as defining the term by reference to the invention itself. (Tr. at 125.) DuPont contends thatthe claims define the scope of the invention, and as such, a claim cannot be defined by referring back to the invention. (Id.)

MacDermid contends that its construction is required by the intrinsic evidence of the '835 Patent. (MacDermid Opening Br. at 8.) It notes that the specification states that the photocurable materials of the invention should cross-link or cure, and thereby harden in at least some actinic wavelength region. (Id. at 7-8.) MacDermid stated, at oral argument, that it "would agree that actinic radiation is radiation capable of effecting a chemical change in an exposed moiety, including cross-linking or curing of the photocurable materials of the invention." (Tr. at 30.) MacDermid argues that it is clear from the '835 Patent that the actinic radiation needs to do a particular job. (Id. at 121.) Thus, the construction should describe this job. (Id.)

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DuPont argues that the patent describes two materials that can undergo a chemical change in reaction to actinic radiation. (Id. at 125.) The photocurable layer is only one of them; the actinic radiation absorbing compound can also undergo a chemical change in reaction to actinic radiation. (Id.) DuPont thus contends thatMacDermid's construction is incomplete and too limiting because it inappropriately narrows the definition of actinic radiation. (Id.) It states that MacDermid's proposed construction gives one example of actinic radiation, but cannot serve as its definition. (Id. at 127.)

The Court agrees with DuPont's construction. The specification clearly states "[a]s used herein, actinic radiation is radiation capable of effecting a chemical change in an exposed moiety." ('835 Patent, col. 5, lines 13-16.) Intrinsic evidence, including the claims and specification, is the most significant source for the legally operative meaning of disputed claim language. Vitronics, 90 F.3d at 1583. The specification here is very clear regarding the meaning of actinic radiation. MacDermid's construction is inappropriately limiting, and the Court will use the definition found in the specification.
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C. "activated SAH-hydrolase"

The parties agree that "inactive SAH-hydrolase" is "SAH-hydrolase that is incapable of acting as a catalyst." It follows that "activated SAH-hydrolase" is "SAH hydrolase that is capable of acting as a catalyst." Axis-Shield's proposed construction is, "SAH hydrolase in a form that is capable of catalyzing the hydrolysis of SAH and the reverse reaction." If specifying the particular reactions which the SAH-hydrolase is capable of catalyzing were critical, presumably the agreed construction of "inactive SAH-hydrolase" would similarly specify that the SAH-hydrolase is only incapable of acting as a catalyst for those reactions. General Atomics' construction is "the inactive SAH-hydrolase that has been activated by addition of a reducing agent." This construction does little to illuminate the meaning of "active," and merely re-states what is obvious from plain meaning of the whole sentence: that the activation occurs by combination with the reducing agent. Accordingly, the proper construction of "activated SAH-hydrolase" is "SAH hydrolase that is capable of acting as a catalyst."
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A. "Shape Memory Activation Temperature"

1. Plaintiff's Proposed Construction

Claim 12(a) of the '196 patent requires that the elongate, hollow thermoplastic liner have a cross-section altered at "a shape memory activation temperature." (D.I. 17, Ex. 2, col. 10, ln. 65) Neither the claims nor the specification of the '196 patent provide a specific temperature associated with the term "shape memory activation temperature." Plaintiffs argue for a functional interpretation of that term, which would include a range of temperatures -- including any temperature "above ambient temperature, which still allows the deformed liner to remain sufficiently deformed for insertion of the liner into a host pipe." (D.I. 127 at 33)

As an initial matter, the court notes that neither plaintiffs nor the '196 patent provide a definition of "ambient." Plaintiffs appear to use "ambient" to refer to normal, "room" temperatures, but they do not specify what those temperatures might be. Commonly understood, "ambient" means "the temperature of the environment in which an experiment is conducted or in which any physical or chemical event occurs." Richard J. Lewis, Sr., Hawley's Condensed Chemical Dictionary 48 (13th ed. 1997). Ambient, then, could refer to a wide array of temperatures and, if applied to the construction of "shape memory activation temperature," it would deprive that claim limitation of any meaning.

Nonetheless, plaintiffs point to the claim language itself for support of this functional interpretation of "shape memory activation temperature." Plaintiffs argue that the term "shape memory activation temperature" is limited "functionally, namely to enable the altered liner to be pulled into the host pipe." (D.I. 128 at 8) The claim language "to enable the liner to be pulled into the pipe," however, does not modify "shape memory activation temperature;" rather, it modifies "having

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reduced cross-sectional dimensions." (D.I. 17, Ex. 2, col 11, lns. 2-3) Thus, the claim language itself sheds no light on the scope of the term "shape memory activation temperature." 3

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3 For these reasons, the court also declines to accord any weight to the testimony of plaintiffs' expert. Plaintiffs' expert, Stanley Mruk, construed the term "shape memory activation temperature" to mean "any temperature above ambient which enables the liner to be temporarily deformed while retaining a memory of the liner's original shape (reformed) by heating the pipe liner to a temperature at or above the temperature used in the deformation of the pipe liner." (D.I. 67 at 4, P 9) Mruk's construction thus rests on an undefined term (i.e., "ambient") as well as an implausible reading of the claim language.

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Plaintiffs also rely heavily on the '365 patent's specification as support for their functional interpretation of shape memory activation temperature. Specifically, plaintiffs point to that patent's description of "a desired deformation temperature of, for example, 160 [degrees] F." (D.I. 65, Tab 1, col. 5, lns. 15-16) Plaintiffs contend that the '196 patent's incorporation of the '365 patent compels the conclusion that shape memory activation temperature "can vary as circumstances require." (D.I. 65, Tab 1, Ex. C., col. 5, lns. 21-22) A careful reading of the '365 patent reveals, however, that the term "shape memory activation temperature" never appears therein. Indeed, both the 160 [degrees] F cited by plaintiffs as a shape memory activation temperature and the phrase, "temperatures [that may] vary as circumstances require," relate merely to the "desired deformation temperature" of the preferred embodiment described in the '365 patent's specification. (D.I. 65, Tab 1, Ex. C., col. 5, ln. 15) Other than plaintiffs' conclusory assertion, there is no basis for equating the '365 patent's use of the term "deformation temperature" with the '196 patent's specific use of "shape memory activation temperature" -- a highly technical term capable of precise calculation. (See, e.g., D.I. 17, Ex. 3 at A363 (providing formula for crystallization temperature, which the coinventor equates with shape memory activation temperature at D.I. 17, Ex. 3 at A351)).

Because the meaning of the term "shape memory activation temperature" is not apparent from the patent, the court must turn to the prosecution history to determine the "meaning that it would be given by persons experienced in the field of invention." See Hoechst Celanese Corp., 78 F.3d at 1578. The prosecution history reveals that plaintiffs took pains to convince the Examiner that "shape memory activation temperature" referred to a specific range of temperatures, identifiable by calculation or by reference to the "specification sheet" of particular thermoplastics, which lists the thermoplastic's crystallization point.

2. The Prosecution History

Because the prosecution history plays such a significant role in determining the meaning of "shape memory activation temperature," the court shall review it in considerable detail. Plaintiffs filed their initial patent application in October of 1987. In this initial application, the proposed specification of the patent referred to 160 [degrees] F as the temperature at which deformation of the thermoplastic liner occurred. (D.I. 17, Ex. 3 at A025) Claim 1 of the initial application also disclosed a process for "altering the cross-sectional shape of the liner to reduce the cross-sectional dimension thereof at a shape memory activation temperature of about 160-180 [degrees] F." (D.I. 17, Ex. 3 at A044) In July of 1988, the Examiner denied claims 1 through 18 of the application as obvious in light of the Laurent patent and other prior art. (D.I. 17, Ex. 3 at A082-088)

In response, plaintiffs amended claim 1 to add, "so as to permit the liner to be pulled into the pipe," following that claim's recitation of a shape memory activation temperature "of about 160-180 [degrees] F." (D.I. 17, Ex. 3 at A102) In February of 1989, however, the Examiner again rejected claim 1 for, among other reasons, obviousness. (D.I. 17, Ex. 3 at A112-118) Plaintiffs again amended their application in June of 1989 and canceled claim 1 along with other claims. Plaintiffs then added several new claims. Of these new claims, claim 31 disclosed a process for installing thermoplastic pipe and

(b) altering the cross-sectional shape of the liner to reduce the cross-sectional dimension thereof at a shape memory activation temperature of about 221-277 [degrees] F so as to permit the liner to be pulled into the pipe . . . .

(D.I. 17, Ex. 3 at A141) Dependent claim 35 of these new amendments also disclosed "[a] process according to Claim 31

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wherein said shape memory activation temperature is about 260 [degrees] F." (D.I. 17, Ex. 3 at A142) Similarly, claim 36 and its dependent claim 40 each disclosed shape memory activation temperatures of "about 221-277 [degrees] F" and 260 [degrees] F, respectively. (D.I. 17, Ex. 3 at A143-44)

Plaintiffs also added claim 41, the predecessor of claim 12 of the '196 patent. Initially, claim 41 taught merely "an elongate hollow liner formed of thermoplastic material having a cross-section altered at a shape memory activation temperature . . . ." Although claim 41 did not provide a specific shape memory activation temperature, its dependent claims 47 and 50 each provided, "[a] process according to Claim 41, wherein said memory activation temperature is within a range of 221-277 [degrees] F." (D.I. 17, Ex. 3 at A146)

Significantly, in their remarks to the preceding amendments, plaintiffs' patent counsel explained that

the reference in the specification and claims to 160 [degrees] F as the melting temperature of the polyethylene liner material is incorrect. . . . Applicants enclose five specification sheets from various companies indicating that the melting temperature of polyethylene was a known parameter at a time prior to the date of this application and specifically known to lie within a range of 221-277 [degrees] F.

(D.I. 17, Ex. 3 at A147) It appears that plaintiffs' patent counsel equated "melting temperature" with "shape memory activation temperature." 4 Each of the specification sheets referred to by plaintiffs' patent counsel pinpoint the melting temperature of the various thermoplastics as above 200 [degrees] F. (D.I. 17, Ex. 3 at A163-67) Plaintiffs' patent counsel also submitted a declaration of one of the coinventors in which the coinventor confirmed that these specification sheets indicated melting points in the range of 221-277 [degrees] F. (D.I. 17, Ex. 3 at A162)

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4 Later in the prosecution, however, the '196 patent's coinventor equates shape memory activation temperature with a thermoplastic's "crystallization temperature" and provided the Examiner with a formula for calculating that temperature. (D.I. 17, Ex. 3 at A363; see also A351)

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Despite these amendments, the Examiner again rejected the newly added claims in September of 1989. (D.I. 17, Ex. 3 at A296-302) In rejecting the claims for, among other reasons, obviousness, the Examiner noted:

It is submitted that the steps of altering the tube's cross-section at 210 [degrees] F and heating to expand the tube in British Application -695 are inherently at the thermoplastic liner's shape memory activation temperature as recited in the instant claims. This temperature is dependent on particular material used.

(D.I. 17, Ex. 3 at A298) (emphasis added). Following this rejection of their newly added claims, plaintiffs again offered amendments to their application in December of 1989. (D.I. 17, Ex. 3 at A303-12) In their remarks to these amendments, plaintiffs' patent counsel distinguished the aforementioned "British Application -695" by noting that, unlike the British Application, "applicants require the cross-sectional shape of the liner to be reduced by altering such shape at a shape memory activation temperature of about 221-277 [degrees] F." (D.I. 65, Ex. 3 at A310) The British Application disclosed a process of deforming polyvinyl chloride ("PVC") tubing at "approximately 210 [degrees] F." (D.I. 17, Ex. 3 at A173) Plaintiffs' patent counsel argued strenuously that, "PVC does not have shape memory characteristics, and . . . . the temperature to which the liner is elevated in [the British Application] is not within the range claimed . . . ." (D.I. 17, Ex. 3 at A310) Contrary to plaintiffs' current contention that shape memory activation temperature is a variable, "functional concept," plaintiffs' patent counsel also acknowledged that, "a shape memory activation temperature is a known property, for example, of polyethylene material, prior to this invention." (D.I. 17, Ex. 3 at A309)

In January of 1990, the Examiner rejected plaintiffs' application on the ground that the recitation of a shape memory activation temperature "of about 221-277 [degrees] F" constituted new matter. Further, the Examiner remarked that this "range would read on any number of polymers dependent on their exact composition." (D.I. 17, Ex. 3 at A325-26) In response to the Examiner's new matter objections, plaintiffs amended their application in April and again in May of 1990. (D.I. 17, Ex. 3 at A331-39; A340-61) In these amendments, plaintiffs deleted reference to 160 [degrees] F in the

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specification as the deformation temperature and replaced it first with 260 [degrees] F and, in May, with 235 [degrees] F. Plaintiffs' patent counsel explained this change in his remarks to the May 1990 amendments:

It must be recognized that patent specifications are directed to those skilled in the art. A person skilled in this art would recognize 160 [degrees] F as an incorrect shape memory activation temperature simply by reference to the specification sheet for this particular type of material specifically disclosed as the preferred embodiment and available at the time of this filing. The person of ordinary skill in the art would be advised by such specification sheet of the actual shape memory activation temperature.

Also, materials such as nylon, Teflon and ABS are disclosed . . . together with the Union Carbide material. All of those materials have shape memory activation temperatures above 200 [degrees] F as indicated on the additional specification sheets for each of those materials accompanying the Declaration of [the coinventor]. Consequently, a person of ordinary skill in the art would recognize that the temperature of 160 [degrees] F could not be the shape memory activation temperature and would be directed by those specification sheets to the appropriate shape memory activation temperature.

(D.I. 17, Ex. 3 at A351-52)

Also in May, plaintiffs canceled claims 31-35 and claim 47 of the application and amended claims 36 and 41. Plaintiffs removed from claims 36 and 41 5 any reference to a specific shape memory activation temperature. Thus, in May of 1990, claim 41 disclosed in relevant part:

An elongate hollow liner formed of thermoplastic material having a cross-section altered at a shape memory activation temperature from a generally cylindrical cross-section having an original diameter substantially comparable to the inside diameter of the pipe to be lined to a reduced cross-section having reduced cross-sectional dimensions to enable the liner to be pulled into the pipe, whereby the liner is maintained in its reduced cross-sectional shape with substantially no tendency to return to its cylindrical cross-section and retains a memory of its cylindrical cross-section, said liner in said altered cross-section having a predetermined wall thickness . . . .

(D. I. 17, Ex. 3 at A343)

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5 Claims 36 and 41 were renumbered as claims 1 and 12, respectively, upon issuance of the '196 patent. (D.I. 17, Ex. 3 at A442)

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In a final supplemental amendment filed in August of 1990, plaintiffs deleted all reference to a specific shape memory activation temperature from the specification and amended claim 41 to read as claim 12 now reads in the '196 patent. (D.I. 17, Ex. 3 at A431-38) In explaining these changes, plaintiffs' patent counsel remarked:

Applicants have attempted to amend the specification to present the proper numerical temperature but without apparent success. Thus, by canceling the numerical temperature for the shape memory activation temperature, the patent issuing from this application will not be misleading and, of course, the actual value is disclosed in the file wrapper. The actual numerical temperature is also not necessary to the claims inasmuch as those claims do not specify the precise numerical shape memory activation temperature.

(D.I. 17, Ex. 3 at A437) (emphasis added).

Thus, the prosecution history reveals (1) that shape memory activation temperature is a specific temperature defined by the particular properties of the thermoplastic at issue, (2) that plaintiffs contemplated shape memory activation temperatures that were well above ambient temperature (assuming "ambient" refers to normal, "room" temperatures), and (3) that the patentee defined shape memory activation temperature first (and, apparently, erroneously) as a given thermoplastic's "melting point" and later as a thermoplastic's crystallization point. In defining shape memory activation temperature as a thermoplastic's crystallization point, the '196 patent's co-inventor declared that:

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[4. The preferred embodiment's] crystallization point is given as 113 [degrees] C, or about 235 [degrees] F. This is the memory activation temperature for that particular material.

5. The crystallization temperature is a temperature defining the maximum crystallization speed and it may be obtained by the formula T[c] [approximately equal to] (T[m] + T[g]) /2 where T[c] is the crystallization temperature, T[m] is the melting temperature and T[g] is the glass transition temperature. Each of nylon, Teflon and ABS, as disclosed in this application as an alternative material to the specifically identified and preferred Union Carbide material has a crystallization temperature above 200 [degrees] F. This is evidenced by calculations and specification sheets for those materials . . . .

(D.I. 17, Ex. 3 at A363-64) (emphasis added). The prosecution history thus establishes that shape memory activation temperature is not, as plaintiffs suggest, a "functional" concept that "can vary as circumstances require."

Instead, the prosecution history reveals that the coinventor himself regarded shape memory activation temperature as a known temperature ascertainable by calculation and dependent upon a given thermoplastic's physical properties. Accordingly, the court shall construe the term, "shape memory activation temperature," as the '196 patent's coinventor understood it -- namely, as the crystallization point of a given thermoplastic, calculated according to the following formula:

T[c] [approximately equal to] (T[m] + T[g])/2 where T[c] is the crystallization temperature, T[m] is the melting temperature and T[g] is the glass transition temperature.

(D.I. 17, Ex. 3 at A363; see also A351 (equating shape memory activation temperature with a material's crystallization temperature)).
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The Court has construed the limitations of Claim 1, in relevant part, as follows:

"Active" means producing an intended action or effect: active ingredients.
"Pharmacologically effective" means an amount that is medically effective.
"Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate 1, dermatan sulfate, keratan sulfate and acemannan, for example.
"Amount effective" means a quantity that produces a result.
"Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
"Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.
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1. Activity of Cytochrome p450 Isozyme

The parties dispute the meaning of "activity of cytochrome p450 isozyme" found in claim 1 of the '566 patent. Plaintiffs argue the term should be construed to mean "the process or function performed by the enzyme as well as the effect of any such process or function." Plaintiffs contend that this definition is the ordinary meaning in light of language found in the specification which explains what information a patient would be provided concerning the effects and activity of cytochrome p450 isozyme. 2 ('566 Patent, 14:34-66; 24:15-18; Doc. No. 1). Defendants contend that the term "refers broadly to the specific activity of the enzyme (i.e., the rate at which the enzyme transforms a substrate per mg or mole of enzyme) as well as the metabolic effect of such transformations." Defendants argue that cytochrome p450 isozyme is an enzyme, and therefore its activity should defined consistent with the specification's language concerning "enzyme activity."('566 Patent, 10: 47-50; Doc. No. 1.)

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2 During the Markman hearing, Plaintiffs argued a construction of the term "activity of cytochrome p450," rather than the term "activity of cytochrome p450 isozyme." As the word "isozyme" is critical to the definition of the activity of cytochrome p450, it would be improper to omit it. Further, all briefing by the parties as well as the joint claim construction chart include "isozyme" in the disputed term.

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Defendants are correct to recognize that cytochrome p450 isozyme is an enzyme. But, as all enzymes are not isozymes, the term must be construed to recognize the scope of the particular activity. Therefore, as Plaintiff points out, to adopt the specification's reference to "enzyme activity" would not be precise to the term as it is used in the claim and therefore not begin and remain on the language of the claim.

Accordingly, the Court will construe "activity of cytochrome p450 isozyme" in claim 1 of the '566 patent as follows: "the specific activity of the isozyme as well as the metabolic effect of that activity." This construction adopts the '566 patent's definition of "enzyme activity," but modifies it to refer to the specific isozyme at issue.The explanatory parenthetical proposed by defendants is confusing and not necessary, and has been omitted.
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f. "an amount of . . . added" & "adding an amount of" Claims 1, 4, and 8

The terms "added" and "adding" should be given their plain and ordinary meaning in this instance. While Rubber Mulch proffers a definition of "joining or uniting without mixing," the patent specification does not support its argument. The detailed description states, in part, "[af]ter the rubber particles are placed in the mixing means an amount of colorant is added to the rubber particles in the mixing means." ('514 Patent, col. 4, lns. 31-33) Nothing in the claims, specification or patent history supports the definition that the colorant is added without mixing. Therefore, the undersigned finds that the terms "added" and "adding" mean "to join or unite so as to bring about an increase or improvement." Merriam-Webster Online Dictionary (visited May 15, 2007) <http://www.m-w.com/dictionary/add>.
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8. adding a mixture of labeled nucleic acid from the two cell types to an array is construed to mean adding a mixture of labeled nucleic acid from the two cell types to the array in a single step, wherein "labeled nucleic from the two cell types" means samples of mRNA, DNA, or cellular other nucleic acid obtained from the two cell types.

Affymetrix contends that this term means adding a mixture, either in a single step or sequentially, of labeled nucleic acid from the two cell types to the array. Affymetrix further states that "nucleic acid from the two cell types" means samples of mRNA, or nucleic acid derived from said mRNA, including, but not limited to cDNA, labeled either before or after isolation from the two cell types.

Incyte contends that this term means the simultaneous and competitive hybridization of samples from different cells to an appropriate array to allow the subsequent quantitation of the resulting relative levels of hybridization. Incyte further asserts that "labeled nucleic acid from the two cell types" means samples of mRNA obtained from the two cell types and then labeled.

The plain language of this claim term requires adding a mixture, or combined sample, to an array in a single step. The Court rejects Affymetrix's proposition that the mixture could be added sequentially, as it is unclear what Affymetrix means when it suggests that a sample containing a mixture of labeled nucleic acids from two cell types could be added sequentially to the array. The plain meaning of adding a mixture to the array at once is consistent with the Examiner's understanding that the

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invention suggests "simultaneous hybridization of mixed nucleic acids." (Livornese Decl., Exh. 30 (9/3/97 Office Action) at 8). Affymetrix presents no citation or evidence to contradict the plain meaning in this respect.

The term also requires that the mixture of labeled nucleic acid is "from the two cell types." The Court agrees with Incyte to the extent that this phrase must be limited to nucleic acid samples collected from the two cell types. That is, cDNA, because it is a nucleic acid made in a reaction outside the cell, is not covered by the plain words of the claim. Affymetrix fails to cite to any evidence, intrinsic or extrinsic, that supports its proposition that cDNA and other nucleic acids derived from a cell's mRNA, which are never components of a cell, are encompassed by this term. Plainly, cDNA is not obtained from any cell, but is synthesized based on nucleic acids obtained from the cell.

Finally, the Court rejects Incyte's restriction of the term to mRNA that is labeled after it is obtained from the cell. The term recites "nucleic acids" and plainly covers DNA as well as any other cellular nucleic acids. Moreover, the claim does not impose any time constraint on when the nucleic acid is to be labeled. Incyte has failed to present any intrinsic or extrinsic evidence to contradict this plain meaning.
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Finally, the district court may have harmlessly erred by reading AFG Industries, Inc. v. Cardinal IG Co., 239 F.3d 1239 (Fed. Cir. 2001), to justify a "substantially" addition to claim limitations. The district court's comment, Astra, 222 F. Supp. 2d at 460, which arguably overstates matters, does not affect the trial court's definition of the limitations and their effect on the infringement analysis. The district court simply used the premise to support a claim construction that this court concludes was correct independent of this aspect of the district court's analysis.
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IV. "(4) an addition rate at which catalyst is introduced into the FCC unit" '236 patent, col. 15, ll. 60-61.

Plaintiff contends that this phrase means an "addition rate at which catalyst additive is introduced into the equipment normally associated with the FCC unit." 52 Defendants contend that it means "the weight of material added to the FCC unit in a given period divided by the time over which the addition was actually made." 53 The Court will examine "addition" and "rate."

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52 (Pl.'s Claim Construction Br. at 28.)

53 (Defs.' Opening Claim Construction Br. at 22.)

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A. "addition"

Plaintiff's proposed construction leaves "addition" unchanged, while Defendants define "addition" as "the act or process of adding." 54 The Court finds that "addition" carries its ordinary and customary meaning of "the act or process of adding." Nothing in the specification or prosecution history contradicts this plain meaning. See Brookhill-Wilk 1, 334 F.3d at 1298-99; Texas Digital, 308 F.3d at 1204.

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54 (Id. at 22, Ex. 5 at WRG-51180 (Merriam Webster's Collegiate Dictionary (10th ed. 1995)).)

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B. "rate"

The Court has previously construed "rate" to encompass both "the amount of change of some quantity during a time interval divided by the length of the time interval" and "a fixed relation . . . between two things: ratio." See supra Analysis Part III. "A word or phrase used consistently throughout a claim should be interpreted consistently." Phonometrics, Inc. v. Northern Telecom Inc., 133 F.3d 1459, 1465 (Fed. Cir. 1998). Here, "rate" has been used consistently in the claim, both in the "rate of consumption" and in the "addition rate." Thus, the Court will interpret it consistently.
C. Summary

Accordingly, the Court concludes that the phrase "(4) an addition rate at which catalyst is introduced into the FCC unit" means "(4) a ratio of the catalyst added into the FCC unit over time, or a ratio of the catalyst additive added into the FCC unit over the fresh catalyst."
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The only differences between claim 1 of the '342 patent and claim 1 of the '303 patent is the inclusion of the phrase "sustained release" before each reference to "dental bleaching composition"; the substitution of the phrase "sustained release dental bleaching agent" for the phrase "dental bleaching composition" in paragraph (c); and the addition of the phrase "said sustained release dental bleaching agent remaining active during a substantial time while the dental tray is positioned over the patient's teeth surfaces" to paragraph (d).

The addition of the term "sustained release" does not alter the meaning of claim 1 such that the interpretation is any different than it is for claim 1 of the '303 patent, nor does the substitution in paragraph (c). The addition of the term "sustained release" simply emphasizes a feature inherent in the composition. Likewise, the additional language in paragraph (d) describes an inherent characteristic of a dental bleaching composition made with carboxypolymethylene. Therefore, as in the '303 patent, this court interprets "said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the sustained release dental bleaching composition" to mean that the composition used in dental bleaching in accordance with the claimed method contains from about 3.5% to about 12% by weight of carboxypolymethylene defined as a slightly acidic vinyl polymer with active carboxyl groups.

The language of claim 2 is likewise similar to that of claim 2 of the '303 patent. The only modification is the deletion of the word "additional" from the phrase "additional bleaching agent." This change has no effect on the interpretation of claim 2; it is identical to that of the '303 patent.
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D. Fuel additive.

The court now turns to the proper definition of "fuel additive." The plaintiff proposes that "fuel additive" or "additive" means "a material added to another, usually in small amounts, to impart or enhance desirable properties or to suppress undesirable properties." For support, the plaintiff points to the Standard Terminology Relating to Petroleum, Petroleum Products, and Lubricants published by the American Society for Testing and Materials. The defendant contends that the term means "[a] pre-formulated composition, other than one composed solely of carbon and/or hydrogen, that is intentionally added to a fuel and is not intentionally removed prior to sale or use." The defendant's definition has its roots in the EPA's definition of additive found at 40 C.F.R. § 79.2(e). In addition, the defendant points to the prosecution history and argues that the term "additive" must be limited, in this case, to a "pre-formulated" composition.

There is authority for the proposition that definitions issued by regulatory agencies carry weight in claim construction proceedings if they are probative of an industry-specific meaning for a disputed claim term. Mars, Inc. v. H.J. Heinz Co., L.P., 377 F.3d 1369, 1374 n.3 (Fed. Cir. 2004) (citing E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1368 (Fed. Cir.

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2003)). Nonetheless, the application of a regulatory definition depends on whether it accurately reflects the industry's understanding of the term. In this case, the defendant has not shown that the EPA's definition was the definition of "additive" accepted by the industry when the regulation was promulgated. The court is reluctant to adopt the EPA's definition of this term because the court is concerned that the definition is the result of policy-making by the EPA as opposed to a codification of an industry-accepted definition. Consequently, the court rejects the regulatory definition of additive in this case.

The court has also considered the defendant's request to incorporate the term "pre-formulated" into the definition of additive. The defendant relies on the prosecution history to urge this limitation. During the prosecution of the 082 patent, the examiner rejected the application as obvious over the combination of the UK and Arkis references. The UK patent disclosed a fuel additive which included zinc oxide, iron oxide, and copper oxide. The Arkis reference also disclosed an additive composition, which the applicant argued comprised about 10% to 90% of an aliphatic alcohol and about 10% of an aromatic solvent. Although neither reference disclosed all of the limitations of the plaintiff's invention, the examiner relied on a passage in Arkis to support an obviousness rejection and urged that one of skill in the art would have been motivated to combine the two references. Specifically, the examiner stated:

it would have been obvious to the artisan skilled in the art to add the additive composition of UK to the fuel composition of Arkis et al because Arkis et al teach the addition of conventional additives to the composition.

The patentee disagreed with the examiner and argued that Arkis did not teach the combination of the two additives, but rather taught the introduction of the additive to a fuel containing antiknock agents, etc.. The patentee's statement was not an admission that the composition of the patent had to be pre-formulated before its introduction into a hydrocarbon fuel. Rather, the applicant was objecting to the examiner's characterization of Arkis as providing a motive to combine. Nothing in the prosecution history requires the inclusion of the "pre-formulated" limitation sought by the defendant. The court therefore rejects it.

Based on these holdings, the court defines "fuel additive" consistent with the plaintiff's definition of "additive" except that the court has included the term "fuel" within the definition of "additive" to provide context. "Fuel additive" means "a material added to fuel, usually in small amounts, to impart or enhance desirable properties or to suppress undesirable properties."
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The first term in dispute concerns the word "adhesive," contained numerous times in the patent claims. Moore asserts that an adhesive is a generic term which includes cohesives. The Court agrees. While a cohesive may have the special property of sticking only to itself, 4 there is nothing that precludes a cohesive from being a subset of the term adhesive. An adhesive is "[a] substance . . . that provides or promotes adhesion." The American Heritage Dictionary of the English Language (3d ed. 1996). Certainly this definition applies to a cohesive as well. Finally, Central States has offered no evidence to show that a cohesive is a term of art that is excluded from the definition of adhesives. 5

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4 The parties appear to be in agreement as to this interpretation.

5 Though extrinsic and not considered by this Court, Central States even quotes its own technical manual definition of a cohesive which describes it as an "adhesive." Def.'s Response at 13.

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Central States contends that the '875 patent is meant to protect only products using heat-seal adhesives. As justification for its assertion, Central States asserts that the patent is "drafted in the context of a heat seal adhesive" and because of that, "Moore's construction of the term 'adhesive' . . . renders the claims invalid under 35 U.S.C. § 112, paragraph 1 (lack of enablement) and paragraph 2 (unduly vague)." Def.'s Response at 12. Central States' justification for this is that since the patent only describes the placement of adhesive on one side of a seal strip, and pressure sensitive adhesive requires adhesive

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on two sides, the patent does not enable a person reasonably skilled in the art to make the claimed invention.

Central States' reliance on section 112 is ill-founded. What paragraph 1 of section 112 requires of the patentee is to state the "best mode" contemplated of making the invention. 35 U.S.C. § 112, para. 1. The patentee has illustrated a "best mode" using a heat-seal adhesive. The use of a heat-seal adhesive as a preferred embodiment does not mean that the claims can be limited to only a heat-seal adhesive. See Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("one may not read a limitation into a claim from the written description"). Furthermore, the claims use the terms "adhesive" and "activated" when relating to the method by which the envelope will be sealed. These are adequately specific and comply with paragraph 2 of section 112. The adhesive may be any type of adhesive that can be activated, whether by heat or pressure.

Central States appears to be forwarding the theory that since the patent claims only describe adhesive strips on one side of the seal, then a product with a matching seal using a cohesive would be non-infringing. However, such a product would still infringe upon the adhesive placement in Claim 1 of the '875 patent. One cannot rightfully add elements to a patented invention because the "improved" invention would still contain all of the claims protected in the existing patent. Therefore, Central States' argument fails.
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The district court found that one of ordinary skill would interpret the term "adipose-derived" to mean simply "derived from fat tissue." The REBAR researchers do not disagree that this is the term's plain meaning, but argue that the construction must also include that the stem cell is "a species of stem cell distinct from the mesenchymal stem cell ('MSC') that is obtainable from bone marrow tissue." This construction is necessary for their claim of inventorship because they alleged that their research proved that the inventive stem cells were in fact distinct from the prior art mesenchymal stem cells. They posit that the district court's construction would allow inclusion of prior art mesenchymal stem cells that traveled from the bone marrow and became lodged in fat tissue, where they are then extracted. They also argue that the specification makes clear that the inventive aspect of the adipose-derived stem cells is not that they are simply recovered from adipose tissue.

The REBAR researchers contend that the specification describes the prior art mesenchymal stem cells in one way, and describes the inventive adipose-derived cells differently, as an improvement upon the mesenchymal stem cells. The district court found that the specification distinguishes between mesenchymal stem cells and adipose-derived stem cells. While the specification says that the mesenchymal stem cells require costly prescreening of culture materials, the inventive cells can be passaged in culture in an undifferentiated state not requiring prescreened lots of serum. Compare '231 Patent col.1 ll.35-39 with id. col.2 ll.16-18 and col.16 ll.1-4. However, the specification does not say that the cells are a separate species from mesenchymal stem cells collected from bone marrow as the REBAR researchers argue, just that those derived from bone marrow have different isolation requirements than those derived from adipose tissue. The court cannot impute a reason for the difference in isolation requirements of cells harvested from bone marrow versus those harvested from adipose tissue by requiring them to be of a separate species. Nor can we conclude that the hypothetical bone marrow originating stem cell that traversed and became lodged in adipose tissue would not lose the qualities that make it more difficult to isolate than its adipose-derived neighbors. That other similar prior art cells are described differently than the inventive cells does not rise to an intent to deviate from the meaning of the terms describing the inventive cells. Voda, 536 F.3d at 1320.

We similarly do not find the REBAR researchers' prosecution history argument persuasive. A patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution. Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). The researchers argue that Katz and Llull clearly and unambiguously disclaimed any construction of adipose-derived that could read on prior-art mesenchymal stem cells when they overcame a rejection of claims by introducing the term adipose-derived. They argue that at an interview recorded in a summary, Katz and Llull "agreed that a submission to distinguish between adipose derived stem cell and bone marrow derived stem cell will be submitted." The subsequent submission was a paper by a UCLA group that included REBAR researchers showing that the mesenchymal stem cells and the inventive stem cells differed in their intrinsic properties. The examiner then agreed with the inventors that the "adipose-derived stem cells are distinct from the mesenchymal stem cells" of the prior art, but also noted that the claims were "now in condition for allowance" without requiring an amendment. This is not a disavowal. The examiner's summary is certainly terse, and its terseness does not allow a definition of any claim terms. It does not state why the adipose-derived stem cells in the invention are distinct from mesenchymal stem cells, and

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thus does not explicitly characterize the invention at all, let alone in a specific manner to overcome prior art. See Purdue Pharma, 438 F.3d at 1136. A wide chasm exists between the weak inference from the summary that adipose-derived stem cells in this invention must be a different species from mesenchymal stem cells and a clear and unmistakable disavowal as required to limit a claim term.
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b. Titanium Dioxide

For purposes of completeness, and because it relates to other pending motions for summary judgment, the Court will also address Teva's use of titanium dioxide as a colorant in capsule shells and tablet coatings. The issue is whether claim 7, describing "[a] stable and pure pharmaceutical composition in unit dry medicinal dosage form consisting essentially of . . . one or more pharmaceutically acceptable adjuvants [that meet certain stability requirements]" is directed at ingredients in capsule shells and tablet coatings.

Teva argues that claim 7 covers all inactive ingredients, regardless of whether they are intimately mixed with the gabapentin or serve as an ingredient to the capsule shell. Teva equates "adjuvant" with any inactive ingredient, invoking the expansive FDA definition of inactive ingredient as any component in the pharmaceutical dosage form other than the "active ingredient," 21 C.F.R. § 210.3(b)(8). An FDA definition for something other than "adjuvant," specifically, while important for FDA purposes, does not advance the claim construction inquiry here.

Warner-Lambert responds that even if the Court construes claim 7 to exclude the eight lactam-promoting adjuvants listed in the '482 patent specification, which it has, Teva's use of titanium dioxide for coloration is irrelevant. The reasoning goes that an "adjuvant" is an ingredient intimately mixed with gabapentin and that while all "adjuvants" are "inactive ingredients," it does not logically follow that all inactive ingredients are adjuvants. Rather, adjuvants are that subset of inactive ingredients intimately mixed with gabapentin to form the drug mixture.

The Court agrees with Warner-Lambert that Teva's use of titanium dioxide as a colorant is irrelevant for purposes of the '482 patent. 8 Intrinsic evidence and extrinsic evidence considered in context support this conclusion.

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8 Warner Lambert alternatively argues that Teva's use of titanium dioxide as a colorant is insufficient to take it outside claim 7's preamble language "consisting essentially of." The Court need not reach that argument in light of its conclusion that use of titanium dioxide as a colorant is irrelevant for purposes of the '482 patent.

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The Court observes that there is nothing in the patent or prosecution history that suggests that ingredients only present in capsule shells or tablet coatings affect the stability of the pharmaceutical formulation, so as to be considered an adjuvant within the meaning of claim 7. Therefore, the fact that Warner-Lambert did test capsule shells for lactam promotion (see 11/18/04 transcript at 108-09; Trondlin Decl.) is not helpful to claim construction.

Ingredients of dosage capsules or coatings could conceivably have an effect on the stability of a gabapentin formulation. Indeed, Warner-Lambert selected talc as a colorant for the film coating of Neurontin(R) tablets because it discovered that talc had 20 times less of an effect on lactam formation than titanium dioxide. (Warner-Lambert Opp. at 41 n.7; Trondlin Decl., Table 1). It is argued that Warner-Lambert thus recognized that a colorant in a tablet's film coating was relevant to lactam formation, even though not intimately mixed with the active ingredient. However, Warner-Lambert also chose to use titanium dioxide in the capsule shells for its gabapentin product. (See Warner Lambert's Opp. at 41 n.7 ("Warner-Lambert selected titanium dioxide as a colorant for the gelatin capsule shells of Neurontin(R) capsules."); Teva's Mem. of Law in Support of Summary Judgment on Non-Infringement at 11 ("The Physician's Desk Reference ("PDR") for Neurontin(R) lists titanium dioxide as an inactive ingredient in Warner-Lambert's Neurontin(R) capsule formulation." (citing Ex. 5, PDR at 2655 (2002))). This suggests that Warner-Lambert did not consider titanium dioxide, when used as a colorant in a capsule shell, to be a significant threat to stability of a gabapentin formulation. 9 Thus, when viewed as Warner-Lambert admissions

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against interest, the foregoing considerations advanced by Teva are somewhat equivocal. In any event, Warner-Lambert's apparent concession that ingredients used in tablet coatings may affect lactam formation does not determine whether the language of the '482 patent is directed at ingredients of capsule shells.

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9 Notably, Warner-Lambert's use of titanium dioxide as a colorant in a capsule shell is consistent with its position (rejected by the Court) that it is permissible to use any adjuvant, even those that are "excluded," if such use is judicious, and is not necessarily inconsistent with a conclusion that an ingredient in a capsule or a tablet coating is not covered by the patent. Warner-Lambert's use of titanium dioxide as a colorant in its capsule shells is certainly consistent with its position (and the Court's claim construction) that titanium dioxide, as so used, is not an "adjuvant."

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The Court rejects the argument briefed and jointly advanced by the generic defendants at oral argument on November 18, 2004 (Tr. at 106) that the titanium dioxide present in capsule shells or tablet coatings is used as an adjuvant for purposes of claim 7. While dependent claim 9 refers to the dry medicinal dosage form as a tablet, and dependent claim 10 refers to the dry medicinal dosage form as a capsule, titanium dioxide as a colorant/coating of those capsules/tablets is not referenced in the patent or prosecution history. There is nothing in the patent that references capsule shells or tablet coatings. The fact that capsule shells (with no defined ingredients) appear in the Trondlin declaration as being tested for their effect on lactam promotion does not answer whether the language of the '482 patent covers those ingredients. This leads the Court to conclude that claim 7 is directed at gabapentin and substances mixed intimately therewith, not the colorants used in capsule shells or tablet coatings.

Furthermore, claim 7 plainly covers a composition "in unit dry medicinal dosage form," of which tablets and capsules are examples. ('482 patent, col. 8, ll. 28-30). It does not follow that an ingredient of the capsule shell or tablet coating should be treated the same way as an ingredient of the composition. However, such would be the result of Teva's argument. While the inventors could have made that connection, nothing in the patent or prosecution history suggests that they did.

It is clear that the inventors were concerned about a catalytic reaction in the presence of certain adjuvants. ('482 patent, col. 5, ll. 30-33). Obviously, that concern is most relevant where the catalyst is intimately mixed with the reactive material, suggesting to the Court that peripheral or partial contact, as in a capsule shell or tablet film coating, between a catalyst and the reactive material was of lesser concern. This, in conjunction with the lack of reference in the patent to ingredients of capsule shells or tablet film coatings, further suggests to the Court that claim 7 of the '482 patent is directed to gabapentin and substances intimately mixed therewith, not the actual ingredients used in capsule shells or tablet film coatings.

When considered in light of the patent claims and specification, extrinsic evidence also supports this conclusion. Phillips v. AWH Corp., 415 F.3d 1303, 2005 WL 1620331, at *15 (Fed. Cir. 2005) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584, 1585 n.6 (Fed. Cir. 1996) (courts are free to consult and rely on dictionary definition when construing claims so long as definition is not at odds with definition found in patent documents)). There is a strong presumption that a claim term carries its ordinary meaning. W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC, 370 F.3d 1343, 1350 (Fed. Cir. 2004). Warner-Lambert's position--that ingredients of capsule shells or tablet coatings are not "adjuvants" because they are not mixed with the drug formulation--comports with the commonly understood definition of adjuvant: "A pharmacological agent added to a drug, predictably affecting the action of the drug's active ingredient." The American Heritage Stedman's Medical Dictionary (2002); A "substance added to a prescription to aid the effect of the main ingredient." The Random House Dictionary of the English Language (2d ed. 1987); "A pharmacological agent added to a drug to enhance its effect." Webster's II New Riverside University Dictionary (1984). While these dictionary definitions do not necessarily defeat Teva's construction of adjuvant as being any "ingredient" that aids the effect of the main ingredient, including those of capsule shells or tablet coatings, the Court finds the general emphasis on ingredients being "added to" a drug to be more consistent with Warner-Lambert's construction.

For these reasons the Court concludes that a skilled formulator would understand the term "adjuvant" in claim 7 to mean that subset of inactive ingredients that is intimately mixed with gabapentin to form the drug mixture, and thus construes claim 7 so as not to refer to the ingredients of capsule shells or tablet coatings. Accordingly, Teva's use of titanium dioxide does not itself compel a finding of noninfringement.

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We next consider appellees' arguments concerning adjuvants. As a preliminary matter, we disagree with Warner Lambert's assertion that the adjuvant issue is not properly before us because it falls outside the scope of the Rule 54(b) judgment. Rule 54(b) provides that:

When more than one claim for relief is presented in an action, whether as a claim, counterclaim, cross-claim, or third-party claim, or when multiple parties are involved, the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

Here, finding no just reason for delay, the district court entered final judgment on Warner Lambert's infringement claims. In reaching its decision to grant the request for certification under Rule 54(b), the district court reasoned that "Federal Circuit review of the Court's claim constructions and noninfringement rulings will advance the ultimate resolution of this multidistrict litigation." R. 54(b) Order, slip op. at 3. The court further stated that "appellate review will benefit the parties in this multidistrict litigation by providing definitive claim constructions, which should narrow the issues." Id. at 4. Thus, contrary to Warner Lambert's assertion, the court's entry of final judgment on the issue of noninfringement was not limited to two particular motions, viz., the burden of proof motion or Apotex's adjuvant motion, but rather encompassed the court's claim construction rulings that pertained to the issue of noninfringement. As such, the court's claim construction of the adjuvant limitation, which is relevant to a noninfringement determination, is properly before us.

We agree with Warner Lambert that the district court did not err in concluding that the adjuvant claim limitation refers to ingredients intimately mixed with gabapentin, and thus excludes ingredients located in the capsule shell or tablet coating. In reaching its determination, the court first examined the claim language. The court noted that claim 7 claimed "a stable and pure pharmaceutical composition in unit dry medicinal dosage form," thus suggesting a distinction between ingredients that are mixed with the active ingredients and ingredients that are separated from the active ingredient because they are in the tablet coating or capsule shell. Gabapentin, 395 F. Supp. 2d at 151-52. The court then considered the specification and correctly observed that the patentees were concerned with the negative effect certain adjuvants had on the stability of gabapentin because those adjuvants catalyzed lactam formation. The court concluded that "that concern is most relevant where the catalyst is intimately mixed with the reactive material, suggesting to the Court that peripheral or partial contact, as in a capsule shell or tablet film coating, between a catalyst and the reactive material was of lesser concern." Id. at 152. Moreover, the court found nothing in the patent or prosecution history indicating that ingredients found in the capsule shell or coating affects stability, and also relied on several dictionary definitions in support of its construction. We find no error in the court's analysis, and are not persuaded by appellees' arguments in support of a broader definition. Accordingly, we conclude that the court did not err in determining that the asserted claims require the adjuvant to be intimately mixed with gabapentin.

Lastly, we reject appellees' assertion that the court erred in construing "modified maize starch" as "maize starch modified by acid treatment." In reaching its conclusion, the court first examined the '482 patent specification. The specification discloses that:

The following adjuvant materials, for example, reduced the stability of the compounds (I) and should be avoided in the preparation of pharmaceutical compositions: modified maize starch, sodium croscarmelose, glycerol behenic acid ester, methacrylic acid co-polymers (types A and C), anion exchangers titanium dioxide, and silica gels such as Aerosil 200.

On the other hand, the following adjuvant materials had no noticeable influence on the stability of the compounds (I): hydroxypropylmethylcellulose, polyvinylpyrrolidone, crospovidon, poloxamer 407, poloxamer 188, sodium starch glycolate, copolyvidone, maize starch, cyclodextrin, lactose, talc, as well as co-polymers of dimethylamino-methacrylic acid and neutral methacrylic acid ester.

'482 patent col.5 ll.5-17 (emphases added). The court noted that while the specification expressly indicated that modified maize starch should be avoided as an adjuvant, the specification further stated that sodium starch glycolate, which, according to Warner Lambert's expert, Dr. Klibanov, is an example of pregelatinized starch, "had no noticeable influence on

the stability of the compounds." That supports the court's construction that modified maize starch does not encompass pregelatinized starch; otherwise the teaching of the specification would be internally inconsistent.

In addition, the court relied on the prosecution history in support of its construction. The prosecution history contains a declaration dated December 10, 1999, by Dr. Friedrich Trondlin, then-head of the analytical department of Parke-Davis Analytical Research. Dr. Trondlin stated that "it is my belief that excipients pretreated with mineral acids, such as maize starch modified by acid treatment would not result in a stable formulation." That statement provides further support for the construction adopted by the district court. Based on those references to the intrinsic evidence, we thus conclude that modified maize starch refers to maize starch modified by acid treatment, which therefore excludes pregelatinized starch.

We have considered appellees' arguments regarding the court's claim construction and find none that warrant reversal of the district court's decision. In light of our conclusion, we thus reject appellees' alternative argument for noninfringement.
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Administer/administration

The Court agrees with MRI and construes the term as "delivering the formulation-in-question into a person's body." BSN argues that the term should be construed as "giving remedially," but fails offer any support for this interpretation.
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I. "administering" and its permutations

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8 The term "administering" and its permutations is contained in claims 1, 2, 3, 6, 7 and 9-27 of the '499 patent; claims 1, 2, 5, and 6-24 of the '458 patent; and claims 13-18 and 20 of the '183 patent.

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Plaintiff's Proposed Construction	Defendants' Proposed Construction
Ordinary and customary meaning.	Putting into a patient

Alternatively, "to mete out."

The patents-in-suit contain the terms "by administering," "administering," "administered," and "administering to said patient." For ease of discussion, the Court will collectively discuss the representative term "administering" and permutations of this term should be given the same construction in each patent. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("we presume, unless otherwise compelled, that the same claim term in . . . related patents carries the same construed meaning").

Pozen contends that the claim term should be given its ordinary and customary meaning and no further construction is necessary becausea person of ordinary skill in the art would readily understand the meaning of "administering" and its permutations. OPENING at 9-10. Pozen argues that if the Court is inclined to provide a construction, "administering" should mean "to mete out," as it is set forth in Webster's general purpose dictionary. Id. at 10.

Defendants respond that the goal of the '499 and '458 patents is to treat migraines in patients, and this can only be accomplished when the drug is "put into a patient." RESPONSE at 6. Therefore, Defendants argue that the term must be construed more narrowly than its ordinary meaning to comport with the patent's description of the invention. Defendants

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cite to passages from the claim language and relevant specifications to argue that when the claims are read in the context of offering clinical treatment, "administering" should mean putting the drug into a migraine patient. Id. at 6.

As discussed at the hearing, it appears that Defendants are asking the Court to construe "administering" as it appears in non-asserted method claims only. This approach is unavailing at the current juncture because Pozen is not alleging infringement of the method claims underlying Defendants' argument.For example, Defendants contend that claim 3 of the '499 patent and claim 5 of the '458 patent teach that "administering" means "putting the drug in a migraine patient." Defendants maintain that for these claims, this is the only definition that allows for the patents' claimed therapeutic effect. Evaluating the patents as a whole, however, this context is not determinative where Pozen is not asserting these particular claims and the claim term can be understood without including Defendants' proposed step that must occur "in a method for treating a migraine patient." See, e.g., '499 patent at 13:39. The manner in which Defendants present the dispute frames a question as to when or how unasserted claims require a step-- putting the drug into the patient-- to perform the medical method.

The Court declines to narrow the meaning of the claim term. Instead, the Court considers the intrinsic record for both the method and composition claims. Pozen has only asserted composition and therapeutic package claims against Defendants, and the Court finds that "administering" and all of its permutations (including those in unasserted method claims) have an ordinary and customary meaning. Abiding bythe "heavy presumption" that a claim term carries its ordinary and customary meaning, CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002), one of ordinary skill in the art would understand "administering" and its permutations as conveying its ordinary meaning in the context of the claim language. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). Defendants' proposed construction, "putting into," does not appear in the'499 patent and the Federal Circuit makes clear that additional limitations should not be read into the claim. Innova/Pure Water, 381 F.3d at 1117-18. The claim terms are the primary source for the meaning of the claim, and "[a]bsent a clear disavowal or contrary definition in the specification or prosecution history, the patentee is entitled to the full scope of its claim language. Home Diagnostics, 381 F.3d at 1358; Enercon GmbH v. Int'l Trade Comm'n, 151 F.3d 1376, 1384 (Fed. Cir. 1998) (requiring that absent some special definition, claim terms are to be given their ordinary meaning). No such special definition or disavowal is found here.

As discussed at the hearing, this readily-understandable term wouldinclude giving a patient a drug in any normal manner (i.e., providing a tablet to a patient under circumstances where it is reasonable to believe that a patient is going to take the tablet). Accordingly, the Court finds that the proper and most internally-consistent construction of the term "administering," and its relevant permutations, is its ordinary and customary meaning. For the sake of further clarity, the Court also determines that the ordinary and customary meaning of "administering" is equivalent to the general purpose dictionary definition of "administer." Should the meaning of "administering" be called into question at trial, "to mete out" is an alternative reflection of the claim language.
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Further, claim 5 discusses "administering" the levofloxacin. Daiichi/Ortho maintains that this term limits the claim to something delivered from outside the body and thereby excludes in vivo production of levofloxacin. In response, Mylan argues that if ofloxacin were to become levofloxacin in vivo, an antimicrobially effective amount of levofloxacin would have been administered when ofloxacin was administered. It therefore maintains that the language does not exclude in vivo production.

Mylan's construction is supported by the Merriam Webster Medical Dictionary's definition of administer, "to give remedially (as medicine)." Whether levofloxacin formed as the claimed compound inside the body or outside the body, as long as it is given remedially as medicine, then levofloxacin has been administered. Thus, claim 5 does not contain a preingestion limitation.
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F. "Administering orally to a patient in need thereof"

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Finally, the parties ask the Court to construe the phrase "administering orally to a patient in need thereof," which is found in asserted claims 20-25 of the '171 patent, 1 of the '120 patent, and 1-6 of the '958 patent. Wyeth's proposed construction is:

> A patient in need of therapeutic blood plasma levels of venlafaxine, such as a patient suffering from one or more depressive or anxiety disorders, and the patient is being treated by a formulation that is swallowed.

Mylan's proposed construction is:

> The claimed extended release formulations are administered to a patient by mouth.

Here, Wyeth and Mylan agree that the formulations are administered by mouth and swallowed by the patient. Mylan further concedes that the language "patient in need thereof" implies a patient "in need of treatment with venlafaxine hydrochloride." Mylan's Resp. Br. at 34. It contends, however, that the patents-at-issue only disclose the usefulness of venlafaxine hydrochloride as an anti-depressant "and nothing more." Id. Wyeth, on the other hand, asserts that a person of ordinary skill in the art at the time of the invention would have understood that a "patient in need thereof" includes patients being treated for any condition responsive to venlafaxine, not only those suffering from depression.

The specification makes several references to venlafaxine hydrochloride as being "an antidepressant" and as being "used in the treatment of depression." Specifically, in the "Abstract," the invention is introduced as being a formulation of "venlafaxine hydrochloride, an antidepressant," and in the "Background of the Invention" the inventors refer to venlafaxine as "an important drug in the neuropharmacological arsenal used for treatment of depression." '171, Col. 1:61. In the "Brief Description of the Invention," the inventors describe the use aspect of the invention as "a method for moderating the plural blood plasma peaks and valleys . . . which comprises administering to a patient in need of treatment with venlafaxine hydrochloride . . . ." '171, Col. 2:40-45. A similar statement is then repeated in reference to a method for reducing the level of nausea and incidence of emesis. '171, Col. 2:55-63.

Wyeth relies on the opinion of its expert in the fields of psychiatry and psychopharmacology, Eric Hollander, M.D. ("Hollander"), that patients with conditions other than depression, such as those with a variety of anxiety disorders, can be successfully treated with venlafaxine hydrochloride. Wyeth Ex. 31, p. 12. He states that, while he had treated individuals with both depression and anxiety disorders using immediate release Effexor(R), he has had much better results treating them with Effexor XR(R). Id. Thus, Hollander, a person of ordinary skill in the art, clearly understood at the time of the invention that venlafaxine hydrochloride was used to treat patients with anxiety disorders, in addition to those suffering from depression.

Mylan does not rely on expert testimony on this point, arguing instead that Wyeth's construction would leave the term open to the future addition of disorders not disclosed in the patents-in-suit, and thus would violate the notice function of the patents. It relies on Phillips for the proposition that the Court should not place undue reliance on extrinsic evidence, and asserts that no legal authority allows "additional disorders [other than depression] to be read into both the patent and the claims." Mylan Resp. Br. at 35.

Although Phillips counsels against undue reliance on extrinsic evidence, that case also states that

> extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, . . . to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.

415 F.3d at 1318. Indeed, courts may rely on such evidence in construing terms so long as the testimony is not "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." Id. (quoting Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998)).

Here, nothing in the written record associated with these patents explicitly limits the use of Effexor XR (R) to treating patients with depression. Accordingly, this Court must determine what "a person of ordinary skill in the art in question at the time of the invention" would have understood "a patient in need of treatment with venlafaxine hydrochloride" to mean. See

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Phillips, 415 F.3d at 1313. Because nothing in the intrinsic evidence reveals what a person of ordinary skill in the art at the time of the invention would have understood, this is an appropriate occasion for reliance on extrinsic evidence, such as an expert opinion.

Hollander's affidavit clearly indicates that a person of ordinary skill in the art at the time of the invention would have known that venlafaxine hydrochloride was commonly used to treat anxiety as well as depression. Indeed, the Court does not rely merely on his opinion on this matter, which, admittedly, was "generated at the time of and for the purpose of litigation and thus can suffer from bias." Phillips, 415 F.3d at 1318. Rather, Hollander states that, prior to the invention of the extended release formulation, he was, in fact, treating patients suffering from anxiety disorders with immediate release Effexor(R). Wyeth Ex. 31, p. 12. Thus, the Court concludes that a person of ordinary skill in the art at the time of the invention would have known that a "patient in need thereof" could include patients suffering from one or more depressive or anxiety disorders, as long as the disorder was then known to be treatable with venlafaxine hydrochloride. 4

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4 Limiting the term to disorders known to those of ordinary skill in the art at the time of the invention to be treatable with venlafaxine hydrochloride dispels Mylan's concern regarding the notice function of the patents.

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Thus, because it finds that a person of ordinary skill in the art would have known, at the time of the invention, that venlafaxine hydrochloride could be used to treat patients with both depression and anxiety disorders, the Court adopts Wyeth's construction of this term.
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A. Claim Construction and Validity of the '342 Patent

The Court construes the claims of the patent according to the hierarchy of evidence articulated in Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), looking first to the intrinsic evidence of the patent:

The court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim. As such, "[a] patent covers the invention or inventions which the court, in construing its provisions, decides that it describes and claims." … "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history."

52 F.3d at 979 (citations omitted). The '342 patent has only one claim:

1. A method for the treatment of Campylobacter infections comprising administering to a patient suffering therefrom an amount of [omeprazole] or a pharmaceutically acceptable salt thereof sufficient for the treatment of said infection.

U.S. Patent No. 5,093,342, col. 4. lines 63-67. The defendants argue that the preamble of the claim, "A method for the treatment of Campylobacter infections" is not a material claim limitation because it merely expresses the purpose of the invention. This argument misreads the Federal Circuit's holding in Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368 (Fed. Cir. 2001), which the defendants cite to support their position. In that case, the Federal Circuit acknowledged that claim language reciting the purpose of a process can constitute a material limitation where the process is directed to a new use, but discarded the purpose language at issue as immaterial because the process was not directed to a new use. See id. at 1376 ("Bristol is correct that new uses of old processes may be patentable …. However, the claimed process here is not directed to a new use; it is the same use"). In this case, the '342 patent's claim and specification demonstrate that while the invention is comprised entirely of an old process, the administration of omeprazole, the old process is directed to a new use, the treatment of Campylobacter 3 infections. If the Court were to read the preamble out of the claim, as the defendants urge, the remaining claim language "suffering therefrom" and "said infection" would have no referent and thus no meaning. The preamble language "A method for the treatment of Campylobacter infections" is therefore

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necessary to give "life, meaning and vitality" to the claim and constitutes a material limitation. See id. at 1373-74 (citing Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)).

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3 Campylobacter is the name scientists formerly used to describe H. Pylori.

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The parties also dispute the proper construction of the term "treatment." Astra argues that the term "treatment" of H. Pylori infection means "medical efforts undertaken to provide a health benefit" to persons with H. Pylori. Specifically, it argues that "treatment" does not require cure or eradication of H. Pylori, but it does require that the omeprazole be administered for the purpose of having some antimicrobial effect on an H. Pylori condition. The defendants dismiss this construction as an untenable "subjective intent" requirement, and argue that "treatment" means merely an antimicrobial effect resulting from the administration of omeprazole to an H. Pylori-infected person.

Defendants' proposed construction is too broad in light of the invention claimed by the patent. 4 It is clear from all of the intrinsic evidence of the '342 patent that the claimed purpose of the administration of omeprazole, to treat H. Pylori infection, is the primary distinction over the prior art, and thus a material claim limitation. Within this context, the term "treatment" must be construed to reflect the purpose that animates the claim, and must therefore contain a limitation of purposeful directedness toward H. Pylori or an H. Pylori - associated condition. This limitation is essential to distinguish uses of omeprazole that are directed to a different purpose (and that are subject to prior patents, such as the '431 patent) but that would nonetheless have an incidental effect on any H. Pylori condition existing in the patient.

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4 Presumably in an effort to invalidate the claim as anticipated by prior art, the defendants have offered a construction of the term "treatment" that is unwittingly self-defeating in the event the defendants, upon the imminent expiration of the '431 patent, intend to offer generic omeprazole for the purpose of suppressing gastric acid secretion. When omeprazole is administered for a purpose other than combatting H. Pylori, such as inhibiting gastric acid secretion, the omeprazole still exerts an antimicrobial effect against H. Pylori in patients infected by the bacteria. If the Court were to accept the defendants' construction, one of the primary uses of omeprazole would be foreclosed because it would infringe the '342 patent.

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Properly construed then, the '342 patent claims 1) the administration of omeprazole alone 2) for the express purpose of treating H. Pylori.
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"Administration," "administered," and "administering"

The parties agreed during oral argument that these terms, which appear in claims from each of the patents-in-suit, mean "application; to bring into use or operation into the body." The Court agrees and construes the terms accordingly for all of the patents-in-suit.
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1. "Admixture"

Plaintiff's proposed construction:

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Act of mixing together.

Defendant's proposed construction:

Having a seed bound or encapsulated within mulch flakes.

The specification explains that "the process of the present invention allows seed to be admixed with the mulch material, and thus to be encapsulated and/or bound thereto." '499 pat., col. 4, lns. 28-31. Language found in the specification may limit the scope of a claim term when it describes a specialized meaning for the claim term, e.g., Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001), or explains features of "the present invention," Verizon Services Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1308 (Fed. Cir. 2007). Although plaintiff points out that the description of "admixture" that defendant identifies is not located with other definitions found in the patent, the location of limiting language is irrelevant; it is its context that matters. Here, the specification describes "the process of the present invention" and explains that to be "admixed with the mulch material" is "to be encapsulated and/or bound thereto."

Plaintiff contends that to read the language as a limitation on "admixture" is inappropriate because the language states that the "process of the present invention allows seed to be admixed." From this, plaintiff argues that admixture does not require encapsulation or binding. That argument misses the mark. If anything, the statement could be taken to mean that the process of the present invention does not require admixture, not that admixture does not require encapsulation or binding. The key phrase is "and thus to be encapsulated and/or bound thereto." By a seed's admixture, the specification states, it is therefore encapsulated or bound. Had the patentee wished, he could have stated that the "process . . . allows the seed to be encapsulated and/or bound to the mulch material during admixture," which is how plaintiff asks the court to read the language. That is not what the specification says, though.

Plaintiff's other argument is that encapsulation and binding are a "secondary" part of the invention. '499 pat., col. 1, lns. 54-56 ("the invention also provides for unique mulch products, including mulch products having seed attached or incorporated within mulch flakes"). However, the description of admixture as "thus" encapsulating or binding a seed leaves little room to argue that admixture could be anything other than encapsulation or binding. As with the language of the limiting phrase, plaintiff's additional references show not that encapsulation or binding is not required for admixture, but rather that not all the claims require admixture. That much is correct. See, e.g., '499 pat., cls. 1-10 (no mention of "admixture").

Because the patentee's only description of admixture involves limiting the term to "encapsulating" or "binding" the seed with the mulch material, the term should include this limitation. I will therefore reject plaintiff's proposed construction and adopt defendant's, with minor changes. Defendant proposes that the encapsulation or binding be "within mulch flakes." Nothing about the identified limiting language requires that (1) the mulch material be "mulch flakes" or (2) binding be "within" mulch material (instead of "to" it). The limiting language identifies only "mulch material," not "mulch flakes" and explains that the seed will be "encapsulated and/or bound thereto," not "within." Thus, the term "admixture" will be construed to mean "having a seed encapsulated within or bound to mulch material."

Court's construction:

Having a seed encapsulated within or bound to mulch material.

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A. Admixture

Aventis and Amphastar request construction of the term "admixture" which appears in claims 1, 2, 3, 4, 5, 6, 7, 23, 24, 25, 27, 28, 30, 31, and 32 of the 618 patent. n1 Amphastar asserts that the common meaning of "admixture" is "the compound formed by mixing different substances together" Webster's Revised Unabridged Dictionary (1998). Using the same dictionary, Aventis claims that the common meaning of "admixture" is simply "mixture" Id.

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n1 Claim 1, representative of all claims referencing "admixture," is as follows:
A heterogeneous intimate admixture of sulfated heparinic polysacchandes, such sulfated polysacchandes having a weight average molecular weight less than that of hepann and said admixture consisting essentially of

from 9% to 20% of polysacchande chains having a molecular weight less than 2,000 daltons

from 5% to 20% of polysacchande chains having a molecular weight greater than 8,000 daltons, and

from 60-86% of polysacchande chains having a molecular weight of between 2,000 and 8,000 daltons,

the ratio between the weight average molecular weight and the number average molecular weight thereof ranging from 1 3 to 1 6

said admixture (i) exhibiting a bioavailability and antithrombotic activity greater than hepann and (n) having an average molecular weight of between approximately 3,500 and 5,500 daltons.

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When a claim term has two plain and ordinary meanings, "intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and distinctly claim the invention" Texas Digital, 308 F.3d at 1203-04 (citing Remshaw PLC v Marposs Societa' per Aziom, 158 F.3d 1243, 1250 (Fed Cir 1998)) There is nothing in the claim language that limits that "admixture" to a compound formed by different substances. The language of claim 1 specifies that "said admixture" consists essentially of various percentages of polysacchande chains having various weights. There is no reference to a different substance. There is nothing in the specification that rebuts the presumption of Aventis' construction which is one of arguably two ordinary and customary meanings of the term "admixture." See Texas Digital, 308 F.3d at 1204. The court is not convinced that Aventis defined "admixture" as requiring two different substances in the prosecution history. Thus, because Aventis' definition stays true to the claim language and "most naturally aligns with the patent's description of the invention," the court finds that it is the correct construction. Texas Digital, 308 F.3d at 1203-04 (citing Renishaw PLC v Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed Cir 1998) ("The construction that stays true to the claim language and most naturally in the end, the correct construction")).

Thus, the court construes "admixture" which appears in claims 1, 2, 3, 4, 5, 6, 7, 23, 24, 25, 27, 28, 30, 31, and 32, as follows: "A mixture of sulfated heparinic polysacchandes having a variety of molecular weights, regardless of how the mixture was prepared."
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53. The term "admixture" means two or more items are commingled and interdispersed to obtain a homogeneous product.
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This case turns on whether the "admixture" limitation in claim 1 of the '791 patent must be "homogeneous." As a general proposition, a limitation that does not exist in a claim should not be read into that claim. See McCarty v. Lehigh Valley R. Co., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240 (1895). Neither the claims nor the specification of the '791 patent require the "admixture" to be "homogeneous." Claim language, however, must be read consistently with the totality of the patent's applicable prosecution history. Vitronics, 90 F.3d at 1582, 39 U.S.P.Q. (BNA) at 1577; Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978, 52 U.S.P.Q.2D (BNA) 1109, 1112-13. (Fed. Cir. 1999).

The '791 patent results from a series of continuation applications stemming from Application No. 721,396 ("the '396 application"), which was filed on June 26, 1991. After multiple amendments, certain claims of the '396 application issued as

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claims in United States Patent No. 5,288,505 ("the '505 patent") on February 22, 1994. Biovail also filed a continuation of the '396 application on May 28, 1993 -- Application No. 68,951 ("the '951 application"). After the '951 application was rejected for, inter alia, double patenting over the '505 patent, Biovail Enhanced Coverage Linking abandoned the '951 application in favor of another continuation -- Application No. 311,722 ("the '722 application"). The '722 application eventually issued as the '791 patent on June 25, 1996.

"When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay, 192 F.3d at 980, 52 U.S.P.Q.2D (BNA) at 1114; see also Jonsson v. The Stanley Works, 903 F.2d 812, 817-18, 14 U.S.P.Q.2D (BNA) 1863, 1868 (Fed. Cir. 1990) (providing that when two patents issued from continuation-in-part applications derived from one original application, the prosecution history of a claim limitation in the first patent to issue was properly applied to the same limitation in the second patent to issue). The claims in the '396 application as originally filed did not include the term "admixture." The "admixture" limitation was added to claims in the '396 application following an amendment after final rejection, and these claims issued as claims in the '505 patent. The '505 and '791 patents both derive from the initial '396 application. The "admixture" limitation appears in a similar context in both the '505 and '791 patents. Therefore, any prosecution history relating to the "admixture" limitation of the '505 patent (which includes the prosecution history of the '396 application) applies with equal force to that limitation in claim 1 of the '791 patent.

The initial '396 application was first rejected, inter alia, as anticipated by United States Patent No. 4,960,596, which issued to Debregeas et al. (the "Debregeas patent"). 2 After an amendment, the '396 application was finally rejected, inter alia, in view of Debregeas. Subsequent to an interview with the examiner, the '396 applicant added the "admixture" limitation to the relevant claims in an amendment after final rejection. 3

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2 The Debregeas patent discloses a bead containing a sugar/starch core surrounded by diltiazem, which is encapsulated by an outer membrane containing shellac.3 For example, this amendment changed a limitation providing, "beads comprising an effective amount of one or more diltiazem salts . . . and a wetting agent" to one requiring "beads consisting essentially of in admixture together an effective amount of [diltiazem] or one or more salts thereof . . . and an effective amount of wetting agent."

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To distinguish Debregeas in the remarks accompanying this amendment, the applicant stated: "By contrast [to the Debregeas invention,] the extrusion-spheronization process [of the invention in the '396 application] leads to homogeneous type beads while the 'building-up' process [of the Debregeas invention], starting with a sugar core, leads to heterogeneous type beads." (emphasis in original). The applicant further argued: "Clearly, it is impossible to have a sugar central core in a homogeneous bead as in [the '396 application]. Such a bead [with a sugar central core] is, by nature, heterogeneous." (emphasis in original). The remarks accompanying the amendment after final rejection also provided that a bead produced by the extrusion-spheronization process of the '791 patent "is necessarily a homogeneous bead composition." (emphasis in original).

The '396 applicant also discussed Debregeas with the examiner in an interview after the final rejection of the '396 application, but prior to the applicant's submission of the amendment after final rejection. The examiner summary of that interview provides: "A declaration will be submitted. . . . A showing of a homogeneous admixture of diltiazem in combination with the wetting agent[] . . . would be considered for distinction over [Debregeas]." The inventor of the product described in the '396 application subsequently submitted a declaration. In the remarks accompanying the amendment after final rejection the applicant discussed that declaration, arguing, "the declaration establishes that the 'core' or 'center' of the present composition is homogeneous with respect to diltiazem and wetting agent." Further, the experiment discussed in the declaration provides, "that the 'center' or 'core' [of the product in the '396 application] is an inherently homogeneous or uniform composition of diltiazem of one or more salts and wetting agent. . . ." After submission of the declaration and the amendment after final rejection -- which added the "admixture" limitation -- the examiner allowed the relevant claims over Debregeas. These claims issued as claims 1, 6, and 11 of the '505 patent.

The prosecution history of the '396 application clearly indicates that at least the "bead" described in the '396 application, in

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claims 1, 6, and 11 of the '505 patent, and in claim 1 of the '791 patent must be "homogeneous." Claim 1 of the '791 patent provides that the "bead" contains a diltiazem salt and a wetting agent in "admixture." Therefore, the admixture of diltiazem salt and wetting agent that comprises the bead of claim 1 of the '791 patent must be homogeneous.
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1. "An Admixture Comprising."

All three claims contain an "admixture clause" which begins with the phrase "an admixture comprising." MBT asserts that the phrase "an admixture comprising" should take its ordinary meaning, and needs no special construction by the Court. Euclid asserts the Court should construe this phrase to mean "an admixture requiring the presence of the following compositions but not excluding unrecited compositions." In other words, Euclid wants it made clear that, while the admixture must contain the certain components listed, it can also contain other, unlisted components.

In Vehicular Technologies Corp. v. Titan Wheel Intern.; Inc., 212 F.3d 1377, (Fed. Cir. 2000), the Federal Circuit Court of Appeals addressed the meaning of the term "comprising:"

The phrase "consisting of" is a term of art in patent law signifying restriction and exclusion, while, in contrast, the term "comprising" indicates an open-ended construction. In simple terms, a drafter uses the phrase "consisting of" to mean "I claim what follows and nothing else." A drafter uses the term "comprising" to mean "I claim at least what follows and potentially more."

Id. at 1382-83 (citations omitted). Or, as put by plaintiff's counsel in this case at the Markman hearing, the term "comprising" is a term of art which, in "patentese," means "including but not limited to," while the term "consisting of" means "it must come from whatever is listed here." Hearing tr. at 5.

Notably, the '194 patent contains both phrases. 6 Claim 1, for example, describes an "hydraulic cement mix comprising" hydraulic cement, aggregate, water, and an admixture, while the third component of the admixture is "a composition or a mixture of compositions selected from the group consisting of alkali, ammonium, and alkaline earth salts of nitric acid." '194 patent, col. 14, lines 37-53. Because the hydraulic cement mix is "comprised of" the four elements listed (cement, aggregate, water, and an admixture), it may include other elements as well. On the other hand, because the third component of the admixture "consists of" one or more of a certain group of related chemicals, the third component may not include any other substance.

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6 Indeed, during the reissue process, the '194 patent was amended specifically to change two uses of the term "comprising," in claim 1, to the term "consisting of." '194 patent, col. 14, lines 37-53.

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MBT agrees with Euclid that "comprising" is a term of art in patent law, and MBT also agrees with Euclid on the meaning of that term. Nonetheless, MBT believes the Court need not provide any special construction for the term, and should simply direct the jury to accord this term its "ordinary meaning." The Court concludes, however, that Euclid's position is correct -- it is appropriate to construe the claim language so that the jury will comprehend accurately this term of art. As noted, Euclid proposes the phrase be construed to mean "an admixture requiring the presence of the following compositions but not excluding unrecited compositions." 7 The Court finds that this construction is needlessly prolix. Instead, the Court construes the phrase "an admixture comprising" to mean "an admixture including, but not limited to." This construction more simply and precisely defines the phrase at issue, as explained by the Federal Circuit Court of Appeals.

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7 Euclid alternatively suggests the word "elements" instead of "compositions."

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II.

This court reviews claim construction as a matter of law. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 46 U.S.P.Q.2D (BNA) 1169, 1173 (Fed. Cir. 1998) (en banc); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995) (en banc). Anticipation is a question of fact, including whether or not an element is inherent in the prior art. See In re Schreiber, 128 F.3d 1473, 1477, 44 U.S.P.Q.2D (BNA) 1429, 1431 (Fed. Cir. 1997). Therefore, this court reviews a finding of anticipation under the clearly erroneous standard. See Gechter v. Davidson, 116 F.3d 1454, 1457, 43 U.S.P.Q.2D (BNA) 1030, 1032 (Fed. Cir. 1997).

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." In re Schreiber, 128 F.3d at 1477. Anticipation of a patent claim requires a finding that the claim at issue "reads on" a prior art reference. See Titanium Metals Corp. v. Banner, 778 F.2d 775, 781, 227 U.S.P.Q. (BNA) 773, 778 (Fed. Cir. 1985). In other words, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art. See id. at 781. Specifically, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. See id. at 780-82 ("It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if one of them is in the prior art."). In chemical compounds, a single prior art species within the patent's claimed genus reads on the generic claim and anticipates. See In re Gosteli, 872 F.2d 1008, 1010, 10 U.S.P.Q.2D (BNA) 1614, 1616 (Fed. Cir. 1989).

As noted previously, both Egly and Butterworth disclose blasting compositions with ingredients identical to those of the Clay patent and its reissue in overlapping amounts. The only element which is arguably missing from the prior art is the requirement that "sufficient aeration [be] entrapped to enhance sensitivity to a substantial degree." To decide the issue of anticipation, therefore, the district court examined whether "sufficient aeration . . . to enhance sensitivity" was inherently part of the prior art compositions. That decision, in turn, required the trial court to interpret the claim term "sufficient aeration." By looking at the express language of the claims and the patent's written description, the district court concluded that the claim term "sufficient aeration" included both interstitial air (between oxidizer particles) and porous air (within the pores of oxidizer particles).

The first task of this court on appeal is to construe independently the disputed claim term. This question requires this court to determine whether the claim term "sufficient aeration" includes porous air, as the trial court determined. The claim term "sufficient aeration" does not limit the air content of the composition to interstitial air. Rather, the broad term "aeration" contains no qualitative limits on the kind of air exposure, only the quantitative limit that the air exposure be "sufficient" to enhance sensitivity. If the inventor intended "sufficient aeration" to carry qualitative limits, he also did not express that intention in the patent's written description. The specification gives no explicit definition of the phrase "sufficient aeration . . . to enhance sensitivity," which appears in the patent for the first time in the claims.

It is, of course, possible that the inventor did not include qualitative limits on the term "sufficient aeration" in the specification because those of ordinary skill in the art understand that only interstitial air enhances sensitivity and satisfies the claim's language. See Autogiro Co. of Am. v. U.S., 181 Ct. Cl. 55, 384 F.2d 391, 397, 155 U.S.P.Q. (BNA) 697 (Ct. Cl. 1967) ("Claims cannot be clear and unambiguous on their face."); Markman, 52 F.3d at 986 ("The focus in construing disputed terms in claim language is . . . on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). The trial record, however, shows that those of ordinary skill in this art at the time the patent application was filed knew that both interstitial and porous air enhance sensitivity. Dr. Clay himself, the inventor of the patents in suit, testified that air from any source would contribute to the explosion of a heavy ANFO composition and, particularly, air trapped within the pores of porous prilled AN. Therefore, this court detects no error in the district court's conclusion that "sufficient aeration . . . to enhance sensitivity" is understood by those of ordinary skill in the art to include both interstitial and porous air. The district court appropriately construed the claims at issue to include aeration from both sources.

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Veltek proposes that I construe the claim term "aerosol" according to its dictionary definition. (D.I. 171 at 5.) "Aerosol" is defined as "a suspension of fine solid or liquid particles in gas (smoke, fog and mist are aerosols)" or "a substance (as an insecticide or cosmetic) dispensed from a pressurized container esp. as an aerosol; also: the container for this." Merriam-Webster's Collegiate Dictionary at 19 (10th Ed. 2002). Miller agrees that I should adopt this common, dictionary definition of aerosol (D.I. 184 at 6) but argues that "a suspension of liquid particles…is obviously a commingling of the alcohol and gas (id. at 4)" within the container.

I disagree with Miller's proposed claim construction. The dictionary definition of aerosol does not require a substance, such as alcohol, that is dispensed from a pressurized container to be mixed or commingled with gas inside a can in order to constitute an aerosol. Further, nothing in the claims, specification, or the intrinsic record of the '900 patent indicates that the patentee intended to deviate from the ordinary and accustomed meaning of aerosol. See '900 patent, col. 4, lns. 12-16 ("When using isopropyl alcohol as the chemical composition, such is generally inserted under pressure with an inert element such as nitrogen or another chemical formulation acting as the propellant into an aerosol can type chemical composition container."). Miller would have me read the "commingling" limitation into the claims of the '900 patent based solely on Miller's interpretation of the dictionary definition of aerosol. I decline to do so.

Therefore, I construe "aerosol" to mean a substance dispensed from a pressurized container as a suspension of fine liquid particles in gas. This construction is consistent with the plain language of the claim and the specification. The claim language itself does not refer to commingling or mixing the alcohol and a gas within an aerosol container; rather, it refers only to "charging the internal volume of the aerosol container with a quantity of alcohol" and then "pressurizing the internal volume of the aerosol container with an inert gas." See '900 patent, col. 6, lns. 50-54. Similarly, the specification states that "isopropyl alcohol" is "inserted under pressure with an inert element such as nitrogen" into an aerosol can. Id., col. 4., lns. 13-16. Miller has not overcome the "heavy presumption that the inventor intended the ordinary meaning to apply" to the claim term aerosol, Bell Atlantic, 262 F.3d at 1268, and it is apparent that the '900 patent discloses an aerosol as it is commonly defined.

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B. "AFFECTED AREA"

The competing constructions of the phrase "affected area" are overdrawn.

Plaintiffs urges the construction of "affected area" as that part of the skin which comes into contact with urushiol at the point in time that the skin displays an outward manifestation of the contact, arguing that the inventor's goal was the treatment of a manifestation of contact dermatitis. Implicit in this construction is the fact that the solution would not be applied to the skin until a rash develops.

Plaintiffs' attempt to impose a limit on the time of application of the solution to the skin is not tenable. 4 As defendants note, the inventor's statement in the written description supports a finding that there is no temporal element to the phrase, stating:

Solution has historically consisted of attempting to remove the oil as quickly after exposure as possible; applying rubbing alcohol, washing affected areas with water, and showering with soap and water. In many instances, however, people either fail to fully remove the toxin before it has bound to the skin or don't realize they have been exposed until after the rash appears.

(col 2 ll 40-46) (emphasis added). Moreover, there is nothing in the written description that suggests application of the composition begins with a manifestation of the effect of the urushiol on the skin. Rather, application of the solution may begin as soon as there is an awareness of the skin contacting the urushiol. Indeed, as noted above, an object of the invention is to provide a solution to "block" urushiol's "allergic reaction." Defendants are correct in stating that "no dermatitis-like

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breakout is required in the patent claim or patent specification and the term 'affected area' should not be construed to require such physical manifestation in order to define the area."

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4 Indeed, if this was the case, no one would carry the solution with them when they went for a walk in the woods for example to apply at the time of contact, and would instead wait to apply the solution when a rash develops.

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"Affected area" is not a term of art and its ordinary meaning is well understood. The American Heritage Dictionary of the English Language defines "affected" as "acted upon" and "area" as "a distinct part."

"Affected area" simply means the area of the skin which comes into contact with urushiol.
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2. "less affinity for said tooth whitening substance than said tooth whitening substance exhibits for itself and for said strip of material" as used in claims 1 and 11

Plaintiff's construction: No construction necessary

Defendant's construction: some affinity for said tooth whitening substance, which affinity is less than the affinity that said tooth whitening substance exhibits for itself and for said strip of material.

The parties dispute whether a release liner that has "less affinity" for the "tooth whitening substance" must have at least "some affinity" for the "tooth whitening substance." Plaintiff takes the reasonable position that the ordinary meaning of the term would include zero affinity. "Zero" is less than any positive affinity.

Relying on two references in the specification in which the "release liner" is described as being "attached" to the strip of material by the oral care substance, defendant argues that an object "attached" to another object must have at least some affinity for the other object. I am not persuaded from my own reading of the specification that the inventors clearly intended to limit the phrase "less affinity for" to mean only "some affinity." The two passages on which defendant relies cite the same figure, which is only a preferred embodiment. The fact that a "release liner" is "attached" in one embodiment does not mean that it must be attached in every case.

Defendant has pointed to no language in the claim or the specification to establish that the patent requires "some" affinity between the "release liner" and the tooth whitening substance. Therefore, I will not adopt its proposed construction. I conclude that "less affinity for" could include zero affinity.
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The district court held a hearing to construe the terms of the '985 patent. PureChoice argued that the term "air quality" as mentioned in each asserted claim should be read broadly and construed simply as "the quality of the air." Honeywell, on the other hand, argued that because the claims, the specification, the prosecution history, and extrinsic evidence suggested that the invention only addressed particulates in the air, "air quality" should be construed only as "the concentration of pollutants or contamina[nts] in the air." It specifically excluded "meteorological, climate, or comfort related variables, such as temperature and humidity." PureChoice also argued constructions for two other terms, "sensor for measuring environmental air quality data" and its homologue, and "air quality sensor adapted to measure non-weather data." It argued that the sensor for measuring limitation should be construed as a "sensor for measuring quantitative information regarding an air quality of the environment in the data acquisition site." It argued that "air quality sensor adapted to measure non-weather data" means an "air quality sensor adapted to measure quantitatively an air property in the controlled environment of a type not normally

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identified with weather (e.g. not temperature or humidity)."

Honeywell responded that both terms were indefinite under 35 U.S.C. § 112 based on its argument that air quality excludes meteorological variables. It also rebutted PureChoice's proposed constructions, arguing that they were so vague and ambiguous as to require constructions that would reclaim in reexamination that which PureChoice surrendered in its initial prosecution.

The district court largely agreed with Honeywell and held that "air quality" means the "concentration of pollutants or contamina[nts] in the air." The court then agreed with Honeywell that it is impossible to construe or differentiate "sensor for measuring environmental air quality data" and "air quality sensor adapted to measure non-weather data," and thus held that these terms were indefinite. PureChoice timely appealed the constructions. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Claim construction is a question of law that we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-55 (Fed. Cir. 1998). Claim indefiniteness is also a question of law that we review de novo. Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc., 336 F.3d 1308, 1318 (Fed. Cir. 2003).

We first address the proper construction of air quality and start with the specification. "The specification is the single best guide to the meaning of a disputed term," and we read the claim terms in view of the specification. Phillips v. AWH Corp., 415 F.3d 1303, 1321 (Fed. Cir. 2005) (internal quotations removed).

PureChoice argues that the term should be construed as its plain meaning, "the quality of the air." This definition however does not inform the public what qualities the invention is concerned with, and is overbroad. The specification never mentions sensing temperature, humidity or other meteorological attributes of the air. However, it does discuss sensing contaminants and pollutants extensively throughout. For instance, at column 4 lines 38 through 40, the specification discusses examples of "smoke or particle sensors, volatile organic compound sensors, [and] carbon monoxide sensors" but does not include any meteorological sensing. Mindful not to impute an attribute of a preferred embodiment into a claim term, see Electro Med. Sys., S.A. v. Cooper Life Sci., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994), preferred embodiments nevertheless are evidence of its meaning. In the '985 patent, the preferred embodiment also does not disclose any meteorological sensing, but rather "employs a particle sensor and a volatile organic compound sensor." '985 patent col. 4 ll. 40-41. Indeed among the listed "various sensors 14a-n" that may be employed for testing air quality attributes, all sense particles or contaminants: other sensors that can produce an electrical signal proportional to the amount of foreign substances, toxins or other chemicals, and ionizing smoke or particle detectors. Id. col. 4 ll. 40-60.

Other evidence in the specification also suggests to persons having ordinary skill that the relevant attributes comprising air quality are contaminants and particles only. While PureChoice argues that air quality should be read broadly because the specification speaks to attributes that affect the health and well-being of a population, the surrounding text in the specification deals with particles and contaminants as the attributes of air quality that adversely affect health and well-being:

> Certain environments are more susceptible to pollutants that negatively effect [sic] air quality, such as a bar, restaurant, nightclub or casino where a high percentage of people smoke. Other environments require a consistent and predetermined air quality, which is free from pollutants, toxins and chemicals, such as hospitals, nursing homes, pharmaceutical manufacturing facilities or other manufacturing facilities that require "clean rooms."

Id. col. 1 ll. 20-28 (emphasis added). The specification clearly shows that the invention is concerned with contaminants and pollutants, and not meteorological attributes.

The lack of any suggestion of meteorological attributes in air quality in the specification and the many mentions at various points of contaminants and particles is enough to conclude that the claimed invention is narrower than the claim language might imply, making it proper to limit the claims. See Alloc, Inc. v. Int'l Trade Comm'n., 342 F.3d 1361, 1370 (Fed. Cir. 2003). However, further buttressing the construction is PureChoice's disavowal of the inclusion of meteorological attributes in air quality during prosecution. To overcome a rejection in light of a Gilbert reference that disclosed a system comprising sensors that monitor temperature and sensors that measure pollution, PureChoice amended its claims, replacing the term

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"measuring environment data" to "measuring air quality data." This amendment is the source of the "air quality" term, which PureChoice argued was distinguishable over Gilbert because it was related to measuring specific pollutants. In particular, PureChoice told the examiner,

Applicants' invention relates to measuring air quality, and . . . discloses use of such sensors as smoke sensors, particle sensors, volatile organic compound sensors, or carbon monoxide sensors for collecting and monitoring air quality. Such sensors produce an electronic signal proportional to the presence of foreign substances. The electronic signal is converted to an air quality measurement, such as particles per cubic meters [sic] of air.

In other words, Gilbert disclosed measuring meteorological attributes, and the application that became the '985 patent disclosed sensing particles. PureChoice argues that this is not a clear and unmistakable disavowal of meteorological attributes because, while Gilbert collected environmental data, PureChoice amended the claims to expressly limit the sensors to the collection of air quality data. This is unpersuasive, however, because the response makes clear that the difference between environmental data, as the examiner stated was present in Gilbert, and air quality data, is the contaminant and particle data mentioned in the passage above. Therefore, PureChoice has clearly and unmistakably disavowed environmental data insofar as it extends beyond contaminants and particles.

PureChoice points out that temperature was mentioned as an attribute the invention senses during prosecution, when it stated to the examiner that "the digital [air quality] value [reported by a sensor] must be put into the context of what is being sensed (for example, smoke level, CO level, temperature)." We are, however, unconvinced that the scant appearance of meteorological attributes in the hundreds of pages of specification and prosecution history would inform a person of ordinary skill that air quality extends beyond contaminants and pollutants, when weighed against references to the latter attributes found throughout the specification and prosecution history. Therefore, we affirm the construction of "air quality."
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The '450 patent sets forth seventeen claims, two of which are independent claims. The independent claims read:

Claim 1

1. A pharmaceutical composition which contains:

(a) a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration;

(b) a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration, and

(c) a suitable amount of a saccharide to inhibit hydrolysis.

Claim 16

16. A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:

(a) a suitable amount of alkali or alkaline earth-metal carbonate and,

(b) one or more saccharides.

On June 3 and 4, 2002 the court held a hearing in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), aff'g 52 F.3d 967 (Fed. Cir. 1995 (en banc). The most serious dispute concerned the construction of the phrase "an alkali or alkaline earth metal carbonate" as used in Claims 1 and 16 of the '450 patent. Teva contended that "carbonate" encompasses "carbonate or bicarbonate." Warner-Lambert contended that the word means only a "carbonate" and does not include a bicarbonate. Ruling on these contentions the court held in its June 13, 2002 opinion that "'an alkali or alkaline earth metal carbonate' as used in Claims 1 and 16 of the '450 Patent means the salt of an

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alkali metal or alkaline earth metal cation, and a carbonate (CO[3]-2) anion; it does not include a bicarbonate (HCO[3]-1) anion." (Slip Opinion at pp. 17,18).
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2. The Term "Alkaline Reacting Compound"

Subparagraph (a) of claim 1 of the '505 patent requires that the core contain a "material selected from the group consisting of omeprazole plus an alkaline reacting compound, an alkaline omeprazole salt plus an alkaline reacting compound and an alkaline omeprazole salt alone." (P1, col. 16:43-47.) That claim language presents alternatives any one of which may be present to meet the claim requirement. See In re Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977). Claim 1 of the '230 patent presents a similar set of three options for the core: an acid labile pharmaceutically active substance and an ARC, an alkaline salt of an acid labile pharmaceutically active substance, or an alkaline salt of an acid labile pharmaceutically active substance and an ARC. (See P2A, col. 13:2-9.) The acid labile compound and the ARC must be different substances. (P2A, col. 13:2-9.) Astra asserts infringement by all Defendants only under the first of the three options: omeprazole, which is an acid-labile pharmaceutically active substance, plus an ARC.

The term "alkaline" standing on its own represents a concept that is well understood by those skilled in the arts of formulation and chemistry. It is fundamental chemistry that an "alkaline" substance is a basic substance--a non-acidic, non-neutral compound having a pH greater than 7. 16 (See Auslander Tr. 2515:4-2516:9; Pilbrant Tr. 1459:24-1460:4.) While the ordinary meaning of the word "alkaline" may be clear, the court finds that without resort to the specification the meaning of the phrase "alkaline reacting compound" is not clear now and was not clear at the time of the patent. See Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). Rather, the phrase "alkaline reacting compound" is a shorthand term that the patentees created for use in the '505 and '230 patents, and one of ordinary skill in the art would not understand what is meant by this phrase prior to issuance of the '505 and '230 patents. (See Auslander Tr. 2513:14-2514:9; Story Tr. 3759:13-18; see also Langer Tr. 386:17-24 (analyzing meglumine in terms of disclosure in specification).) Since the phrase "alkaline reacting compound" has no unambiguous meaning outside the '505 and '230 patents, it must be defined in the context of those patents. Since the patentees chose to act as their own lexicographer, the court must rely on the intrinsic evidence, particularly the specification, to determine the meaning of the phrase See Itron, Inc. v. Cellnet Data Systems, Inc., 34 F. Supp. 2d 1135, 1141 (D. Minn. 1999) (If the inventors choose to be "their own lexicographers" with regard to a particular claim term, "the court must adopt their definition."), aff'd per curiam, 243 F.3d 563 (Fed. Cir. 2000). Here the patentees' own testimony leaves no doubt that the specifications of the '505 and '230 patents are the "single best guide" to the meaning of the term "alkaline reacting compound." See Bell Atlantic, 262 F.2d at 1268 (quoting Vitronics, 90 F.2d at 1582). Kurt Lovgren, one of the inventors, testified that the terms "alkaline reacting compound" and "alkaline buffering compound" mean the same thing in the '505 and '230 patents. (Lovgren Dep. Tr. 548:2-11.) He further testified that the definition of those terms was to be found in the specifications of the patents. (Id. at 543:11-18 ("The meaning of alkaline buffering compound is a meaning and an understanding that is obtained in the specification of the patent.").)

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16 The pH of a material is a numerical index of acidity, based on the hydrogen ion concentration of that material. (Carr Tr. 2361:9-23.) pH is measured on a numerical scale of 1 to 14. (Carr Tr. 2362:1-10, 2363:22-2364:9.) A pH of 7 is neutral, a pH of below 7 is acidic, and a pH of greater than 7 is alkaline. (Pilbrant Tr. 1459:24-1460:4.)

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The clearest indication of what the phrase "alkaline reacting compound" means in the '505 and '230 patents is found in the detailed description of the invention under the subheading "Cores." (See Auslander Tr. 2520:1-9; Langer Tr. 653:24-654:6.) The term "alkaline reacting, otherwise inert pharmaceutically acceptable substance (or substances)" is characterized in the patent specifications. Specifically, the patents state:

Omeprazole is mixed with inert, preferably water soluble, conventional pharmaceutical constituents to obtain the preferred concentration of omeprazole in the final mixture and with an alkaline reacting, otherwise inert, pharmaceutically

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acceptable substance (or substances), which creates a "micro-pH" around each omeprazole particle of not less than pH = 7, preferably not less than pH = 8, when water is adsorbed to the particles of the mixture or when water is added in small amounts to the mixture.

. . . .

The stabilizing, high pH-value in the powder mixture can also be achieved by using an alkaline reacting salt of omeprazole such as the sodium, potassium, magnesium, calcium etc. salts of omeprazole, which are described in e.g. EP-A2-No. 124 495, either alone or in combination with a conventional buffering substance as previously described.

(P1, col. 3:38-47, 59-65; see also P2A, col. 8:33-42.) This portion of the specifications defines the ARC--namely, an alkaline or basic compound that must create a micro-pH around the omeprazole particles of not less than pH 7. (Auslander Tr. 2520:1-2521:13; Langer Tr. 652:18-654:22.) See Vitronics Corp., 90 F.3d at 1582; Itron, Inc., 34 F. Supp. 2d at 1141. This description of the ARC is recited in the patent "as being the invention itself and not only one way of utilizing it;" therefore, the scope of the claims, which would otherwise be utterly unclear, must be limited to the definition of the ARC provided here. See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996), abrogated on other grounds, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000). Because the proper definition is found only in the specification, the scope of the term "alkaline reacting compound" is limited by the disclosure in the specification. Had Astra wanted broader disclosure, they should have used terms that would have been understood more broadly. See generally Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358 (Fed. Cir. 2001).

After defining the term "alkaline reacting compound," the specifications of both patents then proceed to list numerous substances that the inventors considered to be ARCs. (See, e.g., P1, col. 3:47-59.) Alkaline reacting compounds

can be chosen among, but are not restricted to substances such as the sodium, potassium, calcium, magnesium and aluminium salts of phosphoric acid, carbonic acid, citric acid or other suitable weak inorganic or organic acids; substances normally used in antacid preparations such as aluminium, calcium and magnesium hydroxides; magnesium oxide or composite substances, such as Al[2]O[3].6MgO.CO[2].12H[2]O (Mg[6]Al[2] (OH)[16] CO[3].4H[2]O), MgO.Al[2]O[3].2SiO[2].nH[2]O or similar compounds; organic pH-buffering substances such as trihydroxymethylaminomethane or other similar, pharmaceutically acceptable pH-buffering substances.

(P1, col. 3:47-59; see also P2A col. 8:43-55.) Based on the claim language, these and other disclosures in the specifications of the patents, the statements Astra made about the prior art in the patents themselves and during the prosecution history, and the admissions of Astra's own experts, the court finds that an alkaline reacting compound is (1) a pharmaceutically acceptable alkaline, or basic, substance having a pH greater than 7 that (2) stabilizes the omeprazole or other acid labile compound by (3) reacting to create a micro-pH of not less than 7 around the particles of omeprazole or other acid labile compound.

a. The ARC Must Be Alkaline

Numerous dictionaries and treatises confirm that the word "alkaline" refers to a basic substance having a pH of greater than 7. (See Auslander Tr. 2515:13-2516:9.) The court is free to consult dictionaries at any time to help determine the meaning of the claim terms, provided that the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents. Vitronics, 90 F.3d at 1584 n.6; see also Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1332 n.1 (Fed. Cir. 2001). So, assuming that the patentees' definition does not contradict the plain meaning of the word "alkaline" as revealed in dictionaries and technical treatises, the claimed ARC in the '505 and '230 patents must be a non-acidic, non-neutral compound having a pH greater than 7. Various disclosures in the specifications of the '505 and '230 patents confirm that an alkaline reacting compound is, first and foremost, an alkaline or basic compound. The patent specifications indicate that omeprazole is susceptible to degradation in acid media and that the degradation reaction "proceeds rapidly" in neutral media, like pH 7, "while at higher pH values the stability in solution is much better." (P1, col. 1:21-29; P2A, col. 8:11-17.) Thus, the patent teaches one of ordinary skill in the art that the ARC, which is in direct contact with the omeprazole, cannot be acidic or neutral, but must be a basic compound with a pH of greater than 7. (Auslander Tr. 2516:10-2517:10.) Indeed, the specifications of the '505 and '230 patents distinguish a prior art invention, British Patent GB-A-No. 1,485,676 (the "'676 patent"), from the invention of the '505 and '230 patents, by explaining that the prior art formulation could not be adapted for use with omeprazole because "the presence of an acid in contact with omeprazole in

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the cores would give a result that omeprazole [would be] degraded." (P1, col. 2:59-68 (emphasis added); see also P2A, col. 5:25-35.) Thus, this portion of the patent specification emphasizes to one of ordinary skill in the art that the formulation cannot contain an acidic compound in contact with omeprazole. (Auslander Tr. 2517:17-2519:4.) Moreover, the Outline of the Invention section of each patent emphasizes that the ARC is, first and foremost, an alkaline compound. (P1 col. 3:13-21 ("Cores containing omeprazole mixed with alkaline compounds"); P2A col. 7:61-66; see Auslander Tr. 2519:5-25).) The '505 and '230 patent specifications go on to list various types of compounds as examples of ARCs within the meaning of the patents. (See P1, col. 3:47-59; P2A, col. 8:43-55.) All of the examples listed in the specifications are well recognized alkaline substances. (Auslander Tr. 2521:23-2522:12.) Even further light is shed on the fact that "alkaline reacting substances" must be basic when it is considered that the claims of the '505 and '230 patents both allow for the absence of such a substance only when omeprazole is formulated as an "alkaline omeprazole salt." The '505 patent, for example, references a European Patent, EP-A2-No. 124,495 to describe those salts--all of which are basic. (P1, col. 3:59-65.) Thus, this disclosure in both patents teaches one of ordinary skill in the art that an ARC must be alkaline, and cannot be acidic or neutral.

The prosecution history of each patent confirms the court's construction of the term "alkaline reacting compound" to require alkalinity. During the prosecution of the application that issued as the '505 patent, the patent examiner rejected the application based on several references. (G2, Office Action of 12/1/87, at 2-3.) One of those references was the '676 patent. (Id.) As discussed in the '505 patent specification, this reference describes the use of a core containing "pharmaceutically acceptable acid" with the active drug in the core. (P1, col. 2:59-69.) In response to the rejection, Astra amended the claims in its application and, while referring specifically to the core containing omeprazole and the ARC, argued that "according to the invention, the omeprazole is either in the form of an alkaline salt, or is compounded with an alkaline material." (G2, Amendment of 3/1/8, at 5 (emphasis added).) This discussion, in the context of the claimed invention, unambiguously states that the omeprazole is compounded with an alkaline material and confirms that the ARC must be an alkaline material with a pH greater than 7. (Auslander Tr. 2530:6-13; see generally Auslander Tr. 2528:25-2530:13.) In that same amendment, Astra further stated that "an acid containing core would be unsuitable for use with omeprazole because the acid would degrade the omeprazole." (G2, Amendment of 3/1/88, at 8.) This strongly teaches one of ordinary skill in the art that the ARC, which is in direct contact with the omeprazole in the formulation, must not be acidic. (Auslander Tr. 2530:14-2531:11.) Astra is correct that this last statement, in isolation, might be considered a general description of the invention in the prosecution history that would not be understood to limit the invention. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1575 (Fed. Cir. 1996) ("Unless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage."). The entire March 1, 1988, amendment, however, makes it clear that Astra was explaining the meaning of claim language to escape the examiner's rejection, thereby disavowing claim coverage. Arguments and amendments made during the prosecution of a patent application must be examined to determine the meaning of terms in the claims. Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995). The prosecution history limits the interpretation of the claim terms so as to exclude any interpretation that was disclaimed during prosecution. Id.; ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1580 (Fed. Cir. 1988). Simply put, claims may not be construed one way in order to obtain their allowance and in a different way when asserted against an accused infringer. Southwall, 54 F.3d at 1576; Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991); Lemelson v. General Mills, Inc., 968 F.2d 1202, 1206 (Fed. Cir. 1992) ("The prosecution history gives insight into what the applicant originally claimed as the invention, and often what the applicant gave up in order to meet the Examiner's objections."). In a December 18, 1988 amendment made during the prosecution of the '230 patent that occurred simultaneously with that of the '505 patent, the Astra applicants attached the identical amendment, which included the same arguments for patentability as discussed with respect to the '505 patent. Accordingly, these unambiguous statements in the prosecution histories of the '505 and '230 patents further support the interpretation that the ARC must be alkaline. See, e.g., Southwall Techs., Inc., 54 F.3d at 1576; see also Desper Products, Inc. v. QSound Labs., Inc., 157 F.3d 1325, 1335-36 (Fed. Cir. 1998). Indeed, having affirmatively relied on this interpretation during prosecution to obtain allowance of the patent claims, Astra is estopped from asserting a contrary claim interpretation at trial. See Senmed, Inc. v. Richard-Allan Medical Indus., 888 F.2d 815, 820 (Fed. Cir. 1989).

Although extrinsic evidence may not be used to vary or contradict the claim language, it is worthy to note that in this case, the extrinsic evidence directly confirms the claim construction gleaned by the court from the intrinsic evidence. Vitronics, 90 F.3d at 1585. One of the named inventors of the patents admitted at his deposition that to achieve a micro-pH around each omeprazole particle of not less than 7, as required by the specification, (see Pl, col. 3:38-47; P2A, col. 8:33-42), the ARC must necessarily be alkaline--a non-acidic, non-neutral, basic substance having a pH greater than 7. (See Pilbrant Tr. 1465:6-1466:8.) 17 Additional extrinsic evidence shows that during the development of Astra's omeprazole formulation,

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Astra determined that to achieve sufficient stability, it needed to include an alkaline material in the core with omeprazole, and it chose disodium hydrogen phosphate dihydrate 18 as the alkaline compound. (Carlsson Tr. 228:25-230:5, 231:21-232:3; G148 at 9612106-07.) Dr. Enar Carlsson, who was Astra's project leader for the development of Prilosec(R), did not recall Astra ever trying materials of pH less than 7 in the core to solve the stability problem. (Carlsson Tr. 232:4-15.) Thus, a person of ordinary skill in the art would understand that an ARC, as that term is used in the '505 and '230 patents, must be an alkaline or basic compound.

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17 Dr. Pilbrant changed his testimony at trial, stating that he had discussed the matter with others subsequent to his deposition, reaching a new and different scientific conclusion, namely that it was at least hypothetically possible to create a micro-pH environment around omeprazole of greater than 7 by adding a compound having a pH of less than 7. The court finds Dr. Pilbrant's new theory to be implausible and finds his deposition testimony to be more credible. Therefore, the court rejects Dr. Pilbrant's trial testimony on this point. See Markman, 52 F.3d at 983 (finding that self-serving inventor testimony on claim construction adduced at trial is entitled to no deference).

18 This substance is also known as dibasic sodium phosphate, a chemical that has numerous synonyms. (See P17.) Dibasic sodium phosphate may also be called disodium hydrogen phosphate, disodium phosphate, sodium phosphate, and several other names. (Id.) During the trial, several witnesses and numerous documents referred to the chemical by different names. The court will generally refer to this chemical as "disodium hydrogen phosphate" or "DHP."

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b. Stability Through Micro-pH

As discussed above, based on the disclosures in the specification, a person of ordinary skill would also understand that the ARC must stabilize the omeprazole or acid labile compound in the core by creating a micro-pH of not less than 7 around the particles of the active ingredient. (See Pl, col. 3:38-47; P2A, col. 8:33-42.) The ARC must be understood to stabilize the active ingredient in the formulation through creation of a micro-pH of not less than seven around the particles of the active ingredient not only because the specifications say so, but also because it makes sense in light of the goals this invention sought to achieve. As a practical matter, the goal is to stabilize and protect the omeprazole in the core. (Auslander Tr. 2520:24-2521:8; see also Langer Tr. 682:5-18.) Indeed, Astra's experts Dr. Langer and Dr. Davies 19 candidly admitted that the ARC claimed in the patents is an alkaline or basic compound that must create a micro-pH of not less than pH 7 around the omeprazole particles, thereby stabilizing the omeprazole. 20 (Langer Tr. 653:8-654:23, 5106:1-13; Davies Tr. 1209:18-1210:16, 1221:19-1222:8.)

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19 Dr. Martyn Davies is a highly qualified expert in testing, analysis and characterization of drug formulations. Dr. Davies has worked in this area for about fifteen years. (Davies Tr. 784:2-7.) Dr. Davies is the head of the pharmacy school at the University of Nottingham, a highly respected school in Great Britain. (Davies Tr. 784:19-785:6.) In addition, Dr. Davies is the chairman of Molecular Profiles, a company that takes advantage of the expertise Dr. Davies has acquired in the testing of drug formulations. (Davies Tr. 787:3-25, 789:12-22.) Dr. Davies designed and supervised the testing conducted by Plaintiffs in this litigation. In addition, Dr. Davies observed much of that testing. (Davies Tr. 788:1-789:11.)

20 The testimony provided by Plaintiffs' experts is quite telling. Even Astra's experts reject the argument that a microenvironment pH greater than 7 is a preferred embodiment. Specifically, on more than one occasion, Astra's experts admitted that the definition of an alkaline reacting compound is a substance that must be alkaline and that must create a micro-pH around the omeprazole particles in the core of not less than 7. The testimony was as follows:

Q. (By the court): Then that would mean [the alkaline reacting compound] wouldn't have to be a base, right?

A. I think probably it will.

(Langer Tr. 756:18-19; see generally Langer Tr. 756:8-758:1.)

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Q. (By the court): Then you are saying [the compound of interest] doesn't have to be alkaline, it just has to raise the pH. That's what I am trying to find out.

A. To be fair to them, it has to raise it above 7.

(Langer Tr. 759:19-22; see generally Langer Tr. 756:8-763:17.)

Q. So is it your opinion that it has to be at least [pH] 7 for it to be an alkaline reacting compound?

A. Yes, I think that's what I testified to earlier in the trial.

(Langer Tr. 5106:8-11.)

Q. Do you agree with Dr. Langer's testimony that the purpose of the alkaline-reacting compound, according to the '505 patent, at least, is to create a microenvironment, micro-pH around each omeprazole particle of not less than pH 7?

A. My view of the micro environment, as I've read the '505 patent, is that there is a pH which is not less than 7 around the omeprazole particles, yes.

(Davies Tr. 1210:17-1210:23.)

Q. Again, I have to ask you, its important it's around each omeprazole particle?

A. That would be - I guess, yes, it would be important if you could attain that. It would be important.

(Davies Tr. 1211:14-17.)

Astra attempts to construe this trial testimony to refer to a mere "hope" or desire for the invention, as opposed to a requirement. Having heard all of the testimony referred to by both parties, the court does not credit Astra's reading of the transcript. Instead, the court finds that KUDCo has accurately represented not only the bare words, but the import of the testimony as well. As explained in more detail below, the court agrees with Astra that it would be desirable, though not necessary, for the micro-pH around each and every omeprazole particle to be not less than 7. That is, the court acknowledges that the patent does not require perfection. However, the court finds that the alkaline reacting compound must render a micro-pH of at least 7 to sufficient omeprazole particles such that the omeprazole in the core is stabilized.

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Astra has taken the position that claims 1 simply have no micro-pH range limitation whatsoever. (See, e.g., Astra's Cl. Constr. Mem. at 17.) The court finds, however, that the creation of a micro-pH of not less than 7 around the omeprazole particles is not merely a preferred embodiment of the invention, as Astra argues. The disclosure in the patents teaches that this is a required element in the definition of an ARC, and nothing elsewhere in the patents teaches or suggests otherwise. (Auslander Tr. 2521:9-13; see Pl, col. 3:38-47; P2A, col. 8:33-42.) Astra's suggestion that the creation of the micro-pH as set forth in the specifications is a "preferred embodiment" is based on a misreading of the patents. The words "preferred" and "preferably" are used in the specifications only to modify the "desired concentration of omeprazole in the final mixture" and the micro-pH value of "not less than 8." (Pl, col. 3:38-47; P2A, col. 8:33-42.) Recognizing that those two features are preferred embodiments, Defendants do not argue that either of those features form part of the proper claim interpretation of the term "alkaline reacting compound."

Astra also argues that Defendants are improperly trying to read the micro-pH claim limitation from dependent claim 5 of the '505 patent into claim 1, and that the legal theory of claim differentiation precludes Defendants' proposed construction. (See Astra's Cl. Constr. Mem. at 17.) Under claim differentiation, a limitation contained in a dependent claim may not be imported into the independent claim from which it depends. Karlin Techns., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 972 (Fed. Cir. 1999); Transmatic, Inc. v. Gulton Indus., 53 F.3d 1270, 1277-78 (Fed. Cir. 1999). There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence

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of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between the claims is significant. Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987). Astra's argument misses the point, however, that the relevant narrowing limitation in claim 5 is the specific numerical pH range of 7 to 12, which includes an upper bound. Claim 5 of the '505 patent is narrower than claim 1 because it has a narrower numerical pH range. The "alkaline reacting compound" of claim 1 must create a micro-pH of not less than 7, but there is no specified upper limit on pH in claim 1, which covers a range of pH from 7 to 14. Claim 5, however, explicitly specifies a narrower pH range. (Pl, col. 16:43-47, 16:65-68; Auslander Tr. 2535:13-2536:15.) The difference, and what may not be read into claim 1, is the specific numerical range of pH 7 to 12 recited into claim 5. Excluding the pH range from 12 to 14 in claim 5 is not insignificant. There are medical concerns involved with the use of formulations containing caustic, or very high pH, substances. For example, the use of omeprazole salts, which are very basic, may cause etching lesions or other gastrointestinal problems. (Lovgren Tr. 4930:3-4931:1; Langer Tr. 5148:4-5149:11.) Claim 6 of the '230 patent is narrower than claim 1 of that patent for the same reasons that claim 5 of the '505 patent is narrower than claim 1 of the '505 patent. (Pl, col. 16:42-68; Lovgren Tr. 1864:4-1865:13; compare Pl, col. 16:43-47, 16:65-68, with P2A, col. 13:2-9, 14:4-8.) Thus, narrowed claims 5 and 6, which set a maximum pH value of 12, clearly satisfy the presumption of claim differentiation; they are different from claim 1 because they have an upper limit for micro-pH. See Mantech Envtl. Corp. v. Hudson Envtl. Servs., 152 F.3d 1368, 1372 (Fed. Cir. 1998) (finding the patentee's argument based on claim differentiation "unavailing" given that the narrowing language of the dependent claim alone distinguished its scope from that of the independent claim); Manchak v. Chem. Waste Mgmt., Inc., No. 98-1530, 217 F.3d 860, [published in full-text format at 1999 U.S. App. LEXIS 32001], 1999 WL 11003364, at *5 (Fed. Cir. Dec. 6, 1999) (unpublished opinion) (holding that the doctrine of claim differentiation "is inapplicable where one or more added limitations distinguishes the allegedly superfluous dependent claim from its parent independent claim"). Moreover, the doctrine of claim differentiation cannot override the clear statements of scope in the specifications and prosecution histories, which overcome any presumption arising from the doctrine. Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1302 (Fed. Cir. 1999). Simply put, claim differentiation cannot broaden claims beyond their correct scope. Toro Co., 199 F.3d at 1302.

Astra's arguments against the micro-pH requirement fail for another reason. It is a fundamental concept in patent claim drafting that each element of a claim must have an antecedent basis; otherwise, the claim would be rejected as indefinite under 35 U.S.C. § 112. Manual of Patent Examining Procedure ("MPEP") § 2173.05(e), Lack of Antecedent Basis. Section 2173.05(e) of the MPEP states that

[a] claim is indefinite [under 35 U.S.C. § 112] when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to "said lever" or "the lever" where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference."

In claim 5 of the '505 patent and claim 6 of the '230 patent, each of which covers a preparation "according to claim 1," the term "micro-environment" is preceded by the word "the." The use of this definite article mandates that the term "micro-environment" was previously used in claims 1. Indeed, the antecedent basis for this term is derived from the fact that the phrase "alkaline reacting compound" of claims 1 includes, by definition, the element of micro-pH. If this were not true, then the term "micro-environment" would lack antecedent basis, rendering claim 5 of the '505 patent and claim 6 of the '230 patent invalid due to indefiniteness. Therefore, the court must construe the term "alkaline reacting compound" to require the creation of a micro-pH of at least 7 around the particles of the active ingredient. See Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998) ("If the claim is susceptible to a broader and a narrower meaning, and the narrower one is clearly supported by the intrinsic evidence while the broader one raises questions of enablement under § 112, [the court must] adopt the narrower of the two."). Whenever a claim is susceptible to one construction that would render it valid and another construction that would render it invalid, the claim will be construed to sustain its validity. Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999).

Astra's proposed definition of the term "alkaline reacting compound," a substance that when added to omeprazole can increase pH, is not only unsupported but also contradicted by the disclosures of the '505 and '230 patents. For example, if a substance with a pH of 6.8 is added to omeprazole, which Astra contends has a pH of 6.4, 21 and the resulting pH is increased, the substance would be within Astra's definition of ARC. The substance, however, would be acidic, and, therefore, its use would be completely inconsistent with the disclosures of the '505 and '230 patents. (See Pl, col. 3:26-28, 38-47, col. 5:29-33.) There is no disclosure in the patents that the ARC can be acidic or a substance that simply increases pH when added to an acid labile compound, like omeprazole. (See generally Pl; P2A.) Astra's argument that an ARC is anything

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that can raise the pH when added to omeprazole is directly contradicted by the numerous teachings in the patents that the alkaline compound must be truly alkaline, with a pH of not less than 7.

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21 For evidence that pure omeprazole by itself has a pH of about 6.4, see Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 42, 48:14-22; Ex. 43.

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c. The Entire Core Need Not Be Alkaline

The court does not agree with Defendants' argument that the core as a whole, as opposed to simply the ARC, must also be alkaline. 22 That aspect of Defendants' definition improperly requires the entire core to have a pH greater than 7 even though the claims themselves contain no such limitation and the specification expressly permits otherwise. In support of this argument, KUDCo cites to the portion of the '505 patent file history where Astra distinguished the invention over the teachings of the '676 patent. KUDCo misinterprets what Astra said about the '676 patent. Astra explained in its amendment to the PTO that "the formulation [described in the '676 patent] cannot be adopted for a pharmaceutical dosage form containing omeprazole, as the presence of an acid in contact with omeprazole in the cores would give a result that omeprazole was degraded." (Pl, col. 2:64-68 (emphasis added).) The '505 patent does not teach that the core must not contain any acidic components or that the pH of the entire core as a whole must exceed 7. It only states that if an acid is in the core, it must not be in contact with the omeprazole. The '505 patent also allows that the pH of the entire core may be less than 7, yet still contain an ARC. For example, the '505 patent recognizes that cores containing ARCs may have a pH below 7 when suspended in water. At column 5, the patent states:

The alkaline reacting core material and/or alkaline salt of the active ingredient, omeprazole, enhances the stability of omeprazole. The cores [alkaline reacting core] suspended in water forms a solution or a suspension which has a pH, which is higher than that of a solution in which the polymer used for enteric coating is just soluble.

(Pl, col. 5:23-29.) According to this statement, the pH of the core is only limited to being a value higher than the pH at which the enteric coating dissolves. Extrinsic evidence confirms that enteric coats begin to become soluble at pH values higher than those ordinarily present in the stomach, about pH 5. (Langer Tr. 299:6-8.) According to the patent itself, some enteric coatings dissolve at pH values below 7. For instance, as indicated in Table 5, formulation Example 3 dissolved at pH 6.0. (Pl, col. 14:19-33.) Thus, the '505 patent teaches that the pH of the entire core can be less than 7 and as low as 6. This is possible, for example, where a formulator ensures that the environment around the omeprazole particles contains ARC even though other regions of the core contain acidic components that lower the pH.

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22 In addition to the Defendants currently on trial before the court, this argument was raised by Second Wave Defendants Lek, Impax, and Eon Labs.

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In support of their attempt to restrict the pH of the entire core to values in excess of pH 7, Defendants rely on the inclusion of the terms "alkaline core" and "alkaline reacting core" in the patents. However, the use of those terms, which do not appear in claims 1, does not support importation of such a claim limitation, even with respect to claims containing the terms. A reading of both specifications makes clear that the terms "alkaline core" and "alkaline reacting core" are being used as shorthand for cores containing either an alkaline reacting compound or an alkaline salt of the active ingredient. The '505 patent uses the phrase "alkaline core" as a synonym for a core that contains an ARC, as may be seen from the following passages in the '505 patent:

In order to enhance the storage stability the cores which contain omeprazole must also contain alkaline reacting constituents. When such an alkaline core is enteric coated . . . ."

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(P1, col. 1:57-60 (emphasis added).)

Cores containing omeprazole mixed with alkaline compounds or an alkaline salt of omeprazole optionally mixed with an alkaline compound are coated with two or more layers, whereby the first layer/layers is/are soluble in water or rapidly disintegrating in water and consist(s) of non-acidic, otherwise inert pharmaceutically acceptable substances. This/these first layer/layers separates/separate the alkaline core material from the outer layer, which is an enteric coating.

(P1, col. 3:21-29 (emphasis added).)

Thus, the special preparation according to the invention consists of cores containing omeprazole mixed with an alkaline reacting compound or cores containing an alkaline salt of omeprazole optionally mixed with an alkaline reacting compound. . . . . The cores are coated with an inert reacting water soluble or in water rapidly disintegrating coating, optionally containing a pH-buffering substance, which separates the alkaline cores from the enteric coating.

(P1, col. 5:19-33 (emphasis added).) Because one of ordinary skill would understand "alkaline core" to refer to any core containing an ARC or an alkaline salt of omeprazole, such a person would not understand that the entirety of the core necessarily must have a pH above 7. Similar to the definition of "alkaline core" in the '505 patent, the term "alkaline reacting core" in the '230 patent means a core that contains either an ARC or an alkaline salt of an acid labile compound. The patent specification confirms this construction. 23 (See P2A, col. 3:66 - col. 4:43 ("In order to enhance the storage stability, the cores which contain the acid labile substance must also contain alkaline reacting constituents. When such an alkaline core . . . .") (emphasis added); P2A, col. 10:14-25 ("Thus the special preparation according to the invention consists of cores containing the acid labile compound mixed with an alkaline reacting compound or . . . . The cores are coated with a water soluble or in water rapidly disintegrating coating, optionally containing a pH-buffering substance, which separates the alkaline cores from the enteric coating.") (emphasis added).)

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23 Of course, Second Wave Defendants' Lek, Impax and Eon Labs are correct that the term "alkaline reacting core" in the '230 patent cannot always mean simply a core that contains an ARC, because that construction is only one third of the term's definition. That is, the "alkaline reacting core" of the '230 patent must contain one of the following: (1) an acid labile compound plus an ARC, (2) an alkaline salt of an acid labile compound, (3) an alkaline salt of an acid labile compound plus an ARC. In all three cases, the "alkaline reacting core" of the '230 patent is alkaline reacting because it contains a substance, whether an ARC, an alkaline salt of the active substance, or a combination of the two, that stabilizes the active substance and ensures that the micro-pH around the active substance is greater than pH 7. Thus, the term "alkaline reacting core" does not require that the pH of the entire core be greater than 7, it simply requires that the core contain the appropriate mixture of substances, as defined by claim 1, to stabilize the acid labile active ingredient in the formulation and to create a micro-pH of at least 7 around the particles of the active ingredient.

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In a similar vein, the patent claims do not require that a substance be proven to create a micro-pH of not less than 7 around every single, individual omeprazole particle present in the core of a formulation. The law is plain, infringement need not be perfect to be infringement. Shamrock Techs., Inc. v. Medical Sterilization, Inc., 903 F.2d 789, 792 (Fed. Cir. 1990) (inefficient infringement is still infringement). Unless it is expressly excluded by the claim language, the term "substantially" is understood as being incorporated into every patent claim. See AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1250 (Fed. Cir. 2001) (stating that, with respect to a patent for which the parties generally agreed that a 'layer' requires a "uniform" chemical composition, absent any specific statement in the patent of chemical uniformity as a characteristic of a layer, the layer must be understood as only "substantially" uniform.). KUDCo attempts to inappropriately add to "alkaline reacting compound" a requirement that it provide a microenvironment pH of not less than 7 around each omeprazole particle. However, claim terms must be construed practically, and a patent is infringed even if the infringement is less than perfect. See Shamrock Techs. Inc., 903 F.2d at 792. The examples in the patents demonstrate that the inventors did not contemplate that each and every particle of omeprazole must be enclosed perfectly in a microenvironment pH of at least 7 by the ARC. Table 3 of the patent shows that even when using the invention, some degradation of omeprazole occurs. (P1, col. 7:12-28.) Thus, complete inclusion of every particle of omeprazole was not deemed essential to the

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invention, and the court will not import such perfectionism into the definition of the term "alkaline reacting compound" where it is not called for by the claims.

d. Other Limitations

Cheminor seeks a construction of the term "alkaline reacting compound" that would limit claims 1(a) to the narrowed classes of alkaline reacting compounds identified in the specification. Cheminor's proposal unduly limits the claim to specific embodiments in the specification. Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 973 (Fed. Cir. 1999). Moreover, limiting the alkaline reacting compounds solely to those listed is directly contradictory to the patent specification, which expressly states that the list was not meant to be exhaustive. (P1, col. 3:54-56.) The language of claims 1 does not require that every specific alkaline reacting substance alleged to be infringing be identified or listed in the specification. See Specialty Composites v. Cabot Corp., 845 F.2d 981, 989 (Fed. Cir. 1988) (finding unlisted plasticizers within the scope of the claims). Although the definition of the term "alkaline reacting compound" must be found in the specification in light of the other intrinsic evidence, that definition is one based on the function of the ARC, not its identity. Therefore, the appropriate inquiry is whether a particular compound has the required properties to perform the functions required of an ARC, not whether the compound is included in a non-exhaustive list of examples in the specification. See Specialty Composites, 845 F.2d at 987 ("The emphasis is on the suitability of any plasticizer that will achieve the specified properties, not on the particular class of plasticizer.").

Cheminor also argues that the ARC must be water soluble and "otherwise inert." Once again, Cheminor's attempt to define the ARC as a water soluble compound is an attempt to read a preferred embodiment into claims 1. Nothing in the claim language requires water solubility of the ARC, and the specification does not contain such a limitation. Even the portions of the specification relied on by Cheminor to define alkaline reacting compounds refer to practically insoluble ARCs. (P1, col. 3:48-50 (referring to Mg[6]Al[2](OH)[16]CO[3].4H[2]O (hydrotalcite)); Astra's Cl. Constr. Mem. of 11/5/01, Ex. 10, Martindale 13th ed. at 886 (1993).) Similarly, the court rejects Cheminor's argument as to "otherwise inert" because the requirement is not contained in the claims. While the phrase is used in the specification of the patents relative to alkaline reacting substances, (P1, col. 3:41-42), "inert" is not in the claim as a modifier of "alkaline reacting compound," and it should not be imported into the claim. Also, other portions of the specifications do not include that language. (See, e.g., P1, col. 1:57-59; P2A, col. 3:66-68.)

Accordingly, based on the claim language, the numerous disclosures in the specifications of the '505 and the '230 patents, the statements Astra made about the prior art and the claimed invention during prosecution, and the admissions of Astra's own experts, the court finds that the term "alkaline reacting compound" means:

(1) a pharmaceutically acceptable basic substance having a pH greater than 7.0

(2) that stabilizes the omeprazole or acid labile active compound

(3) by reacting to create a micro-pH of not less than 7.0 around the particles of omeprazole or active acid labile compound.

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This court affirms the district court's claim construction in all respects. The district court correctly construed "alkaline reacting compound" to mean "(1) a pharmaceutically acceptable alkaline, or basic, substance having a pH greater than 7 that (2) stabilizes the omeprazole or other acid labile compound by (3) reacting to create a micro-pH of not less than 7 around the particles of omeprazole or other acid labile compound." Astra, 222 F. Supp. 2d at 453. That construction flows from the following definition in the patents: "an alkaline reacting, otherwise inert, pharmaceutically acceptable substance (or substances), which creates a 'micro- pH' around each omeprazole particle of not less than pH = 7." '505 patent, col. 3, ll. 38-44; '230 patent, col. 8, ll. 36-40. This court perceives no error in this construction.

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an alkalinity of less than 30 ppm

The parties and the Court agree that the phrase should be construed as "a raw water measuring less than or equal to 30 ppm of equivalents of Calcium Carbonate [CaCO[3]] in solution; equivalent calcium includes Calcium [Ca], and equivalent carbonate includes Carbonate [CO[3]], as well as Bicarbonate [HCO[3]] and Hydroxide [OH]."
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water of raw alkalinity of less than or equal to 50 ppm

The parties and the Court agree that the phrase should be construed as "a raw water measuring less than or equal to 50 ppm of equivalents of Calcium Carbonate [CaCO[3]] in solution; equivalent calcium includes Calcium [Ca], and equivalent carbonate includes Carbonate [CO[3]], as well as Bicarbonate [HCO[3]] and Hydroxide [OH]."
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As directed by the Federal Circuit, we look first to the language of the patents in our effort to determine the meaning of "alkoxy." Based on the language in Defendants' patents, we conclude that someone with a bachelor's degree in chemistry would clearly interpret and understand the term "alkoxy" to exclude substituted variations. Four separate aspects of Defendants' patents dictate this conclusion: (1) the language of the patents' claims; (2) the language of the patents' specifications; (3) the treatment of a structurally-similar substituent group; and (4) the prosecution history. We address each factor below. n5

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n5 Defendants contend that in our prior claim construction ruling we adopted as the law of this case the district court's decision in Bayer Aktiengesellschaft v. Duphar Intern. Research B.V., 221 U.S.P.Q. 1056 (D. D.C. 1983). See, e.g., Defs.' Reply Brief at 10 (stating: "It is Uniroyal's position that the Bayer case was considered by this Court and is therefore the law of this case"). Defendants are mistaken about this, however, as we neither expressly nor implicitly adopted the Bayer ruling as the law of this case.

Assuming arguendo that Bayer is the law of this case, the Bayer ruling does not resolve the proper construction of the disputed term, "alkoxy." In fact, on appeal the Federal Circuit specifically declined to rule whether Defendants' patents encompass substituted alkoxy groups. The Federal Circuit determined that this issue had not been raised at the trial court level:

Duphar interprets the phrase in the specification "If R sub2 is a substituted phenyl group, the phenyl group contains at least one substituent chosen from the group consisting of [groups (a)-(k)]:" to mean that the enumerated substituents in groups (a)-(k), none of which include-OCF sub3, are the only possible substituents for the phenyl group. We, however, find this contention to be meritless. The record does not support Duphar's contention that it presented this theory at trial. The only reference to this theory is in its Proposed Findings of Fact.

Bayer Aktiengesellschaft v. Duphar Intern. Research B.V., 738 F.2d 1237, 1240-41 (Fed. Cir. 1984). Therefore, regardless of Defendants' contrary belief, the Bayer ruling has no relevance to the claim construction issue now before us.

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1. Language of the patents' claims.

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We turn first to the express language of the claims themselves to determine if it sheds any light on the intended meaning of "alkoxy." Though the claims do not explicitly indicate whether the term "alkoxy" includes substituted as well as unsubstituted variations, we see that the terms for other substituent groups mentioned in the claims repeatedly distinguish between substituted and unsubstituted variations. For example, claim one (1) of the 064 patent states:
R1 is . . . an alkyl group, a halogen substituted alkyl groupk [sic], an alkoxy substituted alkyl group, an alkythio substituted alkyl group, a cyano substituted alkyl group, . . . a benzyl group, a halogen substituted benzyl group . . .

R2 is a substituted or non-substituted phenyl group; . . .

'064 Patent, Col. 29, row 9-15. Similarly, claim two (2) of the 064 patent includes the following provision:
R2 represents an unsubstituted phenyl group or a phenyl group substituted with from [sic] 1-3 substituents selected from the group consisting of from [sic] . . . A C1-15 alkyl group, a halogenated C1-15 alkyl group, a phenyl substituted C1-15 alkyl group, a cycloalkyl group, a halogenated cycloalkyl group, . . .

'064 Patent, Col. 30, 21-27. see also, claim 3, claim 4 (incorporating identical language).

In each of these four claims, Defendants have distinguished between the substituted and unsubstituted variations of alkyl, cycloalkyl, benzyl, and phenyl groups by initially listing the substituent group itself followed by several substituted varieties of the substituent group. If, as Defendants contend, the definitions of these four substituent groups were sufficiently expansive to encompass substituted variations (which is the construction Defendants urge us to adopt for the term "alkoxy"), there seemingly would be no need to list the possible substitutions separately, since listing substitutions would be redundant.

Thus, the only coherent reading of these claims that gives meaning to all the words is that, when possible substitutions to a substituent group are specifically listed, the patent claims encompass such substitutions. Conversely, when the name of a substituent group is not embellished or expanded by any possible substitutions, then no substitutions are encompassed. See Unique Concepts, Inc. v. Brown. 939 F.2d 1558, 1562 (Fed. Cir. 1991) (adhering to the rule that "all the limitations of a claim must be considered meaningful"); see also Advanced Communication Design, Inc. v. Premier Retail Networks, Inc., 46 Fed. Appx. 964, 980-81 (Fed. Cir. 2002) (stating that "the construction of any legal document -- like a statute, contract or patent -- should try to give meaning to every term in that document; otherwise, a lawyer or court will have erred by reading the chosen words of the document into oblivion"). To construe the claims otherwise would render meaningless the numerous possible substitutions specifically listed in the patent.

Defendants have not presented any coherent rationale for treating the disputed term "alkoxy" differently from the references for other substituent groups; indeed, their patents are devoid of any indication that the term "alkoxy" is unique in this regard. Clearly, the term "alkoxy" is to be construed in a manner consistent with the references for other substituent groups.

For these reasons, we reject Defendants' proposed construction of the term "alkoxy" because it is inconsistent with other portions of the claims and would render major provisions redundant. n6 In contrast, Dow's construction of the term "alkoxy" is consistent with the way Defendants have referenced other substituent groups in the claims. Accordingly, from this analysis, we conclude that the language of Defendants' claims indicates that the name of a substituent group, used by itself without reference to possible substitutions such as "alkoxy group," must be read restrictively to exclude substituted variations.

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n6 If the generic name for a substituent group includes substitutions, there is no need to list the possible substitutions separately for the alkyl, cycloalkyl, benzyl, and phenyl groups.

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. Language of the patent specification.

A thorough examination of Defendants' patents' specifications n7 also supports a restrictive construction of the term, "alkoxy." We accept the specification as the "single best guide to the meaning of a disputed term," Vitronics, 90 F.3d at 1582, and note that the specification here strongly implies that, unless otherwise modified, the term "alkoxy," as used in this

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patent, does not include substituted variations. In the relevant portion of the specification, n8 Defendants clearly and repeatedly distinguished which substituent groups could be substituted. In subpoints (b), (d), (g), (h), and (k), for example, Defendants explicitly referenced that the included substituent groups could be substituted. Likewise, in subpoint (i), Defendants include a potential variation that a listed substituent group may possess. In total, six of the eight subpoints which contain substitutable substituent groups (excluding the disputed term "alkoxy") list potential substitutions for those groups. n9

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n7 The relevant language in each patents' specification is the same. Technically, in the context of this case, the term "specification" should be referenced in plural form because the three patents at issue each incorporates its own specification. However, because the three specifications are identical in the relevant parts, we use the term specification in singular form throughout this entry.

n8 We refer to the portion of the specification which we adopted in our previous entry on claim construction. See Dow Agrosciences LLC v. Crompton Corp., 2004 U.S. Dist. LEXIS 8532, 2004 WL 1087362 (S.D. Ind. 2004).

n9 The substituents in subpoint (a) cannot be substituted, and, excluding alkoxy groups, the remaining substituent groups listed in subpoint (e), nitro and cyano, cannot be substituted.

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As a result, the patents' specification strongly indicates that when Defendants wanted their patents to cover a substituted substituent group, they listed the substitutions and, by logical extension, when the patent did not encompass such substitutions, no substitutions were listed. To read the specification otherwise, as Defendants assert in their construction for the disputed term "alkoxy," would render large portions of the specification redundant. n10 We view Dow's construction of the term "alkoxy" to correspond to Defendants' use of other terms for substituent groups in the specification. See Unique Concepts, 939 F.2d at 1562; Advanced Communication Design 46 Fed. Appx. at 980-81.

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n10 Again, if the generic name for a substituent group includes substitutions, there is no need to list the possible substitutions separately in subpoints (b), (d), (g), (h), (I) and (k).

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Accordingly, we conclude that the language of Defendants' specification suggests that the name of a substituent group, such as "alkoxy," requires a restrictive definition which excludes substituted variations, unless possible substitutions are specifically listed, which limitation is then also read into the patent claims. See SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (holding: "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent . . ."); Roberts Dairy Co. v. U.S., 530 F.2d 1342, 1352, 208 Ct. Cl. 830 (Ct. Cl. 1976) (concluding that a patentee is bound by his specification in interpreting his patent claims even when his specification requires a narrower interpretation of the claims than the patentee desires).

3. Treatment of similar substituent groups in the specification.

In the patent specification, Defendants treated the term for a structurally-similar substituent group as including only unsubstituted variations. For example, in subpoint (h) of the relevant portion of the specification, Defendants explicitly mentioned that a "phenoxy" group could be substituted with halogen. n11 This approach creates the critical inference that the term, "phenoxy," by itself, does not encompass substituted variations since explicit reference is made to possible substitutions. We conclude that a person with a bachelor's degree in chemistry would understand the definition of a "phenoxy" group to be similar to the definition of an "alkoxy" group; thus, the fact that Defendants explicitly indicated in their patent that the structurally similar phenoxy group could be substituted strongly indicates that the proper construction for the disputed term "alkoxy" is similarly restrictive. Stated otherwise, a person of ordinary skill in the art would

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understand both the definition of "phenoxy" and the definition of "alkoxy" to exclude substitutions that are otherwise not listed.

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n11 A phenoxy group has the same oxygen-connected-to-substituent-group structure as an alkoxy group.

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4. Prosecution history.

There is nothing in the prosecution history that indicates that Defendants intended their patents to encompass substituted alkoxy groups. An examination of the prosecution history reveals that Defendants never disclosed a substituted alkoxy group. In fact, Defendants' expert, Dr. Fu, conceded that, with respect to alkoxy groups, the patents only disclosed one unsubstituted alkoxy substituent group. n12 Defendants' failure to disclose substituted alkoxy substituents is another indication that their patents do not encompass substituted alkoxy groups.

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n12 Dr. Fu stated the only disclosed alkoxy substituent group was a "methoxy substituted compound," which is an unsubstituted alkoxy. Pl.'s Surreply Ex. 2, Fu Dep. at 184-85, 47-48.

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For the four, above-discussed reasons, we are persuaded that the most coherent understanding of Defendants' patents and prosecution history is that the unmodified n13 term, "alkoxy," does not include substituted variations. This interpretation is consistent with Defendants' use of the terms with respect to other substituent groups in their patents. Accordingly, we side with Dow in its reasoning, concluding that the proper construction of the disputed term, "alkoxy," excludes substituted variations. n14

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n13 We use unmodified in the sense that no possible substitutions were listed.

n14 As we have previously noted, the expansive definition advanced by Defendants would either render large portions of their claims and specification redundant, or would require us to define "alkoxy" in a fundamentally different manner than the terms for other substituent groups (and in a manner not supported by the prosecution history).

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B. Chemical Dictionaries.

The construction of the disputed term, "alkoxy," gleaned from our reading of Defendants' patents, is bolstered by the definitions of "alkoxy" contained in chemical dictionaries. We note that the Federal Circuit has unambiguously endorsed resort to dictionaries to ascertain the ordinary and customary meaning of words used in patents. n15

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n15 The Federal Circuit has explained: "It has been long recognized in our precedent and in the precedent of our predecessor court, the Court of Customs and Patent Appeals, that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms." Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325, 63 USPQ2d 1374, 1380 (Fed. Cir. 2002) ("The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including . . . dictionaries and treatises. . . ." (internal citations omitted)); CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366, 62 USPQ2d 1658, 1662 ("Our precedents show that dictionary definitions may

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establish a claim term's ordinary meaning."); Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1334-35, 54 USPQ2d 1289, 1295 (Fed. Cir. 2000) ("For such ordinary meaning, we turn to the dictionary definition of the term."); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1581, 36 USPQ2d 1162, 1166 (Fed. Cir. 1995) ("We see no error in the district court's use of dictionary definitions to ascertain the ordinary meaning of the relevant claim limitation."); In re Ripper, 36 C.C.P.A. 743, 171 F.2d 297, 299, 80 U.S.P.Q. (BNA) 96, 98 (1948) ("It is clear that in ascertaining the meaning of [the claim term] as it appears herein, reference properly may be made to the ordinary dictionaries.")).

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Dow cites two chemical dictionaries which it claims define "alkoxy" in a manner excluding substituted variations. The first dictionary, Hackh's Chemical Dictionary, contains the following relevant definitions:
alkoxy. An alkyl radical attached to the remainder of the molecule by oxygen; as, methoxy.

alkyl. CnH2n +1 -- Alphyl, aphyl, A monovalent radical derived from an aliphatic hydrocarbon by removal of 1 H[ydrogen]; as methyl --, . . .

Hackh's Chemical Dictionary 27 (4th ed. 1969). These two definitions together clearly reveal that the alkyl radical component of an alkoxy contains only carbon and hydrogen atoms. Further, the Hackh definitions contain no mention of the possibility of substitutions in the alkyl radical.

The second dictionary cited by Dow, McGraw-Hill's Dictionary of Scientific and Technical Terms, also contains a narrow definition for an alkoxy group and its related components:
alkoxy [ORG CHEM] An alkyl radical attached to a molecule by oxygen, such as the ethoxy radical.

alkyl [ORG CHEM] An organic group that results from removal of a hydrogen atom from an acyclic, saturated, hydrocarbon; may be represented in a chemical formula by R-.

alkane [ORG CHEM] A member of a series of saturated aliphatic hydrocarbons having the empirical formula CnH2n +2.

McGraw-Hill's Dictionary of Scientific and Technical Terms 64 (5th ed. 1994). n16 As with the Hackh definition, McGraw-Hill's definition limits the alkyl radical to only carbon and hydrogen atoms. Moreover, there is no indication or suggestion in the McGraw-Hill's definition that the term "alkoxy" can encompass substituted alkyl radicals. Accordingly, based on the clear meaning of the term "alkoxy" in these dictionaries, we read the term not to encompass substituted alkyl radicals. n17

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n16 This edition slightly post-dates the 064 patent, which is dated August 25, 1992.

n17 We find Defendants' arguments against the clear language of these definitions unpersuasive.

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Defendants maintain that the proper source to consult for a definition of "alkoxy" is the International Union of Pure and Applied Chemistry ("IUPAC") Compendium of Chemical Terminology. In apparent support of their untethered construction of "alkoxy," Defendants note that IUPAC does not set forth a formal definition for this term. In addition, Defendants place considerable reliance on the opinion of Dr. Alan McNaught ("Dr. McNaught"), head of the IUPAC Division of Chemical Nomenclature, who opines:
The IUPAC Compendium of Chemical Terminology (the Gold Book -- see http://www.chemsoc.org/chembytes/goldbook/index.htm) does not give a definition of alkoxy, but does list alkyl and various related terms (alkane, cycloalkyl, hydrocarbyl). I think that you could assume that alkoxy is equivalent to alkyl-Oxygen for definition purposes.

Defs.' Reply Brief at 4 (citing Ex. 1, Dr. Lipton's Ex. 15). Following Dr. McNaught's advice, we consulted the IUPAC Compendium of Chemical Terminology ourselves and found the following relevant definitions:
alkyl groups

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Univalent groups derived from alkanes by removal of a hydrogen atom from any carbon atom-CnH2n +1. The groups derived by removal of a hydrogen atom from a terminal carbon atom of unbranched alkanes form a subclass of normal alkyl (n-alkyl) groups H[CH2]n. The groups RCH2, R2CH (R) 1 NH), and R3C (R) 1 H) are primary, secondary and tertiary alkyl groups, respectively.

alkanes

IUPAC Compendium of Chemical Terminology alkanes Acyclic branched or unbranched hydrocarbons having the general formula CnH2n + 2, and therefore consisting entirely of hydrogen atoms and saturated carbon atoms. See also cycloalkanes. 1995, 67, 1313 IUPAC Compendium of Chemical Terminology 2nd Edition (1997)

(Definitions obtained from http://www.chemsoc.org/chembytes/goldbook/index.htm.) n18 Similar to the Hackh and McGraw-Hill's definitions, the IUPAC definitions do not encompass substituted alkyl groups. In fact, since the IUPAC definition of an alkane "consists entirely of hydrogen atoms and saturated carbon atoms," the IUPAC definitions are even clearer than the other two dictionaries' definitions in their explicit exclusion of the possibility of substitutions. n19 If we assume, as Defendants and Dr. McNaught suggest we should, that the definition of alkoxy is "alkyl-Oxygen," then, by extension, the definition of alkoxy explicitly excludes substituted alkoxy groups.

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n18 All three definitions are authored by Dr. McNaught.

n19 In his declaration of September 24, 2004, Dr. McNaught curiously (at least to us) states that "IUPAC has a recommended definition for the term alkyl groups,' which describes the unsubstituted group but does not deal with the question of whether substituted alkyl groups are excluded." McNaught Dec. atP 12. If such an IUPAC definition exists, it has not been presented to the Court in the context of this litigation. Moreover, we are at a loss to reconcile Dr. McNaught's editorial description of the IUPAC definitions with the actual language of the definitions themselves, which explicitly defines an "alkyl group" as being formed by the removal of a hydrogen atom from an "alkane," which is (in turn) defined as "consisting entirely of hydrogen atoms and saturated carbon atoms." Therefore, despite Dr. McNaught's ruminations to the contrary, we find the definitions sufficiently clear in indicting that substituted variations are not included in the formal definition of an alkane or alkyl group.

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Considered individually and collectively, these three definitions clearly indicate that the formal definitions of alkane/alkyl/alkoxy do not include substituted alkyl radicals/groups. n20 Accordingly, we conclude that the ordinary and customary definition of "alkoxy" is an unsubstituted alkyl radical attached to the remainder of the molecule by oxygen which definition is consistent with the claim construction advanced by Dow. This definition is further consistent with the construction of the term "alkoxy" as used in the Defendants' patents that we adopted previously based on the clear reading of the intrinsic evidence.

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n20 We also note that the restrictive definition of "alkyl" provided by the three dictionaries is consistent with Defendants' usage of that term in their patent claims. See, supra, Section I (A)(1).

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C. Extrinsic evidence.

Because we have concluded that the intrinsic evidence in Defendants' patents clearly indicates that the disputed term "alkoxy" does not include substituted variations, and this definition is supported by a variety of chemical dictionaries, we conclude there is no need to consult further any other extrinsic evidence. See Vitronics, Corp., 90 F.3d at 1583. n21 Accordingly, we decline the parties' invitation to consider the expert opinions, articles, and other related submissions and

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deny the various motions related to the use of these submissions as moot. n22

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n21 We note that Federal Circuit precedent leaves unresolved the exact status of the use of dictionaries in claim construction. Although dictionaries are technically extrinsic evidence, see Markman, 52 F.3d at 980, dictionaries are often treated by the Federal Circuit as if they were intrinsic evidence or, at least, a special class of extrinsic evidence more akin to intrinsic evidence, see supra note 14; Vitronics, Corp., 90 F.3d at 1584 n.6 (explaining: "Although technical treatises and dictionaries fall within the category of extrinsic evidence . . . judges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents"). Hopefully, much of the uncertainty under current case law surrounding the role of dictionaries will be resolved in a case currently pending before an en banc panel of the Federal Circuit. See Phillips v. AWH Corp., 376 F.3d 1382, 1383 (Fed. Cir. 2004) (specifically inviting the parties to submit additional briefing on several issues related to the use of dictionaries during claim construction).

n22 See, supra, note 1 for an expanded list of said motions.

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Secondly, we agree with the district court that the term "alkoxy" refers only to unsubstituted alkoxy groups. Neither the claim language or the specification explicitly indicates whether the term "alkoxy" includes substituted as well as unsubstituted variations. However, throughout both the claims and the specification, the patentee explicitly indicated which functional groups can be substituted. Thus, those functional groups which are not explicitly indicated as being capable of substitution cannot be substituted.

For example, claim 1 of the '064 patent distinguishes between substituted and unsubstituted variations of functional groups such as alkyl, cycloalkyl, benzyl, and phenyl groups. Claim 1 states:

R[1] is a hydrogen atom, an alkyl group, a halogen substituted alkyl groupk [sic], an alkoxy substituted alkyl group, an alkythio substituted alkyl group, a cyano substituted alkyl group, a 1-cycloalkenyl group, a benzyl group, a halogen substituted benzyl group, an acyl group . . .

'064 patent, col. 29, ll. 9-14. Thus, claim 1 indicates that R[1] may be an alkyl group substituted with certain substituents, an unsubstituted benzyl group, or a halogen substituted benzyl group. Similarly, claim 1 of the '064 patent states that "R[2] is a substituted or non-substituted phenyl group." Id. at col. 29, ll. 15. Continuing this pattern, claim 2 of the '064 patent distinguishes between those groups which may be substituted (i.e., "a halogenated cycloalkyl group") and those which are not substituted (i.e., "a cycloalkyl group"). Id. at col. 30, ll. 11-30.

In addition, the enumerated list setting out the possible substituents for the substituted phenyl group, the list in which the term "alkoxy" is found, repeatedly distinguishes between those functional groups which may be substituted and those which may not be substituted. Six of the ten substituent groups, (a)-(k), list potential substitutions. '044 patent, col. 2, ll. 30-50. If the phenyl group is substituted with an alkyl, acyl, alkyl sulfonyl, phenyl sulfonyl, alkythio, phenylthio, phenoxy, or phenyl functional group, that functional group may itself be substituted. However, if the phenyl group is substituted with a nitro, cyano, dioxymethylene, dioxyethylene, or alkoxy functional group, that group may not be substituted.

Further, substituent group (h) states that a "phenoxy" group can be substituted with halogen. Id. at col 2, ll. 44-47. A phenoxy group is an oxygen with a phenyl group attached. Thus, it is similar in structure to an alkoxy group; both have the same oxygen-connected-to-hydrocarbon structure and both may be substituted in a similar manner. The patentee explicitly noted when and in what manner a phenoxy group serving as a substituent on the phenyl group may itself be substituted. Therefore, the lack of an express recitation of possible substituents for an alkoxy group serving as a substituent on the phenyl group indicates that the alkoxy group must be unsubstituted.

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1. Disputed Claim Language

We must first determine the meaning of the claims of the '233 Patent. Markman, 52 F.3d at 976. Here, Defendants assert that they have not literally infringed claim 1 of the '233 Patent because their process for manufacturing a precursor to paroxetine hydrochloride does not contain "an alkyl, aryl, or arylalkyl group" in positions R and R' in structures (2) and (4) of claim 1. n32 (Doc. No. 105 at 16, 19-26.) Instead, Defendants state they use a "much larger and more complicated molecular piece in the R' position," a cycloalkyl group consisting of 10 carbon atoms and 19 hydrogen atoms arranged in a cyclic structure, with a chemical name of (-)2-isopropyl, 5-methylcyclohexyl. (Id. at 14; Cunningham Decl. P11; Murthy Decl. P8.) This radical has the following chemical structure:

Figure 7: (-)2-isopropyl, 5-methylcyclohexyl

[SEE Figure 7 IN ORIGINAL]

Defendants argue that this structure, which they call a chiral menthyl group, is not an "alkyl, aryl, or arylalkyl group" as claimed by the '233 Patent.

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n32 Plaintiffs also assert that because dependent claims 2-10 and 14-16 contain claim 1's limitation of "an alkyl, aryl, or arylalkyl group" in positions R and R', Plaintiffs' manufacturing process does not infringe these claims.

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Plaintiffs respond that Defendants' process for manufacturing paroxetine hydrochloride does include an alkyl group in position R' (the (-)2-isopropyl, 5-methylcyclohexyl radical illustrated Figure 7), and therefore literally infringes the '233 Patent. n33 (Doc. No. 119 at 3-8.) Thus, the meaning of the word "alkyl" is key to determining whether Defendants' production of paroxetine hydrochloride literally infringes the '233 Patent.

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n33 Plaintiffs do not argue that the chemical structure in Figure 7 is either an "aryl" or "arylalkyl" group as claimed by the '233 Patent (Doc. No. 119 at 6-8), and both chemists who filed declarations in support of Plaintiffs' memorandum of law, Dr. Brian Adger and Dr. G. Patrick Stahly, concede this point. See Adger Decl. P11 ("Of the three possibilities given for R' in claim 1 of . . . the '233 Patent . . ., menthyl only fits the alkyl definition . . . ."); Stahly Decl. P11 ("[Defendants'] menthyl structure is cyclic and not aromatic. Accordingly, it cannot be described as either an aryl group or an arylalkyl group." (footnote omitted)).

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2. Legal Standards

In claim construction, we must begin our analysis with the words of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see also Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." (citations omitted)). A court construing a patent claim must accord a claim "the meaning it would have to a person of ordinary skill in the art at the time of the invention," Innova/Pure Water, Inc., 381 F.3d at 1116, "unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996). The meaning of a claim's words to a person of ordinary skill in the art may be determined by reviewing a variety of sources, including "the words of the claims

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themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. (citing Markman, 52 F.3d at 979-80); see also Ferguson Beauregard v. Mega Sys., LLC, 350 F.3d 1327, 1338 (Fed. Cir. 2003) (stating that in claim construction, a court may consider "the claims themselves; dictionaries and treatises; and the written description, the drawings, and the prosecution history." (citations omitted)).

At the outset, we note an apparent conflict in Federal Circuit precedent regarding the appropriate procedure and weight in considering the sources relied upon in claim construction. In Vitronics Corp. v. Conceptronic, Inc., a panel of the Federal Circuit stated that a district court should first examine a patent's "intrinsic evidence," which includes the claims themselves, the patent specification, and the prosecution history, to determine the meaning of the words in a claim. 90 F.3d at 1582. Only if there is still "genuine ambiguity" after consideration of the intrinsic evidence may we consider "extrinsic evidence," such as expert testimony, and other sources, such as dictionaries and treatises, to determine the words' ordinary meaning. n34 Id. at 1583-84. Numerous subsequent Federal Circuit decisions have echoed this "intrinsic evidence first, extrinsic evidence second" approach. See, e.g., Vanderlande Indus. Nederland BV v. Int'l Trade Comm., 366 F.3d 1311, 1318 (Fed. Cir. 2004) ("While extrinsic evidence can shed useful light on the relevant art--and thus better allow a court to place itself in the shoes of a person of ordinary skill in the art--the 'intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.' Indeed, a 'court should look first to the intrinsic evidence of record' . . . ." (citations omitted)); Frank's Casing Crew & Rental Tools, Inc. v. PMR Techs., Ltd., 292 F.3d 1363, 1374 (Fed. Cir. 2002) ("In construing patent claims, we first look to the intrinsic evidence of record--the claims, the specification, and, if in evidence, the prosecution history. If ambiguity remains after consideration of the intrinsic evidence, 'extrinsic evidence may also be considered, if needed to assist in determining the meaning or scope of technical terms in the claims.'" (citations omitted)).

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n34 The Vitronics court stated in relevant part:

It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.

. . . .

In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence. In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely. . . .
. . . .
. . . . Only if there were still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court have resorted to extrinsic evidence, such as expert testimony, in order to construe [a] claim . . . .

Vitronics, 90 F.3d at 1582-84 (emphases added) (citations and parentheticals omitted).

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Other recent Federal Circuit decisions, however, adopt a different approach toward claim construction. In Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002), a panel of the Federal Circuit emphasized the importance of first considering dictionaries, treatises, and other "objective resources" to determine the ordinary meaning attributed to the words of a claim by a person of ordinary skill in the art. Id. at 1202-03; see also id. (describing dictionaries, treatises, and encyclopedias as "the most meaningful sources of information" in claim construction). While recognizing that an examination of intrinsic evidence is still necessary to determine (1) whether the inventor used words in a manner inconsistent with their ordinary meaning and (2) if there are multiple dictionary definitions for a word, to determine which definitions are consistent with the inventor's use, the Texas Digital court clearly stated that it is inappropriate for a court to consider intrinsic evidence prior to determining the ordinary and customary meaning of the words in a claim. See id. at 1204 ("Consulting the written description and prosecution history as a threshold step in the claim construction process, before any

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effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims."). The Texas Digital approach therefore appears to contradict the Vitronics decision, which held that dictionaries and other "extrinsic" sources should be relied upon only after considering the intrinsic evidence. n35 See Jennifer R. Johnson, Out of Context: Texas Digital, The Indefiniteness of Language, and the Search for Ordinary Meaning, 35 IDEA 521, 521 (2004) ("The [Federal Circuit's] [recent] focus on dictionaries as primary sources departs from earlier precedent, including Markman and Vitronics, which place primary emphasis on intrinsic evidence in the claim construction analysis."); Ruoyu Roy Wang, Note, Texas Digital Systems v. Telegenix, Inc.: Toward A More Formalistic Patent Claim Construction Model, 19 Berkeley Tech L.J. 153, 174 (2004) ("The [Texas Digital] court stressed that dictionaries ought to be consulted before the intrinsic record, not the other way around, as was often done before.").

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n35 Several recent Federal Circuit decisions have followed or approved the Texas Digital approach. See, e.g., Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc., 336 F.3d 1308, 1315 (Fed. Cir. 2003).

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In light of this apparent conflict, we follow the Federal Circuit's rule that "prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned in banc. Where there is direct conflict, the precedential decision is the first." Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir. 1988); see also SmithKline Beecham Corp. v. Geneva Pharms., 2002 U.S. Dist. LEXIS 25275, at *16 ("In the absence of an en banc decision, when there are directly conflicting panel decisions, 'the precedential decision is the first.'" (quoting Newell Cos., 864 F.2d at 765)). n36 We therefore follow the approach of theVitronics case, the prior panel decision, and first consider the intrinsic evidence of the '233 Patent to determine the inventor's meaning in using the word "alkyl." If we determine that the inventor's use of the disputed word is "genuinely ambiguous," then we may consider other evidence, including treatises, dictionaries, and extrinsic evidence, to determine the ordinary meaning of the word. See Unitherm Food Sys. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1352 (Fed. Cir. 2004) (approving, after Texas Digital, a district court's use of the Vitronics approach to claim construction).

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n36 We note that the Federal Circuit has granted rehearing en banc in Phillips v. AWH Corp., 363 F.3d 1207 (Fed. Cir.), vacated and reh'g granted en banc, 376 F.3d 1382 (Fed. Cir. 2004) (per curiam), on numerous important issues in claim construction, including the appropriate procedure and weight for using intrinsic evidence, dictionaries, treatises, and extrinsic evidence to determine the meaning of the words in a claim. This case may resolve the current conflict in authority. C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004).

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3. Claims and Patent Specification

We first look to "the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." Vitronics, 90 F.3d at 1582; see also Bell Communs. Resarch v. Vitalink Communications Corp., 55 F.3d 615, 619-20 (Fed. Cir. 1995) ("'Resort must be had in the first instance to the words of the claim . . . .'" (quoting Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984))). Because "it is the claims that measure the invention," SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc), we must take care to ascertain the proper scope of the claims, lest we import into the claims limitations that were unintended by the patentee. See, e.g., Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed. Cir. 1993) ("It is improper for a court to add extraneous limitations to a claim, that is limitations added wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim." (citation omitted)).

As mentioned above, words in a claim "take on the full breadth of the ordinary and customary meanings attributed to them by those of ordinary skill in the art," unless there is an express intent in the patent specification "to impart a novel meaning to the claim terms." Ferguson Beauregard, 350 F.3d at 1338 (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313,

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1325 (Fed. Cir. 2002)); see also Vitronics Corp., 90 F.2d at 1582 ("[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history."). "A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Hoechst Celanese Corp., 78 F.3d at 1578. In considering the intrinsic evidence, we must consider that "there is a 'heavy presumption' in favor of the ordinary meaning of claim language as understood by one of ordinary skill in the art." Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001).

As used in the '233 Patent, the word "alkyl" is a technical term from the field of organic chemistry. "Organic chemistry is traditionally described as the chemistry of carbon-containing compounds." Maitlin Jones, Jr., Organic Chemistry at xxxv (2d ed. 2000). Organic compounds may range in size from a simple methane molecule, which contains one carbon atom bonded to four hydrogen atoms (CH[4]), to enormously complex collections of thousands of carbon, hydrogen, and other atoms arranged in an almost infinite combination of chains, rings, and branches. Id. at xxxvi, 45-46. Carbon atoms may also form single, double, or triple bonds between carbon atoms, further expanding the discrete number of different organic compounds. Id. at 1-123. The near-limitless number of organic molecules presents an obvious problem for their naming and classification. A systematic naming protocol for organic compounds was first developed in 1892 by the Commission for the Reform of Nomenclature in Organic Chemistry of the International Union of Chemistry ("IUC"), and has been amended and updated several times by the IUC's successor, the International Union of Pure and Applied Chemistry ("IUPAC"). Int'l Union of Pure & Applied Chemistry, Nomenclature of Organic Chemistry at xvii (J. Rigaudy & S. P. Klesney eds., 1979 ed.) (hereafter "Nomenclature of Organic Chemistry (1979 ed.)"). Thus, we must look at the claim and the patent specification to determine whether the inventor expressly intended to impart the word "alkyl" with a novel meaning.

Defendants assert that an alkyl group is a hydrocarbon (a molecule consisting only of carbon and hydrogen atoms) of the formula C[n]H[2n+1], where n refers to the number of atoms. (Doc. No. 105 at 18; Cunningham Decl. P10.) Under this definition, the simplest alkyl group is methyl, which consists of a carbon atom and three hydrogen atoms (--CH[3]). (Doc. No. 105 at 18-19 & n.8.) Defendants argue that the chemical compound used in the R' position of structure (2) and (4), a cyclical hydrocarbon known as (-)2-isopropyl, 5-methylcyclohexyl, is not an alkyl group because it has 10 carbon and 19 hydrogen atoms and therefore does not fall within the formula C[n]H[2n+1].

Plaintiffs disagree, asserting that Defendants' chemical compound is an alkyl group. They point to the expert declarations of Dr. Adger and Dr. Stahly, who define an alkyl group as any hydrocarbon containing only carbon-carbon and carbon-hydrogen single bonds, regardless of whether it has the formula C[n]H[2n+1] or contains a cyclical structure. (Adger Decl. P11; Stahly Decl. PP7, 13.) Thus, in agreement with Defendants' definition, the simplest alkyl group would be methyl (--CH[3]), which contains only carbon-carbon and carbon-hydrogen single bonds. Under Plaintiffs' definition, however, Defendants' (-)2-isopropyl, 5-methylcyclohexyl radical would qualify as an alkyl group, because it contains only carbon-carbon and carbon-hydrogen single bonds. (Doc. No. 119 at 4-7.) Plaintiffs also assert that (-)2-isopropyl, 5-methylcyclohexyl's cyclical structure is irrelevant, because alkyl groups may include cyclical hydrocarbons. (Id.)

There is no evidence here, from either the words of the claims themselves or the patent specification, to indicate that the inventor of the '233 Patent meant to impart a novel definition to the word "alkyl" in claim 1. The claim itself does not attempt to define the word alkyl. '233 Patent, col. 5 l. 65. The patent specification, however, does describe what may constitute an alkyl. It refers to the Plati process, where a methyl group was present in the R' position in structure (2) and (4). As mentioned, methyl is the simplest alkyl group. The specification continues by stating that after experimenting with the Plati process, the inventor developed an allegedly novel process for producing paroxetine hydrochloride. It observes that the "first aspect of this invention" is the preparation of structure (2), where R' is "independently an alkyl, aryl, or arylalkyl group, most suitably a lower alkyl." '233 Patent, col. 2 ll. 29, 46-47 (emphasis added). According to Defendants, lower alkyl groups would include relatively simple hydrocarbons of the formula C[n]H[2n+1], where there were no more than four carbon atoms. n37 (Doc. No. 105 at 19; Cunningham Decl. P22.)

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n37 These alkyl groups would include methyl (--CH[3]), ethyl (--CH[2]CH[3]), propyl (three carbon atoms and seven hydrogen atoms), and butyl (four carbon atoms and nine hydrogen atoms). (Doc. No. 105 at 19.)

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The '233 Patent specification also gives five examples of the types of R' groups envisioned by the invention. All five use methyl (--CH[3]) as the R' group. '233 Patent col. 41. 42 to col. 5, l. 45. As previously explained, methyl is the simplest alkyl group under either definition. Thus, there is no indication from the patent specification that the inventor intended to impart the word "alkyl" with anything other than its ordinary meaning. See (Doc. No. 119 at 4) (stating Plaintiffs' claim that "the specification and prosecution history do not indicate that [the inventor] used the terms 'alkyl, aryl, or arylalkyl' differently from the way those terms are commonly used by those of ordinary skill.").)

4. Patent Prosecution History

Next, we must consider the prosecution history of the patent, which can assist us in determining whether the inventor made any express representations regarding the scope or meaning of the claims or disclaimed or disavowed a particular interpretation of the claims during prosecution. Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1372 (Fed. Cir. 2002); Bell Atlantic Network Servs., Inc., 262 F.3d at 1268. The prosecution history includes "the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. Bell Atlantic Network Servs., Inc., 262 F.3d at 1268 (citing Vitronics, 90 F.3d at 1582).

The '233 Patent's prosecution history does not indicate that the inventor intended to give the word "alkyl" anything other than its ordinary meaning to a person of ordinary skill in the art. The initial patent application contains the same language as claim 1 of the '233 Patent, stating that the R' group in structure (4) must be "independently selected from an alkyl, aryl, or arylalkyl group." (Doc. No. 105 Ex. I. at 0020.) The patent application's specification is also similar to the '233 Patent--both used a methyl group, the simplest alkyl, in the R' position in all five examples. (Id. at 0018-0019.) Additionally, in the "Remarks" section of the amended patent application, the claimed process was illustrated by using a methyl group in the R' position. (Id. at 0077.) There is no indication anywhere else in the prosecution history that the inventor made any express representations limiting the scope of the word alkyl or giving it anything other than its ordinary meaning.

Because there is no clear intent or express indication that the inventor of the '233 Patent used the word alkyl to mean anything other than its ordinary meaning, we conclude that the inventor's use of the word alkyl in the '233 Patent has its ordinary and customary meaning as understood by a person of ordinary skill in the art. Also, in light of the inventor's use of a methyl group in the R' position of structures (2) and (4) in all examples of the claimed process, which is consistent with both of the proposed definitions of the word "alkyl," we conclude that the intrinsic evidence is "genuinely ambiguous" as to which of the parties' competing definitions, if any, the inventor intended to adopt. We therefore turn to the relevant treatises, dictionaries, and extrinsic evidence to determine the meaning and scope of the word alkyl in the '233 Patent.

5. Dictionaries and Treatises

The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including dictionaries, treatises, and encyclopedias. See, e.g., Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378 (Fed. Cir. 2002); Teleflex, Inc., 299 F.3d at 1325. As the Texas Digital court has explained, these secondary sources are particularly important because they are objective, unbiased evidence of the ordinary meaning of the words of the claim:

Dictionaries, encyclopedias and treatises, publicly available at the time the patent is issued, are objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art. Such references are unbiased reflections of common understanding not influenced by expert testimony or events subsequent to the fixing of the intrinsic record by the grant of the patent, not colored by the motives of the parties, and not inspired by litigation. Indeed, these materials may be the most meaningful sources of information to aid judges in better understanding both the technology and the terminology used by those skilled in the art to describe the technology.

Tex. Digital Sys., Inc., 308 F.3d at 1202-03; see also Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1178 n.4 (Fed. Cir. 2002) (stating that dictionaries and treatises have a "special place" in claim construction).

A technical term often has an "ordinary meaning" as understood by one of ordinary skill in the art, although these same terms may not be readily familiar to a judge. Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1373 (Fed. Cir.

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2001). "Thus, in determining the ordinary meaning of a technical term, courts are free to consult scientific dictionaries and technical treatises at any time." Id. (citing Vitronics, 90 F.3d at 1584 n.6); see also Tex. Digital Sys., Inc., 308 F.3d at 1202-03 ("Dictionaries are always available to the court to aid in the task of determining meanings that would have been attributed by those of skill in the relevant art to any disputed terms used by the inventor in the claims."). As with other non-intrinsic evidence, however, a dictionary definition must be disregarded if "the specification uses the words in a manner clearly inconsistent with the ordinary meaning reflected . . . in a dictionary definition." Texas Digital Sys., Inc., 308 F.3d at 1204 (citations omitted).

a. IUPAC Nomenclature

To determine the meaning of the term alkyl, we first consider the international standard for nomenclature (naming) of organic chemistry, as promulgated by IUPAC. (Cunningham Decl. P7.) For more than a century, IUPAC has developed and adopted a systematic nomenclature for naming organic molecules. Nomenclature of Organic Chemistry (1979 ed.) at xvii. In the IUPAC system, organic molecules are named and classified "by dividing the [molecule] into a core structure and various substituents." Dow Agrosciences LLC v. Crompton Corp., 2004 U.S. Dist. LEXIS 8532, No. 03-CV-0654, 2004 WL 1087362, at *3 (S.D. Ill. May 12, 2004). As the standardized, comprehensive international system of organic nomenclature, we find that the IUPAC system's meaning of the word alkyl would be given great weight by a person of ordinary skill in the art. n38 (Cunningham Decl. P13.)

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n38 Plaintiffs rely upon the declarations of two chemists, Dr. Brian Adger and Dr. G. Patrick Stahly, to assert that a person of ordinary skill in the art would not rely upon IUPAC's nomenclature to determine the meaning of the word alkyl. (Adger Decl. P16; Stahly Decl. P14.) We disagree. Introductory organic chemistry textbooks, which a person of ordinary skill in the art would rely upon in determining the name and classification of a chemical compound, routinely use the IUPAC nomenclature system to name most organic compounds. See, e.g., Jones, Organic Chemistry at 77 ("Once we reach five carbons the IUPAC system largely takes over . . . .").

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i. 1979 Edition

In the 1979 edition of IUPAC's nomenclature of organic chemistry, Rule A-1.2 defines an alkyl as a "univalent radical[] derived from [a] saturated unbranched acyclic hydrocarbon[] by removal of hydrogen from a terminal carbon." Nomenclature of Organic Chemistry (1979 ed.) at 5. In organic chemistry, a "saturated" hydrocarbon is an "organic compound containing only single bonds between carbon atoms." Webster's Third New International Dictionary 2018 (Philip Babcock Grove ed., 1993). An "acyclic" hydrocarbon is a hydrocarbon that does not contain carbon atoms bonded in the shape of a ring. See id. at 23 (defining acyclic as "not cyclic" or "having an open-ended chain structure"); see also 1 Oxford English Dictionary 135 (J.A. Simpson & E.S.C. Weiner eds., 2d ed. 1989) (defining acyclic as "an organic compound that has no 'cycle' or ring of atoms"), available at http://www.oed.com. Thus, under the 1979 IUPAC nomenclature, an alkyl is a hydrocarbon radical that contains only single bonds between carbon atoms, and no carbon atoms bonded in the shape of a ring.

Defendants assert that under IUPAC nomenclature, (-)2-isopropyl, 5-methylcyclohexyl may be classified as a cycloalkyl, which Defendants assert is a mutually exclusive category from alkyls. Rule A-11.2 defines a "cycloalkyl" as a "univalent radical derived from cycloalkanes." Nomenclature of Organic Chemistry (1979 ed.) at 16. A cycloalkane is defined in turn by Rule A-11.1 as a "saturated monocyclic hydrocarbon" radical. Id. A "monocyclic" hydrocarbon is a hydrocarbon that has one group of carbons bonded in the shape of a ring. See Webster's Third New International Dictionary at 1462 (defining monocyclic as "containing one ring in the molecular structure"). Thus, a cycloalkyl is a saturated hydrocarbon radical with one group of carbons in the shape of a ring. From these definitions, it logically follows that a cycloalkyl may not be an alkyl, because a cycloalkyl contains one carbon ring, while an alkyl may not contain any carbon rings.

ii. 1993 Edition

The 1993 IUPAC nomenclature defines an alkyl group as a radial of an alkane. Int'l Union of Pure & Applied Chemistry, A

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Guide to IUPAC Nomenclature of Organic Compounds Recommendations 1993, at 64 tbl. 6, 132 (R. Panico et al. eds, 1993) (hereafter "Nomenclature of Organic Compounds (1993 ed.)") (R-3.2.1 tbl. 6, R-5.8.1) n39. An alkane is defined as a "saturated acyclic hydrocarbon (branched or unbranched)." Id. at 36 (R-2.2.1). Because an "acyclic" hydrocarbon does not contain any carbon atoms bonded in the shape of a ring, Webster's Third New International Dictionary at 2018, the 1993 IUPAC nomenclature thus defines an alkyl as a hydrocarbon radical containing only single bonds between carbon atoms, and no carbon atoms bonded in the shape of a ring. Id. This is consistent with the 1979 IUPAC nomenclature definition of an alkyl.

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n39 "R-" indicates the relevant rule number in 1993 edition.

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Likewise, the 1993 IUPAC nomenclature of a cycloalkyl is consistent with the 1979 IUPAC nomenclature. A cycloalkyl is defined as a cycloalkane radical. Id. at 64 tbl. 6, 132 (R-3.2.1 tbl. 6, R-5.8.1). A cycloalkane is defined as "the generic name of monocyclic hydrocarbons." Id. at 39 (R-2.3.1.1); see also id. ("The names of saturated monocyclic hydrocarbons are formed by attaching the prefix 'cyclo-' to the name of the acyclic saturated unbranched hydrocarbon with the same number of carbon atoms."). Thus, consistent with the 1979 IUPAC definition, a cycloalkyl is a hydrocarbon radical with a group of carbons in the shape of a ring. Accordingly, a cycloalkyl is mutually exclusive from an alkyl under the 1993 IUPAC nomenclature.

b. Technical Dictionaries

Next, we consider the definition of the word alkyl in technical dictionaries. Technical dictionaries are particularly useful for defining technical terms because they "provide specialized meanings as used in particular fields of art." Inverness Med. Switz. GmbH, 309 F.3d at 1378; see also Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1320 (Fed. Cir. 2004) (stating that "technical dictionaries . . . are evidence of the understandings of persons of skill in the technical arts"). The Federal Circuit has routinely relied on chemical dictionaries, such as Hawley's Condensed Chemical Dictionary and Grant & Hackh's Chemical Dictionary ("Grant & Hackh's"), to determine the ordinary meaning of chemical words and phrases as understood by a person of ordinary skill in the art. See, e.g., E.T. Horn Co. v. United States, 367 F.3d 1326, 1333 (Fed. Cir. 2004); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1571 (Fed. Cir. 1983).

Here, the chemical dictionaries' use of the word alkyl is consistent with the IUPAC's definition of an alkyl as a hydrocarbon radical that does not contain carbon atoms bonded in the shape of a ring. Grant & Hackh's defines an alkyl group as a "monovalent radical derived from an aliphatic hydrocarbon by removal of 1 [hydrogen atom]." Grant & Hackh's Chemical Dictionary at 24 (emphasis added). An "aliphatic" hydrocarbon is a compound that does not have a carbon structure in the shape of a ring. Id. at 22 (defining "aliphatic" as an "open-chain carbon compound"); see also Robert B. Fox & Warren H. Powell, Nomenclature of Organic Compounds: Principles and Practice 65 (2001) ("The general term 'aliphatic' should be used with care. . . . The definition does not encompass cyclic compounds of any kind." (emphasis added)). In addition, Grant & Hackh's states than an alkyl has a formula of C[n]H[2n+1], which is inconsistent with a cyclical hydrocarbon radical. n40 Therefore, we conclude that under Grant & Hackh's definition, a hydrocarbon radical with a cyclical or ring structure cannot be classified as an alkyl. n41

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n40 In a cyclical hydrocarbon compound, every carbon atom in the ring is bonded to at least two other carbon atoms. Because a carbon atom may form only four bonds with other atoms, the maximum number of hydrogen atoms a cyclical hydrocarbon may have is C[n]H[2n].

n41 Grant & Hackh's defines a cycloalkyl as the "generic name for radicals derived from cycloalkanes." Grant & Hackh's Chemical Dictionary at 167. Cycloalkanes are defined as the "generic name for saturated, monocyclic hydrocarbons." Id. Thus, a cycloalkyl, which has one cyclical carbon structure (monocyclic), cannot be an alkyl, which has no cyclical carbon structures.

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Another dictionary, Hawley's Condensed Chemical Dictionary ("Hawley's"), provides a similar definition. It defines an alkyl as a "paraffinic hydrocarbon which may be derived from an alkane by dropping one hydrogen from the formula," and states that alkyl groups "have the generic formula C[n]H[2 n+1]." n42 Hawley's at 34. Alkanes, in turn, are defined as "[a] class of aliphatic hydrocarbons characterized by a straight or branches carbon chain." Id. at 33, 838. As explained above, an aliphatic hydrocarbon may not contain a cyclical or ring-shaped carbon structure. Thus, under Hawley's definition, a cyclical hydrocarbon radical may not be classified as an alkyl.

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n42 Hawley's also lists several examples of alkyls, all of which (methyl, ethyl, propyl, and isopropyl) are not cyclical hydrocarbon radicals. Hawley's at 34.

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c. Textbooks and Treatises

We also consider the meaning of the word alkyl in other sources that would be relied upon by a person of ordinary skill in the art, such as treatises or textbooks on organic chemistry. See, e.g.,In re '639 Patent Litig., 154 F. Supp. 2d 157, 161 (D. Mass. 2001) (holding that a person of ordinary skill in the art, which the court defined as a chemist with an advanced degree in the field and at least several years' experience, would rely on chemistry textbooks), aff'd on other grounds, No. 01-1611, 45 Fed. Appx. 915, 2002 U.S. App. LEXIS 16594 (Fed. Cir. Aug. 15, 2002) (per curiam).

Defendants point to a treatise on nomenclature of organic compounds, Nomenclature of Organic Compounds: Principles and Practice, in support of their argument that (-)2-isopropyl, 5-methylcyclohexyl is not an alkyl group. (Cunningham Decl. P16.) In this treatise, alkanes are defined as saturated branched or unbranched hydrocarbons. Fox & Powell, Nomenclature of Organic Compounds: Principles and Practice at 60. According to this definition, cyclic hydrocarbons are not alkanes. The treatise also distinguishes alkanes from cycloalkanes, defining cycloalkanes as saturated monocyclic hydrocarbons. Id. at 67. Cycloalkyls are defined as cycloalkane radicals. Id. at 68. Therefore, according to this treatise, a monocyclic hydrocarbon radical like (-)2-isopropyl, 5-methylcyclohexyl would not be defined as an alkyl because it is a cyclic, rather than a branched or unbranched, structure.

Another objective resource--an introductory organic chemistry textbook by Maitland Jones, Jr., the David B. Jones Professor of Chemistry at Princeton University--also supports Defendants' argument that a cyclical hydrocarbon radical may not be classified as an alkyl. This textbook defines alkyl as a "generic term for derivatives of alkanes." Jones, Organic Chemistry at 57. Alkanes are defined as "the series of saturated hydrocarbons of the general formula C[n]H[2n+2]." Id. at A2; see also id. at 81 (repeating this definition). In contrast, the Jones textbook explains that cyclical hydrocarbons are unsaturated compounds of the general formula C[n]H[2n]. Id. at 81. It teaches that cyclical-shaped hydrocarbons "are named by adding the prefix 'cyclo' to the name of the parent hydrocarbon." Id.; see also id. at 81-84 (describing the properties of "cycloalkanes"). The Jones textbook thus explains that unsaturated cycloalkanes may not be classified as alkanes, which are saturated hydrocarbons.

6. Extrinsic Evidence n43

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n43 We note that neither side requested a Markman hearing to present expert witness testimony regarding the construction of the '233 Patent. Accordingly, we will consider the declarations of the three organic chemists submitted by the parties as extrinsic evidence. See, e.g., Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1166 (Fed. Cir. 2004) (considering expert declarations); Honeywell Int'l, Inc. v. ITC, 341 F.3d 1332, 1340 (Fed. Cir. 2003) (same).

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Finally, we may consider extrinsic evidence, such as expert testimony or affidavits, to assist us in determining how a person

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of ordinary skill in the art would understand terms in a claim, so long as it is not inconsistent with the intrinsic evidence. Vitronics, 90 F.3d at 1584; see also id. ("Extrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language."). Unlike dictionaries or treatises, however, expert testimony is not an objective source constituting "an unbiased reflection[] of common understanding . . . not colored by the motives of the parties, and not inspired by litigation." Tex. Digital Sys., Inc., 308 F.3d at 1203. "We must always be conscious that our objective is to interpret the claims from the perspective of one of ordinary skill in the art, not from the viewpoint of counsel or expert witnesses retained to offer creative arguments in infringement litigation." Dayco Prods. v. Total Containment, Inc., 258 F.3d 1317, 1324 (Fed. Cir. 2001) (citation omitted); see also Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1166 (Fed. Cir. 2004) ("Although expert testimony and declarations are useful to confirm that the construed meaning is consistent with the denotation ascribed by those in the field of the art, such extrinsic evidence cannot be used to vary the plain language of the patent document." (quoting Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1332 (Fed. Cir. 2003))).

Defendants submit the declaration of Dr. Ian M. Cunningham, an organic chemist with over twenty years' experience as a pharmaceutical chemist and manager. n44 (Cunningham Decl. PP1-2, Ex. A.) Dr. Cunningham states that it is his opinion that "a chemist skilled in the art would understand the term 'alkyl' to mean a simple, straight or branched acyclic saturated hydrocarbon group." n45 (Id. P10.) In support of his opinion, Dr. Cunningham states that he relied upon the IUPAC conventions for the nomenclature of organic compounds. (Id. PP13-15.) As previously explained, supra, IUPAC defines alkyl groups as acyclic hydrocarbon radicals. (Id. P14.) IUPAC defines monocyclic hydrocarbon radicals, such as (-)2-isopropyl, 5-methylcyclohexyl, as cycloalkyls. (Id. P15.) Dr. Cunningham also states that he relied upon the treatise Nomenclature of Organic Compounds: Principles and Practice, which defines alkyl groups as alkanes joined to an organic compound by a single bond, and which defines alkanes as saturated, branched or unbranched, acyclic hydrocarbons. (Id. P16.) This treatise also classifies saturated monocyclic hydrocarbons as cycloalkanes, a mutually exclusive group from alkanes. (Id.) Finally, Dr. Cunningham states that in his opinion, a chemist of ordinary skill in the art reading a description of chemical reaction calling for an alkyl group would not consider that description to encompass a cycloalkyl group. (Id. P18.)

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n44 Dr. Cunningham was also Senior Vice President of Chemical Development at GlaxoSmithKline from 2001-2002 and Wordwide Director of Chemical Development of GlaxoWellcome from 1995-2001. (Cunningham Decl. P2, Ex. A.)

n45 Dr. Cunningham also states that, in his opinion, the generic formula for an alkyl group is C[n]H[2n+1].

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Plaintiffs submit the declarations of Dr. Brian Adger, an organic chemist with over thirty years' experience, and Dr. G. Patrick Stahly, an organic chemist with over twenty years' experience. (Adger Decl. P4; Stahly Decl. PP2-5, Ex. A.) Both scientists conclude that a person of ordinary skill would find that Apotex used an alkyl group in the R' position. Dr. Adger states that in his opinion, "the term 'alkyl,' as used in the '233 Patent, encompasses straight chain, branched, and cyclic alkyl groups." (Adger Decl. P5.) Similarly, Dr. Stahly asserts that "the term 'alkyl' as used in claim 1 [of the '233 Patent], would be interpreted by chemists of ordinary skill to include cycloalkyls . . . and a number of substituted cycloalkyl groups such as the menthyl group." (Stahly Decl. P7.)

As evidence for their conclusion, Drs. Adger and Stahly rely on a patent application (Pub. No. 2003/0220370 A1), by Dr. Keshava Murthy and several co-inventors published on November 27, 2003. (Adger Decl. P6, Ex. B; Stahly Decl. PP8, 11.) Dr. Murthy is the President of BCI, a company affiliated with Apotex. (Murthy Decl. P1.) Drs. Adger and Stahly note that in his patent application, Dr. Murthy described a cyclical hydrocarbon radical called a "menthyl group" as an "alkyl group." (Adger Decl. P6; Stahly Decl. PP10-11.)

Dr. Murthy's patent application and its definition of an "alkyl group" are irrelevant, however, for two reasons. First, it is elementary that "[a] court construing a patent claim seeks to accord a claim the meaning it would have to a person of ordinary skill in the art at the time of the invention." Innova/Pure Water, Inc., 381 F.3d at 1116 (emphasis added); see also Markman, 52 F.3d at 986 ("The focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). Dr. Murthy is not a person of ordinary skill in the art, but rather a

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person of exceptional skill--a highly trained and educated chemist with a Ph.D., and an inventor who has received numerous patents for developing processes to produce various pharmaceutical products. n46 As the Federal Circuit has repeatedly instructed, an invention "must be evaluated not through the eyes of [an] inventor, who may have been of exceptional skill, but as by one of 'ordinary skill.'" Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985); see also Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 956 (Fed. Cir. 1997). Thus, it is clearly inappropriate for an expert to rely on the statement of an individual who is not a person of ordinary skill (i.e., Dr. Murthy) to determine what a person of ordinary skill would have understood a term in a claim to mean. Second, the court's inquiry into the meaning of a claim is what a person of ordinary skill would have understood the words of the claim to mean at the time of the invention. Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1356 (Fed. Cir. 2004); Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed. Cir. 2003). Here, Dr. Murthy's patent application's definition of an "alkyl group" is irrelevant because it occurred well after the time of the '233 Patent's invention. The '233 Patent was issued on January 9, 2001, while Dr. Murthy's patent application was not published until November 27, 2003. (Adger Decl. Exs. A, C.) Even allowing for an eighteen-month delay in the publication of Dr. Murthy's patent application, as required by 35 U.S.C. § 122(b)(1)(A), Dr. Murthy's patent application was submitted no earlier than May, 2002, at least fifteen months after the issuance of the '233 Patent. Thus, Dr. Murthy's application cannot inform us as to the meaning of the claims at the time of the '233 Patent's invention.

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n46 See, e.g., U.S. Patent No. 6,635,753 (issued Oct. 21, 2003) (naming Dr. Murthy as an inventor of a process for the preparation of substantially pure stavudine and related intermediates useful in the preparation thereof); U.S. Patent No. 6,600,044 (issued July 29, 2003) (naming Dr. Murthy as an inventor of a process for recovery of the desired cis-1,3-oxathilane nucleosides from their undesired trans-isomers); U.S. Patent No. 6,436,956 (issued Aug. 20, 2002) (naming Dr. Murthy as an inventor of a useful form of anhydrous paroxetine hydrochloride); '689 Patent (naming Dr. Murthy as an inventor of processes for preparing 3-substituted-4-aryl piperidines and methods for controlling their stereochemistry).

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Second, Dr. Adger states that he relied on an organic chemistry textbook by Seyhan N. Ege, a professor of chemistry at the University of Michigan. (Adger Decl. P15.) Dr. Adger states that this textbook supports his opinion because it "defines alkanes as having two classes: open chain alkanes (acyclic compounds) as well as cyclic alkanes. Thus, Ege recognizes that cycloalkanes are a class of alkanes, and, therefore, cyclo alkyls are alkyls." (Id.) However, we find other statements in the Ege textbook that undercut Dr. Adger's conclusion. For example, the textbook states that cycloalkanes have a different general formula from alkanes. See Seyhan N. Ege, Organic Chemistry 163 (2d ed. 1989) ("Cycloalkanes are hydrocarbons that have the general formula C[n]H[2n]. . . ."). More importantly, the Ege textbook makes a clear distinction between cycloalkyls and alkyl groups, stating that "cycloalkyl groups are derived from cycloalkanes, just as alkyl groups are derived from alkanes." Id. at 164. Thus, contrary to Dr. Adger's statements, the Ege textbook appears to view cycloalkyls and alkyls as mutually exclusive groups.

Dr. Adger relies on one other source, an organic chemistry textbook by L. G. Wade, Jr., a professor of chemistry at Whitman College. (Adger Decl. P14.) He states that the Wade textbook states that "cycloalkanes are alkanes in the form of a ring." (Id. (quoting id. Ex. D. at 70).) Based on this brief reference, Dr. Adger concludes that cycloalkyls must be a form of alkyl. (Id.) Similarly, Dr. Stahly relies on one other source, an organic chemistry textbook by Ralph J. Fessenden and Joan S. Fessenden, which states that "an alkyl group contains only -sp<3>-hybridized carbon atoms plus hydrogen." (Stahly Decl. P13 (quoting id. Ex. F at 66).) The textbook then includes an example of a cyclohexyl radical as an alkyl. (Id.)

7. Conclusion

As the Federal Circuit has noted, "it has been long recognized in our precedent . . . that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms." Tex. Digital Sys., Inc., 308 F.3d at 1202. These "objective resources . . . serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art." Id. at 1202-03. They are the "most meaningful sources of information to aid judges in better understanding . . . the terminology used by those skilled in the art to describe the [relevant] technology." Id. at 1203.

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In light of the objective evidence discussed in Part IV.B.5, we conclude that a person of ordinary skill in the art at the time of the '233 Patent's invention would understand the word "alkyl" to mean an acyclic saturated hydrocarbon radical. This conclusion is supported by IUPAC's international standard nomenclature for organic compounds, which explicitly defined an alkyl group in both the 1979 and 1993 editions as an acyclic saturated hydrocarbon radical. Supra Part IV.B.5.a. It is also supported by two chemical dictionaries, Grant & Hackh's Chemical Dictionary and Hawley's Condensed Chemical Dictionary, which defined an alkyl as an aliphatic n47 hydrocarbon radical. Supra Part IV.B.5.b. Finally, we note that this definition is consistent with two treatises, including a specialized treatise on the nomenclature of organic compounds. Supra Part IV.B.5.c.

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n47 As previously explained, an aliphatic hydrocarbon is acyclic--that is, it does not contain any carbons bonded in the shape of a ring. See Fox & Powell at 65 ("The general term 'aliphatic' should be used with care. . . . The definition does not encompass cyclic compounds of any kind." (emphasis added)).

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This definition is also consistent with the intrinsic evidence. There is no evidence, from either the words of the claims themselves or the patent specification, to indicate that the inventor of the '233 Patent meant to impart a novel definition to the word "alkyl" in claim 1. The claim itself does not attempt to define the word alkyl, and the patent specification states that the "most suitable" alkyl is a "lower alkyl." '233 Patent, col. 2 ll. 29, 46-47. The examples of alkyls contained in the prosecution history and the patent specification all employ a methyl radical (--CH[3]), the simplest alkyl group.

We find the declarations of Drs. Adger and Stahly to be unconvincing. Their definitions contradict the ordinary meaning of the term alkyl as determined by IUPAC nomenclature, chemical dictionaries, a treatise on organic chemistry nomenclature, and several textbooks. The overwhelming weight of objective evidence, when coupled with expert evidence from Dr. Cunningham, compels us to reject Plaintiffs' chemists' assertion that the word alkyl encompasses monocyclic saturated hydrocarbon radicals.
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The Court has construed the limitations of Claim 1, in relevant part, as follows:

"Active" means producing an intended action or effect: active ingredients.
"Pharmacologically effective" means an amount that is medically effective.
"Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratan sulfate and acemannan, for example.
"Amount effective" means a quantity that produces a result.
"Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
"Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.
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1. "allowing," "retaining"

In claims 1 and 6 of the '125 patent, the parties dispute the meaning of two phrases related to the biodegradation process. For example, claim 1 recites:

1. A method of removing hydrocarbons from a part and disposing of the hydrocarbons, the method comprising the steps

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of:

suspending, in a biodegradable, non-caustic, non-flammable, oil dispersant, cleaning and degreasing fluid, microorganisms to which the fluid is non-toxic;

providing a parts washer having at least a basin for receiving the part and a tank below the basin for containing the fluid;

bringing the part into contact with the fluid containing the microorganisms;

allowing the fluid to remove the hydrocarbons from the part and flow into the tank; and

allowing the microorganisms within the fluid to biodegrade the hydrocarbons.

'125 patent, col. 8, ll. 28-42; see also id., col. 8, l. 63 - col. 9, l. 10 ("retaining the hydrocarbons within the fluid in the tank while the microorganisms biodegrade the hydrocarbons").

Plaintiff ChemFree argues that no construction is necessary because the meaning of these disputed phrases is obvious; the first phrase means to "let or permit the microorganisms within the fluid to chemically decompose the hydrocarbons" and the second means that "the hydrocarbons remain in the fluid that is in the tank while the microorganisms chemically decompose them." In contrast, Defendant seeks to impose a limitation on these claims -- as well as every other claim involving biodegradation in the parts washing patents -- that would require biodegradation to take place at or near the top of the fluid in the tank. Thus, Defendant suggests that "allowing the microorganisms within the fluid to biodegrade the hydrocarbons" should mean "placing the bacteria in close proximity to the hydrocarbons floating at the top of the fluid so that the bacteria can break down the hydrocarbons into predominantly environmentally safe by-products." Similarly, they argue that "retaining the hydrocarbons within the fluid in the tank while the microorganisms biodegrade the hydrocarbons" should mean "allowing the bacteria to break down the hydrocarbons into predominantly environmentally safe by-products at a location that is at the top of the fluid in the tank."

J. Walter's position is based primarily upon its theory that Plaintiff ChemFree, during prosecution of the '491 patent, disclaimed biodegradation that takes place anywhere other than the top of the tank. (Def.'s Opening Brief at 59-60 ("The prosecution history . . . mandates that the disputed phrase be construed as ensuring the bioremediation occurs at the top of the cleaning fluid."); id. at 62-63 ("[A]ll the patents that claim bioremediation of the grease and oil washed from a part are restricted to an embodiment wherein a substantial amount of the biodegradation takes place proximate to the fluid surface.") (emphasis omitted).)

The Court begins with the language of the claims themselves, which generally "provide[s] substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314. As seen from the text of claims 1 and 6, neither of the claim phrases at issue either explicitly or implicitly require that biodegradation take place at the surface of the fluid. Instead, both claims merely recite that the biodegradation take place "within the fluid [in the tank]." Notably, when the Applicant desired to limit its invention to an embodiment where biodegradation takes place at the surface of the fluid, it knew how to do so. For example, claim 3 of the '110 patent recites a parts washing system "wherein [a] substantial portion of the microorganisms and hydrocarbons accumulate proximate to said fluid surface such that a substantial amount of biodegradation takes place proximate to said fluid surface." The presence of such a limitation there and not in these claims suggests they should not be so-limited.

Defendant also points to language in the specification in support of their position that all embodiments should be limited to biodegradation taking place at or near the surface of the fluid. The portion of the specification cited teaches that:

[T]he fluid 72 and organic contaminants pass through the support grid 58, and drain hole 52 to deposit into the tank cavity 44. . . . Within the tank cavity 44, a large percentage of the microorganisms and organic contaminants will tend to accumulate proximate to the surface of the cleaning fluid 72 such that a large portion of the biodegradation takes place proximate to the surface of the cleaning fluid 72.

'110 patent, col. 6, l. 49 - col. 7, l. 3. The parties do not dispute that, generally speaking, oil and grease, if left undisturbed, will float on top of the cleaning fluid. The specification merely discusses this phenomenon in the context of explaining a

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preferred embodiment of the invention. Nowhere, however, does the Applicant's disclosure indicate that it intended to limit the invention to embodiments where a substantial amount of the biodegradation takes place at the surface of the fluid. Cf. Phillips, 415 F.3d at 1323 ("Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention . . ., or whether the patentee intends for the claims and the embodiments to be strictly coextensive."). It would be inappropriate to import the limitation into these claims due to the Applicant's discussion of a natural phenomenon that "tend[s] to" happen.

J. Walter's primary argument with regard to its proposed construction is that ChemFree, during prosecution of the '491 patent, made a representation that serves to limit all embodiments in all patents stemming from the '902 application to an embodiment where the bioremediation, or a substantial portion thereof, takes place at the fluid surface. (Def.'s Opening Brief at 62-63 ("Applicants' characterization of the scope of the invention during prosecution limits the scope of all the patents-in-suit to the same extent -- all the patents that claim bioremediation of the grease and oil washed from a part are restricted to an embodiment wherein a substantial amount of the biodegradation takes place proximate to the fluid surface.").) To be clear, J. Walter seeks to impose a limitation on the claims in the '125 patent based not on representations made during prosecution of that patent, but on representations made during prosecution of its sibling '491 patent.

During prosecution of the '491 patent, the Examiner initially rejected all pending claims as obvious over three prior art references.'491 patent File History, Examiner's First Office Action at 2 (mailed July 19, 1996). In response to the Examiner's rejection, the Applicant cancelled independent claim 23 and amended remaining independent claims 26 and 35. Id., Applicant's Resp. to First Office Action at 1-3 (filed Dec. 22, 1997). With respect to claim 35, which eventually issued as the only independent claim of the '491 patent, the Applicant added two limitations to the claimed method for cleaning parts: "accumulating the microorganisms and the hydrocarbons adjacent a fluid surface defined by the fluid in the tank[] and biodegrading the hydrocarbons proximate to the fluid surface." Id. at 2-3. These limitations appear in the claim as issued. See '491 patent, col. 8, ll. 41-45. In connection with the amendment, the Applicant argued in the "remarks" portion of the response as follows:

The method of cleaning hydrocarbons from a part in the parts washer, as recited in claims 35-41, as now amended, includes exposing the part to a fluid within the basin and providing a flowpath for the fluid between the basin and the tank, wherein microorganisms are disposed within the parts washer, and the improvement thereto comprises heating the fluid, accumulating microorganisms and the hydrocarbons adjacent a fluid surface defined by the fluid in the tank, and then biodegrading hydrocarbons proximate to the fluid surface.

Such an improved construction of a parts washing system and method for cleaning hydrocarbons from a part are not believed to be taught by the cited art of record.

* * * 8

In addition, even if the cited references were modified as stated by the Examiner, Applicant respectfully submits that such a combination still would not make the invention recited by the claims, as now amended, obvious. As recited in claims 23 9 and 35-41, as now amended, the fluid defines a surface in the tank and a substantial portion of the microorganisms and hydrocarbons washed from the part tend to accumulate proximate to the fluid surface so that a substantial amount of the biodegradation takes place proximate to the fluid surface. Such a feature is not taught by the cited references.

'491 patent File History, Applicant's Resp. to First Office Action at 8 (filed Dec. 22, 1997) (emphases added).

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8 In the portion omitted, the Applicant discusses in detail why the references cited by the Examiner do not render the claimed invention obvious.

9 It is unclear why the Applicant's first amendment refers to claim 23 since that document expressly cancels that claim and thus shows no amendment thereto. '491 patent File History, Applicant's Response to First Office Action at 1 (filed Dec. 22, 1997).

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J. Walter argues this amendment (and accompanying argument) "'unambiguously reflects' [the Applicant's] understanding of the invention in all the related -- and asserted -- patents." (Def.'s Opening Brief at 62.) This understanding, it asserts, "limits the scope of all the patents-in-suit to the same extent -- all the patents that claim bioremediation of the grease and oil washed from a part are restricted to an embodiment wherein a substantial amount of the biodegradation takes place proximate to the fluid surface." (Id. at 62-63.) For this proposition, J. Walter relies upon Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340 (Fed. Cir. 2004). As will be seen below, J. Walter's reliance on Microsoft is misplaced.

In Microsoft v. Multi-Tech Systems, Inc., Multi-Tech sued Net2Phone, Inc. for infringement of several patents related to computer-based systems and methods for simultaneously transmitting voice and/or data to a remote site. Microsoft, 357 F.3d at 1344. In response to Multi-Tech's lawsuit, Microsoft filed suit in the same court seeking a declaratory judgment of noninfringement, invalidity, and unenforceability of seven of Multi-Tech's patents. Id. Multi-Tech filed a counterclaim against Microsoft alleging infringement of five of its patents. Id. The dispute among the parties centered in large part over the construction of three terms: "sending," "transmitting," and "receiving" certain types of data. Microsoft and Net2Phone, the accused infringers, argued that the specification and prosecution history mandated that Multi-Tech's claims be limited to systems using point-to-point telephone lines. Id. at 1346. Multi-Tech argued that the claim language was broad enough to encompass communications over a packet-switched network, such as the Internet. Id.

The Federal Circuit agreed with Microsoft and Net2Phone that the "sending," "transmitting," and "receiving" limitations at issue should be "limited to communications over a telephone line and excluding the use of a packet-switched network." Id. The court first looked to the claims themselves and determined that the language used did not operate to limit the scope of the claims to point-to-point telephone lines because it was broad enough to encompass packet-switched networks. Id. at 1347. Nevertheless, the court concluded that "the specification shared by all three patents leads to the 'inescapable conclusion' that the communications between the local and remote sites of the claimed inventions must occur directly over a telephone line." Id. at 1348. The court's conclusion was based on several important facts. The court noted that the specification common to the three patents "repeatedly and consistently describes the local and remote systems of the claimed inventions as communicating directly over a telephone line." Id.; cf. id. ("[T]he specification refers to data transmission 'over' or 'through' a telephone line roughly two dozen times."). The court also found important that the portion of the specification delineating the "Summary of the Invention" discussed the invention in terms of a standard telephone line. Id. These "clear statements in the specification that the invention . . . is directed to communications 'over a standard telephone line'" led the Federal Circuit to conclude that the "sending," "transmitting," and "receiving" required the communications to occur over a telephone line and not a packet-switched network. Id. at 1347-48.

The Federal Circuit also concluded that placing the telephone line limitation on these claims was required by the prosecution history. During prosecution of one of the patents at issue in that case, in response to an office action rejecting the claims as obvious, the applicant gave a "summary of the invention," which included a representation that the communications system disclosed in the specification "operates over a standard telephone line." Id. at 1349. The court determined that this statement "makes clear that Multi- Tech viewed the local and remote sites of its inventions as communicating directly over a telephone line." Id. Importantly, the court also determined that this limiting statement was applicable to all patents which shared the common specification, even though those patents were not before the examiner when the statement was made, because the general statement directed to the "'communications system' disclosed '[i]n the [] specification' . . . was a representation of [the applicant's] understanding of the inventions disclosed in all three patents." Id. at 1349-50.

Defendant's reliance on Microsoft in this case is misplaced. Neither the common specification shared by the parts washing patents nor the prosecution history of any one of those patents support limiting all embodiments in all patents to biodegradation taking place at or near the fluid surface. As discussed above, the only reference in the specification to the biodegradation occurring at the fluid surface is the disclosure that "a large percentage of the microorganisms and the organic contaminants will tend to accumulate proximate to the surface of the cleaning fluid 72 such that a large portion of the biodegradation takes place proximate to the surface of the cleaning fluid 72." '110 patent, col. 6, l. 49 - col. 7, l. 3. This solitary generalization is a far cry from the "repeated[] and consistent[]" representations in the specification in Microsoft, including the statement in the "Summary of the Invention," which led the Federal Circuit to the "inescapable conclusion' that the communications . . . must occur directly over a telephone line." Id. at 1348.

Defendant J. Walter also relies upon the statement made by the Applicant in the prosecution history that "a substantial

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portion of the microorganisms and hydrocarbons washed from the part tend to accumulate proximate to the fluid surface so that a substantial amount of the biodegradation takes place proximate to the fluid surface. Such a feature is not taught by the cited references." This statement, devoid of context, is surely damning evidence that the invention being discussed must be limited to an embodiment where a substantial portion of biodegradation takes place at the fluid surface. J. Walter does not, however, acknowledge the context in which the statement was made. When the it made this argument to the Examiner, the Applicant specifically referred to the pending claims which explicitly recited those limitations. See '491 Patent File History, Applicant's Resp. to First Office Action at 8 (filed Dec. 22, 1997) ("As recited in claims . . . 35-41, as now amended . . ."). In essence, the Applicant merely recited the language of the claims and stated that the prior art did not teach such an arrangement. Thus, this is not the situation presented in Microsoft, where the statement made during prosecution broadly described the inventions in general as possessing a certain characteristic. Microsoft, 357 F.3d at 1349 ("That statement, which expressly related to the specification shared by all three patents and the communications system disclosed in all three patents, makes clear that Multi-Tech viewed the local and remote sites of its inventions as communicating directly over a telephone line."); cf. Ventana Med. Sys., Inc. v. BioGenex Labs., Inc., 473 F.3d 1173, 1184 (Fed. Cir. 2006) (noting that "[s]tatements made during the continued prosecution of a sibling application may 'inform the meaning of the claim language by demonstrating how the inventor understood the invention,'" but noting that the utility of such analysis is diminished when the claim language is different).

For these reasons, the Court declines to impose a limitation on these claims whereby biodegradation must occur at or near the top of the tank. The Court construes "allowing the microorganisms within the fluid to biodegrade the hydrocarbons" to mean "let or permit the microorganisms within the cleaning fluid to biodegrade the hydrocarbons." The Court construes "retaining the hydrocarbons within the fluid in the tank while the microorganisms biodegrade the hydrocarbons" to mean "the hydrocarbons remain in the cleaning fluid while the microorganisms biodegrade them."
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2. A substrate with an alloyed layer

The plaintiffs argue that "a substrate with an alloyed layer" should be construed to mean "an adjacent, underlying material which includes a layer that is a mixture of a metal and one or more different metals or non-metallic elements." The plaintiffs submit that their proposed construction is consistent with the specification and reflects the ordinary meanings of the terms "substrate" and "alloy." As mentioned above, "substrate" is defined as an "adjacent, underlying material." "Alloy" is defined as "a solid or liquid mixture of two or more metals, or of one or more metals with certain nonmetallic elements, as in carbon steels." Hawley's Condensed Chemical Dictionary (1993).

The defendant proposes that the disputed phrase be construed to mean "a physical mixture of carbon and an element of the substrate that bonds the nanophase diamond film to the substrate without chemically reacting carbon with an element of the substrate." The defendant contends that the alloyed layer is a mechanical bond, and not a chemical bond to the substrate as the plaintiffs suggest. The defendant further contends that the plaintiffs' proposed construction adds an intermediate layer between the nanophase diamond film and the substrate, which is not supported by the specification.

At issue here is whether the nanophase diamond film can be chemically bonded to "a substrate with an alloyed layer." The phrase "a substrate with an alloyed layer" is recited in dependent claim 2 of the '650 patent. Claim 2 provides that "said film is bonded to a substrate with an alloyed layer." '650 patent, col. 16, ll. 34-35. Claim 2 depends from claim 1, which provides that "said film is chemically bonded with a substrate." Id. at col. 16, ll. 32-33. "A dependent claim, by nature, incorporates all the limitations of the claim to which it refers." Jeneric/ Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377, 1383 (Fed. Cir. 2000) (citing 35 U.S.C. § 112, P 4 (1994)). Here, the defendant's proposed construction eliminates the limitation that the film be chemically bonded to the substrate.

The court is persuaded that the plaintiffs' proposed construction is correct. The language of claim 2 and the specification refer to a substrate that has an alloyed layer. '650 patent, col. 16, ll. 34-35; col. 16, ll. 1-3 ("substrate with an alloyed layer of a thickness between about 5 and 50 nm.") It appears from the specification that in cases where the nanophase diamond film cannot be bonded directly to the "ordinary" substrate, the film is bonded to a substrate that has an alloyed layer. See '650 patent, col. 15, l. 46 - col. 16, l. 3. As the plaintiffs underscore, the substrate referred to in claim 1 is any adjacent, underlying material, and the substrate of claim 2 is a substrate that includes an alloyed layer. Claim 2 only mentions that

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"said film is bonded to a substrate with an alloyed layer"; it does not refer to this bonding as chemical or mechanical. Because claim 2 depends from claim 1 and incorporates by reference the limitations of claim 1, claim 2 must be read to provide for chemical bonding of the film to the substrate with an alloyed layer. Accordingly, the court adopts the plaintiffs' construction of "a substrate with an alloyed layer" and construes this phrase accordingly.
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I. [beta] (1,3) glucan of altered carbohydrate structure

The term " [beta] (1,3) glucan of altered carbohydrate structure" appears in claims 1, 5, 11, 15, and 21 of the '542 Patent. Claim 1 provides an example of its use: "An underivatized, aqueous soluble yeast [beta] (1-3) glucan derived from glucan particles composed of [beta] (1-3) glucan of altered carbohydrate structure." Plaintiffs construe "altered" to mean that "the glucan structure has been modified or changed in a manner which endows the altered glucan with properties which are measurably different from those of naturally occurring, unmodified glucan." Immunocorp and Biotec offer this construction of " [beta] (1,3) glucan of altered carbohydrate structure":

Beta (1,3) glucan particles derived from glucan whose carbohydrate structure has been modified or changed artificially (genetically, enzymatically, or chemically) to alter the linkages in the glucan, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucan, so that the altered glucan particles have structural properties which differ from wild-type glucan.

The '542 Patent incorporates by reference U.S. Patent 5,028,703 ('703 Patent), and the parties agree that the '703 Patent defines "altered." The parties differ with respect to how the '703 Patent defines the term. Two passages from the '703 Patent's specification are particularly relevant. The first states:

The term "altered" as used herein and applied to the structure of the glucan (i.e., the [beta] (1-6) or [beta] (1-3) linkages) shall be construed to mean that the glucan structure has been modified or changed in some way, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucans.

'703 Patent, col. 2, l. 65 to col. 3, l. 3. The second is:

The whole glucan particles produced by the present process are altered with respect to whole glucan particles derived from wild type or unmodified, yeast cells. The term "altered" as used herein is meant to indicate whole glucan particles, the structure of which has been artificially changed or manipulated by one of the above techniques, so that the resulting whole glucan particles are different from the particles derived from wild-type yeast. In this process, the glucan-containing cells can be subject to manipulation (e.g., chemical or physical mutagenesis) or the extracted whole glucan particles can be treated to result in the altered whole glucan particles. "Altered" particles generally will have structural properties which differ from wild-type glucan, such as a different proportion of [beta] (1-6) or [beta] (1-3) linkages.

'703 Patent, col. 7, l. 56 to col. 8, l. 2. During the '542 Patent's prosecution, the applicant repeatedly referred to the first quote above to define "altered." Accordingly, the Court construes "altered" to mean that the glucan structure has been modified or changed in some way, endowing the altered glucan with properties which are measurably different from those of naturally occurring unmodified glucans.
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alum

The Court and the parties agree that the term should be construed as "another name for aluminum sulfate, as well as aluminum ammonium sulfate and aluminum potassium sulfate."
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II. MOTION FOR A MARKMAN DETERMINATION.

Plaintiff asks the Court to construe the term "aluminum" as set forth in Claims 1 and 2 of the '050 patent to mean "commercial grade aluminum." Defendants respond that plaintiff's definition is incomplete and that the Court should construe "aluminum" to mean "commercial grade aluminum from 0.010 inches to 0.015 inches in thickness."

A. Legal Standard.

Patent infringement analysis involves two steps: the proper construction of the asserted claim and a determination as to whether the accused method or product infringes the asserted claim as properly construed. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384, (1996). Interpretation and construction of patent claims is a matter of law for determination exclusively by the court. 52 F.3d at 979.

In interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). In examining the intrinsic evidence, the court should first look at the words of the claims themselves to define the scope of the patented invention. See id. While "words in a claim are generally given their ordinary and customary meaning," a patentee may alter the meaning of any words as long as the special definition is clearly stated in the patent specification or file history." Id.

Second, the court should always review the patent specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Id. The specification is a written description of the invention which is designed to be clear and complete enough so that a person of ordinary skill in the art could make and use the invention. Drawings included in the patent application have the same impact on and effect on claim language as other portions of the specifications. See Autogiro Co. of America v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 398 (Ct. Cl. 1967). "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582. The Federal Circuit teaches that "the specification is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Id.

In most cases, analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed term. "In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." Vitronics, 90 F.3d at 1583.

B. Claim Construction.

Here all parties agree that the Court need only review intrinsic evidence. All parties also agree that, at a minimum, "aluminum" means "commercial grade aluminum." The specification the '050 patent states that the laminated component "comprises substrate A of commercial grade aluminum." '050 patent, col. 4, lines 61-62. The specification goes on the state in the next sentence that "aluminum from about, 0.010 to 0.015 inches in thickness has been found to be satisfactory, although the aluminum may be from about 0.001 inches to 0.125 inches thick depending upon the end use." Id., lines 62-66. It states further that "the CAC component show in FIG. 5 includes a substrate layer of commercial grade aluminum A which is illustrate as from about 0.010 to about 0.015 inches in thickness. Id., col. 5, lines 49-52.

Defendants argue that the specification offers no explanation as to how one skilled in the art of how to practice the invention using the outside measurements of 0.001 inches to 0.125 inches thick, other than stating that thickness depends on "end use." Such vague language, defendants contend, violates the enablement requirements of 35 U.S.C. § 112 and therefore "aluminum" must be construed to mean "commercial grade aluminum from 0.010 inches to 0.015 inches in thickness."

Defendants cite no caselaw for the proposition that a claim must be limited to an inventor's preferred embodiment. Moreover, 35 U.S.C. § 112 paragraph one requires the specification to provide "a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a

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desired embodiment of the invention claimed." PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (quoting Ex Parte Jackson, 217 U.S.P.Q. (BNA) 804, 807 (1982)). The '050 specification does just that. "The fact that some experimentation [such as experimentation to determine the thickness of the sheet] is necessary does not preclude enablement; what is required is that the amount of experimentation must not be unduly extensive." Id. Defendants offer no evidence, and indeed do not argue, that any experimentation to determine the appropriate thickness depending on "end use" would be unduly extensive. Accordingly, the Court will adopt the construction of "aluminum" proposed by plaintiff.
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B. "Aluminum and Aluminum Oxide"

Claim 1 of the Ingrey patent claims "a process for gaseous etching of aluminum and aluminum oxide." Samsung contends the language "aluminum and aluminum oxide" must be construed to mean substantially pure aluminum together with the oxide that forms naturally upon it, not any aluminum-based alloy together with its aluminum oxide layer. Samsung manufactures semiconductors from alloys such as aluminum silicon or aluminum silicon copper.

Samsung submits evidence that persons ordinarily skilled in the art in the mid-1970s would understand aluminum to mean substantially pure aluminum. Cecchi Decl. PP 30-32. In support of its position, Samsung argues that etching of aluminum alloys poses different problems than those posed by the etching of pure aluminum. Specifically, etching aluminum alloys requires an additional step of removing a silicon or copper residue that is left on the chip surface after the aluminum is removed.

Northern Telecom submits evidence, contrary to that offered by Samsung, that a person ordinarily skilled in the art in the mid-1970s would understand aluminum and aluminum oxide to encompass aluminum alloys. See, e.g., Taylor Decl., Exs. 51 & 52. Thus, Northern Telecom argues that Samsung's manufacture of semiconductors from aluminum alloys such as aluminum silicon or aluminum silicon copper is included within the scope of the Ingrey patent.

1. Intrinsic Evidence

As Vitronics makes clear,.a court constructing a claim must rely primarily on "intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics, 90 F.3d at 1582. Of paramount importance are the words of the claim itself, which should generally be given their "ordinary and customary meaning." Id. Although "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning," he or she may do so only if "the special definition of the term is clearly stated in the patent specification or file history." Id.

Here, the Ingrey patent claims a process for the plasma etching of "aluminum and aluminum oxide." In the patent, aluminum and aluminum oxide are specified and they are referred to by their periodic table notations (i.e. Al and Al2 03) (subscript notation not available). No alloys are mentioned by name or by their compound periodic table notations. Neither the claim itself nor the specifications specially defines the meaning of either aluminum or aluminum oxide. In addition, the prosecution history of the Ingrey patent contains no information, such as representations by the patent applicant, that is helpful in determining whether "aluminum and aluminum oxide" should be read to include aluminum alloys.

Because terms in a claim are to be given their "ordinary and customary meaning," this court finds that aluminum alloys are not included within the scope of the Ingrey patent. Northern Telecom has offered no intrinsic evidence showing that aluminum alloys are encompassed within the terms "aluminum and aluminum oxide." Rather, Northern Telecom relies on extrinsic evidence such as the testimony of experts 14 to support its claim that "aluminum and aluminum oxide" should be construed to include aluminum alloys. However, as Vitronics makes clear, extrinsic evidence in general, and expert evidence in particular is to be used "only if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms. Such instances will rarely, if ever, occur." Vitronics, 90 F.3d at 1585. Thus, the court concludes that the term "aluminum and aluminum oxide" in the Ingrey patent refers solely to substantially pure aluminum and its native layer of aluminum oxide, and not to alloys such as aluminum silicon or aluminum silicon copper.

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14 Even were the court to find that the intrinsic evidence was insufficient to enable it to construct the disputed term, Northern Telecom would probably not be able to rely on expert testimony. Even in the "rare instances" where extrinsic evidence is necessary to construct a claim, expert testimony is frowned upon. Vitronics, 90 F.3d at 1585. Instead "prior art documents and dictionaries . . . are more objective and reliable guides. Unlike expert testimony, these sources are accessible to the public in advance of litigation," and "are to be preferred over opinion testimony." Id.

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III

Samsung cross appeals the district court's construction of claim 1 and grant of summary judgment of infringement in favor of Northern Telecom. In particular, Samsung challenges: (a) the district court's construction of "aluminum and aluminum oxide" to mean pure aluminum and its native oxide layer without further limitation; and (b) the district court's conclusion that "plasma etching," as claimed in the '967 patent, encompasses processes that combine chemical reactive etching and ion bombardment. We take these arguments in turn.

A

To the district court, Samsung asserted that "aluminum and aluminum oxide," in claim 1, means pure aluminum and aluminum oxide -- that is, not any other metals or alloys in combination with aluminum. See Northern Telecom, No. C-95-499, slip op. at 31. After analyzing the intrinsic evidence of record, the district court agreed with Samsung's construction and concluded that the '967 patent "refers solely to substantially pure aluminum and its native layer of aluminum oxide, and not to alloys such as aluminum silicon or aluminum silicon copper." Id., slip op. at 33. Nevertheless, the district court found that Samsung's process literally infringes the '967 patent because pure aluminum is indisputably present in the aluminum silicon alloy that is etched in that process. See id., slip op. at 34. That is, the district court concluded that there was no genuine dispute of fact that Samsung's process does indeed etch "aluminum and aluminum oxide" as claim 1 requires. See id. The court reasoned that the additional etching of the silicon and copper in the Samsung process was simply an additional step or aspect of the accused process and thus did not prevent a finding of literal infringement. See id.; see also e.g., A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703, 218 U.S.P.Q. (BNA) 965, 967 (Fed. Cir. 1983) ("It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device.").

On appeal, Samsung does not dispute that its accused process etches "aluminum" as defined by the district court: that is, aluminum -- in the aluminum silicon or aluminum silicon copper alloys -- is etched by the Samsung process. Instead, Samsung presents to this court yet another interpretation of the "aluminum and aluminum oxide" limitation of claim 1. Specifically, Samsung now asserts that the aluminum must be arranged in a "layer" to meet the requirements of the "aluminum and aluminum oxide" limitation, notwithstanding that the term "layer" does not appear anywhere in the text of claim 1.

We note at the outset that we look with "extreme disfavor" on appeals that allege error in claim constructions that were advocated below by the very party now challenging them. Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 714-15, 48 U.S.P.Q.2D (BNA) 1911, 1915 (Fed. Cir. 1998). In this case, because we find little merit to its arguments on this point, we need not address whether Samsung is judicially estopped from challenging its own claim construction adopted by the trial court. See, e.g., Yniguez v. Arizona, 939 F.2d 727, 738 (9th Cir. 1991) (judicial estoppel "prevents a party from changing its position over the course of judicial proceedings when such positional changes have an adverse impact on the judicial process.").

1

Samsung's first argument is that the district court's construction of "aluminum" -- as pure elemental aluminum -- would work (in its view) the "absurd" result that claim 1 could cover processes where even very small (i.e., "trace") amounts of

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pure aluminum were etched. In essence, Samsung appears to suggest that the additional "layer" limitation must be read into the claim to ensure that only larger (i.e., non-"trace") quantities of etched aluminum are covered by the '967 patent. We reject this contention. Not only is the term "layer" not found in claim 1, but neither is a limitation that establishes a minimum quantity of aluminum that must be etched to meet the claim. This court has repeatedly and clearly held that it will not read unstated limitations into claim language. See, e.g., Renishaw P.L.C. v. Marposs Societa per Azioni, 158 F.3d 1243, 1248, 48 U.S.P.Q.2D (BNA) 1117, 1120 (Fed. Cir. 1998); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1576 (Fed. Cir. 1996); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-90, 34 U.S.P.Q.2D (BNA) 1321, 1329-30 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S.370, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). In any event, we fail to see how Samsung's suggestion would resolve what it views as an "absurd" result: the addition of a "layer" requirement would only mandate that the aluminum (in whatever quantity) be disposed in a roughly planar fashion. Thus, very small amounts of aluminum ("trace"), if etched, would appear to meet even Samsung's proposed definition, thus perpetuating the result that Samsung finds "nonsensical". The limitation "aluminum" stands unmodified in claim 1; merely characterizing the claim language as "absurd", without more, does not convince us that "aluminum" must be read to incorporate a "layer" limitation. See, e.g., Johnson Worldwide Assoc., Inc. v. Zebco, Corp., 175 F.3d 985, 989, 50 U.S.P.Q.2D (BNA) 1607, 1610 (Fed. Cir. 1999) (canons of claim construction require that "general descriptive terms will ordinarily be given their full meaning; modifiers will not be added to broad terms standing alone."); Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 865-66, 45 U.S.P.Q.2D (BNA) 1225, 1229 (Fed. Cir. 1997); Bell Communications Research, Inc., v. Vitalink Communications Corp., 55 F.3d 615, 621-22, 34 U.S.P.Q.2D (BNA) 1816, 1821 (Fed. Cir. 1995).

2

Samsung's second argument is that the term "layer" must be read into the "aluminum" limitation of claim 1 because the written description of the '967 patent describes embodiments of the invention with references to "layers" of aluminum or "lines" of aluminum. See, e.g., '967 Patent, col. 1, ll. 55-60, col. 1, ll. 64-65, col. 3, l. 8. This we cannot do. In order to overcome the presumption that the meaning of the claim term "aluminum" is other than its plain and ordinary meaning -- what the district court described as "pure" or elemental aluminum -- Samsung must demonstrate either that (1) the patentee provided an alternate definition of "aluminum" in the intrinsic evidence; or (2) that the ordinary meaning of "aluminum" deprives the claim of clarity. See Johnson Worldwide, 175 F.3d at 990, 50 U.S.P.Q.2D (BNA) at 1610. Samsung does not argue that the ordinary meaning of "aluminum" is unclear; instead, Samsung appears to suggest that the several references to aluminum "layers" or "lines" in the written description provide a special definition of "aluminum" -- i.e., that, in the context of claim 1, "aluminum" means only "aluminum layers" or "aluminum lines". Yet, a review of the written description undermines Samsung's arguments: throughout the '967 patent, aluminum is referenced both in terms of its elemental variety (by its symbol Al) and as a "layer". Compare, e.g., '967 Patent, col. 1, ll. 46, col. 1, ll. 67, col. 3, l. 8, col. 3, l. 9, col. 3, l. 16, col. 3 (referring to aluminum as "Al"), with '967 Patent, col. 1, ll. 55-56, col. 1, l. 61, col. 1, ll. 64-65, col. 3, l. 27 (aluminum as "aluminum layer"). As we held in Johnson Worldwide, the "varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition." 175 F.3d at 991, 50 U.S.P.Q.2D (BNA) at 1611 (reference to "heading" as both direction of boat and as direction of motor supports view of "heading" as encompassing both definitions); see also Enercon GmbH v. International Trade Comm'n, 151 F.3d 1376, 1385, 47 U.S.P.Q.2D (BNA) 1725, 1731-31 (Fed. Cir. 1998) (refusing to limit a word used "interchangeably" in the written description to only one of the uses of the term). Thus, Samsung's argument based on the written description fails.

3

Samsung's final argument on this point is that the district court's construction of "aluminum" as "pure" aluminum renders the "aluminum oxide" limitation superfluous. That is, Samsung suggests that because aluminum oxide also includes "aluminum" as defined by the district court, the district court has effectively negated the "aluminum oxide" limitation. Samsung's argument is misplaced. The "aluminum oxide" limitation is an additional limitation in claim 1. That is, to infringe claim 1, both aluminum and aluminum oxide must be etched. Or, to state it differently, both elemental aluminum and the molecular combination of aluminum and oxygen must be etched. Any accused process that fails to etch either aluminum or the molecular combination of aluminum and oxygen (i.e., "aluminum oxide") will not infringe. For example, a process that etches only aluminum silicon alloy will not, of course, etch aluminum oxide. Thus, the district court's definition of aluminum does nothing to render the "aluminum oxide" limitation as other than a limit on the scope of claim 1.

Accordingly, we hold that the district court's construction of "aluminum and aluminum oxide" in claim 1 was correct.

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aluminum chloride

The Court and the parties agree that the term should be construed as "AlCl[3]; aluminum chloride is normally provided in either a dry form or in an aqueous solution. In its dry form it is often referred to in a hydrated form, such as AlCl[3] 6H[2]O."

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aluminum polymer

The parties and the Court agree that the term should be construed as "a polynucleate aluminum compound, such as polyaluminum hydroxychloride, polyaluminum chloride and polyaluminum silicate sulfate (PASS), or the like."

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aluminum salt

The Court and the parties agree that the term should be construed as "a compound formed when the hydrogen of an acid is replaced by aluminum."

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aluminum sulfate

The Court and the parties agree that the term should be construed as "Al[2](SO[4])[3]; aluminum sulfate is normally provided in either a dry form or in an aqueous solution. In its dry form it is often referred to in a hydrated form, such as (Al[2]SO[4])3 (18H[2]0) or (Al[2](SO[4])[3] 14H[2]O)."

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E. "Alzheimer's disease"

Plaintiffs propose that "Alzheimer's disease" be construed as "dementia of the Alzheimer's type, as characterized by the diagnostic criteria set forth in the Diagnostic and Statistical Manual of Mental Disorders." Defendants' proposed construction is: "A progressive, neurodegenerative illness that gradually destroys a person's memory and overall cognitive ability, characterized by the presence of neurofibrillary tangles in brain cells and plaques deposited in brain tissue (also known as senile dementia of the Alzheimer's type)." Both sides agree that "Alzheimer's disease" should be construed according to its plain and ordinary meaning to one having ordinary skill in the art at the time the original patent was granted. (D.I. 223 at 3, 21 (Plaintiffs); D.I. 236 at 24-25 (Defendants))

Although the words proposed by each side differ a great deal, their proposed constructions have much in common. Two substantive points are in dispute. The first concerns whether the claim should be construed to include a reference to the "plaques and tangles" that are found in the brain of one who suffers from Alzheimer's disease. The primary way to identify such plaques and tangles in an individual's brain is through dissection, which can only be done after an individual is

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deceased. Since, obviously, this is not done to live patients -- to whom the patent is directed -- Plaintiffs insist there is no need to reference plaques and tangles in construing "Alzheimer's disease." Defendants disagree.

The record establishes that at the time the '703 patent was issued, in 1989, it was known that, post-mortem, the brain of an individual having Alzheimer's disease would contain plaques and tangles. Defendants cite to two articles demonstrating this point. See JA Ex. C11 at C68 (1988 article in Medicinal Research Reviews stating, "Postmortem microscopic examination of brain tissue [of individual who died of Alzheimer's disease] revealed high densities of lesions currently described as neuritic plaques and neurofibrillary tangles."); JA Ex. C12 at C105 (1984 article in Neurology stating, "The pathologic characteristics [of Alzheimer's disease] are degeneration of specific nerve cells, presence of neuritic plaques, and neurofibrillary tangles."). In connection with the reexamination, the patentees submitted a declaration of Myron Weiner, M.D., who confirmed: "It is now known that Alzheimer's disease is characterized by the presence of neurofibrillary tangles in brain cells and amyloid plaques deposited in brain tissue." (JA978) Dr. Weiner was writing in 2005, and he does not indicate when this knowledge first arose, but neither does he in any way contradict the extrinsic evidence cited by Defendants indicating it was known by 1989. Therefore, I conclude that one having ordinary skill in the art in 1989 would have understood that the plain and ordinary meaning of Alzheimer's disease included the fact that, upon dissection, the brain of one having Alzheimer's disease would be found to contain plaques and tangles.

The parties' second dispute concerns whether, among the accepted diagnostic criteria for diagnosing Alzheimer's disease in 1989, the criteria listed in the Diagnostic and Statistical Manual of Mental Disorders ("DSM") was accorded special prominence. (The then-current version of the DSM was the revised third edition, which will be referred to as "DSM-III-R.") I am persuaded that the DSM did have such a role. Plaintiffs' expert, Steven H. Ferris, Ph.D., declares: "In general, the DSM is relied upon by medical and mental health professionals . . . to arrive at a standardized diagnosis for various mental disorders. . . . The DSM is considered by healthcare professionals to be the 'dominant' reference for clinical diagnostic criteria for dementia, including dementia of the Alzheimer's type." (D.I. 224 at PP 15-16) Defendants agree that the DSM "was one of the resources used in 1989 to diagnose Alzheimer's disease in patients." (D.I. 236 at 26)

Nonetheless, it is also clear that the DSM is not the only source one having ordinary skill in the art would have turned to in 1989 in determining the accepted diagnostic criteria for Alzheimer's disease. As Plaintiffs' Dr. Ferris acknowledges, "[t]he diagnostic criteria in DSM-III-R are also consistent with other well-recognized diagnostic criteria for dementia of the Alzheimer's type." (D.I. 224 at P 18) He notes in particular the 1984 NINCDS-ADRDA Work Group, which promulgated clinical diagnostic criteria that "were compatible with the clinical diagnostic criteria in the DSM." (D.I. 224 at P 20)

Thus, I recommend that "Alzheimer's disease" be construed as: "dementia of the Alzheimer's type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R, and further characterized by the presence of neuritic plaques and neurofibrillary tangles in the brain."
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Claim 21, the only independent claim at issue, reads as follows:

21. A process for the production of an open-cell polyurethane foam with varying degrees of post expansion comprising:

(a) mixing in a mixing zone the following components at ambient temperatures;

(i) a diisocyanate having a functionality of about 2.0 to about 2.7,

(ii) at least one hydrogen donor having a functionality of about 2 to about 4 and which is at least one polyol having a molecular weight of about 2000 to about 6500,

(iii) at least one surfactant which is effective in forming an open-cell polyurethane foam,

(iv) at least one catalyst,

(v) a blowing agent comprising a gas having a boiling point below approximately -100 degrees F. at atmospheric

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pressure, and

(vi) water, the mixture being subjected to a pressure in said mixing zone which is sufficient to maintain said blowing agent in the liquid state at ambient temperatures;

(b) ejecting said mixture from said mixing zone to atmospheric pressure, and

(c) curing the resultant foam at ambient temperatures.

Id. at col. 8, l. 66 to col. 9, l. 27 (emphasis added). Claim 1, the only other independent claim, is similar to claim 21 except that claim 1 does not include water as a component of the foam mixture and states that the ejection step "completely and instantaneously vaporizes said blowing agent to provide substantially total expansion of said mixture." Id. at col. 7, l. 45 to col. 8, l. 3.

Crain utilizes the CarDio TM process to produce open-cell polyurethane foam by mixing together a number of components, including water, at specific temperatures and pressures. Doyle II at 2. However, the CarDio TM process employs a "Froth Laydown Device," which gradually lowers the pressure of the mixture to atmospheric pressure in a "carefully controlled manner" in an attempt to improve foam quality. Id. at 3.

Doyle sued Crain, alleging that Crain's CarDio TM process infringed claim 21 of the '770 patent. Id. at 1-2. After conducting a Markman hearing, the district court interpreted the language "a pressure in said mixing zone which is sufficient to maintain said blowing agent in the liquid state at ambient temperatures" (what the parties refer to as "the pressure limitation") to mean the pressure required to keep the blowing agent in liquid form "at ambient temperatures," which the court defined as "about 70 degrees F to about 100 degrees F" based on the definition given in the specification. Doyle v. Crain Indus., No. H-97-3468, slip op. at 4, 6 (S.D. Tex. July 30, 1999) (Doyle I). Based on this claim construction, the court held that dependent claim 22 was invalid as inoperable because three of the six blowing agents listed could not be used in the patented process. Id. at 6. The court also construed the language "ejecting said mixture from said mixing zone to atmospheric pressure" (what the parties refer to as "the ejection limitation") to require an immediate drop in the pressure in the mixing zone to atmospheric pressure (i.e., a "direct" ejection). Id. at 9. Thereafter, Crain filed a motion for summary judgment that the CarDio TM process does not infringe the claims of the '770 patent. Doyle II at 2. Doyle cross-moved for summary judgment of infringement. Id. The district court granted Crain's motion for summary judgment and denied Doyle's corresponding cross-motion. Id. at 6.

Doyle appeals the district court's infringement rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

B. Standards of Review

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). We review a district court's grant of a motion for summary judgment de novo. Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 149 F.3d 1309, 1315, 47 U.S.P.Q.2D (BNA) 1272, 1275 (Fed. Cir. 1998). "In reviewing a denial of a motion for summary judgment, we give considerable deference to the trial court, and will not disturb the trial court's denial of summary judgment unless we find that the court has indeed abused its discretion." Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1306, 54 U.S.P.Q.2D (BNA) 1910, 1912 (Fed. Cir. 2000).

When reviewing cross-motions for summary judgment, the court must evaluate each motion on its own merits, resolving all reasonable inferences against the party whose motion is under consideration. McKay v. United States, 199 F.3d 1376, 1380 (Fed. Cir. 1999). "If there are no material facts in dispute precluding summary judgment, our task is to determine whether the judgment granted is correct as a matter of law." Elekta, 214 F.3d at 1306, 54 U.S.P.Q.2D (BNA) at 1912.

Claim construction is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71, 34 U.S.P.Q.2D (BNA) 1321, 1322 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), that we review de novo, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1172 (Fed. Cir. 1998) (en banc).

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Whether a claim is invalid is a question of law that we review de novo. Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1359, 52 U.S.P.Q.2D (BNA) 1029, 1035 (Fed. Cir. 1999).

C. Claim Construction

1. The Pressure Limitation

Doyle argues that the district court erred in construing the pressure limitation to mean the pressure required to keep the blowing agent in liquid form "at ambient temperatures." Doyle first contends that the court erred in defining "ambient temperatures" as the range of "about 70 degrees F to about 100 degrees F" because it improperly used a numerical range from the specification to define a limitation that is claimed in general descriptive terms. Doyle also argues that "ambient temperatures" refers to the temperature of the mixing zone, not the blowing agent, because the common scientific definition of "ambient temperature" makes clear that it refers to the temperature of an environment. Doyle further argues that the court's interpretation of the pressure limitation is improper because it makes it impossible to use two-thirds of the blowing agents recited in dependent claim 22.

Crain responds that the specification's definition of "ambient temperatures" is controlling because "i.e." was inserted instead of "e.g." prior to the numerical range. Crain also argues that "ambient temperatures" must modify "blowing agent" because it would be superfluous to apply it to "mixing zone" in light of the fact that the identical phrase modifies "mixing zone" earlier in the same sentence.

In interpreting claims, a court "should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 39 U.S.P.Q.2D (BNA) 1573, 1577 (Fed. Cir. 1996). When the meaning of a term used in a claim is sufficiently clear from its definition in the patent specification, that meaning shall apply. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477, 45 U.S.P.Q.2D (BNA) 1429, 1432 (Fed. Cir. 1998); Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388, 21 U.S.P.Q.2D (BNA) 1383, 1387 (Fed. Cir. 1992).

As an initial matter, we do not agree with Doyle's assertion that the district court erred in construing the meaning of "ambient temperatures." The specification explicitly defines "ambient temperature" to be "about 70 degrees F to about 100 degrees F," and that definition is controlling. Multiform at 1477, 45 U.S.P.Q.2D (BNA) at 1432. No other candidate temperature range appears in the patent. Furthermore, the use of "i.e.," as opposed to "e.g.," demonstrates that the patentee did not intend this numerical range to be merely exemplary of "ambient temperatures." Therefore, the district court's construction is required by the definition of "ambient temperature" given in the specification.

However, the district court erred when it interpreted "ambient temperatures" to modify "blowing agent" rather than "mixing zone." "Ambient temperature" is commonly understood to refer to the temperature of the environment. E.g., Hawley's Condensed Chemical Dictionary 50 (12th ed. 1993) (defining "ambient temperature" as "the temperature of the environment in which an experiment is conducted or in which any physical or chemical event occurs") (emphasis added). The patent has not set forth any special definition of "ambient temperature" that would lead one to conclude that a different meaning was intended. Indeed, nowhere does the specification use the phrase "ambient temperatures" to refer to the temperature of any compound.

Moreover, we agree with Doyle that the district court's interpretation renders it impossible to use some of the blowing agents listed in dependent claim 22. 1 That fact makes the court's interpretation untenable. An independent claim must not be interpreted in a manner inconsistent with a claim that depends from it. Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1445, 43 U.S.P.Q.2D (BNA) 1837, 1841 (Fed. Cir. 1997).

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1 We note that Doyle refers to a chemical compound not found in claim 22 in its claim construction argument. While "tetrafluoromethane," with a critical temperature of -50.0 degrees F (227.6K), falls far outside the range of "about 70 degrees F to about 100 degrees F," the use of that compound was not claimed. CRC Handbook of Chemistry and Physics 6-50 (80th ed. 1999). Tetrafluoroethylene, the compound whose use is actually claimed, has a critical temperature of 92.0 degrees F (306.5K), which clearly falls within that temperature range. Id. at 6-51. Furthermore, hexafluoroethane (cf.

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"hexafluoromethane," the compound referred to by Doyle) has a critical temperature of 67.5 degrees F (293K), which arguably lies close to the prescribed temperature range. Id. Therefore, although we agree with Doyle that the district court's interpretation of the pressure limitation is inconsistent with claim 22, we emphasize that we do so in light of the critical temperatures of helium and nitrogen, not those of "tetrafluoromethane" and "hexafluoromethane" mentioned by Doyle.

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The critical temperature of a gas is the temperature above which a gas cannot be liquefied, no matter how much pressure is applied. Hawley's Condensed Chemical Dictionary 324 (12th ed. 1993). Helium and nitrogen are among the gases recited in claim 22. As the critical temperature of helium is -450.3 degrees F (5.2K), and that for nitrogen is -232.5 degrees F (126.2K), neither can be maintained in liquid form at temperatures anywhere near "about 70 degrees F." CRC Handbook of Chemistry and Physics 6-50 (80th ed. 1999). The pressure limitation of claim 21 therefore cannot be interpreted in such a manner that dependent claim 22 does not meet its limitations.

Crain's argument that it would be superfluous to interpret "ambient temperatures" to modify "mixing zone" is not persuasive. There is no hard and fast rule against the double inclusion of claim language. As our predecessor court stated in In re Kelley, "Automatic reliance upon a 'rule against double inclusion' will lead to as many unreasonable interpretations as will automatic reliance upon a 'rule allowing double inclusion.' The governing consideration is not double inclusion, but rather is what is a reasonable construction of the language of the claims." In re Kelley, 49 C.C.P.A. 1359, 305 F.2d 909, 916, 134 U.S.P.Q. (BNA) 397, 402 (CCPA 1962). As explained above, any interpretation that requires "ambient temperatures" to refer to the temperature of the blowing agent is unreasonable. We therefore conclude that "ambient temperatures" refers to the temperature of the mixing zone.
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The major thrust of the defendants' motion is that Kumar was forced to cede certain claims he made during his patent prosecution for what eventually became the 686 patent, and that the products that the defendants produce and license fall within the ceded areas. 2 Therefore, the defendants conclude that they cannot be infringing Kumar's 686 patent because it does not cover their products. Their related argument is that under Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 152 L. Ed. 2d 944, 122 S. Ct. 1831 (2002), Kumar should be barred from asserting that they infringe under the doctrine of equivalents.

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2 The defendants also argue that they are not liable for infringement, contributory infringement, or inducing others to infringe because they do not meet the statutory requirements set out in 35 U.S.C. § 271, which requires an infringer to "make[], use[], offer[] to sell, or sell[] any patented invention" to be liable. There are disputes of material facts on this issue, to wit, whether the defendants have actively induced others to make infringing batteries and whether the defendants are contributorily infringing. Accordingly, summary judgment is not granted on the basis of this argument.

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Kumar denies that he gave up the subject matter as to which the defendants are licensing products. He also asserts that the patents that the defendants obtained for their inventions were acquired by omitting reference to his earlier 686 patent, and are therefore invalid.

As indicated above, the heart of the debate is as to exactly what Kumar surrendered during his patent prosecution. Again, at issue here are metal alloys that have useful properties for making batteries in varying degrees: each metal alloy has more or less of these properties as compared to others. There are two competing descriptions of these metal alloys, which require explanation.

First, one can describe metal alloys using a continuum of words which denote how orderly the molecules comprising them are aligned. On one side of the continuum are metal alloys whose molecules have no order, and are therefore called "completely amorphous." Far to the other side are metal alloys whose molecules are structured so well that they are

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described as "crystalline." Between the extremes are designations that denote varying levels of orderliness: "partially crystalline" and "metastable crystalline" reflect metal alloys whose molecules are more ordered than "completely amorphous" and less ordered than "crystalline." Within this spectrum are a subset of metal alloys called "nonequilibrium alloys," which comprises "amorphous," "partially crystalline," and "metastable crystalline" alloys. It is these "nonequilibrium alloys" that are in dispute in this case.

The defendants argue that Kumar, who from the outset sought only to patent "nonequilibrium alloys," surrendered "partially crystalline" and "metastable crystalline" alloys to obtain the 686 patent, leaving him with the right to patent only "amorphous" alloys. Since the defendants exclusively produce or license batteries with "metastable crystalline" metal alloys, they assert that they do not and cannot infringe the 686 patent.

Kumar disagrees with the above analysis. He argues that his patent was a "pioneering" patent, which means that the language being used at the time he patented his invention was less clearly defined than it is today. In fact, Kumar contends what he patented is what the defendants patented and are producing and licensing. He asserts that at the time he patented his invention, the term "amorphous" referred to the size of the ordered regions in the metal alloys. That is, a metal alloy has pockets of ordered molecules which are in varying sizes. As the sizes get larger, the alloy is increasingly ordered and therefore more "crystalline." Kumar argues that he claimed everything that was less than "long range order," which has since been defined to be regions of ordered molecules with sizes greater than 100 nanometers. The defendants, Kumar alleges, have patented, produced, and licensed metal alloys with ordered regions far below 100 nanometers in size, and therefore, Kumar concludes that the defendants are infringing the 686 patent.

I find the defendants' version of what Kumar surrendered during the patent prosecution the more persuasive description, and accordingly, summary judgment is granted for the defendants on the infringement count. Construing claims is a question of law for the Court's decision. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 388-90, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). I find that the meaning of the word "amorphous" in claims 1 and 6 of the 686 patent is reasonably construed to mean "completely amorphous," and therefore excludes "partially crystalline" and "metastable crystalline" metal alloys. Accordingly, as the defendants do not produce or license "amorphous" metal alloys, they do not infringe.

I find that the meaning of the word "amorphous" in claims 1 and 6 of the 686 patent means "completely amorphous" based on the 686 patent specification, which sheds light on the meaning of the otherwise undefined term. In the specification, the term "amorphous" is repeatedly used as an opposition to "metastable crystalline," implying they do not overlap. See, e.g., "686 patent, col. 1, 11. 62-63; col. 2, 11. 16-24; and col. 3, 11. 42-43. Similarly, the term "partially crystalline" is differentiated from "completely amorphous" and "metastable crystalline." See, e.g., 686 patent, col. 2, 11. 16-24; and col. 4, 11. 33-35. So understood, the only meaning of "amorphous" consonant with its use in the 686 patent claims is "completely amorphous."

Kumar's nanometer-defined construction is unconvincing because it employs a description of "long range order" (greater than 100 nanometers) developed after his patent was filed, and therefore cannot be taken to describe accurately what he sought to patent. Moreover, it is clear from the prosecution history that the patent examiner at the Patent and Trademark Office was vigorous and vigilant in disallowing -- four times -- Kumar's attempts to include "partially crystalline" and "metastable crystalline" metal alloys. Had Kumar sought to define his patent's scope by using other language, he could have. Kumar chose not to describe the metal alloys by reference to the size in nanometers of ordered regions within them, and cannot now have the benefit of that measuring technique. Simply put, because Kumar elected to exclude from his patent's claims everything but "amorphous" metal alloys, he is not entitled to claim more than that. 3

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3 Similarly, resort to the doctrine of equivalents fails under Festo, 535 U.S. 722, 122 S. Ct. at 1842, which held that "the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question" because the "patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." Kumar has not met his burden here, where it is clear that Kumar made narrowing amendments to get his patent approved, and the narrowing amendments clearly concerned the subject matter area that Kumar now seeks to cover.

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I.

We review the district court's grant of summary judgment without deference. Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1377 (Fed. Cir. 2002) ("Inverness II").

The central question here is one of claim construction, specifically the meaning of the term "amorphous" in claims 1 and 6 of the '686 patent. Claim construction is a question of law that this court reviews without deference. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Under our precedent in Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201-02 (Fed. Cir. 2002), and Inverness II, 309 F.3d at 1378, we look first to the dictionary definition of a contested term. Ovonic urges that the correct definition appears in Webster's Third New International Dictionary, defining amorphous as "without real or apparent crystalline form: uncrystallized." Webster's Third New International Dictionary 72 (1981). Ovonic argues that this definition means that amorphous alloys must be completely lacking in crystalline structure. Kumar, on the other hand, points out that the '686 patent referenced the Polk patent, U.S. Patent No. 4,116,682 (issued Sept. 26, 1978) (the "Polk patent"), as prior art; that the Polk patent was extensively discussed and distinguished during prosecution; and that the Polk patent specifically defined a "solid amorphous metal" as one "in which the constituent atoms are arranged in a spatial pattern that exhibits no long range order, that is, it is non-crystalline . . . . In distinguishing an amorphous substance from a crystalline substance, X-ray diffraction measurements are generally employed." Polk patent, col. 1, ll. 13-27 (emphasis added).

Our cases have recognized that although the dictionary can be an important tool in claim construction by providing a starting point for determining the ordinary meaning of a term to a person of skill in the art, "the intrinsic record" can resolve ambiguity in claim language or, where clear, trump an inconsistent dictionary definition. Tex. Digital, 308 F.3d at 1204; see Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1371-72 (Fed. Cir. 2002) ("Inverness I").

Our cases also establish that prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence. Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1371-72 n.4 (Fed. Cir. 2002); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); Markman, 52 F.3d at 979-80. For example, in Arthur A. Collins, Inc. v. Northern Telecom Ltd., 216 F.3d 1042 (Fed. Cir. 2000), we rejected the district court's claim construction, which "declined to consider the teachings of [prior art referenced in the patent] to ascertain the meaning" of the claim term "time-space-time (TST) switch." Id. at 1044. Instead, we interpreted the term based on its usage in the prior art that was cited in the patent, explaining that "when prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning." Id. at 1045.

In the present case, the Polk patent is not simply cited in the '686 patent as pertinent prior art; nor is there any showing that the Polk patent adopted a special definition at variance with that prevailing in the art. Rather the Polk patent was considered by both the applicant and the examiner to be highly pertinent prior art, and there is no indication that the Polk patent's express definition (even if inconsistent with the general dictionary definition) was in any way at variance with the definition that would have been used by those skilled in the art at the time. Indeed, as noted below, Ovonic's own '440 patent, though issued some few years after the issuance of the Kumar patent, uses the same definition, thus at least suggesting that the "long range order" definition was not unique to the Polk patent.

Under these circumstances, we conclude that the Polk patent definition is to be preferred over the general dictionary definition relied upon by Ovonic. This Polk patent definition should control unless the specification clearly states an alternative meaning or this meaning was disclaimed during prosecution. See Inverness I, 309 F.3d at 1371-72. Here, the specification and prosecution history do not require a different interpretation than the Polk patent's definition of an amorphous alloy, namely one "in which the constituent atoms are arranged in a spatial pattern that exhibits no long range order . . . ." Polk patent, col. 1, ll. 13-15.

II.

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Although it is firmly settled that an applicant may act as a lexicographer in the specification, Markman, 52 F.3d at 980, the specification cannot support a definition that is contrary to the ordinary meaning of a claim term unless it communicates a deliberate and clear preference for this alternative definition. Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 21 n.5 (Fed. Cir. 2000) (citing Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998), for the proposition that in order to act as one's own lexicographer in the specification, "a patentee must deliberately and clearly point out how these terms differ from the conventional understanding"). Ovonic argues that the '686 specification requires that the term "amorphous" be interpreted to mean "completely" amorphous, contrary to the Polk patent definition. In support of this construction, Ovonic contends that the '686 specification defines the terms "amorphous" and "completely amorphous" in the same way, as having a "random atomic" structure. Ovonic cites the following passages from the '686 patent in support of this argument:

The transformation to the low temperature crystalline phase is suppressed to produce either a completely amorphous, solid state, rare earth-transition metal material characterized by the random atomic structure . . . .

'686 patent, col. 2, ll. 19-22 (emphases added).

Recent investigations of rare earth-metal alloys has led to the discovery that the production of the alloy in its amorphous state, characterized by random atomic orientation, as opposed to the regular lattice structure of the crystalline state, produces a material capable of absorbing substantially larger quantities of hydrogen without any tendency to fracture . . . .

Id., col. 3, II. 5-12 (emphases added).

The difficulties with this argument are several. First, our precedent teaches that qualifications such as "completely" or "normally" are to be given significance in interpreting the specification. See E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369 (Fed. Cir. 2003). Second, there is no indication in these passages or anywhere else in the specification that the term "completely amorphous" was used synonymously with the term "amorphous." The fact that the '686 patent refers to the "random atomic" structure or orientation of both amorphous and completely amorphous alloys does not indicate that the patent defines the terms interchangeably. The terms "random atomic structure" or "random atomic orientation" can themselves mean completely random or partially random.

Third, in the very same portion of the specification where amorphous is defined by reference to "random atomic" structure, the term "amorphous" is not used to distinguish material that is partially crystalline but rather material that is fully crystalline, i.e., material characterized by "the regular lattice structure of the crystalline state," and thus has a tendency to fracture. 1

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1 The specification refers to "the production of the alloy in an amorphous state . . . as opposed to the regular lattice structure or the crystalline state, [that] produces a material capable of absorbing substantially larger quantities of hydrogen without any tendency to fracture over repeated absorption/desorption cycles." '686 patent, col. 3, ll. 7-13 (emphases added).

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Fourth, significantly, the specification distinguishes between "totally amorphous" material, which is cooled at "the more rapid rate" approaching 108 degrees centigrade per second, and "amorphous" material, which is cooled over the much broader range of 106 to 108 degrees centigrade per second. '686 patent, col. 3, ll. 17-27; col. 4, ll. 30-35. This plainly suggests that "amorphous" and "totally amorphous" are not the same.

Finally, only "totally" or "completely" amorphous material is distinguished from partially crystalline material. The following excerpts from the '686 specification illustrate this point:

The transformation to the low temperature crystalline phase is suppressed to produce either a completely amorphous, solid state, rare earth-transition metal material . . . or to a partially crystallized or metastable crystalline state depending upon the specific cooling rate utilized.

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Id., col. 2, ll. 16-24 (emphases added).

The more rapid rate produces a totally amorphous state material from complete suppression of the transformation to the low temperature crystalline phase. A partially crystallized or metastable crystalline state in which some crystalline forms, occurs from a less rapid cooling . . . .

Id., col. 4, ll. 30-35 (emphases added).

Because the specification does not clearly and deliberately define the term "amorphous" as completely amorphous, it does not support a construction of the term contrary to its plain meaning as established in the Polk patent.

Nor is the term "amorphous" meaningfully defined in the specification by reference to its "random atomic structure." Id., col. 2, ll. 19-22. The term "random atomic structure" is itself undefined in the specification, which provides no guidance as to its definition beyond contrasting it with the "regular lattice structure of the crystalline state." Id., col. 3, ll. 7-10. As such, amorphous alloys with a "random atomic structure" (1) may encompass a broad range of alloys, except those that are fully crystalline, or alternatively (2) may encompass only those with a fully random structure. The specification provides no guidance as to which of these definitions or even some third definition is intended.
III.

Finally, we turn to the prosecution history. The relevant claims of Kumar's original patent application read as follows:

1. In a system for retrievably storing hydrogen, a material for the retrievable storage of hydrogen comprising:

an alloy material in a nonequilibrium atomic structure state.

2. The system of claim 1 wherein said material is a rare earth-transition metal.

3. The system of claim 2 wherein said nonequilibrium rare earth-transition metal material is in the amorphous state.

4. The system of claim 2 wherein said rare earth-transition metal material is in a metastable crystalline state.

App. at 171 (emphases added). Kumar's application was rejected as obvious in light of the Polk patent. The examiner explained:

Although, the invention is not identically disclosed or described . . . the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious . . . . The applicant's arguments have been considered but [sic] not clear why unobvious to use alloys of Polk et al in process [sic] of basic reference . . . . The amorphous alloys claimed are old in the art . . . .

Id. at 189 (emphasis added). Although the examiner's written comments did not suggest specific amendments, Kumar stated during prosecution that the examiner indicated in an oral interview that "if the claims were limited to amorphous rare-earth transition metal alloys for reversible storage of hydrogen . . . they would likely be allowable." Id. at 224. Accordingly, Kumar cancelled claims 2-4, among other claims, and amended claim 1 to read: "A system for retrievably storing hydrogen comprising: an amorphous rare earth-transition metal alloy material . . . ." Id. at 223. All further references to alloys of a "nonequilibrium atomic structure" or their "metastable crystalline state" were excised from the claims.

Ovonic argues that the surrender of claims to "metastable crystalline" alloys effectively surrendered claims to all partially crystalline alloys. 2 Kumar's theory is that metastable crystalline and partially crystalline are mutually exclusive categories of alloys and that he, therefore, did not surrender partially crystalline alloys by surrendering "metastable crystalline" alloys during prosecution. Appellant's Reply Br. at 19-20. We do not agree that in the present context metastable crystalline alloys and partially crystalline alloys were used as mutually exclusive categories. The specification repeatedly equates partially crystalline with metastable crystalline, stating that "the transformation to the low temperature crystalline phase is suppressed to produce . . . a partially crystallized or metastable crystalline state," '686 patent, col. 2, ll. 17-24 (emphasis added), and that "[a] partially crystallized or metastable crystalline state in which some crystalline forms, occurs from a less rapid

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cooling . . . ." Id., col. 4, ll. 33 (emphasis added). However, the mere fact that a party offers incorrect theories based on the specification and prosecution history to support a particular claim construction (here the Polk definition) does not require that we reject that particular construction. Just as we may consider "new or additional arguments in support of the scope of [a party's] claim construction, on appeal," Inverness II, 309 F.3d at 1381 (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1370-71 (Fed. Cir. 2002)) (internal citations omitted), we may also consider our own independent analysis of the prosecution history to conclude that a party's proffered claim construction is correct. That is the situation here. Although we reject Kumar's interpretation of the prosecution history, we also do not think Ovonic's interpretation is correct. Even assuming that metastable crystalline and partially crystalline were used as synonyms, the prosecution history (and the specification) is equally consistent with an interpretation that metastable crystalline or partially crystalline is a broad term including any material that is not fully crystalline. To be sure, it would include amorphous material exhibiting some very limited degree of crystallinity (but would exclude material that was completely or totally amorphous). But by surrendering the broad claims to metastable crystalline and partially crystalline, Kumar did not surrender everything within the scope of metastable crystalline and partially crystalline. In other words, Kumar surrendered a broad claim covering all partially crystalline material, but did not thereby surrender the subset of such material within the scope of the definition of "amorphous." At most the prosecution history is confusing in this respect, and the surrender is not clear and convincing as required by our cases. See Omega Eng'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1323- 25 (Fed. Cir. 2003).

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2 Ovonic appears to argue that amorphous is a subset of "nonequilibrium" alloys and does not suggest that the surrender of that broader claim was a surrender of everything within it.

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Ovonic further argues that Kumar surrendered partially crystalline alloys by following the examiner's suggestion to limit his claims to "amorphous rare-earth transition metal alloys for the reversible storage of hydrogen." As Ovonic admits, however, there is nothing in the prosecution history that defines the term "amorphous." We have held that "it is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous," as it is in this case. Inverness II, 309 F.3d at 1382.

Accordingly, neither the prosecution history nor the specification supports a definition of amorphous contrary to the plain meaning as defined by the Polk patent.

IV.

This is not the end of the matter. Questions remain as to the meaning of the phrase "long range order" in the Polk definition. Kumar contends that lack of long range order exists when "sizes of ordered regions [are] below 100 nm." In support of this definition, Kumar relies on statements in two textbooks, 3 an article he had published before filing the application that gave rise to the '686 patent, 4 and the language of a prior patent. 5 But none of these sources provides a clear definition of the term. We conclude that testimony from those skilled in the art is required to establish the meaning of the term "long range order," a term which we note was used in one of Ovonic's own patents. '440 patent, col.3, ll. 26-32 ("The types of disordered structures that provide local structural chemical environments for improved hydrogen storage characteristics include amorphous materials, microcrystalline materials, multicomponent multiphase polycrystalline materials lacking long range composition order . . . .") (emphasis added); see Vitronics, 90 F.3d at 1584.

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3 Kumar quotes a passage in Quantum Electron Theory of Amorphous Conductors, stating that "partly ordered [=partially crystalline] solid alloys… exhibit the short-range order in the distribution of atoms without any long-range order; in this respect they are similar to liquids." Appellant's Br. at 9 (quoting Aleksandr I. Gubanov, Quantum Electron Theory of Amorphous Conductors 85 (1965)) (alterations in original).

Kumar also quotes a sentence in Elements of X-Ray Diffraction, stating that "at about 10-5 cm [100nm], the first signs of line broadening, due to small crystal size, begin to be detectable." Appellant's Br. at 10 (citing B.D. Cullity, Elements of X-Ray Diffraction 261-62 (1956)) (alterations in original).

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4 Kumar quotes the following passage from an article he wrote in 1978:

For depositing non-crystalline material in bulk form . . . the thermal conductivity of the deposit influences the rate at which heat is conducted away . . . A greater . . . crystallinity is . . . expected for sprayed material… away from the interface than that which is close to it . . . The X-ray peaks of [material closer to the interface] are considerably less resolved . . . therefore a reduced amount of crystallinity is indicated . . . The difference in . . . crystallinity is attributed to a decrease in the rate of quenching….

Appellant's Br. at 13 n.17 (quoting K. Kumar & D. Das, Equilibrium and Metastable Samarium- Cobalt Deposits Produced by Arc Plasma Spraying, 54 Thin Solid Films 263, 268 (1978)) (deletions in original).5 Kumar cites portions of claims 1, 2 and 3 of U.S. Patent No. 3,949,387 (issued April 6, 1976), which read as follows:

1. A magnetic system, comprising; a magnetic medium exhibiting an amorphous structure without long range atomic ordering . . . .

2. The system of claim 1, where said amorphous medium has microcrystalline structure with atomic ordering over distances about 25-100 angstroms [2.5 to 10 nm].

3. The system of claim 1, where said amorphous medium is substantially amorphous having atomic ordering over distances about 25 angstroms [2.5 nm] and less.

Id., col. 21, ll. 40-62 (emphases added).

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The Court has construed the limitations of Claim 1, in relevant part, as follows:

"Active" means producing an intended action or effect: active ingredients.
"Pharmacologically effective" means an amount that is medically effective.
"Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratan sulfate and acemannan, for example.
"Amount effective" means a quantity that produces a result.
"Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
"Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.
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12. The court construes the term "amount effective" in the context of an invention pertaining to beautification of the skin to mean "an amount sufficient to have a cosmetic benefit by removing keratotic plugs." This construction aligns with both the plain meaning and customary usage of the term. Contrary to defendants' assertion that the amount of copolymer present must be between 0.01 and 70% by weight based on the total weight of the copolymer layer, the language in claim 1 does not expressly require a minimum or maximum amount of copolymer to be effective. The concept of claim differentiation provides added support for the instant claim construction. Dependent claims 6 and 7 recite the preferred embodiments, namely, copolymer of 5 to 70 wt. % and 5 to 40 wt. % based on total weight. (See '382 patent, col. 14 at 11. 6-11) Although defendants argue in favor of a slightly lower limit on the polymer weight range, i.e., 0.01% as opposed to the 5% recited in claims 6 and 7, the court, nonetheless, infers that the juxtaposition of independent claim 1 lacking any reference to a weight

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percentage of copolymer with two dependent claims containing weight percentages of copolymer implies that plaintiffs did not intend to require a weight percentage of copolymer in claim 1. Indeed, "the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim." Liebel-Flarsheim, 358 F.3d at 910 (citing Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001)). Additionally, the specification does not mandate a limited interpretation of the disputed claim language, even though the written description discloses copolymer weight ranges in preferred embodiments and all of the examples recite copolymers of less than 70% by weight. As mandated by the Federal Circuit, the court shall read the claims in light of the specification, but will not read limitations found in the specification into the claims absent a clear manifestation that the applicants intended for their claimed invention to be limited in such fashion. Furthermore, the prosecution history substantiates the court's construction of the term "amount effective." In submitting the second CPA in May 1999, plaintiffs cancelled the pending claims 32-37 and amended claim 38 to remove its dependency on claim 32, presenting it as the broadest independent claim. In doing so, plaintiffs eliminated the limitation requiring the polymer layer to comprise 5 to 70 % based on total weight and added dependent claims reciting both the 5 to 70 wt. % and the 5 to 40 wt. % limitations. The court concludes that this amendment evidences plaintiffs' belief that their invention, in its absolute broadest form, was not contingent upon a particular weight range of copolymer.
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C. Amount of Edetate

The final claim term in dispute is "an amount of edetate sufficient to prevent a no more than 10-fold increase in growth of each of Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027 and Candida albicans ATCC 10231 for at least 24 hours as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said composition at approximately 50 colony forming units per ml, at a temperature in the range 20degree-25degree C., whereafter said aliquots are incubated at 20degree-25degree C. and are tested for viable counts of said organism after 24 hours, said amount of edetate being no more than 0.1% by weight of said composition." (Col. 11, lines 37-48.) n9

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n9 This dispute is directed only to those asserted claims that do not expressly recite an amount for edetate. (Def. Mem. at 21.)

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Defendant argues that this claim term should be interpreted as meaning "edetate in any amount from zero up to no more than 0.1 % by weight of the composition." (Goldberg Decl. Ex. P. at 5.) In support, it argues that "propofol itself possesses sufficient antimicrobial properties to allow the composition to pass the microbiological test when it is present in certain proportions relative to the water-immiscible solvent component. In reading the claim as a whole, therefore, it is quite possible that no amount of edetate would be required to be added to the composition to pass the microbiological test, depending on the amount of the other ingredients (e.g., propofol and oil) that are present in the composition." (Def. Mem. at 22.) Plaintiffs counter that the proper construction of "an amount of edetate" is "at least an amount of edetate which is sufficient in and of itself to meet the microbiological test recited in the claim phrase, regardless of the presence of other components in the composition, up to no more than 0.1% by weight of edetate." (Goldberg Decl. Ex. P. at 5.)

Mayne's proposed definition encompasses the scenario of no edetate in the claimed composition. (Def. Mem. at 21.) Reading an express limitation out of the claim is contrary to case law. See Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1105 (Fed. Cir. 1996) (holding that a court cannot construe claims to read an express limitation out of the claim or render it meaningless); Texas Instruments Inc. v. Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (noting that it is improper to "read an express limitation out of the claims" or "render the disputed claim language mere surplusage"). Further, the specification of the '520 patent states:

Typically the edetate will be present in the compositions of the present invention in a molar concentration (with respect to the EDTA free acid) in the range 3x10-5 to 9x10-4. Preferably the edetate is present in the range 3x10-5 to 7.5x10-4 for

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example in the range 5x10-5 to 5x10-4 and more preferably in the range 1.5x10-4 to 3.0x10-4 most preferably about 1.5x10-4.

(Col. 5, line 1-7.) Thus, the preferred embodiment requires at least a 3x10-5 molar concentration of edetate, with 1.5x10-4 being the most preferred molar concentration. Mayne's suggested claim construction would exclude the preferred embodiment from the claimed invention. "Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics, 90 F.3d at 1583; see also Hoechst Celanese Corp. v. BP Chemics. Ltd., 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("It is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.").

Further, the '520 patent describes that the use of edetate as an antimicrobial agent is one of the key features of the claimed invention: "We unexpectedly found that edetate . . . was the only agent that would meet our requirements." (Col. 3, line 42-Col. 4, line 45.) Thus, it is clear that Claim 1 requires an amount of edetate to be present. The claim further requires, and both parties agree, that the proportion of edetate in the composition cannot exceed 0.1%. (Col. 11, line 46-48; Pl. Reply Mem. at 16; Def. Mem. at 23.)

Accordingly, this Court finds that one skilled in the art would read Claim 1 as "An amount of edetate, greater than 0% but less than or equal to 0.1% by weight of the pharmaceutical composition, which is sufficient to meet the microbiological test recited in the claim phrase."
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B. "an amount of fluid to be infused"

i. The Parties' Proposed Constructions

Smiths proposes that I construe this limitation to mean "a volume of solution to be expelled from the reservoir." (D.I. 190 at 29.) Smiths argues that because "liquid" means a "dose of medication (e.g., insulin) measured in units, one of ordinary skill in the art would understand the claims to require 'fluid' to mean a 'volume of solution.'" (Id.) Specifically, Smiths cites the specification which makes clear that in certain preferred embodiments the concentration of the insulin will affect how much is pumped into the body with every pump stroke. (Id. (citing '798 patent, col. 28:60-63, 29:12-14, 29:17-20).) Smiths argues that one of ordinary skill in the art would understand that the amount of insulin must be converted to a volumetric amount before infusion. (Id.) Smiths also points out that if the terms "fluid" and "liquid" were construed to have the same meaning, the construction would violate the general rule that different words in a claim should be given different meanings. (D.I. 190 at 28 (citing CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1317 (Fed. Cir. 2000)).)

MiniMed argues that the terms "liquid" and "fluid" are used interchangeably throughout the specification and prosecution history. (Id. at 29-31.) Specifically, MiniMed points to numerous instances in the specification where it claims the two are used interchangeably. (Id. at 30 (citing 2:47-54, 3:37-43, 3:53-55, 3:56-57, 3:61-4:5, 4:6-7, 4:12-15, 4:19-20, 4:27-28, 4:41-42, 6:5-54, 6:63-65, 7:3, 11:7-11, 13:24-28, 16:56-60, 23:42-45, 23:64-24:8, 24:13-14, 29:25).) MiniMed asserts that, comparing all of these uses, it is clear that the two words were intended to mean the same thing. Additionally, MiniMed cites to the prosecution history to support its argument that the two terms were used interchangeably. (Id. at 30.) For example, it cites an office action response where the patentee stated that "bolus generally refers to an amount of liquid provided … [and] may be provided as the sole source of fluid." (Id. at 30 (citing D.I. 207 at 19 (emphasis added by MiniMed)).) Finally, MiniMed argues that "an amount of fluid to be infused" should not include a volumetric requirement.

ii. The Court's Construction

It is important to remember that "the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (internal citations omitted). Additionally, "[a] patent claim should be construed to encompass at least one disclosed embodiment in the written description portion of the patent specification." Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1355 (Fed.

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Cir. 1998). "A claim construction that does not encompass a disclosed embodiment is thus rarely, if ever, correct and would require highly persuasive evidentiary support." Id. (internal citation and quotations omitted).

At the Markman hearing, both parties agreed that patients do not care about the volume of solution that is pumped into their body; rather, it is the amount of insulin that the patient wants to know about. (D.I. 269 at 31-32.) Smiths concedes that the preferred embodiment of claim 1 would calculate units of insulin to be delivered and indicate that amount to the patient. (Id. at 21-22.) It also argues, however, that the invention calls for another indication, when "the number of units … has been converted into the solution that needs to be pumped." (Id. at 22.) To understand how Smiths' construction impacts the functioning of Claim 1 it is helpful to examine how the invention would operate under Smiths' construction. If the patient was entering a meal bolus, he would enter his current blood glucose and the "number of carbohydrates to be consumed." ('798 patent, col. 19:24-34.) The bolus estimator would then calculate the number of units of insulin that should be infused into the patient and display that suggestion to the patient. (Id., col. 19:42-45.) The user could then accept the suggestion or change the number of units. (Id., col. 19:39-41.) Smiths argues that the invention would then indicate to the patient that it had converted units of insulin into volume of fluid. (D.I. 269 at 21-22.) Smiths states that this second indication is "important to the user … because one of the primary objectives of this patent is to be able to program and operate the pump while it's concealed." (Id. at 22.) Presumably, this means that the user would instruct the machine to inject the fluid after receiving the second indication that informed him that the conversion from units to volume had been completed.

The operation of the pump, according to Smiths' claim construction, does not comport with common sense. Smiths seems to concede that the user does not care to know the volumetric amount of fluid that is pumped into him. (See D.I. 269 at 31-32.) If this is so, why would the user want to know when the computer has made a simple arithmetic computation, if not to check its validity? This construction does not "naturally align[] with the patent's description of the invention" and therefore is unpersuasive. See Renishaw, 158 F.3d at 1250.

More importantly, however, Claim 1, under Smiths' construction of this term, does not encompass any of the preferred embodiments of the invention. None of the embodiments that are directed to a bolus estimator indicate that there is a "second indication." 16 In fact, the preferred embodiments appear to suggest just the opposite. The preferred embodiments directed to a "bolus estimator" state that once the user selects the units to be infused, he presses the "ACT key" which "starts the bolus." ('798 patent, col. 19:42-45.) The preferred embodiment does not contemplate the argument that a "second indication" occurs after pressing the "ACT key" and before the infusing of the liquid. Consequently, under Smiths' construction of this term, Claim 1 would not "encompass a disclosed embodiment." See Johns Hopkins Univ., 152 F.3d at 1355.

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16 During oral argument, counsel for Smiths argued that two portions of the specification support the argument that there is a "second indication." First, he cited to the preferred embodiments, wherein the patentee stated that "the amount of insulin delivered per pump stroke depends upon the concentration. If the concentration is changed, the constant factors which convert pump strokes into units of insulin are changed accordingly." (D.I. 269 at 26 (citing '798 patent, col. 29:18-21).) This cite, however, does not reference a second indication, only that units must be converted to volume before being infused. Second, counsel for Smiths cited to the summary of the invention, which states that "the indication device indicates when a command has been received and indicates when the command is being utilized to control the external infusion device." (Id. at 29 (citing '798 patent, col. 2:66-69).) This section does not refer to a second indication of a completed calculation either. Rather, this indication is used to tell the user when "the command is being utilized to control the external infusion device." Consequently, neither of the sections of the '798 patent specification cited by Smiths' counsel appears to stand for the proposition asserted.

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An alternative construction of this term that is both logical and in accordance with the disclosures in the specification is one that does not limit the term "an amount of fluid to be infused" to a volumetric amount. Because "an amount of fluid to be infused" can be measured in units, Claim 1 comports with the written description of the specification because no second indication is necessary. The visual indication of the "an amount of fluid to be infused" would simply be the number of units of insulin to be infused. Moreover, although fluid is not normally measured in units, the invention contemplates that the concentration of the insulin is a "constant factor[]." Therefore, a specific number of units of insulin corresponds to a

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volumetric measurement of the fluid. 17 In short, read in light of the specification, the claim language "amount of fluid to be infused" embraces amounts quantifiable in terms which can include measurements other than strictly volumetric measurements. Consequently, the term "an amount of fluid to be infused" means "a quantity of fluid to be infused in the patient." 18

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17 An appropriate analogy is that of converting a particular number of moles of a substance to grams, which occurs through a simple mathematical calculation using a known constant (i.e., the number of moles per gram of a substance). Thus, in such a situation, the number of moles of a substance is appropriately described as an "amount" of that substance, just as here, with a known concentration, the number of units of insulin can be described as "an amount of fluid."

18 I have already construed "liquid" to mean, in the context of this case, "a substance, such as insulin, that is active within the human body." See supra, Part IV.C.1.a. Consequently, to give "fluid" its plain meaning would not raise any of the problems associated with different words in the same claim having the same meanings, as argued by Smiths.

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6. "The Amount Of Signal Label Producing Said Detectable Signal In Said Immunosorbing Zone Is Related To The Amount of Analyte"

This claim dispute boils down to whether a signal label need only indicate the presence of analyte, or whether the signal label must indicate the amount or intensity of the signal given off by a test solution. 16 Biosite argues the claim, specification, and prosecution history all require that the signal intensity change, directly or inversely, with the amount of analyte in the test solution. On the other hand, Dade Behring contends the specification of the '241 Patent confirms its interpretation that the signal produced by the signal producing system must relate in only some way to the amount of analyte present. Such relationship, Dade Behring, asserts can be quantitative, semi-quantitative, or qualitative.

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16 The parties also dispute the meaning of the following closely-related claim language: "an amount of signal label-mip conjugate becoming bound to said mip bound to said support in relation to the amount of analyte in said sample . . . ." Col. 1, lines 59-62. However, because this claim dispute involves the exact same issues presently being analyzed, this claim language will be construed in the same fashion as the claim language presently being analyzed in this section of the Opinion.

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The Court begins, as before, with the language of the claim itself, which requires the "amount of signal label producing said detectible signal . . . is related to the amount of analyte." Col. 1, lines 44-46. Because the nature of the relationship between the amount of signal label and the amount of analyte is not expressly defined in the claim, it is necessary to search the specification and the prosecution history in order to further the Court's understanding of this claim language. Significantly, the specification states in various places that, "the devices of the subject invention . . . provide for qualitative or quantitative results." Col. 3, lines 28-31; see also Col. 8, lines 67-68; Col. 9, lines 23-24; and Col. 11, lines 4-5 (measurement may be "qualitative, semi-quantitative, or quantitative."). Additionally, the specification summarizes the invention by explaining that, "in accordance with the subject invention, a simple rapid technique is provided whereby ligands and their receptors may be qualitatively or quantitatively determined by employing various techniques." Col. 40, lines 28-31. Accordingly, the specification envisions for the relation between the amount of signal and the amount of signal to be manifested in any number of quantitative or qualitative ways.

Although the language of the specification describes quantitative techniques whereby "standard or charts" relate "color intensity to the particular concentration of the analyte," see Col. 14, lines 3-17, Col. 38, lines 33-36, there is no support for

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Biosite's contention that the signal response must be graduated. The specification merely provides examples or preferred embodiments of how its immunoassay technique may be performed. As discussed previously, however,"examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, [but] the scope of the claim is not necessarily limited by such examples." See Ekchian, 104 F.3d at 1303.

Similarly, the prosecution history cited by Biosite does not change the scope or meaning of the patent. Although in numerous places throughout the prosecution history Dade Behring distinguished its invention from prior art by explaining, "it is the level of the detectable signal which is the distinctive factor," see D.I. 127, Ex.2 at 110, 111, and 117, the prosecution history cannot "enlarge, diminish, or vary the languages in the claims." See Markman, 52 F.3d at 980. The claim language only requires some relation between the amount of signal produced and the amount of analyte. 17 The specification further makes clear that quantitative, semi-quantitative, and qualitative methods of detection were contemplated by the patent applicant at the time of the invention. It is not now proper to use the prosecution history to diminish the scope of the claim language to include only quantitative or semi-quantitative methods, especially since the claim language is broader than such embodiments. 18 See Electro Medical Systems, 34 F.3d at 1054.

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17 Although Biosite points to the claim language "amount of signal label produced" and "amount of analyte," see Col. 1, lines 43 and 45 (emphasis added) as proving the claim only contemplates quantitative methods, there is nothing in the claim language which prevents a qualitative method being employed to analyze the relationship between the amount of signal produced and the amount of analyte. Absent express language limiting the type of analysis to be performed on these two related amounts, the Court declines to read in extraneous limitations. See Intervet Am., 887 F.2d at 1053.18 Nor is this a case in which Dade Behring has specifically disclaimed during the prosecution of the '241 Patent an interpretation of this claim language which would preclude qualitative methods of analysis. See Southwall, 54 F.3d at 1576. Dade Behring only sought to distinguish prior art by showing its invention was capable of determining the level or intensity of a signal.

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The Court therefore construes "amount of signal label producing said detectible signal in said immunosorbing zone is related to the amount of analyte," as allowing for quantitative, semi-quantitative or qualitative analysis of the relation between the amount of signal produced and the amount of analyte in the test solution.
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an amount sufficient

The parties and the Court agree that the term should be construed as "a required dosage."
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5. "[stem cells] in an amount sufficient"

"[stem cells] in an amount sufficient" is construed to mean "in a quantity as much as is needed." 1

6. "derived"

"derived" is a commonly understood word and requires no additional construction.

7. "can proliferate within the host"

"can proliferate within the host" is construed to mean "capable of increasing in quantity."

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1 Consistent with the court's oral ruling during the Markman hearing on January 10, 2003, the court will not address the defendants' indefiniteness argument at this stage of the proceedings. While the court recognizes that a determination of indefiniteness is necessarily intertwined to some degree with claim construction, it is clear that the court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness. See ASM America, Inc. v. Genus, Inc., 2002 U.S. Dist. LEXIS 15348, 2002 WL 1892200, *15 (N.D. Cal. Aug. 15, 2002) (recognizing that claim construction must proceed before an indefiniteness challenge); see also Intervet America, Inc. v. Kee-Vet Labs., 887 F.2d 1050, 1053 (Fed. Cir. 1989). The court's position at this time does not, however, represent an actual adjudication on the defendants' indefiniteness defense. At present, the court is merely holding that the claim is sufficiently definite to survive claim construction.

Finally, the court wishes to note that the defendants bear the burden of proving invalidity by clear and convincing evidence. See North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1579 (Fed. Cir. 1993). The defendants have not, however, filed a motion seeking to invalidate the patents on indefiniteness grounds. Rather, they simply assert their arguments in their opposition claim construction brief. Such an approach is clearly an attempt at an end-run around the court's scheduling order regarding the filing of dispositive motions, and will not be sanctioned.

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an amount sufficient to form a flocculated suspension in the water and to remove turbidity from the water

The Court modifies Plaintiffs' proposed construction and construes the phrase as "the dosage required in the water to form a flocculated suspension and increase clarity, reduce reported NTU to an appreciable extent." Defendants argue that the phrase should be construed as "the dosage required in the water to form a flocculated suspension and to eliminate, take away, or do away with all measurable turbidity from the water." The portion of the phrase in dispute is the second half, specifically the term "remove turbidity." For the reasons discussed above with regard to "remove turbidity," the phrase is not construed to require the complete elimination of all measurable turbidity.

Plaintiffs argue that the term should be construed as "the dosage required in the water to form a flocculated suspension and to produce water of a desired clarity." As with the term "remove turbidity," Plaintiffs' proposed construction would impermissibly broaden the scope of the claim language. Accordingly, and for the same reasons discussed above, the Court construes this phrase in accordance with its construction of the term "remove turbidity."

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5. "In an amount sufficient to impart color and/or flavor to the foodstuff"

Defendants ask me to construe this term as, "enough coloring and/or flavoring agent is provided such that desired color and/or flavor effect is produced in the foodstuff when the foodstuff is stuffed and boiled, cooked, or otherwise heated in the casing." Plaintiff offers no alternative construction, arguing that the claim term is indefinite under 35 U.S.C. § 112 P 2. Plaintiff also objects to defendants' proposed construction on a number of grounds.

The standard for determining whether a patent claim is sufficiently definite to satisfy 35 U.S.C. § 112 P 2 is whether "one skilled in the art would understand the bounds of the claim when read in light of the specification." Exxon Research and Engineering Co. v. U.S., 265 F.3d 1371, 1375 (Fed. Cir. 2001). This standard "does not compel absolute clarity," and "[o]nly claims "'not amenable to construction' or 'insolubly ambiguous' are indefinite." Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005)(quoting Exxon, 265 F.3d at 1375). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." Omega Engineering, Inc. v. Raytek Corp., 334 F.3d 1314, 1321 (Fed. Cir. 2003) (quoting Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 875

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(Fed.Cir.1993)).

Plaintiff raises two basic arguments for holding this claim term indefinite. First, it contends that because the '613 patent discusses the inferiority of previously known pure plastic casings based on the latter's inability to "adequately absorb and store impregnating agents," ascertaining the proper scope of this claim term requires reference to "a standard by which to measure the degree of flavor or color transfer," but that none exists in the intrinsic record. Next, plaintiff argues that because flavor is an inherently subjective concept, the claim term has "no objective anchor" and is "insolubly ambiguous."

In support of these arguments, plaintiff relies on Halliburton Energy Services, Inc. v. M-I LLC, 514 F.3d 1244 (Fed. Cir. 2008), and Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). In Halliburton, the court concluded that the claim term "fragile gel" was indefinite because although the patentee distinguished its invention based on the use of a "fragile gel," it provided no consistent way "to distinguish the fragileness of the invention from disclosed prior art." 514 F.3d at 1256. Plaintiff argues that the '613 claims are similarly indefinite because a person of skill in the art could not distinguish the amount of flavoring or coloring agents described in the patent from the inadequate amounts alleged to be found in the prior art. As the Halliburton court recognized, when a claim term is defined in functional language (i.e., "by what it does, rather than what it is," 514 F.3d at 1255 (citing In re Swinehart, 439 F.2d 210, 212, 58 C.C.P.A. 1027 (1971)), "whether that limitation is sufficiently definite is a difficult one that is highly dependent on context." Id. Here, the claim itself imposes parameters on the scope of the phrase "sufficient amount" with reference to what it does ("impart color and/or flavor").

Defendants explain that the invention can be practiced so as to transfer a range of colors ("light caramel color" or "dark caramel color" for example) or flavors, and that one of skill in the art would know how to achieve a variety of results. According to the patent, none of these results was possible using the pure plastic casings in the prior art, regardless of the amount of coloring or flavoring used. That the claims encompass a range of results superior to those available in the prior art does not render the claim scope indefinite under Halliburton.

Nor is the claim term so inherently subjective as to be "insolubly ambiguous" under Datamize. In that case, the Federal Circuit held that the phrase "aesthetically pleasing" was indefinite because its inherent subjectivity "fail[ed] to provide one of ordinary skill in the art with any way to determine" whether the limitation was met. 417 F.3d at 1349. The claim term at issue here is not similarly devoid of any objective anchor. For example, defendants point to objective tests for flavor discussed by their expert at his deposition: "[Y]ou could in the earlier days rely on a suitable taste panel. The state of the art has advanced considerably since those days. Nowadays, I might use a highly sophisticated instrument to determine that, what the composition of the flavoring components are." Although the patent itself makes no reference to these or other tests that may be used, plaintiff does not dispute that such tests were known to, and used by, those of skill in the art. The fact that the tests may incorporate a subjective component does not render the claim term incapable of construction under Datamize.

In sum, I do not find at this stage that the term "in an amount sufficient to impart color and/or flavor to the foodstuff" is indefinite. Nevertheless, I agree with plaintiff that there is no basis for construing the term to include the phrase "when the foodstuff is stuffed and boiled, cooked, or otherwise heated in the casing" in the definition of the term. The only temporal limitation in the claim itself is "when the food barrier casing encloses the foodstuff," and defendants have articulated no argument for redefining this portion of the phrase.

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Amplifiable Gene	DNA corresponding to a gene whose copy number will increase inside a transformed cell in response to manipulation by the operator of a process

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C. The Term "Amplification"

Claim 1 of the '765 patent calls for the plasmid DNA molecule to be "capable of ensuring amplification" of the genes controlling amino acid synthesis. (D.I. 240, Ex. A, col. 12, lines 8-9) ADM argues that the term "amplification" should be interpreted to mean any increase in the number of genes. (D.I. 240 at 10) To support this interpretation, ADM refers to the '765 patent specification that defines "amplification" to mean "increasing the number of genes in a cell." (D.I. 240, Ex. A, col. 1, lines 36-37) ADM seeks this interpretation because Ajinomoto's expert testified at deposition that the term "amplification" means increasing the number of genes in the recipient cell by at least five. (D.I. 240, Ex. E at 225) Dr. Falkinham further testified that one skilled in the art would know this limitation because of published scientific literature. (D.I. 240, Ex. E at 226)

The court concludes that since the '765 patent specification clearly defines "amplification" to mean any increase in the number of genes, the term should not be interpreted to require a minimum increase, such as a five gene increase.
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Amplified Foreign DNA I	Foreign DNA I corresponding to a gene of interest that is present in a cell in increased copy number as a result of gene amplification in the cell
Amplified DNA II	DNA II that is present in increased copy number in a cell as a result of gene amplification in the cell and confers a selectable phenotype of proliferative advantage under specific conditions of culturing the cell, enabling selection of cells which carry an increased copy number DNA II

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B. Claim Construction

Throughout this case, Vysis has repeatedly objected to this Court's construction of the limitation "amplify." In its June 20, 2001, the Court explained the basis of its claim construction. (June 20, 2001 Order [Docket # 144]). As it concluded after carefully applying Federal Circuit rules, "based on the explicit language of the specification, the repeated reference to non-specific amplification methods, and the absence of any reference to specific amplification or PCR, the Court construed the term 'amplifying' as found in the claims of the '338 patent to encompass only non-specific amplification." (Id., at 10). In its November 20, 2001 order, the Court addressed Vysis' motion to reconsider that claim construction. (Nov. 20, 2001 Order [Docket # 200]). Scrupulously applying the framework of claim construction precedent, the Court's order carefully and painstakingly analyzed and cited the overwhelming intrinsic evidence that supported the claim construction. (Id., at 13-32). From that analysis, the Court concluded that its original claim construction was correct. (Id., at 31-32). Both the June 20, 2001 Order and the November 20, 2001 Order are incorporated herein by reference. Consequently, the Court declines to reconsider and change its construction of the limitation "amplify."

The Court also declines to modify its construction of the other claim limitations as interpreted in its April 5, 2002 order. (Apr. 5, 2002 Order Construing Claim Limitations [Docket # 375]). The Court also incorporates by reference the April 5, 2002 Order's extensive analysis. Consequently, the claim constructions remain unchanged.

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d. "Amplifying domain before hybridization"

The parties' dispute about the construction of this term in claim 9 centers on one issue: whether the claim can be met only by a process that performs the amplifying step first, before any hybridization takes place. The dispute arises because the realtime PCR process involves first hybridizing the probes to the target, then extending the DNA (the amplification step).

The claim language is clear and requires no judicial construction. Amplification must occur before hybridization.

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The parties do not dispute that clarithromycin is an "erythromycin derivative." The extended release composition at issue is designed for release in the gastrointestinal environment (e.g., oral administration). The patent specification defines "erythromycin derivative" as meaning "erythromycin having no substituent groups, or having conventional substituent groups, in organic synthesis, in place of a hydrogen atom of the hydroxy groups and/or a methyl group of the 3'-dimethylamino group, which is prepared according to the conventional manner." U.S. Pat. No. 6,010,718, at col. 3:ll. 34-39. The patent specification further states that the "pharmaceutically active compound" of the composition "is an erythromycin derivative." Id., at ll. 58-61. It goes on, "[p]referably, the erythromycin derivative is 6-O-methoxy erythromycin A, known as clarithromycin." Id. The language of the claim is definite ("an erythromycin derivative") but not closed. It does not specify that the pharmaceutically active compound "is a member selected from the group consisting of A, B, and C." Thus, clarithromycin is an erythromycin derivative under this meaning.

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II. BACKGROUND

The '875 patent is entitled, "Stabilized Galenic Formulations Comprising an Acid Labile Benzimidazole Compound and its Preparation." In general, the claims of the '875 patent are related to a stable oral pharmaceutical formulation which does not include the alkaline compounds included in the prior art. Initially, the parties disputed the construction of three claim limitations. Now, Kremers has moved for reconsideration of the court's construction of one of those limitations. The relevant claim language reads in columns 5 and 6:

> A stable oral pharmaceutical preparation . . ., which consists essentially of:
>
> (a) a nucleus formed by an inert core, ...

In its October 14, 2003 Order, the court construed "an inert core" to mean "one or more pharmaceutically inert seeds used to provide a starting material for the preparation of a pharmaceutical." The court based this construction on intrinsic evidence, in particular, the claims themselves and the specification. The '875 specification gives a cursory description of the "inert core" limitation in both the "Outline of the Invention" and "Detailed Description of the Invention" sections. Nothing in the prosecution history is directly relevant to the construction of the "inert core" claim term.

The term "core" is recited in the specification three times, twice in its singular form and once in its plural form. The "Outline of the Invention" section first mentions a singular "inert sugar/starch spherical core" while characterizing the invention and its active and isolation layers. ('875 patent, col. 2, 1. 13). The second reference to "core" states that "the core, the process conditions and the excipients have been selected in order to obtain the required coating efficiency for each layer." Id. at ll. 20-22. Finally, the "Detailed Description of the Invention" recites the plural, "In a fluidized bed apparatus, uniform spherical inert cores (composition as per US Pharmacopoeia) are coated . . . ." Id. at l. 35. Subsequently, the remainder of the '875 specification, with the two exemplary embodiments provided, recite the word "spheres" instead of

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"cores." Id. at cols. 2-4. Ostensibly, but not definitively, the plural recitations of "cores," "spheres" or "pellets" refer to a batch of the formulation; thus, the specification is ambiguous with regard to a plural construction of "an inert core." The specification of the '875 patent focuses instead on the non-alkaline layers surrounding the inert core which differentiate it from the prior art.

Kremers moves for Reconsideration and/or Re-argument of the court's construction of the term, "an inert core." For two reasons, Kremers argues that "an inert core" should be construed as "a single pharmaceutically inert seed used to provide a starting material for the preparation of a pharmaceutical." First, Kremers asserts the Mylan misled the court during the Markman oral argument by suggesting that the '875 patent specification discloses multiple cores. Emphatically arguing that "absolutely nowhere in the intrinsic evidence is [there] a disclosure of a pharmaceutical preparation having more than one core," (D.I. 110 at 3), Kremers bemoans the fact that the court did not allow it a final sur-rebuttal to clarify the alleged misrepresentation made during the final surreply by Mylan.

Secondly, Kremers asserts that claims 12 and 13 do not allow for "one or more" inert cores and that the court has therefore made an error of law by construing the limitation as "one or more pharmaceutically inert seeds . . . ." Kremers attempts to support this argument with the recent Federal Circuit decision, Abbott Laboratories v. Baxter Pharma Products Inc., 334 F.3d 1274 (Fed. Cir. 2003), which held that a closed transition phrase, e.g. "consisting of," restricts the construction of a modified article to a singular form. Id. at 1281. However, the claims presently at issue do not use the phrase "consisting of," or any other closed transition phrase. Instead, claim 3 uses the open transition phrase "comprising" and claims 12 and 13 use the partially-open transition phrase "consisting essentially of." Kremers omits a discussion of this critical difference.

III. STANDARD OF REVIEW

Kremers moves for reconsideration and re-argument pursuant to Fed. R. Civ. P. 59(e) and Delaware Local Rule 7.1.5. A party bringing a motion to alter or amend an order pursuant to Fed. R. Civ. P. 59(e), must establish one of three grounds in order to prevail: (1) there is an intervening change in controlling law; (2) new evidence has become available; or (3) there is a need to correct the court's clear error of law or fact or to prevent manifest injustice. N. River Ins. Co. v. CIGNA Reinsurance Co., 52 F.3d 1194, 1218 (3d Cir. 1995). Similarly, re-argument is not appropriate under Delaware Local Rule 7.1.5, unless: (1) the court has patently misunderstood a party, (2) the court has made a decision outside the issues presented to the court by the parties, or (3) the court has made an error not of reasoning but of apprehension. Schering Corp. v. Amgen, Inc., 25 F. Supp.2d 293, 295 (D. Del. 1998).

Motions for re-argument "should not re-hash arguments already briefed and decided." Id. at 295. Similarly, motions for reconsideration should be granted sparingly and only in limited circumstances. BP Amoco Chem. Co. v. Sun Oil Co., 200 F. Supp.2d 429, 432 (D. Del. 2002). Indeed, motions for reconsideration or re-argument are not a way for litigants to take a second bite at the apple.

IV. DISCUSSION

The core of an apple typically has one or more seeds. The core of an academic curriculum consists of one or more essential courses. The core of a politician's constituency consists of one or more particularly ardent supporters. Similarly, the core of a pharmaceutical preparation may consist of one or more seeds.

Although the context of a claim term may restrict it to a singular form, "it is well settled that the term 'a' or 'an' ordinarily means 'one or more.'" Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1370 (Fed. Cir. 2002). In addition, there is a "heavy presumption" that the ordinary meaning applies. Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). The ordinary meaning of a term is the full range of interpretation reasonable to persons skilled in the art. Id. Since, neither the '875 specification nor the '875 prosecution history unambiguously depart from the ordinary meaning of the term "an inert core," and since the plural form of "an inert core" does render the claim so ambiguous that there is "no means by which the scope of the claim may be ascertained from the language used," the court construes the "an inert core" term according to its ordinary meaning. Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001).

The court's construction of the claim term "an inert core" is in accordance with the law. Kremers' argument that a plural embodiment of "cores" is not disclosed in the specification is irrelevant because the specification does not consistently and

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unambiguously describe the invention with a single unitary core. Second, a plural construction of the term does not materially affect the basic and novel properties of the invention because the "required coating efficiency" does not specify the exemplary "sugar/starch spheres," but a combination of cores, process conditions, and excipients that a person of ordinary skill in the art could devise in many different ways. Therefore, the court's plural construction is reasonable in the context of the ambiguous usage of the plural form in the specification. Finally, contrary to Kremers' implication, the preamble transition phrase of claims 12 and 13 does not necessarily restrict all subsequent limitations to a singular embodiment because "consisting essentially of" is a partially-open transition phrase, rather than a closed one.

A. Kremers' argument that a plural embodiment "cores" is not disclosed in the specification is irrelevant because the specification does not consistently and unambiguously describe the invention with a single unitary core.

The intrinsic evidence supplies the context for determining whether a claim limitation is limited to a singular construction or is entitled to the full range of ordinary meaning. If the specification discloses a singular embodiment it "does not disclaim a plural embodiment." KCJ Corp. v. Kinetic Concepts, Inc. 223 F.3d 1351, 1356 (Fed. Cir. 2000). Only when the intent of the written description is "clear" will the court accordingly restrict the limitation to a singular embodiment. Id. Since the intrinsic evidence is ambiguous regarding a single unitary embodiment of "an inert core," this limitation should be construed according to the full range of ordinary meaning, which includes the plural embodiment.

B. The plural construction of "an inert core" does not materially affect the basic and novel properties of the invention.

Kremers correctly notes in its Answering Memorandum to Plaintiff's Claim Construction that is was not possible to overcome the Examiner's § 103 rejection by distinguishing the claimed "inert core" from the prior art. "Accordingly, neither the applicants nor the Examiner addressed the claim limitation "inert core" in the '875 patent application." (D.I. 90 at 6). At the Markman hearing the parties argued the "inert core" term through sur-reply and sur-rebuttal. The court finally stopped the parley when it was clear that "an inert core" was not a specially defined term, per the HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, but a concept susceptible to a broad, plain and ordinary, interpretation. See Arthur H. Kibbe, Ph. D., HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 548 (3d ed. 2000).

The term "inert core" is a limitation to the claims. In particular, this limitation tells the public that the core must be inert and not contain alkaline reacting compounds. Furthermore, the core must be selected to match the process conditions and the excipients in order to obtain the "required coating efficiency for each layer." ('875 patent, col. 2, 1. 22). The "required coating efficiency" is not detailed in the specification or mentioned in the claims. Nevertheless, the court finds that a person of ordinary skill in the art could obtain the required coating efficiency for each layer with a wide variety of "inert core" embodiments by adapting the process conditions and the excipients. Consequently, a plural embodiment of "an inert core" does not materially affect the basic and novel properties of the invention. Instead, it is the absence of alkaline reacting compounds and the stability of the acid labile compound that are the basic and novel properties of the invention. Thus, a plain and ordinary interpretation of the limitation is proper. Such construction of "an inert core" does not unduly restrict the scope of the entire set of claims.

C. The partially-open transition phrase "consisting essentially of" does not restrict all subsequent modified articles to a singular form.

Kremers correctly argues in its Markman brief that the word "comprises" in the preamble of claim 3, modifies the claim limitations (a), (b), and (c). Then, Kremers argues that the transition phrase "consisting essentially of" in the preamble of claims 12 and 13 must apply to "an inert core." (D.I. 110 at 6). Next, in what might be charitably characterized as a bit of sleight of hand, Kremers implicitly characterizes the transition phrase "consisting essentially of" as a closed transition phrase. Id. Finally, Kremers cites Abbott Laboratories for the proposition that "consisting essentially of" authoritatively restricts "an inert core" to singularity. Id. (citing Abbott Labs. v. Baxter Pharm. Prods. Inc., 334 F.3d 1274, 1281 (Fed. Cir. 2003)). Abbott Laboratories is quite clearly inapposite on the point at issue.

The transition phrases "comprising" and "consisting essentially of" are words of art. For a patent practitioner these phrases may have a distinct meaning. In fact, they are specifically defined when they are used to connect the preamble to the body of a claim. See Schering Corp. v. Amgen Inc., 18 F. Supp. 2d 372, 382 (D. Del. 1998); Cal. Med. Prods., Inc. v. Technol Med. Prods., Inc., 921 F. Supp. 1219, 1227 (D. Del. 1995). The transition phrase "comprising" is an open transition phrase and does not preclude the presence of other elements. AFG Indus., Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1245 (Fed.

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Cir. 2001). The transition phrase "consisting essentially of" is a partially-open transition phrase. PGS Indus. v. Guardian Ind. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). A partially-open transition phrase, as applied to the limitations in the subclause of the (a) limitations of the '875 claims, signals the public that "the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." Id. The court is therefore not required to construe the transition phrase "consisting essentially of" as necessarily restricting the modified articles to a singular form.

V. CONCLUSION

The plural construction of the limiting term "an inert core" does not materially affect the basic and novel properties of the invention. Therefore, the open and partially-open terms "comprises" and "consisting essentially of" both allow a plural construction of "an inert core." Since the word "seed" is well known to those skilled in the art and has a common meaning pertinent to a pharmaceutical preparation, the word "seed" is a starting term for the construction of the "inert core" limitation. Consequently, the limitation "an inert core" is construed as "one or more pharmaceutically inert seeds used to provide a starting material for the preparation of a pharmaceutical."

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With those standards in mind, the court finds that claims of the patents at issue can properly be construed as including analogs or surrogates for white blood cells in its coverage. The terms "analog" and "surrogate" should be afforded their ordinary meanings and construed as any substitute for fresh human white blood cells. Analog is commonly understood to mean something that is analogous to or similar to something else. See, e.g., Webster's II New Riverside University Dictionary 104 (1984). "Surrogate" means one taking the place of another, or substitute. Id. at 1166. In its own documents Coulter has used the terms "analog" and "surrogate" to mean substitutes for white blood cells. (Evidence attached to Filing No. 336, Exhibit 27; evidentiary materials submitted in support of Streck's Motion for Summary Judgment of Literal Infringement, attached to Filing No. 214, Exhibit A at 766, Exhibit B at 791; evidentiary materials submitted in support of Streck's Reply to Coulter's Opposition to Streck's Motion for Summary Judgment of Literal Infringement, Attached to Filing No. 243, Exhibit C (hereinafter, "evidence attached to Filing No. 243")). The definition of "analog" or "surrogate" found in Coulter's own patent documents does not differ significantly from these ordinary meanings. Id., Exhibits F, G, and H (i.e., "a particle which simulates one physical or biological property of a target population," an example being simulated white blood cells from red blood cells). Moreover, the evidence establishes that the terms "analog" and "surrogate" are understood by persons of ordinary skill in the art to mean any substitute for human blood cells.

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D. Analyte

Syntron seeks to alternatively support the judgment of noninfringement as to claims 22 and 23 of the '484 patent based on the argument that the district court's construction of the claim term "analyte" in those claims was erroneous, and that under the proper claim construction no reasonable jury could have found that the limitation was satisfied.

The district court construed "analyte" to mean "the substance of interest, i.e., the substance that the test is designed to detect if present in the liquid being tested." Syntron objected to this construction before the district court and urges on appeal that the district court should have instructed the jury that the "analyte" limitation required quantitative analysis. Syntron does not argue that the plain meaning of the word "analyte" requires quantitative measurement. Nor could it. Although the word "analyte" is not defined in general dictionaries of the English language, the term is used in specific fields of technology including analytical chemistry, and within that field is defined as the component of a sample that is to be determined. See, e.g., Douglas A. Skoog et al., Fundamentals of Analytical Chemistry 1 (7th ed. 1996) ("The components of a sample that are to be determined are often referred to as analytes."). This definition corresponds closely to the definition adopted by the district court, that is, "the substance that the test is designed to detect if present in the liquid being tested."

The law is clear, however, that a patentee may be his own lexicographer (see Renishaw PLC v. Marposs Societa' per Azioni,

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158 F.3d 1243, 1249, 48 USPQ2d 1117, 1121 (Fed. Cir. 1998)), and Syntron argues that Abbott did so here, defining analyte to require quantitative analysis because the patentee explicitly defined the term in the specification as "any chemical moiety which is to be measured quantitatively." (Appellee's Br. at 40.). However, "the patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." Id. (emphasis added) (quoting In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)). Thus, the issue is whether the patentee here defined "analyte" with reasonable clarity, deliberateness, and precession. The definition cited by Syntron is provided in the Summary of the Invention section of the patents-in-suit, and provides in its entirety:

As used herein, "analyte" refers not only to the particular chemical moiety for which analysis is desired, but also to chemical moieties that are reaction products of the moiety to be determined with another chemical moiety. For example, a biological fluid containing an unknown amount of a chemical moiety may be reacted in solution or otherwise with another chemical moiety to provide a product, the concentration of which is related to the initial concentration of the chemical moiety to be measured. The resulting product, then, may become the "analyte" for use in the apparatus and method of the invention. Accordingly, "analyte" refers to any chemical moiety which is to be measured quantitatively.

'484 patent, col. 3, ll. 18-31.

We hold that the passage cited by Syntron, taken in context, does not provide reasonable clarity, deliberateness, and precision sufficient to narrow the definition of the claim term in the manner urged. The first portion of the cited passage defines the word "analyte" in terms of the "moiety for which analysis is desired" and "reaction products of the moiety." Id. at col. 3, ll. 18-22. This portion of the definition comports with the district court's definition of the word as the substance of interest. The last sentence provides a different definition. Because the specification provides two alternative definitions for the term at issue, the specification does not define the claim term in the manner required under Renishaw. As correctly construed, therefore, the ordinary meaning of "analyte" as used to instruct the jury is the proper construction, and there is no basis for setting aside the verdict of noninfringement of claims 22 and 23 of the '484 patent on this ground.
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1. Analyzing

The term "analyzing" appears in Claims 1 and 5. Metametrix argues that analyzing means "using Gas Chromatography-Mass Spectrometry (GC/MS) to identify compounds by comparison to a library of known compounds." Plaintiffs argue that analyzing means "using Gas Chromatography-Mass Spectrometry (GC/MS) or a similar means to identify compounds by comparison to a library or database of known compounds." Plaintiffs' definition is broader in two key respects: 1) plaintiffs' definition includes the possibility that "other similar means" may be used in analyzing; and 2) plaintiffs' definition includes the possibility that the standards may be drawn from a "database" of known compounds and not just a library. Metametrix argues that plaintiffs are attempting to expand the definition beyond the specification.

The court is in agreement with plaintiffs. Although the inventor identified one means of measuring quantities of organic compounds, this was not to the exclusion of other existing technology. The identification of the use of GC/MS in the preferred embodiment should not be used to limit the type of instrument used to make measurements. "References to a preferred embodiment, such as those often present in a specification, are not claim limitations." Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988) (citing Int'l. v. Matsushita Elec. Corp., 775 F.2d 1107, 1121, 227 USPQ 577, 589 (Fed. Cir.1985) (en banc). Importing such a limitation would be equivalent to arguing that the patent specifies using a wooden ruler, and thus the use of a tape measurer is not contemplated by the patent. Such an approach is counterintuitive and unduly restricts an inventor's patent.

Therefore, the court adopts plaintiffs' definition.
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1. "analyzing"

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Claims 1, 2, 7, 8, 13, 14, 19, and 20 contain the phrase "analyzing the coding sequence of a gene derived from a [Bt]." Monsanto argues that the "analyzing" step must involve looking at the actual nucleotide sequence of the gene that is to be modified, and must include something more rigorous than merely looking at that sequence. Mycogen argues that this step can be done by either looking at the actual nucleotide sequence, or by any other method that allows one to determine the preferred codons and frequency of codon usage of the starting gene. For instance, Mycogen argues that the analyzing step is satisfied where one begins with a previously-prepared codon frequency table.

Monsanto points to a representation made by Mycogen in the prosecution of the '831 patent, in which it distinguished between the '831 claims and a previously disclosed method of truncating genes ("the Barton article"). Mycogen wrote to the patent examiner that its claims "explicitly require an analyzing step, which Barton does not disclose or employ." (D.I. 134, tab 22, p. 15). Monsanto argues that this statement is evidence that "analyzing" must involve something more than merely looking at a coding sequence, which would occur while truncating a gene.

Monsanto also points to the declaration of Dr. Michael Murray, executive director of applied genetics at Mycogen, again from the '831 patent prosecution. In his declaration, Dr. Murray describes the patented invention, and uses such words as "selection," "determination," and "comparison," when describing how one determines the modifications to be made. Monsanto argues that these must all be components of any "analyzing" step.

Neither party produces any evidence that the word "analyzing" has some special meaning in the art, or that the patent attaches a specific definition to that word. In fact, the parties do not dispute the meaning of the word "analyzing." Rather, the parties' arguments all appear to relate to the intensity with which one must analyze in order to satisfy the claim, or to the type of information that must be analyzed. These are not claim construction issues, but rather should be taken up when considering whether defendants have infringed, or whether the claims of the patent are valid. Since the court is only concerned with issues of claim construction at this time, and there is no apparent dispute over the meaning of any of the terms, the court does not need to resolve this dispute.
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10. "Analyzing Said Plurality of Amplified DNA Sequences"

GTG proposes the construction "observing any variation in the DNA sequence using any technique," and Applera proposes "applying the selected technique to said plurality of amplified DNA sequences."

The court adopts GTG's position. There is no indication in the claim language that limits the type of analysis that may be performed. Applera's proposed construction improperly imports limitations from the specifications into the claims. Texas Digital, 308 F.3d at 1204-05; Teleflex, 299 F.3d at 1326. The term is thus construed as: observing any variation in the DNA sequence using any technique.
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2. Claims 2, 5, and 10 of the '561 Patent - "anaphylactic manifestations"

The court is not persuaded by the defendants' remaining indefiniteness arguments. The defendants assert that the term "anaphylactic manifestations" is indefinite. The court disagrees, and finds that this term can be construed to have a definite meaning that would be readily understood by a person of ordinary skill in the art. Specifically, the court agrees with the plaintiffs that a person of ordinary skill in the art would readily interpret "anaphylactic manifestations" in thecontext of the patents-in-suit as a reference to the Grade 4 hypersensitivity reaction known as anaphylaxis and the symptoms associated therewith — particularly shock. (See Tr. 117:22-119:14 (discussing the various grades of hypersensitivity reactions under the NCI's Common Toxicity Criteria, under which grade 4 is anaphylactic shock).) The term does not extend to all symptoms (e.g., hives and bronchospasms) that are (or can be) associated with anaphylaxis, regardless of whether the patient is actually suffering from anaphylaxis itself. Rather, the term refers to those symptoms when — and only when —

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the patient is actually suffering from anaphylaxis. In other words, the '561 Patent requires that the formulation be capable of being injected without causing anaphylaxis and, by extension, the symptoms associated with anaphylaxis. With this reasonable construction, the term "anaphylactic manifestations" is not indefinite.
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The parties dispute the meaning of "and" in Claim 1. The word "and" has multiple dictionary definitions. Webster's Third New International Dictionary defines "and" to mean, inter alia: "along with or together with" or "as a function word to express . . . reference to either or both of two alternatives." WEBSTER'S 3d NEW INTERNATIONAL DICTIONARY at 80 (Merriam-Webster 1993) ("Webster's"). Mylan contends that "and" as used in the '006 patent means "along with or together with" and can only be used in the conjunctive sense. (Def. Post-Markman Br. at 6-7.) n3 Ortho contends that "and" is properly being used in the '006 patent to express alternatives. (Pl. Post-Markman Br. at 4-5; Pl. Claim Constr. Br. at 13-14.) The Court agrees with Ortho. n4

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n3 Mylan relies on Patient Transfer Sys. v. Patient Handling Solutions, Inc., 2000 U.S. Dist. LEXIS 7648, No. 97-1568, 2000 WL 726792, at *3 (E.D. Pa. June 6, 2000), for the proposition that "and" should be understood only in its conjunctive sense. (Def. Post-Markman Br. at 8.) The court in Patient Transfer held that "and" should have a consistent meaning throughout the patent. Patient Transfer, 2000 U.S. Dist. LEXIS 7648, 2000 WL 726792, at *3-*4. The controversy in Patient Transfer, however, was whether "and" could be read as "and/or," which was not listed in Webster's as a definition for "and." 2000 U.S. Dist. LEXIS 7648, [WL] at *3. Limiting "and" to a single meaning here would conflict with the principle that a word should have its full range of dictionary meanings that are proper within the context. See Tex. Digital, 308 F.3d at 1202-03.

n4 This case is distinguishable from T.F.H. Publ'ns., Inc. v. Hartz Mt. Corp., 67 Fed. Appx. 599, 601 (Fed. Cir. 2003), where the claim read "formed by the reaction of aliphatic dicarboxylic acid and aromatic diisocyanate." (emphasis added). The court held that since the direct reaction of these two chemicals could not form the patented product, which the "and" implied it could, the patent was invalid. 67 Fed. Appx. 599 at 604. There was no other way to read the disputed language in TFH, whereas here, in the context of the claim, "and" is consistent with a dictionary definition, in that "and" can reasonably express alternatives.

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Ortho used "and" to express alternatives in the '006 patent and patent specification, stating: "R[2], R[3], R[4] and R[5] are independently hydrogen or lower alkyl and R[2] and R[3] and/or R[4] and R[5] together may be a group of the following formula (II)." U.S. Patent No. 4,513,006 (emphasis added). Claim 1 describes R[2] through R[5] when they are in two different conditions. In one condition, R[2] through R[5] are independent of each other and either hydrogen or lower alkyl. In the second condition, R[2] and R[3] are paired together and/or R[4] and R[5] are paired together, creating topiramate, as expressed in formula (II). Claim 1 signals the use of "and" to express alternatives by using the word "independently" to describe one set of circumstances and the word "together" to describe another.

Nothing in this construction requires that R[2] through R[5] must always be hydrogen or lower alkyls as Mylan contends. Instead, R[2] through R[5] must be hydrogen or lower alkyls when they are independent of each other. When R[2] and R[3] and/or R[4] and R[5] are together, they are permitted to be of the group described in formula (II). This case, unlike Chef America, does not revolve around one word changing the meaning of the entire claim. Here, Ortho's use of "and" in Claim 1 might not be the most common use of the word, but it is a permissible use of the word as defined by Webster's. n5 The Court, accordingly, finds that the plain language of Claim 1 expresses alternative chemical structures such that topiramate is expressly claimed by the '006 patent.

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n5 The parties have argued over whether the claim would be permissible if "or" were used in place of "and." (See Pl. Post-Markman Br. at 7-8; Def. Post-Markman Br. at 5-6.) Such an argument is irrelevant since the patentee is bound by the words

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in the patent. See Nellcor Puritan Bennett, Inc. v. Masimo Corp., 402 F.3d 1364, 1369 (Fed. Cir. 2005) ("While it may be that, in hindsight, the patentees would have been wise to choose a word other than 'filtered,' it is clear that they meant for that term to describe the 'relative reduction' process set forth in the specification.").

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The prosecution history also demonstrates that topiramate is claimed by the '006 patent. During the patent prosecution history, the patent examiner struck a portion of independent Claim 1, and the dependent claims stemming from it. See supra Background, III. The examiner, however, did not strike the disputed language in Claims 1 and 5, the language that specifically claims topiramate. See id. The prosecution history, thus, demonstrates that the patent examiner considered both formulas (I) and (II) to be part of the same claim. Instead of disavowing any claim to formula (II) and topiramate, the patent prosecution history was clearly directed to topiramate. This interpretation of the prosecution history is consistent with the context of the '006 patent, as well as the plain language the '006 patent and the patent specification. n6 The Court, accordingly, finds that the prosecution history demonstrates that Claim 1 of the '006 patent may be properly construed to claim topiramate.

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n6 See Renishaw, 158 F.3d at 1250.

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2. treatment of urolithiasis and inhibiting bone reabsorption

Defendants argue that Claim 1 of the '077 Patent should be construed as requiring the treatment of both urolithiasis and the inhibition of bone reabsorption. (D.I. 107 at 4-9). According to the Defendants, claim 1 expressly requires the treatment of both conditions in one patient. (D.I. 107 at 4). In support of their proposed construction, Defendants direct the Court to Northern Telecom Ltd. v. Samsung Electronics Co., 215 F.3d 1281 (Fed. Cir. 2000). Defendants contend that Northern Telecom is on point because the Federal Circuit construed the word "and" to mean "both", and Defendants urge the Court to adopt the same reasoning in this case. (D.I. 107 at 6).

Additionally, Defendants argue that the prosecution history supports the conjunctive use of the word "and" in claim 1. Specifically, Defendants point out that the Italian application leading to the '077 Patent contained a claim to a method of treatment for urolithiasis and another claim for the inhibition of bone reabsorption. (D.I. 107 at 6; DTX 20). Later, when it filed its U.S. application, Gentili combined the treatment of urolithiasis and inhibition of bone reabsorption into a single claim. (D.I. 107 at 6; DTX 20). The examiner then rejected the composition claim and indicated that a method of use claim would be favorably considered. (D.I. 107 at 6; DTX 2 Tab 10). Gentili then submitted a single method of use claim for the treatment of urolithiasis and inhibiting bone reabsorption. (D.I. 107 at 6). Defendants contend that this demonstrates that Gentili intended the '077 Patent to be a single method that involved using alendronic acid to treat two conditions. (D.I. 107 at 6). In further support of this contention, Defendants point to the testimony of Ms. Fernanda Fiordalisi, the attorney who prosecuted the '077 Patent, who testified that claim 1 is directed to treating both conditions with one compound at the same time. (D.I. 107 at 7; DTX 214 at 99-100).

Defendants further assert that their proposed construction is reasonable in the context of invention. (D.I. 107 at 7). Defendants point to the testimony of their urolithiasis expert, Dr. Coe, who testified that 600,000 people in the United States have both conditions and could benefit from a drug that would deal with both at the same time (D.I. 107 at 7; Coe Tr. 430-431). Dr. Coe further testified that at the time the patent application was filed, it would have been reasonable for scientists to believe that alendronic acid would work both to treat urolithiasis and inhibit bone reabsorption. (D.I. 107 at 7; Coe Tr. 431).

Defendants also disagree with Merck's dictionary definition of "and." First, Defendants criticize Merck's reliance on a single dictionary for their definition. (D.I. 113 at 2). Second, Defendants assert that, even in the single dictionary that Merck cites to, the principle meanings of "and" are listed as: along with or together with, added to or linked to, as well as and at the

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same time. (D.I. 113 at 3; Websters Third International Dictionary 80 (1986)). Additionally, Defendants argue that the "or" interpretation of the word "and" is only used when two alternatives are plainly inconsistent. (D.I. 113 at 3). Defendants assert that the treatment of urolithiasis and inhibiting bone reabsorption are not inconsistent alternatives and therefore the "or" interpretation is inapplicable in this case. (D.I. 113 at 3).

Defendants further contend that even though the abstract to the specification uses the word "or" instead of "and", the abstract, according to 37 C.F.R. § 1.72 , cannot be relied upon when interpreting claims. (D.I. 113 at 3). Additionally, Defendants argue that, even though the specification did not disclose an example of the simultaneous treatment of urolithiasis and inhibition of bone reabsorption, it discusses the use of the compounds for both purposes and combining those uses into a single method is consistent with the patent. (D.I. 113 at 4). Thus, Defendants assert, both the intrinsic and extrinsic evidence support their proposed claim construction. (D.I. 107 at 8).

In response to Defendants' proposed claim construction, Merck contends that the phrase "a method of treatment of urolithiasis and inhibiting bone reabsorption" means that the method can be used to treat either condition, but does not require the treatment of both conditions at the same time and in the same patient. (D.I. 106 at 18). In support of their contention, Merck relies on Webster's Third International Dictionary which defines "and" to express "reference to either or both of two alternatives … especially in legal language when also plainly intended to mean or." (D.I. 106 at 18; Webster's Third New International Dictionary 80 (1986)).

Merck also argues that the specification supports their proposed construction. For example, Merck argues, the specification never mentions the two conditions being treated simultaneously. (D.I. 113 at 18). Further, Merck asserts that the abstract to the '077 Patent states that biphosphonic acids are valuable in "the treatment of urololithiasis or in the treatment as inhibitors of bone reabsorption." ('077 Patent, Abstract). Moreover, Merck contends that Tables 7 and 8 in the specification would be meaningless under Defendants' proposed construction because they only disclose results relating to the inhibition of bone reabsorption and not the treatment of urolithiasis. (D.I. 114 at 5). In regard to the prosecution history, Merck asserts that the amendment of the claims, combining the claims dealing with urolithiasis and the inhibition of bone reabsorption, reinforces the fact that claim 1 describes the treatment of the two conditions in the alternative. (D.I. 114 at 6).

Merck also directs the Court to U.S. Patent Nos. 4,054,598 (" '598 Patent") and 4,267,108 (" '108 Patent") to support its contention. (D.I. 106 at 19). Merck asserts that Defendants construe "and" differently in reference to these patents. Specifically, Merck argues that Defendants construe the terms "pharmaceutical and cosmetic preparations" in these patents to mean pharmaceutical or cosmetic preparations. Thus, Merck contends that Defendants adopt different lexicons for the term "and" when it suits their purpose. (D.I. 106 at 19).

Additionally, Merck directs the Court to Thomson Consumer Electronics, Inc. v. Innovatron, 43 F. Supp. 2d 26 (D.C.C. 1999). The Court, in Thomson, held that a strict interpretation of the word "and" would be inconsistent with the patent's specification. Id. at 34. Merck argues that the Thomson case is analogous to the claim in issue, where a strict interpretation of "and" would be inconsistent with the '077 Patent specification. (D.I. 106 at 21). Merck also distinguishes the Northern Telecom case from the instant case because the court was not construing the term "and", but was in fact construing the term "aluminum." (D.I. 106 at 21). As a result, Merck argues, Northern Telecom does not support Defendants' proposed construction. (D.I. 106 at 21).

Merck argues that a conjunctive reading of the term "and" would lead to an absurd result. In support of this argument Merck contends that the diseases are unrelated and only a minuscule percent of people have both disorders. Merck asserts that only 3% of people who have osteoporosis suffer from both disorders. Additionally, Merck argues that this type of limitation in the patent, without any indication in the patent itself, is unreasonable. (D.I. 106 at 23).

Lastly, Merck contends that Defendants improperly utilized extrinsic evidence when intrinsic evidence was available and unambiguous. See Bell & Howell Document Management Prod. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)); (D.I. 114 at 3). Specifically, Merck argues that reliance on the testimony of Ms. Fiordalisi, the patent lawyer who prosecuted the '077 Patent, is improper. (D.I. 114 at 3). Further, Merck argues that even if Ms. Fiordalisi's testimony were properly considered, it is entitled to no weight because Ms. Fiordalisi, who is 80 years old and who prosecuted the patent over 15 years ago, was questioned about a claim that she barely reviewed during her deposition. (D.I. 114 at 3). As a result of the aforementioned arguments, Merck urges the court to construe claim 1 to cover the treatment of urolithiasis or bone reabsorption.

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After reviewing the claim language, specification, prosecution history and extrinsic evidence, the Court agrees with Merck's interpretation of this language. Specifically, the Court concludes that claim 1 of the '077 Patent does not require the simultaneous treatment of urolithiasis and bone reabsorption in the same patient. Additionally, the Court finds that the intrinsic evidence is ambiguous and therefore will also examine extrinsic evidence. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996)(noting that if the intrinsic evidence is ambiguous the Court may examine extrinsic evidence in construing claims). 2 The Court will examine the intrinsic evidence and will also consider the statistics on the occurrence of urolithiasis and bone resorption in the same patient, the dictionary definition of "and", and Ms. Fiordalisi's testimony.

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2 It is important to note that there is an inconsistency in Merck's argument. Merck argues that Defendants improperly utilized extrinsic evidence in the context of Ms. Fiordalisi's testimony, however, Merck utilized statistics on the occurrences of urolithiasis and bone resorption in the same patient, and a dictionary definition of "and" which are extrinsic evidence.

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The Court finds that Merck's construction is supported by the specification. Specifically, the Court finds that the abstract is a useful source in determining the meaning of a claim. 3 See Floors, Inc. v. Maxcess Technologies, Inc., 222 F.3d, 958, 966 n.2 (Fed Cir. 2000)(stating that the abstract of a patent is potentially useful for determining the meaning of a disputed claim); Hill-Rom Co. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1341 3.* (Fed Cir. 2000) (same). The abstract of the '077 Patent recites Merck's proposed claim construction stating that biphosphonic acids are valuable in "the treatment of urololithiasis or in the treatment as inhibitors of bone reabsorption." ('077 Patent, Abstract). Further, Tables 7 and 8 of the specification disclose results relating to the inhibition of bone reabsorption and not urolithiasis; if Defendants' proposed construction were accepted these tables would be meaningless. Thus, in the Court's view, the abstract and specification demonstrate that urolithiasis and inhibition of bone reabsorption do not have to be treated simultaneously in the same patient for purposes of claim 1 of the '077 Patent.

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3 The Court finds that Defendants' assertion that the abstract is disallowed in claim construction is incorrect. Specifically, the Federal Circuit has stated "section 1.72(b), however, is a rule of the Patent and Trademark Office … it does not address the process by which courts construe claims in infringement actions." Hill-Rom Company, Inc. v. Kinetic Concepts, Inc., 209 F.3d 1337, 1341 n* (Fed. Cir. 2000).

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The Court also finds that the prosecution history of the '077 Patent supports Merck's construction. The treatment of urolithiasis and inhibiting bone reabsorption were initially in separate claims. However, Gentili amended the claim and combined the treatment of both diseases into one claim. This amendment reinforces the conclusion that the two diseases are treated in the alternative for purposes of claim 1. Moreover, Defendants' construction of "and" in the '598 and '108 patents, in reference to "pharmaceutical and cosmetic preparations", demonstrate the plausibility of Merck's construction.

Additionally, in reference to the extrinsic evidence, only 3% of people with osteoporosis suffer from both urolithiasis and excessive bone resorption. (D.I. 106 at 23). This would significantly limit the patent and is unreasonable. Also the Court finds the "or" construction of "and" listed in Webster's Third International Dictionary persuasive. Further, the Court gives Ms. Fiordalisi's testimony little weight due to the fact that she was questioned fifteen years after the prosecution of the patent and given little time to actually review the patent.

In addition, the Court finds that Northern Telecom is inapposite because the Federal Circuit was construing the term "aluminum" rather than "and" as in the claim in issue. The Court, however, finds this issue to be analogous to the issue in Thomson Consumer Electronics, Inc. v. Innovatron, 43 F. Supp. 2d 26 (D.C.C. 1999). In Thomson, the District of Columbia District Court had to construe the term "and". The Court held that the term "and" was construed as "or" because if the conjunctive meaning of "and" were adopted it would lead to an absurd result and the specification suggested the "or"

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construction of the term. See Thomson, 43 F. Supp. 2d at 34-35. The claim in issue is highly analogous to Thomson because if the term "and" was used conjunctively it would render the results depicted in Tables 7 and 8 meaningless. Moreover, the abstract of the '077 Patent recites the "or" construction.

For these reasons, the Court concludes that the term "and" should be construed to mean "or". Specifically, the Court concludes that claim 1 of the '077 Patent allows for the treatment of urolithiasis or inhibiting bone reabsorption.
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B. Angres takes issue with the district court's analysis regarding anticipation on two fronts: first, asserted legal errors in the district court's claim construction under Markman v. Westview Instruments, 52 F.3d 967, 34 U.S.P.Q.2D (BNA) 1321 (Fed. Cir. 1995) (in banc), aff'd 134 L. Ed. 2d 577, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461 (1996), and second, perceived problems with Pavlik's testimony accompanying the motion for summary judgment.

With respect to the claim construction, Angres argues that the limitation "anesthetizing the portion of the eye lid . . ." does not encompass "freezing" or application of "cold water." The district court, following what it perceived as the "ordinary meaning" of the term, held that it did. We review the district court's claim construction de novo. Markman, 52 F.3d at 975, 34 U.S.P.Q.2D (BNA) at 1326. Angres argues both that the written description varies the meaning of the words in the claims from their ordinary usage and that the district court improperly relied on extrinsic evidence (Angres's own testimony and that of Pavlik) when the meaning of the disputed term in the claims is clear when read in light of the specification and file history. For the proposition that the intrinsic evidence limits the claim to not cover use of cold water or ice, Angres cites to the "Description of the Preferred Embodiment" at col. 3, ll. 41-43, which states, "Any intradermal anesthetic can be used, such as solutions of novocaine, xylocaine, or the like." Following that sentence, the written description states that in the preferred embodiment, "an anesthetic solution is used comprising 2cc 2% xylocaine, epinephyrine, and hyalurondaze." The preferred embodiment section also discloses the use of a needle and massage of the skin after injection. The preferred anesthetic solution is specifically recited in claim 4.

Angres argues that one skilled in the art would read claim 1 to mean "anesthetizing" by use of a "medical" (i.e., prescription) anesthetic, not ice water or cold water. We disagree. While a patentee may be his own lexicographer, in order to vary the ordinary meaning of the words of a claim a patentee must clearly define the term as used in the claim in the specification. Markman, 52 F.3d at 980, 34 U.S.P.Q.2D (BNA) at 1330; Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578, 38 U.S.P.Q.2D (BNA) 1126, 1129 (Fed. Cir. 1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning.") (citations omitted). Here, Angres's written description merely indicates that in the known best mode of practicing the invention, an injected liquid "medical" anesthetic like xylocaine is used. Angres is not entitled to have his claims limited to the best mode disclosed in the written description unless he specifically defined "anesthetized" to mean injected with the solution in his written description. We hold that he did not.

A skilled artisan (see infra) reading the patent document would not conclude that "anesthetizing" was specifically defined in the written description. Rather, the district court correctly held that, as used here, "anesthetizing" means "to render physically insensible" to pain and other sensations. While it is true, as Angres asserts, that only Dorland's Illustrated Medical Dictionary, 26th ed., specifically mentions refrigeration as a method of anesthesia (crymoanesthesia), none of the other sources of the common understanding in this art of the word specifically exclude freezing or cooling. 2 Rather, these sources define anesthesia in functional terms, as is done in the patent. The purpose of anesthetic is to reduce pain; in the patent, the eyelid is anesthetized so that the person desiring tattooed eyeliner will not suffer undue discomfort or move excessively while the procedure is taking place. Since claim 1 is drafted in broad terms, and "anesthetizing" is not clearly limited by the specification, any method which achieves those goals meets the limitation of the claim. Moreover, claim 4 (which was not asserted) requires anesthetization by injection with a specified prescription solution; this lends support to the construction that claim 1, which has no such "injection," formula or prescription limitations, has a broader scope. See D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574, 225 U.S.P.Q. (BNA) 236, 239 (Fed. Cir.1985) (claim differentiation).

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2 As noted in Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6, 39 U.S.P.Q.2D (BNA) 1573, 1578 n.3 [sic - 6], "Although technical treatises and dictionaries fall within the category of extrinsic evidence, . . . judges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claims terms, as long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents."

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Angres next cites Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1576, for the proposition that even if the written description does not clearly define "anesthetizing," one skilled in the relevant art would recognize that use of ice or cold water would not fall within the meaning of the claim. 3 Further, Angres claims that the artisan is a doctor, and not a tattooist, although Angres argues that even a tattooist would not consider use of cold "anesthetizing."

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3 To support this, Angres cites the declaration of Dr. Stephen VanCampen, M.D., an anesthesiologist, who stated "It is my [expert] opinion that the application of ice or ice water is insufficient to cause anesthesia to do [the] procedure [in the patent] . . . the temperature of the skin must be lowered enough to block nerve conduction, which in turn would cause permanent damage . . . ." The VanCampen declaration was properly rejected because it is inconsistent with the plain language of the claims and the specification. It further conflicts with the testimony of Pavlik, who testified in her affidavit that she performed the procedure without medical anesthetic.

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Although the district court only addressed the relevant skill in the art with respect to obviousness, not claim construction, by implication the district court correctly determined no genuine issues of material fact existed as to the relevant skill in the art and that the relevant artisans are both tattooists and doctors. While a tattooist could not perform the best mode without the assistance of a doctor to administer injected, prescription anesthetic, tattooing was an old art and Angres does not dispute that permanent make-up had been tattooed prior to the issuance of the '106 patent without medical assistance. There is nothing "surgical" about the procedure: the needles used to inject the pigment are similar or identical to the needles used by tattooists to mark other parts of the body. If the relevant artisans include tattooists, then use of cold to reduce pain is clearly within the scope of the patent. 4 Even if the relevant artisans were limited to doctors, however, the medical dictionaries cited by Angres do not exclude freezing and define "anesthesia" broadly; depending on the situation, a doctor could reasonably select from a number of methods for reducing pain, some of which require an injection of prescription medication, and some of which, like ice, do not.

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4 Angres cites Pavlik's testimony in which Angres claims she (Pavlik) equated "anesthetic" with "medication." However, Pavlik merely answered that she did not use any "medication" in response to a question about whether she used "topical anesthetic." Immediately after that statement, she stated she used cold water. Pavlik's statements do not lead to the conclusion that she equated anesthetic with medication only. Further, under Vitronics Pavlik's testimony may not be relied upon to vary the plain meaning of the claim. Vitronics, 90 F.3d at 1584, 39 U.S.P.Q.2D (BNA) at 1578.

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Angres's arguments that tattooing frozen flesh is impossible (since either the needle would bend and the lid could not be properly stretched as described in the preferred embodiment) or that freezing must necessarily kill the flesh are similarly unavailing. No evidence was submitted to show that skin which is cooled sufficiently to reduce pain cannot be punctured; in fact, the only testimony on that issue was Dr. Angres's statement in deposition that the anesthetizing step can be performed "any number of ways" including freezing, "hypothermia or cryo." Angres's testimony may not be relied upon to vary the intrinsic plain meaning of the patent, but may be to confirm that the plain meaning of the claims includes use of cold. See Vitronics, 90 F.3d at 1584, 39 U.S.P.Q.2D (BNA) at 1518. Accordingly, the district court correctly construed the claims under Markman.

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VI. Claim Construction of "Animal"

All asserted claims of the '244 patent are directed to methods for achieving high concentrations of omega-3 HUFA in an "animal." '244 Patent col.1 ll.21-24, col.2 ll.17-19, col.9 l.44-col.10 l.58. The district court construed the claim term "animal" to mean "any member of the kingdom Animalia, except humans." Claim Construction Order at 2. Based on the court's construction, Martek stipulated that Lonza does not infringe the '244 patent claims, because neither Lonza nor its customers use the claimed methods to provide omega-3 HUFA to non-human animals. See Stipulated Order Of Non-Infringement at 1, Martek Biosciences Corp. v. Nutrinova Inc., No. 03-896 (D. Del. Apr. 21, 2006); Cross Appellant's Br. at 9. Martek now appeals the district court's claim construction, arguing it is erroneous in light of the patent's stated definition of "animal." We review such issues of claim construction without deference. See Cybor Corp., 138 F.3d at 1456. For the following reasons, we agree with Martek.

When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls. See Phillips v. AWH Corp., 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc) ("[T]he specification 'acts as a dictionary when it expressly defines terms used in the claims . . . .'" (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)); id. at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."); see also Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 493 F.3d 1358, 1361 (Fed. Cir. 2007) ("When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term."); 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1374 (Fed. Cir. 2003) ("Because 3M expressly acted as its own lexicographer by providing a definition of embossed in the specification, the definition in the specification controls the meaning of embossed, regardless of any potential conflict with the term's ordinary meaning as reflected in technical dictionaries."). Here, Martek explicitly defined the term "animal" in the '244 patent: "The term 'animal' means any organism belonging to the kingdom Animalia." '244 Patent col.5 ll.11-12. That definition controls. Thus, because it is undisputed that humans are members of the kingdom Animalia, 5 it was error for the district court to limit the claim term "animal" to exclude humans.

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5 Lonza does not dispute that humans are members of the kingdom Animalia. Indeed, the record contains evidence detailing the full hierarchical classification of a human as follows--Kingdom: Animalia, Phylum: Chordata, Subphylum: Vertebrata, Superclass: Tetrapoda, Class: Mammalia, Order: Primates, Family: Hominidae, Genus: Homo, Species: Homo sapiens. Helena Curtis & N. Sue Barnes, Invitation to Biology 240 (4th ed. 1985); see also Neil A. Campbell et al., Biology 723 (8th ed. 2008) (explaining that humans are mammalian primates in the kingdom Animalia).

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Lonza, however, argues that when the '244 patent specification is considered in its entirety, it clearly limits the claim term "animal" to non-human animals. See Phillips, 415 F.3d at 1313 ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."). For the following reasons, Lonza's arguments are unpersuasive.

First, the disclosure and enumeration of preferred non-human animals does not constitute a clear and manifest disavowal of human animals. The '244 patent states:

> The term "animal" means any organism belonging to the kingdom Animalia. Preferred animals from which to produce a food product include any economic food animal. More preferred animals include animals from which eggs, milk products, poultry meat, seafood, beef, pork or lamb is derived. Milk products include, for example, milk, cheese and butter.

'244 Patent col.5 ll.11-17. Although the patent contemplates that certain animals are "[p]referred animals from which to produce a food product," that statement does not disavow human animals because it relates to preferred embodiments only; it does not state that all animals covered by the claims must produce a food product. As we have explained:

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[P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect. And, even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1117 (Fed. Cir. 2004) (citations and internal quotation marks omitted). Here, the patentee has used no words or expressions that manifestly exclude coverage of humans, and thus, it would be improper to override the patentee's express definition of "animal" to limit the scope of the claims. Moreover, the patentee's use of modifying language to specify "[p]referred animals" as "economic food animal[s]" ultimately supports a broad construction of the unmodified term "animal" that includes non-food animals, such as humans. 6 In summary, absent a clear intention to restrict the invention to particular members of the kingdom Animalia, we cannot limit the claims to the listed preferred embodiments. See id.

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6 The dissent focuses on statements in the patent that allegedly distinguish between humans and other animals. See, e.g., '244 Patent col.7 ll.51-54 ("[T]he whole-cell biomass can be used directly as a food additive to enhance the omega-3 highly unsaturated fatty acid content and nutritional value of processed foods for human intake or for animal feed." (emphasis added)). The dissent asserts that if the term "animal" includes human animals, "[t]here would have been no need to distinguish between what will be eaten by humans and what will be eaten by animals." See Dissenting Op. at 4. However, as noted here, if the general term "animal" encompasses only non-human food animals, there would have been no need for the patentee to describe preferred animals as "food animal[s]." The fact that the patentee chose to distinguish food animals from other animals indicates that the general term "animal" encompasses nonfood animals, such as humans. And certainly, the isolated statements cited by the dissent do not rise to the level of "a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction," Innova/Pure Water, 381 F.3d at 1117 (internal quotation marks omitted), as would be necessary to override the patentee's explicit lexicography.

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Second, contrary to Lonza's assertions, the '244 patent does not otherwise contain language that can be fairly interpreted as a clear intention to disclaim coverage of humans. See id.; Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language."). For example, the fact that the claims refer to "raising" and "feeding" animals does not clearly disclaim humans. Lonza cites no persuasive reason, and we can think of no reason, why those two generic terms do not apply to human animals. Likewise, the fact that some dependent claims are directed to certain types of animals--such as cows, sheep, and goats--does not limit the scope of broader claims directed more generally to "an animal." In fact, the patent plainly contemplates that the invention is applicable to humans. See, e.g., '244 Patent col.7 ll.8-11 ("The purified omega-3 highly unsaturated fatty acids can then be used as a nutritional supplement for humans, as a food additive, or for pharmaceutical applications."); id. at col.7 ll.42-45 ("As discussed in detail above, the whole-cell biomass can be used directly as a food additive to enhance the omega-3 highly unsaturated fatty acid content and nutritional value of processed foods for human intake or for animal feed."); id. at col.7 ll.51-54 ("A further aspect of the present invention includes introducing omega-3 HUFAs from the foregoing sources into humans for the treatment of various diseases."). Thus, we are "governed by the principle that '[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 (Fed. Cir. 2004) (quoting Northrop Grumman Corp. v. Intel Corp., 325 F.3d 1346, 1355 (Fed. Cir. 2003)). Under our precedent, because the patent does not clearly disclaim coverage of humans, it would be erroneous to limit the claims to certain types of animals that the inventor anticipated would prove useful in the invention. That is especially true in the present case because the patent expressly defines the claim term "animal" broadly enough to encompass humans and discloses uses of the claimed invention applicable to humans.

Finally, Lonza asserts that the extrinsic evidence of record demonstrates that the ordinary meaning of "animal" is a non-human animal. Appellant's Reply Br. at 57. In this case, because the patentee explicitly defined "animal," Lonza's extrinsic evidence is simply irrelevant. See, e.g., Honeywell Int'l, 493 F.3d at 1361 ("When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term.").

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For the foregoing reasons, we hold that the district court's claim construction is erroneous. The proper construction for the claim term "animal" is the one explicitly provided by the patentee: "any organism belonging to the kingdom Animalia," which includes humans. Thus, we reverse and remand for further proceedings under the correct construction.

We have considered the parties' remaining arguments, and we find them unpersuasive.
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With respect to the '199 Patent, the parties contest the terms appearing in Claim 1:

An isolated hydrosoluble salt of creatine of the formula:

[SEE ILLUSTRATION IN ORIGINAL]

wherein A- represents the anion of citric, maleic, fumaric, or malic acid.

An anion generically refers to an ion that has a single or multiple negative charges. The number of negative charges an anion contains determines the number of molecules having a single positive charge (such as creatine) with which it can react. Thus, for example, an anion of citric acid containing two negative charges can react with two molecules of creatine (forming di-creatine citrate). The parties dispute whether "anion" has such a broad definition when it appears in Claim 1 of the '199 patent.

Allmax asserts that the disputed term means "wherein A-represents the anion (i.e., charged particle with a single negative charge) of citric, maleic, fumaric or malic acid." In support thereof, Allmax suggests that the specification for the '199 Patent depicts the anions of the invention with a single "-" and discloses only anions having a single negative charge. It claims that "A" followed by one "-" (as opposed to multiple "-" or "n-" where "n" represents any number of negative charges) would be understood by persons of skill in the art to refer to an anion with a single negative charge, particularly where the claim recites that "A- represents the anion."

Furthermore, Allmax points to the prosecution history during which the applicant for the '199 Patent referred to "the four compounds claimed herein --- salts of creatine with citric, maleic, fumaric, and malic acids." Allmax submits that those four compounds are ones formed by combining creatine and each of the named acids in their ionic form possessing a single negative charge: "creatine citrate", "creatine maleate", "creatine fumarate" and "creatine malate." If the applicant meant to include acids in a form possessing more than a single negative charge (argues Allmax), he would have referred to more than four compounds (those listed in the preceding sentence as well as di-and tri-creatine citrate, di-creatine maleate, di-creatine fumarate and di-creatine malate). 7

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7 Citric acid can carry up to three negative charges (and thus can combine with up to three creatine molecules) whereas the other three acids can carry only up to two such charges (and thus can combine with one or two creatine molecules).

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In addition, Allmax cites to solubility data contained in Table I of the '199 Patent which appears to relate only to salts containing a single negative charge. Finally, it notes that none of the patents citing the '199 Patent as a reference describe it as disclosing anything other than monocreatine salts, thus allegedly indicating how people skilled in the art view the scope of the '199 Patent.

By contrast, Iovate asserts that the term "anion" should not be limited to particles with a single negative charge. It submits that nowhere in the '199 Patent do the inventors state an intention to limit their invention to monocreatine salts. It rejects Allmax's assertion that one skilled in the art would interpret "A-" as referring to an anion with only one negative charge.

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Iovate also rejects Allmax's reliance on the applicant's statement concerning "the four compounds" by explaining that that reference was meant merely to distinguish prior art forms which did not disclose any creatine salts whatsoever and, thus, does not clearly limit the claim scope. Moreover, Iovate argues that Table I is not intended to be limiting, see Phillips, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments"), and that the way in which other patents cite the '199 Patent carries no weight, see Acumed LLC v. Stryker Corp., 483 F.3d 800, 809 (Fed. Cir. 2007) (finding that the usage of a disputed term in other patents merits little consideration).

In place of Allmax's construction, Iovate requests that the Court adopt the construction of Claim 1 reached by Judge Ron Clark of the United States District Court for the Eastern District of Texas in another suit brought by Iovate (to which Allmax was not a party). There, Judge Clark construed Claim 1 to mean:

an isolated … water soluble salt formed by the combination of creatine with one of the ionic (negatively charged) forms of citric, maleic, fumaric or malic acid.

Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc., No. 9:07-CV-46, 2008 U.S. Dist. LEXIS 24989, 2008 WL 859162, at *8 (E.D. Tex. Mar. 28, 2008). He further established that "ionic (negatively charged) forms" refers to "the fact that some acids, like citric acid, can have different forms with one, two, or three negative charges per molecule, depending on solution conditions." Id.

Iovate argues that Judge Clark correctly recognized that the specification for the '199 Patent itself states that "A-represents the anion of a mono, bi- or tri-carboxylic acid" (where a bi-carboxylic acid carries two negative charges and a tri-carboxylic acid has three). Thus, Iovate propounds that the specification expressly contemplates reactions between creatine and anions carrying more than one negative charge.

In response, Allmax reminds the Court that the construction adopted in the Eastern District of Texas is not binding here. See Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp., 540 F. Supp. 2d 1233, 1242 (M.D. Fla. 2008) (noting that even where another district court has construed a patent's terms, "the Court has an independent obligation to determine the meaning of the claims, and to render its own independent claim construction").

Judge Clark's interpretation is, however, entitled to "reasoned deference." See id. (citation omitted). Although some of the evidence offered by Allmax suggests that the inventor of the '199 Patent specifically contemplated monocarboxylic acids, it does not, conversely, suggest that the inventor also specifically contemplated excluding bi- and tri-carboxylic acids. Moreover, the claim specifically uses a generic term, "anion," and does not limit that term to only those particles carrying one negative charge. Accordingly, the Court will adopt Judge Clark's interpretation as Iovate requests.
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Here, the claim construction issue focuses on the claim language "anion of a mineral acid." Purepac urges that the phrase refers to an anion (e.g., chloride ion) from any source that is capable of forming a mineral acid, whereas Warner-Lambert counters that it refers only to anions derived from a mineral acid, namely, hydrochloric acid. Warner-Lambert maintains that such language limits the amount of residual acid, or HCl, for purposes of controlling lactam formation.

The Court adopts Warner-Lambert's claim construction and construes the claim language "anion of a mineral acid" to refer to anions "derived from" a mineral acid. This interpretation is supported by both the intrinsic and the extrinsic evidence.

Turning first to the claim language, the phrase "anion of a mineral acid" arguably supports both parties' constructions. The parties do not dispute the meaning of the terms "anion" and "mineral acid." An "anion" is a negatively charged ion and a "mineral acid" is an inorganic acid, such as hydrochloric acid, sulphuric acid, or nitric acid. The problem is that the claim language "of" does not explain the precise connection between anion and mineral acid. Thus, the phrase could refer to an anion derived from a mineral acid or an anion capable of forming a mineral acid.

The Court believes that Warner-Lambert's construction--that the anions must derive from a mineral acid--makes a better connector with the phrase "a mineral acid." It recognizes that a mineral acid contains an anion and gives full meaning to the

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phrase in that the anion is identified according to its mineral acid source. n4 In contrast, defining the anion according to what it is potentially "capable of" forming, as Purepac does, seems strained and unnecessary. Nonetheless, the Court is not prepared to say that the claim language is unambiguous.

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n4 Warner-Lambert's construction also comports with the primary meaning of the preposition "of" -- "derived or coming from; originating at or from." The American Heritage Dictionary of the English Language (4th ed. 2000).

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Next, the Court turns to the written description of the '482 patent. The written specification does not support Purepac's construction. Purepac basically concedes that point by arguing "the '482 patent's written description offers no aid in discerning the meaning of 'anion of a mineral acid.'" (Purepac Rply. Br. at 10). The question then becomes whether the written specification supports Warner-Lambert's construction.

Purepac argues that the written description, stating that "the proportion of remaining [gabapentin] hydrochloride admixtures should thereby not exceed 20 ppm," ('482 patent, col. 5, 11. 27-29), refers only to keeping the gabapentin hydrochloride admixture below 20 ppm, not to keeping chloride from hydrochloric acid below 20 ppm. Central to this argument is the idea that a "hydrochloride admixture" is entirely different from hydrochloric acid. It follows, according to Purepac, that column 5 includes nothing indicating whether the 20-ppm limit recited in the claims covers only anions derived from mineral acid or all like anions, including anions from both acid and non-acid sources. Warner-Lambert responds that the written description is plainly directed at the need to remove most of the hydrochloric acid from the hydrochloride salt of gabapentin so that the final bulk gabapentin contains less than 20 ppm of this acid (measured as chloride ion).

The Court concludes that the written description, which nowhere defines or uses the phrase "anion of a mineral acid," does not readily aid its claim construction inquiry. The Court thus turns to the prosecution history.

The prosecution history supports construing "anion of a mineral acid" to refer to the amount of mineral acid impurity remaining in the bulk gabapentin. In a December 21, 1993 Declaration, Dr. Herrmann, one of the inventors, reported results of an experiment showing the effect of remaining amounts of hydrochloric acid on stability. (Bartlett Decl., Ex. 3). Dr. Herrmann prepared gabapentin samples according to Warner-Lambert's original gabapentin patent, U.S. Patent No. 4,024, 175 ("the 175 Satzinger patent"). The Satzinger material contained 200 ppm of hydrochloric acid. (Bartlett Decl., Ex. 3 at 5). To determine the stability of the Satzinger material, Dr. Herrmann stored it at room temperature for four months. Based on the observed fifteen-fold increase in the lactam content, he concluded that "this instability can be avoided if specificly [sic] the HC1 content is reduced to 20 ppm as disclosed in the present manufacturing process." (Bartlett Decl., Ex. 3 at 4-5).

Following submission of Dr. Herrmann's Declaration to the Patent and Trademark Office, the Examiner noted at an interview that "Applicants will limit all claims [to] 20 ppm of C1???." (Bartlett Decl., Ex. 4). Warner-Lambert agreed to that change. In a Declaration dated January 25, 1995, Dr. Herrmann described testing done on a gabapentin sample containing 2000 ppm of hydrochloric acid. (Bartlett Decl., Ex. 5 at 8). After reviewing the poor stability results obtained, Dr. Herrmann referred to "the negative effect of small amounts of Gabapentin Hydrochloride in the bulk drug Gabapentin on the stability of this compound." (Id.) All agree that gabapentin hydrochloride is immediately formed from the presence of hydrochloride acid in gabapentin.

In December 1999, the applicants stated in another Submission to the Patent Office that (1) the gabapentin must have "a low level of mineral acid as measured by mineral acid anion, i.e., less than 20 parts per million" and (2) that the Food and Drug Administration's gabapentin chloride specification of 100 ppm differed from the inventors' "20 ppm" chloride specification because the "claim limitation is directed to anions derived from acid, while the specification set forth in the NDA for chloride ion is not limited to that derived from mineral acid." (Bartlett Decl., Ex. 6 at 3, 9-10). n5

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n5 Purepac contends that this submission has little evidentiary value because it was made with a view toward litigation. The idea is that Warner-Lambert made these statements after it sued Purepac and Apotex for infringing U.S. Patent Nos.

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4,894,476 and 5,084,479, and after it had received discovery regarding Purepac's gabapentin products. In addition, Purepac notes that Warner-Lambert's litigation counsel assisted in prosecuting the '482 patent. The Court has nevertheless considered this submission as part of the prosecution history, and finds it relevant and convincing.

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That the "less than 20 ppm of an anion of a mineral acid" claim language is limited to anions derived from mineral acid is further supported by test results in the prosecution history indicating that sodium chloride (or table salt), a totally non-acidic source of chloride, has a low propensity to form lactam. (Bartlett Decl., Ex. 7 at 6).

Purepac's arguments concerning the prosecution history do not suggest a different result. Purepac contends that Warner-Lambert represented to the Patent and Trademark Office that chloride levels, not mineral acid, should be kept low because chloride itself adversely affects gabapentin's stability. It does so by highlighting the following points:
. Warner-Lambert contended that the claimed invention differed from the prior art because the prior art failed to "teach or suggest that chloride ion or other mineral acid anions promote lactam formation." (Pros. Hist. 000766, 785). n6

. Referring to the prior art, Warner-Lambert again contended that the "[U.S. Patent No. 4,894,476 ("the '476 Butler patent")] does not teach or suggest that chloride ion, or other mineral acid anions, promote lactam formation." (Pros. Hist. 000796).

. Warner-Lambert asserted that "there is no recognition by [the] Butler [patent] of the stability problems concerning gabapentin, or for that matter that chloride ion content plays any role in the production of the desired lactam product." (Pros. Hist. 000764, 783).

. Warner-Lambert argued that the "skilled artisan would need to make two independent selections to obtain a stable formulation of gabapentin as disclosed in the present invention. Out of the universe of gabapentin products available, one must choose one with a defined chloride and lactam content. (Pros. Hist. 000877).

Also, in a May 1997 amendment, Warner-Lambert canceled application claim 21 and replaced it with application claim 24, which became patent claim 7. (Pros. Hist. 000550, 843-44). In arguing claim 24's patentability, Warner-Lambert urged:
The present invention involves two specific and interrelated findings. The first was that anions of a mineral acid above 20 ppm promoted lactam formation. The second was that some adjuvants also promote lactam formation. Applicants [Warner-Lambert] submit once these essential findings are disclosed it is a routine matter and simple experimentation to test the adjuvants. However, without the finding and disclosure that both of these were critical, the skilled artisan had no motivation to do that testing. In point of fact, if he did it [adjuvant testing] using typical gabapentin active [ingredient] containing higher levels of an anion of a mineral acid, e.g., higher chloride content, he would conclude that stability was not achievable.

(Pros. Hist. 000845) (emphasis added).

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n6 The Court cites to a bates-numbered version of the '482 patent prosecution history (PC000536-PC000924) attached as Exhibit B to the Declaration of Steven M. Amundson in support of Purepac's Motion.

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The Court acknowledges that Warner-Lambert made direct references to chloride ion promoting lactam formation. However, Purepac's reliance on those "chloride ion" references ignores the context of the positions taken during prosecution by Warner-Lambert, which is that the chloride ion is a surrogate for mineral acid content. The idea is that if the anion is chloride ion, then it must have come from residual hydrochloric acid. Plainly, Warner-Lambert spoke in terms of chloride because it was a direct measurement of acid. For this reason and those discussed above, the Court is not persuaded that select references to "chloride ions" in the prosecution history are sufficient to defeat Warner-Lambert's claim construction.

Purepac also points out that Warner-Lambert distinguished the claims from prior art based on total chloride content. Warner-Lambert relied on statements by Dr. Wolfgang Hermann, one of the inventors of the '482 patent, in urging patentability over

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the cited prior art, including the '476 Butler patent and U.S. Patent No. 4,152,326 ("the Hartenstein patent"). For example, with respect to the Hartenstein patent, Dr. Herrmann synthesized gabapentin according to the process disclosed in it. Using silver nitrate titration. Dr. Herrmann tested two samples of that gabapentin for chloride content. Purepac points out that the silver nitrate titration determines a substance's total chloride content. Warner-Lambert urged that "Dr. Herrmann's data evidences the fact that the product prepared according to Hartenstein having a chloride content of 2100 and 2000 ppm is unstable when stored at room temperature in a closed brown glass bottle." Purepac urges that the Hartenstein process includes multiple sources of chloride, including hydrochloric acid and hydroxylamine hydrochloride. In addition, the Hartenstein process produces sodium chloride in making a certain intermediate compound and then attempts to remove the sodium chloride. Using silver nitrate titration, Dr. Herrmann tested that intermediate compound and measured a total chloride content of 1300 ppm. In performing the Hartenstein process and discussing the results, Dr. Herrmann did not differentiate acid-derived chloride ions from other chloride ions. In other words, he treated all chloride ions the same, regardless of the source. From that Purepac argues that Warner-Lambert's claim construction departs from the positions it took before the Patent Office.

Warner-Lambert points to clarifying testimony of its expert, Dr. Bartlett, who reviewed Dr. Herrmann's Declaration concerning the Hartenstein process and stated that gabapentin samples prepared pursuant thereto contained 2000 ppm of residual HC1. (Bartlett Decl. at P31, Exs. 5, 8; 11/19/04 Tr. at 95-96 (citing 1/31/02 Bartlett Expert Rpt.)). This suggests that HC1 was the sole source of chloride in that process. At best, this creates a factual uncertainty as to the source of chloride in the samples made from the Hartenstein process. The Court is not persuaded that this is sufficient to undermine Warner-Lambert's claim construction.

Thus, the Court construes claim 7, clause (i) of the '482 patent to refer to less than 20 ppm of an anion "derived from" a mineral acid. The Court is persuaded that the only logical purpose of the claim limitation, when read in light of the patent and its file history, is to limit the amount of mineral acid impurity remaining in the bulk gabapentin.
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II.

Appellees argue in the alternative that the judgment can be affirmed because the court erred in its construction of the "anion of a mineral acid" and adjuvant claim limitations, and that they should still be awarded judgment, but based on what they consider to be the correct claim interpretation. Appellees assert that based on the intrinsic evidence, and the prosecution history in particular, "anion of a mineral acid" refers to anions from any source capable of forming a mineral acid. In essence, appellees assert that the term refers to total chloride content and is not limited to acid-derived chloride ions. Under that interpretation, they argue they do not infringe. Appellees further argue that the court correctly concluded that the adjuvant limitation excludes the eight adjuvants identified in the specification of the '482 patent, but erred in concluding that the adjuvant must be intimately mixed with the gabapentin. According to appellees, adjuvant refers to any ingredient other than the active ingredient, and thus encompasses ingredients included in the capsule shell or tablet coating. Because certain accused products include titanium dioxide, one of the excluded adjuvants, in the capsule shell or tablet coating, appellees contend that those products do not infringe. Appellees also challenge the court's construction of the term "modified maize starch," which is identified as one of the adjuvants to be avoided. Under the proper construction of that term, which appellees argue would include pregelatinized starch, appellees contend that their samples likewise would not infringe.

Warner Lambert responds that the court's construction of those terms was correct. As for "anion of a mineral acid," Warner Lambert contends that appellees' proffered construction would read the term "of a mineral acid" out of the claims. Additionally, Warner Lambert asserts that the court's construction is correct in light of the intrinsic evidence and the purpose of the invention. With respect to the adjuvant limitation, Warner Lambert argues that appellees are precluded from appealing that issue because it was not the subject of the Rule 54(b) motion. In the alternative, Warner Lambert asserts that appellees' proposed constructions are contrary to both the intrinsic and extrinsic evidence.

We first address the claim limitation of "anion of a mineral acid," which is present in every asserted claim of the '482 patent. We agree with the district court that the proper construction is "anion derived from a mineral acid." In re Gabapentin Patent Litig., 395 F. Supp. 2d 153, 159 (D.N.J. 2005). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir.

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2005) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Here, the plain language of the claim supports the construction that the anion specifically is derived from a mineral acid. Appellees' assertion that the claimed anion refers to total chloride ions or anions from any source that is "capable of" forming a mineral acid is unsupported by the claim language. Had the patentees intended the anion to refer to any anion, regardless of its source, the patentees could have simply claimed "anions" and omitted the phrase "of a mineral acid." Thus, the construction adopted by the district court gives full meaning to every word of the entire claim term. Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006) ("claims are interpreted with an eye toward giving effect to all terms in the claim"). Moreover, reference to other claims of the patent further supports this definition. Dependent claims 2, 5, 6, and 11 specify that the mineral acid is hydrochloric acid. Those dependent claims would be superfluous or unnecessary if the anions did not derive from mineral acids because there would be no need to identify with particularity the type of mineral acid that must be used. Therefore, based on the claim language, we conclude that the district court did not err in its construction.

We have also held that claims "must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315. While appellees argue that the specification provides no support for their construction, we find that the specification provides further support for the construction adopted by the district court. The specification teaches a multi-step process for making gabapentin that is substantially free from lactam. '482 patent Abstract, col.1 l.41-col.2 l.21. The Summary of the Invention describes a three-step process as:

(a) treating a compound of formula VII substantially free from compound VIII with a semiconcentrated mineral acid, converting the lactam VIII into VII,

(b) removing the anions of the mineral acid by ion exchange, leaving the purified VII, and

(c) converting the product of step (b) to a pharmaceutically acceptable salt thereof, if desired.

Id. col.2 ll.1-8 (emphases added). The specification then states that "[a] preferred process of the instant invention is one wherein the mineral acid hydrochloric acid is used and an ion exchanger is used for anion removal." Id. col.2 ll.9-10. That disclosure further supports the conclusion that the anions that are to be removed are specific to the mineral acid that was used in the first step of the process, and do not derive from any other possible source.

We are not persuaded by appellees' extensive reliance on the prosecution history in support of their construction, particularly in this case where the claim language provides a clear definition of the disputed claim term, supported by the specification. Based on our review of the prosecution history, we find no basis for reversing the district court's construction, which we have already determined comports with the claim language and specification. Accordingly, we conclude that the district court did not err in its construction of the claim term "anion of a mineral acid."

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The district court construed the '754 claims whereby the oxide-forming action in Anitec's first electrolytic cell is not included in the meaning of "anodizing" and does not produce an "anodized" coating, as those terms are used in the claims. This was the major issue in dispute.

The claims define the patent grant and set its boundaries; that is, they establish the patentee's legal rights. When technical or scientific terms in the claims require definition or explanation or understanding in the course of deciding whether the claims are infringed, it is the judicial duty to do so. Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S. Ct. 1384, 1387, 38 U.S.P.Q.2D (BNA) 1461, 1463, 134 L. Ed. 2d 577 (1996) ("We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.") In performing this construction, certain of the technologic facts were undisputed and others were strongly disputed insofar as technologic conclusions based thereon were material to the issue of the meaning and scope of the claims.

It was not disputed that Anitec uses a continuous electrolytic process with direct current flowing from two sources in a cathodic contact cell, and that the Anitec process forms an oxide coating on the aluminum in the first (phosphoric) cell before the aluminum enters the contact cell. Anitec conceded that its electrical connections, its cathodic contact cell, and its second (sulfuric) anodizing cell, are all within the meaning and scope of claims 2 and 11. There was no dispute that in the

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Anitec process the direct current was introduced from at least two sources into at least two cross-sections of the moving aluminum web, as these claims require.

However, Anitec argued that the first electrolytic cell in its process, although labelled by Anitec "Phosphoric Anodizing," is an etching and cleaning step, and that the formation of a thin layer of barrier-form aluminum oxide is not "anodization" as contemplated by the '754 patent. Anitec argued that its process does not, in the phosphoric cell, produce an "anodized oxide coating" (claim 2) or carry out a "portion of the anodizing" (claim 11) before the aluminum web enters the contact cell. Thus the question was whether the "anodized" coating that the '754 claims require before the aluminum web enters the contact cell includes within its scope the oxide coating formed in Anitec's "phosphoric anodizing" cell. The district court viewed the question as one of claim construction under Markman v. Westview Instruments, Inc., 52 F.3d 967, 34 U.S.P.Q.2D (BNA) 1321 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370,
116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577 (1996).

Claim Construction

The analysis of infringement is a two-step progression. In the first step the court construes the claims of the patent; that is, the court explains and defines any disputed technical terms and sets the scope and boundaries of the claims. In so doing the court looks principally to the patent specification and any explanatory information in the patent examination record. The court may gain understanding of the state of the art at the time the invention was made, from the prior art or from experts in the technologic field. Physical and experimental evidence may be helpful, as in this case.

The district court held that the first anodizing step of the '754 process, before the web enters the contact cell, requires not only a porous oxide coating that is electrolytically produced on an aluminum anode, but a thicker layer of porous oxide as distinguished from the thin, non-porous oxide layer that is formed in the Anitec process. The district court relied primarily on the '754 specification which describes Fromson's first anodization step as producing porous oxide, on a Papst reference discussing formation of barrier oxide, and on findings based on extrinsic evidence derived from expert testimony, demonstrative evidence, and scientific tests. Fromson disputes this claim construction, stating that Anitec admitted that anodization occurs in its first electrolytic cell, that the plain text of the '754 claims reads on the Anitec process, and that the weight of the evidence supports Fromson's interpretation of the claims and their scope.

The Specification

To determine the meaning of disputed technical terms in claims, the first resource is the patent specification of which they are a part. Slimfold Mfg. Co. v. Kinkead Industries, Inc., 810 F.2d 1113, 1116, 1 U.S.P.Q.2D (BNA) 1563, 1566 (Fed. Cir. 1987) ("Claims are not interpreted in a vacuum, but are part of and are read in light of the specification.") In general, technical terms are deemed to have the same meaning in the body of the specification as in the claims. .Patent specifications are written for persons of skill in the technical field, not for laymen, and often place the invention in the technologic context in which it must be understood.

The '754 specification requires that an anodized oxide coating be formed on the aluminum web before it enters into the contact cell, and teaches that the purpose of this preliminary coating is to protect the web from burning and current surging in the contact cell. The specification shows this coating to be porous oxide. While Fromson states, correctly, that a limitation from the body of the specification is not read into the claims unless the limitation is required to sustain patentability, the claims must be construed in light of the specification.

Although the '754 specification does not state that the thickness of the oxide, as the aluminum emerges from the first cell, must be greater than the thickness of naturally occurring oxide, the district court so interpreted the specification, concluding with the help of extrinsic evidence that for the coating to protect the web a thicker coating was required. The court resolved disputed testimony and documentary evidence to find that a thin barrier oxide layer enhanced burning rather than inhibited it, and that porous oxide was necessary at that stage. Thus the district court read the specification as supporting Anitec's position that since the oxide formed in its phosphoric cell is barrier oxide of under 5 nanometers in thickness, no thicker than naturally occurring oxide, the anodized oxide coating of the '754 claims can not be construed to include the Anitec process.

The Prosecution History and Prior Art

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Fromson argues that since the aluminum web serves as the anode in Anitec's first cell, and an oxide layer is formed electrolytically, Anitec's process is anodization, whatever the structure of the oxide layer that is formed. The district court did not agree, despite the admission that Anitec itself consistently referred, in contemporaneous documents, to the process in the phosphoric cell as anodization. In reaching its conclusion the court relied not only on the specification, but on the prosecution of the Fromson patent as originally granted and during its reissue.

The prosecution history when a patent is reissued is part of the framework in which the patent is construed, as is the prosecution history of the original patent. Representations made and explanations presented during the reissue procedure may be relevant to interpretation of the claims. Fromson requested reissue of the patent after he learned of a Papst reference, German Patent No. 718,975, showing a two-cell anodization process in which the aluminum web enters the anodizing cell before it enters the contact cell. Fromson had originally broadly claimed this "reverse anodization" step. On reissue Fromson modified or cancelled certain broad claims, retaining the claims that contained the limitation of two or more separate direct current power sources and adding claims specific to formation of porous oxide in the first cell.

Fromson argues that the Papst reference was misapplied by the district court, for whether porous oxide was formed was not an issue in the reissue prosecution. Fromson states that he always intended to cover, and did cover in claims 2 and 11, anodizing to form either porous or non-porous oxide in the first cell. Fromson states that it was known that porous anodic oxide is formed only in a dissolving electrolyte such as sulfuric acid, and that barrier oxide was known to be formed in a non-dissolving electrolyte such as phosphoric acid. Fromson states that the Papst reference did not add to this knowledge, and that Papst did not circumscribe the Fromson teaching in the specification so as to exclude from the claims coverage of the formation of barrier oxide. Fromson states that Papst was significant only because of its teaching of what Fromson calls "reverse anodizing," that is, the anodization before entry of the web into the contact cell.

We take note that Papst states that its process can produce barrier oxide, and that Fromson disputed whether a web bearing barrier oxide can be used in further procedures such as galvanic deposition of metal. We conclude that the reissue prosecution does not of itself limit all of Fromson's claims to porous oxide, but that Papst's (and Fromson's) recognition that barrier oxide can be formed, along with the other evidence, supports the district court's ruling.

Extrinsic Evidence

Fromson argues that when "anodized" is given its standard definition, citing Webster's Third International Dictionary, of "to subject [a metal] to action by making [it] the anode of a cell before coating with a protective or decorative film," the Anitec process fully meets this definition. Fromson states that this standard definition is all that the claims require, and is supported by the specification and prosecution history. Fromson states that since the term has a plain meaning, the district court erred in relying on extrinsic evidence to change that meaning, citing Markman 52 F.3d at 981, 34 U.S.P.Q.2D (BNA) at 1331 ("Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims.")

Although Markman presents a useful general rule, it is adaptable to the needs of the particular case. In this case the technical experts not only aided the court's understanding of the technology, but they also provided evidence material to the interpretation of the claims. On this evidence the court enhanced the broadly stated dictionary definition of the process of anodization, with the understanding of the finer points of the technology that was provided by witnesses during the trial. Based on expert testimony, the court concluded that since not all electrolytically formed oxide coatings will protect the web as it moves into the contact cell -- a fundamental purpose of the Fromson process -- in the Fromson process the "anodized" coating before entry into the contact cell requires such a protective oxide.

Extrinsic evidence may be particularly helpful to the court when a specific technical aspect that is potentially of dispositive weight was not discussed in the specification or explored during the patent prosecution. This case illustrates the use of extrinsic evidence in order to determine the meaning and scope of a technical term as the term is used in the claims.

Witnesses explained that the web emerging from the first anodizing cell, unless sufficiently coated with porous oxide, would not be protected from current surging and burning in the contact cell and the second anodizing cell. Although Anitec's expert Barkman testified that it was known as early as 1958 that barrier oxide can prevent burning if precisely controlled, the district court gave greater weight to Anitec's evidence that the barrier oxide formed in Anitec's phosphoric cell did not have

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this effect. There was also presented analytical data that showed a thinning of the oxide layer while in the phosphoric cell, instead of a buildup of a thicker oxide layer.

There was also expert testimony and evidence based on tests varying the voltage in the phosphoric cell, showing that anodization as it occurred in the second anodization cell did not occur at the voltage used in Anitec's first cell, normally 8 volts. Other tests showed that line speed changes in Anitec's phosphoric cell did not change the oxide thickness of 4-5 nanometers, whereas line speed changes in the sulfuric cell produced proportional changes in oxide thickness, as is characteristic of the anodization process. There was evidence that the oxide formed in Anitec's first cell did not solve the burning problem, but exacerbated it. There was evidence that certain standard tests for anodization were not met for Anitec's barrier oxide (the eraser test, the bubble test, and the copper sulfate test). An expert witness testified that "anodization has different meanings in different contexts," in explaining Anitec's use of "anodization" for its phosphoric cell as contrasted with Fromson's use of the term in the '754 process.

The district court's findings of scientific/technologic fact were material to the issue of construction of the term "anodizing." The district court concluded that the clause in claim 2 "the aluminum having an anodized oxide coating found thereon" must be construed as requiring a thicker layer of oxide than that formed in air, and that it must be porous oxide. Claim 11 was similarly construed. The court held that the barrier oxide formed in the phosphoric cell was not "an anodized surface" as the term was used in the '754 claims:

I find that in 1973 no reasonable practitioner of this process would have had the opinion that a non-porous non-adherent oxide coating, as thin as the native 5 nanometer coating found naturally in the environment, of post-phosphoric oxide, constituted an anodized surface.

The district court found that "the difference between a 1,000 or 2,000 nanometers oxide coating and a 5 nanometer oxide coating is not a difference in degree. It is a difference in kind. Something entirely different is going on." Thus the district court construed all of the claims in suit as limited to a process that produces an anodized coating in the pre-contact cell that achieves the purpose of protection against entry burning and resistance burning. The district court concluded as follows:

I conclude . . . that the terms "anodization," "anodized coating," and "anodized oxide coating" under Markman mean an electrolytically formed, adherent, porous aluminum oxide coating sufficiently thick (meaning thicker than native oxide) to, (A) protect against the burning and arcing problems addressed by the patent and optionally, (B) to provide a suitable porous base for other electrolytic treatments in the second anodizing cell such as electrophoresis, for metal plating.

Fromson readily admits that these purposes prompted his invention, but argues that the invention is not limited to these purposes, but is based on the use of a cathodic contact cell wherein an anodizing step occurs before entry into the contact cell. Thus Fromson argues that it is irrelevant to his process whether the oxide is porous or barrier, that either one can be used in the first step of the process. However, on all of the evidence, we agree that the district court correctly construed these terms in the claims.

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2. "anthracycline glycoside"

a. The Parties' Proposed Constructions

The parties dispute whether "anthracycline glycoside," as it is used in the patent, is limited only to a non-lyophilized preparation n4 of that compound, as Sicor contends, or whether it is not so limited, as Pharmacia contends. The parties agree, however, on the chemical structure of anthracycline glycoside. n5 Pharmacia contends that "anthracycline glycoside" should be construed to mean a class of chemical compounds having the generic structure set forth in note 5, supra. (D.I. 232 at 25.) Pharmacia relies on the fact that the structure of "anthracycline glycoside" was known in the art at the time of the invention, and argues that the definition of the term should end there. (Id.)

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n4 Sicor uses the term "non-lyophilized preparate" in its construction. The patent appears to use the terms "preparate" and "preparation" interchangeably. (See '285 patent at 1:45-51.) "Preparate," although not a word used in common parlance, is the past participle of the verb "to prepare." See Webster's Third New International Dictionary 1790 (Unabridged) (1986).

n5 The parties agree that anthracycline glycoside has the following generic chemical structure:

[SEE ILLUSTRATION IN ORIGINAL]

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Sicor, on the other hand, argues that "anthracycline glycoside" should be construed to mean a non-lyophilized preparation of the class of chemical compounds having the generic structure set forth in note 5, supra. (D.I. 231 at 2.) Sicor asserts that the written description of the invention disclaims coverage of a non-lyophilized form of anthracycline glycoside. (D.I. 234 at 14-15.) Sicor also claims that the prosecution history affirms this reading of the patent. (Id. at 16-17.) Pharmacia argues that Sicor's proposed definition is improper because it imports a limitation from the specification into the claims, because the prosecution history "irrefutably rebuts" Sicor's definition, and because nothing in the specification or prosecution history supports Sicor's arguments. (Id. at 25-28.)

b. The Court's Construction

The debate between the parties centers on whether "anthracycline glycoside," as that term is used in the patent, must be a non-lyophilized preparation of that chemical compound, or whether lyophilized preparations of the compound are included in what is claimed. Each of the prior applications and patents in the '285 patent family had claims containing the limitation "has not been reconstituted from a lyophilizate." (See U.S. Patent Application 878,784, D.I. 232, Ex. 4 at PI775-77; U.S. Patent No. 4,946,831 (issued Aug. 7, 1990), D.I. 232, Ex. 11 at 20:41-42; '856 Application, D.I. 232, Ex. 14 at PI 191-93.) When the '742 application was initially filed as a divisional of the '856 application, it also contained that limitation. (D.I. 232, Ex. 17 at PU 0014911-13.) In fact, the applicant used the lyophilization requirement to distinguish a piece of prior art relied on by the examiner, stating that "[t]he recitation of a sealed container, together with the requirement that the solution has not been reconstituted from a lyophilizate, effectively distinguishes Baurain et al." (D.I. 235, Ex. I at PU 0015609.)

The examiner, however, directly addressed this argument, and found that that argument "has not been found persuasive because a lyophilizate which is reconstituted in water [has] not been [found] to be patentably distinct from an unlyophilized solution." (D.I. 235, Ex. I at PU 0015077.) The applicant responded by removing the language "has not been reconstituted from a lyophilizate" from the claims of the '285 patent, stating:

The Claims of this application were previously drafted in a way that distinguished Applicants' solutions from certain prior art products which are reconstituted from lyophilizate powder in vials by medical personnel at the time of drug administration. The comments of the Examiner in the last Office Action indicated that whether the solution was reconstituted from lyophilizate is immaterial because patentability must reflect the inherent properties of the claimed solution and the prior art. Consistent with the Examiner's comments, [the claims] are now amended (by deleting the lyophilizate limitation) to show the important and claimed properties of the present invention do arise from the inherent properties of the solution, regardless of whether the solution is prepared from lyophilizates in vials.

(D.I. 232, Ex. 22 at PU 0015157 (emphasis in original).) In removing the limitation "has not been reconstituted from a lyophilizate," the applicant for the '285 patent removed a limitation from the claims, expanding their scope.

That argument is reinforced by other aspects of the history of the '285 patent. If "anthracycline glycoside" was construed, as Sicor contends, to mean "has not been reconstituted from a lyophilizate," then the claims in earlier patents and patent applications in the '285 patent family were redundant. These claims included "anthracycline glycoside," and then claimed that such anthracycline glycoside "ha[d] not been reconstituted from a lyophilizate." (See U.S. Patent Application 878,784, D.I. 232, Ex. 4 at PI775-77; U.S. Patent No. 4,946,831 (issued Aug. 7, 1990), D.I. 232, Ex. 11 at 20:41-42; '856 Application, D.I. 232, Ex. 14 at Pl 191-93; '742 Application, D.I. 232, Ex. 17 at PU 0014911-13.) Therefore, the "anthracycline glycoside" in those claims, and in the claims of the '742 application as filed, could only be read as requiring that the "anthracycline glycoside" was a non-lyophilized form of that compound if the later language expressly stating that limitation were read as being entirely redundant. By removing the limitation "has not been reconstituted from a lyophilizate"

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from the claims, the applicant broadened the scope of the claims of the '285 patent.

Sicor argues that, by removing this limitation, Pharmacia did not broaden its claims, but simply removed a limitation that the patent examiner found unimportant. Furthermore, Sicor points to the repeated discussion in the written description of the patent of the problems with lyophilizing and reconstituting anthracycline glycoside, and the repeated assertions in the written description that the invention does not "require either lyophilization or reconstitution." (See '285 patent at 1:56.) Sicor is correct that Pharmacia chose to describe the invention as an anthracycline glycoside "which has not been reconstituted from a lyophilizate," ('285 patent at Abstract), and, were it not for the extensive prosecution history bearing on this point, Sicor's argument would be more persuasive, perhaps conclusively so. But the prosecution history is there, and accepting Sicor's position would require me to ignore it. On this record, Sicor's proposed construction amounts to an impermissible reading of a limitation from the specification into the claims.

Therefore, I will construe the term "anthracycline glycoside" to mean "a class of chemical compounds having the following generic structure:

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With respect to the '284 patent, claims 1, 2, 18 and 19 all include reference, either directly or indirectly, to an anti-settling agent. Claim 1 describes "[a] writing invention, comprising . . . an anti-settling agent to keep the particles of the metallic dispersion in suspension." '284 Pat. col. 7:1-12. Claim 2, a dependent claim, incorporates claim 1 by reference and therefore includes all the terms and limitations of claim 1. See Wolverine World Wide, Inc., v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994). Claim 18 describes "[a] writing instrument, comprising . . . an anti-settling agent to keep aluminum particles from settling out . . ." '284 Pat. col. 8:47-55. Claim 19 is dependant on claim 18.

The defendants argue that the term anti-settling agent is ambiguous and therefore requires certain limitations. Specifically, the defendants propose a construction that narrows the scope of the patent so as to protect only those anti-settling agents that are "both electronically charged [ie., ionic] and derived from a polycarboxylic acid." (National Ink Mem. p. 13).

Dri Mark challenges the proposed limitations and asserts that its patent includes an ink composition with any anti-settling agent and not limited to only those that contain polycarboxylic and ionic elements. Dri Mark contends that "anti-settling agent" is a term well understood by those of ordinary skill in the art and therefore requires no explanation or limitation. See, e.g., Vitronics, 90 F.3d at 1582 (noting that a term used in a patent document is interpreted as having the meaning given by persons experienced in the field of the invention). In support of this assertion, Dri Mark points to extrinsic evidence, in particular the deposition testimony of defendant National Ink's senior chemist, Luis Chavez and National Ink's vice president, Bruce Gindelberger, who indicated that they are familiar with the term "anti-settling agent" and do not know the term to be limited to polycarboxylic acid or ionic chemicals. (Chavez Dep. at 77-78; Gindelberger Dep. at 9-11; 81-82).

I am not persuaded by the plaintiff's argument. While the Federal Circuit in Vitronics, one of the few cases cited by the plaintiff in support of its claim construction, stated that "words in a claim are generally given their ordinary and customary meaning," the court additionally qualified that language by writing "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Vitronics, 90 F.3d at 1582 ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). It belies common sense to presume that the scope of patent '284 was intended to reach all types of anti-settling agents, a range that would include those, as the plaintiff suggested at the Markman Hearing, that can separate oil and water to others that act on metallic particles in the marker at issue here. (Markman Hearing Tr. 8:10-15). As discussed below, the specification and prosecution history add credence to this view.

It is certainly not an uncommon principle to narrow the construction of a claim or term in light of the written description in the patent's specification. See e.g., Scimed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1340-1341 (Fed. Cir. 2001) (citing cases that hold that the scope of the claim is limited to the preferred embodiment expressed in the written description). In particular, I find the facts of Cultor Corp. v. A.E. Staley Manufacturing Co., 224 F.3d 1328 (Fed. Cir. 2002) to be strikingly similar to the instant case. The patents at issue in Cultor concerned the process of

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improving the taste of polydextrose, a low-calorie sugar and flour substitute. While the patent claims generally described this process as accomplished via a "water-soluble polydextrose," the specification further explained that the "water-soluble polydextrose" as used in the invention was produced with "citric acid." As a consequence of this language in the specification, the court denied infringement since the defendant's product was produced with an acid that was phosphoric, rather than citric. The district court reasoned that the inventors of the patent "had repeatedly distinguished their invention" as one achieved through the use of citric acid. Cultor. 224 F.3d at 1330.

As in Cultor, the '284 patent, while referring generally in the claims to the use of an "anti-settling agent, " distinguishes in the specification the nature of the anti-settling agent utilized in the invention and does so in the following language:

The anti-settling agent additive is of particular importance because of the aluminum flakes readiness to settle out. The ionicly charged sites on the additive bond themselves to the aluminum flakes suspending them in solutions for extended periods and keeping them tightly adhered to the surfaces of the colored pigments.

'284 Pat. col. 4:28-34 (emphasis added).

Further, the specification continues to differentiate the anti-settling agent utilized in Dri Mark's marker, citing three examples of possible additives: "The anti-settling agent utilized in this invention is ionic in nature and derived from a polycarboxylic acid. Examples are phtalic acid, adipic acid and tri-metallic acid." '284 Pat. col. 4:39-45 (emphasis added).

The parties agree that all three examples of anti-settling agents referenced above contain ionic and polycarboxylic properties. It therefore becomes apparent that the inventors of the '284 patent explicitly limited the subject matter of their claim to an anti-settling agent with ionic and polycarboxylic qualities. See Cultor, 224 F.3d at 1331 (finding that the explicit limitation in the specification "effected a disclaimer," and "claims are not correctly construed to cover what was expressly disclaimed").

The prosecution history that underlies the '284 patent serves only to reinforce the idea that the inventors sought to emphasize the particular nature of the invention's anti-settling agent. I refer to the statements made to the United States Patent and Trademark Office ("PTO") by Chhman Sukhna, one of the co-inventors of the Dri Mark marker, upon the application for the patent.

Patent '284 was initially rejected by the PTO Examiner with respect to claims 1-21 on the basis, in part, that it was too similar to prior art. In an effort to distinguish the '284 patent from prior art - an effort that ultimately proved successful - Sukhna made the following statement to the PTO on October 12, 1999:

I believe that I am the first to have brought to the market or to have described a writing implement in which metallic particle based ink compositions are carefully worked with various constituents to achieve a true 'suspension' in a sense that is described in my instant patent specification and as set forth in the claims. One of those constituents is an anti-settling agent that I have derived and prepared after much experimentation and effort in order to achieve true effectivity and long term shelf life for the writing implement.

(Dec. David LaSpaluto, Ex. D at p. 2.) (Emphasis added).

In light of Sukhna's statement, I am mindful that "by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover." Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1379 (Fed. Cir. 1998) (citation and internal quotations omitted). Further, "claims may not be construed [by the patentee] one way in order to obtain their allowance and in a different way against accused infringers." Id.

i. Application of 35 U.S.C. § 112, P 6

The defendants additionally argue that the anti-settling agent is a means-plus-function term that should be interpreted by the language of the specification in accordance with 35 U.S.C. § 112, P 6. Although this argument was first raised in the defendants' reply brief, it was amply explored at the Markman Hearing.

35 U.S.C. § 112, P 6 provides:

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An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

While the claims in the '284 patent do not employ the classic means-plus function language, the absence of such language is not dispositive. Isogon Corp. v. Amdahl Corp., 47 F. Supp.2d 436, 449 (S.D.N.Y. 1998) (Scheindlin, J.,) (citing Cole v. Kimberly-Clark Corp., 102 F.3d 524, 530 (Fed. Cir. 1996) (noting that merely because an element does not include the word "means" does not automatically prevent that element from being construed as a means-plus-function element).

However, the failure to use the word "means" in a claim element creates a rebuttable presumption that § 112, P 6 does not apply. See Watts, v. XL Systems Inc., 232 F.3d 877, 880 (Fed. Cir. 2001). The presumption may be rebutted by showing that the claim element recited a function without reciting sufficient structure for performing that function. See Id. As I suggested above, and from a review of the specification and prosecution history, the use of the term anti-settling agent is more akin to a description of function rather than a conveyance of structure.

In this regard, the Federal Circuit's decision in Mas-Hamilton Group. v. LaGard, Inc., 156 F.3d 1206, 1213 (Fed. Cir. 1998) is instructive. In Mas-Hamilton, a patent infringement case with respect to a type of combination lock, the court determined that the term "lever moving element" did not have a "generally understood structural meaning in the art." Id. The inquiry as to whether a term is structural rather than a means-plus-function element "is not whether a term has a commonly understood definition . . . but rather whether the commonly understood definition, if one exists, connotes sufficient structure." Apex Inc. v. Raritan Computer. Inc., 2002 U.S. Dist. LEXIS 3466, 2002 WL 287754, at *10 (S.D.N.Y. Feb. 25, 2002) (Pollack, S.J.,).

Just as the court in Mas-Hamilton reasoned that the plaintiff's claim "cannot be construed so broadly to cover every conceivable way or means to perform the function of moving a lever," Mas-Hamilton. 156 F.3d at 1214, Dri. Mark's claim similarly cannot be construed to cover every type of anti-settling agent.

I find therefore that § 112, P6 applies to limit the "anti-settling agent" to structures disclosed in the specification and equivalents that perform the identical function. However, even if § 112, P6 were not to apply, I find, as discussed above, that there is nevertheless sufficient justification to narrow the scope of the term in light of the specification and prosecution history. I therefore construe the term "anti-settling agent" as "an anti-settling agent that is both ionic and derived from a polycarboxylic acid."
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B. "human variable region"; "human light chain"; "human heavy chain"

Claim term, phrase or clause	Centocor's Proposed Construction
"anti-TNF-[alpha] antibody"	"An immunological protein that binds to TNF-[alpha]"
"human variable region"	"A variable region that is encoded by a gene derived from human DNA"
"human light chain"	"Light chain encoded by a gene derived from human DNA"
"human heavy chain"	"Heavy chain encoded by a gene derived from human

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DNA"

Claim term, phrase or clause	Defendants' Proposed Construction
"anti-TNF-[alpha] antibody"	"A murine or chimeric antibody (combining DNA sequences from different species) that binds to human TNF [alpha]"
"human variable region"	"An antibody variable region (V[H] and V[L] gene products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species."
"human light chain"	"An antibody light chain (C[L] and V[L] gene products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species."
"human heavy chain"	"An antibody heavy chain (C[H] and V[H] gene products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species."

Within the '775 patent, the term "anti-TNF-[alpha] antibody" appears in independent claims 1 and 13 and dependent claims 4, 5, and 6. Within the '239 patent, the term appears in independent claims 3 and 9 and dependent claims 10-16. The term "human variable region" appears in dependent claims 2 and 14 of the '775 patent. The terms "human light chain" and "human heavy chain" appear in claims 3 and 15 of the '775 patent.

The fundamental dispute regarding the above terms is whether the '775 and '239 patents claim an anti-TNF-[alpha] antibody that is wholly encoded by a gene derived from human DNA. The defendants argue that the patents-in-suit claim chimeric antibodies, i.e., antibodies that are not fully human. In support, they point to disclosures in the '827 application and the specification. 3 In relying heavily on the application to the '775 patent, the defendants argue that the patentee discloses a single embodiment and criticizes (or disavows) a human antibody, which, when read together, restrict the patent to a chimeric antibody. Essentially, the defendants are asking the court to limit all instances of "anti-TNF-[alpha] antibody" and "human," with the exception of its use in modifying "constant," to a chimeric antibody or something less than fully human, respectively.

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3 As the defendants correctly assert, the patent instructs the court to read previous applications as incorporated by reference to the present specification of the '775 patent.

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As a threshold matter, in light of the defendants' argument, it is necessary to analyze the cases which arguably support such limiting constructions. The defendants focus primarily on three cases: Astrazeneca, Honeywell, and Kinetic Concepts. Astrazeneca AB, et al. v. Mut. Pharm. Co., 384 F.3d 1333 (Fed. Cir. 2004); Honeywell Int'l, Inc., et al. v. ITT Indus., Inc., 452 F.3d 1312 (Fed. Cir. 2006); Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc., 554 F.3d 1010 (Fed. Cir. 2009).

In Astrazeneca, the Federal Circuit reversed the district court's claim construction for not limiting "solubilizer" as recognized by the patent's specification and prosecution history. Astrazeneca, 384 F.3d 1333, 1335. In its analysis, the

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Federal Circuit first looked to the specification, specifically, a passage that strongly indicated the patentee's intention to define the term. Id. at 1338-39. Although the court rejected a formalistic approach to its search for a lexicographical statement, it found clear intent in the patentee's statement that, "[t]he solubilizers suitable according to the invention are defined below." Id. at 1340. The court then looked for indications of disavowal. Indeed, the court found disavowal in both the patent's discussion of certain features of a "solubilizer" and the patent's subsequent criticisms of other features. Id. The court counseled against rigid formalism and stated, "[w]here the general summary or description of the invention describes a feature of the invention [] and criticizes other products [] that lack that same feature, this operates as a clear disavowal of these other products (and processes using these products)." Id. Finally, the court looked to the patentee's choice of preferred embodiment. The court found further support for disavowal in the patent's consistent use and reference to the limited construction, particularly, references to preferred or "especially preferred" embodiments. 4 The Federal Circuit concluded its analysis by addressing the prosecution history of the patent-in-suit. As it did with the lexicography above, the court cited an instance in the prosecution history in which the patentee referenced a "definition in the specification," finding that "[t]he applicants' characterization of this sentence in the specification as a 'definition' confirms that that the applicants acted as their own lexicographers to redefine 'solubilizer' differently from its ordinary meaning." Id.

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4 The court further noted, "[t]he fact that all of the solubilizers listed in the specification and used in the working examples were surfactants adds further support to the conclusion that the term 'solubilizer' in the claims should be limited, according to the definition employed in the specification, to surfactants." Id. at 1341.

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Faced with a similar issue in Honeywell, the Federal Circuit agreed with the district court's limiting construction of "fuel injection system component" and disagreed with its broad construction of "electrically conductive fibers." Honeywell, 452 F.3d at 1318. Essentially, the court found implicit definitional support for the first term and implicit disavowal of scope for the second term. Citing usage by the patentee of phrases like "this invention" or "the present invention," the Federal Circuit found a number of instances of language within the specification that led to the conclusion that "a fuel filter is the only 'fuel injection system component' that the claims cover, and that a fuel filter was not merely discussed as a preferred embodiment." Id. Regarding the second term, much like in Astrazeneca, the court found disavowal of scope through the patent's discussion of the consequences of using an alternative material; "its repeated derogatory statements concerning one type of material are the equivalent of disavowal of that subject matter from the scope of the patent's claims." Id. at 1320.

Finally, although Kinetic Concepts addressed a number of issues on appeal, the one pertinent to the present inquiry concerned whether the term "wound" should be limited to a narrow construction, supported by the intrinsic record, or a broad construction, supported by extrinsic evidence. Kinetic Concepts, 554 F.3d 1010. As a starting point, the court noted that all of the examples described in the specification pointed toward a limited construction. Furthermore, the court could not find any support for the expanded scope of the construction of "wound."

[I]n the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public--i.e., those of ordinary skill in the art--that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the content of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source." Id. (citing Nystrom v. TREX Co., 424 F.3d 1136, 1145 (Fed. Cir. 2005)).

Against this legal backdrop, the court will now examine the disputed terms and the '775 patent.

Turning to the specification, the great portion of the defendants' argument attempts to convince the court that "human antibody," in the context of the patent and to one of ordinary skill in the art, means something other than fully human. A persuasive portion of the specification, not coincidentally the portion which the defendants contend is "new matter," states as follows:

Anti-TNF antibodies (Abs) are intended to include at least one of monoclonal rodent-human chimeric antibodies, rodent antibodies, human antibodies or any portions thereof, having at least one antigen binding region of an immunoglobin variable region, which antibody binds TNF. '775 Patent, col. 5, ll. 55-59 (emphasis added).

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This portion of the specification favors the plaintiffs' construction. 5 While the defendants argue that the above passage does not define "human antibody," neither does it disclaim a fully human antibody. As indicated above, the balance of the defendants' argument focuses on interpreting what the patentee intended a "human antibody" to mean. 6

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5 The defendants' also suggest that, because the patentee introduced "new matter" in 1992 and 1994 after the first application was filed in 1991, the court should now ignore this and other portions of the specification. This argument is inapplicable for the purposes of claim construction. Several district courts have held that "determining whether a patentee introduced new matter during prosecution is not appropriate during claim construction." See Biax Corp. v. Intel Corp., No. 2:05-CV-184, 2007 U.S. Dist. LEXIS 14250 (E.D. Tex. 2007) (internal citations omitted).

6 Centocor argues that the defendants focus too heavily on the meaning of "human antibody" and not the meaning of the term in dispute, "human." While such a complaint has merit, as Centocor is not asserting a claim which claims "human antibodies," persuading the court that "human antibody" means something other than fully human will necessarily entail convincing the court that "human" means something other than fully human.

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Absent within the specification, unlike in Astrazeneca, is an intention to define the term contrary to ordinary usage. In examining the various applications to the '775 patent and the specification itself, the court cannot find express definitional language regarding the term "human" or "human antibody." Although Astrazeneca teaches against a rigid definitional approach, the court was able to find clear instances of definitional language--definitional language absent from the '775 specification and incorporated applications.

Turning next to a search for implicit definitions, regarding the '827 application, the isolated portion of the "Description of the Background Art" does not indicate that the invention does not include fully human antibodies. The cited portion does discuss some drawbacks to the use of "human m-Ab-producing cell lines;" however, it does not disclaim any claim scope. In fact, the cited passage appears to discuss some drawbacks to "human m-Ab-producing cell lines" in the context of the mass production of certain human antibodies isolated from human cells that have been immortalized by infection with the Epstein Barr virus. See '827 Application (Ex. 5 of Defs.' Opening Claim Construction Brief) at 9. Additionally, as argued by the plaintiffs, in subsequent passages of the '827 application, the patentee describes a solution to the above-cited issue. See id. at 23; see also '775 Patent, col. 14, l. 64-col. 15, l. 9 (discussing the similar solution). Finally, although the '827 application may arguably address the problems associated with human antibodies, the '827 application also includes passages detailing problems associated with murine antibodies. Specifically, in one passage, the '827 application notes that, "due to their murine origin, they are foreign products in humans, induce anti-murine immune responses and tend to be cleared more rapidly from the circulation." See '827 Application (Ex. 5 of Defs.' Opening Claim Construction Brief) at 8-9 ("mouse antibodies may not interact as effectively as human antibodies with human effector cells.").

Other portions of the specification cited by the parties generally fall into two categories--those that discuss "human-human," and those that discuss "human constant regions." 7 The defendants' argument regarding the first category is fairly persuasive. '775 Patent, col. 12, ll. 28-30; col. 16, ll. 27-33; col. 19, l 60-col. 20, l. 2. The specification defines "human-human" as a chimeric antibody, which in turn is defined as being derived from a different animal species. See '775 Patent, col. 20, ll. 45-54 ("[a] chimeric antibody, such as a mouse-human or human-human . . . ."; id. at col. 10, l. 64-col. 11, l. 4 ("[c]himeric antibodies are molecules different portions of which are derived from different animal species . . . .") (emphasis added). The defendants' argument regarding the second category, however, would require inconsistent interpretations of the term "human." '775 Patent, col. 19, ll. 1-8; col. 19, ll. 17-27. The defendants do not dispute that when the term "human" is used to define the constant region, it means "human." See Defs.' Opening Claim Construction Brief at 19. When the term "human" is used to define the above terms, however, the defendants seek to impose a different meaning of "human." Such an argument would violate the principle that a claim term should be construed consistently throughout the claim.

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7 The defendants also cite to portions of the specification which describe "the present invention," and "this invention" for

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support of their contention that the patent discloses only chimeric antibodies, citing Andersen Corp. v. Fiber Composites, LLC. In Andersen, however, the Federal Circuit limited the claims to a particular embodiment in pellet or extrudate form because the patent stated that extruding the composite in pellet or linear extrudate form was "required." Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1367 (Fed. Cir. 2007). The '775 patent does not use such restrictive terms. Furthermore, unlike in Honeywell, the '775 patent specification neither contains persuasive implicit definitional support nor disavowal of scope. Honeywell, 452 F.3d at 1318-19.

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In construing the above terms, the court is not persuaded that the patentee either expressly or implicitly disavowed any interpretation of "anti-TNF-[alpha] antibody" or "human" that would encompass a fully human antibody. Absent from the '775 specification is any language expressly limiting scope. Also absent is any implicit recognition of a limiting construction; the '827 application discusses drawbacks to antibodies comprising murine components as well as to antibodies comprising human elements. The patentee has not given the term "human" the strained meaning now proposed by the defendants, and there is no implicit definition of the term "human" to mean "predominantly human but must include non-human parts." In light of the claim language, read in the context of the specification, the court simply cannot find any instances within the specification which call for a limiting construction. In light of the general claim construction premise that claims should not be limited to the preferred embodiment, the court is not willing to limit the above terms as the defendants suggest.

Accordingly, the court defines the disputed terms as follows.

The court defines "anti-TNF-[alpha] antibody" as "an immunoglobulin protein that binds to TNF-[alpha]."

The court defines "human variable region" as "a variable region that is encoded by a gene derived from human DNA."

The court defines "human light chain" as "light chain encoded by a gene derived from human DNA."

The court defines "human heavy chain" as "heavy chain encoded by a gene derived from human DNA."
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B. "antibiotic" ('753 and '290 patents)

48) The word antibiotic only appears once in the specification and is not further explained. D.I. 70, Ex. A ('753 patent) 6:26-28. The antibiotic claim limitation was added during prosecution of the '753 patent, and the Examiner rejected claims because prior art taught using an antibiotic in a surgical implant to "minimize infection" of the implant and surrounding tissue or "to reduce the chance of infection." D.I. 70, Ex. Q at 3; D.I. 70, Ex. R at 3; D.I. 70, Ex. L at 4; D.I. 70, Ex. T at 3. The Examiner's understanding of "antibiotic" is consistent with the ordinary meaning of the term.

49) Consistent with the ordinary meaning of the claim language, the specification, and the prosecution history, the Court construes "antibiotic" as meaning "a therapeutic agent used to minimize or reduce infection."
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2. "antibiotic tetracycline compound"

Plaintiffs assert that the meaning of "antibiotic tetracycline compound" is clear on its face and requires no construction. (D.I. 53 at 13) Mylan, relying on its proposed construction of "tetracycline compound," proposes that the Court construe "antibiotic tetracycline compound" as "a tetracycline compound that has not had its antibiotic activity substantially or completely eliminated by chemical modification." (D.I. 55 at 10) Mylan stresses that the term "antibiotic tetracycline compound" requires a construction clarifying that "antibiotic tetracycline compounds" do not include "non-antibiotic

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tetracycline compounds." 4 (D.I. 62 at 8)

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4 The Ashley patents state: "[n]on-antibiotic tetracycline compounds are structurally related to the antibiotic tetracyclines, but have had their antibiotic activity substantially or completely eliminated by chemical modification." (Ashley '267 patent, col. 5 lines 4-7)

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I recommend that the Court construe this term according to its plain meaning. The parties are in agreement that the term "tetracycline compound" includes both antibiotic and non-antibiotic tetracycline compounds. Plaintiffs also agree with Mylan that the term "antibiotic tetracycline compounds" excludes "non-antibiotic tetracycline compounds." (Tr. at 26, 29-30) To eliminate any risk of confusion on this point, I recommend that the Court construe "antibiotic tetracycline compound" as "a compound having antibiotic activity within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure."
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B. An Antidotally Effective Amount Of An Antidote Compound Which Is Antidotally Effective (Claims 1 - 4).

All four claims of the 131 patent describe an "antidotally effective amount of an antidote compound which is antidotally effective" for certain substances. Although the parties dispute the meaning of each one of these terms, the patent specification provides the following definitions:

(1) "antidotally effective amount" means "an amount of an antidote compound which counteracts to some degree a phytotoxic response of a beneficial crop to an herbicide;" 2

(2) "antidote" means a "compound which has the effect of establishing herbicide selectivity, i.e., continued herbicidal phytotoxicity to weed species and reduced or non-phytotoxicity to the cultivated crop species;" and

(3) "antidotally effective" means that the antidote is "used in an amount which is effective as an antidote with the herbicide to decrease the extent of injury caused by the herbicide to the desired crop species."

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2 While the patent fails to expressly define the word "phytotoxic," its ordinary definition means "poisonous [or injurious] to plants." See Webster's Third New International Dictionary 1078.

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The defendants argue that all of these terms require the antidote to be applied in an amount which actually counteracts to some practical degree the injury to corn which would have otherwise resulted from the use of the 4-b herbicide. The court, however, declines to adopt this interpretation for the following reasons.

First, as previously discussed, an interpretation that requires the antidote to be applied and actually counteract an injury to the corn would again seem to render the composition claims meaningless. See Exxon, 64 F.3d at 1558 (Fed. Cir. 1995).

Second, the court believes that interpreting these terms as requiring a "practical" reduction in injury would, ultimately, turn the issue of claim construction over to the jury since the question of whether an injury was reduced by a "practical" amount seems to be one of fact, not law. 3

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3 By way of illustration, as the data submitted to the PTO makes clear, in some instances, the antidote may only reduce the injury to corn by a small percentage, e.g., three percent, because the level of the 4-b herbicide applied to the corn causes only minimal damage to the crop. In these instances, the antidote may reduce the injury to the corn caused by the herbicide by a "practical" amount since that injury falls from three percent all the way down to zero.

However, would a three percent reduction in the damage caused by the herbicide to the corn amount to a "practical" reduction if the corn was injured at higher levels? For example, what if the antidote only decreased the level of injury from 15 to 12 percent or 34 to 31 percent? Since these reductions are fairly insignificant, could they be seen as practical? Merely asking the question seems to suggest that it is one for the jury which is improper under Markman and its teachings. 517 U.S. at 388-91 (noting how the "construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis" and emphasizing the "importance of uniformity in the treatment of a given patent" while pointing out that "uniformity would . . . be ill served by submitting issues of document construction to juries").

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Thus, the court affords these disputed terms the meaning provided by the patent specification. Under these definitions, the antidote compound need only combine with the 4-b herbicide in an amount which is capable of reducing or eliminating the phytotoxic response a corn crop might have to a 4-b herbicide while, at the same time, interfering as little as possible with the injury which that herbicide causes to the weeds. 4

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4 Finally, while the defendants point out that Claims 1 and 3 of the 131 patent appear to use the clause "which is antidotally effective" somewhat inconsistently, the court agrees with the plaintiffs that the disputed language "makes it plain that the crop at issue [in these claims] is corn and that the herbicides at issue are 4-b[']s." Consequently, the court interprets the phrase "which is antidotally effective" as meaning that the antidote is "used in an amount which is effective as an antidote with the 4-b to decrease the extent of injury caused by the 4-b to the corn."

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A. "An antigen"

The parties agree that the "antigen" of claim 1 is something to which an antibody binds. (Pl.'s Br. at 8; Def.'s Br. at 6.) The only dispute is whether the antigen in claim 1 should be construed as a "substance to which antibodies bind" according to the Plaintiff's construction or as "a molecule to which antibodies bind" as in Defendants' construction.

The "words of a claim are generally given their ordinary and customary meaning" -- "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312. In this case, Defendant has not shown that the word "antigen" limits the invention to a molecule. If such a limitation exists, it stems from language following the term "antigen." See Hitzeman v. Rutter, 243 F.3d 1345, 1349 (Fed. Cir. 2001) (discussing a different antigen "comprised of a cluster of protein molecules"). Accordingly, because Plaintiff's construction is an accurate definition of the term and is consistent with all intrinsic evidence, the Court adopts it.

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D. Should the claims be construed to require "adenylate cyclase activity"?

All of the claims of the '052 and '120 patents are directed to "A purified Bordetella pertussis antigen," while all of the claims of the '080 patent call for "a vaccine which comprises a proteinaceous material." Defendants contend that even though none

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of the claims specifically requires adenylate cyclase activity, the terms "antigen" and "proteinaceous material" should be construed, in light of the specification, as limited to a material having adenylate cyclase activity. Defendants base this contention principally upon the specification's statement that:

. . . Control vaccines containing no adenylate cyclase activity were found to provide little or no protection against challenge with B. pertussis, suggesting that ACAP may, in fact, be the most important factor in immunity.

('080, 4/18-21; emphasis added.) Defendants further point out that in all of the illustrative vaccines disclosed in the specification, "antigen according to the invention" is the only immunogenic material listed. Thus, they reason, the patents teach that the claimed "antigen" or "proteinaceous material" must have adenylate cyclase activity. 8

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8 "Adenylate cyclase activity" is the enzymatic activity of adenylate cyclase, which is measured, e.g., by the rate of the conversion of ATP (adenosine 5'-triphosphate) to cAMP (cyclic adenosine 3',5'-monophosphate).

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In opposition, plaintiffs point out that the specification refers to:

. . . This discovery that proteinaceous material usually associated with adenylatecyclase activity is a major protective antigen against B. pertussis. . . .

('052, 2/33-35; emphasis added.) Plaintiffs argue that the use of the word "usually" means that the claimed antigen need not have adenylate cyclase activity. However, the force of this argument is somewhat weakened by the fact that the sentence immediately preceding the one partially quoted by plaintiffs, which identifies what is referred to as "this discovery," does not contain the word "usually":

It has now been discovered that certain proteinaceous material, associated with adenylate cyclase activity, as hereinafter described, found in the cultures of B. pertussis, is capable of providing protection against challenge by B. pertussis when administered to experimental animals.

('052, 2/28-33.) Moreover, immediately after stating that ACAP may be "the most important factor in immunity," the specification adds:

. . . Analysis of batches of non-protective whole-cell vaccine has also shown that non-protection tends to be associated with a lack of adenylate cyclase activity, further suggesting that ACAP may be the key antigen necessary for eliciting an immune response against B. pertussis.

('052, 4/45-50; emphasis added.) The use of the words "key" and "necessary" strongly suggests that adenylate cyclase activity is not a merely optional characteristic of the antigen.

Finally, as previously discussed, in the U.K. application on which plaintiffs' claim of priority is based, the patented antigen was not described as merely having adenylate cyclase activity but as being adenylate cyclase per se. Before the parent U.S. application was filed, Novotny had talked to others, including Dr. Hewlett, and concluded that the critical antigen might not be adenylate cyclase but could be either "the adenylate cyclase enzyme per se or a binding protein for the enzyme." ('052, 2/48-49.)

Now plaintiffs seek to broaden the scope of their protection even further beyond the patentee's original concept and the teachings of his specification to cover antigens and vaccines that do not even have adenylate cyclase activity. The broader coverage they now seek not only is unsupported by the teaching of the specification, as required by 35 U.S.C. § 112, but is flatly contradicted by that teaching.

In Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed. Cir. 1994), the Court ruled that the terms of the patent claims, even though worded broadly enough to cover many permutations, should be construed to cover only those

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permutations which are enabled by the specification:

. . . As Dr. Goeddel testified, an infinite number of permutations of natural t-PA are covered by these other definitions. Many of these permutations would not be capable of binding to fibrin and would thus be inoperative. There is no basis provided in the specification for determining which of these permutations are operative and which are not. . . . Thus we are unwilling to say that the specification satisfies the enablement requirement of 35 U.S.C. § 112 P 1 (1988) with respect to these broader definitions, or that the PTO could have relied on these definitions in issuing the patent. . . . We conclude therefore that the phrase "human tissue plasminogen activator" appearing in the '075 and '330 claims means natural t-PA.

Id. at 1564-65 (internal citations omitted).

Here, the circumstances much more strongly favor a narrow reading of the claims, because the specification not only fails to teach the preparation of antigens having no adenylate cyclase activity, but affirmatively teaches that such antigens have little or no immunogenic efficacy. The very essence of the specification's message is that a protein having adenylate cyclase activity, or ACAP, may be "the key antigen necessary for eliciting an immune response against B. pertussis," and that vaccines without it "provide little or no protection against challenge with B. pertussis." The claims surely cannot validly be interpreted to cover materials which the specification expressly declares to be inoperative. There would be no quid pro quo for granting a patentee the right to exclude others from using something that his specification clearly instructs them not to use.

At the oral argument, plaintiffs' counsel attempted to downplay the importance of adenylate cyclase activity by making the startling assertion that none of the vaccines actually being produced and used has adenylate cyclase activity because all of it is destroyed in the purification process. (Tr. at 98.) He argued that Novotny's specification discusses adenylate cyclase activity not because it is needed in the vaccine, but only because it "is present at some stages so you know you're on the right path." (Tr. at 99.) He added that Novotny did not say "a single word . . . that tells the worker to test for adenylate cyclase activity." (Tr. at 99-100.) Defendants' counsel immediately corrected the latter assertion by pointing out that the specification states: "Adenylate cyclase activity was assayed by the method of Hewlett, E., and Wolff, J. (J. BACTERIOL. (1976) 127, 890-898)." (See Tr. at 102-03 (citing '052, 2/50-52).)

Plaintiffs' argument is nothing more than a desperate attempt to disown the core teaching of Novotny's specification. Novotny taught not only that "control vaccines containing no adenylate cyclase activity were found to provide little or no protection against challenge with B. pertussis" and that "ACAP may be the key antigen necessary for eliciting an immune response against B. pertussis," but also that "ACAP may, in fact, be the most important factor in immunity" and that "non-protection tends to be associated with a lack of adenylate cyclase activity." ('052, 4/41-50.)

Moreover, nowhere in Novotny's specification is there the slightest suggestion that adenylate cyclase activity is destroyed in the purification process, or that it is unnecessary in the final vaccine. On the contrary, in its discussion of each successive step of purification, the specification expressly states that both the objective and the result of the step were to purify the ACAP (i.e., adenylate cyclase activity protein) which had been extracted from the outer membrane of B. pertussis cells. For example, in describing the result of the first purification step, "Example 2(a)," the specification states: "The ACAP was present in the material unretarded by the column, as shown by SDS-PAGE, but was also present in the retarded material eluted by 0.2M NaCl." ('052, 6/37-40.) In describing the next purification step, "Example 2(b)," the specification states: "The ACAP was detectable as two bands, one of pI 7.0, and the other (diffuse) band of pI 7.2-7.4. Adenylate cyclase activity was associated almost entirely with the central band (pI 7.0) but monoclonal antibodies to ACAP bound both bands strongly." ('052, 7/3-7.) The final purification step, "Example 3," is entitled "Purification of ACAP Using a Monoclonal Immunosorbent Column," and the objective of this procedure is described as "to separate the ACAP on the immunosorbent column . . . ." ('052, 7/57-58.)

In view of the undisputed fact that defendants' ACEL-IMMUNE(R) vaccine has no adenylate cyclase activity, it is understandable that plaintiffs would strain to rewrite Novotny's specification, but they cannot discard it altogether because its teaching was the sole consideration for the patent grant. If what plaintiffs now say about the irrelevance of adenylate cyclase activity is correct (as it apparently is), there was a total failure of consideration.

The Court therefore concludes that the terms "antigen" and "proteinaceous material" in the claims of the patents in suit must be interpreted to cover only antigens having adenylate cyclase activity.

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G. "Human c-erB-2 antigen"

Magistrate Judge Hollows recommends the following construction for the claim term "Human c-erbB-2 antigen": "Human c-erbB-2 antigen" means the approximately 200kD protein associated with human breast cancer.

Although Genentech originally proposed a different construction, it does not object to Magistrate Judge Hollows' interpretation of this term. Having reviewed the record, the court finds that the recommended construction is accurate and therefore adopts it.

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C. "Human Breast Cancer Antigen That is Also Bound by Monoclonal Antibody 454 C11"

The court has also been asked to construe the term "antigen" as it is used in Claim 1 of the patent. n23 The antigen of Claim 1 is described by reference to the monoclonal antibody 454 C11:
A monoclonal antibody that binds to a human breast cancer antigen that is also bound by monoclonal antibody 454 C11 which is produced by the hybridoma deposited with the American Type Culture Collection having Accession No. HB 8484.
'561 Patent, Claim 1.

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n23 The parties agree that generally, an antigen refers to any substance that may be specifically bound by an antibody.

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Chiron contends that the referenced antigen is human c-erbB-2, which is sometimes referred to as HER2. This argument is based on the text of the patent specification, which describes laboratory tests showing that antibody 454 C11 bound to c-erb-B2:

Immunoprecipitation tests on the antibodies indicated that seven of them (454 C11 ... 520 C9 ...) bind a common monomeric c.a. 210,000 dalton protein found in cancerous breast tissue ... The 520 C9 antibody binds an approximately 200 kD protein found in cancerous breast tissue which has been identified as c-erbB-2 ... The 200kD proteinaceous antigen bound by monoclonal antibody 520 C9 is identical to the 210 kD antigen mentioned herein above ... The 200,000 dalton protein bound by 520 C9 and 454 C11 was designated as the 210,00 dalton protein in U.S. Pat. No. 4,753, 894.
'561 Patent at 27:1-17.

Thus, the patent states that 454 C11 binds to a 210kD antigen that is identical to the 200kD antigen that has been identified as c-erbB-2. All parties agree that c-erbB-2 is synonymous with HER2. Therefore, when claim 1 refers to the antibody bound by 454 C11, it is referring to the antibody known as c-erbB-2 or HER2.

Genentech argues that whether the referenced antigen is actually human c-erbB-2 is a factual question that the court should not resolve at this time. The court does not purport to resolve this question as a factual matter, however. The court is simply relying on the express language in the specification equating the antigen bound by 454C 11 with human c-erbB-2. Even if it were necessary to resort to extrinsic evidence, experts for both parties appear to agree that the antigen referred to in claim 1 is, in fact, c-erbB-2. (See 3/7 Markman Tr. at 28:17-25). Therefore the court adopts Magistrate Judge Hollows' recommended construction of the phrase containing the referenced antigen:

The claimed monoclonal antibodies bind to the same breast cancer antigen as the identified reference antibody produced by the identified hybridoma. The 454 C11 monoclonal antibody binds to the human breast cancer antigen now referred to as "c-

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erB-2," sometimes referred to as "HER2."
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F. "Antimicrobial Lotion Composition," "Antimicrobial Lotion" And "Effective Antimicrobial Lotion"

Plaintiffs' Construction	Defendants' Construction
A lotion that effectively kills microorganisms present on the skin.	A lotion containing 0.001%-5% of an antimicrobial chemical agent and an absorption enhancer.

The dispute among the parties is whether these terms should be construed to require (1) a concentration of antimicrobial agent within a particular range and (2) an absorption enhancer. The Court addressed essentially the same issues for the claim terms "moisturizing composition" and "amount of triclosan effective to kill microorganisms on the skin." (See supra Parts II.A, II.D.). For the present claim terms, Defendants rely largely on the same arguments as they did for those terms. To the extent Defendants add additional argument, they simply note that the specification explains that "[s]kin care products of the instant invention are further formulated to rapidly penetrate the skin, whereby active ingredients of the formulation are more effective." ('516 patent at 2:64-67 (emphasis added).) Thus, Defendants ostensibly contend that the specification correlates "effectiveness" with rapid skin penetration, which is provided by an absorption enhancer. (D.I. 145 at 19.)

For the reasons set forth above, the Court finds that these claim terms should not be construed to require either a particular concentration of antimicrobial agent or an absorption enhancer. (See supra Parts II.A, II.D.) Accordingly, the Court will not adopt Defendants' proposed construction.

Plaintiffs' proposed construction adds little to the raw claim language other than a definition of the term "antimicrobial." However, the Court finds that Plaintiffs' definition of "antimicrobial" is unsatisfactory. Specifically, Plaintiffs' definition limits the term "antimicrobial" to components that "kill" microorganisms. The specification, however, supports a broader definition, explaining that "a chemical antimicrobial agent . . . functions to inhibit the growth of pathogenic or potentially pathogenic bacteria and fungi, or to kill such organisms." ('516 patent at 4:26-29.) The specification further explains that the "the chemical antimicrobial agent may be bacteriostatic, bacteriocidal, fungistatic, or fungicidal in its action." (Id. 4:30-31.) In line with this description, the Court shall construe the terms "antimicrobial lotion," "antimicrobial lotion composition" and "effective antimicrobial lotion" to be "a lotion that effectively inhibits the growth of or kills microorganisms present on the skin."
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The language "administering to said patient an antimicrobially effective amount" of levofloxacin could be read to provide a quantity limitation. Specifically, it could limit the claim to levofloxacin in quantities that are antimicrobially effective.

The Federal Circuit was presented with a similar claim construction issue in Key Pharmaceuticals v. Hercon Laboratories Corp., 161 F.3d 709 (Fed Cir. 1998), which involved the construction of the term "pharmaceutically effective amount" in a patent for a patch that delivered nitroglycerin through the skin. It affirmed the district court's use of extrinsic evidence, in the form of FDA ranges for the required quantity, to place a numerical value on "pharmaceutically effective." Although the parties in that case disputed how much nitroglycerine would constitute a "pharmaceutically effective" amount, there was no suggestion that the term did not limit the claim at issue. Applying that implied principle to the case at bar, the Court finds that the term "antimicrobially effective" limits the claim by requiring enough levofloxacin molecules to exhibit antimicrobial activity.
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A. Claim Construction

Bristol argues that the district court erred by not giving effect to the preamble "for reducing hematologic toxicity" and the expression "an antineoplastically effective amount" in the '803 claims. In particular, Bristol asserts that "an antineoplastically effective amount" is limiting because it was added by amendment to distinguish over Kris, who observed no antitumor efficacy. Similarly, Bristol argues that the court improperly read out the phrase "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" from claims 5, 6, 8, and 9 of the '537 patent, asserting that this expression is the only difference between claims 1 and 5 and therefore must be given effect under the doctrine of claim differentiation. Finally, Bristol argues that these expressions are limitations because they distinguish the new use of the process over the prior art, which did not show usefulness for treating cancer in three-hour paclitaxel infusions.

The defendants respond that the expressions "reduced hematologic toxicity" and "antineoplastically effective amount" in the '803 patent claims merely state the intended result of those claims and are non-limiting. Furthermore, the defendants point out that "antineoplastically effective amount" was not required by the examiner to distinguish over the prior art because Bristol voluntarily added the phrase to the claims after the examiner had found them allowable. The defendants also assert that the preamble language of the '537 claims, "to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity," only states an intended result of that claimed method. Moreover, the defendants assert that the doctrine of claim differentiation does not apply to distinguish the scope of claim 5, which recites that expression, from claim 1, which does not, because both claims are independent. The defendants also argue that Bristol's claim construction arguments violate the rule of consistency, which requires courts to construe claims consistently for both validity and infringement. Finally, the defendants respond to Bristol's argument that the asserted claim limitations are necessary to distinguish over the prior art on the basis of the discovery of the new "usefulness" of three-hour paclitaxel infusions, arguing that the prior art was directed to that same use -- treating cancer -- and that Bristol's sole contribution was in recognizing a new result of that same use, i.e., that it worked to treat cancer.

We first address the preamble language of the claims in the '803 patent, "for reducing hematologic toxicity." We discern no error in the district court's interpretation of that language as non-limiting, and merely expressing a purpose of reducing hematologic toxicity relative to the toxicity experienced by a patient undergoing a twenty-four-hour infusion. The steps of the three-hour infusion method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim. See, e.g., In re Hirao, 535 F.2d 67, 70, 190 U.S.P.Q. (BNA) 15, 16-17 (CCPA 1976) (holding that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim). Furthermore, this is not a case in which a new use of a process should be considered to be a limitation because that new use distinguishes the process over the prior art, as we will discuss infra. We therefore affirm the district court's construction of this expression as non-limiting.

We reach the same conclusion with respect to the expression "an antineoplastically effective amount," also in the '803 claims. That expression of intended result essentially duplicates the dosage amounts recited in the claims that are also described in the specification as "antineoplastically effective." '803 patent, col. 5, ll. 40-44 ("It has also been surprisingly discovered that lower taxol dosages, such as about 135 mg/m2 can be administered via infusions lasting about 3-hours to about 28-hours, and still be antineoplastically effective."). The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim.

We also agree with the defendants that the amendment adding "antineoplastically effective amount" was voluntarily made after the examiner had already indicated to Bristol that the claims were allowable. See Supplemental Response for Application No. 08/544,594 (Jan. 10, 1997). These unsolicited assertions of patentability made during prosecution do not create a material claim limitation where we have determined that the language does not create one. Indeed, for purposes of infringement, Bristol apparently does not see this expression as requiring efficacy; Bristol stated its view in response to requests for admission that the claims of each patent would be infringed without a showing of an objective response in every patient. Bristol cannot have an expression be limiting in this context and non-limiting in another. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1279, 6 U.S.P.Q.2D (BNA) 1277, 1280-81 (Fed. Cir. 1988) ("Having construed the claims one way for determining their validity, it is axiomatic that the claims must be construed in the same way for infringement."). We therefore affirm the district court's interpretation of "antineoplastically effective amount" as non-limiting.

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B. "An antiretroviral agent" 3

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -
3 The definition of "anti-HIV agent," consistent with "anti-retroviral agent," is thus "at least one substance having or capable of having an effect against HIV."

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Roche argues that "an antiretroviral agent" should be defined as "antiretroviral agents available to doctors for the treatment of AIDS/HIV infected patients in 1992. " This construction is based on two arguments: 1) the specification defines the term to be those antiretroviral agents "known" at the time; and 2) that the terms must be given their meaning as of the time of the invention. Each argument is discussed below, followed by the three independent and fatal flaws that mar Roche's construction.

Roche argues that the statement: "Antiretroviral agent, as used herein, includes any known antiretroviral agent including, but not limited to, dideoxynucleosides " limits the patent only to agents known at the time of the patent. '730 patent at 8:39-41. The plain meaning of the phrase, however, is the opposite. The statement is inclusive and seeks to include, without limiting the scope, agents known at the time. The specific inclusion of known agents presupposes the existence of agents unknown at the time that may also be considered to be antiretroviral agents. See Amgen, 457 F.3d at 1302. Kopyake Enterprises, Inc. v. Lucks Co., 264 F.3d 1377, 1382-83 (Fed. Cir. 2001) is not on point because it discussed which forms of screen printing were "conventional" forms of screen printing at the time of the patent--the patent itself limited its scope to "conventional" forms. Id. at 1380. The method of printing in question existed at the time of the patent application was filed but was only later adapted for use as screen printing. Thus, the Kopyake court declined to consider it "conventional." See id. at 1383 ("[W]hen a claim term understood to have a narrow meaning when the application is filed later acquires a broader definition, the literal scope of the term is limited to what it was understood to mean at the time of filing."); see also PC Connector Solutions LLC v. Smartdisk Corp., 406 F.3d 1359, 1364 (Fed. Cir. 2005) (finding that claim language referring to an "standard input/output port" that is "traditionally connectable to a computer" or an I/O port "normally connect[a]ble to a conventional computer input/output port" is a "port that was in common use at the time of filing in 1988"). In contrast, there are no limiting words in the patents in question here.

Roche relies on Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005), for the proposition that there is a temporal context to claim construction. The language of the opinion states that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Id. Thus, Roche argues, claims cannot be construed to cover later developed technology that was unknown at the time of the invention.

The term "antiretroviral agents" describes a category of pharmaceuticals. This is clear because Roche itself uses the term antiretroviral agents to describe new drug therapies that were unveiled in 1995. Opp. Br. at 8. In May 1992, when Stanford applied for the patents in question, those antiretroviral agents that had been developed were of the type that inhibited reverse transcription. After 1995, this category expanded to include protease inhibitors. For instance, Highly Active Antiretroviral Therapy ("HAART") combination therapy was not available until 1995-96. However, this new type of antiretroviral therapy was anticipated. Articles published in 1990 and 1991 discussed protease inhibitors, indicating they were known. It just took three or four years for their development and availability.

Roche's reliance on Phillips misses the mark because the temporal context espoused by Phillips is the meaning of the term to a person of ordinary skill at the time of the invention. The term in question may be a category, the contents of which expand over time. It is clear that the term "antiretroviral agents" describes a category of pharmaceuticals because Roche itself uses the term antiretroviral agents to describe new drug therapies that were unveiled in 1995. Opp. Br. at 8. It is clear from the publication history and the prolific research being conducted by HIV researchers on protease inhibitors, that a person of ordinary skill in the art would have known that the category of "antiretroviral agents" would only expand over time to include these new agents.

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SuperGuide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870 (Fed. Cir. 2004) is instructive. The SuperGuide court, when construing a system claim, had to decide whether "regularly received television signal" included digital signals that were not in regular use when the patentee applied for the patent. The court held that since the "claim language does not limit the disputed phrases to any particular type of technology or specify a particular type of signal format" the term should be construed as "video data that is customarily received by the television viewing public . . . [t]he form of the television signal is irrelevant." Id. at 878-81. Thus, the Federal Circuit declined to limit the claim to what was actually broadcast for mass consumption at the time. Roche attempts to distinguish SuperGuide by arguing that SuperGuide only extended to technology that was known and available to skilled artisans with knowledge when the patent was granted. Thus, they argue, the patents in question here must be limited because only agents that inhibit reverse transcription were known or available before May 1992.

The SuperGuide opinion focuses only on the knowledge of one skilled in the art. Specifically, "[i]t appears indisputable that it was known to those skilled in the art during the pendency of the '578 patent application that video data could be communicated in either analog or digital format. Although analog may have been the dominant format of video data when the '578 patent application was filed, we have little doubt that those skilled in the art knew of the existence of digital video data at the time." Id. at 879. In addition, the court stated that it found "no reason here to limit the scope of the claimed invention to analog technology, when 'regularly received television signals,' i.e., video data, is broad enough to encompass both formats and those skilled in the art knew both formats could be used for video." Id. at 880. The situation here is indistinguishable. Although agents that inhibit reverse transcription may have dominated the category of antiretroviral agents in May 1992, the court has no doubt that those skilled in the art anticipated antiretroviral agents that were protease inhibitors and other inhibitors yet to be developed. See Bartlett Dec., Exh. B. The conceptual work for identifying antiretroviral agents other than those that had been federally approved had begun as of May 1992. See id. Thus, even if they were not available, these after-developed technologies were certainly known in May 1992. See Rhyu Supp. Dec., Exh. 27 at 28:5-24 (persons of skill in 1992 knew the steps of the HIV replication cycle and that inhibiting any of the steps could inhibit replication of HIV). Furthermore, the law "does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention." SRI, 775 F.2d at 1121. Since the ordinary and customary meanings of the words are not dependant on time, the court finds no reason to limit the scope of "antiretroviral agents" to those agents available when the patentee applied for the patent. The claims can therefore be construed to cover later developed technology that was unavailable but known at the time of the invention. In sum, even if specific agents were not available in May 1992, the conceptual framework for them had been laid and they were reasonably known to those skilled in the art.

This case is distinguishable from Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1354 (Fed. Cir. 2000), where the court concluded that the claim reference to "polypeptide of the IFN-a type" did not include later-discovered species of "IFN-a" that were unknown at the time of the application. Schering defined "IFN-a, " originally used to refer to a particular type of interferon but ultimately understood to refer to several categories of proteins, of which the patentee was only concerned with one. See Mark A. Lemley, The Changing Meaning of Patent Claim Terms, 104 Mich. L. Rev 101, 104 n.12 (2005). The court held that "the [claim] term as used in the . . . patent . . . did not and could not enlarge the scope of the patent to embrace technology arising after its filing." Schering, 222 F.3d at 1353. Here, there is no evidence that the patentee intended to limit the patent "antiretroviral agents" to known and available technologies, nor is there evidence that the categorical term, antiretroviral agents, was ever used to refer only to agents that inhibit reverse transcription.

Turning from the principles of claim construction that govern the temporal issues to Roche's construction, the court notes that first of all, it is self-referential. The purpose of claim construction is to resolve disputed meanings and technical scope in order to aid the fact-finder. See United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir.1997); see also Opp. Br. at 2 ("claim construction is intended to . . . provide meaning to a lay juror who may not be familiar with technical terms."). Roche's construction does not help the lay juror. Defining "an antiretroviral agent" as "antiretroviral agents" available for HIV treatment in 1992 does nothing to elucidate the meaning of the disputed term. Roche's proposed construction, therefore, only seeks to insert further limitations into the term "antiretroviral agent" without defining the term itself.

Second, Roche seems to have admitted what the definition of "an antiretroviral agent" ought to be, even though it proposes that the court adopt a different construction. Roche states that "[a]ntiretroviral agents are drugs that are effective in reducing or stopping replication of retroviruses. " Opp. Br. at 2, 22; Bartlett Dec., PP38-41. Roche's clear and succinct definition of

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"an antiretroviral agent" undercuts all of their other arguments regarding any alternate construction. Furthermore, this construction is very close to Stanford's proposed construction.

Third, Roche seeks to include three limitations that are not present in the term. Specifically, Roche seeks to limit the scope of antiretroviral agents to: 1) those available to doctors; 2) those available for the treatment of AIDS/HIV infected patients; and 3) those available in 1992. Each of these limitations fails for the same reasons described above regarding after-developed technologies--they all attempt to limit the scope of "antiretroviral agents" when there is no evidence that the patentee intended the same.

Stanford, in turn, argues that "an antiretroviral agent" should be construed as "at least one substance having or capable of having an effect against a retrovirus, such as HIV. " This effect may be either positive or negative. Roche does not argue that the construction may include more than one substance as its own definition construes the term in the plural. The plain language of the term is not limited to monotherapy. Indeed, the patents in suit specifically refer to combination therapy. '730 patent at 7:63-8:14; 9:46-48; 13:9-11. This demonstrates that the inventors and those of ordinary skill in the art were aware of combination therapy.

The rest of Stanford's construction describes antiretroviral agents using generally accepted dictionary definitions. The construction closely matches the definition given by Roche, that "[a]ntiretroviral agents are drugs that are effective in reducing or stopping replication of retroviruses. " Opp. Br. at 2; id. at 22; Bartlett Dec., PP38-41. Roche's construction requires that the agent be effective in reducing or stopping replication of retroviruses. The same, however, goes against the patent construed as a whole. The patent is designed to measure the effectiveness of antiretroviral agents and therefore the construction must include the fact that the agent may or may not be effective in reducing or stopping replication of the retrovirus. Thus, Stanford's construction is superior because it allows for the possibility that the agent may not in fact be effective against the retrovirus. The court therefore adopts the following construction for "an antiretroviral agent": "at least one substance having or capable of having an effect against a retrovirus, such as HIV."
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C. Antithrombotic Activity Greater than Heparin

Aventis and Amphastar request construction of the phrase "antithromobic activity greater than heapann" which appears in claims 1, 31, and 32 of the 618 patent. Aventis urges that this phrase should be construed as, "the claimed substance prevents the growth of thrombi better than hepann in at least one in vivo setting." Amphastar argues that antithrombotic activity should be construed either as "anti-Xa activty, measured as described in Tien" or as indefinite.

Generally, "antithrombotic" is defined as "preventing or interfering with the formation of thrombi" Dorlands Illustrated Medical Dictionary (28th ed 1994). "Thrombi" are defined as "an aggregation of blood factors frequently causing vascular obstruction at the point of its formation." Id. Aventis' proposed construction comports with the plain and ordinary meaning of "antithrombotic" because it refers to preventing growth of thrombi. Moreover, the definition of "thrombi" supports the "in vivo" portion of the proposed definition because thrombus formation is a biological activity. Finally, the specification itself supports the "in vivo" portion of the proposed definition because it refers to the following which implies an in vivo construction "thrombotic episodes in a human patient," 618 patent, abstract, "useful therapeutic compositions for the prevention of venous thromboses in patient risk situations," 618 patent, 6 24-26, and "orthopedic surgery," 618 patent, 6 29-30.

Amphastar asserts that the specification defines "antithrombotic" as in vitro. In particular, Amphastar cites a passage which states, "The anti-factor Xa (antithrombotic) activity was measured by the amidolytic method on a chromogenic substrate, described by Tien et al using the Primary International Standard for low molecular weight hepann" 618 patent, 7 10. Amphastar argues that this scientific measurement favors an in vitro construction because it was conducted in an artificial environment. However, one reference to prior art which the rest of the patent contradicts does not "provide reasonable clarity, deliberateness, and precision sufficient to narrow the definition of the claim term m the manner urged." Abbott Labs v Syntron Bioresearch, Inc, 334 F 3d 1343, 1355 (Fed Cir 2003). While the court recognizes that Aventis may act as its own lexicographer, the court is not convinced that Aventis redefined "antithrombotic" by this reference to Tien.

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The court adopts Aventis' construction It is consistent with the plain and ordinary meaning of "antithrombotic." It is reinforced by the specification which has repeated in vivo references. It is not redefined by one in vitro reference in the patent specification. Thus, the court construes "antithrombotic" as "the claimed substance prevents the growth of thrombi better than heparin in at least one in vivo setting."
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any combination of an alum and an aluminum chloride

The Court and the parties agree that the phrase should be construed as "every possible proportion of alum to aluminum chloride."
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3. What is the Proper Construction for the Phrase "thereafter applying pressure and shear to the heated mixture" in the '311 Patent?

Claim 1 and claim 94 of the '311 patent contain the phrase "thereafter applying pressure and shear to the heated mixture sufficient immediately to convert at least a portion of the binder material. . . ." KXI contends this phrase means applying sufficient pressure and shear to convert the heated binder into either a continuous web matrix, as disclosed in claims 1 and 94, or forced point-bonds, as disclosed in claim 94. KXI contends no specific amount of pressure or shear is required. KXI argues its construction is supported by the plain meaning of the words in the claims.

Culligan contends this phrase means applying pressure and shear sufficient to convert at least a portion of the binder materials after the entire mixture has been heated to a temperature above the softening temperature of the binder. Culligan contends the pressure required during the conversion step must be (1) greater than the pressure applied during the heating step; and (2) greater than 400 psi to achieve "forced point-bonds" and greater than 4,000 psi to achieve a "continuous web matrix."

Regarding the temporal limitation, Culligan argues that the plain meaning of the claims imposes this requirement. Culligan responds to KXI's arguments by alleging KXI has ignored the "thereafter" limitation in the claim, which imposes a temporal restriction requiring that the pressure and shear sufficient to convert the mixture be applied after the heating step. Culligan argues that its definition of the claim takes into consideration the continuous nature of the extrusion process. According to Culligan, "if . . . you take a cross-section of mixture at any given position along the length of the extruder, the conditions that piece of mixture has to be seeing have to conform to the process steps. In other words, that piece of the mixture has to be first heated. Then it has to be pressurized."

Culligan argues the specification of the '311 patent establishes that the pressure required to achieve "forced point-bonds" is at least 400 psi. The patentee distinguished the Degen '683 patent (U.S. Patent No. 4,664,683) at column 2, lines 43-45 of the specification. This reads in relevant part:

The levels of compression disclosed by Degen et al. are exceedingly low, 0.3-10 psi . . . most preferred maximum 40 psi. . . . Accordingly, it describes process conditions well outside the range of compression utilized in the present invention, which would be 400-1000 psi . . . for granular materials . . . and approximately 8,000 psi . . . or more for powders. . . . Without such higher pressures, the binder resins are not activated and the novel structure produced by the current invention are not obtained.

Culligan argues KXI is estopped from arguing now that their process covers pressures lower than 400 psi, because KXI disclaimed lower pressures in distinguishing the Degen '683 patent.

Culligan argues the '311 patent's specification establishes that pressure required to achieve a "continuous web matrix" is at least 4,000 psi. Culligan cites passages from examples drawn from the patent's specification stating that successful examples

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of "continuous web matrix" formation occurred only at pressures in excess of 4,000 psi. Culligan cites passages from the examples section using pressures below 4,000 psi that produced unsuccessful results. Culligan argues that patent claims should be construed consistently with examples given in the patent, citing Johns Hopkins v. CellPro, Inc., 152 F.3d 1342, 1349 (Fed. Cir. 1998).

KXI argues in response that "no specific amount of pressure and shear is required by the claims." According to KXI, the '311 patent only requires the application of "sufficient" pressure and shear to convert the heated binder into either a "continuous web matrix" or a "forced point-bonding."

The court agrees with Culligan that the term "thereafter" applies a limitation that "applying pressure and shear to the heated mixture sufficient immediately to convert at least a portion of the binder material" occurs after the mixture is heated "substantially above" the binder's softening temperature.

The court finds that the specification does not define pressure to mean greater than 400 psi to achieve "forced point-bonds" and greater than 4,000 psi to achieve a "continuous web matrix." The court finds, however, that the patentee disclaimed using pressures below 40 psi in the claimed invention when the patentee distinguished the pressures used in the Degen '683 patent. Accordingly, the court construes the phrase "thereafter applying pressure and shear to the heated mixture sufficient immediately to convert at least a portion of the binder material" to mean applying pressure greater than 40 psi and shear sufficient to convert at least a portion of the binder materials after the entire mixture has been heated to a temperature above the softening temperature of the binder.
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3. "thereafter applying pressure and shear to the heated mixture"

KXI contends that the phrase "thereafter applying pressure and shear to the heated mixture" requires the application of pressure and shear sufficient to convert the binder after at least a portion of the binder has been heated to a temperature substantially above its softening temperature. KXI argues that the pressure and shear may be applied even if the entire mixture has not been heated to a temperature above the softening temperature of the binder.

PUR counters that the phrase "thereafter applying pressure and shear to the heated mixture" in a compression molding process means that pressure is applied only after the prior heating step. PUR argues that the plain language of the phrase reiterates the fact that heating occurs before the maximum levels of pressure or shear are applied. According to PUR, "the heating without pressure step followed by the 'thereafter' pressurizing step thus requires at least an increase in pressure between the heating and pressurizing phases, such that the level of pressure is great enough to 'convert' the mixture after but not before or during heating."

The court finds, as it did in Culligan, that the phrase "thereafter applying pressure and shear to the heated mixture" means that the pressure and shear sufficient to convert at least a portion of the binder material occurs after the entire mixture has been heated to a temperature above the softening temperature of the binder material.
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C. "Approximately"

Plaintiffs' Construction	Defendant's Construction
No construction necessary.	Almost exactly.

Pointing to a definition from the American Heritage College Dictionary 67 (3d ed. 2000), Defendant contends that the term "approximately" should be given its "plain and ordinary meaning" of "almost exactly." (D.I. 40 at 22.) Defendant further notes that in Claim 1 the dissolution results are reported to a tenth of a percentage point, a consideration that supposedly militates in favor of a narrow construction for "approximately." (Id. at 22-23.)

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Again, there is a significant disconnect between the intrinsic evidence relied upon by Defendant and its proposed construction. Specifically, although Claim 1 reports dissolution results to the nearest tenth of a percentage, the Court fails to see how this compels a construction for "approximately" of "almost exactly." Though Defendant's extrinsic dictionary definition clearly supports such a construction, without some meaningful corresponding basis for it in the intrinsic record, the Court will not paraphrase the ordinary word "approximately" as "almost exactly." Indeed, the Court sees no reason to believe that the American Heritage College Dictionary is particularly authoritative in the pharmaceutical sciences, or that the definition of "almost exactly" is particularly well accepted. In this regard, the Court notes that the Merriam-Webster's Online Dictionary - a resource that litigants in this Court are, unfortunately, all too familiar with - defines "approximate" to simply be "located close together," a much broader definition than "almost exactly." Accordingly, the Court agrees with Plaintiffs that the no further construction is warranted for the term "approximately."
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II. "approximately ambient temperature"

The phrase "approximately ambient temperature" is used in claim 1 of the '903 patent to describe the temperature the wear layer is cooled to after being cured in the preceding step of the claimed process. '903 at 11:29-12:3. The parties dispute the meaning of this phrase.

Mannington argues that the phrase "means approaching the surrounding temperature." D.I. 326 at 23. In support of this construction, Mannington asserts that the '903 specification refers to "cooling to ambient temperature prior to softening for mechanical embossing." Id. at 24. Therefore, contends Mannington, a "skilled artisan would understand 'ambient temperature' to mean the temperature surrounding or encircling the product … as it moves from step (b) to step (d) [in claim 1 of the '903 patent]." Id. at 23-24. Furthermore, asserts Mannington, since "approximately" modifies "ambient temperature" "a person of ordinary skill in the art would further understand that 'approximately ambient temperature' need only be a temperature below the temperature of step (d) where the wear layer is subsequently softened (i.e., by reheating) prior to mechanically embossing." Id. at 24. Moreover, argues Mannington, the prosecution history of the '903 patent distinguishes prior art that teaches mechanical embossing without cooling first, thus, supporting its proposed construction. Id.

Armstrong makes no argument as to this phrase since the '903 patent is not asserted against it. Domco, however, argues that the phrase means "the range of temperatures in an area of a shop or factory where resilient surface covering manufacturing workers are ordinarily present; in other words, the range of temperatures in the environment in which such workers ordinarily perform their assigned duties." D.I. 142 at 16.

The clear import of the expression "ambient temperature" to those skilled in the art of vinyl surface coverings, as well as, to those with a modest scientific background, is room or, as the case may be, factory temperature. This court therefore construes "approximately ambient temperature" as used in claim 1 of the '903 patent to mean that the surface covering is cooled after being cured in step (c) of claim 1 of the '903 patent to a temperature approximately equal to factory or room temperature. Hawley's Condensed Chemical Dictionary 48, 973 (13th ed. 1997) (Stating that ambient temperature refers to a temperature in the room between 68-77F.). Any other interpretation menaces the English language. Moreover, the inventors provide no disclosure in the written description to support a contrary interpretation consistent with their arguments now before the court.
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5. "Having Approximately 30% by Weight Vinyl Acetate"

Finally, Magistrate Judge Smith recommended that this Court construe the disputed term "having approximately 30% by weight vinyl acetate" to mean "having about, roughly, or around 30% by weight vinyl acetate." (R&R 21.) Dentek objects to this proposed definition, claiming that it renders the claim impermissibly ambiguous and indefinite. (Dentek Obj. 5-10.) According to Dentek, the disputed term should be defined as follows: "having at least 25.0% by weight vinyl acetate but not

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more than 33.0% by weight vinyl acetate." (Dentek Mem. 24.) Dentek argues that "[e]xpanding the scope of the phrase 'approximately 30% by weight' outside of that [25-33%] range would leave Claim 17 insolubly ambiguous as to how much vinyl acetate could be present without infringing the claim." (Dentek Obj. 7.)

Every patent has a definiteness requirement, which means that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. "[T]he purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). Absolute clarity is not mandated by the definiteness requirement; indeed, only claims "not amenable to construction" are indefinite. Id. (internal quotation omitted). Issues of indefiniteness "often arise when words of degree are used in a claim." BJ Servs. Co. v. Halliburton Energy Servs., Inc., 338 F.3d 1368, 1372 (Fed. Cir. 2003) (construing claim using the word "about") (internal quotation marks omitted). The focus of the definiteness inquiry is on "whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification." Id.

After undertaking a de novo analysis of this disputed term, the Court adopts Magistrate Judge Smith's proposed construction for the reasons aptly and thoroughly set out in the R&R. The Court is not persuaded by Dentek's claim that the 25-33% range is necessary or warranted for this claim. The imposition of such a range would improperly impose a limitation from the specification into the claims. See Interactive Gift Exp., 256 F.3d at 1331. Further, the Court is satisfied that, given the other resin specifications clearly set out in the claims, a person of ordinary skill in the art of resins would be able to discern what is claimed by use of the phrase "having approximately 30% by weight vinyl acetate" in Claim 17. See Andrew Corp. v. Gabriel Elecs., Inc., 847 F.2d 819, 821 (Fed. Cir. 1988) (noting that words such as "closely approximate" are "ubiquitous in patent claims" and "have been accepted in patent examination and upheld by the courts") (emphasis in original).
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C. Aqueous Dispersion of the Calcined Gypsum

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
aqueous dispersion of the calcined gypsum	an aqueous dispersion of the calcined gypsum and water (and optionally other desired additives) but no foam	an aqueous dispersion of at least calcined gypsum and water (and optionally other desired additives)

Claims 25 and 36 both involve an "aqueous dispersion of the calcined gypsum" created by mixing calcined gypsum and water. ('635 Patent, Claim 25, 36.) The parties agree that the term is not limited to mixtures containing only calcined gypsum and water, but Plaintiff argues that it cannot refer to a mixture that contains foam. (Def's Opening Br. at 28-29, Pl's Br. at 23-24.) Plaintiff supports its proposed construction with references to the specification, which states three times that the aqueous dispersion contains no foam. ('635 Patent, col. 5, ll. 11-15, col. 8, l. 67-col. 9, l. 1, col. 11, ll. 5-7.) Defendants respond by pointing to different places in the specification that suggest that the aqueous dispersion may contain some foam. ('635 Patent, col. 5, ll. 60-65, col. 9, ll. 50-51.) This back and forth reveals that Claim 25, an open-ended "comprising" claim contemplates embodiments that contain no foam as well as embodiments that do contain some foam. See CollegeNet Inc. v. Apply Yourself, Inc., 418 F.3d 1225, 1235 (Fed. Cir. 2005). Accordingly, Plaintiff's proposed limitation is rejected, and the court construes "aqueous dispersion of the calcined gypsum" as "aqueous dispersion of the calcined gypsum and water (and optionally other desired additives)."
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2. Aqueous Solution/Balance

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The independent claims of the '793 patent disclose an aqueous solution, with constituents falling in ranges of percentages by weight specified for carbohydrate and chloride salt content, and with water identified as constituting the "balance". As was the case in Cargill, the parties in this action disagree over the terms "aqueous solution" and "balance" and whether, in combination with the specification of the carbohydrate and chloride salt content range, they permit inclusion of any incidental impurities or additional ingredients other than the colorants and thickeners specified in some of the claims, and if so to what extent. 9

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9 Cargill urged a confined, closed-ended reading of the terms, to the exclusion of other, non-specified ingredients. Sears, on the other hand, maintained that they should be interpreted in such a fashion as to allow for some incidental, unspecified ingredients.

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With the parties' focus upon issues of purity and limitations as to non-essential ingredients, the phrase "aqueous solution", while seemingly non-controversial, became a significant point of contention in Cargill. Cargill urged a definition requiring a "uniformly disbursed liquid mixture containing water as the primary solvent." Cargill, 334 F. Supp. 2d at 217. Sears offered a more relaxed requirement of a "single-phase, liquid mixture of two or more components, one of which is water and with possible incidental amounts of insoluble components." Id.

The term "solution" is defined in one source as constituting a "homogeneous mixture of two or more substances, which may be solids, liquids, gases, or a combination of these." American Heritage Dictionary 1655 (4th ed. 2000). The term "homogeneous" is defined elsewhere as "often loosely used to describe a mixture or solution composed of two or more compounds or elements that are uniformly disbursed in each other." Hawley's Condensed Chemical Dictionary 655 (15th ed. 2007). While both of those sources associate the term "homogeneous" with "solution," the Hawley's definition goes on to observe that "[a]ctually, no solution or mixture can be homogeneous; the situation is more accurately described by the phrase 'uniformly disbursed.'" Id.

Use of the term "aqueous" constricts the solution in issue in the '793 patent to a liquid with water as a component, or even the primary solvent. This much is not in dispute. The critical issue presented is the degree of homogeneity required in the aqueous solution. As even the Hawley's dictionary definition recognizes, no solution or mixture can be entirely homogeneous. In practice, there are no solutions which are completely free of extraneous materials, however microscopic they may be. Indeed, even contemporary drinking water standards provide for inclusion of certain impurities including asbestos particles, albeit within exceedingly narrow defined limits.

In consideration of the patent claim language and use of the term aqueous, derived from "aqua" -- which means "[w]ater", American Heritage Dictionary at 89, in Cargill I interpreted the phrase "aqueous solution" to mean a uniformly disbursed liquid mixture of two or more components, one of which is water, and which can contain incidental amounts of insoluble components.

Taking the terms aqueous solution and balance together, the ADM defendants now argue for a different interpretation, asserting that for the '793 patent the term should be read together to mean that

> [a]side from the specified low molecular weight carbohydrate, chloride salt, [and thickener, for claims reciting a thickener], and impurities ordinarily associated therewith, the solution shall contain only water. The aqueous solution may not include additional ingredients included for purposes related to de-icing or anti-icing. 10

ADM's Opening Brief on Claim Construction (Dkt. No. 172) at 17. Defendants' argument is bottomed upon what they claim to be ordinary principles of sentence construction, as well as the Federal Circuit's intervening decision in Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349 (Fed. Cir. 2006).

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10 Defendants assert that for purposes of the '622 patent a similar definition should apply, with the word "sugars" being substituted for the phrase "low molecular weight carbohydrate."

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Having carefully considered the argument of the parties in Cargill, and discerning no material difference in this case, I find no basis to revisit my ruling regarding the term "aqueous solution."

* * *

ORDERED as follows:

1) The disputed terms of the '793 and '622 patents are hereby construed by the court as follows:

Terms	Construction
* * *	
"aqueous solution"	a uniformly disbursed liquid mixture of two or more components, one of which is water, and which can contain incidental amounts of insoluble components

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Arginine [alpha]-ketoglutarate

The parties and the Court agree that the term should be construed according to the patent definition as

arginine [alpha]-ketoglutarate which is a salt also known as arginine 2-ketoglutarate, arginine 2-oxoglutamate, and arginine 2-oxopentanedioic acid. Unless specified, the term covers racemic mixture as well as any other (non-50/50) mixture of the enantiomers including substantially pure forms of either the R-(+) or the S-(-) enantiomer. Further, unless specified otherwise the term covers pharmaceutically acceptable salts (e.g. Na and K salts) and amides, esters and metabolites of the acid.

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2. Construction Of "Arranged in A Spacially Defined And Physically Addressable Manner"

Affymetrix's proposed construction of "arranged in a spacially defined and physically addressable manner" is "located in a particular location and capable of being addressed." (D.I. 243 at 23.) Illumina's proposed construction is "each probe in an array is placed in a different pre-determined location on the surface." (D.I. 240 at 24.) The dispute here is whether each probe's location within an array must be determined before it is attached to, or synthesized on the substrate. The Court concludes that neither the claim language nor the specification requires such a limitation.

Illumina cites six passages from the specification in support of its contention that each probe's location within an array must be pre-determined. (D.I. 240 at 25; D.I. 249 at 24-25.) Three of the cited passages, however, do not pertain to the arrangement of probes within an array, but to the arrangement of probe arrays on a wafer. (See '531 patent, col 2, ll. 64-7; col. 8, ll. 61-col. 9, l. 1; col. 11, ll. 58-64.) Furthermore, the other three passages, while pertinent to the arrangement of probes within an array, say nothing about when the probes' locations must be determined. (See Id., col. 1, ll. 15-16; col. 10, ll. 36-44, 45-47.) Therefore, the Court construes "arranged in a spacially defined and physically addressable manner" to mean "located in a particular location and capable of being addressed."

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5. array is construed to mean a plurality of polymers arranged on a solid support.

Affymetrix contends that "array" is a plurality of polymers arranged on a substrate.

Incyte contends that "array" means single stranded polymers synthesized monomer by monomer on spatially addressable regions of a solid support.

The Court adopts the plain, ordinary meaning of the term "array." For the reasons previously discussed, the Court rejects Incyte's attempt to limit the term to arrays which Incyte argues are enabled by the specification. Incyte has failed to identify any intrinsic evidence suggesting that Affymetrix intended "array" to have any meaning other than the plain meaning of the term.
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1. array of oligonucleotides is construed to mean a plurality of polymers of nucleotides ranging in length from 2 to about 100 nucleotides, arranged on a solid support.

Affymetrix and Incyte assert that "array" and "oligonucleotide" as used in the '305 patent have the same meanings as respectively proffered by the parties for the '934 patent.

Hyseq contends that "array of oligonucleotides" means a two-dimensional arrangement of oligonucleotides covalently attached to a surface in positionally defined and distinguishable predefined regions, wherein each of the predefined regions includes a mixture of single stranded oligomers of nucleotides synthesized monomer by monomer on each predefined region by stepwise attachment of a nucleotide to a surface-bound growing oligomer, where the mixture includes synthesis failures and full-length synthesis products.

For essentially the same reasons discussed in its construction of the terms, "array" and "oligonucleotides" in the '934 patent, the Court adopts the construction recited above. Hyseq's proffered definition is unsupported by any portion of the '305 specification or prosecution history indicating that the patentee intended that the specific terms, "array" and "oligonucleotide" be limited in this manner. Hyseq's additional limitations thus would constitute impermissible importation of limitations from the specification to the claims.
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1. "an array of oligonucleotides"

a. The Parties' Proposed Constructions

OGT argues that the preamble (i.e., the phrase "A method of making an array of oligonucleotides, which comprises:") is not limiting and therefore, does not require construction. (D.I. 174 at 9.) If found to be a limitation, OGT proposes that I construe the phrase "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support." (Id.; D.I. 173 at 1.) Mergen proposes that I construe "an array of oligonucleotides" to mean "a single structured array of oligonucleotides having related sequences, such that the pattern of binding 6 of the sample polynucleotides to the oligonucleotides reveals the sequence of the sample polynucleotides." (D.I. 175 at 27; D.I. 209 at 5.)

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6 Mergen uses the term "hybridization" in the Joint Claim Construction Chart, D.I. 173 at 1, instead of "binding," which it used in its Opening Claim Construction Brief, D.I. 175 at 27, and its Answering Brief, D.I. 209 at 5. The difference is

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negligible because I consider the terms essentially synonymous for the purpose of construing the phrase "an array of oligonucleotides" in claim 1 of the '270 patent.

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OGT argues that the preamble is not limiting and does not require construction. (D.I. 174 at 9.) If construed, OGT argues that this term is entitled to its ordinary and plain meaning. (D.I. 174 at 10.) The plain meaning of "an array" is a set of elements with two or more locations. (Id.) Mergen argues that the preamble needs to be construed because it gives meaning to the claim. (D.I. 209 at 5; D.I. 175 at 27-30.) Mergen further argues that there are two issues in dispute with regard to this claim term: (1) whether "an array" can be construed to mean more than one array, and (2) whether the "array of oligonucleotides" is a structured array of related sequences for sequencing analysis. (D.I. 175 at 27.) As to the latter, Mergen asserts that the answer is yes, the term is so limited. (Id. at 29.) It cites several parts of the specification that it believes support its proposed construction. (Id. at 28-29.)

b. The Court's Construction

A preamble is only limiting where "it recites essential structure or steps, or if it is necessary to give 'life, meaning, and vitality' to the claims." Intirtool, Ltd. v. Texar Corp., 369 F.3d 1289, 1295 (Fed. Cir. 2004) (internal quotations and citations omitted). If deletion of the preamble "does not affect the structure or steps of the invention," it should not be considered limiting unless there is "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art. Id. (internal quotations and citations omitted).

While I do not think that the preamble's deletion affects "the structure or steps of the invention," id., to the extent that it is limiting, I agree with OGT's construction. This construction is consistent with the ordinary and plain meaning of "an array." I will not read limitations into the claim from the specification when the term is easily construed according to its ordinary meaning as understood by a person of ordinary skill in the art. See Texas Digital Sys., Inc., 308 F.3d at 1205. Claim 1 states a method of making an array, not what uses that array may have, or what information may be gained by its use. Therefore, I do not accept Mergen's proposed construction. I construe "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support."
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C. "ascorbic acid"

The parties' dispute -- or, more accurately, Sara Lee's argument -- over the meaning of this term is somewhat obscure. Sara Lee argues that the term "ascorbic acid" must be read to require the simultaneous presence of both ascorbic acid and food acid in prescribed amounts. (Sara Lee's Claim Construction Brief, at 14-15; Sara Lee's Response to Plaintiff Yoon Ja Kim's Claim Construction Brief, at 7; Sara Lee's Claim Construction Reply Brief, at 9-10). Kim simply argues that the term should be assigned its common and ordinary meaning. (Plaintiff's Reply to Defendant's Claim Construction Brief, at 7-8).

We recall that there is a "heavy presumption" that a claim term carries its ordinary and customary meaning. Teleflex, Inc., 299 F.3d at 1325. Ascorbic acid -- also known as vitamin C or L-ascorbic acid -- is a water soluble vitamin that is found in fruits and vegetables, is a strong reducing agent, and is reversibly oxidized to dehydroascorbic acid. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, at 127 (1986). Its chemical notation is C[6]H[8]O[6]. Id. As such, the claim term is rather easily, and definitively construed. It would seem that this would be sufficient to, disclose the invention to one skilled in the relevant art of baking. Sara Lee, however, is dissatisfied with so obvious a conclusion, but has difficulty explaining why.

First, Sara Lee urges the court to construe "ascorbic acid" to mean "the simultaneous presence of ascorbic acid and food acid in the claimed amounts." (Sara Lee's Claim Construction Reply Brief, at 9). Then, Sara Lee explains that it is "simply asking that ascorbic acid be given its ordinary meaning, and not construed to be something other than ascorbic acid." Id. There is nothing "simple" about this: obviously, construing "ascorbic acid" to mean "ascorbic acid and food acid" is construing it as something other that "ascorbic acid." As best the court can decipher it, Sara Lee's argument would appear to be that, where the claims indicate that food acid is added to ascorbic acid, the ascorbic acid must still be ascorbic acid. This

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would seem to be clear from the language of the patent and would not appear to necessitate a novel definition of ascorbic acid, but the court will engage in a brief explanation.

As noted in the discussion of basic breadmaking chemistry and the above-quoted dictionary definition, ascorbic acid (C[6]H[8]O[6]) oxidizes into dehydroascorbic acid (C[6]H[6]O[6]). As the patent teaches, food acid is added to ascorbic acid in order to slow down the oxidation of ascorbic acid into dehydroascorbic acid. ('355 patent, at 3:13-18; 5:26-34; 6:3-7; 7:26-32). The court finds no language in the patent -- and Kim has not directed us to any -- that teaches that food acid may be added to dehydroascorbic acid. At that point, ascorbic acid will have been oxidized, so the effect of the food acid described in the patent -- the slowing of the oxidation rate -- would be irrelevant. The patent does not discuss the effect -- if any -- of adding food acid to dehydroascorbic acid. The claims discuss only the addition of food acid to ascorbic acid. As such, the court is confident that the construction of ascorbic acid to have its ordinary and customary meaning, vitamin C or C[6]H[8]O[6], is sufficient. It is clear from the language of the patent that food acid is to be added to this substance.
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I. Aseptically Packaged, Aseptically Packaging, Aseptic Packaging

The parties dispute the meaning of the terms "aseptically packaged," "aseptically packaging" and "aseptic packaging." Michael Foods claims that "aseptically packaged" means "packaged to the exclusion of microorganisms other than those carried by the liquid whole egg product." (Michael Foods' Initial Markman Br. at 40.) Sunny Fresh asserts that "aseptically packaged" means "a sterile packaging environment, sterile packaging materials and sterile (hermetic) sealing." (Sunny Fresh's Resp. at 19.)

The specification clearly defines aseptically packaged. It states that "aseptically packaged means packaged to the exclusion of microorganisms other than those carried by the liquid whole egg product." (Kempf Aff., Ex. 1, Col. 6, ll. 57-59.) Sunny Fresh argues that such a construction does not give the term its ordinary meaning. However, a patentee is free to be his own lexiographer, so long as the patentee makes his intentions clear in the patent, Vitronics, 90 F.3d at 1582; Chisum on Patents, § 18.03[3](1999), and the patentee in this case has done just that by clearly defining the term "aseptically packaged" in the specification. 15

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15 Sunny Fresh asserts several other arguments as to why its construction of the term is clear. However, each of these arguments fails to account for the clear definition of the term in the patent. That definition controls.

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The court looks to extrinsic evidence to determine whether the patent's aseptic packaging includes extended shelf life packaging ("ESL") because the intrinsic evidence does not answer this question. Sunny Fresh's 30(b)(6) witness testified:

Q: Aseptic packaging, in your understanding in the context of non-egg food products, is introducing an aseptic product into an aseptic package?

A: Not necessarily. Aseptic packaging by itself is aseptic packaging, aseptic filling environment. Now what comes into the system dictates what would be the storage requirements for the finished product. Sometimes they would - in the food industry they would introduce nonsterilie product into a nonaseptic - into an aseptic packaging system to get more of a shelf life under refrigerated conditions of this product. Most frequently it would be, as you indicated before, sterile product into sterile package - sterile packaging environment to get the shelf stable product.

Q: Can you give me an example of what you meant by "they would introduce a nonaseptic product"?

A: In the diary business they would pasteurize product that - in a way that will result in a nonsterile stream, and then they will introduce it into - into an aseptic packaging system and that would result to, as it's called now, I didn't know the term before, an extended shelf life product. (Kempf Aff., Ex. 21 at 102, ll. 18 - 103, ll. 19, (emphasis added).

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This testimony shows that one of ordinary skill in the art reading the patent would understand that taking a nonsterile stream of product and introducing it into an aseptic packaging system "… would result to [sic], as it's called now, I didn't know the term before, an extended shelf life product." Id. The court therefore construes the terms "aseptically packaged," "aseptically packaging" and "aseptic packaging" to mean packaged to the exclusion of microorganisms other than those carried by the liquid whole egg product and notes that those terms may include ESL.
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3. "Assaying a Sample"

PerkinElmer and NTD argue that the term "assaying a sample" means "determining the amount of a particular constituent of a mixture," while Intema contends that the term has the more specific meaning, "detectingand quantifying a biochemical screening marker in a sample using a device and reagents designed for such purpose [a process which] changes the composition of the sample." According to the plaintiffs, the plain meaning of "assaying" is unambiguous, and the Court thus should not resort to extrinsic evidence. Intema responds that "assay" is ambiguous, because it could have either this general meaning or a narrower meaning that is specific to Down syndrome screening. Since both meanings appear to be consistent with the plain language, and neither party has offered intrinsic evidence to support its preferred reading, I find that the term could have either construction. 8

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8 Plaintiffs cite the specification's description of prior screening methods, but this discussion is consistent with either definition. See '103 Patent Specification 1:40-55. Of course, the existence of similar assays in the prior art may affect the patent's validity, but that question is not before the Court at this time.

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Therefore, I may consider extrinsic evidence to clarify the term's meaning. See Phillips, 415 F.3d at 1324. The plaintiffs offer a technical dictionary, which defines assay as "determination of the amountof a particular constituent of a mixture." Dorland's Illustrated Medical Dictionary 149 (28th ed. 1994) (document # 44-11). Moreover, the plaintiffs cite cases defining "assay" similarly in different contexts. See, e.g., General Atomics, Diazyme Labs. Div. v. Axis-Shield ASA, No. C 05-04074 SI, 2006 U.S. Dist. LEXIS 73671, 2006 WL 2792428, at *6 (N.D. Cal. Sept. 27, 2006). In contrast, an Intema expert states that an assay generally "involves the use of dedicated and specialized equipment and reagents designed to test for the presence of that certain substance in the sample." First Declaration of Jacob A. Canick PP 26-27 (document # 46). The addition of a reagent "changes the composition of the sample, generally enabling the measurement of the substance or making the measurement more effective." Id. P 27.

It may be true that assay has the more expansive meaning offered by plaintiffs in the broader field of medicine. Moreover, courts generally should prefer technical dictionaries to expert testimony when looking at extrinsic evidence. See Vitronics, 90 F.3d at 1585. In this case, however, Intema's proposed construction is more specific to the processes involved in this patent. As a result, I adopt Intema's constructionof this term.
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D. "assaying homocysteine in a sample"

General Atomics' proposed construction of "assaying homocysteine in a sample" is "the entire process of determining the relative amount of homocysteine in a mixture, including but not limited to the contacting and assessing steps of the claim." Axis-Shield convincingly argues that "the entire process" is unnecessary, and potentially confusing. Similarly, "including but not limited to the contacting and assessing steps of the claim," while not incorrect, appears superfluous. Accordingly, the Court construes "assaying homocysteine in a sample" to mean "determining the amount or concentration of homocysteine in

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a sample."
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4. "Associates with"

Caliper proposes that the term "associates with" be construed as: "associates with, interacts with, binds to, or forms a complex with in a non-specific and charge-dependent manner."

MDC proposes that, in the context of the '774 patent, one compound "associates with" another when it "binds to it in an non-specific charge dependent manner." MDC does not object to the construction of the term to include "associates with," "interacts with" or "forms a complex with." The only real dispute, therefore, is the meaning of the term "non-specific and charge dependent" which has already been construed.

Accordingly, the Court adopts Caliper's construction of the term "associates with" to mean: associates with, interacts with, binds to, or forms a complex with in a non-specific and charge-dependent manner. The disputed terms "non-specific" and "charge-dependent" have already been construed.
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I.

The '112 patent issued to Hans Joachim Rothe, et al., (Rothe) on December 20, 1977. Rothe assigned the patent to his employer, Zimmer Aktiengesellschaft (Zimmer). The '112 patent claims a process for making granules of container-grade polyethylene terephthalate (PET). Container-grade PET granules are the central ingredient for a variety of products, including two-liter soft drink bottles.

Rothe's invention solved a significant problem in producing PET granulate. To make a granulate suitable for unbreakable bottles requires an increase in the molecular weight and intrinsic viscosity of PET. This increase occurs through the process of polycondensation or solid state polymerization. Polycondensation takes place in a "fixed bed" reactor. In the reactor, the PET granulate flows slowly downward while hot, inert gases pass through the PET to remove aldehyde by-products. During polycondensation, the PET granulate can stick together and plug the large reactor vessel.

Rothe's invention solved this sticking problem without the addition of anti-sticking agents or expensive modifications to the reactor. Rothe learned that a crystallization step before polycondensation would prevent sticking. To prevent sticking, however, the crystallization must occur at temperatures at or above the polycondensation temperatures. Claim 1, the broadest claim of the '112 patent, from which all other claims depend, expresses the invention:

1. A process for the continuous production of high molecular weight polyethylene terephthalate by polycondensation in the solid phase from a dried, granulated polyethylene terphthalate, having an intrinsic viscosity of at least 0.15, which comprises crystallizing the granulate to a density of at least 1.390 g/cm3 under forced motion at a temperature of 220 C to 260 C under an inert gas atmosphere, passing the crystallized granulate at a constant or reduced temperature to a continuous fixed bed reactor, and, continuously polycondensing the crystallized granulate in said reactor while in contact with an inert gas stream at a temperature equivalent to, or lower than, the crystallization temperature.

'112 patent. (Emphasis supplied.)

Eastman Kodak Company 1 (Eastman) acquired the exclusive right to enforce the '112 patent from Zimmer in April 1990. In September of that year, Eastman brought suit against Goodyear in the Eastern District of Tennessee to enjoin Goodyear from making container-grade PET under the patented process. Shell purchased Goodyear's accused production facility in December 1992. As part of this purchase agreement, Goodyear agreed to indemnify Shell for costs incurred in this infringment action.

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1 Eastman Chemical Company, which had previously been a division of Eastman Kodak Company, became a separate corporation in December 1993.

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Soon after Eastman filed suit, Goodyear filed its own action in the United States District Court for the District of Columbia. Goodyear charged that Eastman's acquisition and enforcement of the '112 patent violated federal antitrust and state unfair competition laws. On Eastman's motion, the district court transferred this suit to the Eastern District of Tennessee, where it was consolidated with Eastman's suit. At this point, Goodyear sought reexamination of the '112 patent. In February 1993, the Patent and Trademark Office (PTO) confirmed the patentability of all claims of the '112 patent. After discovery stretching into 1994, the district court dismissed Goodyear's federal antitrust claims with prejudice and struck the related patent misuse defenses.

Thus, after lengthy proceedings, the district court began trial. At trial, the parties principally contested the meaning of the claim phrase "at a temperature of 220 C to 260 C." Eastman read this language as one of several process parameters, suggesting the heating medium must comply with these limits. Goodyear, on the other hand, insisted that this claim limitation referred to the granulate or polymer itself, not the temperature of the heating medium.

During trial, this court issued its in banc decision in Markman v. Westview Instr., Inc., 52 F.3d 967, 34 U.S.P.Q.2D (BNA) 1321 (Fed. Cir. 1995) (in banc), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461 (1996). In accordance with this decision, the district court instructed the jury on the meaning of the patent claims. The court construed the temperature limitation in the crystallizing step to refer to the temperature of the heating medium, not the temperature of the granulate. Before giving the case to the jury, the trial court granted defendants' motion for JMOL precluding a finding of infringement by CSS lines 3-8, 10, and 11. The court also declined to apply laches and equitable estoppel. Thus, the jury received only plaintiffs' claim of infringement by CSS lines 1 and 2. The jury found infringement of the '112 patent. The court convened a damages trial before the same jury, which awarded plaintiffs $ 12,000,000. The district court entered judgment on April 28, 1995, and denied defendants' subsequent JMOL motions.

II.

Claim Construction

As noted earlier, the central issue in this appeal -- as is often the case in patent appeals in the wake of Markman, 52 F.3d at 989 (Mayer, J., concurring)("To decide what the claims mean is nearly always to decide the case.") -- is the district court's claim interpretation. Claim interpretation proceeds under the guidelines set forth by the Markman case. Markman, 134 L. Ed. 2d 577, 116 S. Ct. 1384; Markman 52 F.3d at 979. This court, speaking in banc, restated familiar principles of claim interpretation:

> 'To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history.' . . . 'Expert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used.

Markman, 52 F.3d at 979 (citations omitted). The claim language itself defines the scope of the claim. See York Prods., Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572, 40 U.S.P.Q.2D (BNA) 1619, 1622 (Fed. Cir. 1996). To learn the necessary context for understanding the claim language, however, a construing court may consult other sources, including the patent specification, the administrative record of patent acquisition, expert commentary from those of skill in the art, and other relevant extrinsic evidence. Markman, 52 F.3d at 979. In other words, a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language.

The trial court construed the claim language "crystallizing the granulate to a density of at least 1.390 [grams per cubic centimeter] under forced motion at a temperature of 220 C to 260 C under an inert gas atmosphere" to set the temperature of

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the heating medium, not the temperature of the granulate, at between 220 C to 260 C. To determine the proper referent for the claim's temperature clause, this court examines principally the claim language and any syntactic signs of its meaning. See Credle v. Bond, 25 F.3d 1566, 1571, 30 U.S.P.Q.2D (BNA) 1911, 1915 (Fed. Cir. 1994); In re Hyatt, 708 F.2d 712, 714, 218 U.S.P.Q. (BNA) 195, 197 (Fed. Cir. 1983) ("A claim must be read in accordance with the precepts of English grammar.").

The claim calls for "crystallizing the granulate to a density of at least 1.390 g/cm3 under forced motion at a temperature of 220 C to 260 C under an inert gas atmosphere." '112 patent, col. 10, ll. 28-31 (emphasis added). In this context, according to Webster's II New Riverside University Dictionary, the word "to" means "with the resultant condition of" or "toward a specified state," the word "at" means "in the state or condition of," and the word "under" means "undergoing or receiving the effects of." Webster's II New Riverside University Dictionary, 1214, 134, 1256 (1988). Under normal rules of syntax, therefore, "at" and "under" implies a controlled value (such as a process parameter), whereas "to" implies a measured and intended goal or condition (such as a polymer temperature). This context suggests that a step performed "at" a temperature indicates a process condition, not the condition of the matter under process.

Removing the intervening phrases leaves the language "crystallizing the granulate . . . at a temperature of 220 C to 260 C." The "at" in the temperature clause thus modifies "crystallizing," a process, not "the granulate." Indeed the claim thrice refers to temperatures as process steps with the introductory preposition "at": (1) "crystallizing . . . at a temperature of 220 C to 260 C"; (2) "passing . . . at a constant or reduced temperature"; and (3) "polycondensing . . . at a temperature equivalent to, or lower than, the crystallization temperature." '112 patent, col. 10, ll. 28-36 (emphasis added). This sentence structure discloses that the preposition "at" preceding the temperature limitation refers to the process temperature of the heating medium, rather than the temperature of the polymer itself.

In addition, the final phrase in the claim discusses "a [polycondensation] temperature equivalent to, or lower than, the crystallization temperature." This reference to "the crystallization temperature" identifies the earlier temperature limitation with the crystallization process step, rather than the temperature of the granulate. The claim does not say "equivalent to, or lower than, the temperature of the granulate during crystallization," but instead says "equivalent to, or lower than, the crystallization temperature." As a process parameter, the 220 C to 260 C language specifies the temperature of the heating medium which performs the process, rather than the temperature reached by the polymer itself during crystallization.

More importantly, however, a central requirement of the claim is a particular relationship between crystallization temperature and polycondensation temperature, which is stated by the final phrase in the claim. Because the second step -- "continuously polycondensing the crystallized granulate in said reactor while in contact with an inert gas stream at a temperature equivalent to, or lower than, the crystallization temperature" -- expressly refers to a heating medium temperature, a proper comparison refers to the heating medium temperature in the first step as well. To ensure the proper relationship, the claim logically compares process conditions during crystallization to process conditions during polycondensation. Otherwise, the claim would compare granulate temperature during one phase of the process with heating medium temperature during another phase. Thus, the syntax of the claim suggests comparison of like entities to like entities -- apples to apples, oranges to oranges, heating medium to heating medium.

The claim language alone, however, does not settle the claim interpretation issue. One of the parameters in the process sequence, namely "to a density of at least 1.390 g/cm3," specifies a property of the polymer, rather than of the heating medium. Moreover, on the point of comparison of like entities, a comparison of polymer temperature after crystallization to heating medium temperature during polycondensation, although syntactically unconventional, can be explained in terms of process chemistry. Thus, without manifest clarity in the claim language alone, this court consults other sources about the intended meaning of the claim language. See E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 U.S.P.Q.2D (BNA) 1129, 1131 (Fed. Cir. 1988).

The specification, of which the claims are part, teaches about the problems solved by the claimed invention, the way the claimed invention solves those problems, and the prior art that relates to the invention. These teachings provide valuable context for the meaning of the claim language. The specification states: "Polyethylene terephthalate . . . was crystallized, using the apparatus described in the examples 1-18, at a temperature, Tk, of 235 [C] for a time, tk, of 1.5 hours." '112 patent, col. 4, ll. 56-59. The specification uses the abbreviation Tk, or crystallization temperature, with apparent reference to the temperature of the heating medium. '112 patent, col. 6, ll. 66-68 ("The crystallization temperature Tk was always selected to conform to the polycondensation temperature Tf.") (emphasis added).

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Table 1 in the specification, however, is even more revelatory of the meaning of Tk, or the crystallization temperature. In showing the temperature values for various parameters and the corresponding presence or absence of "stickiness," Table 1 lists the crystallization temperature values for a sequence of samples in whole numbers, falling in increments of five or ten degrees. By recording temperatures in exact increments of 5 to 10 degrees, the table suggests that the crystallization temperature refers to the setting of the heating medium, rather than a precisely measured polymer temperature. The table apparently reports the dialed-in temperature settings of the heating apparatus, which would likely be selected in increments rounded to the nearest five degrees, rather than the temperature of the polymer which likely would be measured and recorded with greater precision. Values for the polycondensation temperature, which is unquestionably a process parameter, also appear in exact increments of five to ten degrees. Thus, Table 1 points to Tk as the temperature of the heating medium, not the granulate.

Again, however, the specification -- though helpful -- does not supply entirely conclusive proof of claim meaning. For instance, the specification also indicates: "that the granulate was heated in the continuously operating mixer to the temperature values, Tk." '112 patent, col. 3, ll. 45-46 (emphasis added). This passage suggests that the granulate achieves the crystallization temperatures. Moreover the specification refers in another passage to the temperature of the heating medium separate from the crystallization temperature, '112 patent, col. 7, ll. 52-53, suggesting that the patent drafter knew how to refer to the temperature of the heating medium when he so intended. Thus, although the specification tends to support the trial court's claim reading, this court has cause to look further at other sources for the meaning of the claim language.

The administrative record of patent acquisition also supplies further context for the meaning of the claim language. During prosecution, Zimmer, the original assignee of the '112 patent, emphasized the invention's surprising results. In response to an office action, Zimmer noted that sticking "may be prevented if the polycondensation is preceded by a crystallization reaction utilizing temperatures which are higher than or equal to the temperature at which the solid state fixed bed polycondensation reaction is performed." In this passage, the term "utilizing" suggests the claims refer to the temperature of the heating medium rather than the temperature of the polymer. Zimmer used similar language throughout the prosecution history, with words like "used," "utilized," and "while heating at" the claimed temperature range. Further, Rothe submitted a drawing to the Patent and Trademark Office (PTO) that clearly shows a "hot oil jacket" at a temperature of 220 C to 260 C surrounding the crystallization chamber. Thus, the prosecution history supports the conclusion that the temperature specified in the claims is the temperature of the heating medium. This conclusion also finds support the observation that the medium temperature is the only temperature that the operator can directly control during processing.

Again, however, the evidence from the prosecution history is not conclusive. In other parts of the administrative record, Zimmer distinguished the temperatures claimed in the patent from polymer temperatures in the prior art. Among other distinctions from the prior art, Zimmer argued that the polymer temperature in its invention decreases or stays the same upon entry into the polycondensation stage. In making this distinction, Zimmer apparently refers to polymer temperatures. In the prior art, a preheater preceded the polycondensation step. In the prior art Jaeger process, the preheater heating medium temperature is higher than at polycondensation, U.S. Pat. No. 3,756,990, col. 10, ll, 69-75, and in the prior art British Hoechst patents, the preheater heating medium temperature is approximately the same as at polycondensation, British Pat. No. 1,215,093. Thus Zimmer's temperature distinctions from prior art rely on polymer temperature, rather than heating medium temperatures. At no point, however, does the prosecution history show that Zimmer intended that the crystallization temperatures in its claim refer only to polymer temperatures.

Accordingly, the district court properly consulted extrinsic evidence relevant to claim meaning. As a general rule, the construing court interprets words in a claim as one of skill in the art at the time of invention would understand them. See Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387, 21 U.S.P.Q.2D (BNA) 1383, 1386 (Fed. Cir. 1992). Therefore, the testimony of one skilled in the art about the meaning of claim terms at the time of the invention will almost always qualify as relevant evidence. Fed. R. Evid. 401; Markman, 52 F.3d at 981 (In "pronouncing the meaning of claim language as a matter of law based on the patent documents themselves. . . the court is looking to the extrinsic evidence [i.e., testimony of one skilled in the art] to assist in its construction of the written document, a task it is required to perform."). If, of course, the meaning of the claims is clear from their language in view of the context provided by the specification and the prosecution history, the trial court should limit its consideration of extrinsic evidence. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 U.S.P.Q.2D (BNA) 1573, 1577 (Fed. Cir. 1996). Extrinsic evidence -- whether providing context for the claims or explaining claim meaning to one of skill in the art -- cannot contradict claim language. Id. The trial

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court is best situated to gauge the relevance and need for additional evidence to explicate claim terms. See International Communication Materials, Inc. v. Ricoh Co., 108 F.3d 316, 318-19, 41 U.S.P.Q.2D (BNA) 1957, 1958 (Fed. Cir. 1997) (allowing the trial judge "to complete the picture" by developing a "more complete record").

As often occurs, each party presented experts vouching for their usage of the crystallization temperature limitation in the claim. According to the district court, Dr. Paul Phillips best reconciled these competing experts, and we agree. Dr. Phillips noted that the ordinary meaning of crystallization temperature in the field of polymer science is generally the temperature of the polymer undergoing crystallization, but the meaning of the term in the more specialized field of industrial chemical production is the temperature of the heating medium. Thus, in scientific writings focused on properties of a particular chemical, crystallization temperature often refers to the temperature of that chemical. Even Dr. Phillips used crystallization temperature to refer to the temperature of the polymer in such scientific writings. In technical writings about chemical processes and production methods, however, crystallization temperature generally refers to the temperature of the heating medium.

After a careful consideration of the entirety of the relevant evidence, the district court concluded and instructed the jury: "In this [first] step [of the claimed process], "220 C to 260 C" is the temperature of the heating medium and not the temperature of the granulate or polymer." Upon review of the entire record, and recognizing both the trial court's "trained ability to evaluate [expert] testimony in relation to the overall structure of the patent" and the trial court's "better position to ascertain whether an expert's proposed definition fully comports with the specification and claims," see Markman, 116 S. Ct. at 1395, this court sustains the trial court's claim interpretation.

Indeed, the district court's claim interpretation is supported by a review of the 1993 reexamination, one of four reexaminations (three of which Goodyear requested in connection with this litigation) of the '112 patent at the PTO. The claims require that the PET granulate polycondenses at a temperature "equivalent to, or lower than, the crystallization temperature." '112 patent, col. 10, ll. 35-36. During the 1993 reexamination, the examiner's Reexamination Interview Summary Form stated that this claim language meant "not exceeding the initial crystallization temperature during further crystallization and after condensation." To the extent that the examiner's certificate purports to ascribe meaning not found in the claim language, this court must not permit prosecution history evidence to "enlarge, diminish, or vary" the meaning of claim language. Markman, 52 F.3d at 980. The claim language does not mention "initial crystallization" as distinct from "further crystallization." Nor did the 1993 reexamination require any changes in claim language.

In sum, the limitation in the examiner's statement does not appear anywhere in the claim language. The "initial" and "further" crystallization was apparently the examiner's way of distinguishing Jaeger which precrystallized some granulate before it entered the reactor for so-called "further crystallization" and polycondensation. Jaeger, however, does not disclose the temperature of its precrystallization, nor the critical '112 patent feature of holding the subsequent temperatures below that first crystallization step. Thus, without creating any additional limitations, as the examiner conceded by granting the reexamination certificate without any changes in claim language, the claims sufficiently distinguished Jaeger. Moreover, the examiner's statement might well render the claim inoperable. This court seeks to interpret claims to preserve, rather than defeat, their validity. ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 U.S.P.Q. (BNA) 929, 932 (Fed. Cir. 1984). Thus, we affirm the trial judge's decision to exclude the limitation concerning "further crystallization" not found in claim language.

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I respectfully dissent from the court's decision to affirm the district court's judgment with respect to infringement by lines 1 and 2.

I do not agree that the claim limitation "crystallizing the granulate . . . at a temperature of 220 C to 260 C" refers to the temperature of the heating medium. The claim is clear on its face, when read in light of the specification, that it refers to the temperature of the granulate. Thus, the court erred in its instruction to the jury concerning the meaning of the claim and in permitting the jury to rely on such extrinsic testimony as that given by Dr. Phillips.

When the granulate is crystallized "at a temperature," the granulate is at that temperature. I do not believe the specification is unclear on this point. Nothing in the patent, the prosecution history, or even the trial testimony indicates otherwise. The

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majority opinion, with great care, provides much analysis on this issue, but it is incorrect. Each of the bases for its conclusion that heating medium temperature is intended is a speculative guess; the opinion repeatedly uses the words "suggests" and "apparently," whereas the references in the specification to the temperature of the material being acted upon are clear references to that material.

The summary of the invention indicates, '112 patent, column 2, lines 30-32, that the granulate is crystallized at temperatures of 220 degrees C to 260 degrees C. It then states that the crystallized granulate is then transferred at the same temperature to a reactor where it is polycondensed at a temperature equivalent to, or lower than, the crystallization temperature. It also states, at column 2, lines 56-58, that, according to a preferred embodiment, the crystallization is effected at a temperature of 230 degrees C to 245 degrees C. The specification also, at column 4, lines 33-35, makes a statement that the examples are "run at [particular] temperatures," indicating that the materials being treated are "at" that temperature. It is clear from the specification, consistent with conventional chemical terminology, that the temperature of the granulate is what is meant in each case. The examples are similarly clear. At column 3, lines 46-47, the text of examples 1-18 states: "The granulate was heated in the continuously operating mixer to the temperature values, TK, as indicated in Table 1 . . . ." When the granulate is heated to a temperature, it, not the heating medium, gets to that temperature. Examples 19-26, at column 5, line 14, refer to "temperature measurements." One obviously "measures" the temperature of the reactant rather than "setting" the temperature of a heating medium. Equally telling is this use of a symbol for the temperature of the substance undergoing crystallization, TK, which the record shows conventionally means the temperature of the substance being crystallized. (Eastman's expert witnesses, Drs. Phillips and Gintis, as well as Goodyear's expert witness, Dr. Harris, each indicated that he and other polymer chemists generally use this symbol and the synonymous phrase "crystallization temperature" to refer to the temperature of the material undergoing the reaction.) See Markman v. Westview Instruments, Inc., 52 F.3d 967, 980, 34 U.S.P.Q.2D (BNA) 1321, 1330 (Fed. Cir. 1995) (in banc), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461 (1996) ("[A] patentee is free to be his own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification.") (citations omitted). At column 7, lines 22-23, examples 45-50, the specification states: "The crystallization temperature was 245 degrees C. The solid state polycondensation temperature was 240 degrees C." Nothing could be clearer; during crystallization and polycondensation the granulate was at those temperatures.

Nowhere in the description of the process in the specification is there reference to setting the temperature of a heating medium. The words "heating medium," constantly referred to in the majority opinion as the referent of the phrase "at a temperature" in the claims, do not appear in the portion of the specification describing the claimed process. They only appear in the portion describing apparatus to measure granulate stickiness, see column 7, lines 52-53, which is not the invention and which it is a purpose of the invention to prevent, see column 2, lines 39-41. Even in this section, at column 8, lines, 31-32, the specification describes a temperature feeler which measures the granulate temperature to correlate it with granulate stickiness. This is distinctly different from the description of the process provided earlier in the specification, and the claims track the description of the process. I will not prolong this opinion by citing further places in the specification indicating that temperature references refer to the material being acted upon, not to the temperature of the heating medium. 2 Clearly the temperature is that of the granulate, not the heating medium.

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2 Not surprisingly, the prosecution history in reexamination also contains multiple references to the temperature of the granulate, including, e.g., the passages: "the PET granules 'provide as much as a 10 degrees C increase in their temperature . . .'"; "the plastics material has been preheated to a temperature in the range . . ."; and, "the granular material was preheated to 220 degrees C . . . ."

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The trial court and, regrettably, the majority of this panel, have simply been misled concerning what the specification clearly states and means. The analyses in the majority opinion leading to the contrary conclusion are not in my view convincing, even to show an ambiguity. The interesting analyses of sentence structure and the meaning of the words "at," "to," "under," "utilizing," and "used" prove nothing. They do not indicate that the temperature is not of the granulate. Likewise, granulate temperature is fully consistent with the five-degree increments in Table 1.

Given the clear meaning of "at a temperature," I believe that there is no need to resort to extrinsic evidence to resolve an

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ambiguity in the claim. The majority opinion acknowledges that extrinsic evidence cannot be admitted to contradict the claims, the specification, and the prosecution history. See Markman v. Westview Instruments, Inc., 134 L. Ed. 2d 577, 116 S. Ct. 1384, 1395, 38 U.S.P.Q.2D (BNA) 1461, 1470 (1996) ("Any credibility determinations will be subsumed within the necessarily sophisticated analysis of the whole document, required by the standard construction rule that a term can be defined only in a way that comports with the instrument as a whole."); Trilogy Communications, Inc. v. Times Fiber Communications, Inc., 109 F.3d 739, 744, 42 U.S.P.Q.2D (BNA) 1129, 1133 (Fed. Cir. 1997) ("Extrinsic evidence may be relied on when needed to interpret claims, but only when it does not contradict the intrinsic record consisting of the claims themselves, the specification, and the prosecution history."); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584, 39 U.S.P.Q.2D (BNA) 1573, 1578 (Fed. Cir. 1996) ("Extrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to a proper understanding of the claims; it may not vary or contradict the claim language. Nor may it contradict the import of other parts of the specification.") (citation omitted). While correctly quoting the rule, the majority misapplies it. It has ratified the trial court's use of extrinsic testimony to contradict the specification.

However, even if extrinsic evidence such as Phillips's testimony is considered, it is ambiguous at best. Notwithstanding his admission of the common meaning of the phrase "crystallization temperature," Phillips stated that in the more specialized field of industrial chemical production someone of "ordinary skill in that art" would read that phrase as a "setting" for the heating medium. That contradicts the specification. One must read and rely on the specification, not invent categories of activity to which witnesses can assign different meanings for the same language. The patent teaches others of skill in the art how to make the claimed polymer, consistently using language meaningful to chemists; the claims track this language. It does not tell how to implement the fine points of industrial-scale techniques. It speaks to those who read the specification and carry out the claimed process, not to plant technicians.

Although proper interpretation of the claims as above is sufficient to result in a judgment for Goodyear, the majority opinion's interpretation of the meaning of the claim phrase "continuously polycondensing . . . at a temperature equivalent to, or lower than, the crystallization temperature" is also wrong. As the majority opinion states, quoting from the Supreme Court's Markman opinion, 116 S. Ct. at 1395, 38 U.S.P.Q.2D (BNA) at 1470, this interpretation is based upon "the trial court's 'trained ability to evaluate [expert] testimony' . . . and . . . 'better position to ascertain whether an expert's proposed definition fully comports with the specification and claims.'" This language, while directed to the differences between judge and jury in Markman, is inapplicable here because the trial court's "trained ability" and "better position" to evaluate witnesses are irrelevant when reading the specification is what counts. The appellate court is equally well situated to read the specification. The majority opinion's claim interpretation is also based upon a reexamination examiner's distinction between an initial crystallization temperature and further crystallization in relation to prior art. This is irrelevant to the present infringement question because Goodyear's polycondensation occurred at a temperature greater than either crystallization step; therefore Goodyear could not infringe the claims, which require that polycondensation occur at an equivalent or lower temperature.

Given the proper claim construction, the trial court should have granted judgment as a matter of law that lines 1 and 2 do not infringe the '112 patent.

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D. "At least a portion of"

Claim 17 reads: "The vector of claim 10 wherein said enhancer element comprises at least a portion of the nucleotide sequences set forth in FIG. 10." Claim 22 reads: "The transformant of claim 20 wherein said enhancer element comprises at least a portion of the nucleotide sequences set forth in FIG. 10." There is no indication in the patent that this phrase was meant to have anything other than its normal meaning of "at least a part of."

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3. "at least about 98.4% enantiomeric excess"

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This term is found in claim 4, which reads: "Magnesium salt of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole in an optical purity of at least about 98.4% enantiomeric excess." '872 patent, col. 14, lines 24-27 (emphasis supplied). Astra asserts that the entire disputed phrase should be construed to mean "at least 98% enantiomeric excess." DRL argues that the term "at least about" should be construed to mean "equal to or more than approximately." Unlike Astra, DRL's construction assigns no specific numerical value to the level of purity described.

The Court finds DRL's construction to be more consistent with the ordinary and customary meaning of the term. The issue being only briefly addressed in the voluminous submissions of the parties, Astra simply provides no adequate justification for assigning a numerical limit of 98% to this claim term. Therefore, the Court shall construe the term "at least about" in this phrase as "equal to or more than approximately."
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2. Claim Construction Of "At Least About 95% By Volume Hydrogen"

The next issue to resolve is the meaning of the hedge phrase "at least about" that appears in all of the claims of the Kilbane and Boston patents. Sollac argues that in each patent, the phrase must be interpreted to mean "approaching exactly 95% or greater than 95% and no less than 94%" Sollac 1st Mot. at 36-38. AK argues that the phrase means "an imprecise amount of hydrogen, loosely defined as approximately or near 95% (with a contemplated variation) by volume hydrogen." AK 1st Opp'n at 30-31.

a. "About" in Claims

The term "about" appears often in patent claims and the courts have routinely had to interpret it. "About" has been interpreted by the Federal Circuit, generally, as "with some approach to exactness in quantity, number, or time." Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1561 n.2 (Fed. Cir. 1994) (citing Webster's Third New International Dictionary). This appears to add nothing to the ordinary meaning of "about." Even though the word "about" avoids a strict numerical boundary, its range must be interpreted in light of the specification, prosecution history and technology embodied in the invention. Pall Corp. v. Micron Separations, Inc. 66 F.3d 1211, 1217 (Fed. Cir. 1995), cert. denied, 520 U.S. 1115, 117 S. Ct. 1243, 137 L. Ed. 2d 326 (1997); Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed. Cir. 1996), cert. denied, sub. nom Showa Aluminum Corp. v. Modine Mfg. Co., 518 U.S. 1005, 135 L. Ed. 2d 1048, 116 S. Ct. 2523 (1996). In this respect, it is appropriate to consider the effects of varying that parameter in order to discern the inventor's intended meaning. Pall, 66 F.3d at 1217.

b. The Patent Specification

In the Kilbane patents, several references are made to the percentage of hydrogen by volume in the protective atmosphere. Kilbane teaches that: "the protective atmosphere must contain at least about 95%, more preferably at least 97%, and most preferably as close to 100% as possible, by volume hydrogen." (Emphasis added). '214 at 4:21-24. Furthermore, in the section providing examples of the claimed process, Kilbane states:

> When the atmosphere was about 92% by volume hydrogen and the balance nitrogen, the coating quality was unacceptable. Increasing the hydrogen to about 94% by volume produced what was considered to be marginally acceptable coating quality. When the hydrogen was increased to 97% by volume, the coating quality observed was considered to be excellent and the coating layer had substantially no uncoated areas.

Id. at 6:3 1-38.

c. Conclusions as to "At Least About 95% By Volume Hydrogen" in the Kilbane Patents

Although the Kilbane prosecution histories do not elucidate the meaning of "about" any further, the specification makes it clear that the term "about 95%" cannot mean 92% by volume hydrogen, since that percentage produced a coating quality that was unacceptable. See, e.g., Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1105 (Fed. Cir. 1996) (stating that claim language must be interpreted in a manner that would not result in the inoperativeness of the claimed invention). With 94% to 100%

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by volume hydrogen, the coating quality ranges from "marginally acceptable" to excellent. Thus, it is recommended that the claim term "at least about 95% by volume hydrogen" be given its ordinary meaning, except that its lower limit is to be interpreted in light of the specification statements that 94% is marginally acceptable and 92% is unacceptable.
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4. "Having at least 25% water by weight"

The plaintiff proposes "25% or more of the weight of the contact lens in its hydrated state (at equilibrium conditions) is water." The defendants propose "the claimed lens has at least 25% by weight as measured by a method understood by one of ordinary skill in the art through reading the patent specification." The dispute is how one measures "25% water by weight."

The defendants argue that, at the time of the invention, there were several methods to calculate water weight and any of these methods could be used to measure the water content. The plaintiff, on the other hand, argues that the method of measuring water content is known in the art and, therefore, it is inappropriate to include a method of measuring water weight into the definition. Furthermore, according to the plaintiff, the various methods of measuring water weight substantially provide the same results.

It is unnecessary to include a limitation that the weight is measured "by a method understood by one of ordinary skill in the art." In addition, the defendants do not appear to dispute that one of ordinary skill in the art would understand that the percentage of water weight is measured at equilibrium conditions. 1 Accordingly, the Court adopts the plaintiff's proposed construction.

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1 A contact lens in its hydrated state at equilibrium condition usually occurs when the lens is immersed in saline solution at a constant temperature for a minimum of one hour. See Plaintiff's Claim Construction Brief, Ex. 9, ISO PROPOSED STANDARD (1989), at 3.

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2. "having an interfacial tension of at least about 15.0 dynes per centimeter"

The claim terms and the specification also support Beautone's proffered reading of the interfacial tension limitation -- that the phrase "at least about 15.0 dynes per centimeter" encompasses suspension stabilizers with interfacial tensions no lower than 14.8 dynes per centimeter. 17 Starting with the claim terms themselves, the phrase "at least about" modifies the tension value of 15.0 dynes per centimeter identified in the disputed claims. The words "at least" establish a lower limit to the tension value (i.e., no less than 15.0 dynes per centimeter), while the term "about" suggests that there is some degree of flexibility in that lower limit, but does not resolve the extent of that flexibility. 18

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17 3M's argument that the stabilizer's function and purpose should guide the interpretation of the "interfacial tension" limitation is not persuasive. To hold that Beautone's stabilizers infringe simply because they provide sufficient stabilization during polymerization to avoid agglomeration ignores the express language of the claim which specifies a numerical limitation with a lower limit and would enlarge the scope of the claims beyond the terms and specification.

18 It is noteworthy that during the ITC proceedings two ALJs construed the "interfacial tension" limitation. Judge Saxon interpreted the limitation to cover stabilizers with interfacial tensions as low as 13.0 dynes per centimeter. On remand, Judge Luckern concluded that the limitation included stabilizers with tensions as low as 14.8, but no lower.

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The specification is instructive in this regard. All of the exemplary stabilizers contained in Table I have interfacial tensions greater than 15.0 dynes per centimeter. Moreover, a review of the specification in conjunction with the claims teaches that a tenth of a dyne per centimeter is a significant degree of specificity. The tension value of each exemplary stabilizers is given to the tenth of a dyne. The numerical value of 15 point zero (15.0) recited in the claims also specifies the tension to a tenth of a dyne. Moreover, the standard procedure for measuring interfacial tension specified in the specification is accurate to within two tenths (+/- 0.2) of a dyne per centimeter. Therefore, because the specification warns that if the interfacial tension "falls below about 15.0 dynes per centimeter, there is insufficient stabilization of the final polymerized droplets and agglomeration may occur," a reader of the patent would not risk using a stabilizer with a tension of more than two tenths of a dyne per centimeter lower than 15.0. Accordingly, it follows that "at least about 15.0" means no less than 14.8 dynes per centimeter. See e.g. Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1455 (Fed. Cir. 1996) (affirming a district court construction of an "at least about" limitation in which the district court had used measurement errors to aid its construction).
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"At least about 40 days"

The parties agreed during oral argument that this term, which appears in claims from the '623 and '156 Patents, means "at least 40 days." The Court agrees and construes the term accordingly.
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at least an effective amount

The Court and the parties agree that the term should be construed as "a minimum dosage required."
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A.

Rodime is the owner of the reexamined '383 patent, which issued on November 29, 1988. The reexamined '383 patent is directed to a micro hard-disk drive system (3.5 inch drive) suitable for use in portable computers with performance parameters comparable to those available in 5.25 inch disk drive systems. Quantum, the plaintiff in this declaratory judgment action, is the manufacturer of disk drives which, Rodime alleges in its counterclaim, infringe its patent.

The claim limitation at issue in this appeal relates to the storage capability of the hard-disk. The storage capability of a hard-disk is a function of the track density; the greater the track density, the more data that can be stored in a given area of the disk. Track density may be defined in terms of "tracks per inch" (tpi), calculated based on the number of concentric tracks present within an inch along the radius of the hard-disk.

On November 19, 1985, James G. McGinley and Roderick M. Urquhart, two engineers at Rodime, filed a patent application for the invention described above. Claim 1 of this application recited, inter alia, a track density of "approximately 600" tpi. The examiner, in a first office action, rejected all the claims as obvious under 35 U.S.C. § 103. With respect to the track density limitation in Claim 1, the examiner stated:

The art described in the preceding paragraph [regarding 5.25 inch disks] demonstrates that such a density is within the state of the art. Such a density would seemingly be achievable on a [3.5 inch] disk in the same manner by which it was achieved on a larger disk. Consequently it would seem that the subject matter of claim 1 - which is seemingly quite general - should not be considered patentable.

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In a response dated May 23, 1986, applicants cancelled the original claims and inserted new claims some of which recited a track density of "at least 600" tpi. Although applicants had replaced "approximately" with "at least" in the track density limitation of these new claims, they made no reference to this in their response, but instead focused on the difference between the size of their disks (3.5 inch) and those in the prior art (5.25 inch) as a basis for overcoming the examiner's rejection. The examiner subsequently allowed these new claims, and the patent issued on January 20, 1987, as U.S. Patent No. 4,638,383 (the original '383 patent). Claims 4, 6, 7, 9, and 14 of the original '383 patent all recited a track density of "at least 600 concentric tracks per inch."

On September 28, 1987, Rodime, the owner of the original '383 patent pursuant to an assignment from the inventors, requested reexamination of its patent. Finding a substantial new question of patentability, see 35 U.S.C. § 303, the United States Patent and Trademark Office (PTO) granted Rodime's request for reexamination of all 16 claims in the original '383 patent. In an office action dated April 19, 1988, the examiner rejected all but two of the original claims. Rodime responded by cancelling certain claims, amending others, and adding dependent Claims 17-31. With respect to the claims at issue in this appeal, Rodime made substantial amendments including changing the track density limitation from "at least 600" tpi to "at least approximately 600" tpi. These claims were allowed, as amended, and the '383 reexamined patent issued on November 29, 1988, as U.S. Patent No. B1 4,638,383. As issued, independent Claims 4, 6, 7, 9, and 14 of the reexamined '383 patent all recite a track density of "at least approximately 600" tpi, and the newly added dependent claims which are at issue in this appeal, i.e. Claims 19-27, either explicitly contain this limitation or incorporate it through their dependency. 2

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2 Illustrative of the amendments made is Claim 4 with the sections within the brackets being the matter that was deleted and the underlined sections indicating the additions made to the claim during reexamination:

4. A computer disk drive system [for operating a micro hard-disk, said disk drive system] comprising:

a sealed housing;

at least [one] two micro [hard-disk] hard-disks each having a diameter of between 92 and 96 millimeters and each having a plurality of concentrically adjacent tracks on both planar sides thereof, said micro hard-disks fixedly mounted in [a] the sealed housing;

means for rotatably supporting said [hard-disk] micro hard-disks;

means for rotating said [hard-disk] micro hard-disks;

first and second transducer means [having two

read/write heads] for writing digital information on and reading digital information from said [hard-disk] micro hard-disks on both planar sides of [said] each micro hard-disk in a format so that [said] each micro hard-disk has digital information stored on [concentric] said concentrically adjacent tracks at a density providing at least 5 Megabytes of storage per [disk] micro hard-disk with the digital information being stored at a density of at least [6000] approximately 600 concentric tracks per inch, said first and second transducer means each comprising two read/write heads; [and,]

positioning means for moving said first and second transducer means between the concentrically adjacent tracks on said [hard-disk] micro hard-disks, said positioning means including:

a positioning arm disposed within the sealed housing and mounted for movement relative to said micro hard-disks;

a pivot shaft coupled to one end of said positioning arm and supporting said positioning arm for rotational movement relative to said micro hard-disks, four support arms, each supporting one of said heads at one end and each connected to said positioning arm at its other end; and

means for moving said positioning arm including a stepper motor having a shaft extending into said sealed housing and

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means for operating said stepper motor in step increments, each increment causing [said transducer means] said read/write heads to move from one track to the next adjacent track on said [hard-disk] micro hard-disks.

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B.

Quantum filed the present action in the United States District Court for the District of Minnesota on February 26, 1993, seeking a declaration that the reexamined '383 patent is invalid, unenforceable and not infringed. Rodime subsequently filed an answer and a counterclaim for infringement. On February 22, 1994, Quantum filed a motion for summary judgment that Claims 4, 6, 7, 9, 14, and 19-27 of the reexamined '383 patent are invalid under 35 U.S.C. § 305 for being impermissibly broadened by Rodime during reexamination. According to Quantum, Rodime's amendment during reexamination of the track density limitation from "at least 600" tpi to "at least approximately 600" tpi broadened the scope of the claims to cover certain disk drives with approximately but less than 600 tpi that were not covered by the original '383 patent claims, and therefore these claims are invalid under 35 U.S.C. § 305.

The district court, in an order dated April 11, 1994, granted Quantum's motion for summary judgment. The court, after examining the claims, specification, and prosecution history, concluded that the addition of the word "approximately" to the track density limitation during reexamination was not a mere clarification, as Rodime argued, but was instead a substantive change that expanded the scope of the claims at issue in violation of 35 U.S.C. § 305, and that no reasonable juror could have found otherwise. In support, the court relied on the difference in the ordinary meaning of the disputed claim limitations: a track density of "at least 600 tpi" indicates densities starting at, but greater than 600 tpi, whereas the addition of "approximately" in the track density limitation of the reexamined '383 patent modifies the 600 tpi value, thereby eroding the "not less than" meaning of "at least." Based on these definitions, it followed, according to the court, that the claims had been broadened during reexamination since the reexamined '383 patent covered devices with track densities less than 600 tpi that were not covered by the original '383 patent. The court then concluded, without analysis, that the improperly broadened claims were invalid.

Since the district court's ruling disposed of all the claims which Rodime in its counterclaim had alleged Quantum to infringe, the district court, on April 26, 1994, ordered that final judgment be entered under Fed. R. Civ. P. 58 in favor of Quantum for a declaratory judgment of nonliability and against Rodime for its counterclaim of infringement of the reexamined '383 patent. This appeal followed.

II. DISCUSSION

There are two issues in this case: first, whether Rodime broadened the scope of the claims at issue during reexamination in violation of 35 U.S.C. § 305 by changing the track density limitation from "at least 600 tpi" to "at least approximately 600 tpi," and, second, assuming the claims were impermissibly broadened, the legal effect of violating section 305. We review the district court's grant of summary judgment in favor of Quantum on these issues -- that the claims were broadened and are therefore invalid -- to determine whether any genuine issues of material fact are in dispute, and whether any errors of law were made. London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1537, 20 U.S.P.Q.2D (BNA) 1456, 1458 (Fed. Cir. 1991).

A.

35 U.S.C. § 305 states, in relevant part, that "no proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding." An amended or new claim has been enlarged if it includes within its scope any subject matter that would not have infringed the original patent. In re Freeman, 30 F.3d 1459, 1464, 31 U.S.P.Q.2D (BNA) 1444, 1447 (Fed. Cir. 1994). "A claim that is broader in any respect is considered to be broader than the original claims even though it may be narrower in other respects." Id. (quoting Tillotson, Ltd. v. Walbro Corp., 831 F.2d 1033, 1037 n.2, 4 U.S.P.Q.2D (BNA) 1450, 1453 n.2 (Fed. Cir. 1987)). Accordingly, the claims at issue have been improperly broadened in violation of 35 U.S.C. § 305 if the track density limitation in the claims of the reexamined '383 patent -- "at least approximately 600 tpi" -- is broader than the track density limitation in the claims of the original '383 patent -- "at least 600 tpi."

Whether claims have been enlarged is a matter of claim construction, a question of law subject to complete and independent

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review on appeal. Id. at 1464, 31 U.S.P.Q.2D (BNA) at 1447. When construing the meaning of disputed terms in a claim, we look to the claims, specification and prosecution history. Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1577, 27 U.S.P.Q.2D (BNA) 1836, 1839-40 (Fed. Cir. 1993). Although a patentee can be his own lexicographer, the words of a claim will be given their ordinary meaning to one of skill in the art unless the inventor appeared to use them differently. Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 951, 28 U.S.P.Q.2D (BNA) 1936, 1938 (Fed. Cir. 1993).

Rodime's principle argument on appeal is that the addition of the word "approximately" to the track density limitation only made explicit what was already implicitly included in the claim, and therefore did not expand the scope of the claims at issue. In support of this proposition, Rodime cites Laitram Corp. v. NEC Corp., 952 F.2d 1357, 21 U.S.P.Q.2D (BNA) 1276 (Fed. Cir. 1992), Tennant Co. v. Hako Minuteman, Inc., 878 F.2d 1413, 11 U.S.P.Q.2D (BNA) 1303 (Fed. Cir. 1989), and Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 1 U.S.P.Q.2D (BNA) 1202 (Fed. Cir. 1986). Specifically, Rodime asserts that to one of skill in the art the term "600 tpi" means "approximately 600 tpi." In support, Rodime proffers the testimony of various technical experts who maintain that, because of manufacturing tolerances and variations inherent in rotary actuator drives, industry literature referring to a specific track density value is understood by those skilled in the art to represent a range. This interpretation, according to Rodime, is consistent with the specification which uses the terms "600 tpi" and "approximately 600 tpi" interchangeably. Since "600 tpi" means "approximately 600 tpi" to one of skill in the art, it necessarily follows, Rodime argues, that one of skill in the art would interpret "at least 600 tpi" to mean "at least approximately 600 tpi." Accordingly, Rodime concludes that the district court erred in not granting summary judgment in their favor, or, at a minimum, concluding that this evidence created a genuine issue of material fact to be resolved at trial.

We disagree. The major flaw in Rodime's argument is that it focuses solely on the term "600 tpi" instead of the claim limitation as a whole, in context. See United States v. Telectronics, Inc., 857 F.2d 778, 781, 8 U.S.P.Q.2D (BNA) 1217, 1219-20 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046, 104 L. Ed. 2d 423, 109 S. Ct. 1954 (1989). Even if "600 tpi" means "approximately 600 tpi," as Rodime argues, it is unnecessary to read in an implicit range when interpreting "at least 600 tpi" because this limitation as a whole already expressly represents an open-ended range, i.e. 600 tpi and up. Therefore, that one skilled in the art understands "600 tpi" to connote a range is irrelevant because the limitation in dispute is "at least 600 tpi," and Rodime offered no evidence to show that one skilled in the art understood "at least 600 tpi" to be the same as "at least approximately 600 tpi" or that the patentee defined it as such in the patent or during prosecution.

Absent such a definition or evidence that the claim limitation as a whole has a special meaning to one of skill in the art, we see no error in the district court's use of dictionary definitions to ascertain the ordinary meaning of the relevant claim limitation. See, e.g., Hoganas, 9 F.3d at 951 n.8, 28 U.S.P.Q.2D (BNA) at 1938 n.8 (using Webster's New World Dictionary, Third Edition, to define the word "straw"). Regarding the limitation "at least 600 tpi," the term "at least" means "as the minimum," Webster's Third New International Dictionary 1287 (1986), and therefore when coupled with a specific number sets forth an absolute lower limit of a range, i.e., 600 on up. See Lantech, Inc. v. Keip Mach. Co., 32 F.3d 542, 546, 31 U.S.P.Q.2D (BNA) 1666, 1670 (Fed. Cir. 1994) ("The term 'at least two' sets forth the minimum number of a particular element required."). The addition of "approximately" which means "reasonably close to," 3 eliminates the precise lower limit of that range, and, in so doing extends the scope of the range. The term "at least approximately 600 tpi" therefore defines an open-ended range starting slightly below 600. See, e.g., Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1455, 7 U.S.P.Q.2D (BNA) 1191, 1199 (Fed. Cir. 1988) (reasonable likelihood of success of proving that accused products with affinities of 4.8 x 107 and 7.1 to 7.5 x 107 liters/mole literally infringe patent with a recited claim limitation for affinity of "at least about 108 liters/mole"); Ex parte Neuwirth, 229 U.S.P.Q. (BNA) 71, 73 (Bd. Pat. App. & Int. 1985) (addition of the word "substantially" during reexamination as a modifier for "rounded bottom wall" broadened the scope of the claim in violation of 35 U.S.C. § 305).

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3 Webster's Third New International Dictionary 107 (1986).

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B. '928 Patent, Claim 1: A moiety is "at least three carbon atoms and an indicator molecule selected from the group

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consisting of fluorescent dyes, electron-dense reagents, enzymes which can be reacted with a substrate to produce a visually detectable reaction product, and radioisotopes."

The '928 patent utilizes a different definition of signalling moiety" from that in patents '767 and '824. Claim 1 of that patent reads: ". . .wherein A represents at least three carbon atoms and an indicator molecule selected from the group consisting of fluorescent dyes, electron-dense reagents, enzymes which can be reacted with a substrate to produce a visually detectable reaction product, and radioisotopes." (emphasis supplied). Despite the differences from the '767 and '824 Claim 1 language, plaintiffs construe this Claim in the same fashion as the comparable claims in the '767 and '824 patents, namely, that the A moiety can be the entire indicator molecule.

Plaintiffs support the view that Claim 1 of the '928 patent should be construed the same as the '767 and '824 patents by pointing to the abstracts and specifications of all three patents which contain the same definition of A (". . .wherein A represents a moiety consisting of at least three carbon atoms which is capable of forming a detectable complex with a polypeptide when the compound is incorporated into" DNA or RNA).

Nonetheless, the Claim 1 language of the '928 patent is clearly different from the two earlier patents. Rather than saying A "represents" the indicator molecule described, it states that A has "at least three carbon atoms and" the indicator molecule. The plain language therefore precludes a construction where A is the entire molecule.

Accordingly, the Court adopts defendants' construction of Claim 1 of the '928 patent, such that " A must have at least three carbon atoms and an indicator molecule selected from the group consisting of (i) fluorescent dyes, (ii) electron-dense reagents, (iii) enzymes which can be reacted with a substrate to produce a visually detectable reaction product, or (iv) radioisotopes."
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D. At Specific Locations Thereon

The parties dispute the meaning of "at specific locations thereon" in the claim 1 language, "where said donor and said acceptor are each covalently bonded to a backbone chain at specific locations thereon." The parties agree that the patent avoids random attachment of the labels, and that the spacing between the donor and acceptor flurophores along the backbone chain may be varied to ensure efficient energy transfer and to adjust the mobility of the labels. The dispute now turns on whether the term "at specific locations thereon" means controlling to which of the three or more potential potential attachment sites on the backbone chain the donor and acceptor are covalently bonded, as Perkin-Elmer urges.

Amersham urges a construction where "at specific locations thereon" means that there is one atom of the backbone chain to which the backbone acceptor dye will always covalently bond and another atom to which the donor dye will always covalently bond. As explained in the specification, the specific locations ensure that the proper spacing between the donor and the acceptor dyes will always be established. Patent, Col. 3:35-59. This is possible because the covalent bonds between the backbone chain and the donor and the acceptor dyes are predetermined and proper orientation of the backbone chain is controlled by the method of synthesis, rather than occurring in a random fashion. Id., Col.5:33- 40. See TR 38:12- 44:22; 47:9-16. The specification discloses the need to ensure that appropriate spacing is maintained between the donor and acceptor fluorophores to promote efficient energy transfer (Patent, Col.2:62-67; 3:1-60), and to control mobility. Id., Col.4:17-31; 6:10-20; 7:56-67; 8:1-38; 10:5-16. See also TR 42:11-19; 44:11-22.

Amersham points to the prosecution history to support this construction. The applicants amended their claim to distinguish their "chemically pure labels" from the mixture of labels produced by the random synthesis disclosed in certain prior art, U.S. Patent No. 4,996,143 (the "'143 Heller patent"). 24 A single Heller label is a mixture of chemical species -- it is a mixture of labels with their component dyes in alternative orientations. To distinguish the labels claimed in the '890 application from those disclosed in the Heller patent, the applicants added the claim limitation "at specific locations thereon." This term indicates that the method of synthesis controls the location of the donor dye and the location of the acceptor dye, such that the reaction of each dye with the backbone chain produces a chemically pure label.

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24 See the '143 Heller patent, Col.8:51-9:52, submitted at Tab 2 to Amersham's post-hearing brief; Ex.61 at 66, 71-72; exhibit at Tab 5 to Amersham's post-hearing brief; TR 48:21-49:6 (Rebek testimony).

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The applicants argued during prosecution that,

"[i]n [the Heller patent], the method of synthesis is not specific and does not permit control of the location of the donor and acceptor fluorophores…Heller et al. specifically acknowledge that their probes are a mixture of chemical species…. If one attempted to make families of donor-acceptor labels following the non-specific synthetic methods of Heller et al., the spectroscopic properties would necessarily vary due to unavoidable variations in the synthetic method…. Through the use of specific and covalent linkages as claimed by Applicants, these problems are obviated, producing labels with the desirable pure spectroscopic properties expected for chemically pure labels.

Ex.61, at 71-72. Consequently, the phrase "at specific locations thereon" limits the type of fluorescent labels that can be used in the claimed method to exclude mixtures of labels such as those described in the Heller patent, because "each donor and acceptor fluorophore is covalently bonded in a unique and specific position to the backbone to form the label." Id. at 63. Thus, Armersham argues, this limitation simply refers to the fact that the covalent bonds between the backbone chain and the donor and the acceptor dyes are predetermined and controlled by the method of their synthesis rather than occurring in a random fashion. Patent, Col.3:41.-59; 5:33-40.

Perkin-Elmer argues that, "at specific locations thereon" means controlling to which of three or more potential attachment sites on the backbone chain the donor and acceptor are covalently bonded. It argues that three or more potential attachment sites are required because the specification discloses that the spacing between the donor and acceptor can be varied. 25 Because two sites are needed to attach the donor and acceptor dyes, a third site is required to provide an alternative attachment point and thus to vary the distance between the donor and acceptor dyes.

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25 E.g., Patent, Col.3:35-59; 3:67- 4:2; 4:17-39; 4:66-5:8; 8:18-38.

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While the specification plainly discloses that the distance between the donor and the acceptor fluorophore may be varied to adjust the desired attributes of the label, the specification does not support Perkin-Elmer's construction. The spacing between the donor and acceptor may be varied by using a different backbone chain to bridge these two fluorophores, and by varying the number of intervening atoms: "the distance between the two fluorophores as determined by the number of atoms in the chain separating the two fluorophores can be varied with the nature of the chain" (Patent, Col.3:38-3:46) and, "[s]eparation of the donor and acceptor based on number of atoms in the chain will vary depending on the nature of the backbone, whether rigid or flexible, involving ring structures or non-cyclic structures or the like." Id., Col.4:65-5:8. By altering the type of backbone chain used to bridge the donor and acceptor, the number of atoms in the chain is varied, which varies the spacing.

For example, varying the backbone chain to alter the distance between the donor and acceptor dyes is disclosed in the specification in an example using three monosubstituted nucleic acids, each with a different number of nucleotides between the dye attached at the 5' end, and the second site of attachment -- the modified based containing a linker arm. Patent, Col.8:42-67. Each of these monosubstituted nucleic acids has a single potential attachment site for a second dye. The second dye is subsequently attached to the linker arm. Id., Col.9:1-35. At no time are three sites of attachment available, yet the spacing between the two dyes is still varied.

The intrinsic evidence does not support Perkin-Elmer's argument that the phrase "at specific locations thereon" requires that the backbone chain contain three or more attachment sites. Having reviewed the claims, the specification and the prosecution history, the Court finds that, "at specific locations thereon" means that the covalent bonds between the backbone chain and donor and acceptor dyes are predetermined and controlled by the method of synthesis rather than occuring in a

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random fashion.
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The Court construes atherosclerosis as "a disease, symptom, or condition characterized by a progressive narrowing and hardening of the arteries." The patent does not define atherosclerosis, but extrinsic evidence supports the Court's construction. See WEBSTER'S NEW WORLD MED. DICTIONARY 29, 33 (2d ed. 2006); Phillips, 415 F.3d at 1318. BSN's proposed construction of atherosclerosis as "a disease, involving abnormal fatty deposits in a[] fibrosis of the inner lining of arteries" is too narrow. BSN relies on a dictionary definition that does not support its contention that fatty deposits are necessary; the definition states that "[a]therosclerosis is a multistage process set in motion when cells lining the arteries are damaged ... high density lipoproteins accumulate at the site of arterial damage," making clear that fatty deposits occur after arterial linings are damaged. STEDMAN'S MED. DICTIONARY 162 (26th ed. 1995). Furthermore, BSN's interpretation includes terms that would also require construction (e.g., fatty deposits, fibrosis). To the extent that atherosclerosis involves accumulating arterial deposits, these symptoms are reflected in the Court's construction (i.e., "a progressive narrowing and hardening of the arteries").
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E. "atomized precipitated silica particulates"

1. The Parties' Proposed Constructions

Rhodia's proposed construction of "atomized precipitated silica particulates" is "silica particulates obtained by precipitation which are shaped and dried in a fluid stream such as by spray drying." (D.I. 167 at 8.) Rhodia argues that this construction is proper because a person skilled in the art would understand that the term "atomized" "refers to a spraying operation for forming and shaping the particulates." (D.I. 108 at 12-13.)

PPG suggests that the phrase be construed to "mean[] that a pulverized slurry of precipitated silica is spray dried using a liquid pressure nozzle as an atomizer to form the claimed silica particulates." (D.I. 167 at 8.) PPG asserts, based upon statements by the inventors during patent prosecution, that the construction of the phrase must be limited to atomization of a pulverized slurry of precipitated silica with a liquid pressure nozzle sprayer. (D.I. 106 at 18-22.)

2. The Court's Construction

I construe the phrase "atomized precipitated silica particulates" to mean that a pulverized slurry of precipitated silica is spray dried using a liquid pressure nozzle as an atomizer to form the claimed silica particulates.

The word "atomized" encompasses a number of techniques for atomizing fluids. However, the inventors expressely narrowed the meaning of "atomized precipitated silica particulates" during patent prosecution via claim amendments and arguments to distinguish their invention over the prior art and to obtain allowance of their claims. Southwall Technologies Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.") (citations omitted).

To traverse a rejection during patent prosecution, the inventors amended their claims to require that the "particulates have[] a mean particle size in excess of 150 microns" (D.I. 169, Ex. 17 at 8087) and stated that "to obtain the claimed silica particulates, liquid pressure nozzle sprayers must be used …." (Id., Ex. 18 at 8145.) The inventors also submitted a declaration in support of their argument that provided that "a liquid pressure nozzle - as opposed to a two fluid nozzle or air pressure nozzle - needs to be used to obtain precipitated silica particles … of a mean particle size greater than 150 [mu]m (microns)." (Id., Ex. 27 at 1190.) Similarly, to distinguish their invention over another prior art reference, the inventors stated that "no slurry which has not been pulverized per applicants' invention would be capable of ultimately providing a homogenous and solid particulate product …." (Id., Ex. 8 at 7450 (emphasis removed).)

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Therefore, although the '234 patent written description teaches that the silica particulates of the patented invention may be formed by known spray drying techniques in the art (D.I. 1, '234 Patent at col. 5 ll. 10-29), the inventors effectively narrowed the meaning of their claims by making arguments and amendments during patent prosecution to distinguish their invention over the prior art. I have accordingly narrowed the construction of "atomized precipitated silica particulates".
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2. "attaching a plurality of oligonucleotides"

a. The Parties' Proposed Construction

OGT proposes that I construe "attaching a plurality of oligonucleotides" to mean "fastening (as by tying or gluing) or affixing two or more oligonucleotides." (D.I. 174 at 12; D.I. 173 at 1.) Mergen proposes that I construe "attaching a plurality of oligonucleotides to mean "monomer by monomer synthesis of oligonucleotides on an impermeable surface of a support." (D.I. 175 at 13; D.I. 209 at 9; D.I. 173 at 1.)

The focus of the parties' dispute in this claim term is the word "attaching." 7 OGT argues that "attaching" should be construed according to its ordinary and plain meaning. (D.I. 175 at 12.) Mergen argues that I should read into the term "attaching," the method by which the oligonucleotides are attached. (D.I. 175 at 13.) In support of its proposed construction, Mergen relies on a theory of prosecution disclaimer. (D.I. 175 at 16-18.) 8

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7 It does not appear that the parties contest that the phrase "a plurality of oligonucleotides" means "two or more oligonucleotides." Therefore, I need not construe it further.

8 Mergen, however, has not carried its burden of demonstrating a clear and unambiguous disclaimer with respect to this claim term. See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003).

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b. The Court's Construction

"Attaching" is a common, everyday word. As discussed above, I will not read in limitations from the specification when the term is easily construed according to its ordinary meaning as understood by a person of ordinary skill in the art. See Texas Digital Sys., Inc., 308 F.3d at 1205. To construe "attaching a plurality of oligonucleotides," I do not need to find further limitations regarding the method of attachment. "Attaching," when read in light of the specification means "affixing." Therefore, I construe "attaching a plurality of oligonucleotides" to mean "affixing two or more oligonucleotides."
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3. Autism Condition

The term "autism condition" appears in the final step of Claim 1. Metametrix argues that autism condition means a state of being autistic or having the disorder of autism. Metametrix disputes that this is synonymous with any alleged "symptom" or other individual component of the disorder of autism. Plaintiffs argue that autism condition means a condition, feature or symptom of autism. The court is in agreement with plaintiffs.

In the discussion of correlating, the court began distinguishing autism and autism condition. In the final step of Claim 1, the inventor instructs that one is to correlate the quantity of said at least one compound with "an autism condition." "An autism condition" is not synonymous with autism. Rather, it may be a part of having autism, such as having elevated levels of certain organic compounds. The claim language differentiates the likelihood of autism with having one of its symptoms by

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using "autism" to modify "condition."

The claim specification continues to distinguish "autism" from "an autism condition." For instance, Example 1 describes the analysis performed on the urine of two brothers "with autistic features" to determine whether there was "the presence of elevated amounts of abnormal Kreb cycle metabolites. These metabolites include citramalic, tartaric acid (3-OH-malic), and 3-oxo-glutaric acids...." (Col. 4, lines 59-63). Additionally, in discussing the observed correlation between high levels of tartaric acid and certain conditions of autism, the specification states that "[a] much smaller peak at 12.1 min. was also detected in some of the urine samples of the siblings with autistic features." (Col. 6, lines 48-50). The patent repeatedly uses the terms "autistic features" (Col. 10, lines 63-65; Col. 7, lines 1-5) or "symptoms of autism" (Col. 15, lines 22-27). Thus, the use of autism condition is distinct from reference to autism.

Therefore, the court finds "autism condition" means "a condition, feature, or symptom of autism."
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b. "BRCA1" and "BRCA2"

Plaintiffs define the term "BRCA1" as "a particular fragment of DNA found on chromosome 17 that relates to a person's predisposition to develop breast and ovarian cancer." Pl. Br. at 11. Similarly, Plaintiffs define the term "BRCA2" as "a particular fragment of DNA found on chromosome 13 that relate[s] to a person's predisposition to develop breast and ovarian cancer." Pl. Br. at 14. As with Plaintiffs' proposed definition of "isolated DNA," Myriad argues that these definitions are inconsistent with the patents' definition of "BRCA1" and "BRCA2" as "cancer-predisposing gene[s], some alleles of which cause susceptibility to breast and ovarian cancers" because they suggest that the BRAC1 and BRCA2 genes are not integrated into a chromosome, but are broken, detached, or otherwise easily removed from their respective chromosomes, Myriad Br. at 16.

The specifications of the patents-in-suit define the terms "BRCA1" and "BRCA2" as "a human breast cancerpredisposing gene . . . some alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer." '282 patent, col. 4:33-36; see also '282 patent, col. 1:22-23; '492 patent, col. 1:20-21, 4:28-29. Further, neither party disputes that "genes" refer to segments of DNA incorporated into chromosomes.

"BRCA1" is therefore construed to refer to a human gene, normally integrated into chromosome 17, some alleles of which cause susceptibility to breast and ovarian cancer. Similarly, "BRCA2" is construed to refer to a human gene, normally integrated into chromosome 13, some alleles of which cause susceptibility to breast and ovarian cancer.
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1. "Bacillus stearothermophilus Alpha-Amylase"

a. The Parties' Proposed Constructions

13. Novozymes contends that a Bacillus stearothermophilus alpha-amylase is "the functional enzyme product that is produced from the alpha-amylase gene of a Bacillus stearothermophilus organism." (D.I. 118 at 18.)

14. Defendants propose two constructions of the term. First, they argue that the '031 patent prosecution history shows that the applicants defined Bacillus stearothermophilus alpha-amylase as "an alpha-amylase having the amino acid sequence of SEQ ID NO:3." (D.I. 116 at 5.) Alternatively, they argue that a person having ordinary skill in the art would understand that a Bacillus stearothermophilus alpha-amylase is "a 514- or 515-amino acid protein encoded by a wild type Bacillus stearothermophilus alpha-amylase gene, minus the signal sequence." (Id. at 8-9.)

15. The parties at least agree with the starting proposition that a Bacillus stearothermophilus alpha-amylase is produced from a gene taken from a Bacillus stearothermophilus bacterium. The narrowing constructions proposed by Defendants

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require that the alpha-amylase have either a particular sequence or a particular length.

b. The Court's Construction

16. I conclude that Novozymes's construction is the correct one. Neither the prosecution history nor the evidence concerning the expected length of an alpha-amylase supports the adoption of the narrower constructions proposed by Defendants.

i. The Term is Not Limited to SEQ ID NO:3

17. Defendants' argument for their first proposed construction is based on the prosecution history of the '031 patent, specifically, the applicants' response to the examiner's written description and enablement rejections. (D.I. 116 at 5-8.)

18. In the first office action, when the examiner issued rejections for failure to satisfy the written description and enablement requirements, she suggested that the rejections could be overcome by amending the claims to require "at least 80% identity" between the variant and SEQ ID NO:3. (FF P 29.) In their response, the applicants did not make the suggested change, and instead amended the claims to require "at least 80% homology" between the variant and the parent Bacillus stearothermophilus alpha-amylase. (FF P 37.) In the second office action, the examiner, upon further consideration, again rejected the claims, and suggested that the rejections could be overcome by requiring "at least 90% identity" between the variant and SEQ ID NO:3. (FF P 41.) The applicants responded by canceling the claims and adding new claims that required "at least 95% homology" between the variant and the parent Bacillus stearothermophilus alpha-amylase. (FF P 50.) In support of those new claims, the applicants noted the examiner's suggestion that the variants have 90% homology to SEQ ID NO:3 and argued that the rejection was "rendered moot . . . as the new claims recite a homology of 95%." (Id.)

19. According to Defendants, that exchange demonstrates that the applicants and the examiner both understood that the "Bacillus stearothermophilus alpha-amylase" n22 was the same as "SEQ ID NO:3." (D.I. 116 at 7-8.) However, the prosecution history establishes that the examiner and the applicants recognized that the terms were not synonymous. In the second office action, the examiner pointed out that the applicants had not adopted her suggestion, but that the amendments were "similar." (FF P 40.) In their response to the second office action, the applicants stated that their invention was "directed to variants of Bacillus stearothermophilus alpha-amylase enzymes and to alpha-amylase variants having 95% homology to SEQ ID NO:3." (TX 101, D.I. 121 at A-7736.) The applicants also stated that the specification described "variants of Bacillus stearothermophilus and variants having at least 95% homology to SEQ ID NO:3." (Id. at A-7735.) Those statements describe two different sets of variants, those defined relative to Bacillus stearothermophilus alpha-amylase and those defined relative to SEQ ID NO:3. Thus, contrary to Defendants' argument (D.I. 116 at 7-8), the record shows that the examiner and applicants understood that "SEQ ID NO:3" was not used interchangeably with "Bacillus stearothermophilus alpha-amylase" or "parent Bacillus stearothermophilus alpha-amylase." That record is also consistent with the claims: claims 1 and 5 refer to a "Bacillus stearothermophilus alpha-amylase," and claim 3 refers to "SEQ ID NO:3." ('031 patent, 65:11-17, 65:21-66:12, 66:16-19.)

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n22 Defendants' argument sometimes purports to construe "parent Bacillus stearothermophilus alpha-amylase." (D.I. 116 at 7-8.) I understand it to be an argument about the construction of "Bacillus stearothermophilus alpha-amylase," because Defendants seek to apply the construction to claim 5 (id. at 8, 18-19), which does not contain the term "parent," and because Defendants assert that there is no dispute about the construction of "parent" (D.I. 115 at 61, P 9). In any case, I conclude that the term "parent," as used in claim 1, is properly construed as the protein from which the variant is derived, and that the term "parent" does not alter the meaning of "parent Bacillus stearothermophilus alpha-amylase" in a way that is relevant to the parties' dispute.

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20. Therefore, the term "Bacillus stearothermophilus alpha-amylase" is not limited to SEQ ID NO:3.

ii. The Term is Not Limited to Proteins of a Particular Length

21. Defendants' argument for their second proposed construction is based on the examples in the '031 patent and on extrinsic

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evidence about alpha-amylases.

22. First, Defendants note that the examples of Bacillus stearothermophilus alpha-amylases disclosed in the patent have either 514 or 515 amino acids. (D.I. 116 at 9 (citing '031 patent, Fig. 1, 7:32-35, sequence listing for SEQ ID NO:3).)

23. Second, Defendants emphasize extrinsic evidence to show that, at the patent's critical date in 1995, Bacillus stearothermophilus alpha-amylases would have been expected to have 514 or 515 amino acids after the removal of the N-terminal signal sequences. (Alber, Tr. at 209:2-18, 209:25-210:5, 211:6-212:3, 212:19-214:8; TX 142; TX 568; TX 628; TX 629; TX 630; TX 633; TX 634; TX 635.) According to Defendants, that information means that, by definition, a "Bacillus stearothermophilus alpha-amylase" must be 514 or 515 amino acids in length. (D.I. 116 at 9-10.)

24. I disagree with Defendants' conclusion that length is a defining feature of Bacillus stearothermophilus alpha-amylases. First, none of the evidence adduced by Defendants reports the complete, experimentally determined amino acid sequence of an alpha-amylase. Instead, that evidence shows the results of DNA sequencing of genes, alone (TX 142; TX 629; TX 630; TX 666) or in combination with amino acid sequencing of the N-terminus of the protein (TX 568; TX 628; TX 634; TX 666), and the results of gel electrophoresis experiments (TX 633; TX 635). That evidence may lead to the expectation that, if one were to do the experiment, an alpha-amylase would have a precise length of 514 or 515 amino acids. However, in 1995 the experiment remained to be done.

25. Second, even if Defendants had shown that all Bacillus stearothermophilus alpha-amylases had a specific length--which they have not shown--none of the evidence, including the '031 patent itself, dictates that a Bacillus stearothermophilus alpha-amylase must have a particular length. The fact that examples in the patent have a given length is not sufficient to make that length a defining feature of Bacillus stearothermophilus alpha-amylases. I conclude that a person having ordinary skill in the art would not understand the '031 patent to impose such a length requirement.

26. Therefore, the term "Bacillus stearothermophilus alpha-amylase" is not limited to proteins having 514 or 515 amino acids.

27. Accordingly, I conclude that the construction proposed by Novozymes is correct. A Bacillus stearothermophilus alpha-amylase is "the functional enzyme product that is produced from the alpha-amylase gene of a Bacillus stearothermophilus organism."
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C. Backbone Chain

The parties dispute the meaning of the claim 1 language, "said labels are characterized by: (1) having a donor-acceptor fluorescent pair where said donor and said acceptor are each covalently bonded to a backbone chain at specific locations thereon with energy transfer from said donor to said acceptor." The dispute over "a backbone chain" turns on whether, as Perkin-Elmer contends, the backbone chain is limited to polymers in general and, in the particular context of nucleic acid analyses, to a nucleic acid backbone. In addition, Perkin-Elmer argues that the "backbone chain" term excludes any linker arms used to connect the fluorophore dyes.

Amersham would define "backbone chain" to mean, "different types of molecules that are made up of atoms that separate the donor and acceptor dyes." This "backbone chain" is the chain of atoms between the point where the donor dye is covalently bonded and the point where the acceptor dye is covalently bonded. It is described in claim 1 as the entity to which the acceptor and donor dye are covalently bonded at "specific locations." Covalent bonds occur between atoms and so the backbone chain is the entire chain of atoms between the donor and acceptor, including any linker arms.

If a claim term is given a particular meaning in the specification, that meaning should control. The specification never defines "backbone chain" expressly but confirms that the terms "backbone" and "chain" describe the chain of atoms between the donor and acceptor: "the distance between the two fluorophores as determined by the number of atoms in the chain separating the two fluorophores can be varied in accordance with the nature of the chain." Patent, Col.3:43-46. Also, "[s]eparation of the donor and acceptor based on number of atoms in the chain will vary depending on the nature of the

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backbone, whether rigid or flexible, involving ring structures or non-cyclic structures or the like. Patent, Col.4:65-5:8. Thus, Amersham argues, those skilled in the art will understand "backbone chain" to mean any chain of atoms which are specifically and covalently bonded to the two separate dyes to form an energy transfer dye unit.

Perkin-Elmer argues that "backbone" is an adjective modifying "chain" and so the phrase "backbone chain" and the terms "backbone" and "chain" cannot be used interchangeably. The applicant is entitled to be his own lexicographer. "Backbone chain," which appears in the '648 patent only in claim 1, is a unique term. Amersham contends that the applicants combined the words "backbone" and "chain," both of which are used freely in the specification to describe the joining of the donor and acceptor fluorophores (e.g., Patent, Col.2:1-4; 3:35- 4:2; 4:67-5:12; 5:24-25; 6:11-20; 6:25-39), to lend the claim a distinct clarity and emphasis, analogous to "o-ring." TR 47:3-8; 60:2-4; 72:5-22. The analogy is an apt one, particularly as the word "chain" also figures in the specification's discussion of nucleic acid extensions, nucleic acid chains as primers in sequencing and also polymerase chain reaction [PCR]. See Patent, Col.5:23-32.

The specification describes the labels to "usually" or "particularly" employ a "nucleic acid backbone" (Patent, Col.2:1-4; 6:25-28), or "nucleic acid chain" (id., Col.3:46-53; 5:23-29), or "polymeric chain." Id., Col.3:35-37. The specification also provides a non-exhaustive list of potential chains and backbones, including molecules that are polymeric (nucleic acids, polypeptides and polysaccharides) and non-polymeric (various groups which may be added stepwise, such as di-functional groups, e.g., haloamines or the like). Id., Col.3:46-53. See also id., Col.6:31-38; and structures 1-3. The specification uses the terms backbone, chain, oligomer and "linking arm" in describing different ways the labels may be structured, using chains of atoms that may be either part of a polymer or not.

Perkin-Elmer relies on two sentences to argue that "backbone chain" must be limited to a chain of polymers. One states that "fluorophores are bound to a backbone, particularly a nucleic acid backbone." Patent, Col.2:1-2 (emphasis added). The other states that "the two fluorophores will be joined by a backbone or chain, usually a polymeric chain." Id., Col.3:35-36 (emphasis added). These statements merely confirm that polymeric backbones or chains are contemplated as embodiments, not as a claim limitation. Burke, Inc., 183 F.3d at 1341 ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."); Intervet Am., Inc. v. Kee-Vet Labs, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("[I]nterpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper."). Indeed, Dr. Roberts agreed that a "polymeric chain" was not required by the specification. TR: 178:10-179:9; Roberts Dep. (10/11/99) at 86:6-13.

Perkin-Elmer argues that the specification statement, "the labels will be separated along the backbone" (Patent, Col.6:12-13), does not make sense if the backbone chain is defined as the chain of atoms between the two fluorophores. However, "backbone" as used in the specification refers alternatively to the chain of atoms between the two fluorophores and to a nucleic acid backbone, and in this instance Perkin-Elmer singles out a reference to a nucleic acid backbone. But, as shown at Patent, Col.9:15-20, "nucleic acid backbone" is not coextensive with "backbone chain," as the latter may include a linker arm. The expert testimony supports this construction and the Court rejects Perkin-Elmer's contention in its post-hearing brief (at pp. 17-20) that the specification draws a distinction between "backbone chains" and linking arms or linkers. 20

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20 Having reviewed the specification, Dr. Rebek testified that, if the donor and acceptor are covalently bonded through linker arms to some other molecule, those linker arms are part of the backbone chain because the attachment of the donor and acceptor defines the ends of the backbone chain. TR 42:7-10; 46:24-48:20. Professor Glazer's testimony is entirely consistent: "I think that the definition of what lies between the donor and the acceptor is explicit in the embodiment. It simply says that there is a number of atoms which represent the shortest covalent path between the donor and acceptor, and that's the backbone chain. It doesn't leave much room for confusion." TR 126:4-25. See also, Glazer Dep.I at 190:11-15 ("[The linking arm] cannot be the entire backbone chain."), Toohey Decl., Ex. E. Dr. Roberts also conceded that, for the amino acid structures disclosed in the specification, the linker arms are included in the "backbone chain." TR 180:23-182:1.

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Similarly, Perkin-Elmer insists that the statement, "the fluorophores may be bound internal to the chain" (Patent, Col.3:67-4:1), means that "backbone chain" cannot refer to any chain of atoms connecting the donor and acceptor. They also contend that Professor Glazer admitted that "backbone chain" must refer exclusively to a nucleic acid chain. Glazer Dep.I, at 180:8-

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13, Toohey Decl., Ex. B; TR 124:22-125:5; 127:8-23. However, this statement, and Professor Glazer's testimony, refer to one aspect of the invention, described at Patent, Col.3:28-34 and Col.5:9-22, in which more than two fluorophores are used in a single label. These additional fluorophores must necessarily be bound internal to the chain of atoms between the two most widely separated fluorophores. This particular example described in the specification should be read as a claim limitation to polymers or to a nucleic acid. 21

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21 E.g., Burke, Inc., 183 F.3d 1334, 1340 ("Consistent with the principle that the patented invention is defined by the claims … limitations cannot be read into the claims from the specification or the prosecution history"); Electro Med. Sys. S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed. Cit. 1994) ("[C]laims are not to be interpreted by adding limitations appearing only in the specification. . . . although the specifications may well indicate that certain embodiments are preferred, particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments.") (citations omitted).

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During prosecution of the '890 patent application, the applicants overcame the very same argument that Perkin-Elmer now raises, that the backbone chain must be a polymer. Initially, the Examiner wrote that the chain joining the donor and acceptor had to be a polymer and rejected claims which were not limited to a polymeric backbone chain: "the disclosure is enabling only for claims limited to nucleic acid backbone chains. . . . The specification does not disclose or exemplify backbone chains other than nucleic acids." Ex.61, at 46; exhibit at Tab 3 to Amersham's post-hearing brief, at 2. This rejection was withdrawn when the applicants demonstrated that "backbone chains" could include flexible (such as -(CH[2])[n]- or oligopeptides) or rigid (such as steroids or bi-steroid structures) non-nucleic acid and non-polymeric molecules. Ex.61, at 67-68. The applicants provided the Examiner, both textually and graphically, with examples of fluorescent pairs "linked by flexible (primarily -CH[2])[n]-) chains" and "bridged by a polypeptide" or "rigid (or partially rigid) spacers" such as "a rigid steroid structure." Id. at 67-76; TR 45:23-25; 46:1-20.

The applicants also indicated that no particular chemical composition or structure placed a limitation on this part of claim 1: "[t]he scope and utility of this invention is not limited to the specific nature of the backbone, nor is the usefulness of any particular backbone structure relative to any other point of novelty in this invention." Ex.61, at 69 (emphasis added). This same point is implicit throughout the specification. 22 Instead, what the applicants emphasized to the Examiner, in distinguishing their labels from prior art while responding the Examiner's rejection (see Ex.61, at 70-74), was their use of "highly specific covalent structures….with precise and nonheterogeneous spectroscopic properties…critical to Applicants' multiplex applications." Id. at 72. In distinguishing their claims from Benson et al., for example, the applicants emphasized that they specifically, not randomly, positioned the flurophores and covalently joined the label to the subject component:

In Applicant's invention, the labels are formed by covalently linking the donor and acceptor fluorophores to specific positions on the backbone and then covalently and specifically linking the label to the components to be detected. This provides a stable structure that does not change its spectroscopic properties as a function of time and conditions. These are critical advantages in the design and performance of multiplex detection."

Ex. 61, at 73.

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22 C.f., Pitney Bowes, 182 F.3d 1298, 1311 ("In circumstances…where the language of the written description is sufficient to put a reader on notice of the different uses of a term, and where those uses are further apparent from publicly-available documents referenced in the patent file, it is appropriate to depart from the normal rule of construing identical terms in the same manner. This entirely accords with the public notice function of claims.").

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The extrinsic evidence supports reading the term "backbone chain" to allow both polymeric and non-polymeric structures. Consistent with the specification (Patent, Col. 4:66-5:8), Dr. Rebek testified that the structure of the atoms can be "rigid,

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flexible, cyclical or linear" (TR 43:2-5), and that one skilled in the relevant art (as to this term, chemistry) would read the specification and understand that "backbone chain" includes polymers. 23 TR 42:23-44:10. Dr. Roberts agreed that the specification's description of the structures includes non-polymeric chains. TR 179:10-180:1. Dr. Roberts' testimony, and the other extrinsic evidence Perkin-Elmer introduces from technical dictionaries, concerning useage of the term "backbone" in molecular biology as referring to polymers, is not inconsistent with the specification or the testimony of Drs. Chamberlin, Rebek and Glazer concerning nomenclature. This extrinsic information is merely incomplete insofar as the specification explicitly does not limit the scope of the claims to a single backbone structure or require a polymer.

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23 Perkin-Elmer would have the Court completely discount the testimony of Dr. Rebek, director of the Skaggs Institute, for Chemical Biology and a professor of Chemistry at the Scripps Ranch Institute, with extensive experience in organic, synthetic and combinatorial chemistry, simply because he is not a molecular biologist. But Dr. Rebek testifies that one of skill in the relevant art is skilled in chemistry (TR 71:2-11), as is one of the inventors, Dr. Glazer, who was called to testify by Perkin-Elmer in part because he is skilled in the art. Perkin-Elmer's other expert, Dr. Roberts, currently an assistant professor in the Department of Chemistry at the California Institute of Technology (TR 131:15-24), agrees that one skilled in the relevant art must have a "substantial" background in chemistry and the use of fluorescent dyes. TR 133:8-16; 133:25-135:4; Ex. 1012, at 3:24-4:6.

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Together, the language of claim 1, the specification, and the prosecution history demonstrate thai "backbone chain" refers to the fewest number of atoms between the donor and the acceptor dyes, whether those atoms are in a polymeric or non-polymeric molecule. While extrinsic, evidence is not needed to construe this disputed claim term, this evidence supports the Court's construction.

The Court finds that "backbone chain" means the entire chain of atoms that separate the donor and acceptor dyes.
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2. Aqueous Solution/Balance

The independent claims of the '793 patent disclose an aqueous solution, with constituents falling in ranges of percentages by weight specified for carbohydrate and chloride salt content, and with water identified as constituting the "balance". As was the case in Cargill, the parties in this action disagree over the terms "aqueous solution" and "balance" and whether, in combination with the specification of the carbohydrate and chloride salt content range, they permit inclusion of any incidental impurities or additional ingredients other than the colorants and thickeners specified in some of the claims, and if so to what extent. 9

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9 Cargill urged a confined, closed-ended reading of the terms, to the exclusion of other, non-specified ingredients. Sears, on the other hand, maintained that they should be interpreted in such a fashion as to allow for some incidental, unspecified ingredients.

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With the parties' focus upon issues of purity and limitations as to non-essential ingredients, the phrase "aqueous solution", while seemingly non-controversial, became a significant point of contention in Cargill. Cargill urged a definition requiring a "uniformly disbursed liquid mixture containing water as the primary solvent." Cargill, 334 F. Supp. 2d at 217. Sears offered a more relaxed requirement of a "single-phase, liquid mixture of two or more components, one of which is water and with possible incidental amounts of insoluble components." Id.

The term "solution" is defined in one source as constituting a "homogeneous mixture of two or more substances, which may

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be solids, liquids, gases, or a combination of these." American Heritage Dictionary 1655 (4th ed. 2000). The term "homogeneous" is defined elsewhere as "often loosely used to describe a mixture or solution composed of two or more compounds or elements that are uniformly disbursed in each other." Hawley's Condensed Chemical Dictionary 655 (15th ed. 2007). While both of those sources associate the term "homogeneous" with "solution," the Hawley's definition goes on to observe that "[a]ctually, no solution or mixture can be homogeneous; the situation is more accurately described by the phrase 'uniformly disbursed.'" Id.

Use of the term "aqueous" constricts the solution in issue in the '793 patent to a liquid with water as a component, or even the primary solvent. This much is not in dispute. The critical issue presented is the degree of homogeneity required in the aqueous solution. As even the Hawley's dictionary definition recognizes, no solution or mixture can be entirely homogeneous. In practice, there are no solutions which are completely free of extraneous materials, however microscopic they may be. Indeed, even contemporary drinking water standards provide for inclusion of certain impurities including asbestos particles, albeit within exceedingly narrow defined limits.

In consideration of the patent claim language and use of the term aqueous, derived from "aqua" -- which means "[w]ater", American Heritage Dictionary at 89, in Cargill I interpreted the phrase "aqueous solution" to mean a uniformly disbursed liquid mixture of two or more components, one of which is water, and which can contain incidental amounts of insoluble components.

Taking the terms aqueous solution and balance together, the ADM defendants now argue for a different interpretation, asserting that for the '793 patent the term should be read together to mean that

[a]side from the specified low molecular weight carbohydrate, chloride salt, [and thickener, for claims reciting a thickener], and impurities ordinarily associated therewith, the solution shall contain only water. The aqueous solution may not include additional ingredients included for purposes related to de-icing or anti-icing. 10

ADM's Opening Brief on Claim Construction (Dkt. No. 172) at 17. Defendants' argument is bottomed upon what they claim to be ordinary principles of sentence construction, as well as the Federal Circuit's intervening decision in Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349 (Fed. Cir. 2006).

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10 Defendants assert that for purposes of the '622 patent a similar definition should apply, with the word "sugars" being substituted for the phrase "low molecular weight carbohydrate."

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Having carefully considered the argument of the parties in Cargill, and discerning no material difference in this case, I find no basis to revisit my ruling regarding the term "aqueous solution."

Turning to the term "balance", I note that although not necessarily restricted to the art of chemistry, it is generally accepted to mean "the remainder or rest", Random House Webster's College Dictionary 101(2d ed. 1991), or "something left over, remainder", Merriam-Webster Collegiate Dictionary 87 (10th ed. 1995). Strictly construed, use of the closed-ended term "balance" in the formulation specified indicates that other than the low molecular weight carbohydrate source and chloride salts, as well as possible addition of thickeners and colorants, the remainder of the solution practiced in the '793 patent is water only. Such a strict definition, however, ignores the realities associated with the patent, and in particular the designated sources of its carbohydrate and chloride salt constituents. Commercially available sources for the low molecular weight carbohydrates and the chloride salts, as well as the water, specified within the invention by definition all include impurities by their very nature. Clearly, what the term "balance" was intended to exclude were the harmful, unlisted ingredients associated with the prior art, based on agricultural waste products which

utilize materials which have highly undesirable or unnecessary ingredients leading to practical difficulties by manufacturers and users, such as stratification in storage, biological degradation, odor, plugging of filters and spray nozzles and environmental difficulties e.g. . . . high organic contents (about 40% by weight), presence of phosphorus compounds and heavy metals.

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'793 patent, col. 1, ln. 66 - col. 2, ln.6.

Defendants' argument, while addressing the term "balance", in reality focuses upon use of the term "comprising" in the two patents in suit. It should be noted that while the use of such partially open-ended terms as "consisting essentially of" can allow for the presence of "unlisted ingredients that do not materially affect the basic and novel properties of the invention," PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998), the phrase "comprising" is traditionally regarded under patent law as having special meaning, defining the scope of the claim and providing an indication of what additional, unrecited components are intended to be excluded from its scope. Conoco, 460 F.3d at 1359-60. As the Federal Circuit noted in Conoco, however, the restriction associated with phrases such as "comprising" is not absolute; instead, use of the phrase does not exclude "impurities that a person or ordinary skill in the relevant art would ordinarily associate with the component on the 'consisting of' list." Id. at 1360. Similarly, the phrase does not exclude other components unrelated to the invention. Id.

In light of these considerations, and the language of the '793 patent itself, I adhere to my earlier construction, and will interpret the term "balance", as used in the '793 patent and '622 patents, to mean that aside from the other specified ingredients, including low molecular carbohydrates (or sugars) and chloride salts, and with the possible addition of colorants and thickeners, as well as incidental impurities or harmless ingredients associated with the commercial sources of the key components in the invention, the solution shall contain only water. To hold otherwise would be to reject the reality of impurities in all of the stated '793 and '622 ingredients.

It should be noted that in seeking the exclusion of even a single molecule of a high molecular weight carbohydrate outside of the ranges specified in the '793 and '622 patents, defendants rely upon the patent prosecution history which shows that it was not until the inventor identified specific low molecular weight carbohydrate ranges that the PTO determined it had sufficiently distanced itself from prior art, which did not contain any carbohydrate weight limitations. While it is true that the patentee cannot adopt inconsistent positions before the PTO and in a subsequent infringement litigation, that has not occurred in this case. Instead, the inventor, in response to PTO concerns, identified a specific range of low molecular weight carbohydrates as required constituents in its composition but noted the possible presence of impurities, including high molecular weight carbohydrates, which a person of ordinary skill in the art would associate with the sources of those low molecular weight carbohydrates.

In this regard my construction in Cargill gave recognition to the reality that absolute purity in a composition such as that specified in the '793 patent is a virtual impossibility, particularly in light of the likely sources of its constituents. Indeed, during the prosecution of the underlying applications and in the patent itself, corn syrup was prominently mentioned as a potential source of a low molecular weight carbohydrate identified in the patent claims. Those of ordinary skill in the art, I am convinced, would have known at the time of the filing of the patent application that the low molecular weight carbohydrate specified would principally be derived from corn syrup through hydrolysis from starches, leaving high molecular weight carbohydrates as impurities associated with those constituents. For this reason, in Cargill I read "balance" as a closed term, but with room for the possibility of such impurities. Finding that this approach is consistent with the Federal Circuit's case law, including Conoco, I adhere to my prior decision defining the terms "aqueous solution" and "balance."

* * *

ORDERED as follows:

1) The disputed terms of the '793 and '622 patents are hereby construed by the court as follows:

Terms	Construction
* * *	
"balance"	aside from the other specified ingredients, including low molecular carbohydrates (or sugars) and chloride salts, and with the possible addition of colorants and thickeners,

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as well as incidental impurities or harmless ingredients associated with the commercial sources of the key components in the invention, the solution shall contain only water

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IV. "Based on the Dry Weight"

For the same reasons discussed with regard to the phrase "surface active material," the Court adopts plaintiffs' proposed construction of the term "based on the dry weight" and will instruct the jury as follows:

The '301 patent includes the phrase "based on the dried weight of the surface active material. The '839 patent includes the phrase "based on the dry weight" of the surface active material. These two phrases mean the same thing. They mean the dry weight of the lung surfactant extract material before it is combined with a pharmaceutical carrier. For example, with respect to the '839 patent, the limitation requiring 1.0-27.7% free fatty acids content "based on the dry weight of the material" refers to the free fatty acids content of the surface active material before it is combined with, for example, physiological saline to make a pharmaceutical composition.

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The Effect of Judge Arcara's Decision

Defendants argue that Judge Arcara construed the same claim language that is disputed in this case and that his construction should carry the day here as well; they contend that the doctrine of issue preclusion bars plaintiffs from relitigating those claim construction issues. Plaintiffs argue that the Court should not apply issue preclusion in this case because to do so would be unfair to them.

The doctrine of issue preclusion compels a court to honor the first actual decision of a matter that has been litigated. See Chicago Truck Drivers v. Century Motor Freight, 125 F.3d 526, 530 (7th Cir. 1997) (citing 18 Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure § 4416, at 136 (1981 & Supp. 1997)). 3 Generally, issue preclusion is appropriate if: (1) the issue sought to be litigated is identical to one decided in a prior action; (2) that issue was actually litigated in the first action; (3) the determination of the issue was essential to the final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action. Century, 125 F.3d at 530 (citing La Preferida, Inc. v. Cerveceria Modelo, S.A. de C.V., 914 F.2d 900, 906 (7th Cir. 1990)); A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 702 (Fed. Cir. 1983), cert. denied, 464 U.S. 1042, 79 L. Ed. 2d 171, 104 S. Ct. 707 (1984). All of these conditions are met here. The claim construction issues disputed in this case are the same issues litigated in the Forest case; Abbott and Tokyo Tanabe briefed and argued the issues before Judge Arcara, and the judge's claim construction ruling was necessary to the final judgment in the case concerning infringement.

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3 The Court looks to Seventh Circuit law because that is where the Federal Circuit would turn in applying issue preclusion in this case. See Epic Metals Corp. v. H.H. Robertson Co., 870 F.2d 1574, 1576 (Fed. Cir.), cert. denied, 493 U.S. 855, 107 L. Ed. 2d 117, 110 S. Ct. 160 (1989); Hartley v. Mentor Corp., 869 F.2d 1469, 1471 n.1 (Fed. Cir. 1989) (the application of principles of claim preclusion and issue preclusion is not a matter committed to the exclusive jurisdiction of the Federal Circuit, so the court looks to the law of the circuit to which an appeal would lie in non-patent cases from the particular district court).

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But that does not end the inquiry. In some circumstances, even when these conditions are met, the court may decline to

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apply issue preclusion. The United States Supreme Court, the Seventh Circuit and the Federal Circuit have all said that courts should not apply non-mutual offensive collateral estoppel (or issue preclusion), which is what this is, if it would be unfair to the defendant. See Parklane Hosiery Co. v. Shore, 439 U.S. 322, 331, 58 L. Ed. 2d 552, 99 S. Ct. 645 (1979); Century, 125 F.3d at 531; A.B. Dick, 713 F.2d at 702. The court should refuse to apply issue preclusion if, for example, the defendant had little incentive to defend vigorously in the first suit because he was sued for small or nominal damages, or if the first judgment is inconsistent with one or more previous judgments in the defendant's favor, or if the second action affords the defendant procedural opportunities (e.g., discovery procedures) unavailable in the first action that could cause a different result. See Parklane, 439 U.S. at 330-31, cited in Century, 125 F.3d at 531. Nor should the doctrine be applied "when the issue is of general interest and has not been resolved by the highest appellate court that can resolve it." Century, 125 F.3d at 531 (citing Restatement § 29 Comment i; United States v. Alcan Aluminum Corp., 990 F.2d 711, 719 (2d Cir. 1993)). The Seventh Circuit has held that "determining 'whether or not application of [issue preclusion] is fair depends upon a case by case analysis,' and that courts should be sensitive to the 'practical realities which surround the parties.'" Century, 125 F.3d at 531 (quoting Butler v. Stover Brothers Trucking Co., 546 F.2d 544, 551 (7th Cir. 1977)). Thus, in Century, where the issue involved the validity of the PBGC's regulation delaying withdrawal liability payments when an employer has filed for arbitration, the court refused to apply the doctrine to prevent the employer from relitigating the regulation's validity because the issue decided was an unmixed question of law that was likely to arise again, all other courts to consider the issue had come out the other way, and the district court failed to distinguish any of those cases. Id. 125 F.3d at 532.

This case does not appear to fall within any of these exceptions. The record suggests that Abbott and Tokyo Tanabe defended the Forest case with vigor, there are no judgments concerning the Tanabe patents that are inconsistent with Judge Arcara's, and the discovery procedures available in this Court are likely the same as those available in the Forest case. Although it is true that the Federal Circuit has not yet ruled on whether Judge Arcara correctly construed the patent claims in the Forest case, this issue is not a matter of general interest; indeed, the universe of parties who have an interest in how these claims are construed is quite small. And although claim construction presents a purely legal question, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995) (en banc), aff'd 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), the issue of how these particular claims should be construed is unlikely to arise again.

There appear to be only two reported decisions in which the court was asked to consider the preclusive effect to be given the claim construction decision of a prior court involving the same patents and the same patent holders but not the same opposing party. Sadly, the courts deciding those two cases reached opposite results. In TM Patents, L.P. v. International Business Machines Corp., 72 F. Supp. 2d 370 (S.D.N.Y. 1999), the district court held that issue preclusion foreclosed the patent holder from relitigating the meaning of certain claim limitations that had already been raised and litigated in a prior infringement action. In deciding to apply the doctrine, the court analyzed precedent--not only Markman v. Westview Instruments, Inc., 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), which emphasized the need to promote uniformity in the meaning to be given a particular patent's claims and to that end took the question of claim construction away from the jury and handed it to the judge--but the cases leading up to that decision as well:

Even prior to Markman, the Federal Circuit had held that determination of the scope of a patent claim in a prior infringement action could have [issue preclusive] effect against the patentee in a subsequent case. See Pfaff v. Wells Elec. Inc., 5 F.3d 514, 517-18 (1993). After Markman, with its requirement that the Court construe the patent for the jury as a matter of law, it is inconceivable that a fully-litigated determination after a first Markman hearing would not be preclusive in subsequent actions involving the same disputed claims under the same patent. The nature of the Markman proceeding is such that finality is its aim. Id. 517 U.S. at 377.

By contrast, in Graco Children's Products, Inc. v. Regalo International, LLC, 77 F. Supp. 2d 660 (E.D. Pa. 1999), the court concluded that issue preclusion did not apply to bar relitigation of claim construction issues. In so doing, the court recognized that "by instructing courts to decide issues of claim construction in patent cases, the Court in Markman recognized the importance of uniformity in the treatment of a given patent." Id. at 663. But, the court reasoned, even Markman did not require courts to apply issue preclusion in every case; "circumstances may exist where . . . despite a previous court having held a hearing on the claim construction of a patent pursuant to Markman, [issue preclusion] will not apply to such decisions." Id. at 663, 665. Given the particular circumstances of the Graco case (Graco lost on the claim construction issues but won on the ultimate infringement issue and so could not have appealed the claim construction decision), this Court does not necessarily disagree with the outcome reached in that case. But such circumstances are not present in this case. Unlike Graco, Abbott and Tokyo Tanabe lost on both the claim construction issues and the infringement issue, and they can and have appealed. Although that appeal has not yet been decided, the law in the Seventh Circuit is clear

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that exhaustion of appellate remedies is not a normal requirement of issue preclusion, and a final judgment by a district court has preclusive effect even though judgment is pending on appeal. See, e.g., Amcast Industrial Corp. v. Detrex Corp., 45 F.3d 155, 160 (7th Cir. 1995); Prymer v. Ogden, 29 F.3d 1208, 1213 n.2 (7th Cir.), cert. denied, 513 U.S. 1057, 130 L. Ed. 2d 599, 115 S. Ct. 665 (1994).

Additionally, in Graco the claim construction was not the reason for the loss; here it was. Because of the way he construed the claims, Judge Arcara found that no reasonable trier of fact could find that Forest's product infringed the Tanabe patents. For these reasons, the Court does not believe it would be unfair to apply the doctrine of issue preclusion in this case. The Court finds that Judge Arcara's construction of "surface active material" and "based on dry weight" are binding on this Court.

The Court notes that even if it were not bound to follow Judge Arcara's ruling, it would nonetheless apply the same claim construction--at least with respect to the meaning of the phrases "surface active material" and "based on the dry weight of the material." Judge Arcara's reasoning on these points is persuasive. The plaintiffs argue that Judge Arcara's construction of these claim terms was "plainly wrong" for several reasons, and that they should therefore be permitted to relitigate the claim construction issues anew in this Court. There is some authority for the proposition that a "plainly wrong" determination may not be entitled to preclusive effect, see Restatement (2d) of Judgments § 29(8) and cmt. j (1980), but the Court does not believe that exception would cover the situation presented here. Section 29(8) instructs that a court need not apply issue preclusion if "other circumstances justify affording [the losing party] an opportunity to relitigate the issue"; comment j instructs that the "other circumstances" that may be important include "disclosure that the prior determination was plainly wrong or that new evidence has become available that could likely lead to a difference result." The fact that these two circumstances are linked in the same comment suggests that the "disclosure that the prior determination was plainly wrong" would not come from a second court revisiting the merits of the first court's decision, but from new evidence or a change in facts or circumstances. The Restatement does not seem to contemplate a second court being able to revisit the merits of the prior determination, as the plaintiffs urge here. Indeed, such an exception would make no sense in light of the purpose behind the doctrine of issue preclusion, which is to place the first judgment beyond question by subsequent courts; if the second court is going to examine the first court's decision to decide if it was right or wrong, what is the point of having issue preclusion to begin with?

Moreover, the Court does not believe Judge Arcara's decision was "plainly wrong." In support of its argument in this regard, the plaintiffs first argue that Judge Arcara should not have read a temporal limit into the term "surface active material" because the claims do not limit that term to dry powder or impose a temporal element on that material. The Court disagrees. The claims clearly contemplate that the "surface active material" exists first, and then, after a "pharmaceutically acceptable carrier" is added to the surface active material, the surface active material ceases to exist and becomes a "pharmaceutical composition." See, e.g., U.S. Patent No. 4,397,839, at col. 18, lines 15-19. As Judge Arcara noted, it was undisputed that the chemical composition of the lung surfactant extract material changes when it is added to water (one of the claimed elements of the "pharmaceutically acceptable carriers," see id., col. 18, lines 26-28). If that is the case--and the parties in this case certainly seem to agree that it is--once the pharmaceutically acceptable carrier is added to the surface active material, the surface active material no longer exists, or at least it does not exist in the same form.

Second, the plaintiffs argue that Judge Arcara's construction of "surface active material" is wrong because a solid, which is what the surface active material must be under Judge Arcara's view, cannot be added "dropwise" as required by claim 1, and cannot be administered orally or intraperitoneally (through a syringe) as discussed in the specification. The plaintiffs have not explained why this is so, however. In fact, their argument seems to assume that the terms "solid" and "liquid" are black and white, and that only "liquids" can be dropped or put into a syringe. Not that the Court has any particularized knowledge about the specific state of matter of the "surface active material" described in the patent, but as a matter of common sense, some "solids" are more solid (in the sense of being unmalleable) than others. For example, cake frosting and toothpaste, which most people probably think of as solids, can be added dropwise onto a surface, which is what the claims of the patent contemplate. So just saying something is a "solid" does not necessarily mean that it cannot be made to perform in the ways required under the patent. More importantly, the intraperitoneal insertion language comes from the examples provided in the specification, not from the claims themselves, and it therefore may not be read into the claims. See, e.g., Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.").

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The plaintiffs next argue that Judge Arcara's claim construction was wrong because he held that claim 1 is a subset of claim 9, which is impossible if claim 9 depends from claim 1, which it unquestionably does. The Court disagrees with this characterization of the ruling. Judge Arcara did not hold that claim 1 depended from claim 9; rather, he held (correctly in this Court's view) that the "surface active material" claimed in claim 1 is one component of the "pharmaceutical composition" claimed in claim 9. The plain language of the claims makes this much clear; claim 9 claims "[a] pharmaceutical composition . . . comprising an effective amount of a surface active material as set forth in claim 1 and a pharmaceutically acceptable carrier thereof." U.S. Patent No. 4,397,839, col. 18, lines 15-19.

Tying this argument in with their point that a solid cannot be inserted intraperitoneally, the plaintiffs argue that Judge Arcara was wrong to infer that "surface active material" is a solid because even Dey's own surfactant expert, Joseph Zasadzinski, testified that the phrase did not "fit within a particular state of matter." See Plaintiffs' Brief on the Correct Construction of [Claim Terms], p. 8 (quoting Zasadzinski's deposition testimony). But the deposition excerpt makes clear that Zasadzinski was asked to define the phrase as a general proposition, whereas Judge Arcara was asked to define that phrase as it used in the context of the '301 and '839 patents. Those patents define "surface active material" as something that must be combined with water and physiological saline (i.e., made more liquid) to form the "pharmaceutical composition" to be used in treating RSD. See U.S. Patent No. 4,397,939, col. 18, lines 15-19, 26-31. Judge Arcara was right to conclude that "surface active material" and "pharmaceutical composition," as used in the patent, do not mean the same thing.

As further evidence that "surface active material" is not limited to a solid state, the plaintiffs offer a copy of the extension it received from the PTO under 35 U.S.C. § 156. The plaintiffs reason that because the patentee submitted "testing conducted on the post-suspension product Survanta,(R) but did not submit any testing on a 'dry' precursor product" in support of its application for the extension, and because the PTO granted the extension, the PTO necessarily found that Survanta(R) was a "surface active material" within the meaning of claim 1. See Plaintiffs' Brief on the Correct Construction of [Claim Terms], at 7-8. This evidence is extrinsic and, absent an ambiguity in the patent's claims, specification and prosecution history (which is lacking here), it should not be considered in determining what the claims of the patent actually mean; certainly, this evidence cannot be used to contradict the claim construction unambiguously apparent from the intrinsic evidence. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999). Moreover, the granting of the extension appears to have had nothing to do with determining what the claims of the patent mean, and even if it did, the PTO is not required to interpret a patent's claims in the same manner as courts are required to during infringement proceedings, see In re Morris, 127 F.3d 1048, 1053 (Fed. Cir. 1997), which means that the PTO's claim interpretation would in no way be binding on Judge Arcara or on this Court.

Finally, the plaintiffs argue that Judge Arcara's ruling prevents the patentee from determining whether a publicly-available product produced by a potential infringer actually infringes the '839 patent because they would have to test the precursor to the publicly-available product--what Dey has referred to in court as "the paste"--which may well be unavailable to test (indeed, plaintiffs have had some difficulty obtaining it from Dey in this case). This is the most compelling (indeed the only compelling) of all the plaintiffs' arguments. The Court is mindful that the claims as construed require the plaintiffs to test the precursor, which may mean that the patent holder and licensees have to file an infringement suit just to have access to that material to determine whether it infringes the '839 patent. But that is, in fact, what the claims as written require, and the Court is neither willing nor able to rewrite the claims to alleviate this potential hurdle to enforcement of the patent rights. See K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1364-65 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.") (citing Texas Instruments Inc., v. International Trade Commission, 988 F.2d 1165, 1171 (Fed. Cir. 1993)).
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2. "Based on the Dry Weight"

Abbott argues that the district court erred in its construction of the expression "based on the dry weight" as meaning that the weight of the lung surfactant extract material is measured before it is combined with a pharmaceutical carrier. Abbott urges that that expression, according to one of skill in the art, means that a liquid suspension or solution may be tested on a "dry weight" basis by first drying the material and then assaying the solid components of that dried material by percentage.

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ONY responds that water is a component of the surface active material to be measured like any other, and that the district court did not err in requiring that the surface active material be measured in the dry state before it is combined with physiological saline to form a pharmaceutical composition.

We agree with ONY that the expression "based on dry weight" means based on the dry weight of the surface active material before it is combined with a carrier to form a pharmaceutical composition. The surface active material may be part of a pharmaceutical composition, but it is a distinct component of that composition and must be evaluated independently of the pharmaceutical composition in order to determine if it meets the claim limitations to surface active material.

Abbott's proposed construction impermissibly ignores the claimed water percentages. The specification and the claims set forth without ambiguity that the surface active material must have specific, measurable percentages of water, presumably the residual water remaining in the material after lyophilizing (i.e., freeze-drying) a purified solid residue suspended in distilled water, which is the final synthetic step in the preparation of the surface active material. See, e.g., '301 patent, col. 10, ll. 45-57; col. 12, ll. 2-8; '839 patent, col. 12, ll. 57-66. The patentee defined the residual water to be that measured by a method such as the Karl Fischer method, and present in the specifically claimed percentages. The extrinsic evidence of what would be understood by someone of skill in the art -- that water is an irrelevant reference point -- contradicts the express requirement of the claims and the description in the specification that water is a relevant and measurable ingredient. We consider extrinsic evidence, such as how a skilled artisan would interpret the expression "based on dry weight," only when it helps the court come to a proper understanding of the claims; "it may not be used to vary or contradict the claim language." Vitronics, 90 F.3d at 1584, 39 U.S.P.Q.2D (BNA) at 1578. We therefore conclude that the expression "based on the dry weight" means based on the dry weight of the surface active material before it is combined with a carrier, and that this phrase does not negate the claim limitations to water.
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basicity equal to or greater than 50%

The parties and the Court agree that the phrase should be construed as "a basicity of equal to or greater than 50% for an aluminum polymer may be expressed chemically as Al[n](OH)[m]Cl([3n-m]), the relative amount of hydroxyl [OH] ions compared to the amount of chloride [Cl] ions and hydroxide [OH] ions."
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1. Construction Of "Said Beads Being Coded With An Encoding System"

Affymetrix's proposed construction of "said beads being coded with an encoding system" is "said beads being distinguishable one bead from another." (D.I. 243 at 10.) Illumina's proposed construction is "said beads having a property associated with each bead (separate from the binding polymer) that can be used to distinguish one bead from another." (D.I. 240 at 16.) The parties dispute only whether the Court should construe the term so as to preclude the use of the binding polymers themselves as the encoding system. The Court concludes that it should.

The language of claim 1 and the specification indicates that the inventors did not contemplate using the binding polymers as the system to encode the beads to which they are attached. Claim 1 requires that the beads be "coded with an encoding system whereby the target specific sequence of the polymer attached to the beads can be identified." (Id. col. 82, ll. 53-55.) The specification teaches that "[a]fter the relatively small number of beads that have bound the target have been collected, the encoding scheme may be read off to determine the specificity of the reagent on the bead." n1 (Id. col. 21, ll. 58-61.) Thus, the patent teaches that the encoding system is used to identify which binding polymer is attached to a particular bead. Using the binding polymers as the encoding system then, would amount to using a binding polymer to identify itself. This circular identification cannot be what the inventors intended.

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n1 In this context, the term "reagent," used in the specification, is synonymous with the term "binding polymer" used in the claims.

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Affymetrix describes what it says is an example of a system using the polymers attached to the beads as both binding polymers and an encoding system. (D.I. 243 at 11-12.) However, what Affymetrix describes is not an encoding system per se, but a means of identifying the polymers attached to the beads by hybridizing them to known polymer sequences. To be useful, this system would still require a means of encoding the beads separate from the binding polymers. Subsequent to hybridization and identification of which polymer was attached to which bead, the beads would have to be encoded in some way, either by labeling them directly or by recording their positions within an array of immobilized beads. Otherwise, the identifying information gained through hybridization with a known sequence would be lost when the known sequence was detached to free the binding polymer for further hybridization with an unknown target polymer.

Affymetrix also cites a section of the specification that it contends is a preferred embodiment teaching the use of the binding polymers as the encoding system. (D.I. 243 at 12; D.I. 250 at 10.) Affymetrix mischaracterizes the cited section. That section is a discussion of adding polymers to various products as markers to identify the origins of those products. It has nothing to do with using binding polymers as a system for encoding beads to which they are attached. (See '432 patent, col. 58, ll. 8-34.)

For the reasons discussed above, the Court construes "said beads being encoded with an encoding system" to mean "said beads having a property associated with each bead (separate from the binding polymer) that can be used to distinguish one bead from another."
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III. Part b) -- "said fibers being uniformly treated…"

A. Relevant Claim Language

The next section of text from Claim 1 to be analyzed consists of the following: "said fibers being uniformly treated with a durable flame retardant of aprepolymer of urea and tetrakis (hydroxymethyl) phosphonium salt which has been applied, ammoniated and oxidized in a manner such that." ('545 Patent, col. 8, lns. 34-39).

B. Parties' Positions

Defendants contend that the inclusion of the verbs "applied," "ammoniated" and "oxidated" make Claim 1 a "product-by-process" claim. (Id. at 20). According to Defendants, the specific process that must be applied to the fabric is the detailed process described in the specification. Defendants believe the proper construction of this section is as follows:

"the fibers throughout the wash resistant durable fabric undergo the same treatment process to produce the results recited in claim 1, said treatment process being, in a single application and cure process, the steps of: (1) drawing the fabric through an aqueous bath containing a sufficiently high concentration of the THP/urea prepolymer to apply to the fabric, at 60% to 80% wet pickup, a calculated amount of 3.0% to 4.0% of phosphorus by weight of the fabric, (2) squeezing the fabric through a pad roll to control wet pickup to 60% to 80%, (3) drying the fabric to between 8% to 12 % moisture level, (4) ammoniating the THP/urea prepolymer in thefabric by exposing the fabric to ammonia, and (5) oxidizing the THP/urea prepolymer in the fabric by exposing the fabric to hydrogen peroxide"

(Defs.' Claim Construction at 19).

Plaintiffs claim that the process detailed in the specification is simply one example of a method by which the desired product can be achieved. "The fact that claim 1 includes a process step does not convert it to a process claim." (Pls.' Rebuttal at 14). "Nowhere does the specification say or even imply that a single pass process must be used or is essential, nor does it indicate that specific wet pick-up, moisture levels, or calculated amounts of phosphorous must be used or are

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essential." (Pls.' Rebuttal at 17). "The inventors simply complied with the basic statutory requirements for the patent's specification -- providing at least one example of how to make the inventive fabric." (Pls.' Rebuttal at 18 (citing 35 U.S.C. § 112, P 1)). "After wedding through the entirety of their arguments, the Defendants basically imply that just because the specification describes additional details related to one exemplary way to make the claimed fabric, this fact alone somehow compels rewriting the claims to include theseadditional details." (Pls.' Rebuttal at 18).

Plaintiffs assert that the phrase "uniformly treated" means "the flame retardant is uniformly distributed across the interior diameter of the cotton fibers." To rebut this construction, Defendants make three main arguments. First, looking to Plaintiffs' choice of language, Defendants argue, "Had the inventors of the '545 Patent intended to merely claim a product characteristic, as Plaintiffs contend, the inventors could have recited phrases such as 'said fibers having micro-uniformity' or 'said fibers having a uniform distribution,' in claim 1, but they did not do so." (Defs.' Rebuttal at 6). Furthermore, Defendants point out that in the specification of the '545 Patent, the inventors used the terms "distributed" and "treated" differently, so they can't be read to have the same meaning now. (Defs.' Rebuttal at 7-9). Second, relying on the PTO's assessment of the '545 Patent, Defendants explain that in the first reexamination of the '545 Patent, the PTO said that this element of the claim is a process limitation (uniform treatment of fibers with a chemical containing phosphorous), not a result (fibers having uniformly distributed phosphorous).(Defs.' Rebuttal at 6, 10). Third, Defendants turn to the definition of the technical terminology used in this portion of the claim, arguing that Plaintiff's construction does not make technical sense. The claim refers to "prepolymer," which is different from "polymer." "Prepolymer" refers to the substance applied to the fabric when treating is, whereas "polymer" is the flame retardant substance that results after the prepolymer is ammoniated. Since the claim refers to "prepolymer," it must be referring to the substance used to initially treat the fabric, not the distribution of the resulting substance (polymer). (Defs.' Rebuttal at 7).

Plaintiffs address this final, technical point by providing the following explanation:

The actual claim language requires the fibers to be uniformly treated with the "durable flame retardant" (i.e., the end result) and not the prepolymer. It then defines that the durable flame retardant is the "prepolymer" that has been "applied, ammoniated and oxidized." Therefore, the "durable flame retardant" is the end result of the prepolymer being "applied, ammoniated and oxidized."

(Pls.' Sur-Reply at 2). Plaintiffs go on to argue that the entirety of the specification"clearly confirms that it is the end resulting durable flame retardant that is uniform throughout the yarn rather than the prepolymer." (Id. (emphasis in original)).

Plaintiffs then state, "To the extent the Court analyzes 'uniformly treated' as a process limitation rather than a product limitation, the Defendants' wholesale rewrite of claim 1 to include over 100 additional words is still completely improper." (Pls.' Sur-Reply at 2). If the Court takes this perspective, the phrase "needs no construction because it simply means treatment in a uniform or consistent manner." (Id. at 4).

C. Court's Construction

We agree with Defendants and the PTO that this portion of the claim language refers to a process limitation, rather than a characteristic of the resulting product. However, we do not adopt Defendants' view construing the process to be limited to the particular process described in the specification. The specification simply sets forth one example of a process that can be used to achieve the necessary result. Therefore, this court concludes that the phrase "uniformly treated" refers to a process, but does not require construction. As Plaintiff stated in its sur-reply brief, the phrase"uniformly treated" carries its natural meaning -- "treatment in a uniform manner."
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2. "Below Limits for Imparting Smoke Flavoring to Food"

In addition, HISI and TPI disagree over the meaning in Claim 67 of the phrase "below limits for imparting smoke flavoring to food." TPI requests that the "limits for imparting smoke flavoring to food" be defined as "having phenolic fractions less than 2.3 ppm for vapor and 1.4 ppm for particulate." (TPI Brief 17 (emphasis removed).) TPI bases this request on Table 3

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in the Background Art section of the Kowalski Patent, which identifies 2.3 ppm and 1.4 ppm as the taste recognition thresholds for the vapor and particulate phases, respectively, of wood smoke. (Kowalski Patent, Col. 11, at 1-20.) HISI responds that this table is merely part of the background art, and cannot be drawn upon to limit the claims of the Kowalski Patent. HISI argues that "Claim 67 is a perfectly good claim without any numbers, and the lack of numbers serves a legitimate purpose." (HISI Reply 10.)

The Court here agrees with HISI that the numerical ranges described in the background art may not be read into this particular limitation. The specifications of the Kowalski Patent do not disclose a numeric limitation for "smoke flavoring" in either the smoke or the food with which the smoke is treated. The table listing the "Odor and Taste Recognition Thresholds (ppm) and Most Desirable Concentrations (ppm) of the Phenolic Fraction Isolated From the Vapor and Particulate Phases of Wood Smoke" (Kowalski Patent, Col. 11, at 1-19) is neither referenced nor commented upon at any other point in the specifications.

Furthermore, while an operable numeric range for tasteless smoke was given for the preferred embodiment of the Kowalski Patent, this was a range which was "determined empirically" for that particular embodiment of the patent. (Kowalski Patent, Col. 17, at 14-36.) The process claimed by the Kowalski Patent and disclosed in its specifications, however, is substantially broader; namely, the treatment of smoke "such that the phenols in both particulate and gaseous vapor phases are reduced to concentrations below recognition thresholds for odor and taste that impart a smoked flavor to the treated food. (Kowalski Patent, Col. 12, at 3-6.) Unlike the "heating" limitation discussed above, where the specifications uniformly disclosed a narrow operable temperature range of between 204 [degrees] and 510 [degrees] C., here the specifications disclose a range that is not numerically defined, and further disclose one particular embodiment for which numerical ranges have been determined. The claim here does not exceed the specifications of the patent, and the Court declines to add any numerical boundaries to the phrase "below limits for imparting smoke flavoring to food."
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With respect to the "beneficial amount" limitation, MSM Investments contends that this limitation should be interpreted as "the amount of MSM (R) that produces a nutritional benefit." We disagree. While the district court's construction of "a beneficial amount of methylsulfonylmethane" as meaning "any nonzero amount of methylsulfonylmethane that does not occur naturally in food actually eaten by an animal," MSM Invs. Co. v. Carolwood Corp., No. C 98-20238 EAI, slip op. at 8 (N.D. Cal. Jul. 23, 1999) (order regarding claim construction), misses the implication of the word "beneficial" that the amount must "promote a favorable result" for the animal, the claim language plainly encompasses both pharmacological and nutritional benefits. Furthermore, the written description explains that while it is desirable to ingest "from about 0.5-1.0 milligram/kg body weight/day" to maintain optimum good health, "any lower level will serve some benefit." Id. at col. 4, ll. 60-66. The specification discloses many of such benefits, which include pharmacological benefits. We therefore conclude that the district court's construction of the phrase "a beneficial amount of methylsulfonylmethane," while incomplete, at most constituted harmless error.
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2. "Benzalkonium Chloride"

The parties next dispute whether a functional limitation should be incorporated into the term "benzalkonium chloride" as it is used in Claim 1 of the '565 Patent. The parties are in agreement as to most of the term's proper construction. Plaintiffs claim the term means "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C[6]H[5]-CH[2]-NR(CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]" (Pl. Memo. at 11). Defendants claim the term means "a concentration of benzalkonium chloride that increases the bioavailability of calcitonin when administered to the nasal mucosa. Benzalkonium chloride is the name commonly employed for known mixtures of quaternary ammonium salts typically of the generalized formula C[6]H[5]-CH[2]-NR(CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]" (Def. Memo. at 13). Thus, the distinction in the proposed constructions lies in defendants' addition of the functional limitation on the definition of benzalkonium chloride to "concentration[s] of benzalkonium chloride that increase the bioavailability of calcitonin when administered to the nasal mucosa."

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Considering the language of the claim itself first, I find the additional limitation proposed by defendants contradicts the language of the claim itself and should, therefore, be rejected. Claim 1 of the '565 Patent expressly defines the amount of benzalkonium chloride as a range from "about 0.002% to about 0.02% on a weight per volume basis of a benzalkonium chloride." Adding the functional limitation proposed by defendants, here "increasing the bio-availability of calcitonin," contradicts the unqualified plain language in the claim. See Phillips v. AWH Corp., supra, 415 F.3d at 1324 (claim construction process cannot be used to contradict unambiguous claim language); Crystal Semiconductor Corp. v. Tritech Microelec. Int'l, Inc., 246 F.3d 1336, 1349 (Fed. Cir. 2001) (rejecting claim construction that would contradict express claim language); Scientific Games Int'l, Inc. v. Oberthur Gaming Technologies, 2005 U.S. Dist. LEXIS 34772, 1:02 CV 3224 TWT, 2005 WL 3307522 at *6 (N.D. Ga. Dec. 5, 2005) (same).

Plaintiff also correctly argues that one skilled in the art would not read the name of a chemical compound as implying any particular amount of that compound (Pl. Memo. at 13). The plain and ordinary meaning of a chemical compound is simply that compound, without any limitation as to amount. For example, the sodium chloride, or table salt, in a postage-stamp sized package at a cafeteria's condiment bar is just as much sodium chloride as a truckload of the same material. The name of a composition simply does not imply an amount. Thus, one skilled in the art would read benzalkonium chloride to mean "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C[6]H[5]-CH[2]-NR(CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]." This construction is not contradicted by other claim language or the specification.

Defendants argue that the specification and prosecution history support their construction of the term because, they contend, that plaintiffs distinguished their claims "over prior art references on the basis that the inventive calcitonin formulation included an amount of benzalkonium chloride which provides an unexpected improvement by increasing the bioavailabilty of calictonin upon nasal administration" (Def. Memo. at 13-15).

The portion of the specification on which defendants rely states:

In accordance with the present invention it has now been surprisingly found that pharmaceutical compositions can be obtained comprising a calcitonin as active ingredient which meet the high standards of stability and tolerability required for nasal application and which are, for example, eminently suitable for use in multiple dose spray applicators, i.e. applicators capable of delivering a series of individual dosages over e.g. [sic] period of several days or weeks, by the use of benzalkonium chloride as a coingredient and preserving agent. Surprisingly it has also been found that use of benzalkonium chloride, even at the very low concentration required for use as a preserving agent, may confer beneficial advantages in relation to the nasal resorption characteristics of calcitonin containing compositions and hence enhance calcitonin bio-availability levels consequential to nasal application.

('565 Patent, col. 2, lines 52-67). Defendants contend that this language makes it clear that the "concentration of benzalkonium chloride must be sufficient in concentration so as to confer the beneficial advantage of enhanced bioavailability levels for calcitonin upon nasal application" (Def. Memo. at 14). Plaintiffs again argue that using this language in the construction improperly reads a limitation from the specification into the claim (Pl. Memo. at 13-14).

I agree with plaintiffs that accepting defendants' proposed construction would improperly read a limitation from the specification into the claim. As noted above, Claim 1 of the '565 Patent expressly claims a fairly specific range of concentrations of benzalkonium chloride to be added to the composition and does not qualify that range by stating any functional limitation. Where a claimed composition expressly sets forth the amount of an ingredient, either by precise amount or by range of amounts, it is improper to import a functional limitation from the specification to vary the scope of the claim. n2

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n2 Indeed, defendants themselves admit as much, stating, "functional limitations expressed in the specification but not in the claim may not be read into the claim terms" (Def. Mem. at 9). See also Micro Chem., Inc. v. Great Plains Chem. Co., Inc., 194 F.3d 1250, 1258 (Fed. Cir. 1999); Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1278 (Fed. Cir. 1995).

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An analogous issue was presented in Jeneric/Pentron, Inc. v. Dillon Co., 205 F.3d 1377, 1382-83 (Fed. Cir. 2000). In that case, the patentee of a composition used in dental restorations sought to enjoin defendant's manufacture and sale of an allegedly infringing composition. The relevant claim language limited the amount of cerium oxide in the composition to 0 - 1%. Although the accused product, marketed under the name "Sensation," contained 1.61% cerium oxide, plaintiff claimed that it literally infringed because the cerium oxide in defendant's composition performed the same function as the cerium oxide in the claimed composition. The Federal Circuit rejected plaintiff's literal infringement argument, stating:

Claim 1 requires a two-phase dental porcelain composition with 0-1% of cerium oxide. Claim 1 does not place functional limitations on the percentage of cerium oxide, thus distinguishing opacifying, coloring, or fluorescing cerium oxide from anti-greening cerium oxide. Rather, the claim specifies 0-1% cerium oxide. Sensation contains 1.61% - an amount well outside the precisely claimed range. This court rejects any attempt to carve out a portion of cerium oxide according to functions not recited in the claim. Jeneric's infringement theory essentially proposes that the precisely claimed ranges do not limit the amount of porcelain compositions. That argument fails because it would read out of claim 1 the express claim ranges. See Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1563. Thus, this court agrees with the district court's determination that Jeneric has not shown a reasonable likelihood of success on literal infringement by Sensation.

205 F.3d at 1382-83.

Claim 1 of the '565 Patent also sets forth a range of the concentration of benzalkonium chloride in the claimed composition. As in Jeneric/Pentron, importing the functional limitation suggested by defendants would read that quantitative limitation out of the patent. Thus, Jeneric/Pentron requires that defendants' argument be rejected.

Defendants further argue that in the prosecution of the '565 Patent, plaintiffs expressly relied on the "unexpected benefit" of benzalkonium chloride quoted in the specification quoted above to distinguish plaintiffs' invention from prior art. Thus, defendants contend, the language should be read into Claim 1 because it would be improper for plaintiffs to rely on this feature to distinguish prior art in their patent application and then deny its significance in later litigation (Def. Memo. at 15-21).

Defendants are correct that the prosecution history distinguishes the invention from prior art, at least in part, by emphasizing that adding benzalkonium chloride to the composition can increase absorption and bioavailability (e.g., Def. Memo. Ex. F at 3). However, enhanced absorption and bioavailability were not the only features cited to distinguish prior art. Plaintiffs also cited improved "tolerability and ciliary function" n3 (Def. Mem. Ex. F at NX 2280 & Ex. G at NX 2292). Moreover, Claim 1 of the '565 Patent claims compositions with beneficial amounts of benzalkonium chloride by limiting the claimed compositions to those that contain from "about 0.002% to about 0.02% on a weight per volume basis of [] benzalkonium chloride" -- the precise range of amounts found to provide the greatest benefit (see '565 Patent at col. 3, lines 47-50 ("A preferred concentration for the benzalkonium chloride component in the compositions of the invention is from about 0.002 to about 0.02, typically about 0.01% (w/v) of the total composition.")). Since the patentee chose to claim a numerically-defined range of benzalkonium chloride concentrations that confers the "surprising" benefit, there is no reason to convert that quantitative limitation into a qualitative one.

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n3 "The nasal mucosa is lined with small hairs called 'cilia' covered with mucous. The cilia transports mucous and foreign particles to the throat. This function is essential to human health" (Klibanov Decl. at 9, n.2).

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Finally, adoption of defendant's proposed functional limitation would lead to inconsistent definitions of benzalkonium chloride in the '569 and '565 Patents. Since the '569 and '565 Patents result from the same application, identical terms in both patents should be construed to have the same meaning. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003); Fin. Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001). Claim 1 of the '569 Patent claims a composition that includes "an effective amount of benzalkonium chloride to enhance the bioavailability of said calcitonin when administered, to the nasal mucosa . . . ." If the functional limitation suggested by defendants were read into the definition of benzalkonium chloride, the functional limitation that is expressly set forth in Claim 1 of the '569 Patent would

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be redundant and meaningless. See Merck & Co. v. Teva Pharms. USA, Inc., supra, 395 F.3d at 1372 ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.").

Therefore, I find that "benzalkonium chloride," as the term is used in the '565 patent, should be construed as "pharmaceutically acceptable mixtures of quaternary ammonium salts of the generalized formula C[6]H[5]-CH[2]-NR (CH[3])[2]Cl, wherein R is C[8]H[17] to C[18]H[37]."
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III. PARTY ARGUMENTS CONCERNING CLAIM CONSTRUCTION

Defendant Synthon seeks to limit Pfizer's patent to the "anhydrous besylate salt of amlodipine. " In this way, Synthon's product would not literally infringe Pfizer's patent. As stated previously, Synthon's product is amlodipine besylate monohydrate. The difference between anhydrous amlodipine besylate and amlodipine besylate monohydrate is an attached H2O group. In contrast to Synthon's claim construction, Pfizer argues that "the besylate salt of amlodipine" simply means a salt in the form of an amlodipine cation attached ionically to a benzene sulphonic acid anion. This claim term therefore identifies the base (amlodipine) and acid (benzene sulphonic acid) that forms the salt, but leaves unspecified the physical form that the salt takes (hydrates, solid solutions, different crystal structures, different morphological shapes of a crystal structure) and whether any other molecules, if any, are associated with it, such as water.

Synthon makes a number of arguments as to why Pfizer's patent should be limited to the anhydrous version of amlodipine besylate. For example, Synthon points to the use of singular language in Claim 1 itself, "The besylate salt of amlodipine," which uses such words as "the" and "salt" as opposed to "salts." Synthon points to the fact that this use of singular language must indicate that only one specific compound is covered by the claim. Moreover, Synthon argues that amlodipine besylate monohydrate is a different salt than anhydrous amlodipine besylate. As part of this same argument, Synthon posits that the claim specification indicates that the patent is limited to a single compound. This is because the specification states that "it has now unexpectedly been found that the benzene sulphonate salt (hereafter referred to as the besylate salt) has a number of advantages over the known salts of amlodipine and, additionally, has unexpectedly been found to have a unique combination of good formulation properties which make it particularly suitable for the preparation of pharmaceutical formulations of amlodipine." Again, Synthon points to language indicating a singular, unique compound and not a variety of compounds.

In response, Pfizer states that the construction "the [salt] of [base]" is commonly used by scientists and is not used to signify anything more than that a particular acid-base pair constitutes a salt. As such, hydrates of that particular acid-base pair are still considered to be that same "salt." Pfizer also submits to the Court an expert declaration that states that whether a compound is anhydrous or a monohydrate does not change the kind of salt that is formed. (See McGinity Decl., Document # 86, at 5.) Thus, Pfizer argues that the use of a singular noun "salt" does not preclude the claim from including both the anhydrous formation and the monohydrate.

Synthon's second argument is that Pfizer was only able to get the '303 patent, which was initially rejected by the PTO for "obviousness," by arguing that this particular salt had previously unknown good qualities that were not evident in the '909 patent. Synthon argues that Pfizer tested the monohydrate in 1985 but rejected it as "not a suitable form for development" because it was hygroscopic, that is, that it had a tendency to take up or to lose water in excess of any water already in the compound. Accordingly, Synthon argues that either the patent does not include the monohydrate, or that Pfizer must have misrepresented to the patent office the scope of its invention by not reporting that the monohydrate was unsuitable for development and thereby receiving a patent broader than Pfizer's testing would support.

In response to this argument, Pfizer states that the language pointed to by Synthon, "not a suitable form for development," was only available in its nonpublic New Drug Application filed in December 1987 with the FDA. Accordingly, such information should not be considered by this Court during claim construction, and cannot constitute a disclaimer of the subject matter of claims in the '303 patent, because it was not available to a practitioner of ordinary skill in the art on the date that Pfizer filed its patent application in 1986. Moreover, and more importantly, Pfizer states that such language only concerned using the monohydrate for the pill or tablet form of the drug and not as an aqueous solution, such as that disclosed in Claim 9, in which the hygroscopicity of the substance is not important. Finally, Pfizer states that it was not

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inequitable conduct not to report test data as to the monohydrate because while a patent applicant has a duty to report the "best mode," to the PTO, an inventor need not disclose every possible way in which an invention could be practiced, including less desirable modes. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001) ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.").

Synthon's third and primary argument is, although the patent does not state as such, that Pfizer only used anhydrous amlodipine besylate in its testing and development of Norvasc(r), and relatedly, that the patent specification teaches that any hydrate is unsuitable. Pfizer admits that its marketed product Norvasc(r) only uses anhydrous amlodipine besylate. Moreover, Pfizer's patent specification states that, "Although amlodipine is effective as the free base, in practice it is best administered in the form of a salt of a pharmaceutically acceptable acid. In order to be suitable for this purpose the pharmaceutically acceptable salt must satisfy the following four physiochemical criteria: (1) good solubility; (2) good stability; (3) non-hygroscopicity; (4) processibility for tablet formulation." The patent then goes on to discuss the solubility of various salts, the stability of various salts, the hygroscopicity of various salts, and the stickiness of various salts. None of these charted salts differentiates between anhydrous, monohydrates, and dihydrates as part of the listed name in the patent. Synthon emphasizes, however, that the words "must satisfy" are in the patent specification statement, therefore indicating a clear disclaimer by Pfizer of any substance that does not contain those four qualities. Synthon then states that Synthon's expert's own testing of the monohydrate shows it to be quite sticky. Thus, Synthon argues that Pfizer stated that this particular compound "must satisfy" those four criteria, but that the monohydrate version does not satisfy all four criteria, so therefore Pfizer has disclaimed the monohydrate.

Synthon submitted the expert declaration of Walter Chambliss [Document # 90] in order to show that Pfizer did not test amlodipine besylate monohydrate when developing the '303 patent. This expert opined that the various weights of "the besylate salt of amlodipine" used in testing indicate that only the anhydrous form of the salt was utilized in that testing. Accordingly, Synthon argues that the patent teaches that only the anhydrous form is proper for producing a salt that improves upon the prior art salt of amlodipine maleate, and that "hydrates" in general must be rejected. Synthon further emphasizes that the patent specification of '303 states that,

Only the maleate, tosylate and besylate salts do not pick up any moisture when exposed to 75% relative humidity at 37degree C. for 24 hours. Even when exposed to 95% relative humidity at 30 degree C. for 3 days both the besylate and maleate remain anhydrous whilst the tosylate formed the dihydrate salt. Therefore the besylate salt can be considered to be non-hygroscopic and thus provides stale formulations while minimising the risk of intrinsic chemical breakdown."

(Patent No.4,879,303, filed April 4, 1986 (emphasis added).)

This statement, according to Synthon, is also a clear disclaimer of any hydrates in this invention.

However, Pfizer denies that it ever clearly disclaimed amlodipine besylate monohydrate in this patent. Pfizer points out that the patent specification must not be read without considering the language in all of the claims, and not just the claims referring to tablets and capsules. More specifically, Pfizer points to Claim 9 of the patent, which states, "A sterile aqueous solution comprising an antihypertensive, antiischaemic or angina - alleviating effective amount of the besylate salt of amlodipine for parenteral administration." Pfizer argues that an aqueous solution cannot by its very nature employ an anhydrate, because once the salt is dissolved in the water it is no longer "anhydrous." Moreover, Pfizer states that there is no advantage (or disadvantage) obtained by starting with anhydrous amlodipine besylate over a hydrate form when both forms of the salt are in a water-based solution. Accordingly, Pfizer states that it is impossible that the invention claimed in all aspects of the claims is limited to the physical form of salt known as anhydrous amlodipine besylate, n4 and accordingly, the word "anhydrous" should not be read into any of the claims, including Claims 1 through 8. In response to this last point by Pfizer, Synthon's only response appears to be that, based upon the weight of the salt tested, it is presumed that Pfizer only dissolved anhydrous amlodipine besylate in solution, and not the monohydrate. Accordingly, Synthon argues that the patent does not teach one of ordinary skill in the art that use of the monohydrate form is possible within the '303 patent context.

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n4 Moreover, Pfizer states that the preferred quality non-hygroscopicity as stated in the patent specification as a "must satisfy" quality is simply irrelevant to amlodipine besylate in an aqueous solution.

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IV. COURT FINDINGS AS TO CLAIM CONSTRUCTION

As previously discussed, this Court must start its analysis of the correct interpretation of the phrase "the besylate salt of amlodipine" by examining the words of the claims themselves. See Phillips v. AWH Corp., 415 F.3d at 1312 (Fed. Cir. 2005). Unless the patent otherwise provides, a claim term should not be given a different meaning in the various claims of the same patent. See Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1331 (Fed. Cir. 1999); Fin Control Sys. Pty Ltd. v. OAM Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001); Patents and the Federal Circuit, Robert L. Harmon, § 6.7(b). Interpretation of a disputed claim term thus requires reference to the other claims. Id. The Court has examined the patent specification, and finds that it does not either define the contested phrase, "the besylate salt of amlodipine," nor does it teach that the phrase "the besylate salt of amlodipine" should be read differently as between Claim 1 and Claim 9. Accordingly, the Court finds that any interpretation given to the contested phrase should be the same in both Claim 1 and Claim 9. Because the Court finds that the meaning of the phrase in Claim 9 will shed light on the meaning of the phrase in Claim 1, the Court will examine the words of Claim 9 first.

The Court notes that as Pfizer clearly argued during the Markman hearing in this matter, Claim 9 is not a process claim. It does not attempt to teach one skilled in the art how to make such a substance, but instead, claims the substance itself. Claim 9 states, "A sterile aqueous solution comprising an antihypertensive, antiischaemic or angina-alleviating effective amount of the besylate salt of amlodipine for parenteral administration." The term "comprising" is generally understood by patent attorneys to have the same meaning as the term "including." See Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., 123 F.3d 1445, 1451 (Fed. Cir. 1997); Patents and the Federal Circuit, Robert L. Harmon, § 6.2(d) ("The claim term 'including' is synonymous with 'comprising,' thereby permitting the inclusion of unnamed components.") It does not mean, as Synthon urged during the Markman hearing, "made from," and the Court does not find any evidence within the patent itself to indicate that the term "comprising" does not mean "including."

Experts for both parties appear to agree that when a salt is in an aqueous solution, it would be meaningless to term it as being "anhydrous." (See McGinity Decl., Document # 86, at 23 ("The salt in solution is in the form of ions surrounded by water, and cannot be anhydrous."); Chambliss Dep., Document # 109, at 84 ("Q: Well if you have pure amlodipine besylate monohydrate in an aqueous solution, the amlodipine ion and the besylate anion are no longer physically joined; is that correct? A. Yes. They've separated. Q. And they are separated by water, if it's a pure water solution? A. Just in water, yes. Q. And if you have amlodipine besylate that started off as anhydrous in solution, you'd also have a separate amlodipine anion - or a cation and a besylate anion? A. Yes. Q. Surrounded by water, correct? A. Correct. Q. And those two, the monohydrate and the anhydrate surrounded by water would be, from all appearances, identical . . . if that's all there is, completely pure material? A. They are going to be separated. I don't know how from what you mean by appearances, how. Q. Well if you analyze both solutions, they would appear to be identical? A. If you're analyzing for the besylate and you're analyzing for amlodipine, you should get the same result.").) Accordingly, based upon the record before the Court, the Court finds that it would be error to read the term "anhydrous" into Claim 9, because Claim 9 concerns an aqueous solution including the besylate salt of amlodipine, which cannot be "anhydrous." Therefore, because Claim 9 cannot be read as anhydrous, Claim 1, which only claims "The besylate salt of amlodipine," also cannot be read as requiring the modifier "anhydrous."

Accordingly, there is no need in this matter to move beyond the language of the claims themselves in order to determine the meaning of the phrase "the besylate salt of amlodipine." However, the Court has also considered the language of the specification, which also teaches that Synthon's preferred interpretation, requiring the insertion of the word "anhydrous," still does not hold up to close scrutiny. For example, while Synthon argues that Pfizer specifically disclaimed hydrates by stating in the specification that "both the besylate and maleate remain anhydrous whilst the tosylate formed the dihydrate salt," the Court does not find this to be a clear disclaimer of all hydrates, nor more specifically of amlodipine besylate monohydrate. See Eolas Techs., Inc. v. Microsoft Corp., 399 F.3d 1325, 1336 (Fed. Cir. 2005) ("Absent a clear disclaimer in the specification, the embodiments in the specification do not limit broader claim language."), cert. denied, 126 S. Ct. 568, 163 L. Ed. 2d 499 (2005). Amlodipine besylate monohydrate and its particular properties are not distinguished within patent number '303. In much of the patent specification, it remains unclear to this Court whether Pfizer tested anhydrous, monohydrate, or dihydrate versions of various salts. However, even assuming that Pfizer only tested the anhydrous form, Pfizer created the monohydrate form by dissolving the salt in water to test for solubility. (See McGinity Decl., Document # 86, at 6 ("Amlodipine besylate hydrate is formed when the besylate salt of amlodipine is precipitated from water. It follows

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that a saturated aqueous solution of the besylate salt of amlodipine will produce the hydrate form of amlodipine besylate as water is evaporated from solution. The '303 patent refers to a measurement of solubility of amlodipine besylate. Because such measurements are necessarily run with a saturated solution of the amlodipine besylate, the hydrate form of amlodipine besylate would form as water is evaporated from the saturated solution.).) Accordingly, the Court finds that it cannot say as a matter of law that Pfizer either disclaimed the monohydrate form of amlodipine besylate or that Pfizer did not use the monohydrate form in its testing of this substance. See Phillips, 415 F.3d at 1323 ("Although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.")

Therefore, based upon the language of the claims and the patent specification, it does not appear that Pfizer specifically disclaimed the monohydrate form of the salt, and in fact claimed a version of the salt within an aqueous solution in Claim 9, which by its very nature cannot be anhydrous. Thus, the Court will adopt this claim construction for the phrase "the besylate salt of amlodipine," as "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt."
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5. This Court conducted a claim construction hearing as to the phrase "the besylate salt of amlodipine." The Court, thereafter, in a March 7, 2006 Order construed the phrase to mean "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt."
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h. "between about 3% and about 10% by weight of said rubber particles" Claims 1 and 8

Defendant GroundScape contends that this phrase means "no less than 3% and no more than 10%." Plaintiff Green Edge, on the other hand, maintains that the terms "about" mean "approximately," allowing said percentages to include volumes not literally within the specifically identified percentages, but those which are close. The undersigned agrees with Green Edge that the language in the claims does not limit Green Edge to a hard minimum or hard maximum. According to the Merriam-Webster Online Dictionary, the word "about" means "reasonably close to." Merriam-Webster Online Dictionary (visited May 15, 2007) <http://www.m-w.com/dictionary/about>. In this case, therefore, the Court will construe "between about 3% and about 10%" as "an amount equal to between [reasonably close to] 3% and [reasonably close to] 10%." Indeed, the patent itself mentions that "[t]he amount of colorant added to the stainless steel bucket was equal to one (1) cup or 2.5% by volume of the rubber particles." ('514 Patent, col. 5, lns. 40-42) There is no justification for using extrinsic, deposition testimony to construct these terms. Whether the amount that GroundScape uses falls within this definition is a determination for the jury.
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3. "wherein the length of HPV 52 DNA is between approximately 15 and 8000 nucleotide bases" means "between 15 and approximately 8000 nucleotide bases."

* * *

C. "Between Approximately 15 and 8000 Nucleotide Bases"

The patent refers repeatedly and consistently to the length of HPV 52 DNA as being "between approximately 15 to 8000 nucleotide bases." Ordinarily, the modifier "approximately" preceding the numbers would indicate that the applicant was claiming an HPV 52 DNA that could consist of slightly fewer than 15 bases and slightly more than 8000 bases, which is the way plaintiff reads it. E.g., Quantum Corp. v. Rodime, LLC, 65 F.3d 1577, 1581 (Fed. Cir. 1995) (term "at least approximately 600 tpi" held to define an open-ended range starting slightly below 600 tpi). Defendant contends, however,

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that the prosecution history shows that the applicant disavowed any HPV 52 DNA shorter than 15 bases. Defendant points out that throughout the extended prosecution of the patent application, whenever the examiner raised an objection to the inventor's attempt to claim a length shorter than 15 bases, the applicant assured her that "between approximately 15 and 8000 nucleotide bases" did not include a length shorter than 15 bases.

Plaintiff denies that the applicant's statements to the applicant amounted to a disavowal of a length shorter than 15 nucleotide bases. If that were true, it asks, why would the examiner have allowed the patent to issue without moving the word "approximately" to a position preceding 8000, as she had recommended in the last rejection before issuance?

Plaintiff would construe the phrase as including a range of HPV 52 DNAs shorter than 15 bases and longer than 8000 bases or, stated slightly differently, "an HPV 52 DNA of a length ranging from a relatively small hybridization probe to the length of a complete HPV genome." In support of its position, it makes a number of arguments. First, it denies defendant's assertion that the applicant clearly and unequivocally disclaimed any HPV 52 DNA shorter than 15 bases during the prosecution of the patent. Second, it cites cases in which courts have read words such as approximately or about as eliminating the precise lower limit of the range, such as Quantum Corp., 65 F.3d at 1581. Third, it notes that the applicant attached to his November 1992 proposed amendment an article by Szostak, J.W. et al., "Hybridization with Synthetic Oligonucleotides" from Methods in Enzymology, in which the authors write that "Oligonucleotides 10 to 20 bases long are potentially useful as hybridization probes for the detection of unique genes in Southern blot filter hybridization experiments and for the screening of colony or bacteriophage banks for particular sequences." FH 0227. Fourth, it asserts that one of ordinary skill in the art would understand the term to include fragments shorter than 15 bases; and finally, it cites the statement in the specification at col. 12, lns. 14-16, that "[t]he particular size of the HPV 52 DNA or HPV 52 RNA fragments which can be employed as hybridization probes in the present invention is not critical."

Taking these in order, I start with plaintiff's denial of defendant's contention that the applicant's statements on minimum fragment length during the prosecution amounted to a clear and unequivocal disclaimer of any HPT 52 DNA shorter than 15 bases. Plaintiff cites a number of cases for the proposition that ambiguous disavowals of claim scopes do not amount to prosecution disclaimer. E.g., Northern Telecom Ltd. v. Samsung Electronics Co., 215 F.3d 1281, 1293-95 (Fed. Cir. 2000) (declining to to apply doctrine of prosecution disclaimer in a case in which court found alleged disavowal of claim scope to be ambiguous; disavowing statements must be so clear as to show both "reasonable clarity and deliberateness"); Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1347 (Fed. Cir. 2001) (refusing to apply doctrine of prosecution disclaimer because alleged disclaimer in prosecution history was inconclusive); Schwing GmbH v. Putzmeister Aktiengesellschaft, 305 F3d 1318, 1324-25 (Fed. Cir. 2002) ("Prosecution history . . . cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter.").

The cited cases are on point only if the applicant's statements to the examiner were ambiguous or inconclusive. A close look at those statements in the context of the prosecution history shows that they cannot be characterized in this way. The applicant told the examiner again and again that the length was between 15 and 8000 bases, not that it was between "approximately 15 and 8000 bases." He made a point of telling the examiner that "those skilled in the art discourage the use of probes having less than 15 bases," FH 0143-44, and he never objected to the examiner's characterization of the fragments as being "at least 15 bases" when she asked, "[W]here is the support for fragments of at least 15 bases, or 300-800 bases that do not hybridize to other HPV under conditions of moderate stringency?" FH 0134. In these circumstances, the apposite cases are ones such as Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999) ("Arguments made during the prosecution of a patent application are given the same weight as claim amendments."), and Standard Oil, 774 F.2d at 452 (prosecution history includes "arguments made to convince the examiner").

Second, although it is the case that the Szostak paper disclosed the use of probes shorter than 15 bases in hybridization probes in general, the applicant made it clear throughout the extended prosecution of the patent application that his particular invention called for probes no shorter than 15 bases. His statements describe the metes and bounds of his claims. E.g., "[T]he claims similarly limit the fragments to those having a length between 15 and 8000 nucleotide bases." FH 0145-46. The public has a right to rely on these statements.

Plaintiff's third argument relates to what a person of ordinary skill would understand the term "approximately 15 bases" to mean. Plaintiff asserts that such a person would read the term as referring to fragments shorter than 15 and it has submitted the affidavit of Dr. Peter Howley to that effect. The submission is of no assistance. The affidavit is extrinsic evidence, which

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ranks below intrinsic evidence in the hierarchy of claim construction evidence. Courts do not resort to extrinsic evidence until they have determined that the intrinsic evidence is inadequate to resolve a question of construction. Even if that problem did not exist, the affidavit does not provide any information about what a person of ordinary skill would have understood the term "approximately 15 bases" to mean in the context of the '715 patent at the time the application was filed. Howley says only that in his opinion, plaintiff's proposed construction is "correct and more useful." Howley Affid., Plt.'s Exh. # 39, at 2.

Plaintiff's final point rests on the statement in the specification to the effect that the size of the fragments is not critical. This statement falls short of establishing that the fragments may be shorter than 15 bases. It can be read reasonably as saying only that the size between 15 and 8000 is not critical.
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2. "A liquid absorbing member comprising a bibulous material"

Dade Behring argues the term "bibulous" is an adjective which describes a property or function of a material. Dade Behring then suggests that the property or function of the material is to pull or draw liquid through the immunosorbing member. Biosite contends the "bibulous material" refers to a physical part of the assay device which is comprised of an absorbent, porous material which allows for the flow of solutions.

Starting with the language of the claim itself, the liquid absorbing member is said to be comprised of a "bibulous material." See Col. 2, lines 3-4. As the term "bibulous" has not been used in a special or unique way in the specification, it is interpreted according to its ordinary and customary meaning. 23 See Vitronics, 90 F.3d at 1582; Ekchian, 104 F.3d at 1303. Additionally, by adding extraneous limitations only found in the specification or prosecution history, the Court would be violating a cardinal rule of claim construction by importing limitations found only in the specification into the claim. See Electro Medical Systems, 34 F.3d at 1054 ("claims are not to be interpreted by adding limitations appearing only in the specification."); Zenith Laboratories, 19 F.3d at 1422 ("It is axiomatic that terms in the specification cannot simply be read into the claims where they do not appear.").

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23 Much has been made by both parties of the following specification language:

The important features of the assay device material are that they are able to absorb liquid, particularly aqueous solutions, without substantially impeding the movement of the solutes employed in the assay. In effect, the materials are bibulous; they are porous and allow the flow of solutions. . . .

See Col. 15, lines 16-22. The Court does not believe that the term "bibulous" is being used in a special or unique way in this passage in the sense that the patentee was attempting to be his own lexicographer or a special definition of the term is clearly stated in the patent specification or prosecution history. See Vitronics, 90 F.3d at 1582 ("Patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.") The Court therefore declines to import this specification language into the claim.

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The dictionary definition of "bibulous" is "readily taking up fluids or moisture." 24 See Webster's Dictionary at 212. No further gloss is required. Such words as "porous" or "absorbent" may or may not be equivalent. The important point is that for one reason or another, the patent applicant decided not to use these terms.

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24 The dictionary definition is consistent with the definition adopted for "liquid absorbing zone," which has been previously found to be identical to the "liquid absorbing member." As the "liquid absorbing member" is comprised of the "bibulous

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material," the adopted definition of "liquid absorbing zone" proves insightful. The specification relates that the "liquid absorbing zone" "acts as a pump to pull liquid through and out of the immunosorbing zone." Col. 4, lines 67-68; see also Col. 2, lines 32-33; Col. 3, lines 18-19; Col. 14, lines 35-37; Col. 16, lines 61-62; Col. 17, lines 1-3, 21-22.

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Accordingly, the Court construes "bibulous material" as any material which is able to readily take up fluids or moisture.
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4. "Bibulous Support Serving As An Inlet Port for Liquids Into Said Device"

On this claim construction issue, the parties dispute whether the test solution must pass through the immunosorbing zone before entering the liquid absorbing zone. Dade Behring argues that since there can be parts of the solid support to which no mips are bound, solution may pass through portions of the solid support without going through the immunosorbing zone. Biosite, on the other hand, contends the test solution must pass through the immunosorbing zone before continuing on to the liquid absorbing structure.

The Court is persuaded that the test solution must pass through the immunosorbing zone before entering the liquid absorbing zone. To properly determine the immunoassay method established in Claim 1, the Court must construe the entire following phrase:

Immunosorbing zone comprising mip non-diffusively bound to at least a portion of a bibulous support serving as an inlet port for liquids into said device.

Col. 1, lines 33-36.

The claim language grammatically intimates that the structure serving as the "inlet port" is the "bibulous support" because the verb "serving" directly modifies the "bibulous support." As it has already been determined that the "bibulous support" refers to the "immunosorbing zone," the "immunosorbing zone" serves as the "inlet port." This construction makes perfectly good sense because the test solution sample is in fact applied to the immunosorbing zone, which acts as an inlet for the device.

This interpretation is also consistent with other claims in the patent and considering Claim 1 as a whole. See Southwall, 54 F.3d at 1579; General Foods, 972 F.2d at 1274. With regard to other claims found in the '241 Patent, similar language is found in Claim 25 in which a "immunosorbing member is enclosed in an impermeable enclosure to inhibit contact with solutions except through said immunosorbing member . . . ." Col. 2, lines 8-11. Although Claim 1 concerns an "immunosorbing zone" and Claim 25 concerns a "immunosorbing member," it is clear these structures operate in a similar fashion, i.e., they both promote the binding of the analyte to a mip by concentrating the analyte in a relatively small area of the assay device. 15 Although all the test solution may not come into contact with mips in the immunosorbing zone as they are non-diffusively bound, the fact of the matter is that the immunosorbing zone acts as the inlet port for the test solution, and therefore, the test solution must enter the immunosorbing zone before coming into contact with the liquid absorbing zone, regardless of whether the analyte in the test solution actually comes into contact with individual mips. The crucial distinction is that the claim language refers to the fact that the test solution must enter the "immunosorbing zone," and does not require contact with mips non-diffusively bound therein.

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15 The Court's reasoning for construing immunosorbing zone and immunosorbing member consistently is discussed below. See infra p. 47.

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Accordingly, finding nothing in the specification and prosecution history to indicate otherwise and construing this claim

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language with reference to similar language found in Claim 25, the Court finds the structure that serves as the "inlet port" is the "immunosorbing zone," and therefore the test solution must come into contact with the immunosorbing zone before coming into contact with the liquid absorbing zone

Combining the previous two claim constructions, the Court construes the claim language "immunosorbing zone comprising mip non-diffusively bound to at least a portion of a bibulous support serving as an inlet port for liquids into said device" as covering an immunoassay method where the test solution must enter the immunosorbing zone before proceeding to the liquid absorbing zone, but not all of the solution must necessarily come into contact with mips while in the immunosorbing zone.

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D. "Natural or synthetic binder" (claims 11 and 13)

Plaintiff's proposed construction:

A substance that has the ability to bind materials together either itself or after the materials are processed.

Defendant's proposed construction:

A binder that is a natural or synthetic substance that itself exhibits adhesive/tacky/sticky properties for the purpose of adhering/holding materials together.

The parties disagree about what the "binder" disclosed in claims 11 and 13 must do. According to defendant, it must "itself" be adhesive; according to plaintiff, the binder need only have "the ability to bind materials together either by itself or after the materials are processed." At first glance, it is not clear what the parties are fighting over; both constructions would require the binder to do the job it appears designed to do: hold together the mulch. Their disagreement, however, is about whether the binder must be independently capable of doing its job.

Defendant contends that "binder" should be defined to be "itself" adhesive by pointing out that: (1) the dictionary defines a binder as "something . . . that creates uniform consistency, solidification or cohesion," The American Heritage College Dictionary 142 (4th Ed. 2004); (2) the specification refers to "a natural 'adhesive' binder" that helps maintain the integrity of the mixture, '499 pat., col. 2, lns. 62-63; (3) the specification's only examples of binders are of materials that have adhesive properties; and (4) according to defendant, the purpose of the invention is "to create a tenacious bond," id., col. 6, lns. 14-18 ("upon comminution, some seed will remain embedded within mulch, a fair percentage will be exposed but will be still attached to mulch particles, while some will be entirely set free. Such mulch products are not believed heretofore available.").

I am not persuaded that a "binder" must be independently adhesive as defendants argue. The dictionary definition suggests only that a binder must "create" cohesion, not that it be independently adhesive. A product could create cohesion by interacting with the materials to be joined. The specification does little to support the limitation that defendant requests. The fact that the specification uses only adhesive binders as examples of binders does not mean the patentee intended to exclude non-adhesive binders, particularly because there is no discussion of the independently adhesive nature of the examples listed. Moreover, the specification's reference to "adhesive" binders does not imply that all binders must be adhesive; indeed, it suggests that binders could just as well be non-adhesive (otherwise it would be redundant to use the word "adhesive" to modify "binders"). Finally, to the extent it can be said that the purpose of the invention is to "create a tenacious bond," the independent adhesiveness of the binder is irrelevant to that purpose; what matters is that the binder be capable of creating such a bond when put in the right setting. Therefore, defendant's proposed construction must be rejected.

Plaintiff's proposed construction allows for a binder doing its work "after the materials are processed." Defendant contends that the binder must do more than "have the ability" to bind, it must actually bind. This appears to be a valid point, and I am eliminating this three-word phrase from the court's construction, while keeping that portion of plaintiff's proposed construction that explains when a binder should bind: "either by itself" (which means at any time), or "after the materials are processed." If a binder does not actually bind at those times, it fails the test under this construction. The claim language does

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not appear to require more. I am accepting plaintiff's proposed construction as modified, with one additional stylistic--i.e., immaterial--change: rather than define the term "binder" by using the related term "bind," I will replace the word "bind" with the word "hold," which conveys the same idea.

Court's construction:

A substance that holds materials together either by itself or after the materials are processed.

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2. "Binder" as a means-plus-function element

Acon argues that most of its assays do not use "specific" binding proteins, proteins that bind to the target analyte and not to others, and so do not infringe. While Acon recognizes that the claims asserted by Inverness do not require a "specific" binder, it argues that the phrases "first binder for a ligand" and "second binder for capturing the ligand or the complex" are properly interpreted as means-plus-function elements under 35 U.S.C. § 112, P 6, as they do not describe structures. If these are means-plus-functions elements, in Acon's view, the phrases are entitled only to the structural scope given in the specification, which describes a "specific" binder. See Lockheed Martin Corp. v. Space Sys./Loral, Inc., 324 F.3d 1308, 1320 (Fed. Cir. 2003) ("Literal infringement of a § 112, P 6 claim requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification.").

"It is well settled that … a claim term that does not use [the word] 'means' will trigger the rebuttable presumption that § 112, P 6 does not apply." Apex, Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 1371 (Fed. Cir. 2003) (citing CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002)). "This presumption can collapse when a limitation lacking the term 'means' nonetheless relies on functional terms rather than structure or material to describe performance of the claimed function." Apex, 325 F.3d at 1372 (citing Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1257 (Fed. Cir. 1999)). "As an aid in making this determination, this court inquires into whether the 'term, as the name for the structure, has a reasonably well understood meaning in the art,' keeping in mind that a claim term 'need not call to mind a single well-defined structure' to fall within the ambit of § 112, P 6." Apex, 325 F.3d at 1372 (citing Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1583 (Fed. Cir. 1996)). "The fact that a particular claim term is defined in functional terms is not sufficient to convert a claim limitation into a 'means for performing a specified function' within the meaning of 112(6)." Apex, 325 F.3d at 1372 (citing Greenberg, 91 F.3d at 1583). To make this determination, "the record should reflect the ordinary meaning of the claim limitations, as a whole, and whether these limitations suggest sufficiently definite structure to one of ordinary skill in the art." Apex, 325 F.3d at 1374. "In this situation, it is appropriate to look to extrinsic evidence, including but not limited to dictionaries and expert testimony to assist the trier of fact in understanding the evidence." Id. (citing Greenberg, 91 F.3d at 1583).

According to Acon, "a 'binder' does not have an established meaning to one of skill in the art." (Aff. of David of 10/17/2003 at P 11.) Turning to the intrinsic evidence, Acon argues that the use of the terms "first binder" and "second binder" in the claims demonstrates the lack of structure indicated by the term "binder," as the same word refers to two different types of chemicals performing separate functions. Acon also argues that there are too many possible structures called to mind by the term "binder" to claim the invention with the particularity and distinctiveness required by 35 U.S.C. § 112(2). Finally, Acon argues against Inverness's use of a non-technical dictionary for the definition of binder (although it does not argue for a particular definition).

Noting that a means-plus-function test is limited to the structure disclosed in the specification, Acon argues that the specification describes the use of "specific" binders. "specific" binders, according to Acon, are those that have "the ability … to distinguish the analyte of interest from other substances in a sample to be assayed." (Aff. of David of 10/17/2003 at P 19.)

Certain (but not all) of Acon's products, by contrast, use binders that do not distinguish between the ligand and other substances; rather, the products use "a scavenger antibody that specifically binds to a possible interfering substance" (Aff. of David of 9/15/2003 at P 39) "to ensure that the overall assay is specific for [the desired ligand]." (Id. at P 41). "Accordingly,

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the unlabeled and/or labeled antibodies used in Acon's pregnancy, ovulation and H. pylori test kits are not specific for their respective analyte." (Aff. of David of 10/17/2003 at P 29.)

Acon has failed to overcome the presumption against means-plus-function construction in the case for a number of reasons. First, while claims 1, 2, 3 and 4 explicitly require as the immobilized binder, a "binder …. which specifically binds to the analyte" (see., e.g., '982 patent at 9:14-15 (Claim 1)), the patent claims at issue do not require any "specific" binder. Second, the technical dictionary definition of binder does not encompass a requirement of specificity. According to the McGraw-Hill Dictionary of Scientific and Technical Terms (1984), a "Binder" is: "a resin or other cementlike material used to hold particles together and provide mechanical strength or to ensure uniform consistency, solidification, or adhesion to a surface coating; typical binders are resin, glue, gum, and casein."

Third, Inverness's expert Dr. Katz states that a person of ordinary skill in the art would understand the phrase "binder for a ligand" as a structure, specifically "one or more possible structures, such as proteins or antibodies of various types, that will 'bind' with the ligand in an immunoassay which is used to detect a ligand in a liquid sample." (Decl. of Katz of 10/2/2003 at P 11.) Dr. David disagrees with Dr. Katz's opinion that a "binder for a ligand" would mean, to a person of ordinary skill in the art, anything with sufficiently definite structure. Thus, Dr. David states, "a 'binder' does not have an established meaning to one of skill in the art." (Aff. of David of 9/16/2003 at P 31; Aff. of David of 10/17/2003 at PP 10-11.)

While the structure of the binder might well vary depending on for which ligand the test was intended, the use of the term "binder" is not a function even though it might not call to mind a single well-defined structure. Using the plain meaning of the claim, the Court concludes that one of ordinary skill in the art would understand "binder" for a ligand as used in the patent to mean a composition of matter that is capable of binding to a ligand. The Court does not construe the term "binder for a ligand" to require a protein that "specifically" binds with a ligand; therefore, Acon's devices infringe regardless of whether they use specific binders.
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a. Claim Interpretation

Claim construction is a question of law for the court. Markman, 517 U.S. at 372; Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1455 (Fed. Cir. 1998). "Claim construction begins, as it must, with the words of the claims." Vehicular Techs., 141 F.3d at 1088 (citing Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619-20 (Fed. Cir. 1995)).

Here, Laporte has asserted infringement of only Claim 1 of the '505 patent. The language of Claim 1 reads as follows:

A process of dying concrete comprising mixing pigment-containing granules with cement and aggregate at conditions sufficient to result in a generally homogeneous dispersal of pigment in the concrete, wherein:

pigment-containing granules other than compacted or briquette granules are used,

each granule consisting essentially of at least one pigment selected from the group consisting of manganese oxide and iron oxide and of at least one binder for promoting the dispersal of the pigment in the concrete,

at least 90% of the granules have a particle size of about 20 microns or more, and

the finite water content of the granules is not in excess of about 4.2%.

('505 Patent, Column 7, lines 12-27).

The parties agree that for the most part, Claim 1 is straightforward and unambiguous. The only disputed term is the requirement that each granule include "at least one binder for promoting the dispersal of the pigment in concrete." There is no dispute regarding the meaning of the term "binder" itself. It is a substance used to bind a minute quantity of pigment in granular form. Several examples of commercially available binders are listed in the '505 patent specification. See Col.3, lns.

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Claim 1's language specifies that the binder must serve to promote dispersal of the pigment in concrete. Claim 1 further specifies that not just any type of pigment dispersal is desired, but rather "homogeneous dispersal." See Col. 7, lns. 14-15. As the '505 patent specification explains, one of the problems of prior art granules is that they cause "spots" and "color nests." See Col. 2, lns. 27-31. These terms refer to clumps of pigment that mar the surface of the concrete when pigment is not evenly distributed. The '505 patent specification explains that by using its method, "[the pigment] will become homogeneously distributed in the concrete so that exposed concrete will be dyed satisfactorily without a formation of spots and color nests." See Col. 3, lns. 5-7. Accordingly, Claim 1 must be read to require a binder that promotes the homogeneous dispersal of the pigment in concrete.

A primary dispute between the parties is whether Claim 1 specifies a particular mechanism for promoting homogeneous dispersal. Laporte argues that a binder that promotes homogeneous dispersal of pigment by any method falls within Claim 1's scope. Axel, however, urges a more narrow reading, contending that Claim 1 requires a water-soluble binder. Plainly, there is no water-solubility requirement expressly stated in Claim 1. 2 Relying upon the '505 patent specification and the prosecution history, Axel argues that this limitation must be read into the Claim. The Court will first address Axel's argument regarding the '505 patent specification.

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2 Interpreting Claim 1 requires the court to give the terms in the claim their ordinary and accustomed meaning. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999) (citing Renishaw PLC v. Marposs Societa per Azioni, 158 F.3d 1243 (Fed. Cir. 1998); York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996)). "General descriptive terms will ordinarily be given their full meaning; modifiers will not be added to broad terms standing alone." Id. (citing Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 865-66 (Fed. Cir. 1997) (unmodified term "reciprocating" not limited to linear reciprocation); Bell Communications Research, Inc., 55 F.3d at 621-22 (unmodified term "associating" not limited to explicit association); Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988) (unmodified term "plasticizer" given full range of ordinary and accustomed meaning).

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Axel's expert, Dr. Carmel Jolicoeur, opined that the '505 patent specification identified water-solubility of the granule binder as a mechanism for promoting homogeneous dispersal of pigment in concrete. When the binder dissolves in the water contained in the concrete mix, he explains, pigment is released into the surrounding concrete, resulting in homogeneous pigmentation. Dr. Jolicoeur also notes that all of the examples of binders set forth in the specification are water-soluble. Because water-solubility of the binder is a mechanism for promoting homogeneous dispersal of the pigment, and all of the binders described in the specification are water-soluble, Dr. Jolicoeur testified that a person of ordinary skill in the art would understand the '505 patent to require a water-soluble binder.

Laporte responds that there is no language in Claim 1, or in the specification, limiting the invention to water-soluble binders. Further, Laporte argues that Dr. Jolicoeur is in error in contending that all of the example binders in the '505 patent specification are water-soluble. Dr. Stoffer, Laporte's expert, testified that Igepal type materials are sometimes water-insoluble. See Hearing Tr. at 106, ln. 1-p. 107, ln. 6. Igepal C is one of the binders listed in the '505 patent. See Col. 3, ln. 37.

The Court concludes that Laporte has the better argument on this issue, in part because the specifications indicate more than one mechanism for the binders to homogeneously disperse the pigment. The '505 specification notes that one of the main disadvantages of prior art granules was that because they were too strongly bound together, the pigment was not homogeneously dispersed: "during the mixing cycle the shear forces exerted in the concrete on the granules are not sufficient for dispersion of the pigment." See Col. 2, lns. 27-29. It is thus clear that to homogeneously disperse pigment, the binder must surrender the pigment at some point during the mixing process.

It appears that the '505 patent specification identifies at least two mechanisms for breaking down the binder and surrendering the pigment. First, as noted above, shear forces exerted on the granules during mixing serve to disperse the pigment, albeit in the prior art granules, the dispersal is inadequate. See '505 patent, Col. 2, lns. 27-29; see also Jolicoeur

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Decl., III(D)(3) (recognizing that shear forces are one mechanism of dispersal discussed in the '505 patent). Thus, the more susceptible to shear forces a binder is, the better able it is to promote dispersal. Second, the specification describes a problem with prior art granules as follows: "the moisture content of the concrete and the time available are not sufficient for a dissolving of binder-containing granules." See '505 patent, Col. 2, lns. 42-44. Thus, the specification contemplates that moisture-solubility of the binder in concrete mix is another mechanism to surrender the pigment and promote pigment dispersal. 3

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3 Based on the record before the Court, there appears to be a distinction between water-solubility and moisture-solubility in concrete mix. As both parties' experts testified, while pure water has a pH of seven, the ingredients combined with water in concrete mix lower the pH to between 12 and 13. Thus, substances that might not be soluble in pure water are soluble in the extremely basic environment of the concrete mix. The specification only uses the term "moisture," not "water," in discussing solubility of the binder.

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As previously noted, Claim 1's language contains no water-solubility limitation on the binder. Although the '505 patent specification explains that moisture-solubility is one mechanism of dispersing pigment, there is no indication there that even this mechanism is required. For example, it appears that a binder that promotes homogeneous dispersal of pigments by being more susceptible to breakdown by shear forces than prior art granules would fall within Claim 1. Accordingly, because multiple mechanisms are disclosed in the specification for promoting homogeneous dispersal of pigments, with no indication that any particular mechanism is required, the specification cannot be read to limit Claim 1 to a water-soluble binder.

The Court also finds Axel's arguments regarding the example-binders in the '505 patent specification unpersuasive. As previously noted, Laporte's expert testified that at least one of the example binders, Igepal C, can be water-insoluble, depending on the formulation used. Axel did not rebut this contention. Further, even if all of the example-binders were water-soluble, the Court does not believe that fact alone would limit Claim 1 to a water-soluble binder. A binder that takes advantage of both shear forces and moisture solubility to promote dispersal may be the "best mode" of practicing the invention in the '505 patent. Inventors are statutorily required to disclose in the patent specification the best mode they know of practicing their invention. See 35 U.S.C. § 112. Accordingly, one should not be surprised to find example-binders that could utilize both mechanisms of dispersal. The Federal Circuit has repeatedly made it clear, however, that "references to a preferred embodiment, such as those often present in a specification, are not claim limitations." Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301-02 (Fed. Cir. 1999) (quoting Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988), cert. denied, 490 U.S. 1068, 104 L. Ed. 2d 634, 109 S. Ct. 2069 (1989)); SRI Int'l. v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc); Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994) (quoting Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)). Thus, even if all of the example-binders utilize both shear force susceptibility and moisture-solubility to promote pigment dispersal, that does not mean that Claim 1 requires that its binder be water-soluble.

Finally, Axel notes the following language in the specification: "it has surprisingly been found that the granules mentioned above are effectively dissolved in the concrete mixer." Axel argues that the word "dissolved" indicates water-solubility. The Court believes that this reading is unduly narrow. Dissolve can mean "to cause to pass into solution (dissolve instant coffee in water)," as Axel suggests. See Webster's II New College Dictionary 330 (1995). It can also mean "to cause to disappear (dispel)," "to separate into component parts (disintegrate)," or "to bring to an end by or as if by breaking up (terminate)." Id. All of these latter definitions are consistent with the rending apart of the binder by shear forces, a mechanism for promoting pigment dispersal discussed in the specification. Thus, the specification's discussion of the binder being "dissolved" does not limit Claim 1 to a water-soluble binder.

Axel also argues that the prosecution history limits Claim 1 to a water-soluble binder. "The prosecution history gives insight into what the applicant originally claimed as the invention, and often what the applicant gave up in order to meet the Examiner's objections." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978 (Fed. Cir. 1999), cert. denied, 529 U.S. 1066, 120 S. Ct. 1672, 146 L. Ed. 2d 482 (2000) (quoting Lemelson v. General Mills, Inc., 968 F.2d 1202, 1206 (Fed. Cir. 1992)); see also Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) ("The prosecution history (or file

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wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.").

Two of Axel's prosecution history arguments suffer from the same narrow interpretation of the word "dissolve" Axel urged in reading the '505 patent specification. During the '505 patent prosecution history, the applicant overcame rejections raised by the Examiner based on Japanese patent 149224 ("Japanese patent") and United States Patent No. 4,336,546 ("Edwards patent"). In both instances, the applicant argued that the '505 patent granules more readily dissolved than the granules described in the Japanese patent and Edwards patent, and thus produced homogeneous dispersal of pigment. As previously discussed, dissolve here can mean that the granule binder is moisture-soluble, or that it is susceptible to being broken down by shear forces, or both. The '505 patent applicant's focus on the ease with which the binder "dissolves" cannot be interpreted as a representation to the Examiner that the '505 patent binder must be water or even moisture soluble.

Axel also relies on a rejection raised by the Examiner concerning United States Patent 4,366,139 ("Kuhner patent"). The '505 patent applicant distinguished the Kuhner patent, stating, "in general, Kuhner deals with the problem of hydrophobic [water insoluble] carbon black as a color pigment. With the hydrophilic [water soluble] color pigments of the present invention, e.g., manganese oxide and iron oxide, this problem does not occur at all." (original emphasis). While water-solubility was clearly at issue, it is equally clear that the focus was on the water-solubility of the respective pigments, not the binders. There is no suggestion that this representation to the Examiner limits the '505 patent to a water-soluble binder, or indeed, concerns the binder whatsoever.

Axel's final argument relies on Dr. Jungk's declaration that when he explained the invention underlying the '505 patent to the patent attorneys who drafted it, he informed them that a water-soluble binder was a necessary element of the invention. Although he was present, Dr. Jungk did not testify at the hearing. Further, given Dr. Jungk's personal interest in this litigation, and the fact that this alleged limitation is expressed nowhere in the patent or file history, his declaration is not persuasive. As, the Federal Circuit has made clear, "the inventor's subjective intent as to claim scope, when unexpressed in the patent documents," has no effect on claim construction, and should be disregarded. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996). The Court thus accords no weight to Dr. Jungk's declaration.

In summary, Claim 1 requires at least one binder for promoting the homogeneous dispersal of the pigment in the concrete. The '505 patent specification recognizes at least two types of binder mechanisms for promoting homogeneous dispersal. One is moisture-solubility of the binder. Another is susceptibility of the binder to breakdown by shear forces. There is no indication in Claim 1, the '505 patent specification, or in the prosecution history, that water-solubility of the binder is required. Accordingly, the Court finds that a granule that utilizes a binder that promotes homogeneous pigment dispersal either by moisture-solubility, being more susceptible to shear forces than prior art granules, or both, and otherwise satisfies Claim 1's elements, literally infringes the '505 patent.
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On appeal, Axel argues that the court improperly construed the term "binder" as requiring that it be more susceptible to shear forces than prior art granules, asserting that the specification does not support that interpretation and that a binder's susceptibility to shear is not necessarily related to its ability to promote dispersal. Axel asserts that, under a proper interpretation of the claim, the NeoCryl and K-702 granules do not infringe the '505 patent because they do not promote dispersal of the pigment. Alternatively, Axel argues noninfringement on the ground that the term "binder" should be construed according to 35 U.S.C. § 112, P 6, because it is defined by its binding function, and that a broader construction of the term "binder" that is not limited to the specific embodiments in the specification would be invalid for indefiniteness or lack of enablement. Axel also contends that use of the K-702 granules does not infringe the patent because they contain hydraulic material that was specifically disclaimed during prosecution. Finally, Axel argues that the court erred in denying its motion for judgment as a matter of law that Dr. Jungk is not liable for inducing infringement in his individual capacity.

Laporte responds that the court properly interpreted a "binder" as a material that holds the pigment in granular form and then releases it either for chemical reasons relating to its moisture solubility or for mechanical reasons relating to its susceptibility to shear forces. Laporte asserts that substantial evidence supports the jury's verdict that both the NeoCryl and K-702 granules are "binders" under that construction of that term. Moreover, Laporte argues that § 112, P6, does not apply to the "binder" limitation because the claim does not recite any "means" and because the term "binder" denotes a material,

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and that Axel's allegations that a broader interpretation would be invalid are precluded by the doctrine of assignor estoppel. Laporte also responds that Dr. Jungk waived the issue of his individual liability by not raising it in his motion for a directed verdict at the close of all the evidence.

In the exercise of our plenary review of the court's claim construction, we disagree with the district court's limited interpretation of the term "binder" as being either moisture-soluble or more susceptible to shear forces than prior art granules. To the extent the court erred by interpreting the claim too narrowly, however, that error was harmless. The jury determined that Axel infringed the '505 patent even under the court's restricted interpretation and thus a fortiori would have arrived at the same conclusion under our broader construction.

To begin, we look to the ordinary meaning of the claim, which is directed to "at least one binder for promoting the dispersal of the pigment in the concrete." '505 patent, col. 7, ll. 21-23. Nothing in the claim limits the term "binder" to materials that are either moisture-soluble or more susceptible to shear forces than prior art granules. The specification sets forth a significant number of appropriate materials that are exemplary of the claimed binders, but does not restrict the meaning of that term to those materials. Id. at col. 3, ll. 27-51.

The specification also discusses problems found with certain prior art granules used for dyeing concrete. In particular, it points out that the shear forces exerted during mixing have been insufficient to disperse those granules, id. at col. 2, ll. 27-29, and that the moisture content of the concrete and the time available for mixing were not always sufficient to dissolve binder-containing pigment granules, id. at col. 2, ll. 42-44. Those statements concerning the properties of prior art granules apparently prompted the district court to construe the term "binder" as having properties different from binders used in the prior art. We disagree with that interpretation. The specification does not limit the term "binder" to exclude disadvantageous prior art granules, as a binder is but one of the components of the pigment granules used in the prior art. See, e.g., '505 patent, col. 7, ll. 19-23. The disadvantages of prior art granules or processes are not limitations on properties of the binders, which are defined in the claim only as having to promote the dispersal of the pigment in the concrete. Other components of the granules may contribute to the results of processes described in the prior art. Moreover, the claimed process for dyeing concrete has a number of other limitations not at issue on appeal that may be responsible for the alleged superior performance of the granules of the present process over the prior art. We therefore conclude that the specification does not compel the district court's construction of the claim term "binder."

We agree with the district court, however, that other intrinsic evidence does limit the proper interpretation of the term "binder." During prosecution, the examiner rejected the claims over a prior art reference that disclosed the use of cement or hydraulic (water-reactive) material as a binder. In response, the applicant amended the claim to add the language "consisting essentially of," which, the examiner explained in the notice of allowability, "eliminates the possibility of hydraulic material in the pigment-containing granule." Id. We therefore construe a "binder" as a material that promotes dispersal of the pigment in the concrete, subject to the express disavowal during prosecution that it not contain hydraulic material. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").

We are not persuaded by Axel's arguments that the term "binder" should be construed according to 35 U.S.C. § 112, P 6. The absence of the term "means" in the claim creates a presumption that § 112, P6, does not apply. Micro Chem., Inc. v. Great Plains Chem. Co., 194 F.3d 1250, 1257, 52 U.S.P.Q.2D (BNA) 1258, 1263 (Fed. Cir. 1999). Moreover, the term "binder" describes a material, as shown by the numerous suitable binder materials listed in the '505 patent specification at col. 3, ll. 33-51, that connotes structure to those skilled in the art. Consequently, the presumption against application of § 112, P 6 has not been overcome.

We are also not persuaded by Axel's arguments that the term "binder" must be construed narrowly in order to preserve the validity of claim 1. The clear language of the claim and the intrinsic evidence support a broad interpretation of that term and we therefore accord the term "binder" its full breadth, even if invalidity issues could be raised as a result of that broad construction. See Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1372, 61 U.S.P.Q.2D (BNA) 1647, 1658 (Fed. Cir. 2002) ("Where claim language is clear we must accord it full breadth even if the result is a claim that is clearly invalid.") (citations omitted). In any event, we cannot consider the validity of the claim, as Axel is estopped from asserting the invalidity of the patent that Dr. Jungk previously assigned to Brockhues. See Diamond Scientific v. Ambico, Inc., 848 F.2d 1220, 1224, 6 U.S.P.Q.2D (BNA) 2028, 2030 (Fed. Cir. 1988) ("Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or a patent application) from later contending

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that what was assigned is a nullity.").
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7. "Binding component comprising multivalent metal ions associated therewith"

The '141 patent contains several dependent claims specifying that the embodiment of the polyionic component is made up of a large molecule and associated metal ions. The patents explain that the metal ions have a "relatively high affinity for oxygen, nitrogen, and sulfur groups. As a result, they can impart a significant binding affinity to a large molecule (as a polyion) towards, e.g., phosphate groups . . . or phosphorylated substrates and the like." ('141 Patent at 14:46-51.)

Caliper proposes that the term "binding component comprising multivalent metal ions" be construed as: "a polycationic component that includes but is not limited to metallic ions, which are metal atoms or groups of atoms, bearing multiple electrical charges." Caliper further proposes that the term "multivalent metal cations" be construed as: "multivalent metal ions having more than one positive charge." Lastly, Caliper urges the Court to adopt its construction of the term "binding component comprising multivalent metal ions associated therewith" to mean "a compound that includes but is not limited to multivalent metal ions, is of sufficient size to cause a change in the level of fluorescence polarization upon its association with the fluorescently labeled phosphorylated product, and binds to the fluorescently labeled phosphorylated product in a non-specific, charge dependent manner. The binding component may include, inter alia, large molecules having associated therewith multivalent metal ions that have a relatively high affinity for oxygen, nitrogen, and sulfur groups and as a result impart a significant binding affinity to a large molecule towards, for example, phosphate groups in nucleic acids."

MDC proposes that the term "binding component comprising multivalent metal ions associated therewith" be construed to mean: "a polyionic polymer that includes but is not limited to multivalent metal ions, is of sufficient size to cause a change in the level of fluorescence polarization upon its 13 association with the fluorescently labeled phosphorylated product, and binds to the fluorescently labeled phosphorylated product in a non-specific, charge dependent manner. MDC further contends that "multivalent metal ions" are "metal ions that must include one of the following: Fe<3+> (iron having 3 positive charges), Ca<2+> (calcium having 2 positive charges), Ni<2+> (nickel having 2 positive charges), and Zn<2+> (zinc having 2 positive charges)."

The central remaining dispute between the parties regarding this term is whether the multivalent metal ions must include one of the listed metal ions, or whether the patent claims other possible metal ions, and the list is not exclusive. The claim language does not specifically limit the range of possible metal ions to those listed in the specifications. Further, the specification states that "the polyionic component may alternatively comprise a large molecule, e.g., a protein or the like, that has associated therewith multivalent metal cations selected from, e.g., Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+>." ('141 Patent at 14:41-44.) With the use of the "e.g." the specification sets out the list of possible metal ions as a non-exhaustive list. In addition, Claim 11 of the '141 patent expressly limits the expression of "multivalent metal ions" of Claim 10. Claim 10 covers the "method of [the earlier claim] wherein the polycationic component comprises multivalent metal ions." ('141 Patent at 37:60-61.) Claim 11 covers the "method of [the earlier claim] wherein the multivalent metal ions are selected from the group consisting of Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+>." ('141 Patent at 37:62-64.) Clearly, the inventor intended to claim a broader range of potential metal ions in Claim 10, and specifically limited the range of possible metal ions in Claim 11. Lastly, MDC's contention that the inventor was not successful in his efforts to use even the metal ions listed in the patent is unpersuasive. (MDC Opp. Br. at 23.) An inventor need not ever practice his invention and need not specifically identify each and every embodiment of his invention in the specification. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 62, 119 S. Ct. 304, 142 L. Ed. 2d 261 (1998); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997) (holding that construction limiting term to examples listed in the specification was erroneous). Therefore, the construction of "multivalent metal ions" should not be necessarily limited to a selection of the examples listed in the specification.

Accordingly, the Court adopts the construction of the term "binding component comprising multivalent metal ions associated therewith" to mean: a polycationic component that includes but is not limited to metallic ions, which are metal atoms or groups of atoms, bearing multiple electrical charges, and that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Further, the metallic ions are not limited to the non-exclusive list of Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+>, but may include other metal atoms or groups of atoms bearing multiple electrical charges.

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B. "Binds"

The parties also dispute the meaning of the term "binds" as it is used in the patent claims. See e.g. '561 Patent, Claims 1, 9 ("A monoclonal antibody that binds to a human breast cancer antigen ...");'561 Patent, Claim 19 ("A monoclonal antibody that binds to human c-erbB-2 antigen)(emphasis added).

The term "bind" has a specific meaning to those skilled in the art of microbiology. As previously discussed, the antigen binding sites on an antibody are custom-tailored to attach or "bind" to a specific receptor site on the antigen, much the way a lock and key fit together. However, sometimes an antibody will randomly and weakly attach at a site other than the specific one recognized. Both parties agree that the term "binds" as used in the patent does not refer to this random, background binding; it would make little sense for Chiron to patent an antibody that bound at random to human breast cancer cells. Thus, the parties agree that one skilled in the art in 1984 and 1985 would interpret the term "bind" to mean the attachment between an antibody and antigen that occurs at the specific antigen-binding site.

The parties' agreement ends there. Genentech contends that the term should be construed to mean a degree of attachment greater than background levels, while Chiron argues that the term should be construed more narrowly to refer to a degree of attachment that is immunologically significant given the purposes of the invention.

The specification does not define the term "binds," but "immunological binding" is defined as "the non-covalent interactions of the type which occur between an immunoglobulin molecule and an antigen for which the immunoglobulin is specific." This definition suggests that specificity is an important aspect of binding, but nothing more. Thus, on its face, it is consistent with Genentech's interpretation of the term binds.

However, a reading of the patent as a whole reveals that the term "binds" as used in the claims has a more precise meaning. Claim terms should be construed in accordance with the purposes of the claimed invention. See Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243 at 1251 (Fed. Cir. 1998); CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1160 (Fed. Cir. 1997). In addition, where alternative interpretations exist, the court should not construe the patent in a way that would render it useless. Process Control Corp. v. Hydreclaim Corp., 190 F.3d 1350, 1356 (Fed. Cir. 1999).

In this case, the invention claimed in the '561 patent relates to antibodies that are "useful in specific binding assays, affinity purification schemes, drug or toxin targeting, imaging, and genetic or immunological therapeutics for various cancers ...." '561 Patent, 1:27-31. For these uses, it is important that the antibody does more than just specifically bind to the antigen of interest. Sometimes, antigens that are present in high numbers on cancer cells are also present in lower numbers on normal, healthy cells. Thus, if an antibody used for cancer diagnosis attaches to normal tissue in addition to cancer cells, it will give false positives. Similarly, an antibody used for therapy that is incapable of distinguishing between normal and cancerous tissue can have fatal effects. In cancer treatment, toxins are attached to the antibodies so that when the antibodies bind with cancer cells, the toxin kills that cell. If the antibodies also attaches to healthy cells, it can kill the healthy cells.

Accordingly, the patent states that "it is desirable to target malignant lesions while avoiding normal tissue." Id. 1: 67-4. The ability of an antibody to target a specific type of cell or tissue to the exclusion of others is called "selectivity." As is evident from the stated purposes of the invention, selectivity in binding is an important aspect of the claimed invention.

"Affinity," or strength of binding, is also an important aspect of the invention. An antibody that binds weakly to an antigen will not be particularly useful in therapy or diagnosis. Thus, the specification begins by stating that "it is an object of the invention to provide novel compositions that are derived from the antigen-biding sites of immunoglobulins having affinity for cancer antigens." ('561 Patent Col 3:30-33)(emphasis added).

The methods described in the specification for making the invention confirm that the inventors were concerned with isolating antibodies with specificity, affinity, and selectivity for breast cancer antigens. See '561 Patent, 15:34-45 ("monoclonal antibodies capable of binding specifically to a human tumor antigen ... were produced ...."); id. at 16:43-45 ("Wells that gave a reaction on the breast cancer membrane extract of greater than 0.7 O.D. were saved."); id. at 16:63

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("Hybridoma wells showing strong fluorescent binding to breast cancer cells but no fluorescent binding to fibroblasts were saved."); id. at 17:38-42 ("Antibodies were deemed to bind selectively to breast cancer if they bound strongly to less than about 1/3 of the normal tissues and blood cell types"); id. at 18:31 (describing how the inventors ran the isolated antibodies through a series of immunoassays n21 to "evaluate their selectivity for breast cancer"); id. at 25:35-45 (describing tests to termine the "affinity constant," which measures the affinity of binding). Reading the patent as a whole, one skilled in the art would understand the term "binds" to mean a degree of attachment that is immunologically significant in the context of the uses for the monoclonal antibody described in the patent. n22

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n21 The term "immunoassay" as used in the patent is construed below.

n22 Genentech argues that the court should construe the term to mean binding that is greater than background binding because Chiron's expert, Dr. Lanier, testified that "immunologically relevant" binding refers to binding that is "greater than background binding." First, it is unnecessary for the court to rely on extrinsic evidence in the form of expert testimony to construe the term. Second, Genentech ignores other statements by Dr. Lanier that indicate more than mere specificity is required for immunologically relevant binding. See Transcript of Proceedings, Vol. 2, at 17 ("Q: is a certain level of affinity required for what you referred to earlier as immunologically relevant binding? A: Yeah. In fact .. you want something which binds much stronger in order to have good resolution powers for selectivity and specificity.") Third, the term "specificity" as used by Dr. Lanier incorporates the idea of affinity: ("Q: Could you explain what [specificity] means? A: Specificity comes back to this lock and key idea where ... the antibody specifically binds quite firmly and specifically to its particular antigen.") (emphasis added).

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Therefore, the court adopts the following construction of "binds":
The term "binds" refers to a degree of attachment that is immunologically significant, i.e. a degree of attachment that is (1) above background levels; (2) specific; (3) selective for cancer as opposed to normal cells and/or tissues; and (4) has a useful degree of affinity.

This definition departs slightly from the construction recommended by Magistrate Judge Hollows. He proposed that "except where the context of 'binding expressly indicates a phenomenon of isolated, random attachment, "binds" refers to a degree of attachment that is immunologically significant in the context of the uses for the monoclonal antibodies described in the patent." (F & R's at 39-40.) In an effort to promote clarity, the court's construction defines what is meant by "immunologically significant," something that the proposed construction does not do. In addition, the court's construction omits the first phrase of the proposed definition, which is unnecessary and may be confusing. The question is not how the term is used elsewhere in the patent specification, but how it is used in the terms of the claims. Although the specification sometimes uses "binds" to refer to background binding, the claims universally use "binds" in the sense of immunologically significant binding. See Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1311 (Fed. Cir. 1999) ("In circumstances such as this, where the language of the written description is sufficient to put a reader on notice of the different uses of a term ... it is appropriate to depart from the normal rule of construing seemingly identical terms in the same manner. This entirely accords with the public notice function of claims.").
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D. "binds to a neutralizing epitope of human TNF-[alpha] in vivo with an affinity of at least 1 x 10&t;8&t; liter/mole, measured as an association constant (Ka), as determined by Scatchard analysis"

Claim term, phrase or clause	Centocor's Proposed Construction
"binds to a neutralizing epitope of human TNF-[alpha] in vivo with an affinity of at least 1 x 108 liter/mole,	"Results in a loss of biological activity when it binds to human TNF-[alpha] in vivo; and associates (binds) with human TNF-[alpha] with an

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measured as an association constant (Ka), as determined by Scatchard analysis"	affinity of at least 1 x 10&t;8&t; liter/mole as calculated using a method for data analysis known as a Scatchard analysis"

Claim term, phrase or clause	Defendants' Proposed Construction
"binds to a neutralizing epitope of human TNF-[alpha] in vivo with an affinity of at least 1 x 108 liter/mole, measured as an association constant (Ka), as determined by Scatchard analysis"	"Binding of the anti-TNF [alpha] antibody is to a 'neutralizing epitope' if binding results in a loss of biological activity associated with the human TNF [alpha], and further binds to the epitope in the organism with an affinity of at least Ka=1x10&t;8&t; liter/mole as measured in the living organism using Scatchard Analysis."

Within the '775 patent, the above phrase appears in independent claims 1 and 13 and dependent claims 4, 5, and 6.

In construing the above phrase, the parties dispute whether the claim requires the affinity to be tested in vitro or in vivo. Affinity, in the context of the patent, can generally be described as the measure of the strength of the interaction between an antibody and an antigen. One of the embodiments describes determining the affinity of an antibody for an antigen involving, for example, radioactive labeling of an antibody and subsequent calculation of an affinity constant, all conducted in vitro. '775 Patent, col. 49, ll. 5-21; see '775 Patent, col. 7, ll. 21-25; Figs. 10A, 10B. The defendants seek to literally interpret the claim language and require the analysis to be conducted in vivo. The portions of the specification that the defendants cite do not support such a literal construction; each portion discusses the neutralizing or inhibition effect of the anti-TNF-[alpha] antibody, not the affinity analysis. See col. 6, ll. 5-10; col. 13, ll. 21-26; col. 36, l. 65-col. 37, l. 5. Although a construction that would render the claim nonsensical may be appropriate in certain circumstances,] in this case, the claim is susceptible to a reasonable construction. See Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fe. Cir. 2004). It is well known in the art that such analysis is conducted in vitro, and that the data correlates with the affinity in vivo. 9

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9 Scatchard analysis often involves labeling an antibody with radioactive material.

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For these reasons, the court adopts the plaintiffs' proposed construction.

The court defines "binds to a neutralizing epitope of human TNF-[alpha] in vivo with an affinity of at least 1 x 108 liter/mole, measured as an association constant (Ka), as determined by Scatchard analysis" as "results in a loss of biological activity when it binds to human TNF-[alpha] in vivo; and associates (binds) with human TNF-[alpha] with an affinity of at least 1 x 10&t;8&t; liter/mole as calculated using a method for data analysis known as a Scatchard analysis."
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The term "bioavailability" in the context of the '718 patent means the total exposure of the erythromycin derivative in the bloodstream as measured by the logarithm-transformed area under the plasma concentration-time curve ("AUC"), which is a mathematical and visual representation of the aggregate amount of the drug reaching systemic circulation over a given period of time. Bioavailabilty does not encompass both the rate and effect of release because extended release and immediate release formulations have different rates of release by definition. That is also why the claim calls for a lower mean fluctuation index for the extended release formulation versus the immediate release formulation- to highlight the importance of changing the rate of release without changing the overall amount of erythromycin derivative in the plasma. Both parties agree that in claim 1, the term "substantially equivalent to that of the immediate release composition" means the extended release composition AUC values must be between 80% to 125% within a 90% confidence level as compared to

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the immediate release composition AUC values.
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B. Bioavailability

Aventis and Amphastar request construction of the phrase "bioavailability greater than heapann" which appears in claims 1, 31, and 32 of the 618 patent. Aventis contends that the term "bioavailability" should be given its ordinary meaning to those skilled in the art. It asserts that the ordinary meaning of bioavailability is "a percentage, based on subcutaneous ("S C ") anti-Xa activity over time divided by intravenous ("I V ") anti-Xa activity over time," greater than heparin Amphastar contends that the term is indefinite under Section 112 of Title 35 of the United States Code.

Generally, "bioavailibility" is defined as "the degree to which or rate at which a drug or other substance is absorbed or becomes available at the site of physiological activity after administration." American Heritage Dictionary (4th ed 2000), see also Merriam-Webster Medical Dictionary (2002) (defining bioavailability as the degree and rate at which a substance is absorbed into a living system or is made available at the site of physiological activity). As evidenced by the general definition of bioavailability which uses rates and degrees and as indicated by both parties' briefs, "bioavailability" needs to be construed because it must be measured in relation to some other activity. In the case of heparin, it is measured in relation to a biological activity. Thus, because the meaning of "bioavailability" is not conspicuous from the 618's claim language, the court will consider the specification. "For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims" Markman, 52 F 3d at 979-80, see also Bell Atl Network Servs. Inc v Covad Communs Group, Inc, 262 F 3d 1258, 1268 (Fed Cir 2001) (stating that the specification may define claim terms "by implication" such that the meaning may be "found in or ascertained by a reading of the patent documents").

The reference to bioavailability in the 618 patent specification is in the "Summary of the Invention" section. It states, "[I]n humans, the mixtures of the invention display excellent bioavailability, as measured by the anti-Xa activity. Thus, this value is approximately 30 IU for heparin, but is approximately 90 IU for the mixtures of this invention." 618 patent, cols 2-3. The first sentence of this reference supports Aventis' construction. It specifically refers to anti-Xa activity. However, the second sentence frustrates Aventis' construction because it quantifies bioavailability for hepann as "30 IU" and for the 618 patent as "90 IU." "IU" is an abbreviation for international unit. An international unit is an amount of a substance that produces a specific effect as defined by an international body. See. e g, Webster's II New Riverside Dictionary (1994), see also, American Heritage Dictionary (4th ed 2000) (defining IU as the "quantity of a biologically active substance, such as a hormone or vitamin, required to produce a specific response"). This is a barrier to Aventis' construction because Aventis argues that "bioavailability" should be construed as a percentage, however, the specification describes the value of bioavailability in its specification in IUs.

Aventis advances that the patent specification was mistakenly altered during prosecution. As a result of this mistake, Aventis claims the specification contained the reported anti-Xa values expressed in IUs Aventis argues that this error is "readily apparent" because hepann's anti-Xa activity per se was widely known to be around 160 to 180IU, about six times more than the 30IU figure described in the specification.

Aventis cites Biotec Biologische Naturverpackungen GmbH v Biocorp, Inc, 249 F 3d 1341 (Fed Cir 2001), for the proposition that errors apparent to those skilled in the art should not alter the ordinary meaning of claims In Biotec, the Federal Circuit stated that a court may ignore an error made by an attorney during patent prosecution if "a person of reasonable intelligence would not be misled into relying on [the] erroneous statement." Id. at 1348. However, the Biotec court also noted that in the case before it, the error was clear because "the statement was contrary to the plain language of the claims and specification as well as other statements in the same document." Id.

The court concludes that applying Biotec to Aventis' proposed construction goes beyond the limits set by Biotec. First, unlike Biotec, the error extends beyond a single statement in the prosecution history. See id. (characterizing the mistake as "an isolated statement and manifestly contradicted by the rest of the prosecution history "). Both the prosecuting patent attorney and PTO examiner, presumably individuals of "reasonable intelligence", agreed on the IU term of measurement. The patent examiner objected to the specification because it "[F]ail[ed] to adequately define the manner of describing anti-Xa activity by employing a percentage." In response, the prosecuting attorney seems to have agreed and explicitly requested

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that the PTO "change 30%' to -- 30 IU -- and 90%' tp -- 90IU-" The "IU" term then goes from the prosecution history directly into the specification of the 618 patent. Finally, the IU term is not self-evidently contrary to the plain language of the claim because, as described above, at least with reference to which biological activity, the plain language of the claim requires interpretation at least to the extent of defining the biological activity used to measure bioavailabihty.

Aventis also argues Novo Indus, L P v Micro Molds Corp, 350 F 3d 1348 (Fed Cir 2003), supports its argument that the court can correct its error. In Novo, the Federal Circuit held that "a district court can act to correct an error in a patent by interpretation of the patent where no certificate of correction has been issued only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims" Id. at 1354. Notwithstanding the first part of the Novo test, the second part precludes its application. As discussed above, the prosecution history explicitly advances an interpretation in international units. Thus, the prosecution history does suggest an interpretation different than what Aventis proposes. This precludes application of Novo.

The court refuses to correct the purported error in the 618 patent and to adopt Aventis' construction of "bioavailability." The term "bioavailability" has various meanings. The specification refers to bioavailability in terms of international units. The patent history shows the patent examiner objected to percentages because of its lack of definition. As a result, the prosecuting patent attorney apparently agreed and affirmatively adopted international units. With respect to the reissue proceeding, the court is not persuaded that the reissue examiner's silence is sufficient to overcome the intrinsic evidence of the patent. Thus, the court concludes the term bioavailability is indefinite. n2

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n2 The court wants to make clear that this conclusion pertains only to the word "bioavailability" and only to claim construction. It does not imply indefiniteness or invalidity with respect to any claim as a whole or to any other part of the 618 patent.

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a. "Biodegradable"

Both Claims 3 and 10 identify a "biodegradable material" that encapsulates a line of elements. The specification provides examples of biodegradable materials with respect to spacers and plugs, such as processed collagen (catgut), Nylon or various other organic substances. ('760 Patent col. 3, ll. 58-59 and col. 4, ll. 2-7.) The World Wide Plaintiffs suggest the following construction: "While inside the human body, the material decays over time by a specific mechanism and eventually eliminated." AnazaoHealth suggests "capable of being broken down by the action of microorganisms."

The Medical Dictionary defines "biodegradable" as "susceptible of decomposition by natural biological processes, as by the action of bacteria, plants, animals, etc." Dorland's at 198. Mirriam-Webster's Collegiate Dictionary contains a similar definition, "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." Id. at 114 (10th ed. 1996). The Court finds nothing in the Patent itself, the specification, or prosecution history that discusses the rate of breakdown or eventual elimination. Therefore, the Court will adopt AnazaoHealth's proposed construction with one slight modification since it is clear from the Patent that the goal of this device is to place radioactive seeds in the human body for the treatment of cancer. Thus, the Court construes the term "biodegradable" as "capable of being broken down in the human body by the action of microorganisms."
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1. "Biodegradable"

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The Court construed the term "biodegradable" in Claims 3 and 10 as "capable of being broken down in the human body by the action of microorganisms." Plaintiffs convincingly argue that there is nothing in the '760 Patent that limits degradation to actions of microorganisms in the human body. Indeed, even the dictionary definitions on which the Court relied do not so limit the term. Dorland's Illustrated Medical Dictionary defines "biodegradable" as "susceptible of decomposition by natural biological processes, as by the action of bacteria, plants, animals, etc." Id. at 198. Merriam-Webster's Collegiate Dictionary, cited by Defendant (Def.'s Mem. at 21) and relied upon 6] by the Court, defines "biodegradable" as "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." Id. at 114 (10th ed. 1996). As Plaintiffs point out, both of these definitions indicate that action by microorganisms is illustrative of only one method of biodegradation. Other dictionary definitions are in accord. For example, the American Heritage Medical Dictionary (2007) defines "biodegradable" as "capable of being decomposed by biological agents, especially bacteria," and Dorland's Medical Dictionary for Health Consumers (2007) defines it as "susceptible of degradation by biological processes, as by bacterial or other enzymatic action." 2

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2 http://medical-dictionary.thefreedictionary.com/ biodegrade.

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While it is clear from the '760 Patent that the goal of the patented device is to place radioactive seeds in the human body for the treatment of cancer, the Patent does not limit the method of biodegradation to the action of microorganisms, so long as the biodegradation occurs in the body. Thus, the Court agrees with Plaintiffs that its original construction was too narrow and adopts instead the construction now advanced by Plaintiffs that includes other natural biological processes. On reconsideration, the term "biodegradable" in Claims 3 and 10 is construed as "capable of being broken down in the human body by natural biological processes." 3

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3 Defendant objects to the Court's consideration of the scientific articles attached to Plaintiffs' memorandum, since these exhibits were not listed as exhibits on Plaintiffs' Exhibit List for the Markman Hearing. The Court has not considered this extrinsic evidence in its ruling on reconsideration and, therefore, need not rule on this issue raised by Defendant.

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A. "Biodegradable Article[s]"

Defendants ask the court to construe the claim term "biodegradable article [s]" to mean non-edible biodegradable articles. They contend that this meaning is warranted by the specification language which establishes that the inventors expressly described their invention as a process for making non-edible articles, and also because the inventors added this language to the patent specification during patent prosecution in order to evade the prior art. MGPI, on the other hand, contends that defendants' proposed meaning is unsupported by the plain language of the claim and, furthermore, that even if the court were to import non-edible into this claim term, the court should further construe the term non-edible to mean non-edible by humans.

1. Claim Language and Language Contained in the Specification

The court begins with the words used in the claims themselves. Claims 1 and 24 disclose "biodegradable article[s]" without any reference to whether those articles are edible or non-edible. Defendants point out that the patent Abstract discloses "[a] method of forming solid, non-edible biodegradable, grain protein-based articles." '152 Patent, Abstract (emphasis added). The Field of the Invention states that "[t]he present invention is broadly concerned with a method of forming solid, non-edible biodegradable articles such as eating utensils, cups, plates, sheet items, packaging, and other convenience products."

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Id. col. 1, ll. 10-13 (emphasis added). The Description of the Prior Art explains that "[p]etroleum-based synthetic resins have achieved widespread use in the fabrication of a multitude of products . . . such as eating utensils and cups," id. col. 1, ll. 25-28, and acknowledges "a growing concern about the indiscriminate use of petroleum-based synthetic resins, and their accumulation in the environment." Id. col. 1, ll. 33-35. The Summary of the Invention states that "[t]he present invention overcomes the problems outlined above and provides an improved method of forming biodegradable non-edible solid articles using essentially completely biodegradable starting materials and avoiding petroleum-based synthetic resin." Id. col. 2, ll. 23-27 (emphasis added). The Preferred Embodiment discusses "solid biodegradable articles" without referring to those articles as non-edible, but it gives an example of a formulation for non-edible items. Id. col. 5, at ll. 7-8 ("injection molding of large, flat annular washers").

The claim terms (which do not contain the "non-edible" limitation) must of course be read in view of the specification (which does). See Phillips, 415 F.3d at 1315. But, at the same time, the Federal Circuit has repeatedly warned against importing limitations from the specification into the claims. Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1373 (Fed. Cir. 2007); Varco, L.P. v. Pason Sys. USA Corp., 436 F.3d 1368, 1373 (Fed. Cir. 2006); CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005). Recognizing that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice, Phillips, 415 F.3d at 1323; see also Anderson Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1373 (Fed. Cir. 2007) ("We have . . . recognized the difficulty faced by district courts in trying to walk that tightrope."), the Federal Circuit has instructed courts to remain focused on "understanding how a person of ordinary skill in the art would understand the claim terms." Phillips, 415 F.3d at 1323. "To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." Id. If the specification reveals a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess, the inventor's lexicography governs. Id. at 1316. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." Id.

Here, defendants are arguing that MGPI's inventors expressly described their invention as a process for making non-edible articles, disclaiming the use of the claimed process for manufacturing edible items. An inventor's intent to disclaim or disavow the broad scope of a claim must be clear from the specification. Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1357 (Fed. Cir. 2006). Absent a clear disavowal of claim scope, the patentee is entitled to the full scope of its claim language. Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004). "A patentee may claim an invention broadly and expect enforcement of the full scope of that language absent a clear disavowal or contrary definition in the specification." Id.

After careful consideration of the intrinsic record, the court is unpersuaded that the "non-edible" language in the specification of the '152 Patent represents a clear disavowal of the full scope of the claim language. To be sure, the specification's references to "the present invention" as a method of forming articles that are, among other things, "non-edible" are some evidence that the term "non-edible" applies to the invention as a whole. See Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (claim term "fuel injection system component" was limited to a fuel filter where, among other things, the written description referred to the fuel filter as "this invention" or "the present invention" on at least four occasions); cf. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343 (Fed. Cir. 2001) ("[T]he characterization of the coaxial configuration as part of the 'present invention' is strong evidence that the claims should not be read to encompass the opposite structure."). But, the specification of the '152 Patent does not contain any additional language that leads the court to believe that the inventors intended to disclaim biodegradable articles produced by the claimed methods simply because those items might happen to be edible. The specification refers to the biodegradable articles with various additional adjectives throughout the specification: the Abstract refers to them as also solid, non-edible, and grain protein-based; the Field of the Invention refers to them as solid and non-edible; the Summary of the Invention refers to them as non-edible and solid; and the Description of the Preferred Embodiment refers to them as nothing more than "solid," entirely omitting any reference to "non-edible." Thus, the term "non-edible" is not consistently included throughout the specification. Moreover, despite the fact that the specification describes the articles formed by the patented method as biodegradable, solid, non-edible, and grain protein-based, the inventors notably chose to include in the claim language itself nothing more than the "biodegradable" limitation. See Ventana Med.
Sys., Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1181-82 (Fed. Cir. 2006) ("When the claim addresses only some of the features disclosed in the specification, it is improper to limit the claim to other, unclaimed features.").

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In support of defendants' argument in reliance on the language contained in the specification they rely on Honeywell Int'l, Inc., 452 F.3d at 1312, in which the Federal Circuit held that the claim term "fuel injection system component" was limited to a "fuel filter" because the written description used language that led to the conclusion that a fuel filter was the only fuel injection system component that the claims cover. Id. at 1318. In that case, the written description referred to the fuel filter as "this invention" or "the present invention" on four occasions. Id. Additionally, the fuel filter was the only component of an electronic fuel injection system that the written description disclosed as having a polymer housing with electronically conductive fibers interlaced therein; the only other fuel component specifically mentioned in the written description, the fuel line, was not required to be made of an electrically conductive polymer material, as the claims required; and the prior art problem addressed by the patented invention was leakage of non-metal fuel filters in electronic fuel injection systems. Id.

The applicability of the specification language to the meaning of the claim term "biodegradable" in this case is distinguishable from the specification language at issue in Honeywell. In Honeywell, the court was confronted with the task of construing the claim language "fuel injection system component," the meaning of which was unclear from the ordinary and customary meaning of the words used in the claim itself. Thus, the court was entitled to use the specification to resolve the ambiguity concerning the meaning of that claim term. See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2002) ("The specification may assist in resolving ambiguity where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone."). But, without a claim term that is susceptible of clarification by the written description, there is no legitimate way to narrow the property right. NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1310 (Fed. Cir. 2005). Thus, "it is manifest that a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). Here, defendants are not really asking the court to resolve an ambiguity concerning or to clarify the meaning of the claim term "biodegradable." Instead, they are asking the court to construe the claim language, which says nothing about whether the subject article is edible, based on the extraneous concept of non-edibility as derived from the specification. In asking the court to construe the claim to mean only non-edible articles, defendants are not really asking the court to construe the meaning of any term already existing in the claim, but rather to add a new claim limitation. "That claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims." Teleflex, Inc., 299 F.3d at 1326 (quotation omitted).

To illustrate this point, if the court were to construe the term "biodegradable articles" to be limited to "non-edible biodegradable articles," the court would further have to determine what is meant by "non-edible," a term which is not even included in the claim language itself. To put the matter in context, this case is about dog chews. If the court were to construe the patented invention to claim a method of forming non-edible items, such a claim construction would not assist with resolution of the parties' dispute in this lawsuit in the absence of a further determination about whether the term non-edible means non-edible to humans and/or non-edible to dogs. This demonstrates that such a claim construction would be more akin to improperly importing an additional limitation from the specification than it would be to using the specification to interpret the meaning of an existing claim term, as it would import an entirely new concept into the claim language that is separate and distinct from the concept of biodegradability.

Defendants also rely on the case of SciMed Life Systems, Inc., 242 F.3d at 1337. There, the specification led to the "inescapable conclusion" that the references in the asserted claims to an inflation lumen "separate from" the guide wire lumen must be understood as referring to coaxial lumens rather than side-by-side lumens. Id. at 1342. Additionally, the patents distinguished the prior art in part on the ground that it used a disadvantageous dual lumen structure and pointed out the advantages of the coaxial lumens. Id. at 1343. The specification described a sleeve structure (for coaxial lumens) and stated that it "is the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." Id. at 1343 (quoting the patents at issue). The court held that the words "all embodiments of the present invention" broadly and unequivocally made the point that the coaxial lumen configuration was a necessary element of every variant of the claimed invention. Id. at 1344; see also Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1348 (Fed. Cir. 2004) (specification led to the "inescapable conclusion" that communications must occur over a telephone line rather than a packet-switched network such as the Internet).

Unlike in SciMed, in this case the '152 Patent specification contains no such broad and unequivocal language which leads to the inescapable conclusion that the claims should be construed to disclaim edible articles. Mindful that the purpose of the specification is to teach and enable those of skill in the art to make and use the invention and to provide a best mode for

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doing so, the court believes that one of ordinary skill in the art would understand that the specification's reference to "non-edible" articles derives from the historical context of the invention. The invention is broadly concerned with an improved method for forming biodegradable articles by avoiding petroleum-based synthetic resins due to problems associated with accumulation of synthetic resins in the environment. The Description of the Prior Art explains that this formerly included non-biodegradable items made from synthetic resins such as eating utensils, cups, plates, and the like. Hence, one of ordinary skill in the art would understand the novelty of the invention to be concerned with a method of forming those types of items so that they are biodegradable. Just because the invention seeks to cure a problem which has historically been associated with such non-edible items does not, however, mean that one of ordinarily skill in the art would necessarily interpret the method to exclude the formation of biodegradable items which also happen to be edible. Simply put, the specification would not lead one of ordinary skill in the art to the "inescapable conclusion" that claims 1 and 24 of the '152 Patent exclude methods of forming articles which are edible. In the absence of a clear disavowal of claim scope coverage, then, MGPI is entitled to the full scope of its claim language.

2. Prosecution History

Defendants further contend that limiting the claims to non-edible items is warranted by the prosecution history. "[T]he prosecution history may not be used to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage." SuperGuide Corp. v. DirecTV Enters., Inc., 358 F.3d 870, 875 (Fed. Cir. 2004) (quotation omitted); accord Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1306 (Fed. Cir. 2003). "To be given effect, such a disclaimer must be clear and unmistakable." Sunrace Roots, 336 F.3d at 1306 (quotation omitted); Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) (the alleged disavowing actions or statements made during prosecution must be both clear and unmistakable).

Here, there is no such clear and unmistakable disavowal of claim scope in the prosecution history. The court has carefully reviewed the relevant prosecution history. Claims 1 and 24 were initially rejected as being anticipated by Mullen. The PTO interview summary notes that they discussed Mullen as the prior art; that "[p]rior art products have gone through denaturation in the extruder"; that "Mullen discloses extruder temperatures/conditions that would denature the product"; and that it was agreed that the inventors of the '152 Patent would file a continuation-in-part (C-I-P) patent application "to enhance description of Process of claim one . . . to include step of denaturation of article in mold." When the PTO ultimately allowed the claims, the stated reasons for allowance were that the prior art "fails to teach or suggest the improvement wherein the grain protein article is denatured only in the molding step." Thus, the prosecution history reveals that the amendments made to distinguish over Mullen were concerned with denaturation of the grain protein during step [iii] of the claimed method.

Defendants point out that in response to the PTO's concerns regarding the prior art Mullen patent, in the C-I-P application the inventors inserted the "non-edible" language cited above in the '152 Patent specification. Additionally, the remarks to the C-I-P application explain that "[t]he present invention is directed to a method of forming solid, non-edible biodegradable articles such as eating utensils, sheet items and packaging using grain protein-based formulations." As defendants point out, the abstract of the Mullen patent refers to edible sausage casings. Specifically, it states as follows: "Films are formed by extruding plastic masses containing particulate silica or silicate and derived from non-heat coagulable simple proteins. The films find value as edible packaging materials and in the form of casings are useful in sausage making and the like." U.S. Patent No. 3,615,715 to Mullen, Abstract. Notwithstanding this statement in the Mullen abstract, however, it does not appear from the remainder of the written description in the Mullen patent that the invention disclosed by Mullen is necessarily limited to edible materials. Nor is there anything else in the prosecution history of the '152 Patent which establishes that the inventors clearly and unmistakably disclaimed edible materials from the scope of the claims. As MGPI points out, although this issue was arguably "teed up" during patent prosecution by virtue of the inventors adding the "non-edible" language to the written description, the inventors did not add this language to the claims and the examiner did not require them to do so in order to evade the prior art. The remarks to the C-I-P application are no more informative than the non-edible language contained in the written specification. In fact, the overall thrust of the remarks appears to be explaining how the step [iii] denaturation limitation was added to distinguish over Mullen. In sum, the prosecution history is ambiguous, at best, concerning why the "non-edible" language was added to the '152 Patent specification; it certainly does not support the notion that it was added to the written description to distinguish over Mullen. See Mars, Inc. v. H.J. Heinz Co., L.P., 377 F.3d 1369, 1377 (Fed. Cir. 2004) ("It is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous." (quotation omitted)). Thus, it would be improper to limit the scope of the claim based on this ambiguous prosecution history.

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3. Extrinsic Evidence

Defendants also rely on the opinion of their expert, E. Allen Foegeding, Ph.D., that a person of ordinary skill in the art would understand the term "biodegradable articles" to mean non-edible items. Dr. Foegeding explained in his deposition that "we don't put the qualifications of 'biodegradable' on our biological materials that we eat." Foegeding Depo. at 79:7-8. He opines that, consequently, the term "biodegradable articles" would be understood to be non-edible, non-food items that will eventually end up in the environment. The court discounts the significance of this extrinsic evidence, as it is far less reliable than the intrinsic evidence which is a matter of public record. Furthermore, his opinion is at odds with the intrinsic evidence as well as the ordinary and customary meaning of the word biodegradable, which is generally associated with the extent to which an item will decompose, not whether the item is edible.

Accordingly, the court rejects defendants' argument that the claim term "biodegradable article" should be limited to non-edible articles. The court finds that the claim terms "biodegradable article[s]" require no further claim construction.
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E. "BIOEQUIVALENT" ('939 PATENT).

In the '939 patent, claims 1 and 2 state that "an amount of the antagonist released from the composition which has been administered intact is bioequivalent to 0.125 mg naltrexone or less." '939 patent, col. 52, ll. 29-31, 48-50 (emphasis added). King contends the term "bioequivalent" is indefinite within the context of the '939 patent claims because the common definition of "bioequivalent" used by those skilled in pharmaceutical manufacturing only applies to compounds with the same active ingredient, such as brand-name and generic drugs, but the '939 patent seeks to compare naltrexone with antagonists containing distinct active ingredients, such as naloxone and nalmefene. Purdue admits that the '939 patent does not use the traditional, FDA definition of "bioequivalent." It asserts instead that "bioequivalent" is used to mean "equivalent antagonistic effect" (also termed as "equiantagonistic effect"). (See Def.'s '939 Rebuttal Cl. Constr. Br. 17.) Reading the term in the context of patent, I find the '939 patent and its prosecution history support Purdue's interpretation.

A claim is prohibited from being indefiniteunder 35 U.S.C.A. § 112, para. 2, which requires that a claim "particularly point[] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." The burden is on King as the challenging party to prove that "bioequivalent" is indefinite as a matter of law by "clear and convincing" evidence. See Gen. Creation, 232 F. Supp. 2d at 675. In general, "[b]ioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes." Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1298 (Fed. Cir. 2009). Federal regulations for the FDA define bioequivalent as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e) (2009) (emphasis added). This definition demonstrates that the FDA assumes bioequivalent drugs have the same active ingredient.

Even though the typical definition used by those skilled in the art is a baselineat which to start interpreting claim terms, "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning." Vitronics, 90 F.3d at 1582. Though perhaps not the most common use, in some instances, "bioequivalent" is used more broadly by those skilled in the art of pharmaceuticals than as defined by the FDA. For example, in Taber's Cyclopedic Medical Dictionary 220 (18th ed. 1997), bioequivalence is defined as "[t]he property of having the same biological effects of that to which a medicine was compared," with no requirement that the medicines compared contain the same active ingredient.

The language of the patent supports Purdue's assertion that the inventors were in fact using "bioequivalent" to compare different opioid antagonists rather than drugs with the same active ingredient. Both the specification and claim 22 state "0.025 mg of naltrexone or a bioequivalent dose of another antagonist." ('939 patent, col. 6, ll. 2-3, col. 54, ll. 63-64.) The prosecution history also demonstrates that one skilled in the art could understand "bioequivalent" to mean "equinantagonistic effect." The patent examiner himself used "bioequivalent" synonymouslywith "equiantagonistic effect" writing in reference to another patent,

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[The] Palermo [patent] teaches that the combinations of opioid antagonists/opioid agonists which are orally administered in ratios which are equivalent to the ratio of e.g., naltrexone to hydrocodone set forth are considered to be within the scope of the [Palermo] invention. For example, in some embodiments, naloxone is utilized as the opioid antagonist, the amount of naloxone included in the dosage form being large enough to provide an equiantagonistic effect as if naltrexone were included in the combination (p. 19-31). This demonstrates bioequivalency of the dosage forms.

(Def.'s '939 Opening Cl. Constr. Br., Ex. K at 5 (emphasis added).)

Additionally, King's expert, Arthur H. Kibbe, Ph.D., states that this is an acceptable, although non-traditional, use of the term, but faults the inventors for not stating the definition somewhere in the patent. Yet, it is not necessary to define terms explicitly in the specification, if the meaning is clearly implied. See Gen. Creation, 232 F. Supp. 2d at 665 ("'The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms byimplication.'" (quoting Vitronics, 90 F.3d at 1582)). It is plain from the claims and the specification that the inventors were using the non-traditional meaning even though the definition was not expressly stated.

King contends that even if "bioequivalent" is defined as Purdue suggests, the term is nevertheless indefinite because there is no way to determine how much of an antagonist is "bioequivalent to 0.125 mg naltrexone or less" without undue experimentation. However, Purdue's expert, J. David Haddox, D.D.S., M.D., testified that to determine the amount of another antagonist "bioequivalent" to 0.125 mg naltrexone, a clinician would go to a standard pharmacological reference book and perform "a relatively simple" calculation. (Def.'s '939 Rebuttal Cl. Constr. Br., Ex. B at 279.) There are indeed reference books that "present pharmacokinetic data in a format that allows the clinician to make rational choices of doses of drugs." Leslie Z. Benet, et al., Appendix II: Design & Optimization of Dosage Regimens; Pharmacokinetic Data, in Goodman & Gilman's The Pharmacological Basis of Therapeutics 1707, 1707 (9th ed. 1996). One such reference book is Enno Freye, Opioid Agonists, Antagonistsand Mixed Narcotic Analgesics 43 (1987), which has a table comparing the potency of naltrexone and naloxone, among other opioid antagonists.

Because of this substantial evidence demonstrating that one determining "bioequivalent" doses would not need to perform undue experimentation, I find that King has not shown by clear and convincing proof that "bioequivalent" is indefinite, and I construe "bioequivalent" to mean "equivalent antagonistic effect."
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1. Construction Of "Biological Polymers Immobilized On A Surface"

Affymetrix's proposed construction of "biological polymers immobilized on a surface" n3 is "two or more surface-immobilized biological polymers that are recognized by a particular target." (D.I. 243 at 26.) Illumina's proposed construction is "two or more biological polymers of different sequence chemically linked to a single surface." (D.I. 240 at 28.) The dispute here is whether the construction should be limited to require that the polymers be chemically attached, and that they be attached to a single surface. The Court concludes that these limitations are not required.

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n3 Both parties agree that the various permutations of this term in the '365 patent claims have the same meaning. (D.I. 243 at 26; D.I. 240 at 28.)

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The claims require only that the biological polymers be immobilized; there is no claim language requiring that the immobilization be accomplished via a chemical linkage. In support of its proposed construction, Illumina cites one preferred embodiment in which the polymers are chemically linked to the substrate. (D.I. 240 at 28.) The Court will not import this limitation from that embodiment into the claims. See JVW Enterprises, 424 F.3d at 1335.

Illumina also contends that the language of both the claims and the specification requires that the polymers in the probe arrays be attached to a single surface. (D.I. 240 at 28-29.) Illumina's contention rests mainly on the fact that the claims and

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the specification refer to substrates or surfaces in the singular form, e.g. "a substrate," "a first substrate." (Id. at 29.) As Affymetrix points out, however, the Federal Circuit has held that "[u]nless the claim is specific as to the number of elements, the article 'a' receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article." KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000). The Court finds no such intent here.

Moreover, Affymetrix points to three embodiments in which a probe array's substrate may comprise multiple surfaces. One of those embodiments is in the '365 patent itself and the other two are in the '854 patent, which is incorporated by reference in the '365 patent. (D.I. 243 at 27; D.I. 250 at 21 n.14.) Illumina's proposed construction would exclude these embodiments, and a claim construction that excludes a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support . . . ." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) (citations omitted). The Court finds no such support here. Therefore, the Court construes "biological polymers immobilized on a surface" to mean "two or more surface-immobilized biological polymers that are recognized by a particular target."
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3. "Biologically effective amount" (all asserted claims) -- means an amount of active ingredient -- the 3-isothiazolone -- sufficient to obtain effective control of organisms or microorganisms when used or applied by methods such as spraying, fumigating, dusting, and soaking. See Joint Markman Hearing Statement, at 27.

The 827 patent specification references U.S. Patent No. 3,761,488 (488 patent). See 827 patent, at 1:22-23. The specification of the 488 patent, entitled "3-isothiazolones," speaks to the manner and means of effective control:

Generally, control of an organism is achieved in accordance with this invention by contacting the organism with an isothiazolone in an amount which is effective to control said organism. Any of the techniques known in the art can be employed to disseminate the isothiazolones in a manner so as to achieve the desired contact with the organism to be controlled. Spraying and fumigating are typical of such techniques.

488 patent, at 18:50-57. The 488 patent specification also states: "Effective . . . control" of microorganisms "may be accomplished by varying means common to the art, such as slurrying, soaking, dusting, spraying and the like." Id. at 17:49-50 and 54- 56.

The parties do not dispute the meaning of "biologically active." See supra part I, P 6. However, defendants would construe the phrase to signify enough 3-isothiazolone biostatic or biocidal activity as is necessary to produce a solution that is safe and non-deleterious to humans and animals. See Joint Markman Hearing Statement, at 29. Defendants also cite the 488 patent specification: "By seed treatment is meant the disseminating of a biocidally active material over a seed subject to the attack of microorganisms, and particularly fungi, in an amount which is effective to control such microorganisms without deleteriously effecting the seed." 488 patent, at 17:46-51. This 488 excerpt is not helpful to defendants' position. Biocidal effectiveness and nondeleteriousness are listed as components of 488's definition of "seed treatment." The former is directed to the pest; the latter to the host.

The same is true of the 827 patent: A "biologically effective amount" refers to pest control. A "nondeleterious" result or effect denotes that low levels or absence of nitrosamine and nitrosamine precursors in 3-isothiazolone solutions would avoid harmful consequences to humans and animals. The two points are definitionally distinct. 7

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7 For example, 3-isothiazolone solution could be biologically effective and yet harmful if high levels of nitrosamines or nitrosamine precursors were present.

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1. The parties at bar argue that the phrase "ripe human growth hormone" requires a protein having the same amino acid sequence as hGH produced by the pituitary gland. (D.I. 202 at 5) Plaintiffs argue that the phrase also requires that the hGH be biologically active and substantially pure. In response, defendants assert that neither the intrinsic nor extrinsic evidence imposes either of the latter two limitations.

2. Claim construction is question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc).

3. In interpreting the claims, a court should begin with the intrinsic evidence of record (i.e., the patent itself, including the claims, the specification, and the prosecution history). Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Id.

4. First, a court should look to words of the claims themselves to define the scope of the patented invention. Id. There is a heavy presumption that the claim terms carry their ordinary and customary meanings as would be understood by one of ordinary skill in the art. Markman, 52 F.3d at 986. Put differently, the court must determine how a person of experience in the field of this invention would, upon reading the patent documents, understand the words used to define the invention. Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Dictionaries and scientific treatises may help to supply the pertinent context and usage for claim construction. Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201, 1202 (Fed. Cir. 2002).

5. Second, because a patentee may choose to be his own lexicographer and use a term in a manner either more or less expansive than its general usage in the relevant art, the court also should review the specification to determine whether an inventor has used any term in a manner other than its ordinary meaning. Vitronics, 90 F.3d at 1582. The specification may act as a dictionary when it either expressly defines terms used in the claims or when it defines terms by implication. Id.

6. Third, a court may consider the prosecution history of a patent, if in evidence. Id. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id. (quoting Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)). That is, a court must look to the prosecution history to determine if the patentee has limited the scope of the claims by disclaiming a particular interpretation during prosecution. Biodex Corp. v. Loredan Biomed, Inc., 946 F.2d 850, 862 (Fed. Cir. 1991).

7. Additionally, if the meaning of a term is not clear from the intrinsic evidence, then a court may consult extrinsic evidence, such as expert testimony, in construing claim terms as they would be understood in the relevant art. Markman, 52 F.3d at 980-81.

8. When construing the claims, courts must take great care to avoid importing unnecessary limitations into the claims from the specification. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003). "If we once begin to include elements not mentioned in the claim in order to limit such claim . . . we should never know where to stop." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (quoting McCarty v. Lehigh Val. R.R., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240, 1895 Dec. Comm'r Pat. 721 (1895)). Nevertheless, a court should look to the specification to determine whether it refers to a limitation only as a part of less than all possible embodiments or whether it suggests that the very character of the invention requires the limitation be a part of every embodiment. It is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002). On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345 (Fed. Cir. 2001).

9. After reviewing the language of claim 1 (i.e., biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone) in accordance with the above principles of claim construction, the court construes this claim to mean a protein produced by recombinant DNA techniques composed of a 191 amino acid sequence identical to

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that of hGH produced by the human pituitary gland with the full biological activity of hGH produced by the human pituitary gland, and free of the contaminants present in hGH produced by the human pituitary gland.

10. One of skill in the art at the time the '352 patent application was filed would have understood the term "biosynthetic" to mean that the human growth hormone must be made by recombinant DNA techniques, consistent with its ordinary meaning.
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The only claim at issue is claim 1 of the '352 patent:

Biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone.

Consistent with the specification of the '352 patent, "biosynthetic" requires that the human growth hormone be made by recombinant DNA techniques, and "ripe" indicates that it has the 191 amino acid sequence identical to that of the hormone produced by the human pituitary gland, as well as the full biological activity of the human pituitary gland. ('352 patent, col. 1, lns. 20-25, 30-36; col. 5, lns. 36-38; see also D.I. 30, Ex. 4 at 2-4)
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II.

The claim construction dispute in this case centers on the interpretation of the term "block copolymer" as used in claims 1 and 2 of the '719 patent. Phillips argues that the term "block copolymer" encompasses compositions that contain "a relatively small proportion of block copolymer molecules." Huntsman and Aristech maintain that the term is only intended to refer to compositions in which the presence of block copolymer molecules is not insignificant. For purposes of the motion for summary judgment of noninfringement, Huntsman stipulated that its product contained a maximum of 25 ppm block copolymer molecules, making 99.9975% of its product other polymer substances, while Aristech stipulated that its product contained a maximum of 60 ppm block copolymer molecules, making 99.994% of its product other polymer substances. See Recommendations at 13.

Based on our review of the claims, the written description and the prosecution history, we conclude that Edmonds used the term "block copolymer" to refer to an overall polymeric product, i.e., the composition of claim 1 and the product of the process of claim 2. We read Edmonds' statements during prosecution as requiring that the polymeric product contain a sufficient amount of block copolymer molecules such that the polymeric product may be properly classified as a "block copolymer." We conclude that the claims require the block copolymer molecules to contain at least two polymeric blocks that form a not insignificant and identifiable portion of the molecules. We also conclude that the use of the term "block copolymer" precludes the product or composition from being a blend or a graft copolymer. 11

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11 During prosecution Edmonds used the term "blend" to refer to a mixture of homopolymers and copolymers that were not chemically bonded together. Such a mixture lacks an appreciable quantity of block copolymer molecules. We recognize that Edmonds' composition and the product of his process are "blends" in that they contain block copolymer molecules physically mixed with, but not chemically bonded to, homopolymers and copolymers. We use "blend," as Edmonds did, to refer to a mixture of homopolymers and copolymers that lacks an appreciable quantity of block copolymer molecules.

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A.

Claim construction begins, as it must, with the words of the claims. See Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 U.S.P.Q.2D (BNA) 1816, 1819 (Fed. Cir. 1995). Generally, we give a

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technical term its ordinary meaning, that meaning it would be given by persons skilled in the art, unless "it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578, 38 U.S.P.Q.2D (BNA) 1126, 1129 (Fed. Cir. 1996); see Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1576-77.

Phillips contends that the plain meaning of the term "block copolymer" was well known to those skilled in the art when Edmonds filed his patent application in 1958. We disagree. An affidavit from Dr. Quirk, one of Phillips' experts, states that the precise makeup of block copolymer products has been disputed over the last thirty years and that "some persons apparently believed these products contained predominantly block copolymer molecules . . . [while] others apparently believed that these products contained small amounts of block copolymer molecules." Given that the ordinary meaning of the term "block copolymer" was disputed by those skilled in the art at the time the application was filed, we turn to the written description and prosecution history for clarification as to the patentee's intended meaning.

B.

The written description suggests that the claimed composition and the product of the claimed process are made of blocks or segments. It provides:

The polymers prepared by the instant process are to be distinguished from copolymers in that the final polymer product is made up of blocks or segments, each of which is substantially a homopolymer of one of the olefins employed in the process. The product of this invention can also be formed of blocks of copolymers and homopolymers as well as blocks of copolymers only.

'719 patent, col. 1, ll. 30-37. The written description refers to "the product which is produced" by the claimed process as a "block copolymer," and refers to the products produced in Examples I and III as block copolymers. Id. at col. 3, ll. 60-62; see id. at col. 4, ll. 3-10. Thus, the written description suggests that the term "block copolymer" was used by the inventor to refer to the claimed composition and the product of the claimed process and that these products were made of blocks or segments adjacent to each other. However, the written description does not further define "block copolymer" or specify what is necessary for a composition or a product to qualify as a "block copolymer" as the term is used in claims 1 and 2. We turn next to the prosecution history.

C.

Phillips argues that the district court erred by using the prosecution history of the interference proceedings to interpret the claims. 12 However, because the interference proceedings are part of the public record and shed light on the meaning of the claims, it is proper to rely on the record of those proceedings in construing the claims. See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1579-81, 40 U.S.P.Q.2D (BNA) 1019, 1024-26 (Fed. Cir. 1996) (using the arguments made in support of a request for a declaration of interference as part of the prosecution history used to construe a claim term). 13

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12 The prosecution history of the '719 patent is extensive, including two interference proceedings. In July of 1962, Interference No. 92,869 ('869 interference) was declared, involving the claim that ultimately became claim 4 of the '719 patent. In August of 1963, Interference No. 93,747 ('747 interference) was declared, involving the claim that ultimately became claim 2 of the '719 patent. In June of 1972, Edmonds prevailed in both interferences.

13 See also Vitronics, 90 F.3d at 1582-83, 39 U.S.P.Q.2D (BNA) at 1577 (the prosecution history may be used to interpret claims because it "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims"); Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1143, 42 U.S.P.Q.2D (BNA) 1589, 1594 (Fed. Cir. 1997) (using arguments made in a request for a declaration of interference during claim construction).

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1.

The term "block copolymer" only appears in the preamble of the claims. However, a term appearing in the preamble is limiting when, as here, it is found to be required to confer meaning on the claim. See In re Paulsen, 30 F.3d 1475, 1479, 31 U.S.P.Q.2D (BNA) 1671, 1673 (Fed. Cir. 1994) ("Terms appearing in a preamble may be deemed limitations of a claim when they give meaning to the claim and properly define the invention." (internal quotations omitted)).

As originally filed, Edmonds' application did not contain the term "block copolymer(s)," but instead used the term "block polymer(s)." In an amendment, dated March 15, 1960, Edmonds replaced the term "block polymer(s)," in the claims and written description, with "block copolymer(s)." Subsequently, on two separate occasions during the course of the two interference proceedings, Edmonds attempted to delete the word "block" from the claim, explaining in one instance that the term was an "unnecessary feature in defining the process invention." 14 On both occasions the Examiner disagreed. In one proceeding, the Examiner indicated that "the term 'block copolymers' gives life and substance to the claim in that it imports into the claim those necessary conditions for obtaining block copolymers rather than other products." In a second proceeding, the Examiner rejected the elimination of the term because the formation of a "block copolymer" was the "heart of the invention." 15 Finally, again in the course of the '869 interference, the Examiner summarized his position as follows:

> [The use of the term "block copolymer"] is recognized as an essential part of this invention and unless the application teaches what steps and conditions are to be followed in order to obtain this product (block copolymer) as contrasted to other types of copolymers, the application does not disclose the invention.

(Emphasis in original). The Examiner also noted that "block copolymer" was necessary to point out that block copolymers were produced "to the exclusion of other products." The patentee acquiesced to the Examiner's logic.

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14 The first instance was in connection with a May 28, 1964 motion in the '869 interference. In a May 18, 1966 response to Edmonds' request for reconsideration of rulings on motions in the '869 interference, the Examiner stated:

> The Examiner has . . . concluded, in reasoning with which the party Edmonds finds no fault, that the limitation "block copolymers" is of patentable significance in the preamble of the count and that the term "block copolymers" gives life and substance to the claim in that it imports into the claim those necessary conditions for obtaining block copolymers rather than other products. The Examiner states . . . that all of the parties . . . have as their very objective the obtaining of block copolymers in distinction to grafts, blends, etc. . . .
>
> The statement of the intended product is recognized as an essential part of this invention and unless the application teaches what steps and conditions are to be followed in order to obtain this product (block copolymer) as contrasted to other types of copolymers, the application does not disclose the invention.
>
> . . . The very reason for considering the term "block copolymers" in the claim to be a material limitation is that the linking of the result with the procedure by which this result can be obtained is crucial to the invention.

In a December 2, 1966 decision on a request for reconsideration of prior motion rulings in the '869 interference, the Examiner again stated that "elimination of the concept of 'block copolymer' from the count would eliminate the basic concept of the invention."

15 This was on February 10, 1966, in connection with the '747 interference. Thus, despite attempts to eliminate references to "block copolymer" in both interferences, the term was maintained because it was what made the counts patentable, because it was "the whole inventive concept of the" interference counts, and because it was the "heart of the invention."

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2.

Having determined that the term "block copolymer," as used in the preambles, is a meaningful limitation to the claims, we

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are left to determine what the patentee intended by the term. After reviewing the prosecution history, we conclude that the patentee intended the term "block copolymer" to require (1) that the composition contain a threshold amount of block copolymer molecules with adjacent polymer blocks; and (2) that the polymer blocks comprise a significant portion of the molecules that make up the "block copolymer."

The prosecution history is replete with statements that lead us to the conclusion that "block copolymer," as used by the patentee, requires that the composition be made of block copolymer molecules that contain adjacent polymer blocks. By way of example, in 1969, in an appeal brief before the Board contesting the denial of the declaration of a third interference, Edmonds stated that his invention was "a block copolymer in which the molecules consist of two adjacent polymeric blocks." In April, 1974, in an appeal brief before the Board contesting the final rejection of the claim that would become claim 1 of the '719 patent, Edmonds stated that "the invention is a block copolymer in which the molecules are made up of at least two adjacent polymeric blocks." In the same brief, Edmonds also stated that he "was the first to make a polymer which has segments of polypropylene and ethylene-propylene copolymer in the polymer molecules." Additionally, in the Patent Owner's Statement during the reexamination proceedings, Edmonds stated that the claims were directed to "a block copolymer comprising block copolymer molecules."

Finally, in a 1974 appeal, the Board reversed the Examiner's rejection of the claim that would become claim 1 of the '719 patent, stating:

The basis of the Examiner's rejection is that it is not clear from the claim how many blocks would be required to achieve the desirable properties recited in the specification. However, the claim encompasses any block copolymer containing at least one propylene homopolymer block and at least one adjacent ethylene-propylene copolymer block, without limitation as to its physical properties.

In light of the Examiner's rejection, we read the Board's statement as addressing the number of polymer blocks required in a given block copolymer molecule. We do not construe this statement as inconsistent with the remainder of the prosecution history requiring the polymer blocks to be a significant portion of the block copolymer molecules. We read the Board's ruling as simply not requiring the block copolymer molecules of the claimed block copolymer composition to contain more than two adjacent polymer blocks.

3.

Phillips asserts that claim 1, which uses the open term "comprising," encompasses compositions that contain molecules other than block copolymer molecules. As far as claim 2 is concerned, it argues that the term "block copolymer" is not limited to block copolymer molecules, but includes the entire polymer product made by the recited polymerization process, regardless of the block copolymer molecule content. Phillips contends that the district court 16 misconstrued the claims of the '719 patent by limiting the term "block copolymer" to block copolymer molecules and by focusing on the individual molecules rather than the entire composition of claim 1 and the entire product of the process of claim 2.

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16 Since the district court adopted the Special Master's recommendations, this opinion uses "district court" when referring to the findings.

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However, the prosecution history supports a conclusion that polymer blocks must be a significant portion of the molecules that make up the "block copolymer." The use of "comprising" and "which comprises" in the composition and process claims generally would mean that the claims require the presence of a sufficient quantity of block copolymer molecules, but that additional elements or process steps may be present. See Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 U.S.P.Q.2D (BNA) 1608, 1611-13 (Fed. Cir. 1997) ("comprising" allows the addition of other elements so long as the named elements, which are essential, are included); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271, 229 U.S.P.Q. (BNA) 805, 812 (Fed. Cir. 1986) ("comprising" opens a method claim to the inclusion of additional steps, but does not affect the scope of the structure recited within the steps).

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The patentee indicated a clear intent to limit the term "block copolymer." In an amendment dated October 2, 1973, Edmonds stated:

These composition claims define the invention as a "block copolymer" having defined first and second polymer blocks. The specification clearly teaches that these polymer blocks are each a significant portion of the entire macromolecule and the claims could not be reasonably interpreted to read on polymers in which the macromolecules contained an insignificant number of serially lined monomer units. Without question each block would have to be identifiable as a segment of the polymer and be of some consequence in determining the properties of the polymer.

(emphasis added). Edmonds reiterated this contention in his 1974 appeal brief before the Board. 17

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17 This is consistent with Ex parte Mowry, 91 U.S.P.Q. (BNA) 219 (Patent Office Board of Appeals 1950), which defines the term "copolymers" to mean a product produced from the polymerization of "material amounts" of two components as distinct from the polymerization product of the individual components.

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Moreover, the prosecution history is buttressed by technical articles, presented to the PTO during the course of prosecution. In a 1974 reply brief before the Board contesting the rejection under 35 U.S.C. § 112, para. 2, of the claim that would become claim 1 of the '719 patent, Edmonds stated:

The prosecution record of this case clearly shows that block copolymers broadly were well known before applicant's invention. The meaning of the term "block" is not different in the present invention from its commonly understood meaning in the polymer art. This terminology was well developed in 1958 when the subject application was filed.

. . .

The record of prosecution of this application contains adequate authority for the appellant's proposition that one of normal skill in the art was familiar with block copolymers and block copolymerization and appreciated the significance of the term "block" when used to describe a significant portion of the polymer molecule.

Edmonds attached pages from the Encyclopedia of Polymer Science and Technology to support this contention. This reference used the term "block copolymer" to refer to polymers obtained by sequential polymerization "in which the like monomer units occur in relatively long sequences." 2 Encyclopedia of Polymer Science 201 (1965). The reference also stated:

In the majority of the syntheses that have been considered the block or graft copolymer is contaminated with at least one of the homopolymers of the species which make up the copolymer segments. Furthermore, in many of the syntheses the block copolymer is present as a minor fraction of the total polymeric material. Before these copolymers can be characterized it is necessary to isolate them from the homopolymers or random copolymers present in the polymerization product.

Id. at 216.

We do not read this excerpt as establishing that the term "block copolymer," as used by Edmonds, refers to any material which contains block copolymer molecules regardless of amount. The reference addresses a number of polymerization methods for obtaining block copolymers, and its references to ethylene-propylene block copolymers were subsequent to Edmonds' priority date. The excerpt does not address the claimed composition or process, nor does it define "minor fraction of the total polymeric material." Thus, unlike Phillips, we do not believe that this reference supports the contention that polymer products containing a relatively small portion of block copolymer molecules are necessarily within the scope of the claims. As properly construed, the claims require enough block copolymer molecules to allow the polymeric product to be classified as a block copolymer.

4.

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Phillips further argues that the district court's claim construction is flawed because if the claims were read as construed by the district court, they would not cover Example III disclosed in the written description and because the district court's construction adds a limitation by restricting the claims to cover only block copolymer molecules. Phillips argues that no one can produce a block copolymer containing predominantly block copolymer molecules, thus showing the error in the district court's claim construction.

However, we find no support in the written description or the prosecution history for Phillips' contention that Example III of the patent discloses a "block copolymer" product in which block copolymer molecules are only a minor fraction of the entire product. While Example III discloses a process that produces a product in accordance with the claimed invention, the amount of block copolymer molecules in this product is not disclosed. The written description provides the physical properties of the product produced in Example III, suggesting that the entire product is a "block copolymer" as the term is used in the patent, but the Example fails to elucidate the meaning of "block copolymer."

5.

Finally, we conclude that the claims do not extend to blends or graft copolymers. The Examiner recognized that "blends or graft copolymers are not the equivalent of the block copolymers which are provided by the present invention." The Examiner reiterated this point during the '869 interference:

[Ex parte Schilling, Patent file 3,200,173, Appeal No. 324-84, Paper No. 18 (Patent Office Board of Appeals 1965)] disclosed a process very similar to that of the present count wherein a Ziegler catalyst was contacted first with propylene and then with a mixture of ethylene and propylene to obtain a blend of polypropylene and copolymer. The prior art showed the same process steps as those claimed but disclosed that a block copolymer was obtained. The recitation "blend" was taken to import into the claim those necessary conditions for obtaining blends rather than block copolymers with the method of the claim. Here the same logic applies. Except for Burke et al the very objective of all the parties is to obtain block copolymers in distinction to grafts, blends, etc. Therefore the recitation "block copolymer" in the count limits process steps to those which will yield a block copolymer.

The Examiner used the logic applied in Schilling to again emphasize that Edmonds' claims were directed to "block copolymers to the exclusion of other products" such as blends and graft copolymers. 18 We interpret these statements to preclude the claims from covering compositions or processes that produce blends or graft copolymers. See E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1438, 7 U.S.P.Q.2D (BNA) 1129, 1135 (Fed. Cir. 1988) (arguments made during the prosecution history and other aspects of the prosecution history are relevant in determining the scope and meaning of the claims); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) (the prosecution history limits the interpretation of claims to exclude interpretations disclaimed during prosecution). While we agree with Phillips' argument that the Schilling reference cannot be used as prior art, the Examiner referred to the proceedings before the Board in Schilling in explaining his logic, not as a basis for a prior art rejection. Given that the Examiner's reference to Schilling in explaining his logic is part of the prosecution history, we find nothing improper about using this portion of the prosecution history to elucidate the meaning of the claims.

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18 We reiterate that we use "blend" to refer to a polymeric product, that is a mixture of homopolymers and/or copolymers, which lacks an appreciable quantity of block copolymer molecules. Our interpretation is consistent with the meaning of "blend" used by Edmonds throughout prosecution.

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The parties' dispute has two separate components. First, although the parties purported to stipulate to a definition for "blocking nucleic acid," they apparently disagree as to the meaning of the word "enriched" in the stipulated construction. Abbott interprets "enriched" as meaning that the DNA must have a high ratio of repeat to unique sequences. Dako argues

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that "enriched" means that the ratio of repeat to unique sequences must be above that found in naturally occurring DNA. Although neither party addressed the proper claim construction in their briefs, both offered various citations to the intrinsic record at oral argument.

Assuming for the sake of argument that Dako's proposed interpretation is correct, Abbott also claims that the total human DNA used in Dako's kits may have a higher proportion of repeat sequences than naturally occurring DNA. At oral argument, Abbott claimed that total human DNA is generally manufactured by subjecting a single set of DNA to amplification. During the amplification process repeat sequence fragments are duplicated at a higher rate than unique sequence fragments. Thus the resulting DNA contains a higher proportion of repeat sequence fragments than normal human DNA.

The court finds that the record submitted in connection with Dako's motion is not developed enough to permit construction of "blocking nucleic acid" or application of the properly construed phrase to Dako's kits. The parties were unable to address the issue in detail in their briefs because Abbott did not disclose its literal infringement contention based on the total human DNA as part of its preliminary infringement contentions. See Hoffman Dec., Exh. BB. The court also notes that Abbott's representations at oral argument about the effect of creating large quantities of total human DNA through amplification appear to lack support in the current factual record. Abbott submitted a supplemental declaration from Professor David Pinkel in support of its contention that total human DNA can be an effective blocking agent, but the article attached to the declaration does not appear to describe the process by which total human DNA is manufactured. The only relevant passage the court has discovered describes the total human DNA as follows: "Placental DNA (Sigma) was treated with proteinase K, extracted with phenol, and sonicated to a size range of 200-600 base pairs (bp)." Supp. Pinkel Dec., Exh. A at 9139. This passage appears to describe the preparation of total human DNA without the use of amplification.

Without a clear record, the court must deny Dako's motion under Rule 56(f), subject to renewal at the point when a fully developed record as to the proper construction of "blocking nucleic acid" and the use of total human DNA in Dako's accused kits becomes available.
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"Blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol"

These terms appear in claims from the '156 Patent. Neither party squarely addressed the terms in its briefs. In the Joint Claim Construction Chart, Nutrition 21 asks that the terms "be given [their] plain and ordinary meaning, i.e., the amount of HDL-cholesterol in blood serum." GNC does not propose constructions for these terms, but proposes constructions of "increasing blood serum levels of HDL-cholesterol" and "undesirable low levels of blood serum HDL-cholesterol." Nutrition 21's construction will be helpful to a jury because the construction clarifies the proper relationship between the components of the term -- specifically that HDL-cholesterol is found in blood serum. Therefore the Court construes the terms to mean "amount of HDL-cholesterol in blood serum."
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"Blood serum LDL-cholesterol"

This term appears in claims from the' 156 Patent, and like for "blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol," Nutrition 21 asks that this term "be given its plain and ordinary meaning, i.e., the amount of LDL-cholesterol in blood serum." GNC proposes no construction whatsoever. Nutrition 21's construction is appropriate for the same reason Nutrition 21's construction of "blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol" are appropriate. This is notwithstanding the fact that, unlike those previous terms, the instant term does not contain the word "level" or "levels." In all three claims where "blood serum LDL-cholesterol" is found -- Claims 20, 21, and 22 -- the word "lowering" immediately precedes the term. Evidently, then, the claims refer to LDL cholesterol as something existing in amounts that can be altered. Nutrition 21's construction properly captures this reference. For these reasons, the Court construes "blood serum LDL-cholesterol" to mean "amount of LDL-cholesterol in blood serum."
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"Blood serum lipids"

Neither party's briefs squarely address the isolated term "blood serum lipids," which appears in claims from the '156 Patent. However, in the Joint Claim Construction Chart, Nutrition 21 asks the Court to construe the term to mean "substances found in blood plasma including serum triglycerides, total cholesterol, LDL-cholesterol, and HDL-cholesterol." GNC proposes no construction. The jury may be unfamiliar with what types of substances constitute blood serum lipids, and defining the term may assist the jury.

Nutrition 21's construction is technically correct. See '156 Patent, cols. 3:40-41 (specifying that "[p]lasma cholesterol and triglycerides are transported in lipoproteins"), 7:29-31 (noting in reference to Example 3 that "[s]erum parameters included total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, apolipoprotein A1 and apolipoprotein B"). However, the proposed construction may confuse the jury because the patent refers both to reducing "undesirable high levels of blood serum lipids" and increasing the lipid HDL-cholesterol as desired and beneficial effects of chromium administration. See, e.g., id. at cols. 15:12-29 (encompassing independent Claims 1, 2, and 3, all of which are directed to methods for reducing "undesirable high levels of blood serum lipids"), 16:66-17:2 (encompassing Claim 25, directed toward a method for preventing "undesirable high levels of blood serum lipids"), and 16:8-20 (encompassing independent Claims 17 and 18, which are directed toward methods of increasing undesirable low levels of blood serum HDL-cholesterol).

Skilled artisans who read Claims 1, 2, 3, and 25 in their proper context will likely interpret those claims' methods to be directed toward reducing only those types of blood serum lipids that have undesirably high levels, not every type of blood serum lipid. See id. at Abstract ("The administration [of CP] is for controlling blood serum lipid levels, including the lowering of undesirably high blood serum LDL-cholesterol levels and the raising of blood serum HDL-cholesterol levels."); col. 12:19-27 (referring to beneficial results in Examples 3 and 4 and stating "[t]otal cholesterol, LDL-cholesterol and the related transport protein apolipoprotein B were decreased while apolipoprotein A1, the HDL-cholesterol related protein, was elevated when the supplement contained [CP]. . . . each of these parameters is associated either directly or inversely to the onset of coronary artery disease. . . ."). C.f. id. at col. 12:49-67 (implying that "investigators" look to total, LDL-, and HDL-cholesterol levels as predictors of coronary artery disease). Nevertheless, Nutrition 21's explicit inclusion of "HDL-cholesterol" in its construction risks confusing a lay-person jury as to CP's desired effect on HDL-cholesterol levels.

Accordingly, the Court construes "blood serum lipids" generally as "substances found in blood plasma including, for example, triglycerides, cholesterols, or apolipoproteins."
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1. Construction of the "Boiling Point" Limitation

Dow challenges the district court's claim construction of the codistillate boiling point limitation used in clause 1. 8 Specifically, Dow contends that the "boiling point" phrase involves a simple and practical relative comparison in which the codistillate (consisting of the organic solvent, epi, and water) has a boiling point below that of other components in the mixture, and vaporizes before the other components. Thus, under Dow's preferred construction, one need not actually compare the numerical boiling point of the codistillate to that of the components. In the alternative, Dow argues that any numerical measurement of the codistillate boiling point must be taken in the vapor phase. In other words, Dow contends that the district court improperly construed the boiling point of the codistillate to require measurement of the reaction temperature in the reaction pot. Dow contends that it is well known to one of ordinary skill in the art that the true boiling point of a codistillate should be measured in the vapor phase.

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8 The "boiling point" is the temperature of a liquid at which its vapor pressure is equal to or very slightly greater than the atmospheric pressure of the environment. Hawley's Condensed Chemical Dictionary 153 (13th ed. 1997).

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Clause 1 requires that the reaction be conducted "in the presence of an organic solvent which codistills with water and said epihalohydrin at a boiling point below the boiling point of the lowest boiling compound among the components in the reaction mixture." Dow contends that this limitation simply requires the codistillate to boil before the other components in the reaction mixture. Because one of the key components of the improvement process is maintaining the water content in the reaction mixture below six percent by weight, Dow asserts that one of ordinary skill in the art would understand that the boiling point limitation simply requires the codistillate (containing water) to boil before the other components. It may well be true that one of ordinary skill in the art would understand that clause 1 simply requires the codistillate to boil before the other components in the reaction mixture, nevertheless, as the district court noted, "clause 1 does not state that the codistillate must boil off before the individual components evaporate from the reaction mixture." Dow, No. 96-10330, slip. op. at 35 (Jan. 21, 2000). Instead, clause 1 specifically requires the organic solvent, water, and epi to codistill "at a boiling point below the boiling point of the lowest boiling compound among the components in the reaction mixture." '255 patent, col. 11, ll. 8-12. Thus, as written, clause 1 requires a numerical comparison between the boiling point of the codistillate and the lowest boiling compound in the reaction mixture.

The district court also reasoned that a numerical comparison is required because "clause 1 of claim 1 was developed on the model of a minimum boiling azeotrope." 9 Dow, No. 96-10330, slip. op. at 35 (Jan. 21, 2000). The district court noted that in the grandparent and parent applications of the '255 patent, the phrase "ternary azeotrope" was used instead of the word "codistillate." Although our construction requires a numerical comparison of boiling points, this determination is not based on the fact that the claim language was "developed on the model of" an azeotropic mixture. Dow, No. 96-10330, slip. op. at 35 (Jan. 21, 2000). The fact that the claim language was changed from "ternary azetrope" to "codistillate" in the continuation-in-part application suggests that the terms have different meanings. Indeed, Sumitomo's experts admit that an azeotropic mixture has a "constant composition," and if the "composition is changing at a defined temperature and pressure, then the composition changing would not be an azeotrope." Because the compositions involved in the claimed process constantly change during the process, the codistillate disclosed in claim 1 of the '255 patent is not an azeotropic mixture.

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9 An azeotropic mixture is a liquid mixture of two or more substances that behaves like a single substance in that the vapor produced by partial evaporation of liquid has the same composition as the liquid. The constant boiling mixture exhibits either a maximum or minimum boiling point as compared with other mixtures of the same substances. Hawley's Condensed Chemical Dictionary 104 (13th ed. 1997). An azeotropic mixture with a minimum boiling point is a rare mixture that has a boiling point below those of its constituent components, and thus boils before its components. Therefore, the district court reasoned that a numerical comparison is necessary "in order to give meaning to the disputed phrase" because an azeotropic mixture with a maximum boiling point would contradict the literal language of the limitation.

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Although the construction of the "boiling point" limitation used in clause 1 requires a numerical comparison of boiling points, we conclude based on the following reasoning that the district court was incorrect in ruling that the codistillate boiling point is determined by measuring the temperature of the reaction mixture. Rather, the boiling point of the codistillate is properly measured in the vapor phase. We start with the proposition that the boiling point of a codistillate must be given its ordinary meaning as understood by one of ordinary skill in the art. Interactive Gift, 2001 WL 792669 at *7; Hockerson-Halberstadt, 222 F.3d at 955, 55 U.S.P.Q.2D (BNA) at 1490. In determining whether the codistillate boiling point is properly measured in the vapor phase or in the reaction mixture, we are free to consult technical treatises so long as such treatises do not contradict any definition found in or ascertained by a reading of the intrinsic evidence. Interactive Gift, 2001 WL 792669 at *6 n.1; Vitronics, 90 F.3d at 1584 n.6, 39 U.S.P.Q.2D (BNA) at 1578 n.6.

Dow contends that compounds that are not part of the codistillate, such as novolac and the alkali metal hydroxide, decrease the overall vapor pressure of the mixture (notwithstanding superheating or other impurities), thus requiring a higher reaction temperature to commence boiling. 10 Thus, Dow argues that one of ordinary skill in the art would understand that the true boiling point of the pure codistillate (consisting of organic solvent, epi, and water) must be measured in the vapor phase. Accordingly, Dow has submitted various technical treatises explaining that the boiling point of the pure codistillate is

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properly measured in the vapor phase. One such treatise explains that: " A thermometer immersed in the boiling liquid will . . . record a temperature a little above the boiling point. A thermometer in the vapor space, however, records the true boiling point even if the liquid is superheated or if it contains a nonvolatile solvent." Louis F. Fieser, Organic Experiments 23 (Heath 1964) (emphasis added).

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10 Sumitomo agrees that the codistillate consists only of epi, solvent, and water, and that clause 1 requires codistillation "of these three components, and each component alone cannot boil off from the reaction mixture to the extent that codistillation occurs."

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A number of other treatises use the example of the distillation of a sugar and water solution to explain why the distillate boiling point must be measured in the vapor phase. One treatise explains that when "a solution of sugar in water is distilled, the boiling point recorded on a thermometer located in the vapor phase is 100 degrees C . . . throughout the distillation, whereas the temperature of the boiling sugar solution itself is initially somewhat above 100 degrees C and continues to rise as the concentration of sugar in the remaining solution increases." Kenneth L. Williamson, Macroscale and Microscale Organic Experiments 85-86 (Heath 2d ed. 1994) (emphasis added). An increased concentration of nonvolatile constituents in a mixture decreases the vapor pressure in a solution. When the vapor pressure of a solution decreases, a higher reaction mixture temperature is required for boiling. Id. However, the true boiling point of the pure distillate never changes, and must be measured in the vapor phase. Id.

Sumitomo points to one reference that criticizes the procedure of measuring the boiling point of a codistillate in the vapor phase as "of dubious value." Hala et al., Vapour-Liquid Equilibrium 253 (2d English ed. 1967). Yet the same reference also strongly criticizes the method of measuring the temperature of the liquid as "weighted with errors" because "the boiling liquid is always superheated" and "this source of error cannot even be diminished." 11 Id. Sumitomo cites no other technical treatise to refute the proposition that one of ordinary skill in the art would understand the ordinary meaning of the boiling point of the codistillate to entail measuring the temperature of the vapor phase.

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11 The Hala reference actually describes a Cottrell measuring apparatus that measures the temperature in the vapor phase, but uses a sheath to prevent cold condensate from reaching the thermometer which causes a "deviation of the condensation temperature from the boiling point." Id.

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Furthermore, that the ordinary meaning of the codistillate boiling point entails measuring the temperature of the codistillate in the vapor phase is supported by the ordinary definition of the term "distillate." As discussed above, distillation is "a separation process in which a liquid is converted to a vapor and the vapor then condensed to a liquid. The latter is referred to as the distillate, while the liquid material is the distill and." Hawley's Condensed Chemical Dictionary 418 (13th ed. 1997) (emphasis added). Claim 1 of the '255 patent specifically calls for measuring the boiling point of the distillate, not the distill and. Moreover, one of ordinary skill in the art would understand that the temperature of the reaction mixture would likely be higher than the true codistillate boiling point due to superheating or contamination with other substances that do not evaporate. Therefore, it is clear that the ordinary meaning of the codistillate boiling point as used in claim 1 entails the measurement of the codistillate in the vapor phase.

We next examine the intrinsic evidence to determine whether the patentee has given the term an unconventional meaning based on any definition found in or ascertained by a reading of the intrinsic evidence. Vitronics, 90 F.3d at 1584 n.6, 39 U.S.P.Q.2D (BNA) at 1578 n.6. The district court stated that, "the intrinsic evidence does not distinguish between a distillate boiling point and the reaction mixture temperature, and does not teach that any temperature should be measured in the vapor phase." Dow, No. 96-10330, slip. op. at 9 (Apr. 19, 2000). However, the question before us is not whether the '255 patent teaches that the boiling point should be measured in the vapor phase; as discussed above, one of ordinary skill in the art would understand that the ordinary meaning of a codistillate boiling point involves measuring the temperature in the vapor

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phase. Instead, the question is whether the '255 patent sufficiently redefines the meaning of "boiling point" such that one of ordinary skill in the art would believe that it is measured in the reaction mixture.

The district court observed that, "the only notations of temperature in the '255 patent specification relate to the reaction mixture." Dow, No. 96-10330, slip. op. at 9 (Apr. 19, 2000). The district court reasoned that, "when identifying the temperature of the reaction mixture in conjunction with the pressure, the examples are clearly referring to the boiling point." Id. at 10. We agree that all of the examples described in the '255 patent specification discuss the reaction temperature. However, we disagree that the specification equates the temperature of the reaction mixture with the codistillate boiling point disclosed by claim 1. The '255 patent specifically uses the phrase "boiling point" in claim 1. '255 patent, col. 11, ll. 8-15. The specification also explains that the codistillate "has a boiling point below that of the lowest boiling component of the reaction mixture at the pressure employed." '255 patent, col. 5, ll. 28-30. At the same time, the '255 patent specification discusses the "reaction temperature" of the reaction mixture in numerous instances when it describes the preferred embodiment experiments. However, as discussed above, the ordinary meaning of the reaction temperature is different than the ordinary meaning of the boiling point of the codistillate. The fact that the '255 patent specification also describes the reaction temperature is consistent with the different meanings of these phrases.

That the specification identifies the reaction temperature in conjunction with a notation of the pressure does not signify that "the examples are clearly referring to the boiling point." Dow, No. 96-10330, slip. op. at 10 (Apr. 19, 2000). Indeed, one example describes an experiment where the reaction temperature is maintained at 65 degrees C, yet the reaction pressure is varied between 180 and 240 mm Hg absolute. '255 patent, col. 10, ll. 26-55. As discussed above, because the boiling point of a codistillate is necessarily defined by a fixed vapor pressure at a fixed temperature-- the reaction temperature of 65 degrees used in this example cannot be the same as the codistillate boiling point. 12

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12 The district court came to the opposite conclusion, reasoning that "the variation of the pressure in order to maintain the reaction temperature at 65 degrees C refutes, rather than supports, Dow's proposed construction." Dow, No. 96-10330, slip. op. at 11 (Apr. 19, 2000). We disagree. Having determined that the ordinary meaning of a codistillate boiling point entails measuring the codistillate in its vapor phase, the question becomes whether the specification redefined "boiling point" to mean the reaction temperature. This example describes maintaining the reaction temperature at 65 degrees C while varying the reaction pressure. This example is consistent with the different meanings of the codistillate boiling point and the reaction temperature, and does not implicitly redefine the meaning of the boiling point limitation used in claim 1.

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Finally, we note with great significance that the district court's construction would exclude many of the preferred embodiment experiments. Dr. Lowery's declaration of February 3, 2000 explains that equating the codistillate boiling point with the reaction temperature would exclude six examples from the scope of the claims. 13 Sumitomo conceded at oral argument that the district court's construction excludes six of the preferred embodiments described by the '255 patent specification. 14 Indeed, even the district court recognized that its construction would "exclude certain examples from the claim." Dow, No. 96-10330, slip. op. at 13 (Apr. 19, 2000). In response, Sumitomo argues that, "there is no requirement that claims be construed to include every embodiment disclosed in the specification." 15

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13 In determining whether a preferred embodiment is excluded by a certain claim construction, we may look to extrinsic evidence so long as the extrinsic evidence does not "contradict the meaning otherwise apparent from the intrinsic evidence." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309, 51 U.S.P.Q.2D (BNA) 1161, 1169 (Fed. Cir. 1999).

14 We note that Dr. Lowery's declaration of May 9, 2000 states that the district court's construction actually excludes nine of fifteen preferred embodiment experiments. However, because the district court excluded Dr. Lowery's May 9, 2000 declaration as untimely, we do not rely on it.

15 Sumitomo attempts to rely on Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1310, 51 U.S.P.Q.2D (BNA) 1161, 1169-70 (Fed. Cir. 1999), and argues that forty-two of forty-four uses of a term in a specification were excluded in

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that case. However, Sumitomo misstates the holding of our decision in Pitney Bowes. In that case, we held only that it was acceptable for certain portions of the specification to use a term differently than it was used in the claim. We reasoned that the intrinsic evidence put "the reader on notice that the term 'spot' has different meanings in the written description depending on its context." Pitney Bowes, 182 F.3d at 1311, 51 U.S.P.Q.2D (BNA) at 1170. We did not, as Sumitomo seems to argue, hold that the properly construed term excluded forty-two of forty-four uses of the term in the specification.

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It is axiomatic that "claims, not the specification embodiments, define the scope of protection." American Permahedge, Inc. v. Barcana, Inc., 105 F.3d 1441, 1444, 41 U.S.P.Q.2D (BNA) 1614, 1617 (Fed. Cir. 1997). However, it is also well established that a claim construction that excludes a preferred embodiment is "rarely, if ever, correct." Vitronics, 90 F.3d at 1583, 39 U.S.P.Q.2D (BNA) at 1578 (emphasis added); see also Interactive Gift, 2001 WL 792669 at *19. This is because "it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way." Hoechst Celanese Corp. v. BP Chem. Ltd., 78 F.3d 1575, 1581, 38 U.S.P.Q.2D (BNA) 1126, 1130 (Fed. Cir. 1996).

The claim language calls for the measurement of the boiling point of the codistillate. One of ordinary skill in the art would understand that the ordinary meaning of a codistillate boiling point entails measuring the temperature of the codistillate in the vapor phase. The intrinsic evidence does not reveal that the patentee has given the term an unconventional meaning as ascertained by a reading of the patent documents. Vitronics, 90 F.3d at 1584 n.6, 39 U.S.P.Q.2D (BNA) at 1578 n.6. Therefore, the meaning of the claim limitation is apparent from a review of the intrinsic evidence alone, and it is improper for us to rely on extrinsic evidence other than that used to determine the ordinary meaning. Id. Finally, our construction is bolstered by the fact that the alternative would exclude many of the preferred embodiments.
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Claim 1 of the 356 patent is representative, with emphases added to indicate the terms whose construction is material to the issues of infringement:

1. A low Reid Vapor Pressure 2 liquid gasoline for use in a standard carbureted internal combustion engine; said gasoline comprising a priming agent and a hydrocarbon mixture having an intermediate carbon range relative to C[4]-C[12] fuel; said intermediate carbon range consisting essentially of C[6]-C[10] hydrocarbons with C[9] and C[10] paraffinic hydrocarbons being present in the mixture; said gasoline having a boiling point range of 121 [degreess]-345 [degreess] F at 1 atmosphere pressure; and said priming agent consisting of a hydrocarbon selected from the group consisting of C[4] and C[5] hydrocarbons and mixtures thereof and said priming agent being present in a minimum effective amount for raising the front end volatility of the gasoline to a minimum level for cold engine starting with said minimum effective amount being less than that required for C[4]-C[12] gasoline.

The district court focused on the boiling point range of 121 [degrees] F-345 [degrees] F. The 356 patent explains that 121 [degrees] F is the boiling point of the lowest-boiling C[6] component, 2,2-dimethylbutane (C[6]H[14]), and 345 [degrees] F is the boiling point of decane, C[10]H[22], the highest-boiling C[10] component. The district court construed claim 1 as limited to gasolines having a final boiling point of 345 [degrees] F, and excluding gasolines having a higher final boiling point.

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2 Reid Vapor Pressure is a gasoline's vapor pressure in a sealed container at 100/F.

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Talbert argues that the district court erred in defining 345 [degrees] F as a final boiling point, pointing out that the word "final" does not appear in claim 1. Talbert argues that some higher boiling hydrocarbons can be present, such as C[11] and C[12] hydrocarbons, due to the generally recognized imprecision of the refining process, which does not produce gasolines of specific hydrocarbon composition with precise end points. Talbert explains that refinery distillation produces cuts of

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distillate which may include hydrocarbon components that when pure boil above or below the range of the refinery cut. The 393 patent explains that a refinery stream cut at 345 [degrees] F will contain "a small amount" of hydrocarbons boiling above 345 [degrees] F and having 11-12 carbons.

Talbert states that the claim term "consisting essentially of C[6]-C[10]" recognizes that gasoline in the 121 [degrees] -345 [degrees] F boiling range contains mostly C[6] to C[10] hydrocarbons, but that some hydrocarbons outside that range can be present. Talbert argues that since some hydrocarbons higher than C[10] can be present, they necessarily would raise the final boiling point of the gasoline above 345 [degrees] F. Talbert argues that claim 1 is not limited to gasolines whose final boiling point is 345 [degrees] F because even traces of hydrocarbons above C[10] will raise the final boiling point above 345 [degrees] F, without significantly altering the fuel's performance for standard carbureted engines. Thus Talbert urges that when reading the claim as a whole including its preamble, taking cognizance of the imprecision of refinery methods, a claim construction is required that does not limit the boiling point of the gasoline to 345 [degrees] F.

The basic tools of claim construction are the words of the claim, understood in light of the specification and the prosecution history, in accordance with the usage and knowledge in the field of the invention. A term of technical art, unless defined otherwise, by the patentee, has the meaning by which it would be understood by persons experienced in the field of the invention. See, e.g., Multiform Dessicants v. Medzam, 133 F.3d 1473, 1477, 45 U.S.P.Q.2D (BNA) 1429, 1432 (Fed. Cir. 1998).

The district court, rejecting Talbert's proposed construction, ruled that claim 1 is limited to gasolines whose final boiling point is 345 [degrees] F. In doing so, the district court focused on the "explicit limitation" in the clause "said gasoline having a boiling point range of 121 [degrees] -345 [degrees] F." We agree with the district court that the plain meaning of a boiling point range that is used to define a composition and distinguish it from other compositions is that the range limits the composition to that stated in the claim, and that compositions of a different boiling range are not covered by the claim. While the signal "consisting essentially of" allows for the presence of small amounts of components outside of the designated paraffinic C[6]-C[10] hydrocarbons, the boiling range of 121 [degrees] -345 [degrees] F is designated as describing the entire claimed gasoline. The phrase "consisting essentially of" thus cannot negate the limiting effect of the claimed temperature range of 121 [degrees] -345 [degrees] F, a limitation added in acquiescence to the examiner's requirement for specificity. Thus, Talbert's argument that the recited range does not exclude gasolines with a higher upper temperature is untenable.

During prosecution Talbert stressed that 345 [degrees] F was the "final boiling point" for standard carbureted gasoline as well as for the gasifier gasoline of Talbert's original application. Talbert told the examiner: "Furthermore, it will be noted that applicant's fuel which contains C[9] and C[10] hydrocarbons has a final boiling point of 345 [degrees] which corresponds to the boiling point of C[10] paraffinic hydrocarbon." Although Talbert argues that this statement was not intended to limit the boiling point of the claimed gasoline, but simply to highlight that the newly added description "paraffinic hydrocarbons" was not new matter under 35 U.S.C. § 112, Talbert consistently stated during prosecution that its fuel has a final boiling point of 345 [degrees] F.

Talbert also relied on the 345 [degrees] F upper limit to distinguish various references during prosecution of the 356 application. For example, in discussing Hamilton Patent No. 3,002,917, Talbert stated that "the temperature range of the boiling points of the hydrocarbons of the gasoline of the presently claimed invention is between 96.8 [degrees] and 345 [degrees] F. There is absolutely no suggestion of such a gasoline composition in the Hamilton reference." Talbert also argued that Hamilton "teaches away from [the claimed] fuel by providing for a fraction having a boiling range up to 390 [degrees] F (column 1, lines 42-43). This fraction is not the same as, nor equivalent to, that which is the subject of applicant's composition claims." Talbert also stated that "fuel having hydrocarbon components with boiling points above those claimed" would function in a manner that "completely negates an important characteristic of the composition of the invention." Although Talbert now argues that Hamilton's high-octane aviation gasoline differs in several ways from that of Talbert, and that Talbert was not required to recite all the differences from Hamilton during prosecution, nonetheless Talbert emphasized the difference in boiling point ranges as the distinction on which he premised patentability.

Again, in distinguishing the Schulze 2,409,157 patent, Talbert stressed his "final boiling point of 345 [degrees] which corresponds to the boiling point of C[10] paraffinic hydrocarbon," and also the limitation of the C[9]-C[10] hydrocarbons to paraffinic hydrocarbons. Talbert argues that Schulze is directed to an aviation gasoline containing a high proportion of aromatic hydrocarbons, and that Schulze was distinguished by Talbert's inclusion of the paraffinic limitation in the claims.

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While that is an accurate description of the prosecution, Talbert also emphasized, for Schulze as well as for Hamilton, that 345 [degrees] F marked the upper boiling point of the Talbert claimed gasoline. Even if such a precise limit was not necessary for patentability, as Talbert now argues, it is explicitly stated in the claims. Thus we confirm the district court's conclusion that the upper boiling temperature limit for the gasoline defined in claim 1 is 345 [degrees] F.

Talbert states that this claim construction is incorrect because it is inoperable. We agree that a construction that renders the claimed invention inoperable should be viewed with extreme skepticism. See generally Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557, 37 U.S.P.Q.2D (BNA) 1609, 1617 (Fed. Cir. 1996) ("When claims are amenable to more than one construction, they should when reasonably possible be interpreted so as to preserve their validity."). However, Talbert did not demonstrate inoperability or provide any basis for judicially interpreting the claim to adjust the temperature range that Talbert states is the inoperable limitation.

Talbert also states that the district court's construction of the claim excludes the preferred embodiment. See Hoechst Celanese Corp. v. BP Chem. Ltd., 78 F.3d 1575, 1581, 38 U.S.P.Q.2D (BNA) 1126 (Fed. Cir. 1996) ("it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way"). Again, Talbert has not supported this argument. It does not contradict the specification's teaching that refinery distillations are imprecise, to apply the specification's teaching and the prosecution history's argument that the upper temperature limit of the gasoline is 345 [degrees] F.

We confirm the district court's claim construction. On this construction Talbert conceded that there was not literal infringement; we have been directed to no contradiction of Unocal's statements that its production records show "true boiling point endpoints ranging from 373.8 [degrees] F up to 472.9 [degrees] F."
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As to the '001 patent, the term "bronze" refers to the chemical composition of a particular metal and not how that metal conducts electricity. In the '001 patent, conductivity is only used to describe the central conductor and the bonding agent used in the '001 patent. See United States Patent and Trademark Office's Office action, page 4, May 18, 1993 (Defendant's Markman Brief A0085). The term "bronze" is used, in the '001 patent, to describe the type of metal allowed for use as the metallic braid or the metallic foil. In looking at the prosecution history, "bronze" is not any of the following: plated copper, copper covered steal, plated copper covered steel, copper alloy, or plated copper alloy. The intrinsic evidence of the '001 patent, however, offers little guidance in determining what chemical composition makes a particular substance in the '001 patent a "bronze."

Turning to the initial category of extrinsic evidence, technical treaties, which are "worthy of special note," see Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996), this court will consider the Copper Development Association, Inc. ("CDA")'s handbook on standards for copper and copper alloys. The CDA handbook defines copper, copper alloy, and bronze solely for their chemical composition, and according to the CDA handbook, copper is a metal designated to have a minimum of 99.3% copper content. The CDA defines a high copper alloy as a metal containing less than 99.3% copper, but more than 96% copper, which does not fall into any other copper alloy group. The CDA defines a "bronze" as a particular copper alloy where the major alloying element is more than likely tin and a third element but is not zinc or nickel. CDA Standards Handbook-Wrought and Cast Copper and Copper Alloy Products, Sixth Edition, p. 7 (1994) (Defendant's Brief A0301).

This court declines to use the American Society of Metals ("ASM")'s handbook to define what metal is a "bronze" because the ASM's handbook defines copper, copper alloy, and bronze primarily as to conductivity. The ASM handbook offers very little guidance as to the distinctions between the chemical compositions of copper, copper alloy and bronze.
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On appeal, Belden Wire argues that the district court erred by relying on the CDA Handbook because that handbook states that it does not pertain to cable used for electrical transmission (the pertinent art), it is internally inconsistent, and it

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postdates the patent's filing date. According to Belden Wire, the court should have relied on other extrinsic evidence -- the ASM Handbook; George S. Brady & Henry R. Clauser, Materials Handbook (12th ed.) ("Materials Handbook"); and CDA UK Copper Site, Oct. 23, 2000, available at http://www.edu.com.uk -- sources that classify C162 as a "bronze." Belden Wire also argues that the district court erred in construing the phrases "disposed about" and "bonding said braid and said thin film." Finally, Belden Wire contends that standing to sue is based on ownership of an asserted patent at the time of suit, and since it had standing when the action commenced, the March 13, 2001 assignment gave Belden Wire the right to collect past damages for infringement of the '001 patent.

Cable Design responds that Belden Wire waived any objection to the use of the CDA Handbook by having urged the court to rely on it. Cable Design further asserts that one skilled in the art would appropriately consult the CDA Handbook for guidance concerning a metal braid in a coaxial cable because such a braid would be selected for its mechanical strength, not its electrical conductivity. Cable Design also defends the court's reliance upon the 1994 edition of the CDA Handbook, asserting that earlier editions contained the same relevant content. Cable Design also argues that other extrinsic evidence submitted by Belden Wire is irrelevant. Cable Design further contends that the specification and the prosecution history of the '001 patent support its assertion that the term "bronze" has a meaning distinct from other copper alloys. Finally, Cable Design defends the court's construction of the phrases "disposed about" and "bonding said braid and said thin film" as well as the court's decision not to permit Belden Wire to claim damages incurred during the period when Belden Technologies, not Belden Wire, owned the patent.

The infringement analysis with respect to the "bronze" limitation involves a dispute only as to the first step of the analysis -- claim interpretation. The identity of the material of the metallic braid in the accused cable is not contested. Instead, the parties dispute only whether the term "bronze" includes that material. We agree with Cable Design that it does not. In light of that conclusion, Cable Design's arguments concerning other claim limitations and standing are moot, and we will not address those other arguments. 2

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2 At oral argument, both parties represented that, if we affirm the district court's construction of the term "bronze," its construction of the other limitations and the standing issue are moot.

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To begin, we look to the intrinsic evidence to determine the meaning of the term "bronze," see Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996), and we find that during prosecution Belden Wire clearly surrendered certain materials, including "copper" and "copper alloy," from the scope of what became claim 1, while claim 6 issued listing all three materials: "copper," "copper alloy," and "bronze," '001 patent, col. 4, II. 34-38. 3 Because those terms are potentially overlapping (i.e., a bronze is clearly a copper alloy in the sense that it is an alloy of copper and one or more other metals), their appearance together in the same Markush group is confusing. Belden Wire's cancellation of the term "copper alloy" from what became claim 1 during prosecution compounds the confusion. Under such a circumstance, we will take the patentee at its word and give effect to its surrender during prosecution. "Bronze," at least for purposes of this patent, means something different from "copper alloy." Moreover, because claim 6 lists both the terms "copper alloy" and "bronze," we will assume that, by retaining the term "copper alloy," Belden Wire intended that claim to encompass subject matter other than "bronze."

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3 For reasons not apparent to us, claim 6 is not at issue in this appeal.

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As indicated above, the district court relied on the CDA Handbook to interpret that term. We agree with the district court's conclusion. The CDA Handbook draws distinctions similar to those drawn by the applicant during prosecution of the '001 patent. In particular, the CDA Handbook divides metals containing copper into a number of categories, including "coppers," which have a copper content of at least 99.3%, CDA Handbook at 7; "high copper alloys," which have a copper content between 96% and 99.3%, id.; and "bronzes." Regarding the latter, the CDA Handbook states:

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Broadly speaking, bronzes are copper alloys in which the major alloying element is not zinc or nickel. Originally "bronze" described alloys with tin as the only or principal alloying element. Today, the term is generally used not by itself but with a modifying adjective . . . tin bronzes . . . aluminum bronzes . . . manganese bronzes.

Id. Although the C162 material with its 99.17% copper clearly fits within the CDA's "high copper alloys" category, it might also be within the CDA's "bronzes" category because it is a copper alloy in which the major alloying element (cadmium) is neither zinc nor nickel. However, closer inspection of the handbook reveals that it actually classifies C162 as a "high copper alloy" only, not as a "bronze." The handbook tabulates a large number of wrought metals within each category, listing for each metal its designation number (e.g., "C162" or its equivalent "C16200"), trade name if applicable, and component elements. Id. at 9-18. An entry for C162 appears only once, in a table listing the "high copper alloys," Id. at 10. That entry denotes the trade name "cadmium copper" and a chemical composition of 0.7-1.2% cadmium, 0.02% iron, and the remainder copper. No entry corresponding to the C162 material appears in the tables listing the "bronzes." See id. at 13-16. The CDA Handbook therefore categorizes C162 only as a "high copper alloy," not as a "bronze."

Other extrinsic documents are argued by Belden Wire to support the opposite conclusion. The ASM Handbook refers to a "series of bronzes . . . covered by ASTM B105," including a copper-cadmium alloy designated as "alloy 85," which the referenced ASTM publication equates with C162, Am. Soc'y for Testing & Materials, Designation B 105-94: Std. Spec. for Hard-Drawn Copper Alloy Wires for Elec. Conductors at 1 (2000). The Materials Handbook states, "Copper containing 0.5 to 12.2% cadmium is called cadmium copper or cadmium bronze." Materials Handbook at 127-28. Finally, the CDA UK Copper Web Site also uses the terms "cadmium copper" and "cadmium bronze" to mean copper-cadmium alloys having 0.7-1.3% cadmium.

The district court resolved the uncertainty by relying on the CDA Handbook. Markman Order at 1. The court's opinion discussed only two extrinsic sources, the CDA Handbook and the ASM Handbook, and chose the former because its definitions are solely in terms of chemical composition, whereas the latter's definitions are primarily in terms of conductivity. Id. We agree with the court's reliance on the CDA Handbook, although the most compelling reason for us is that it reflects the parties' positions in the district court. Belden Wire initially embraced the CDA Handbook, apparently believing that C162 fell within the Handbook's definition of "bronzes." Indeed, three experts retained by Belden Wire relied upon the CDA Handbook to support their opinions that C162 was a bronze. Furthermore, in Belden Wire's statement of facts in response to Cable Design's Motion For Partial Summary Judgment, Belden Wire conceded as "uncontested" the following statement: "The Copper Development Association ('CDA') classification scheme for copper, copper alloys, bronzes, and brasses is accepted in the industry." Only after Cable Design pointed out that the CDA Handbook classifies C162 among the "high copper alloys" did Belden Wire retreat from its original position by questioning both the date of the particular edition of the CDA Handbook being cited and relevance of the CDA Handbook to the electrical cable art. We therefore do not accept Belden Wire's newly-crafted interpretation of the term "bronze" which disavows the position it took in the district court.

Although Belden Wire is correct in both stating the rule that claim terms must be construed as of the time when the patent application was filed, Wiener v. NEC Elecs., Inc., 102 F.3d 534, 539, 41 USPQ2d 1023, 1027 (Fed. Cir. 1996), and in noting that the edition of the CDA Handbook published in 1994 followed the '001 patent's filing date by two years, Cable Design introduced evidence that the relevant portions of the handbook have been unchanged since at least 1973. Belden Wire thus failed to demonstrate error based on the date of the particular CDA Handbook edition that was cited by the court.

Belden Wire's second attack on the relevance of the CDA Handbook is based on a disclaimer appearing in the handbook which reads, "The Standards Handbook does not cover wire and cable for electrical transmission and distribution or for other power and electronic applications." Cable Design responds that the metallic braid is chosen primarily for its mechanical strength, not its electrical properties. Belden Wire's point might have been more persuasive if it had taken this position consistently. However, Belden Wire's own experts' reports, experts' testimony, and concession significantly detract from its later position. Considering the evidence as a whole, the district court correctly concluded that the CDA Handbook defines the meaning of the term "bronze" for purposes of the '001 patent.

For the foregoing reasons, we conclude that the district court did not err in interpreting the meaning of the term "bronze" in the '001 patent as excluding the "high copper alloys" defined in the CDA Handbook. Because there is no genuine issue of material fact concerning whether C162 is such a high copper alloy, we affirm the court's grant of summary judgment of

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noninfringement.
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Thus, the issue here is one of claim construction -- the parties dispute the meaning of AstraZeneca's claim term "budesonide composition" and whether that claim term includes the composition containing budesonide described in the '528 Patent. To resolve this dispute, the Court must determine how a person of ordinary skill in the art would understand the claim term. Pfizer, 429 F.3d at 1372-73 ("'[t]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to being claim interpretation") (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998)).

During the hearing, Dr. Williams testified that a person of ordinary skill in the art would understand "budesonide composition" to mean "budesonide dispersed [directly] in a solvent in the form of a solution or suspension." (Tr. May 4, 2009, at 13). Thus, unlike the composition in the '528 patent which involves liposomes, the term "budesonide composition", as defined by Dr. Williams in the context of the '603 patent, does not involve liposomes. The distinction between the budesonide composition of AstraZeneca's '603 patent and the liposome suspension of the '528 Patent is critical. As Dr. Williams explained, in the method taught by the '603 Patent, "the budesonide is provided in immediate contact with the solvent, such that when the budesonide molecules begin to dissolve from these particles, they are available to be absorbed by the airway cells and be conjugated and act as a depot effect." (Id. at 26-27). This "depot effect" is at the heart of AstraZeneca's revolutionary method and it could not occur if the liposomes involved in the '528 Patent were present. Thus, the '528 Patent actually teaches away from the '603 Patent.

Notwithstanding the opposing methods taught by the '603 and '528 patents, Apotex still argues that the budesonide composition of the '603 patent embodies the composition containing budesonide of the '528 patent. In support of their position, they point to Column 3 of the '603 patent, which states that "[s]olutions or suspensions can be encapsulated in liposomes or biodegradable microspheres." ('603 Patent, Col. 3, ln. 38-39). However, as Dr. Williams explained, one mention of the liposome delivery method does not overcome the larger lesson the patent is trying to teach -- i.e., the use of a budesonide composition where the budesonide is dispersed directly in a solvent. (Tr. May 4, 2009 (Williams) at 47) ("I think that even though it's mentioned in column three as solutions or suspensions can be encapsulated in liposomes' biodegradable microspheres, it's one sentence out of the whole patent and I don't' think that this patent in the context of what's being taught really addresses the complexity of administering budesonide either in a liposome or frankly in a biodegradable microsphere. So even though it mentions it, I don't really think it teaches it.").

Finally, the language of the patent itself makes clear that the term "budesonide composition" means "budesonide dispersed in a solvent in the form of a solution or a suspension." Throughout the patent specification, the compositions used in the inventive method are consistently described as being either a suspension or solution of budesonide in a solvent. The SUMMARY OF THE INVENTION describes the budesonide composition as "including 0.05 mg to 15 mg budesonide and a solvent." ('603 Patent, Col. 2, ln. 3-4). The DETAILED DESCRIPTION section also describes the budesonide composition as "budesonide suspended in a solvent" and explains that the budesonide "can be delivered dispersed in a solvent, e.g., in the form of a solution or a suspension." (Id. at Col. 2, ln. 51; Col. 3, ln. 22-23). The patent goes on to define the "solvent" into which the budesonide is dispersed as "an appropriate physiological solution", containing the inactive ingredients, for example, "physiological saline or a buffered solution containing [defined inactive ingredients]." (Id. at Col. 3, ln. 22-25). Moreover, all of the clinical studies described in the EXAMPLES section involved a budesonide composition consisting of budesonide suspended in a solvent. (Id. at Col. 4, ln. 30-col. 10, ln. 7). The EXAMPLES section also describes the solvent as the water and other inactive ingredients in which the budesonide is suspended. (Id. at Col. 5, ln. 3-7; see also Tr., May 4, 2009, at 29 (Williams)).

In sum, the Court agrees with Dr. Williams that the term budesonide composition does not contemplate the involvement of liposomes as described in the '528 Patent; rather, it means "budesonide dispersed in a solvent in the form of a solution or a suspension." Accordingly, the '528 Patent does not anticipate the '603 Patent as it does not disclose each and every element of the claim. 13

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13 Because the '528 Patent does not disclose each and every element of claim 1 of the '603 Patent, there is no need to analyze the remaining dependent claims of the '603 Patent, as they all recite the same "budesonide composition" element.

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B. "BUFFER"

Defendant Bayer disputes the definition of the term "buffer" that is used in claim 1 of the 268 patent. Bayer argues that "buffer," in the context of claim 1 means a solute that maintains the pH of the reaction solution during oxidation. Bayer Br. on Claim Constr. of U.S. Reissue Patent No. 36,268, at 28 ("Bayer Br."). Bayer argues that the plain meaning of buffer is "a dissolved material in a solution that maintains the pH of the solution when acid or base is added." Id. (citing Weber Dep. at 203; Lowe Report PP 8-10). Moreover, in the context of the 268 patent, "there is only one solution involved in the method of the 268 patent -- that created when the oxidant and buffer dissolve in the sample fluid (i.e., are reconstituted)." Id. at 29. Finally, Bayer argues that the prosecution history confirms that the reconstituted solution is the relevant solution because the inventors "explained that the buffer functioned to maintain pH during the reactions in the cell." Id.

In contrast, Roche urges that "buffer" means "a substance or solution capable of resisting a change in pH." Roche Opening Br. on Claim Constr., at 24-25 (citing VAN NOSTRAND REINHOLD, ENCYCLOPEDIA OF CHEMISTRY 149 (4th ed. 1984)) ("Roche Br."). The dictionary definition reads in its entirety:

When acid is added to an aqueous solution, the pH (hydrogen ion concentration) falls. When alkali is added, it rises. If the original solution contains only typical salts without acidic or basic properties, this rise or fall may be very large. There are, however, many other solutions which can receive such additions without a significant change in pH. The solutes responsible for this resistance to change in pH, or the solutions themselves, are known as buffers.

ENCYCLOPEDIA OF CHEMISTRY, at 149. Roche avers that this dictionary definition is part of the prosecution history, therefore, it should provide the basis for the definition of buffer in the context of the 268 patent. Moreover, during the Markman hearing, Roche argued that the claim language and the patent specification do not require that the buffer perform its function during the oxidation reaction; it could buffer any solution referenced in the claims or the specification, including the solution used to apply the reagents to a substrate.

In the context of the 268 patent, the Court finds that "buffer" means a solute that resists a change in pH of the reaction solution. Apparently the term "buffer," as suggested by Roche, was well known to those skilled in the art at the time of the invention to mean a solute capable of resisting a change in pH. See ENCYCLOPEDIA OF CHEMISTRY, at 149 (stating that "the solutes responsible for this resistance to change in pH, or the solutions themselves, are known as buffers"). During prosecution of the 268 patent, the inventors described the function of a buffer similarly:

A concise explanation of the general purpose and mechanism of buffers is disclosed by the Encyclopedia of Chemistry (Van Nostrand Reinhold Co., 1984). Buffers keep the pH of the system in a desired range. This is especially helpful for systems which include enzymes. For example, Claim 16 of the reissue application recites a method which employs enzymes.

Respective enzymes have optimum pH ranges for operation as taught by Biochemica Information, (J. Keesey, ed., Boehringer Mannheim Biochemicals, 1987). Buffer solution is used to maintain the optimum pH during detection of the sample. This achieves a precise and reliable assay.

Defs.' Joint App. at D124. These explanations also confirm that the buffer must perform its function in a solution. But, the only solution referenced in Claim 1 of the 268 patent is the solution in which the buffer and oxidant are reconstituted--the sample where oxidation takes place.

The Court starts with the language of claim 1, in which the word "buffer" appears. Claim 1 requires that the buffer be contained in the measuring cell along with an oxidant. 268 Patent, col. 13, ll. 60-62. The claim also requires that both the

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buffer and the oxidant reconstitute in the sample fluid "to generate a predetermined reaction." Id. col. 13, ll. 64-65. Because the claim requires that the buffer be reconstituted with the oxidant in the sample fluid to generate the oxidation reaction in the cell, it seems clear that the buffer is meant to function during the oxidation reaction.

This interpretation is supported by the 268 patent specification. In the description of the preferred embodiment, the patent states that in experiments run to prove the technology described in the patent, "the electrolyte consisted of a phosphate buffer of pH 6.8 which was about 0.1 molar total phosphate and 0.5M potassium chloride reagent." Id. col. 7, ll. 63-66. In addition, the patent teaches that the reagent layer of the preferred embodiment "imbibes" the sample fluid and has those concentrations of buffer and reagent. Id. col. 7, ll. 29-30 & 47-53. The patent also teaches that the relevant measurement made by the method is the current in the electrolytic solution containing the sample and the reagent. See id. col. 3, ll. 43-47; id. col. 3, ll. 64-67; id. col. 4, ll. 28-31; id. col.6, ll. 31-37; col. 7, ll. 63-67 to col. 8, ll. 1-12; id. col. 11, ll. 11-13. Taken together, these passages identify the buffer as part of the electrolytic solution that contains the sample and the reagent before a potential is applied to measure the current.

Similarly, the disclosure in the specification related to another preferred embodiment for the measurement of cholesterol evidences that the inventors intended for the buffer to perform its function in the solution used to oxidize the cholesterol in the blood sample. For example, the patent states:

Additional examples where CO catalyzes cholesterol oxidation by ferricyanide include a Nocardia source in TRIS buffer with a variety of surfactants . . . . Furthermore, CO from Nocardia will also catalyze substrate oxidation with ferricyanide in phosphate buffer . . . . The buffer concentration is from 0.1 to 0.4 molar.

Id. col. 10, ll. 47-56. See also id. col. 10, ll. 26-29 (describing catalyzation of the oxidation reaction of cholesterol with CO in phosphate buffer); id. col. 10, ll. 36-46 (describing oxidation of cholesterol with cholesterol oxidase in 0.2 molar TRIS buffer, with ferricyanide in TRIS buffer, and with either ferricyanide or benzoquinone in phosphate buffer). Moreover, the patent teaches that for certain catalyst enzymes used in the oxidation of cholesterol, "buffers acceptable for this reaction to occur with the enzyme include phosphate, TRIS, MOPS, MES, HEPES, Tricine, Bicine, ACES, CAPS, and TAPS." Id. col. 11, ll. 1-14.

The prosecution history of the 268 patent confirms that the "buffered" solution in claim 1 is the reaction solution. Claim 1 of the 268 patent is one that appeared in parent application disclosures. See Defs.' Joint App. at A18 (File History of U.S. Patent Application No. 07/168,295, Claim 1); id. at B41 (File History of U. S. Patent No. 5,128,015 ("'015 Patent"), Claim 1, that matured from Application No. 07/322,598, a continuation in part of Application No. 07/168,295). In their reissue application for the 268 patent the inventors stated: "All claims of the original patent require the presence of a buffer and oxidant when the claimed methods are practiced." Id. at D40. Moreover, the inventors stated that "although Applicants do not view [a] buffer as being absolutely required in the invention, the inclusion of [a] buffer is preferred. To include a buffer when practicing the Applicants' invention, the buffer can either be included in the electrochemical cell when a sample to be analyzed is added to the cell, or the buffer can be in the sample being analyzed." Id. at D41. Therefore, the inventors make clear that if a buffer is necessary, it must be in the electrochemical cell during the oxidation reaction. The plain language of claim 1 requires a buffer in the cell; therefore, the buffer "buffers" the solution in which the oxidation reaction occurs.

For these reasons, the Court finds that "buffer" in the context of the 268 patent means a solute that resists a change in pH of the reaction solution.

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"Buffered Composition"

Each of the independent composition claims of the 255 Patent begins with the following language: "A concentrated phosphorous fertilizer comprising a buffered composition . . ." Plaintiffs argue, and this court agrees, despite defendants' arguments to the contrary, that according to the language of the patent claims, the patent prosecution history, and this court's earlier ruling on the preliminary injunction, this language in the 255 Patent claims simply requires that the concentrated composition be buffered. There is no additional requirement that the buffering be provided from any particular source or material in the composition, so long as the resulting composition exhibits the traits of buffering.

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Plaintiffs first argue that no separate buffering agent is required by the 255 Patent. This is so because the term "comprising" as used in patent claims is "inclusive or open ended and does not exclude additional, unrecited elements or method steps" Georgia Pacific Corp, 195 F. 3d 1322 at 1328. Accordingly, plaintiffs' contend that while a separate material (e.g. an organic acid) may provide the buffering, it is not required that it do so.

Conversely, Grow More argues that the 255 Patent specification supports a claim construction requiring a separate buffer. In support of this contention, Grow More directs the court to the following statement in the "Summary of Invention" in the 255 Patent specification:

The above objects and features are accomplished by a concentrated phosphorous fertilizer comprising a buffered composition comprising an organic acid and salts thereof. (Unikel Decl., Exh. E, col. 3, 1. 17-20).

Likewise in the "Detailed Description of the Invention," the 255 Patent specification states:

The phosphorous fertilizers are prepared by first forming solutions of the phosphorous and organic acids. Other nutrient can then be added with constant stirring. The amount of phosphorous relative to organic acid is not critical, as long as appropriate buffering and solubility are achieved." (Unikel Decl., Exh. E, Col 6,1. 23-28).

The parties next direct the court's attention to the prosecution history of the 255 Patent Reexamination. Plaintiffs argue that this confirms that no separate buffering agent is required. Specifically, plaintiffs' direct the court to The Regent's October 18, 1999 response the first Office Action in Reexamination addressing the subject of buffering:

". . . [T]he concentrated phosphorous fertilizer of the subject invention also comprises a buffered composition. This buffered composition can be due, as is exemplified by Example 9 of the subject application, from the formation of salts of phosphorous acid in an incomplete neutralization. However, the preferred embodiment is wherein the buffered composition also includes at least one organic acid or salt, which embodiment is recited in dependent claims 4, 14, 24, 34 and in each of amended claims 49-52." Miller Decl., exhibit B, 21, (underlying in original).

Example 9 of the subject application calls for preparing a mixture containing phosphorous acid, copper hydroxide, ammonia and water. Importantly, according to plaintiffs, is that the mixture of this example does not contain any organic acid that might otherwise provide buffering. They specifically note that the copper hydroxide in this example is insoluble such that it cannot provide any buffering. Instead, plaintiff's claim the only buffering in this example is provided by the phosphite salts themselves, created from phosphorous acid material.

In its response, The Regents also pointed out that the preferred embodiment also included at least one organic acid as reflected in dependent claims 4, 14, 24, 34 and 49-52, clearly illustrating the difference between such dependent claims and the subject base claims which did not include the organic acid buffer. After that response containing this statement was filed, the patent examiner allowed all of the claims, noting that:

". . . Claims 1, 2, 4-12, 24-32, 34-53 are patentable since these claims all require a concentration of phosphorous-containing acids or salts thereof in an amount of about 30 to about 40 weight percent, and also require that this concentrated composition be buffered. While Robertson and Boyer begin with concentrated compositions, these concentrated compositions are not buffered. Instead, they are taught as first being diluted to 0.1 molar stock solutions, and only then are formed as buffered solutions. There is no teaching, disclosure or suggestion in the article by Robertson and Boyer to provide a concentrated (i.e. about 30 weight percent to about 40 weight percent) phosphite solution which is also buffered. Nor would there be any motivation from the prior art to do so." (Miller Decl., exhibit B, p. 28.) (Underlying in original).

"The presumption of patent validity under 35 U.S.C. § 282 carries with it a presumption that the examiner did his duty and knew what claims he was allowing." Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989). Thus, according to plaintiffs, the statements in the patent file history and example 9 of the patent specification support the interpretation that "buffered composition" in the 255 Patent claims does not require any separate buffering agent.

In opposition, Grow More notes that during reexamination, The Regents amended the Key claims after they were rejected

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by the patent examiner. In arguing for the patentability of the Key Claims over the prior art and to overcome the patent examiner's rejection, The Regents stated:

"Finally, there is no teaching in the cited art in which a concentrated phosphorous composition comprising at least one phosphorous-containing acid or salt thereof further includes at least one organic acid or salt thereof. The presence of such an organic acid or salt is in an amount sufficient to provide buffering function and to result in an ability to formulate various combinations of other essential plant nutrients or other inorganic compound, as desired, while still maintaining solubility." (Unikel Decl., Eh. A, at A71.

Additionally, Grow More disputes plaintiffs' contention that example 9 does not include a separate buffering agent. Grow More relies on the September 28, 2001 Declaration of Dr. Farone, P 8 which states:

C. I have reviewed Dr. Grech's statements regarding Example 9 in the specification of the 255 Patent. I disagree with Dr. Grech's statement that the "only buffering provided in the formulation of this example is from the phosphites created from the phosphorous acid" for the following reasons:

i. A buffer solution is one that resists changes in pH and is usually composed of a conjugate acid-based mixture. [citation omitted]

ii. NH[4]+ and NH[3] are conjugate acid-base pair.

iii. Based on the foregoing, in my opinion the NH[4]OH in Example 9 of the specification of the 255 Patent acts as a separate buffering agent and is available to provide buffering for the resulting fertilizer.

D. All nine examples in the specification of the 255 patent include a separate buffering agent.

Finally, plaintiffs argue that this court's October 24, 2000 ruling granting Biagro's motion for preliminary injunction is consistent with plaintiffs' interpretation. In the October 24th Order, this court found that the claims of the 255 Patent required three elements: (1) a buffer, (2) a phosphorous containing acid or salt thereof, and (3) dilution in water with a pH range of 6.5 to 8.5. Order at 16:24-25. Plaintiffs note that nowhere in the decision did this court state that the buffer must be separate from the phosphorous-containing acid or salt. In fact this court states:

"With respect to the buffer, it is clear from the specification that a number of acids and their salts may be used as buffers. The claims do not limit the type of buffer although the specification recommends the use of an organic acid and its salt as a buffer." Order at 17:1-5.

This court finds that according to the language of the patent claims, the patent prosecution history, and this court's earlier ruling on the preliminary injunction, the 255 Patent claims simply require that the concentrated composition be buffered. The buffering itself need not be provided by a separate agent.

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4. "Bulk Density"

The final claim term at issue goes to the heart of the invention disclosed in the patents-in-suit. The '665 patent teaches that "the bulk density of calcium acetate varies according to its source. Bulk density is the density, typically of a solid, as poured or passively filled into a measurement device." '665 patent, Col. 1, l. 65 - Col. 2, l. 1.

Claim 1 discloses that the invention is achieved by

the calcium acetate having a bulk density of between about 0.55 kg/L and about 0.75 kg/L, and where the quantity of calcium acetate is compressed to form a caplet for fitting within a capsule . . . .

'665 patent, Col. 5, ll. 36-39. While Paddock argues that the term is indefinite and incapable of construction, Amneal argues

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that the term must be construed as referring only to a quantity of calcium acetate that has not been modified by any "excipient(s) such as fillers, dispersants, lubricants and the like." Amneal's Post-Hr'g Mem. at 1. Fresenius rejects such a limitation, and argues that the term simply refers to the bulk density of the calcium acetate composition "immediately before compression." Fresenius's Post-Hr'g Mem. at 2.

The express language of the '665 patent could not be clearer in its support of Fresenius's proffered construction. It states, in referring to the calcium acetate composition, that

[a]dditional excipients, fillers, dispersants, lubricants and the like may be added to the composition of the present invention to improve its manufacture, and such modifications will be recognized as being within the[] spirit and the scope of the present invention.

'665 patent, Col. 5, ll. 24-28.

The court therefore construes bulk density as

the mass-to-volume ratio of the calcium acetate composition immediately prior to compression, as measured by one of two methods set forth in the patent specifications.

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After preliminary claim construction briefing, the parties agree that the only term necessary for the court to construe is "bulk volume." As an example, claim 14 of the '694 patent states:

14. A method for making expanded graphite from lamellar graphite comprising:

a) providing lamellar graphite particles having at least a minimal purity;

b) intercalating the lamellar graphite particles with an expandable graphite intercalation method;

c) expanding the graphite intercalation compound to exfoliate the graphite particles; and

d) air milling the exfoliated graphite particles to further delaminate them to create an exfoliated graphite product having a surface area to mass ratio of at least 18 m2/g and a bulk volume of at least 20 ml/g.

II. Analysis

Claim construction is a question of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). The Federal Circuit sitting en banc recently clarified the appropriate methodology for a court to use when performing claim construction. Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc). The words of the claims in a patent are to be given the ordinary and customary meaning that would have been attributed to them by a person of ordinary skill in the art at the time the invention was made. Id. at 1312-13. The person of ordinary skill in the art is deemed to have read the term in the context of entire patent, including the claims themselves, the specification, and the prosecution history. Id. at 1313. The claims, specification, and prosecution history are so-called intrinsic evidence.

Extrinsic evidence is everything "external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. at 1317. Review of technical dictionaries and treatises can be helpful to the court in understanding the technology of the invention and can assist the court in determining the meaning of terms to those of skill in the art of the invention. Id. at 1318. Where extrinsic evidence conflicts with the intrinsic evidence of the patent, however, the intrinsic evidence controls. Id.

Like claim construction, claim indefiniteness is a question of law. Marley Mouldings Ltd. v. Mikron Industries, Inc., 417 F.3d 1356, 1359 (Fed. Cir. 2005). "A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342,

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1347 (Fed. Cir. 2005) (quoting Personalized Media Communications., L.L.C. v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998)).

The requirement that claim language be sufficiently definite arises from 35 U.S.C. § 112 P 2 which states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." If a person of ordinary skill in the art can reasonably understand the claim when read in light of the specification, the claim is not indefinite. Marley Mouldings, 417 F.3d at 1359 ("The statute is satisfied if a person skilled in the field of the invention would reasonably understand the claim when read in the context of the specification."). "When a claim 'is not insolubly ambiguous, it is not invalid for indefiniteness.'" Id. at 1361 (quoting Bancorp Servs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1372 (Fed. Cir. 2004)). The Federal Circuit has recently emphasized that the court must keep in mind the presumption of validity when determining whether a claim in invalid for indefiniteness:

In this regard it is important to note that an issued patent is entitled to a statutory presumption of validity. See 35 U.S.C. § 282 (2000). "By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of validity and we protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal." Exxon Research & Eng'g v. U.S., 265 F.3d 1371, 1375 (Fed. Cir. 2001) (citation omitted). In this way we also follow the requirement that clear and convincing evidence be shown to invalidate a patent. See Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376 (Fed. Cir. 2001).

Datamize, 417 F.3d at 1347-48.

Timcal argues that the term "bulk volume" as used in the '694 patent is indefinite, rendering the claims invalid, because the patent does not specify the method used to measure bulk volume. According to Timcal, the calculation of bulk volume depends on the method used to determine it, and because no method of measuring bulk density is specified in the patent, the term is devoid of meaning. Thus, Timcal argues that the claims of the '694 patent which include a bulk volume limitation are indefinite. In order to be sufficiently definite, Timcal argues, the patent would need to specify: (1) whether it refers to "loose bulk density," "tapped bulk density," or "packed bulk density"; and (2) the precise procedures for measuring the bulk density such as the type of measuring instrument and the method of adding material to that instrument among other things.

Superior argues that, although no method of measuring bulk density is provided in the patent itself, a person of ordinary skill in the art would understand how to measure it. Superior argues that "bulk density" has a recognized meaning in the graphite processing industry: loose bulk density measured using the Scott volumeter. 1

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1 In its initial claim construction contention, Superior proposed a broader definition of bulk volume, "the physical measurement of the volume to unit mass ratio of the air milled graphite which physical property is the mathematical inverse of the measured bulk density (mass to unit volume ratio) value." In response to Timcal's contention that the term is indefinite, Superior provided a narrower construction, loose bulk density measured using the Scott volumeter. Since the dispute in this case involves the view of one of ordinary skill in the art, the court finds that it is appropriate to consider Superior's narrower proposed construction.

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A. Intrinsic Evidence

If a claim term is unambiguous after reviewing the intrinsic evidence (i.e., the claims, the specification, and the prosecution history of the patent), the court need not consider extrinsic evidence, such as the expert declarations submitted by the parties. Intel Corp. v. VIA Technologies, Inc., 319 F.3d 1357, 1367 (Fed. Cir. 2003) (holding that if a claim not indefinite after construed it in light of the intrinsic evidence, "reference to extrinsic evidence is improper"). Thus, the court will first review the claims, specification, and prosecution history of the '694 patent.

In this case, at least to a lay person, the intrinsic evidence provides little guidance as to the meaning of "bulk volume." The claims themselves indicate that bulk volume is a ratio of volume per unit mass (or more specifically ml/g). The specification

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indicates that bulk volume is the inverse of bulk density. '694 Patent, Col. 4, 11. 2-3 ("a bulk volume of approximately 20 ml/g (or a bulk density of 0.050 g/cc"). 2 The prosecution history provides little additional information, except that the bulk density as used in the '694 patent is not the "true density." See Ex. B, Tab 18 to Timcal's Preliminary Claim Construction Contentions.

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2 The inverse of 20 ml/g is 0.050 g/cc, as a ml is the equivalent of a cc and 0.050 equals 1/20.

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Based on the intrinsic evidence, the parties agree that "bulk volume" is the mathematical inverse of bulk density. The intrinsic evidence, however, does not indicate the method of measuring bulk density.
B. Person of Ordinary Skill in the Art

Since the intrinsic evidence does not resolve the issue, the court must review the extrinsic evidence submitted by the parties to determine whether the failure to specify a method for determining bulk volume renders the claims indefinite. The court views this evidence to determine how a person of ordinary skill in the art would have interpreted this term. In doing so, it is helpful to determine the description of a person of ordinary skill in the art.

Timcal states that a person of ordinary skill in the art has at least a four-year college degree in a field that is related to graphite or its uses and has at least four years of experience working with graphite. Alternatively, Timcal states that a person can possess ordinary skill if he does not have a four-year degree but has a combination of equivalent education and experience. Timcal's Response at 4 n.6. Superior simply states that a person of ordinary skill in the art is a person experienced in the field of processing graphite through education, experience, or both. Superior's Response at 4. Since the parties' definitions are consistent for the most part and the court agrees with them, the court need not comment further on the qualifications of a person of ordinary skill except to note that, since the '694 patent relates to processing graphite, some experience or knowledge as to graphite processing is necessary to be a person of ordinary skill in the art. That having been said, since Timcal has the burden to prove indefiniteness by clear and convincing evidence, the court will review Timcal's evidence first.

C. Extrinsic Evidence Upon Which Timcal Relies

Timcal argues that the term "bulk volume" is devoid of meaning without reference to the method of measuring it. In support of its argument, Timcal relies on the declaration of Dr. John Fischer ("Dr. Fischer"). Ex. L to Timcal's Response. Dr. Fischer has a doctorate degree in nuclear science and engineering and is currently a professor of materials science and engineering at the University of Pennsylvania. Dr. Fischer declared that Superior's proposed definition for "bulk volume" could include both loose bulk volume and tapped bulk volume. After reviewing the intrinsic evidence of the '694 patent, Dr. Fischer concluded that nothing in it informed those of skill in the art as to which was intended.

Dr. Fischer relied in part on the Patent Application No. 09/213,544 ("the '544 application"). Ex. D to Timcal's Preliminary Claim Construction Contentions. As part of that application, the applicant included a table which showed testing data for various samples and reported, among other properties, the Scott density (g/cm3), bulk volume (g/cm3), and tap density (g/cm3). 3 Dr. Fischer declared that the bulk volume measurement reported in the '544 application is significantly different from the tap density reported. Other than the '544 application, Dr. Fischer reviewed only the intrinsic evidence of the '694 patent in making his declaration.

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3 It is curious that this application used the same units of measure for bulk volume and tap density. Bulk volume should have been the inverse.

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Timcal relies on several ASTM standards to show that "numerous other detailed standards [besides the Scott method] also

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exist for how to measure specific types of 'bulk volume/bulk density' of carbon and graphite materials." Timcal's Response at 9 (citing its Ex. O). Dr. Fischer did not reference any of these standards in his declaration, and thus Timcal has not provided any evidence that these standards are used to measure bulk density in the field of the '694 patent.

A review of the specification of the '694 patent and the ASTM procedures cited by Timcal shows that it is unlikely that any of these standards apply to testing the type of product disclosed in the '694 patent. First, some of the standards are directed toward testing metal powders. See ASTM Standard B703-05, Standard Test Method for Apparent Density of Powders Using Arnold Meter, at 1 n. 1 ("This test method is under the jurisdiction of ASTM Committee B09 on Metal Powders and Metal Powder Products and is the direct responsibility of Subcommittee B09.02 on Base Metal Powders."); ASTM Standard B527-93, Standard Test Method for Determination of Tap Density of Metallic Powders and Compounds (emphasis added). It is well-known, however, that carbon (and therefore graphite) is nonmetallic. See Webster's Ninth New Collegiate Dictionary 206 (1985) (defining carbon as "a nonmetallic chiefly tetravalent element . . ."); Phillips, 415 F.3d at 1314 ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful.") (citation omitted). While the court recognizes the possibility that graphite (despite its technical classification as a nonmetal) might be used in some powder metallurgy applications, Timcal has provided no evidence that the product of the claimed process in the '694 patent could be so used.

Other ASTM standards cited by Timcal require a particle size that is inconsistent with the disclosure of the '694 patent. ASTM Standard D2854-96, Standard Test Method for Apparent Density of Activated Carbon states: "This test method covers the determination of the apparent density of granular activated carbon. For the purposes of this test method, granulated activated carbon is defined as a minimum of 90% being larger than 80 mesh." Eighty mesh corresponds to a 177 micron opening. Perry's Chemical Engineers' Handbook 21-15 Tbl.21-6 (6th ed. 1984). Yet the '694 patent teaches that after air milling, the product has a preferred mean particle size of 30 microns. See '694 patent, col. 3, 11 30-31. A person of ordinary skill in the art would not believe that bulk density should be measured by a procedure used for particles more than six times the preferred size disclosed in the patent, particularly when the patent teaches that the method results in product with a high surface area to mass ratio. See '694 patent, col. 1, 11 14-15. The same holds true for ASTM Standard C357-94, Standard Test Method for Bulk Density of Granular Refractory Materials, which states: "This test method covers a procedure for determining the bulk density of granular refractory materials, commercial products which usually have particles that are retained on a 0.265-in. (6.7 mm) or coarser sieve." That size sieve corresponds to 6730 microns, over 200 times larger than the preferred particle size disclosed in the patent. Perry's Chemical Engineers' Handbook 21-15 Tbl. 21-6.

The remaining standards cited by Timcal appear to apply to products different from the claimed invention. ASTM Standard C1039-85, Standard Test Methods for Apparent Porosity, Apparent Specific Gravity, and Bulk Density of Graphite Electrodes, at 1 ("These test methods cover the determination of . . . bulk density of cores taken from graphite electrodes manufactured for use in electric arc furnaces."); ASTM Standard C914-95, Standard Test Method for Bulk Density and Volume of Solid Refractories by Wax Immersion; ASTM Standard C838-96, Standard Test Method for Bulk Density of As-Manufactured Carbon and Graphite Shapes (emphasis added). In short, while the ASTM standards cited by Timcal show that there are multiple methods of determining bulk density, they do not show that there are multiple methods of determining bulk density in the field of the invention of the '694 patent.

The only remaining evidence provided by Timcal relates to the Scott method for determining bulk volume. This evidence includes: Superior's internal procedure which uses a Scott volumeter, Ex. I to Timcal's Preliminary Claim Construction Contentions; Superior's customer Eveready used the Scott method in testing Superior's product, Id. at Ex. E; ASTM has a standard test method (albeit for metal powders) for testing apparent density using a Scott volumeter, Id. at Ex. M, N. Therefore, the only credible evidence that Timcal has provided to support its indefiniteness argument is Dr. Fischer's declaration in which he states that a person of ordinary skill in the art cannot tell whether the patent refers to loose bulk density or tap bulk density.

C. Extrinsic Evidence Upon Which Superior Relies

Superior argues that a person of ordinary skill in the art would read bulk density as loose bulk density measured using a Scott volumeter. In support of this position, Superior relies on an industry standard publication and two declarations. First, Superior relies on the National Electrical Manufacturers Association ("NEMA") Standards Publication CG 2-1196,

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Powdered Graphite. NEMA Pub. CG 2-1196, Ex. 13 to Superior's Responsive Claim Construction Brief. The publication states: "This Standard covers terminology and test methods for those physical properties and chemical properties relevant to the material characterization of powdered graphite, generally less than 75 microns, used in the electrical industry." Id. at 1. It defines bulk density as "Apparent density. The mass, under specified conditions, of a unit volume of a powder including its pore volume and inter-particle voids." Id. at 2. The publication includes a method for determining "bulk density" using the "Scott volume method," and separate methods for determining "compressed density" and "tap density." Id. at 6, 9. Unlike the ASTM standards cited by Timcal, the NEMA standard applies to powder graphite of the particle size taught in the '694 patent.

Superior next cites to the declaration of Sim Henry ("Henry"), who worked in the graphite processing industry for twelve years. Henry declared that, as General Manager at Dixon Southwestern Graphite, he was responsible for International Standards Organization ("ISO") 9000 certification for the graphite processing plant. That process required the plant to maintain quality assurance procedures, including testing for bulk density. Based on his experiences in the graphite processing industry, Henry declared that he and others of ordinary skill would equate bulk density as used in the '694 patent to Scott density, that is, loose bulk density measured using a Scott volume machine. He declared that this density would be measured after the graphite had been air milled, and that, if the power had settled prior to testing, it would be reconditioned to its just-processed state by fluffing. He declared that if a tapped density measurement was intended, the word "tap" or "tapped" would expressly be used. Henry did not refer to any evidence other than his own experience and the '694 patent in making his declaration.

Finally, Superior provided the declaration of David Derwin ("Derwin"), one of the named inventors of the '694 patent. Derwin has been at Superior for over 30 years. He is currently a group leader in Superior's graphite technology area. Derwin declared that persons of skill in this art area would interpret "bulk density" as used in the '694 patent to be the loose density of the product immediately after processing and would have equated "bulk density" to the Scott density. Derwin declared that Superior's internal method for determining bulk volume is equivalent to the method described in the NEMA publication. Finally, Derwin declared that although differences in the procedure used to measure the bulk density could cause the results to vary (as they did when Eveready tested a Superior product using a different size screen and a plastic scoop instead of a paint brush), the variance did not affect whether the product fell within the scope of the claims of the '694 patent. Derwin relied on his own experience, the NEMA standard, and Superior's in-house procedure for measuring bulk density in making his declaration.

D. Analysis of the Extrinsic Evidence

Because Superior's patent is presumed valid, Timcal has the burden of proof to show that bulk density (and thereby bulk volume) is not amenable to construction. Timcal has not met that burden.

Honeywell International, Inc. v. International Trade Commission, 341 F.3d 1332 (Fed. Cir. 2003), relied upon by Timcal, is instructive in reviewing Timcal's arguments that the term"bulk volume" is indefinite. In Honeywell, the patent-in-suit was for a polyethylene terephthalate ("PET") yarn used as reinforcement in automobile tires. Id. at 1334. The claims required a specific melting point elevation ("MPE") of the yarn produced by the claimed process. Id. at 1335. The written description did not disclose the method of preparing the PET yarn specimen for testing, although four methods of preparing a sample were known to those of skill in the art at the time of the invention. Id. at 1336. The sample preparation method selected mattered a great deal; only one of the four methods resulted in the accused product falling into the MPE range claimed. Id.

The Federal Circuit reviewed whether "MPE" could be construed as "any one method," "all methods," or "the ball method," the method used by the patentee. Id. at 1339. First, the court rejected the patentee's proposed construction of the ball method, the only method that resulted in infringement, because the other three methods were well-documented in publications and prior art and because the ball method, although perhaps known, was unpublished. Id. at 1340-41. Next, the court reviewed the "any one method" construction under which the claims would be satisfied if the MPE fell within the claimed range using any one of the four methods. Id. at 1339. The court rejected this approach because the sample would fall into or out of the claimed range depending on the method chosen, and the court held that such a construction would not give competitors sufficient notice of the scope of the claims. Id. at 1341. Finally, the court rejected the "all methods" construction, under which the accused product would infringe only if it fell within the claimed range when tested using all four methods, because such a construction would render the invention inoperable. Id. at 1339, 1341.

As will be discussed below, the instant case is distinguishable from Honeywell. Timcal has made two arguments that the

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term "bulk volume" is indefinite: (1) the term "bulk volume" could refer to either tap bulk volume or loose bulk volume, and (2) Timcal did not specify the precise equipment for measuring bulk volume.

1. Loose or Tap Density

Timcal argues that there are two recognized methods of determining bulk density: tap bulk density and loose bulk density. 4 Tap density is measured after tapping a container of powder; tapping causes the powder to settle and results in a higher density. See Ex. 13 to Superior's Response. In the NEMA procedure for tap density, the density is measured after tapping" for a one-minute period or until no further decrease of the volume of the powder takes place," whereas the NEMA procedure for bulk density requires a person to "avoid any jarring or vibration that can compact the powder." Id. at 7, 11. Timcal relies on sample results provided in the '544 application, which show that testing of samples of graphite powder would have a bulk volume of at least 20 ml/g when measured using a loose bulk volume test but would have a significantly lower bulk volume when measured using the tap test. Ex. D to Timcal's Preliminary Claim Construction Contentions, at Fig. 4. These results show that the tap density can be more than three times greater than the bulk density. Id. Because of the wide variation in result between tap and loose bulk density, if a competitor used one test, it might believe its product was infringing, but if the competitor used the other test, it might believe the product was not infringing. Based on this, the court agrees that if Timcal is correct that a person of ordinary skill in the art could not discern whether the claims refer to loose bulk density or tap bulk density, the claims would be indefinite.

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4 Timcal also mentions other types of bulk density measurements in its briefs such as packed bulk density. Since Timcal's expert, Dr. Fischer, opined only about tap and loose bulk density in any detail, the court considers these two types of bulk density measurements.

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In support of its position, Timcal relies on its expert, Dr. Fischer, who declared that Superior's proposed definition in its Preliminary Claim Construction Brief would encompass both loose and tapped bulk density, that the intrinsic evidence of the patent does not indicate which method to use, and that given the variation of values of loose and tapped bulk density and the lack of guidance in the intrinsic evidence of the patent, one of ordinary skill in the art could not determine whether a product met the bulk volume limitation of the claims of the '694 patent. Dr. Fischer relied only on the '544 application (Ex. D to Timcal's Preliminary Claim Construction Contentions), the intrinsic record of the patent, and his knowledge. The court notes that while Dr. Fischer has impressive academic credentials, his level of practical experience with the type of process and product disclosed in the '694 patent is unclear.

On the other hand, Superior relies on the declarations of Henry and Derwin, one of the named inventors. Both declared that a person of ordinary skill in the art would have equated bulk density as used in the '694 patent with a loose density measured using a Scott volumeter and that a person of ordinary skill in the art would not have understood bulk density to refer to tap density unless the word "tap" or "tapped" was explicitly used. Ex. 11 to Superior's Response at 3-5; Ex. 12 to Superior's Response at 3, 6.

The Federal Circuit has held that "it is particularly inappropriate to consider inventor testimony obtained in the context of litigation in assessing validity under section 112, paragraph 2, in view of the absence of probative value of such testimony." Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379 (Fed. Cir. 2000) (holding that the inventor's deposition testimony could not be used to invalidate the patent claims). Thus, the court finds that Derwin's declaration is of little, if any, probative value in determining whether the claims are definite.

Henry, however, has significant experience in materials testing in a graphite processing plant. His declaration, although based primarily on his own experience working in the field, is consistent with the NEMA publication that referred to loose bulk density only as bulk density and provided a separate procedure for tap density. Because the court finds both the NEMA publication and Henry's declaration persuasive, it holds that a person of ordinary skill in the art would read the term "bulk density" as referring to loose bulk density only.

2. Equipment for Measuring Bulk Volume

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Timcal also argues that the term "bulk volume" is indefinite because the patent does not disclose the precise equipment used for measuring it. Specifically, Timcal relies on data from tests performed by Superior and Eveready. These data showed that when measuring loose bulk density using a Scott volumeter, variables in measurement technique such as type of sieve and brush make a difference in the result. Timcal, however, has not provided any evidence that any such differences are determinative of infringement. The tests performed by both Superior and Eveready resulted in a bulk volume of at least 20 ml/g as required by the claims of the '694 patent. Ex. E to Timcal's Preliminary Claim Construction Contentions.

Additionally, the variations in the test results between Superior's tests and Eveready's tests occurred because Eveready used a scoop instead of a paint brush to push the material through the screen and because Eveready used a size 18 mesh screen instead of a size 35-40 mesh screen. The ASTM method cited by Timcal requires a 16 mesh screen and a one-inch wide nylon brush. Ex. M to Timcal's Response. The NEMA standard uses a one-or two-inch wide paint brush and does not specify the size of the screen. Ex. 13 to Superior's Response. Thus, there is no evidence that it is acceptable in the industry to use a scoop instead of a brush to move the powder across the screen and into the volumeter. While it may be acceptable to use various size screens to measure bulk density using a Scott volumeter, there is no evidence as to how much of the difference in results between Superior's method and Eveready's method was attributable to the scoop and how much was attributable to the screen. In any event, since all of the results fell within the scope of the bulk volume required by the patent claims, the court finds that Superior's failure to specify the precise equipment used to test bulk density does not render the term "bulk volume" indefinite.

Since the term "bulk volume" is not "insolubly ambiguous" and can properly be given a narrowing construction, the court holds that the term "bulk volume" as used in the '694 patent is not indefinite. As part of this determination, the court reiterates that the patent is entitled to a presumption of validity and Timcal had the burden to show by clear and convincing evidence that the term "bulk volume" as used in the '694 patent is indefinite. After reviewing all of the evidence in detail, Timcal has not met that burden.

Thus, the court construes "bulk volume" as the mathematical inverse of bulk density, and "bulk density" as the mass of a unit volume of graphite powder including its pore volume and inter-particle voids, measured in its loose state using a Scott volumeter. Unlike the proposed construction in Honeywell which would have limited the claim scope to one method even though there were four known methods, this construction does not improperly redraft the claims because a person of ordinary skill in the art would find that bulk density as used in the '694 patent refers only to one method of testing, loose bulk density using a Scott volumeter. See Honeywell, 341 F.3d at 1341.

III. Conclusion

For the foregoing reasons, the term "bulk volume" as used in the '694 patent is amenable to construction and is not indefinite. The court construes "bulk volume" as the mathematical inverse of bulk density, and "bulk density" as the mass of a unit volume of a powder including its pore volume and inter-particle voids, measured in its loose state using a Scott volumeter.
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A. "Burning a Smoking Material at 250 [degrees] to 400 [degrees] C"

TPI first requests that "burning a smoking material at 250 [degrees] to 400 [degrees] C" be interpreted as claiming "the production of smoke at a beneficial temperature through the burning of a smoking material unless such smoking material cannot produce any smoke at temperatures of 400 [degrees] C or less, or the equivalent thereof." (TPI Brief 41.) In particular, TPI argues that this claimed temperature range of 250 [degrees] to 400 [degrees] C pertains to the temperature of the smoking material itself. It contends that any given material can "burn" only at one specific temperature, just as the only temperature at which water boils is 100 [degrees] C. The specific burning temperature of wood, according to TPI's expert testimony and treatises, varies from 200 [degrees] to 500 [degrees] C depending on the type of wood or wood product. TPI contends that adopting its proposed construction would mean that "unless a smoking material was used that did not combust or smoke at 400 [degrees] C or less, the resulting gas produced would contain, at least in part, gas produced that literally infringes the Yamaoka claim range." (TPI Brief 16).

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HISI, on the other hand, argues that the phrase "burning a smoking material at 250 [degrees] to 400 [degrees]" means that the smoking material is to be burned in a medium heated to between 250 [degrees] and 400 [degrees]. They base their arguments on the syntax of the claim, the language of the specifications, the prior statements of TPI officers, and expert testimony on the practice and feasibility of measuring the temperature of smoke-producing materials.

The Court will first examine the language and syntax of the claim itself. See Eastman Kodak, 114 F.3d at 1552. Here, the syntax of the claims indicates that the 250 [degrees] to 400 [degrees] temperature range likely refers to the temperature of the medium, not the temperature of the material. In Eastman Kodak, the Federal Circuit held that where the word "at" modified the transitive verbs "crystallizing," "polycondensing," and "passing" in a process patent, it "refer[red] to the process temperature of the heating medium, rather than the temperature of the polymer itself." 114 F.3d at 1553; see also Chef America, 358 F.3d at 1374 (distinguishing between "heating to" a certain temperature and "heating at" a certain temperature). This is very similar to the case here, where "at" modifies the transitive verb "burning," and instructs the person doing the burning to perform the process in a particular way, namely at 250 [degrees] to 400 [degrees] C.

The Court recognizes, however, that just as in Eastman Kodak, "[t]he claim language alone . . . does not settle the claim interpretation issue." 114 F.3d at 1554. The interpretation proposed by TPI, while less likely than HISI's interpretation, is not implausible. Thus, the Court turns to the specifications of the patent for additional guidance.

Unfortunately, the specifications of the Yamaoka Patent are also ambiguous. Some of the language in the specifications seems to confirm HISI's position that the stated temperature range refers to the temperature of the medium and not the material. The description of the preferred embodiment of the patent, for example, describes how "[a] temperature sensor-controller is fitted to the smoke generating chamber to direct and control the temperature therein." (Yamaoka Patent, Col. 5, at 17-20). This indicates that it is the temperature of the smoke generating chamber that is to be controlled, not the temperature of the smoking material itself.

At the same time, however, the specifications also state that the "thermostat-controlled heater" installed on the bottom of the combustion chamber "controls the production of smoke by measuring the combustion temperature." (Yamaoka Patent, Col. 4, at 21-24). Given the location of the heater directly beneath the smoking material and the phrase "combustion temperature," this specification seems to indicate that it is the temperature of the smoking material, and not the temperature of the medium, that is to be regulated by the Yamaoka Patent. Other language in the specifications is unhelpful, and can be read to support either of these two interpretations.

Because some ambiguity still remains after examining the intrinsic evidence, the Court will now turn to the extrinsic evidence for additional guidance. The extrinsic evidence in this case proves decisive. It shows (1) that people of ordinary skill in the art believed that the Yamaoka patent's temperature range referred to the temperature of the medium, not the material; and (2) that the temperature of the smoking material is not typically measured, nor is it easy to do so. Given this unrefuted evidence, the Court concludes that the 250 [degrees] to 400 [degrees] C temperature limitation of the Yamaoka Patent refers to the temperature of the medium, not the temperature of the smoking material.

First, TPI officers' own past interpretation of the claim language indicates that people of ordinary skill in the art interpreted the Yamaoka patent's claimed temperature range as referring to the temperature of the heating apparatus rather than the temperature of the smoking material. While attempting to obtain patent insurance in 2000, Richard Friend, Vice President of TPI, and someone with years of experience in the industry, stated in reference to "the Yamaoka smoke machine" that the "problem with the original design was that it took a long period of time to reach the desired temperature" and that "[a] system that . . . could combust wood at a constant high temperature was strongly desired." (HISI Am. Opp., Ex. 8). The "desired temperature" is not the temperature of the smoking material, but the temperature of the smoke machine itself.

Similarly, in a 2003 letter urging the Philippines Bureau of Patents to reject Kowalski's patent application, Friend stated that this new machine "enabled commercialization of the Yamaoka patent[] . . . by applying heat at high temperatures (360 [degrees]-400 [degrees]C) to thermally decompose the sawdust and thereby generate smoke." (Defs.' Ex. 10.) Again, the temperature that Friend emphasizes here as a unique feature of the Yamaoka Patent is not the temperature of the combustion itself, but the temperature that the device is "applying" to that smoking material. These statements show that at least one person skilled in the art actually believed that the temperatures referenced in the Yamaoka process referred to the temperatures of the combustion chamber, and not the temperature of the wood or sawdust.

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Second, HISI provides expert testimony that measuring the temperature of the smoking material itself is not the actual practice of people in the industry, and moreover, may not even be technologically feasible. In his expert report, Dr. Joseph Maga states that "members of the food smoking industry do not measure the actual temperatures of the sawdust or wood in their production of smoke for treating food commercially." (HISI Am. Opp., Ex. 13, P 13.) Rather, he believes that "the temperatures stated in the Yamaoka patent's claim would be read by commercial producers of smoke for treating food as the temperature at which the heating unit is to be operated, as opposed to the actual temperatures of the sawdust." (HISI Am. Opp., Ex. 13, P 12.) In addition, TPI's expert, Dr. Kumazawa, admitted in his deposition that "sawdust temperature is very difficult to measure" (HISI Am. Opp., Ex. 12, at 34:8-9.) Another of TPI's experts, Dr. Hagadone, similarly indicated in his deposition that the sawdust temperature would be difficult to measure in a Yamaoka smoke machine, although he thought that perhaps it could be done "if you had some kind of transmitter device, like a Martian land[er]." (HISI Am. Opp., Ex. 11, at 175:10-11.) This sort of transmitter device, however, is nowhere mentioned in the Yamaoka Patent, leading to the conclusion that the temperature limitation claimed in the patent refers instead to the temperature of the medium. Accordingly, the Court concludes that "a person of ordinary skill in the art in question at the time of the invention," Phillips v. AWH, 415 F.3d 1303, 1312 (Fed. Cir. 2005), would have interpreted the Yamaoka Patent's temperature limitation to refer to the temperature of the heating medium, and not the temperature of the smoking material.

TPI also requests that the Court construe the Yamaoka Patent's literally claimed temperature range of 250 [degrees] to 400 [degrees] as extending beyond the stated numerical boundaries to include any "beneficial temperature," (TPI Brief 41). While TPI contends that it is not estopped from asserting this broader range by its prosecution history, it does not provide any affirmative reason as to why "250 [degrees] to 400 [degrees]" should be construed as "beneficial temperature." The language of the claimed numerical range is plain and unambiguous. The Court therefore rejects TPI's proposed claim construction and finds that "burning a smoking material at 250 [degrees] to 400 [degrees] C" means burning a smoking material in a chamber or other medium heated to a temperature between 250 [degrees] and 400 [degrees] C.
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1. "By the addition of water"

As previously stated, the patents in suit are easy to understand. They use plain language to describe common concepts and familiar products. However, AstraZeneca argued that summary judgment would be premature because there has been no Markman hearing to construe disputed claims.

Defendants not surprisingly viewed this as another stalling tactic by Plaintiff. There is nothing particularly complicated about a phrase like "70% crystalline." However, AstraZeneca insisted that the phrase "by the addition of water" required construction.

Exercising my authority to handle Markman issues at any point in the lawsuit and in any way that seems best suited to disposing of them, I decided to hold a Markman hearing "on papers" after I became apprised of this dispute. In accordance with my customary procedure. which is to address the issue of claim construction only considering intrinsic evidence as a first step, I directed counsel to point me to any intrinsic evidence that would support a construction broader than the normal and natural construction of the words "by the addition of water." (See Docket No. 53.)

The parties submitted concise briefs that (to borrow a salient word) "crystallized" their dispute over the meaning of the phrase "by the addition of water." After considering both sides' submissions, I agree with DRL that that AstraZeneca's proposed interpretation of that phrase--aside from making absolutely no sense--represents a desperate attempt to extend its patents by stretching the concept of "adding" water to incorporate the natural and perpetually ongoing process of atmospheric evaporation and absorption. I therefore reject it in favor of Defendants' sensible construction of the phrase. I see no need for any second Markman phase, which would involve the submission of extrinsic evidence.

The plain meaning of the phrase "crystallizing magnesium omeprazole by the addition of water" is "turning magnesium omeprazole into crystalline form by affirmatively putting extra water into" whatever mixture or substance contains the omeprazole magnesium. There is a strong presumption that the words used in a claim take on their ordinary and customary meaning to those of ordinary skill in the art (not just their ordinary and customary meaning), but there is no evidence that

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the phrase "addition of water" is a term of art. Rather, the words chosen by the patentee are simple and easily understood--even by those of us who are not skilled in the art of crystallizing salts, but who are skilled in the "art" of adding water to something (such as a pot of tea or a box of cake mix).

AstraZeneca argues, however, that the phrase should be construed to mean "by the use of water in sufficient proportion to other solvents to facilitate crystallization." (Pl. Br. Claim Constr. at 1.) It contends that the specification--which of course provides texture and context to the claims, thereby allowing one skilled in the art to understand the invention, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)--necessitates this broad reading of the word "addition."

Some background is in order. As the reader is by now aware, the claimed invention is a salt that is first treated with magnesium and then rendered highly crystalline "by the addition of water" (which facilitates crystallization) to the mixture in which the treated salt is present. In its interrogatory answers, DRL revealed that a certain amount of water was present in each of the batches of omeprazole magnesium that it manufactured--between 6.5% and 9.1% by weight. (Griem Decl. Ex. 16 at 6 (Response to Interrogatory No. 7).). In its brief opposing summary judgment, AstraZeneca noted that the highly crystalline salts manufactured using AstraZeneca's "novel, water-based" process had between 5 and 10% water by weight, and argued that this coincidence created a genuine issue of fact concerning whether DRL's manufacturing process infringed on the patented process by "adding water."

The problem with this argument is that DRL had responded fully to an interrogatory asking it to describe the process by which it manufactured omeprazoIe magnesium. (Id. at 13-14 (Response to Interrogatory No.10).) Nowhere in the process described was any water added to anything.

Recognizing this, and having no evidence to contradict it, AstraZeneca does not argue that DRL affirmatively pours new water into a mixture or solution containing omeprazole magnesium prior to evaporating that solution in a Agitated Thin Film Drier (which is how DRL creates its finished salt). Rather, Plaintiff suggested that water could have been introduced into the process at some point, either via the raw materials that were used to make the salt (some of which might have contained miniscule portions of water), or by absorption from the atmosphere. (Pl. Opp'n at 12.) While conceding that water was added as a "separate solvent" in the embodiment set forth in the patent specification--thereby admitting that the specification did not reveal any example in which water that was merely present in either the ingredients or in the atmosphere precipitated the requisite crystallization--AstraZeneca contended, "[T]he claims do not require that the water be added as a separate solvent. Water can be added to the process through other means as well, so long as the water is added in some way, whether through solvent, atmosphere, and is present in sufficient amounts when needed." (Id. at 6) (emphasis added.)

The clear import of AstraZeneca's argument is that any batch of omeprazole salt that contains water will somehow infringe the patents in suit--even if additional quantities of water were not deliberately added to the salt (or to any solution containing the salt) during the manufacturing process, but were instead absorbed into the mixture from the surrounding air. AstraZeneca effectively says as much in its Claim Construction Brief; it argues that the phrase "by the addition of water" should be read as equivalent to "in the presences of water"--specifically, in the presence of enough water to facilitate crystallization of a salt. (It is for that reason that AstraZeneca equates "addition" with "use" in its proposed definition).

To support this strained (to say the least) reading of the phrase "by the addition of water," Plaintiff focuses on the following language from the specification: "The process for manufacturing the new form of magnesium omeprazole differs from the earlier known processes in that the product is recovered after a controlled crystallization step in aqueous alcohol, preferably methanol . . . ." (Griem Decl. Ex. 1 at 3:14-15.) From this, AstraZeneca says, one skilled in the art would deduce that "water is clearly present during the crystallization step." (Pl. Br. Claim Constr. at 2.) Plaintiff notes that crystallization is facilitated when water "is added to the methanol solvent . . . so that its proportion increases" relative to its prior concentration in what is clearly described as an "aqueous" (i.e., water-based or water-containing) alcohol solvent. (Id.) Plaintiff argues that one skilled in the art would understand that, "the essential aspect of the addition of water in the specification is that when the proportion of water is increased relative to the methanol in the process, crystallization is facilitated . . . ." (id. at 3) and asserts that, "Any process that 'adds water' relative to the amount of other solvents to facilitate crystallization meets the literal terms of Claims 11 and 20 in this regard." (Id.)

DRL argues that AstraZeneca's proposed construction of the phrase "by the addition of water" is unwarranted for a number

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of reasons.

First, Defendants note that the claims in suit describe a process comprising four sequential steps. Sequential steps bear a temporal relationship to each other, with one taking place prior to the next. The third of these consecutive steps--and claim 11 explicitly requires "consecutive steps" (Weinstein Second Decl. Ex. 2 at 4:53 (emphasis added))--is "crystallizing omeprazole magnesium by the addition of water." (Id. at 4:57-8.) This step comes after step one (treating the omeprazole in an aqueous solution containing magnesium) and step two (separating the inorganic salts from the resulting mixture). (Id. at 4:54-56.) Likewise, claim 20 explicitly requires the separation of inorganic salts "prior to the crystallization step by the addition of water." (Id. at 6:4-5 (emphasis added).)

The plain meaning of adding water to something is affirmatively and deliberately putting water into that something. In the context of this patent--adding water in a deliberately sequential crystallization step--the word "adding" can only mean putting water that was not present in the mixture during steps 1 and 2 into the mixture at step 3. DRL's proposed construction flows naturally from the language of the claims; Plaintiff's does not.

Second, DRL urges that the specification--far from supporting AstraZeneca's broad reading of the word "addition"--actually supports the more literal construction it espouses. The specification describes a process in which a lot of water is added in order to induce crystallization of omeprazole magnesium from solution. The specification's generalized process describes a crystallization step that follows the step of separating the inorganic salts: the solution is seeded and, "An amount of water, which is approximately equal to the volume of the solution, is added to start the crystallization." (Id. at 3:3-6) (emphasis added.) As Plaintiff itself notes (see Pl. Br. Claim Constr. at 2), this suggests that a very generous amount of water is put into an existing solution (which already contains water, since it is an aqueous solution)--an amount of water so great that it literally doubles the volume of the mixture, giving the new water and the old mixture a 1:1 ratio (as Plaintiff concedes in its Claim Construction Brief). Thus, the embodiment described in the specification plainly calls for affirmatively putting in water that was not already there. Water in such a volume could not be "added" during a manufacturing process by extraction from the solution's constituent raw materials (which water would not be "added," since it would already be present). Nor could it occur by absorption from the ambient air.

Underscoring that the addition of a large amount of water is anticipated, the lone example of the process given in the specification describes a process in which the liquid that remained following the separation of inorganic salts "was seeded with magnesium omeprazole crystals whereafter the magnesium omeprazole was precipitated by addition of 900 [liters] of water." (Weinstein Second Decl. at 3:42-45 (emphasis added).) This embodiment, which refers to putting more than 237 gallons of water into a pre-existing liquid, can likewise only be understood to contemplate putting in water that was not already present.

Not surprisingly, Plaintiff contends that Defendants are trying to limit the scope of the claim language to the preferred embodiment. But if there were any doubt that the specification undermines rather than supports AstraZeneca's proposed definition, it was put to rest in the recent case of Netcraft Corp. v. eBay, Inc., 549 F.3d 1394, 1399 (Fed. Cir. 2008). In that case, the Federal Circuit squarely held that where no language (much less express language) in the specification indicated that a disputed term was meant to disclose an alternative embodiment, the specification would be deemed not to include additional embodiments. In other words, courts should not construe claims expansively if no disclosure in the specification supports a broad construction.

Nothing in the specification of AstraZeneca's patents (particularly the '424 patent) supports the notion that an increase in the amount of water in a mixture containing omeprazole by virtue of some naturally-occurring process (like absorption) would embody the claimed invention. Therefore, applying Netcraft, the disputed term cannot be read so broadly.

Third, DRL, contends that the prosecution history supports its literal reading of the disputed phrase. It notes that AstraZeneca amended all the process claims to include "by the addition of water" as a claim limitation. In an amendment filed on July 31, 1998, Plaintiff inserted the term "by the addition of water" into the crystallization step of pending claim 9 (which eventually became claim 11 in the '424 patent). (Choi Decl. Ex. 23 at 2 (the underscoring in the amendment shows the words being added).) AstraZeneca told the Examiner that this amendment put the limitation of pending dependent claim 12 (Choi Decl. Ex. 33 at 9:17-18 ("the crystallization is accomplished by addition of water")) into pending independent claim 9. (Choi Decl. Ex. 23 at 4.) Because pending claim 9 was the only pending independent process claim, this amendment necessarily added the limitation "by the addition of water" into the crystallization step of each and every

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pending process claim.

The same amendment also added new claim 36, which became issued claim 20 in the '424 patent. (Id. at 3.) AstraZeneca specifically averred that new claim 36 corresponded to original claim 9. (Id. at 4.) New claim 36 stated, as does claim 20 of the issued patent, that "the improved process comprises separating inorganic salts from the reaction mixture prior to the crystallization step by the addition of water." (Id. at 3 (emphasis added).)

As a result of the amendment, all of the process claims were limited to crystallizing by the "addition" of water in some sort of clearly sequenced series of steps.

After amending the claims in this manner, AstraZeneca filed a Supplemental Amendment on October 1, 1998, (Weinstein Second Decl. Ex. 8), in which it told the Examiner that its basic invention resided in a controlled crystallization step. where water is added to form crystals of omeprazole magnesium after the step of separating inorganic salts:

Advantageously, the inventors of the subject invention discovered that a magnesium omeprazole salt having a high degree of crystallinity could be recovered after a controlled crystallization step in aqueous alcohol and this salt was more suitable and, hence, preferred for use in full scale production (Lindberg Declaration, P6). Specifically, inorganic salts are separated from the mother liquor prior to the addition of water to form crystals of magnesium omeprazole (See, amended claim 9).

(Id. at 4-5 (emphasis added).) Logic dictates that if the separation of inorganic salts is prior to "the addition of water" the "addition of water" must come after. In this context, the addition of water must mean putting water into the mixture that was not there when the salts were separated from the mother liquor. The water cannot be part of the ingredients in the salt's raw materials, because that water would be part of the mixture before the second (separation) step. And the new, additional water cannot come from the air, because there is no telling when it was absorbed--certainly not limited to a discrete third step.

The argument in the Supplemental Amendment that "the addition of water" comes after separating inorganic salts was not a mere slip of the pen by AstraZeneca's patent attorney, according to DRL. Rather, it is confirmed by Dr. Per Lindberg, the Head of the Preclinical Alliances Group of Astra Hassle AB. (Choi Decl. Ex. 21 at P l.) AstraZeneca submitted his Declaration to the Examiner to support the patentability of the claims over the prior art. Dr. Lindberg twice declared, under penalty of perjury, that the water used to form the crystals is added after the step of separating inorganic salts.

Specifically, in paragraph 14 of his declaration Dr. Lindberg declares that "Inorganic salts are separated from the mother liquor prior to the addition of water to crystallize magnesium omeprazole." (Id. at P 14 (emphasis added).) In paragraph 6 of his Declaration Dr. Lindberg is even more explicit about the criticality of adding the water after the separation of the inorganic salts:

According to the invention, inorganic salts are separated from the mother liquor prior to the addition of water to form crystals of magnesium omeprazole.

(Id. at P 6 (emphasis added).) Far from suggesting that water from the ambient air can enter the product at any point, Dr. Lindberg's declaration demonstrates that the needed water must be deliberately put into the mixture during a crystallization step that comes after separating the inorganic salts.

The Examiner accepted this argument. In the Notice of Allowability the Examiner stated under the heading "Reasons for Allowance" that it was the step of adding water to crystallize the product that made the process claims patentable:

The process claims are patentable because of the step of adding water to crystallize the claimed product.

(Choi Decl. Ex. 34 at 2 (emphasis added).) 3

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3 The Examiner's use of this formulation gives the lie to AstraZeneca's argument, made at page 6 of its Claim Construction Brief, that the only thing that has to happen at the third step is crystallization--not the addition of water.

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Having made this statement, the Examiner invited AstraZeneca
Enhanced Coverage Linking to submit any comments it considered necessary. (Id.) No comments were submitted--certainly not any comments suggesting that the patent claims as amended contain "no restriction on when or how water is added to the process," rather than requiring that it be added as part of a properly sequenced, separate and identifiable step. For Plaintiff now to argue otherwise, DRL urges, is wrong.

The Court agrees. AstraZeneca's construction disregards the simple, plain and easily understood words of the claim ("by the addition of water") in favor of a construction ("the use of water in sufficient proportion to other solvents to facilitate crystallization") that is litigation-driven and overly complex. Plaintiff takes the clear words of the claims and renders them far less comprehensible to a trier of fact. At no point in the patent prosecution did Plaintiff so much as suggest that the word "addition" had anything other than its ordinary and commonly understood meaning, or that it ought to be construed as some sort of term of art. Indeed, the meaning of the words "addition" and "adding" is so obvious that AstraZeneca did not define it, but simply used it, over and over again, in its submissions to the Patent Office--which indicates that the term, far from requiring explanation, defines itself. AstraZeneca even continues to refer to "the addition of water" in a self-defining way in its Claim Construction Brief.

In the end, AstraZeneca's proposed construction cannot be accepted because it is inherently self-contradictory. It reads out of the patent the patentee's own description of the way that extra water (over and above that which is already present in the aqueous solution) gets into the mixture--via a discrete and sequenced step that facilitates controlled crystallization. If, as Plaintiff here maintains, there is "no restriction on when or how water is added to the processes," then the crystallization step is not really a step at all, let alone one that occurs at a specific point in the manufacturing process, after the inorganic salts are separated from the mother mixture. And if water that is present in the raw materials used to create the mixture, or that is absorbed into the mixture from the ambient air, causes the crystallization, then crystallization is not controlled--it occurs at whatever rate, and to whatever degree, the naturally-occurring water allows it to occur!

Thus, AstraZeneca's proposed construction does violence to its own carefully-crafted description of its invention. While I think DRL goes too far when it describes Plaintiff's AstraZeneca's proposed construction as "shockingly Orwellian," it is clearly beyond the pale.

Finally, Plaintiff's proposed claim construction is barred by law. During prosecution all of the process claims were repeatedly rejected and no process claims were allowed until AstraZeneca added the words "by the addition of water" to the crystallization step. Plaintiff argued that the "addition" of the water in a discrete step that took place after separating the inorganic salts was the basis of the invention. As a result, AstraZeneca cannot obtain the much broader construction it now seeks. 4

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4 DRL exhibits 33. 35, 4, 38, 39 and 23 (listed in date order) (attached to Choi Decl.), show the status of the claims during prosecution and DRL exhibits 36, 37 and 22 (listed in date order) (attached to Choi Decl.) show the three rejections that issued on August 9, 1996, April 22, 1997, and January 27, 1998, respectively. DRL exhibits 8 and 21 (attached to Choi Decl.) show the argument AstraZeneca made to obtain allowance of the claims.

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Under Supreme Court precedent, AstraZeneca's amendment of the crystallization step to include "by the addition of water," after the repeated rejection of claims that did not have that limitation, absolutely prohibits it from obtaining a construction that would cover what it gave up. See Smith v. Magic City Kennel Club, Inc., 282 U.S. 784, 790, 51 S. Ct. 291, 75 L. Ed. 707, 1931 Dec. Comm'r Pat. 716 (1931) ("limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and looked upon as disclaimers.") (emphasis added); accord Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1334 (Fed. Cir. 2003) (quoting Smith and affirming a summary judgment of no infringement).

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By contrast, in Carboline Co. v. Mobil Oil Corp., 301 F. Supp. 141 (N.D. 111. 1969), the case on which Plaintiff relies, the claim at issue (unlike the claims here) was not a process claim with recited steps. Id. at 143 n.2. Carboline's holding of infringement was under the doctrine of equivalents, and the court did not construe what the claims literally meant. Id. at 152 (applying the function, way, result test). Most importantly, the court found that there was nothing in the prosecution history of that patent to indicate that the patentees "intended to restrict themselves" to any particular process for making the claimed product. Id. at 152-53. Here that cannot be said. Claim 20

While the parties have agreed that the claim limitation "by the addition of water" in claim 20 modifies the words "crystallization step" and not "separating inorganic salts from the reaction mixture." AstraZeneca nevertheless seeks to read the limitation out of the claim. Claim 20 does not need a separate construction. Rather, claim 20 claims the same process as claim 11, and its construction is controlled by the same intrinsic evidence.

The plain language of claim 20 states that the improvement over the prior art process is "separating inorganic salts from the reaction mixture prior to the crystallization step by the addition of water." (Choi Decl. Ex. 23 at 3.) This plain language makes clear that the crystallization step (1) follows the step of separating inorganic salts, and (2) is performed by putting water into the mixture during that step.

The claim that became claim 20 was added in the July 31, 1998 Amendment, in which AstraZeneca explained that the added claim corresponded to the claim that became claim 11 in the issued patent, but that it was being written in different form to highlight the claimed invention. (Id. at 4 ("which have been written in Jepson form to clearly recite the improvement vis-a-vis the prior art").) There is nothing in the prosecution history to support a conclusion that "by the addition of water" in claim 20 should be interpreted differently from "by the addition of water" in claim 11.

Plaintiff asserts, at page 8 of its Claim Construction Brief, that "there can be no suggestion that the term 'by the addition of water' has to require that the water be added only at the time of crystallization." Having told the Examiner it was using the same words in a different form to claim the same process in order to obtain allowance of the claims, it is improper for AstraZeneca to argue now that the different form of the same words means something else.

I therefore conclude that the phrase "by the addition of water," as used throughout the '424 patent--in every claim in which it appears--means that a quantity of water that was not present during steps I and 2 of the four step process must be deliberately and affirmatively placed into the mixture during step 3 (the "crystallization" step), which takes place following the separation of organic salts from the reaction mixture. I agree with Defendants that there is no basis in the intrinsic evidence to suggest AstraZeneca's construction that the crystallization need only be "facilitated" by water that happens to be present, rather than being deliberately put into the process.
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Although the district court found that the term "calcium orthophosphate" as used in claim 1 of the 600 patent is limited to tricalcium orthophosphate, that determination is not necessary to resolve this case. We need only determine whether the term "calcium orthophosphate" in claim 1 of the 600 patent covers monocalcium orthophosphate or TSP. In regard to this limited question, we find that the term does not because those compounds were disclaimed during the prosecution of the patent application. We do not find it necessary to determine whether the term "calcium orthophosphate" is limited to tricalcium orthophosphate.

Arguments and amendments made during prosecution of a patent application must be examined to determine the meaning of terms in the claims. Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995). "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id., 34 U.S.P.Q.2D (BNA) at 1676-77 (citations omitted); see also Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378, 49 U.S.P.Q.2D (BNA) 1065, 1068-69 (Fed. Cir. 1998) ("Explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of the claim."); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452, 227 U.S.P.Q. (BNA) 293, 296 (Fed. Cir. 1985) ("The prosecution history . . . limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance."). Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations because "the public has a right to rely on such definitive

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statements made during prosecution." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347, 47 U.S.P.Q.2D (BNA) 1418, 1427 (Fed. Cir. 1998).

Rheox stresses that the ordinary and accustomed meaning of "calcium orthophosphate" to one of ordinary skill in the art is a family of compounds containing a Ca2+ cation and a PO[4]3- anion, and that claim language should not be interpreted differently from its ordinary and accustomed meaning based on prosecution history unless it contains a clear disavowal of that meaning. Rheox asserts that there was no clear disavowal of TSP in the 600 patent's prosecution history. It contends that a fair reading of the prosecution history is that Rheox intended to cover all of the compounds in the family of calcium orthophosphates, all of which fall substantially below the 5.0g/100mL solubility benchmark set by O'Hara. TSP is substantially water-insoluble under this definition at 1.8g/100mL water. Entact emphasizes and the district court recognized that there is no evidence that Rheox ever made an argument to the examiner that any compound under the 5.0g/100mL water-solubility mark referred to in O'Hara is not water-soluble. The examiner did not limit the final rejection to phosphates that cleared the alleged O'Hara 5.0g/100mL water-solubility limit. To the contrary, the examiner explicitly identified monocalcium orthophosphate and TSP as prior art water-soluble phosphates and stated that it would have been obvious to one of ordinary skill in the art to select such phosphates for use in the O'Hara process.

Entact argues that the relevant inquiry to see if the prosecution history limits the interpretation of a claim is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457, 46 U.S.P.Q.2D (BNA) 1169, 1175 (Fed. Cir. 1998) (en banc). Entact further argues that Rheox overcame the O'Hara obviousness rejection by canceling and amending its claims to delete all references to monocalcium orthophosphate and TSP and then arguing to the examiner that its amended claims should be allowed because its "presently claimed compound (calcium orthophosphate) is substantially water-insoluble." According to Entact, the prosecution history conclusively shows that Rheox disclaimed and disavowed monocalcium orthophosphate and consequently TSP in order to achieve patentability.

We assess whether a patentee relinquished a particular claim construction based on the totality of the prosecution history, which includes amendments to claims and arguments made to overcome or distinguish references. Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979, 52 U.S.P.Q.2D (BNA) 1109, 1113 (Fed. Cir. 1999) ("Because it is the totality of the prosecution history that must be assessed, not the individual segments of the presentation made to the Patent and Trademark Office by the applicant, it is irrelevant whether Elkay relinquished this potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference.").

As originally filed, claim 2 of the 600 patent was specifically directed to TSP, and claim 18 was directed to a group that included TSP, phosphate rock, and hydroxyapatite. After an initial and final rejection and an interview with the examiner, Rheox cancelled claim 2, which was explicitly directed to TSP. With painstaking surgical precision, Rheox also deleted the single reference to TSP in claim 18. 6 Rheox stated that it made the changes to "distinguish the invention from the water-soluble compounds and method of treatment taught by O'Hara." It continued: "[A] central difference between the invention and the prior art is that the presently claimed compound (calcium orthophosphate) is substantially water-insoluble, whereas the compounds utilized in the prior art processes are highly water-soluble." It then stated that "in this regard, Applicants point out that the solubility of calcium orthophosphate is 0.002 g/100 [mL] [water]." Rheox finally stated that the "water-soluble phosphates disclosed by O'Hara et al. are believed to be thousands of times more water-soluble than Applicants' preferred (and presently claimed) calcium orthophosphate material."

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6 Rheox also cancelled claim 3, which was directed to monocalcium orthophosphate and tricalcium diorthophosphate. Entact does not dispute Rheox's claim that tricalcium diorthophosphate is the same compound as tricalcium orthophosphate.

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We cannot agree that Rheox only disclaimed coverage of compounds with solubility over 5.0g/100mL, but still retained coverage of TSP or monocalcium orthophosphate. Rheox tried to claim TSP, but had to delete all reference to it to gain patentability. The deletion of only two words: "triple superphosphate [TSP]" from original claim 18, now claim 8, is telling. If Rheox wanted only to distinguish O'Hara based on 5.0g/100mL solubility, it would not have deleted TSP, one of its preferred embodiments, from the claims. In the final rejection, the examiner stated that it is well known to one of ordinary

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skill that monocalcium phosphate is water-soluble and routinely available as TSP. The examiner did not reject the original claims based on a 5.0g/100mL solubility limit. Rather, he indicated that monocalcium orthophosphate and TSP are water-soluble. Therefore, when Rheox distinguished the present invention based on its "water-insolubility," it was arguing around the examiner's comments and limiting itself to claims not encompassing monocalcium orthophosphate and TSP. Indeed, it stated that the covered compounds were thousands of times less soluble than the soluble compounds of the O'Hara patent, but TSP, with a solubility of 1.8g/100mL water, is not even three times less soluble than O'Hara's disclosed solubility of 5.0g/100mL water.

Although we recognize that an interpretation excluding a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support" Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583-84, 39 U.S.P.Q.2D (BNA) 1573, 1578, (Fed. Cir. 1996), where the prosecution history requires a claim construction that excludes some but not all of the preferred embodiments, such a construction is permissible and meets the standard of "highly persuasive evidentiary support." This follows from our precedent that "the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) (citations omitted).

Rheox also argues that the written description of the 600 patent precludes a finding that TSP was disclaimed, because it indicates that TSP, which is indisputably primarily monocalcium orthophosphate, is defined by the '600 patent as "calcium orthophosphate." Reading the written description alone, this argument might be effective, but in light of the prosecution history, which was generated after the written description was drafted, it is apparent that Rheox relinquished any coverage of TSP. Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 1392, 59 U.S.P.Q.2D (BNA) 1763, 1769 (Fed. Cir. 2001), petition for cert. filed, 70 U.S.L.W. 3341 (Nov. 5, 2001) ("Even where the ordinary meaning of the claim is clear, it is well-established that 'the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.'") (citing Southwall, 54 F.3d at 1576, 34 U.S.P.Q.2D (BNA) at 1676).
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7. "can proliferate within the host"

"can proliferate within the host" is construed to mean "capable of increasing in quantity."
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VI. "(4) an addition amount of the catalyst which is capable of raising the concentration of the catalyst from the lower concentration limit to the upper concentration limit" '236 patent, col. 16, ll. 3-6.

Plaintiff asserts that this phrase means an "addition amount of the catalyst which is capable of raising the concentration of the catalyst additive from a concentration area within the lower boundary to a concentration area within the upper boundary." 66 Defendants assert that it means "the quantity in weight of catalyst that is determined to have the ability to increase the concentration or weight percentage of the catalyst from the lower concentration limit established in Step I to the upper concentration limit established in Step I when injected during the first period (T1) of the basic cycle period." 67 The Court will examine the terms "the upper concentration limit" and "the lower concentration limit" and "an addition amount" in turn.

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66 (Pl.'s Claim Construction Br. at 29.)

67 (Defs.' Opening Claim Construction Br. at 26.)

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A. "the upper concentration limit" and "the lower concentration limit"

As to "the upper concentration limit" and "the lower concentration limit," the Court has previously construed the former to mean "an upper boundary (but not necessarily the maximum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage)" and has construed the latter to mean "a lower boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage)." See supra Analysis Part II.C. Because these phrases are used consistently throughout the claim, the Court gives them the same constructions here. See Phonometrics, Inc., 133 F.3d at 1465.

But the parties dispute whether the upper and lower boundaries referred to in the instant phrase are the same boundaries that were determined during the "obtaining data" step. Defendants contend that they are the same. 68 The Court agrees. As noted above, when a previously identified element is referred to in a patent after it has been introduced by "a" or "an," "the definite article ['the'] should be used." Robert C. Faber, Landis on Mechanics of Patent Claim Drafting § 23 (2002); see Zenith Elec., 1995 U.S. Dist. LEXIS 6177, at * 12. By using the definite article "the" in "the lower concentration limit" and "the upper concentration limit," the patentee is referring to "an upper concentration limit" and "a lower concentration limit" that were previously established during the "obtaining data" step. 69

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68 (Defs.' Opening Claim Construction Br. at 25.)

69 That the boundaries may change over time, see supra Analysis Part II.B, does not alter the construction that the boundaries are previously established during the "obtaining data" step.

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B. "an addition amount"

As to "an addition amount," the parties dispute whether it raises catalyst concentration somewhere within the upper and lower boundaries (Plaintiff's view), or whether it raises catalyst concentration from the lower boundary to the upper boundary (Defendants' view).

The Court agrees with Defendants' view. First, the claim explicitly states that the "addition amount . . . is capable of raising the concentration . . . from the lower concentration limit to the upper concentration limit." '236 patent, col. 16, ll. 3-6 (emphasis added). It does not say "within" the upper and lower limits. Second, the specification teaches that an addition amount is an amount "which, when added to a minimum amount, gives the maximum amount. . . ." Id., col. 8, ll. 57-61. Third, the prosecution history describes an addition amount as ". . . the amount of catalyst needed to get from the minimum permissible additive concentration . . . to the maximum permissible concentration. . . ." (Defs.' Opening Claim Construction Br. Ex. 4 at I-3153 (emphasis added).) Finally, after illustrating in an example that one ton of catalyst is added to every one ton of catalyst lost, the prosecution history states that the '236 patent answers the question of how this amount of catalyst should be added. (See id. Ex. 4 at I-3151.) Thus, the intrinsic record reveals that the "addition amount" is the amount of catalyst added to raise the concentration of the catalyst from the desired lower concentration boundary to the desired upper concentration boundary. 70

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70 That the boundaries may change over time, see supra Analysis Part II.B, does not alter the construction that the addition amount raises the catalyst concentration from the lower boundary to the upper boundary.

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C. Summary

Accordingly, the Court concludes that the disputed phrase "(4) an addition amount of the catalyst which is capable of raising the concentration of the catalyst from the lower concentration limit to the upper concentration limit" means "(4) an amount

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of catalyst added to raise the concentration of the catalyst from the previously established lower boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) to the previously established upper boundary (but not necessarily the maximum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage)."
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C. The Meaning of "Capable of Transducing"

The parties agree that "transducing" is a word commonly used in the field, although they dispute its precise definition, and agree that its plain meaning as understood by one of skill in the art of reading the specification and claims should apply. The parties agree that "capable of transducing" means at a minimum that genetic material can be "introduced" into the nucleus of a cell. "Introduction" means that the RNA from the viral vector first enters the cell, is reverse transcribed into DNA, and then crosses the nuclear membrane and enters the nucleus of the cell.

The principal disagreement is whether the transduction ends with the entry of DNA into the nucleus of a cell, or also includes "integrating" DNA into the cells genome (DNA) after it enters the nucleus. Sigma and Oxford contend that "capable of transducing" means that the lentiviral vector has the ability to both "introduce" the genetic material into the nucleus and "integrate" it into the cells DNA. Open proposes a more general definition, that "capable of transducing" means only that the vector is "able to transfer genetic material into the nucleus of a cell," and is silent concerning integration. The Court agrees with Sigma and Oxford.

The terms "transduction," "transducing," and "capable of transducing" are not expressly defined in the specification. The specification discloses that prior lentiviral vectors were capable of transducing cells and integrating into the host cells DNA. See 123 patent, col. 2, ll. 10-12 ("The HIV-based vectors produced to date result in an integrated provirus in the transduced cell that has the HIV LTRs at its ends."). The specification distinguishes between "infection"--getting into the cell--and "transduction," which includes integration:

The lentivirus of the invention provides the ability to infect and transduce non-dividing and/or slowly-dividing cells. During the infection process, lentiviruses form a pre-integration complex . . . . The complex is able to pass across the nuclear membrane of the target cell, by means of signal sequences in the proteins.

'123 patent, col. 5, ll. 29-35.

The specification goes on to explain that "integration" is essential in order to provide effective gene therapy, which is a stated goal of the invention. As explained in the specification and confirmed by Dr. Cullen, the purpose of the invention is to modify the genome of a diseased cell so that the cell can produce (or "express") beneficial proteins, such as dopamine for a patient with Parkinsons disease. See, e.g., id., col. 2, l. 60-col. 3, l. 40; col. 3, ll. 63-66; col. 4, ll. 26-27; col. 9, ll. 25-27; col. 13, ll. 48-55; Declaration of Dr. Bryan R. Cullen, Docket No. 87 ("Cullen Decl."), at P 15-16; Tr. at 19:14-17. The cells will only express beneficial proteins in significant quantities if the vector becomes integrated with the host cell's DNA.

In other words, if the vectors merely enter the nucleus without integrating into the DNA, as suggested by Open, they will be useless for therapeutic purposes or related research. This is confirmed by the language in the specification and file history discussed above emphasizing that the LTRs must remain capable of "integration," not only "introduction." '123 patent, col. 8, ll. 59-65; see also id., ll. 6-8, 27-30, 37-39, 47-51; Amendment and Response to Office Action dated Oct. 21, 2004 (Pls.' Ex. 13), at 6. Thus, in order to carry out a stated purpose of the invention, gene therapy, and related research, transduction must include both introduction and integration.

This conclusion is also consistent with the extrinsic evidence, which generally defines "transduction" as requiring both introduction into the nucleus and integration into the host cell's DNA. For example, Sigma and Oxford offered an article from 1996 from the Proceedings of the National Academy of Sciences USA, that is directed to a "lentiviral vector suitable for in vivo gene delivery." Naldini, et al., Proc. Natl. Acad. Sci. USA 93; 11382 (1996) (Pls.' Ex. 19). The article states that "[t]ransduction occurs by integration of the vector genome." Id.

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Open itself cites extrinsic evidence that emphasizes integration into the DNA is essential for gene therapy:

Because of the way replication-defective retroviral vectors are designed, virus particles containing vector genomes can be produced and can be used to infect target cells. The vector genome then undergoes reverse transcription and integration into the cell's genome, where it can express the foreign gene(s) of interest, but is unable to replicate an additional time and spread to other cells[.]

Buchschacher, Lentriviral Vector Systems for Gene Transfer (2003) (Def.'s Ex. G) at 6 (emphasis added). Integration "into the genome" means that the vector is integrated with the host cell's DNA, where it is used to express genes, i.e., make proteins based on those genes.

Another reference cited by Open states that transduction requires integration. See Steadman's Medical Dictionary (26th ed. 1995) (Def.'s Ex. R) at 1837 ("Transfer of genetic material (and its phenotypic expression) from one cell to another by viral infection."). Dr. Cullen testified that this definition implicitly requires integration, particularly in the context of the patents, because gene expression (or "phenotypic expression") can only occur if the virus has integrated with the DNA. Tr. at 63:13-65:22.

At the claim construction hearing, Open produced for the first time a 1990 publication by Stevenson to support its position that integration is not necessary for expression in HIV. See Tr. at 54:22-55:3. In response to the Stevenson paper, Dr. Cullen testified that by 1996, before the Oxford invention, it was known that integration is critical for gene expression. This is shown in the 1996 paper from the National Academy of Sciences, Pls.' Ex. 19: "if [the researchers] had lentiviral vector that cannot integrate, they did not get perceptible expression of the protein of interest." Id. at 63:4-64:11; Naldini, et al., Proc. Natl. Acad. Sci. USA, 93; 11382 (1996). Open did not challenge Dr. Cullen or present rebuttal testimony from its expert on this matter.

The weight of the extrinsic evidence, including Dr. Cullen's testimony, supports Sigma and Oxford's position that "transduction" in the context of these patents requires "integration." To the extent that the Stevenson reference uses a different definition of "transduction," it is inconsistent with the term's use in the patents. See Phillips, 415 F.3d at 1319 (extrinsic evidence is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence"). 12

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12 Open also notes testimony by one of the inventors, Dr. Susan Kingsman, in which she agreed that "in the general field outside of this patent" the term "transducing" does not "always" require integration. She further explained that "in the context of this patent," transduction always requires both introduction and integration. Kingsman Dep. at 99:2-15. The parties have offered extrinsic evidence showing that integration is part of transduction and extrinsic evidence showing that integration is not part of transduction. This makes the use of the term transduction "in the context of the patent" all the more critical. To the extent that Dr. Kingsman merely acknowledged the uses of "transduction" in contexts that are inconsistent with this term's use in these patents, this testimony is likewise not relevant to construction of the patents.

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Open argues that including integration as part of "transduction" would render portions of claim 6 of the '699 patent superfluous. Claim 6 depends from claim 2, which in turn depends from claim 1. These claims read:

1. A lentiviral vector capable of transducing a non-dividing or slowly-dividing cell, said vector comprising a lentiviral LTR-deleted vector.

2. The lentiviral vector according to claim 1, further comprising a nucleotide sequence encoding a protein of interest.

. . .

6. A method of performing gene delivery on a target cell comprising the steps of:

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a) transducing the target cell with the lentiviral vector according to claim 2; and

b) delivering the nucleotide sequence to the target cell.

Open asserts that "delivering the nucleotide sequence to the target cell" in step (b) of claim 6 means integration and argues that if "transducing" includes integration, the step of "delivering the nucleotide sequence" in step (b) would be superfluous with "transducing" in claim 1 and step 6(a).

The Court disagrees. The claims themselves reveal no problem of superfluous language. Claim 1 of the patent says that the vector is "capable of transducing" a cell. In the method of claim 6, step (a) explains that this vector actually transduces the cell. Step (b) further states that in so doing, the nucleotide sequence of claim 2 is actually and successfully delivered to the target cell. There is nothing superfluous, and the plain meaning of the terms is preserved.

Open relies on Bicon, Inc. v. Straumann Co., 441 F.3d 945 (Fed. Cir. 2006), in which the Federal Circuit declined to adopt a claim interpretation that "would [require] the public to look past the plain language of the claims and guess whether a detailed description of a structural feature in a claim is superfluous." Id. at 951. Here, the Court would have to look past the plain language of the claim to adopt Open's "superfluous" argument. The Court declines to do so. The Court finds that Open misreads Bicon, in which "superfluous" meant assigning no meaning at all to a claim term, rather than assigning the same meaning to two claim terms. See id. at 950 (under patentee's proposed claim construction, "'a frusto-spherical basal surface portion' . . . has no role in the claim and thus is entirely superfluous").

In addition, if the claim did contain superfluous language, the general preference to avoid superfluous language in claims is not strong enough to cause the Court to overlook the plain meaning of the term "transducing" in the context of the patents. See Power Mosfet, 378 F.3d at 1410 "[W]hile interpretations that render some portion of the claim language superfluous are disfavored, where neither the plain meaning nor the patent itself commands a difference in scope between two terms, they may be construed identically.").

Consequently, the Court construes "capable of transducing" as meaning "the ability to introduce and integrate genetic information carried by a viral vector into a cell."
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3. "capacity to infect some host and to be maintained therein, and the progeny thereof"

Amgen contends this language requires that the joined segments of DNA must not only be able to infect a host cell and be maintained therein but also these same DNA segments must not be lost by its progeny. Schering retorts that Amgen has misconstrued this phrase by not properly applying the comma in the phrase, which would actually make two separate phrases of the claim language. As a result, Schering argues this claim language does not require the desired DNA segments to be maintained by the progeny of the initial host cells.

The Court is persuaded that the comma does not act to distinguish between two separate phrases. As stated previously, Claim 1 reads in pertinent part:

A recombinant DNA molecule consisting of segments of DNA from different genomes which have been joined end-to-end outside of living cells and which have the capacity to infect some host and to be maintained therein, and the progeny thereof . . . .

See Col. 36, lines 4-8. Reading this claim language as a coherent whole, the claim language does require that the recombinant DNA molecules infect the progeny of the host, but does not require the recombinant DNA molecules be maintained in the progeny. If the claim language was to be construed otherwise, the sentence would have been written in the following manner: ". . . which have the capacity to infect some host and its progeny and be maintained therein . . . ." Instead, the claim language merely reflects that the patentee wishes not only to cover the first generation of host cells that were infected by the recombinant DNA molecule but also the progeny which result from the reproduction of the host cells. While the purpose is not readily apparent, the claim language, as written, also takes into account the instance where even if the

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recombinant DNA molecule infects the progeny of the host, there is still a chance the recombinant DNA molecules may not be maintained in the progeny. As such, the Court finds "which have the capacity to infect some host and to be maintained therein, and the progeny thereof," requires that the recombinant DNA segments infect the progeny of the host cells, but not necessarily to be maintained therein.

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1. "Caplet"

Claim 1 of the '665 patent recites

[a] composition for binding phosphorous within the gastrointestinal tract of an individual, the composition comprising:

a quantity of calcium acetate sufficient to bind the phosphorous in the gastrointestinal tract of the individual,

the calcium acetate having a bulk density of between about 0.55 kg/L and about 0.75 kg/L, and

where the quantity of calcium acetate is compressed to form a caplet for fitting within a capsule in a manner which optimizes the volume of the capsule, and

where at least about 85% of said compressed calcium acetate dissolves in not more than 15 minutes when tested according to USP standard #24, test #711 at 50 to 100 RPM, apparatus 1 or 2.

'665 patent, Col. 5, ll. 31-44 (emphasis added). 3 Claim 1 of the '445 patent recites

[a] drug delivery vehicle for a composition for binding phosphorous within the gastrointestinal tract of an individual, the drug delivery vehicle comprising:

an outer capsule defining an inner volume; and

an inner caplet comprising a quantity of calcium acetate sufficient to bind to and reduce absorption of phosphorous in the gastrointestinal tract of the individual;

the calcium acetate having a bulk density between about 0.55 kg/L and 0.75 kg/L and

being compressed to a caplet form dimensioned for fitting within and optimizing the inner volume of said capsule.

'445 patent, Col. 5, ll. 41-51 (emphasis added).

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3 "USP" refers to the United States Pharmacopoeia, which is described in the specification as "a widely recognized organization that sets some of the standards that pharmaceutical manufacturers must meet to sell their drugs." '665 patent, Col. 2, ll. 12-15.

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Fresenius contends that "caplet" should be construed to mean

a generally oblong cohesive mass for fitting into a capsule body so that, after the capsule top is fitted onto the capsule body, the volume of the resulting finished capsule is substantially completely filled.

Paddock, on the other hand, argues that the caplet must have sufficient integrity to be "an independent dosage form."

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No express definition of "caplet" is provided in either of the patents-in-suit. In its background section, the '665 patent states simply that "the present invention relates to an encapsulated calcium acetate caplet," '665 patent at Col. 1, ll. 11-12, and further that "an encapsulated caplet that provides an effective dosage of medication for the treatment and management of terminal illnesses, without the risk of dosage side effects, is desired. An encapsulated caplet that also seals the taste of the medication and compresses the medication to ease or reduce the dosage volume necessary for effective illness treatment or management is desired, as well." Id., Col. 2, ll. 48-54. The patent's summary of the invention states that

[t]he calcium acetate composition is dimensioned to form a caplet for fitting within a capsule in a manner that optimizes the volume of the capsule, i.e., fills the internal volume of the capsule substantially completely. Insertion of the calcium acetate composition within the capsule masks the unpleasant and unpalatable taste of the enclosed caplet.

Id., Col. 3, ll. 9-15 (emphasis added).

The dispute between the parties centers on what precisely the term "calcium acetate composition" requires - must it be simply a mass that coheres long enough to permit its insertion into the capsule, as Fresenius asserts, or must it have sufficient integrity to be delivered as an independent dosage form, as Paddock argues? On this point, the parties offer warring definitions of "caplet" and "tablet." Fresenius contends that the term is synonymous with the definition of "tablet," which is described in a "well-respected" treatise as: "a solid body that has been formed by placing it in a cavity, and applying sufficient pressure to it so 'it hangs together.'" Plaintiff's Mem. at 15, quoting J.T. Carstensen, Ph.D., Pharmaceutical Principles of Solid Dosage Forms 63 (1993).

For its part, Paddock argues that tablets are "'solid medicaments prepared by compaction,' and are the most commonly used independent solid dosage form." Paddock's Mem. at 14, citing Gilbert S. Banker and Christopher T. Rhodes, Modern Pharmaceutics 333 (3d ed. 1996). Paddock additionally relies on the American Heritage College Dictionary 208 (3d ed. 1993), which defines "caplet" as "[a] smooth, coated, oval-shaped medicine tablet intended to be tamper resistant." Paddock Br. at 14. However, the only discernable similarity between this dictionary definition and the caplets claimed in the patents-in-suit is that they both contain medicine (and are perhaps oval). Beyond that, there is no hint in the express language of the patent or the prosecution history that the caplets must be smooth. Nor is there is any mention that they are coated, nor that they are tamper-resistant. 4 Finally, Paddock argues that a "caplet" cannot be an oblong cohesive mass because such a mass might fall apart and become powder or granulate once placed in a capsule. Paddock states that the caplet must be an independent dosage form in order to withstand the rigors of packaging, as stated in Modern Pharmaceutics, at 334.

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4 The outer capsule may be tamper-proof, but there is no similar limitation in the patents with respect to the inner caplet.

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In responding to Paddock's arguments, Fresenius maintains that the only pertinent "rigors of processing and packaging" are those involved in the insertion of the mass into a protective capsule. Fresenius argues that any potential of the mass to disaggregate once it is encapsulated has no patent significance. What is important to Fresenius is that the mass coheres long enough without "capping" or "picking" so that the entire dose can be inserted into the capsule without incident. 5

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5 "Capping" is the splitting along a plane parallel to the long axis of the capsule. "Picking" is the loss of small punctuate flecks of material from a surface.

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Prosecution History

Paddock's argument is not aided in any material way by the prosecution history. During the prosecution, the patentees wrote that a caplet was "formed by placing the unit dose of the powdered medication in a cavity and applying sufficient pressure that the caplet will hang together." July 18, 2002 Remarks at 7. Fresenius contends that by construing the term to mean a

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"cohesive mass," it captured the concept of the calcium acetate "hang[ing] together." Fresenius further argues that the claim language defines "caplet" in functional terms; as in the sense of being "fitt[ed] within a capsule." Thus, the caplet must hang together or remain a cohesive mass only long enough to be inserted with optimal density into a capsule.

The court finds Fresenius's arguments to be persuasive. There is nothing in the intrinsic evidence to indicate that either of the patents-in-suit require that the disclosed caplet have sufficient integrity to be an independent dosage form. However, it goes without saying that to fit optimally within a capsule, the caplet must be capsule-shaped. The court therefore construes the term "caplet" as

a capsule-shaped tablet with sufficient integrity to survive insertion into the capsule delivery vehicle.

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2. "Capsule"

The second claim term at issue, "capsule," is disputed only insofar as the parties disagree as to whether the term imposes a dimensional limitation. Capsules are sold in various sizes ranging from #000, the largest size that can be swallowed by most patients, to #5, the smallest. While capsules sized #00 are not uncommon, they are difficult for many patients to swallow. Fresenius insists that none of the claim terms imposes a size requirement on the associated capsule. Paddock, for its part, argues that the term "capsule" must be construed as meaning capsules smaller than size #00. Paddock argues that its construction is supported by the importance given to capsule size by the applicants (that is, the capsules must be easily swallowed), as well as statements made by the applicants during the prosecution history that, in Paddock's view, disclaimed any capsules that are sized #00 or larger.

The '665 patent discloses that "[t]he present invention takes advantage of the surprising discovery that, by selecting calcium acetate raw materials within a particular range of bulk densities, it is possible to compress and dimension the raw material to form a calcium acetate caplet, capsule or tablet that is smaller than heretofore formed and is more easily ingested." '665 patent, Col. 3, ll. 30-35 (emphasis added). 6 The '665 patent additionally states that in using the prior art, manufacturers were "unable to produce a calcium acetate capsule or tablet of the usual dosage amount that is less than #00 in size." Id., Col. 2, ll. 25-32. The patent notes that the "unfortunate consequence" of using the #00 capsules "is that patients needing this medication, such as end stage renal disease patients have heretofore found such medications due to their bulk size difficult to swallow." Id., Col. 2, ll. 32-37.

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6 There does not appear to be any dispute that Fordtran, the relevant prior art, utilized #00 capsules.

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It is true that the '665 patent offers capsules sizes #0 and #2 as the preferred embodiments, but not necessarily the only choices: "In one embodiment the calcium acetate is dimensioned to form a caplet for fitting within a volume defined by a #0 size capsule. . . . In another embodiment, the calcium acetate is dimensioned to form a caplet for fitting within and substantially completely filling a volume defined by a #2 size capsule." '665 patent, Col. 4, ll. 39-47. The specification additionally states: "More preferably: a narrower range of bulk density may be used to fit a 667 mg dose into a size #0 capsule or a 333.3 mg dosage into a size #2 capsule."

Fresenius argues that dependent claims 4 to 9 of the '665 patent, as well as dependent claims 7 to 12 of the '445 patent are in fact limited to "#0 size" or "#2 size" capsules. In Fresenius's view, this indicates that had Fresenius intended to place size limitations on capsules in the independent claims, it would have done so. The court notes that the specification is clear that:

[t]he foregoing description has been directed to specific embodiments of this invention. It will be apparent, however, that other variations and modifications may be made to the described embodiments with the attainment of some or all of their advantages. Accordingly, this description should be taken only by way of example and not by way of limitation. It is the object of the appended claims to cover all such variations and modifications as come within the true spirit and scope of the

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invention.

'665 patent, Col. 5, ll. 15-23.

Prosecution History

Paddock argues that applicants maintained their position that size #00 capsules were "unpalatable to and disfavored by patients" throughout the patent prosecution. After the examiner rejected the initial application, applicants focused on the present invention's utilization of calcium acetate with a range of bulk density that is compressible to "form a composition that is optimally dimensioned to fit within a #0 or #2 capsule." Jan. 28, 2002 Remarks at 7. Applicants at one point described Fordtran (the prior art) as follows:

> the dosage of calcium acetate administered by Fordtran in the study described in the '105 patent was administered in the #00 capsules that are described by applicants in the "Background" section of their application as a capsule size which is unpalatable to and disfavored by patients.

Id. After a final rejection dated May 21, 2002, the examiner held a telephone interview with applicants. In his notes summarizing the interview, the examiner stated, "Applicants more clearly explained the necessity for using their bulk density range (allowing the compression of calcium acetate in small size tablets)."

In a further amendment following the interview, applicants stated that

> the gelatin capsule must be a size that can be conveniently swallowed. A dose of calcium acetate such as that disclosed by Fordtran would require at least a size #00 capsule. This capsule is colloquially described as a horse pill. By compressing the calcium acetate to form a caplet having a size and shape that optimally fills the volume in a smaller standard capsule as recited in the independent claims, Applicants have overcome the disadvantage of the unpleasant bitter taste, while administering the dose in a more easily ingested capsule. . . . The advantages of using a caplet in a capsule compared to untabletted powder in a capsule can be seen by comparing the size of the #0 capsule that contains a caplet with a #00 capsule that has been used to administer the calcium acetate powder. . . . Thus, forming a caplet that fits in the smaller capsule allows the dose to be presented to the patient in a much smaller, more easily swallowed dose.

July 18, 2002 Remarks at 8-9 (emphasis added).

Paddock argues that to interpret the claims to include capsule sizes #00 and larger would "materially affect the basic and novel properties of the invention." AK Steel Corp. v. Sollac, 344 F.3d 1234, 1239-1240 (Fed Cir. 2003). Paddock contends that Fresenius clearly disclaimed capsules size #00 and larger to distinguish their invention from the prior art and argues that Fresenius cannot now reclaim these larger capsule sizes through claim construction litigation. L&P Prop. v. JTM, LLC, 578 F. Supp. 2d 318, 325 (D. Mass. 2008).

While the invention disclosed in the '665 and '445 patents indisputably sought a remedy to the problem of difficult-to-swallow pills, there is no clear disclaimer of the use of capsules of size #00 or greater. "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Eng'g, Inc., 334 F.3d at 1324. See also Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1359 (Fed. Cir. 2001) ("When a patentee advises the examiner (and the public after patent issuance) that a particular structure is not within his invention, the patentee is not permitted to assert in a subsequent infringement action that the same structure is equivalent to the structure described in the patentee's specification."). A limitation based on disclaimer must, however, be shown "with reasonable clarity and deliberateness." Revolution Eyeware, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1368 (Fed. Cir. 2009).

Consistent with what the record will support, the term "capsule" will be construed as meaning

> a capsule within a size range consistent with what a human patient with chronic renal failure can manipulate and swallow.

While it is the court's assumption from the parties' assertions that this construction might well include a capsule size #00, that is an issue for a jury to determine on the expert medical evidence offered at trial.

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A. "Simulated Capsule-Like Medicament"

This phrase appears at the beginning and the end of Claim 1, and is used the same way in each instance. The parties are essentially in agreement that the ordinary meaning of this phrase is "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell containing medicine." This is essentially the definition derived from Webster's Third New International Dictionary (1961), an extrinsic source to which the Court may properly turn.

Defendant argues, however, that "capsule-like" is effectively defined in the specification and the prosecution history of the '524 patent as meaning "similar to a hard gelatin capsule". Defendant's sole argument with regard to the specification is that "the only capsules disclosed or referred to in the '524 patent are hard gelatin capsules with overlapping separable halves… [having] an overlap where the one capsule half fits inside the other, and a visible raised portion" (Defendant Bayer Corporation's Markman Brief at 25 - 26), so that when the phrase "capsule-like" appears in the '524 patent, it must mean "similar to a hard gelatin capsule".

Defendant would have the Court place too much weight on indirect references in the specification to "hard gelatin capsules". The claims do not specifically state that the claimed medicament is intended to simulate a "hard gelatin capsule," and the specification does not do so either. "Capsule" has a clear, ordinary meaning, as the parties agree, so that there is no automatic need to turn to the specification for clarity, and therefore the '524 patentee could not have assigned a different meaning to the term unless he had explicitly set out a special definition in the specification. See Johnson Worldwide, 175 F.3d at 990.

The two distinct references to hard gelatin capsules in the specification, when read carefully in context, do not purport to use that phrase as a definition for the term "capsule." The narrative description of the background of the invention mentions "hard gelatin capsules" as a means of encapsulating medicine that was popular and widespread until the mid-1980's, when a need arose to replace the capsules with products such as the medicament claimed in the '524 patent, and the detailed description of the invention in the '524 patent mentions the particular use of hard gelatin capsule-producing machinery as instruments which may be converted to the production of the "simulated capsule-like medicaments" claimed in the patent. In neither case does the patent define "hard gelatin capsules" as the only type of capsules used in this industry; indeed, the phrase "hard gelatin capsule" is not set out in the specification as a definition at all - it is merely a type of capsule to which the specification happens to make reference, and a mere reference to this type of capsule in the specification cannot serve to define "capsule" as meaning specifically "hard gelatin capsule" for purposes of the claims. The finished product resulting from the process described in Claim I may very broadly resemble a hard gelatin capsule, as a cylindrical caplet is coated with gelatin layers of different colors, but the claim terms and the specification do not define the specific phrase "simulated capsule-like" to mean only medicaments that simulate the hard gelatin capsules to which the specification makes reference.

Defendant argues that "capsule" is given a particular definition by the prosecution history. The first application by the patentee of the '524 patent, Mr. Berta, was rejected by the PTO, and in order to escape rejection, he filed an amended version of his claims, along with remarks explaining the changes and the manner in which they distinguished this patent from the 1898 Richards patent and thus warranted granting of this patent; these remarks are now part of the prosecution history. In these remarks, the patentee states that "the change in thickness at the end of the outer gelatinous coating accompanied by the changing color makes it appear that rather than a coated caplet, the medicament is actually a hollow, hard gelatin capsule."

This phrasing in the prosecution history is not enough to limit the construction of the disputed terms in the claims, however, because, under clear Federal Circuit precedent, the prosecution history cannot be used to enlarge, vary, or diminish the limitations in the claim language, unless the patentee has disclaimed or disavowed a certain scope or definition for the purpose of escaping rejection by the PTO. In this case, the phrase "simulated capsule-like medicament" appears in both the original application by the patentee and the amended application, and the remarks in the amended application state that it is the new language, regarding the color dichotomy and the seam resulting from the overlapping of the layers of gelatin, that has been added in order to avoid rejection. The patentee did not amend the wording of the phrase "simulated capsule-like medicament."

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In addition, the seven pages of remarks accompanying the newly worded claims describe how the claim terms, as amended, disclose an invention which is different than the invention disclosed in the Richards patent. The remarks specifically emphasize a change in color and a change in thickness as elements which set the claimed invention off from the older patent, but they do not state that the claimed invention is distinct from the Richards patent by virtue of resembling a "hard gelatin capsule." The description quoted by defendant is made in passing, in a single place in the remarks. Elsewhere in the remarks, the patentee says simply that the appearance of the medicament provides an "illusion that the medicament is actually a capsule," and that it "would fool the viewer into believing that it was, in fact, a capsule." The patentee did not disclaim or disavow other possible types of capsules by making a single reference to a "hollow, hard gelatin capsule," given that in several other places the patentee represented that the general illusion of a "capsule" was sufficient to achieve the effect required for his claimed invention. Since the patentee did not endeavor to escape rejection by arguing to the PTO that his invention was limited to a medicament specifically simulating a "hard gelatin capsule," and he did not 'clearly disavow' coverage of simulated capsules other than simulated hard gelatin capsules, he did not limit the '524 patent to such type of medicament, and the Court will not read that limitation into the claims from the prosecution history. See, e.g., York Products, 99 F.3d at 1572. The phrase "simulated capsule-like medicament" will be construed to have its ordinary meaning.

In this case, where the term has a clear ordinary meaning, the specification does not provide an explicit alternative definition, and the prosecution history does not require such a definition, the Court would only apply a different definition for the term if there were clear evidence that the term would have a meaning other than the ordinary meaning for one skilled in the art of the patent. Here, defendant offers expert testimony as extrinsic evidence that "capsule-like" would be understood by an ordinary person skilled in the art of pharmaceutics to mean "like a hard gelatin capsule." Defendant's witness, Dr. Gilbert Banker, did not provide an interpretation of the term "capsule" from the perspective of pharmaceutics, however. Rather, Banker offered his own opinion of how one skilled in the art would understand the phrase "simulated capsule-like medicament" in light of the other remarks in the specification and the prosecution history. Asked to give his understanding of the phrase, Banker remarked, "We have a hard gelatin capsule. There are, by the way, soft gelatin capsules, but they are not at issue here. This patent is clearly related to hard gelatin capsules… It was made clear in the specification that we were dealing with hard gelatin capsules." Markman Hearing on Patent Claim Construction, transcript at 148 - 149.

Having testified that hard gelatin capsules have strictly circular cross-sections, Banker then also testified that the United States Pharmacopeia, a standard reference work in the field, refers to flat, pancake-shaped caplets as "capsule-shapes." Id. at 205. He agreed that this definition is "a general definition… that people use," id. Having defined "cylindrical" as meaning "shaped like a hard gelatin capsule," Banker was asked, "Capsule-shaped then does not necessarily mean cylindrical?", and he replied, "That's right." Id. at 210. Banker thus conceded that there are other common capsule forms aside from hard gelatin capsules, and that the phrase "capsule-shaped" is commonly used to refer to a shape other than that of a hard gelatin capsule. The expert testimony was therefore not conclusive on whether "simulated capsule-like" would be understood by one of ordinary skill in the art of pharmaceutics to mean "like a hard gelatin capsule." Banker thus did not offer expert testimony as to how the term "capsule" is understood by one skilled in the art of pharmaceutics, but rather offered his own construction of the term based upon limitations that he perceived as implicit in the intrinsic evidence of the '524 patent. As a matter of law, claim construction is the duty of the court. Here, the Court does not agree with Banker's assessment that the patent, using the regular rules of claim construction, is "clearly" limited to hard gelatin capsules. The disputed phrase is not ambiguous in the claim, the specification does not lay out a particular definition for the phrase, and the prosecution history does not indicate that the patentee disavowed claims to medicaments defined by the phrase as commonly understood. Therefore, the Court will assign the plain, ordinary meaning to the phrase "simulated capsule-like." 1

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1 It may be that the '524 patent, read as a whole, discloses only medicaments that turn out to resemble hard gelatin capsules, but that fact would not, by itself, mean that the specific phrase "simulated capsule-like medicament" is limited to such a narrow definition.

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* * *

IV. CONCLUSION

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The Court concludes that the disputed terms have the following meanings:

1. "Simulated capsule-like medicament" shall mean "a medicinal form that imitates, resembles, or suggests in form or appearance a gelatin shell enclosing medicine."
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c. "Carbohydrate"

The issue relating to SEACO's use of the term "carbohydrate" as it appears in each of the claims in the '310 patent and claims 9-14 and 18-20 in the '325 patent is whether the term encompasses solutions using waste stream components. Although the claim language is the first thing to be considered when constructing a term,

> [w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1319 (Fed. Cir. 2006) (quoting SciMed Life Sys. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1341 (Fed. Cir. 2001)). In Honeywell Int'l, the Federal Circuit concluded that the inventor renounced the use of carbon fibers based upon the criticism included in the patent's specification. Id. The court found that the inventor "informed its readers specifically why carbon fibers would not be suitable as 'electronically conductive fibers' in the claimed invention. If the written description could talk, it would say, 'Do not use carbon fibers.'" Id. at 1320.

Much like the inventor in Honeywell Int'l, SEACO criticized previously patented de-icing solutions for the use of agricultural residues, including corn based distillers solubles and solubles from the corn wet milling industries. (See '310 Patent, col. 1, lns. 56-67; '325 Patent, col. 1, lns. 56-67.) SEACO's disparagement of agricultural residues was stated as follows:

> These naturally occurring substances, which also include brewers condensed solubles, are extremely variable in composition, viscosity, film forming tendency, freezing temperature, pH etc., and consequently give varying performance when used in de-icing solutions. Depending upon the source and batch, these materials at low temperatures sometimes exhibit such resistance to flow that they cannot be applied evenly to a road surface or mixed with a chloride, rendering them virtually unsuitable for use.
>
> Furthermore, these patents utilize materials which have highly undesirable or unnecessary ingredients leading to practical difficulties by manufacturers and users, such as stratification in storage, biological degradation, odor, plugging of filters and spray nozzles and environmental difficulties, e.g., high biological oxygen demand due to the very high organic contents (about 40% by weight), presence of phosphorus compounds and heavy metals.
>
> To improve quality and performance, and to meet current mandated standards, there is an immediate need for synthetic, chemically modified thickeners, and carefully purified materials which can be substituted for the currently used agricultural residues. Such a formulation would improve performance and reduce metal corrosion, spalling of concrete, toxicity and addresses environmental concerns.

('310 Patent, col. 1, lns. 56-67, col. 2, lns. 1-15; '325 Patent, col. 1, ln. 56-col. 2, ln. 15.) Based upon these statements, SEACO made clear to a person of ordinary skill in the art why waste stream products consisting of agricultural residues are problematic for deicing solutions and should not be used if possible. To further elucidate upon the intention of the '310 and '325 patents, SEACO stated:

> It is therefore an object of the present invention to provide a deicing formulation which exhibits improved performance standards which overcomes the prior art problems described above . . . .

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It is a further object of the present invention to provide a deicing formulation which provides consistent physical and chemical properties, thereby assuring consistent quality and performance.

('310 Patent, col. 2, lns. 16-19, 29-32; '325 Patent, col. 2, lns. 16-19, 29-32.)

Without more, SEACO would have expressly disavowed any use of carbohydrates derived from waste streams or agricultural residues due to the many problems associated with these components. However, oddly enough, SEACO later in its specification makes the following disclosure:

From the above discussion and laboratory evaluations the basic composition consists of at least the first two of the following components in aqueous solution depending upon ambient weather conditions, terrain, nature and amount of freezing/snow precipitation, environmental concerns, etc.:

(1) An inorganic freezing point depressant in the form of inorganic electrolytes, mainly chlorides, but also others, such as sulfates and acetates . . . [, and]

(2) A carbohydrate, especially lower molecular weight carbohydrates in a range of about 180 to 1500. A preferred range is about 180 to 1,000. The carbohydrates can be obtained primarily from a wide range of agricultural based products such as those derived from corn, wheat, barley, oats, sugar cane, sugar beet, etc.

('310 Patent col. 6, lns. 60-67, col. 7, lns. 3-8; '325 Patent, col. 6, lns. 60-66, col. 7, lns. 3-8 (emphasis added).)

MLI contends this passage signifies SEACO's original intention to include carbohydrates derived from unrefined and inconsistent sources. Although the specification for the '310 and '325 patents indisputably teaches that carbohydrates for use in the aqueous solution can be obtained from agricultural products, MLI has pointed to nothing in the specification that contradicts SEACO's express disparagement of carbohydrates derived from inconsistent or unrefined sources. There has been no evidence presented to show that the agricultural based products used to obtain the carbohydrates are unrefined sources. To the contrary, the carbohydrates used in the examples stated in the specifications are derived from refined agricultural products. See Sears Petroleum Transp. Corp., 2007 U.S. Dist. LEXIS 53576, 2007 WL 2156251, at *16 (finding that the embodiments within SEACO's '793 parent patent "utilize[d] refined agricultural products," including commonly available glucose, fructose, maltose, lactose, corn syrup DE44, corn syrup DE20, molasses, and maltodextrin).

MLI's emphasis on the inclusion of Brewers Condensed Solubles in various tables of the '310 and '325 patent specifications is equally unpersuasive because, after reading the specification in its entirety, it is apparent that SEACO conducted laboratory tests of the Brewers Condensed Solubles as a test sample for purposes of establishing that low molecular weight carbohydrates had the greatest effect upon the freezing point of the solution. Even under the most reasonably broad construction of the term "carbohydrate," a person of ordinary skill in the art would recognize this distinction based upon the criticism of carbohydrates derived from unrefined, inconsistent waste-stream sources as well as the discussion of the effect of low molecular weight carbohydrates upon freezing point depression following the testing of Brewers Condensed Solubles. Therefore, SEACO's use of the term "carbohydrate" in its '310 and '325 patents must be construed to exclude carbohydrates derived from unrefined, inconsistent waste-streams.

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II.

Schwarz Pharma and Warner-Lambert disagree on the proper method of claim construction as set forth in three of our cases: Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294 (Fed. Cir. 2003); Texas Digital Systems v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002); and Rexnord Corp. v. Laitram Corp., 274 F.3d 1336 (Fed. Cir. 2001). In arguing that the district court erred in its claim construction, Schwarz Pharma interprets this trilogy as requiring that a claim term carry the full range of its ordinary, art-recognized meaning unless the specification and prosecution history compel a contrary conclusion or express a "manifest exclusion or restriction limiting the claim term." Brookhill-Wilk 1, 334 F.3d at 1301. Accordingly, Schwarz Pharma contends that, in this case, we should presume that the broadest, ordinary, art-recognized definition of the term "carbonate," the one that includes both the carbonate and bicarbonate ions, applies before examining

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the specification and prosecution history.

Schwarz Pharma contends that the specification and the prosecution history of the '450 patent support this broad definition. The section of the specification titled "STABILIZERS" reads, "borates, silicates, and carbonates are contemplated. Carbonates are preferred." '450 patent, col. 3, ll. 30-39 (emphases added). Use of the plural "carbonates," Schwarz Pharma states, discloses to one of ordinary skill in the art that the anionic, or negatively charged, portion of the stabilizer molecule may consist of any type of "carbonate," including the bicarbonate ion. In addition, Schwarz Pharma urges that because the construction and scope of the term "carbonate" did not arise during prosecution, the prosecution history is irrelevant. Thus, according to Schwarz Pharma, without a manifest exclusion or restriction limiting the term "carbonate" to only the carbonate ion, we are bound to give the term the full range of its ordinary, art-recognized meaning, which includes both the carbonate and bicarbonate ions.

Warner-Lambert disagrees with Schwarz Pharma's conclusion that the caselaw dictates a presumption in favor of the broadest, ordinary, art-recognized meaning of a disputed claim term. To the contrary, Warner-Lambert contends that in a case such as this, where the parties do not agree as to a single ordinary meaning for a claim term, and the dictionaries fail to establish one, the court must use the specification and prosecution history to determine which definition is more consistent with the inventor's use of the term. Brookhill-Wilk 1, 334 F.3d at 1300; Tex. Digital, 308 F.3d at 1203. Thus, according to Warner-Lambert, no presumption operates in favor of either definition prior to examination of the intrinsic evidence.

Turning to such evidence, Warner-Lambert reads the patentee's use of the singular "carbonate" in the claim language to mean that only the carbonate ion was meant to be covered by the claims. Warner-Lambert also notes that the bicarbonate ion does not appear in the patent, while the term "carbonate" is consistently used in the specification to refer specifically to the carbonate ion. Warner-Lambert also relies heavily on the incorporation into the '450 patent of two other Warner-Lambert patents, U.S. Patent Nos. 4,425,355 (issued Jan. 10, 1984) ("the '355 patent") and 4,344,949 (issued Aug. 17, 1982) ("the '949 patent"). Both expressly differentiate between alkali "carbonates" and "bicarbonates," and the '355 patent was even prosecuted by the same Warner-Lambert attorney as the '450 patent. Accordingly, Warner-Lambert urges that because it had previously differentiated between the two compounds in other patents, yet failed to do so in the '450 patent, we should narrowly construe "carbonate" to be limited to the carbonate ion.

With respect to the prosecution history, Teva contends that, accepting the district court's claim construction, the patentee's claim amendments give rise to a presumptive application of prosecution history estoppel. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 738-41, 152 L. Ed. 2d 944, 122 S. Ct. 1831 (2002). As originally drafted, the claims disclosed a "metal containing stabilizer" and an "alkali or alkaline earth-metal salt," and it was only after the examiner rejected them as obvious that the patentee amended them to disclose an "alkali or alkaline earth metal carbonate . . . ." Because this amendment narrowed the claims to distinguish prior art, Teva argues that Schwarz Pharma is thereby estopped from claiming any range of equivalents to the term "carbonate."

B.

This case squarely triggers the trilogy of Brookhill-Wilk 1, Texas Digital, and Rexnord. The parties do not dispute the district court's conclusion that the term "carbonate" has two ordinary, art-recognized meanings: a narrow definition limited to the carbonate ion, and a broader definition including both the carbonate and bicarbonate ions. Our guidance in Rexnord is therefore instructive: "unless compelled to do otherwise, a court will give a claim term the full range of its ordinary meaning as understood by an artisan of ordinary skill." 274 F.3d at 1342 (citing Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). We also explained in Texas Digital that "if more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." 308 F.3d at 1203; see also Brookhill-Wilk 1, 334 F.3d at 1300. Consequently, consistent with the full range of its ordinary, art-recognized meaning, we begin with the definition of carbonate that includes both the carbonate and bicarbonate ions until compelled otherwise.

Having ascertained the ordinary meaning of the disputed term, "the next step is to examine the written description and the drawings to confirm that the patentee's use of the disputed terms is consistent with the meaning given to it by the court." Rexnord, 274 F.3d at 1342. The same process must be undertaken with the prosecution history as well. Id. at 1343. The presumption in favor of the dictionary definition is only overcome where the patentee "has clearly set forth an explicit definition of the term different from its ordinary meaning" or if the inventor has "disavowed or disclaimed scope of

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coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Tex. Digital, 308 F.3d at 1204.

Upon examination of the specification and prosecution history of the '450 patent, we can find no clear disavowal of or restriction on the scope of the term "carbonate." There is simply no evidence that the narrower construction advocated by Warner-Lambert is more consistent with the patentee's use of the term. The broad definition therefore stands, and we construe the term "alkali or alkaline earth metal carbonate" to include both the carbonate and bicarbonate ions.

Starting with the specification of the '450 patent, we see no restriction on the scope of the term "carbonate." Warner-Lambert's reliance on the specification's incorporation by reference of the '355 and '949 patents and their explicit distinction between carbonate and bicarbonate is insufficient to overcome the presumptive breadth the claim language enjoys under our precedent. As we noted in Johnson Worldwide, 175 F.3d at 991, "varied use of a disputed term . . . demonstrates the breadth of the term rather than providing a limited definition." Differing uses of the word "carbonate" in the incorporated patents demonstrate the fact that the term had more than one meaning to those of skill in the art. But the incorporated patents are not conclusive proof that the patentee selected a single meaning for the term in the '450 patent.

Furthermore, the '355 and '949 patents were incorporated into the '450 patent not for their distinction between carbonate and bicarbonate, but instead for their disclosure of the ACE inhibitor compounds:

DRUG COMPONENTS

* * * *

The ACE inhibitors which can be used in the invention are any of a group of well-known compounds which have antihypertensive properties.

* * * *

Compounds of this type are disclosed in U.S. Pat. Nos. 4,344,949 . . . and 4,425,355, the disclosure of which are hereby incorporated by reference.

'450 patent, col. 2, ll. 4-37 (emphasis added). The incorporation is expressly limited to the "disclosure" of the drug component compounds; it makes no reference to the synthesis of the compounds, to which the '355 and '949 patents are directed, or to the composition of the stabilizers in connection with which the term "carbonate" is used in the '450 patent. The incorporation of Warner-Lambert's prior patents is therefore not instructive with respect to the claim construction of the '450 patent. To be sure, the '450 patent does incorporate by reference other patents that distinguish between carbonate and bicarbonate, and it is of course common knowledge that there is a difference between the two chemicals. But, as we have noted above, more than the circumstances of this particular incorporation is necessary to overcome the solid precedent that points to the broad meaning of the term in the '450 patent. Warner-Lambert has not come to grips with the law that affords breadth to the patent. Indeed, aside from making its incorporation by reference argument, Warner-Lambert points to nothing in the specification that could be interpreted as limiting the scope of the claim language.

Not only is there no clear disavowal or restriction on the scope of the claim term "carbonate," but also the specification actually supports the broader interpretation of the term. The section titled "STABILIZERS" explains that

The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred.

The anionic portion of the salt employee may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.

Id. at col. 3, ll. 30-39 (emphases added). A salt is composed of a positively charged cation and a negatively charged anion. Use of the plural "carbonates" for the anionic portion of the stabilizer means that more than just the carbonate ion is contemplated for that portion, the only other possibility being the bicarbonate ion. This is evidence that the patentee actually

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intended for "carbonates" to include bicarbonate. Warner-Lambert's only counterargument relies on the fact that the inventors of the '450 patent failed the only time they attempted to use bicarbonate as the anion; thus, they could not have intended for the '450 patent to cover bicarbonate. As this constitutes extrinsic evidence, however, and as we find the term "carbonate" to be unambiguous, it is not properly considered in our claim construction analysis. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996).

With regard to the prosecution history, we agree with Schwarz Pharma that it is simply not pertinent to the claim construction analysis. Warner-Lambert's application that issued as the '450 patent claimed "a suitable amount of a metal containing stabilizer," but was initially rejected by the patent examiner as obvious in light of a prior art patent: "Veber et al., Examples, teach pharmaceutical compositions containing enalapril and lactose. It is the examiner's opinion that the claimed composition would be obvious in view of Veber et al." In response, Warner-Lambert amended the application to claim "a suitable amount of an alkali or alkaline earth metal carbonate . . . ." In presenting its amendment, Warner-Lambert explained that the Veber patent taught a new method of use for known ACE inhibitors, such as enalapril, for treating senile macular degeneration, without suggesting or even mentioning stability problems in those ACE inhibitors. In contrast, Warner-Lambert stated, the application for the '450 patent, amended to claim an "alkali or alkaline earth metal carbonate," solved a severe degradation problem of those inhibitors. After the amendment, the patent issued.

The prosecution history does not demonstrate any intent by the patentee to exclude the bicarbonate ion from the stabilizer compounds. The term "alkali or alkaline earth metal carbonate" is used throughout the prosecution history in the same way it is used in the claims of the '450 patent. The patentee never identified "carbonate" with a chemical symbol, CO[3]2- or anything else. The scope of the term "carbonate" is simply not addressed by the prosecution history of the '450 patent.

Thus, as in Brookhill-Wilk 1,

where, as here, the written description and prosecution history fail to express a manifest exclusion or restriction limiting the claim term, and where the written description otherwise supports the broader interpretation, "we are constrained to follow the language of the claims," and to give the claim term its full breadth of ordinary meaning as understood by persons skilled in the relevant art.

334 F.3d at 1301-2 (quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1328 (Fed. Cir. 2002)) (citations omitted). In the absence of any intrinsic evidence of a disavowed or disclaimed scope of coverage, and without words or expressions of manifest exclusion or restriction representing a clear disavowal of claim scope of the term "alkali or alkaline earth metal carbonate," the broad definition of the term "carbonate" stands. We therefore construe the term to include both the carbonate and bicarbonate ions.

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I respectfully dissent from the decision of the majority to vacate and remand. I would affirm. The district court did a thorough job of analyzing all the aspects of the claim construction of the term "carbonate" and arrived at the correct conclusion. There was no ambiguity and it is clear to me from the record that bicarbonate was not part of the definition of carbonate.

It is very clear that the bicarbonate anion, which contains a hydrogen atom, is not the same as the carbonate anion, which lacks a hydrogen atom. They are different ions. Sodium carbonate even has a different common name (soda ash) from sodium bicarbonate (baking soda). Solutions of the compounds have different pHs (strongly alkaline vs. weakly acidic). See The Merck Index (Maryadele J. O'Neil ed., 13th ed. 2001) (stating that the hydrogen atom brings a degree of acidity to what is a more basic compound).

Most importantly, when the patentee, Warner-Lambert ("WL"), wanted to include both compounds in a patent, it did that expressly. See U.S. Patent 4,425,355, col. 6, ll. 51-53 ("a suitable basic reagent, such as . . . alkali carbonates or bicarbonates"); U.S. Patent 4,344,949, col. 3, ll. 18-20. It thus knew how to distinguish one ion from the other. It is absolutely compelling, beyond anything just stated, that WL intended to include only carbonates in its formulation in this patent because it knew of Merck prior art which, if bicarbonate were included in its patent, might render that patent invalid. Merck's product in the public domain contained an ACE inhibitor, a saccharide, and a bicarbonate, exactly what would be

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claimed if Schwarz's interpretation of the claim here were adopted. That is why we have the unusual situation in which a licensor, the patentee WL, is urging the narrower formulation against the broader interpretation of its licensee.

We have often said that a patentee's litigation statements do not count for much when a claim is being interpreted. That is because they are self-serving and after-the-fact. See Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379-80 (Fed. Cir. 2000). However, when a patentee argues for a narrower interpretation, essentially against its interest, at least in an infringement context, that fact is meaningful.

As for the plural reference to "carbonates" in the patent, that relates to magnesium, calcium, and sodium carbonates, for example, not to bicarbonates.

Thus, with all due respect to my colleagues, I must dissent. The district court arrived at the correct decision and should be affirmed.
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Also at issue in claim 1 is the meaning of the term "carboxypolymethylene." Carboxypolymethylene, when combined with other chemicals to form the matrix material, provides the desired viscous and tacky characteristics of the bleaching composition. In view of Exxon's requirement that the end product contain the specified range of carboxypolymethylene, defendants assert that when an initial amount of carboxypolymethylene is combined with a neutralizing base as described in the specification, the resultant chemical reaction creates a composition that no longer includes carboxypolymethylene, but instead a neutralized salt of carboxypolymethylene. Thus, defendants maintain either that the proportion of carboxypolymethylene is reduced, or that there no longer exists any "carboxypolymethylene."

Ultradent, on the other hand, argues that the term "carboxypolymethylene" as used in claim 1 is understood by those skilled in the art to encompass both non-neutralized carboxypolymethylene as well as neutralized salts of carboxypolymethylene, and hence infringement may be shown by establishing the existence of either one in the requisite amount in an accused dental bleaching composition. Further, Ultradent claims that the mixing of chemicals to make the claimed composition only raises the pH of the carboxypolymethylene and does not change the chemical identity or the weight percentage of the carboxypolymethylene in the composition.

The language of claim 1 provides no additional clarification of the meaning of the disputed term, nor does the language of any of the other claims in the '303 patent. None of the prosecution history the court has seen has discussed the meaning of carboxypolymethylene. The specification of the '303 patent, however, is helpful in construing the term's meaning. The detailed description of the preferred embodiments states that "one currently preferred high viscosity matrix material is a concentrated carboxypolymethylene composition. Carboxypolymethylene is a slightly acidic vinyl polymer with active carboxyl groups." The specification further informs that "because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of the resulting bleaching composition." These are the only definitions found in the specification. There is additional mention elsewhere in the specification of the use of "carboxypolymethylene compositions," referring to compositions made with carboxypolymethylene as a starting ingredient, and in each of nine examples of formulas for making the claimed composition n5 Carbopol 934P, a commercially available carboxypolymethylene resin, is listed as an ingredient to be mixed with other chemicals including the carbamide peroxide active bleaching agent and sodium hydroxide, a neutralizing base.

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n5 One of the nine examples given is a formula for a dental fluoride treatment composition, rather than a bleaching composition, also to be used with a dental tray according to the method of claim 1.

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The dictionary defines carboxylic acid as "any organic acid containing one or more carboxyl groups," The Random House Dictionary of the English Language, 313 (2d ed. unabridged 1987), and defines a carboxyl group as "the univalent radical COOH, present in and characteristic of organic acids." Id. Ultradent provided the court with an excerpt from a chemical

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encyclopedia defining carboxypolymethylene as "[a] vinyl polymer with active carboxyl groups" and further describing it as a "white powder," "highly ionic and slightly acidic," and noted that it "reacts with fatty amines to form thick and stable emulsions of oils in water." The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals 278 (Susan Budavari et al. eds., 1989). Similarly, one of Ultradent's experts, Dr. Garold Yost, submitted a declaration to the court stating "carboxypolymethylene is a slightly acidic vinyl polymer." The defendants submitted a declaration by an expert, Dr. Harry Albers, stating that "the carboxypolymethylene . . . would have reacted with (i.e., would have been neutralized by) the added [base] to form a complex or a new ingredient altogether. The resulting complex would not have the active carboxyl groups of carboxypolymethylene due to the reaction of the carboxypolymethylene with the [base]."

Ultradent nonetheless argues that claim 1 ought to be interpreted to read on all carboxypolymethylene compositions, whether they contain non-neutralized acids or neutralized salts of carboxypolymethylene. Claim 1 likely was drafted as it was because the applicant intended to define the claim by specifying an amount of carboxypolymethylene to be used as an initial ingredient used in formulating the composition. Exxon, however, requires that a chemical composition claim, as opposed to a process claim, must recite the components of the composition, not the ingredients to be combined to make the composition, if it wishes to claim as an invention a composition of specific proportions of particular elements. Exxon, 64 F.3d at 1558.

Courts "are not free to read the claims as they might have been drafted, even if as drafted they do not accomplish what the inventor may have intended." Id. at 1563 (Plager, J., concurring). "There is no room in patent claim interpretation for the equivalent of the cy pres doctrine; that would leave the claiming process too indefinite to serve the purposes which lie at the heart of the patent system." Id. (Plager, J., concurring).

Therefore, this court interprets "said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the dental bleaching composition" to mean that the composition used in dental bleaching in accordance with the claimed method contains from about 3.5% to about 12% by weight of carboxypolymethylene defined as a slightly acidic vinyl polymer with active carboxyl groups.
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C. Carrier liquid/90% weight limitation.

The court now turns to the construction of the carrier liquid limitation, followed by a construction of the 90 wt. % limitation. Claim 1 requires the presence in the composition of "90 wt. %" of a carrier liquid selected from a Markush group. The plaintiff contends that "carrier liquid" means "a liquid to which an active ingredient or agent is added as a way of applying, transferring, or bringing into close proximity the ingredient or agent so that reaction can occur." The defendant contends that the term "carrier liquid" means "a liquid into which the bicyclic aromatic and inorganic metal oxide components are dispersed for transport to the hydrocarbon fuel."

The claim language, read in light of the specification, resolves these issues. The language "carrier liquid" suggests a liquid or fluid which carries or transports active ingredients. The specification explains: "the metal oxides and the bicyclic aromatic compound(s) in the composition of the present invention are dispersed in a carrier liquid, such that the composition is comprised at least 90% by weight of a carrier liquid selected from" the Markush group. 082 patent, col. 6, ll. 7-11 (emphasis added). This language suggests that a carrier liquid is a liquid into which the active ingredients or agents are dispersed as a way of transferring (or "carrying") those ingredients so that the intended reaction can occur. Although the plaintiff appears to object to the use of the term "dispersed," the court is considering the term "carrier liquid" in the context of the claim language as well as the specification. The cited passage of the specification emphasizes the function performed by the "carrier liquid." In this patent, the carrier liquid transports or carries (i.e. by having dispersed therein), certain active ingredients. The court therefore defines "carrier liquid" as "a liquid into which the active ingredients or agents are dispersed as a way of transferring those ingredients or agents so that the intended reaction can occur."

In addition, the parties dispute the calculation of the 90 wt. % limitation. The plaintiff contends that the 90 wt. % limitation applies to the total weight of the combination of the carrier liquid, the bicyclic aromatic component, the zinc oxide, and the group 8-11 metal oxide. The defendant contends that the 90 wt. % limitation applies to the entire composition accused of infringement, inclusive of both listed and any unlisted ingredients. The passage cited from the specification also informs the

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court's decision on this issue. The claim language, supported by the cited portion of the specification, states that the 90 wt. % limitation refers to the amount of the carrier liquid selected from the Markush group when combined with the listed ingredients of the claim. The specification refers to the combination of the metal oxides and the bicyclic aromatic being dispersed in the carrier liquid such that the claimed composition (i.e. the total of the carrier liquid and the listed limitations) is comprised at least 90% by weight of a carrier liquid. Accordingly, the court adopts the plaintiff's proposed construction of the 90 wt. % limitation.
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As an initial matter, we conclude that the district court properly relied on scientific and technical dictionaries to construe the ordinary and customary meaning of the term "catalyst" as "a substance that alters the velocity of a chemical reaction without being consumed." Because there is no suggestion that the intrinsic evidence defines the term "catalyst," one may look to technical dictionaries for assistance in determining that term's meaning to a person of ordinary skill in the art. Phillips, 415 at 1318 ("Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention. Such evidence, we have held, may be considered if the court deems it helpful in determining 'the true meaning of language used in the patent claims.'"). The McGraw-Hill Dictionary of Scientific and Technical Terms 307 (4th ed. 1989) defines a catalyst as a "substance that alters the velocity of a chemical reaction and may be recovered essentially unaltered in form and amount at the end of the reaction." The district court correctly accepted that ordinary and customary meaning.
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Catalyzing Material

All the asserted claims contain the term "catalyzing material." ReedHycalog contends the term means "a material used to help form bonds between adjacent crystals during the formation of the body of bonded diamonds." Defendants argue the term "catalyzing material" means "the material used to help form bonds between adjacent diamond crystals during sintering of the diamond table." 8 The parties' constructions raise three disputes: (1) whether the claims cover PCD elements made from multiple catalysts; (2) whether the catalyzing material is used during the formation of the body of diamonds or during sintering of the diamond table; and (3) whether the crystals used with the catalyzing material are limited to diamond crystals. 9

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8 Defendants, in their response brief, indicated they were amenable to replace the "adjacent diamond crystals" portion of their construction with "adjacent superhard, diamond, or diamond-like crystals." Defendants' Joint Responsive Claim Construction Brief, Docket No. 179, p. 11. However, at the Markman hearing, Defendants retreated to their initial proposed construction.

9 The parties in Tyler I disputed the construction of this term but then agreed to ReedHycalog's construction at the Markman hearing. Tyler I Claim Construction Opinion & Order, 12.

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The Term "A Catalyzing Material" is Not Limited to a Single Material

The asserted claims contain the term "a catalyzing material," which presumptively covers one or more catalyzing materials. Good Sportsman Mktg. LLC v. Testa Assocs., LLC, 440 F. Supp. 2d 570, 578-79 (E.D. Tex. 2006) (Davis, J.) (citing Free Motion Fitness, Inc. v. Cybex Int'l, Inc., 423 F.3d 1343, 1350-51 (Fed. Cir. 2005)). If the claims specifically limit the catalyzing material to a single material or the patents reveal the inventors' clear intent to limit the Patents-in-Suit to PCD elements with a single catalyzing material, the presumption of plurality no longer applies, and the term "a catalyzing

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material" has a singular meaning. Id. (citing Free Motion Fitness, 423 F.3d at 1350).

Nothing in the Patents-in-Suit--including the portions Defendants cite in their responsive brief--rebuts the presumption of plurality. Defendants contend the claims' usage of "the catalyzing material" indicates the inventors' clear intent to limit the term to a single catalyzing material. Claim 1 of the '985 Patent, for example, claims:

> a polycrystalline diamond element comprising a body of bonded diamond crystals . . . and a working surface on the body, wherein a first volume of the body remote from the working surface contains a catalyzing material, a second volume of the body adjacent to the working surface is substantially free of the catalyzing material, the catalyzing material remaining within the second volume of the body increases with distance from the working surface . . . .

'985 Patent, col. 14:21-31 (emphasis added).

The usage of "the catalyzing material" does not limit the claims to a single catalyzing material. The term "the catalyzing material" refers to the previously claimed "a catalyzing material." Free Motion Fitness, 423 F.3d at 1350-51. Thus, unless the intrinsic record otherwise requires a contrary construction, "the catalyzing material" means "the one or more catalyzing materials." Id.

The specifications support a plural construction of "a catalyzing material." The specifications indicate PCD elements are most often formed by sintering diamond powder with a suitable binder-catalyzing material in a high-pressure, high-temperature press. '985 Patent, col. 2:1-3. In one common process, diamond powder is applied to the surface of a preform tungsten carbide substrate that incorporates Cobalt. Id. at col. 2:6-9. A press then subjects the assembly to high temperatures and pressures, during which the Cobalt migrates from the substrate into the diamond layer. Id. at col. 2:9-15. The Cobalt acts as a binder-catalyzing material, causes the diamond particles to bond diamond-to-diamond, and causes the diamond layer to bond to the tungsten carbide substrate. Id. While Cobalt is the most commonly used catalyst, the specifications do not limit the binder-catalyzing material to Cobalt. Id. at col. 2:44-46.

The specifications explicitly explain the catalyzing material may contain "any group VIII element, including cobalt, nickel, iron, and alloys thereof." Id. Alloys are combinations of multiple elements. Thus, the specification supports the presumption that the term "catalyzing material" is not limited to a single material.

In total, nothing in the intrinsic record rebuts the presumption that the term "a catalyzing material" means "one or more catalyzing materials." For that reason, the Court will not import a singular meaning into the claims.

The Catalyzing Material is Used to Form Bonds During Formation of the Body of Bonded Diamonds

As described above, the specifications describe a process where the catalyzing material helps form the diamond-to-diamond bonds of the PCD element. Id. at col. 2:1-15. While the specifications describe a "sintering" process, that process is an example of a process to create a PCD element and does not limit the claim language, which describes a PCD element comprised of a body of bonded diamonds where the body contains a catalyzing material. Id. at col. 2:1-15, col. 14:21-34. Thus, the claims indicate the catalyzing material is used to form bonds during the formation of the body of bonded diamonds.

It is Improper to Limit the Catalyzing Material to Materials that Bond Diamond Crystals

The Patents-in-Suit indicate that it is improper to limit the term "a catalyzing material" to materials used to bond diamond crystals. The claims do not exclude non-diamond materials from the PCD body. The claims generally describe a PCD element that comprises a "body of bonded diamonds." E.g., '447 Patent, col. 14:24-32. A number of claims require the claimed body to comprise at least an 85% by volume diamond density. E.g., '137 Patent, col. 16:57-67. The claims do not require the catalyzing material to comprise a specific volume of the PCD body, and some claims indicate the PCD body may contain other superhard polycrystalline materials. E.g., '308 Patent, col. 16:50-64 (claiming a "preform cutting element comprising a body of superhard polycrystalline material comprising a plurality of bonded diamond crystals"). Thus, the claims indicate the catalyzing material may act to bond other crystals in the PCD body.

The specifications also indicate the catalyzing material need not only bond diamond crystals. The specifications explain that the PCD element of the present invention may contain a plurality of partially bonded superhard, diamond or diamond-like

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crystals. E.g., '447 Patent, col. 2:16-24. In total, the Patents-in-Suit do not limit the catalyzing material to materials that only help bond diamond crystals.

For the above reasons, "catalyzing material" means "a material used to help form bonds between adjacent crystals during the formation of the body of bonded diamonds."
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9. "causes"

This term appears in claims 12-19. Astra asserts that the Court should construe "causes" as "to produce the effect of." DRL does not propose a construction for this term, but rather argues once again that the phrases in which this term appears in claims 12-19 do not require construction because they are not limitations. Although it rejects DRL's argument, the Court shall nevertheless decline to construe the term. Astra provides only a dictionary definition as the basis for its construction. The Court finds no ambiguity as to the meaning of the term "causes," and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the "causes" as it is used in claims 12-19 of the '192 patent. The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply.
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b. CDR-grafted

Genentech argues that the term "CDR-grafted" of Claims 1 of the Page patents describes a particular type of recombinant antibody in which all six CDRs are transferred in their entirety from a non-human antibody onto a single human framework. The CDRs are six specific regions in the portion of the antibody corresponding to the arms of the "Y" shape that form the antigen binding site. Genentech contends that its proposed construction is supported by the specification and the examples of CDR-grafted antibodies referenced therein.

Glaxo argues in response that the term "CDR-grafted" describes a recombinant antibody where individual non-human CDRs or the amino acids therein have been altered before grafting into a human antibody framework region. Moreover, Glaxo points out that the specification does not state a specific number of CDRs, nor does it include the term "completely" in conjunction with "CDR-grafted." Thus, Glaxo contends that partial replacement is sufficient to satisfy the patent claims. In light of these proposed constructions, the essence of the dispute over this term is whether an antibody must have six complete non-human CDRs to be considered "CDR-grafted."

In support of its construction, Genentech refers the court to a portion of the specification describing a CDR-grafted antibody in a murine cell context as an antibody "where the murine constant domains and the murine framework regions are replaced by equivalent domains and regions of human origin." Genentech argues that this passage indicates that the CDRs are replaced by corresponding portions from a non-human antibody. Genentech further refers the court to a portion of the specification describing a CDR-grafted antibody as a "composite antibody, wherein parts of the hypervariable region in addition to the CDRs are transferred to the human framework." Genentech contends that this passage requires that a CDR-grafted antibody contain "parts" of a non-human hypervariable region along with all six non-human CDRs. Glaxo counters that the term "parts" refers to the CDRs, and as a result, CDR-grafted antibodies may include less than six complete non-human CDRs.

After reviewing the disputed passage of the specification, the court concludes that the term "parts" refers to the hypervariable region and not the CDRs. Moreover, the article "the" modifying CDRs makes the term "CDRs" inclusive of all CDRs. The court, therefore, finds that one skilled in the art would understand the passage to describe the presence of all CDRs in addition to other parts of the hypervariable region. As such, the court construes the phrase "CDR-grafted" to describe a recombinant antibody where all six CDRs have been replaced with complete non-human CDRs.
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(1) A prokaryotic or eukaryotic cell . . . The Court concludes that the first element of claim 1 of the '931 Patent applies to both prokaryotic and eukaryotic cells by virtue of the presence of the word "or".
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8. "cells transformed or transfected with an isolated DNA sequence encoding human erythropoitein" ('868 claims 1 and 2) and "isolating said glycosylated erythropoietin polypeptide expressed by said cells/therefrom" ('868 claims 1 and 2, '698 claims 4-9)

At the Markman hearing the parties suggested to the court the possibility of reaching an agreement as to the construction of these two phrases. Tr. 99:20-103:21. The Court gladly deferred to the parties on this matter since, in case of agreement, there would be no case or controversy and no need for judicial resolution. See Vivid Techs., Inc., 200 F.3d at 803 ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."). 1 While the parties have made substantial progress, a narrow dispute still remains. The present dispute centers on the phrase "and purified," as set forth below: 2

"cells transformed or transfected with an isolated
DNA sequence encoding human erythropoitein"
1868 claims 1 and 2

Amgen	Roche/Hoffmann	This Court (earlier case)
Cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions	Cells that have been genetically modified with isolated and purified DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions	Did not discuss, but defined "purified" in another context as "recovering in pure form" and "isolating" as not requiring "in pure form." Tr. 93:15-98:14

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1 Where the parties agree upon claim construction, that construction properly governs the course of subsequent proceedings just as would a stipulation of fact. Agreed upon claim constructions, however, ought not grow into interpretations enjoying stare decisis effect because it is only the judiciary -- not the parties -- that declares what the law is. Such agreements, of course, may, where appropriate, implicate judicial estoppel and, where a final judgment occurs, the doctrine of issue preclusion.

2 The substantial agreement in interpretation of these terms was communicated to the Court by a joint letter from the parties. Letter from Lloyd R. Day, Jr., Attorney for Amgen Inc., Leora Ben-Ami, Attorney for Roche, & Lee Carl Bromberg, Attorney for Roche to the Hon. William G. Young, United States District Court Judge for the District of Massachusetts (June 12, 2007).

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Roche/Hoffman seeks to add this limitation by drawing upon references to the prosecution history. As explained in Sky

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Techs., LLC v. Ariba, Inc., -- F. Supp. 2d --, 491 F. Supp. 2d 154, 2007 U.S. Dist. LEXIS 43100, 2007 WL 1705641 (D. Mass. June 14, 2007), however, to import into a claim at the Markman stage a limitation found in the prosecution history requires clear and unequivocal admissions by the patent holder, id. at *3. This is, after all, an exercise leading to determination as matter of law. Markman, 517 U.S. at 391. There is no such compelling evidence here. Accordingly, this Court, construing the language of the claim itself and according the language its plain and ordinary meaning, adopts Amgen's position.

"cells transformed or transfected with an isolated DNA sequence encoding human erythropoitein": cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions.

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A. "Cerebral ischemia"

The parties' first dispute concerns the term "cerebral ischemia," which appears in Claims 1 and 14. Plaintiffs propose that "cerebral ischemia" should be construed as "an imbalance of neuronal stimulation mechanisms." Plaintiffs assert that this construction is proper because the patentee was its own lexicographer; that is, the Plaintiffs' proposed construction is the definition that the patentee gave "cerebral ischemia" in the patent specification. (D.I. 223 at 2)

The Majority Defendants propose that "cerebral ischemia" should be construed as what they contend is its plain and ordinary meaning: "An acute interruption of blood supply to the brain characterized by a destruction of brain cells." To the extent the "destruction of brain cells" is a consequence of cerebral ischemia, and not strictly speaking part of cerebral ischemia, the Majority Defendants insist on including this within the construction because one of ordinary skill in the art reading the patent would understand that such brain cell destruction is part of the context of how the term is being used. (Tr. at 108-09)

Defendant Apotex also proposes that "cerebral ischemia" should be construed according to its plain and ordinary meaning, but what Apotex posits as the plain and ordinary meaning of the term differs from the meaning proposed by the Majority Defendants. Apotex proposes to construe "cerebral ischemia" as "an acute interruption of blood supply to the brain." In Apotex's view, the death of brain cells, which the Majority Defendants' construction requires, is a consequence of cerebral ischemia (one of many consequences), but it is not part of cerebral ischemia. On this point the Plaintiffs are in agreement with Apotex.

According to Plaintiffs, choosing between their construction and Defendants' proposed constructions turns largely on determining whether the patent relates to a problem of neuronal imbalance, as Plaintiffs contend, or instead deals essentially with a problem of blood supply to the brain, as Defendants' constructions imply. Plaintiffs acknowledge that the term "ischemia" has a plain and ordinary meaning to one of ordinary skill in the art having to do with an interruption in blood flow. (Tr. at 40-41) However, Plaintiffs insist that, in the context of the patent specification, it is clear that the patentee was using the term "cerebral ischemia" not to refer to an interruption in blood supply to the brain (i.e., cerebrum) but, instead, to refer to an imbalance of neuronal stimulation mechanisms.

According to Plaintiffs, one of ordinary skill in the art reading the entire patent would understand "that memantine acts on the NMDA [-methyl D-aspartate] receptor to deal with the neuronal imbalance. It does not act on blood flow." (Tr. at 14) Plaintiffs assert, therefore, that "the basic dispute between the parties is did the patent invent compounds, chemicals, directed to interfere with calcium ions through the NMDA receptor or did the patent invent chemical compounds that prevent the interruption of blood flow?" (Tr. at 20)

The Defendants, by contrast, argue that the issue requiring decision is not the broad question of whether the patent relates to nueronal activities or blood supply. Rather, the issue is whether the patentee met its burden of establishing that the patent used the term "cerebral ischemia" in some manner other than its plain and ordinary meaning. To the Majority Defendants, "the nub of the dispute" is "did the plaintiffs act with sufficient deliberateness and clarity such that they told readers that when they're talking about the word 'cerebral ischemia,' they are excluding from the definition the very essence of cerebral ischemia, which is the stoppage of blood flow." (Tr. at 90) To answer this question, one must first look at the pertinent parts

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of the specification and then "look at the rest of the specification and the intrinsic record and see if [the Plaintiffs'] argument really makes sense." (Tr. at 90-91)

I agree that the Defendants have properly framed the question presented, but I have concluded that Plaintiffs' answer is the correct one. Looking at how "cerebral ischemia" is used in the specification, and then considering the remainder of the specification and the intrinsic evidence, I find that the patentee defined "cerebral ischemia" with sufficient and "reasonable clarity, deliberateness, and precision" in the manner Plaintiffs propose. Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1354 (Fed. Cir. 2003) (internal quotation marks and emphasis omitted).

I reach this conclusion first by looking at how the patent specification uses the disputed term "cerebral ischemia." See generally ICU Medical, Inc. v. Alaris Medical Systems, Inc., 558 F.3d 1368, 1374 (Fed. Cir. 2009) (stating that because person having ordinary skill in art is deemed to read claim term in context of entire patent, including specification, "not only is th[is] written description helpful in construing claim terms, but it is also appropriate to rely heavily on the written description for guidance as to the meaning of the claims") (internal quotation marks omitted). The first two uses -- in the Abstract and then the first sentence of the patent -- do not tell one much that is helpful to resolving the parties' dispute. The Abstract begins by stating that the '703 patent discloses "[a] method for the prevention and treatment of cerebral ischemia using an adamantane derivative" of a formula. (JA1 (emphasis added)) The patent then begins with the statement: "The present invention relates to a method for the prevention or treatment of cerebral ischemia using an adamantane derivative" of a disclosed general formula. (JA2 at col. 1 lines 6-8 (emphasis added))

The patent goes on to state:

> The compounds according to formula (I) known from the above-cited patents have so far been used for the treatment of parkinsonian and parkinsonoid diseases. Their mode of action is attributed to a dopaminergic influence on the CNS [central nervous system] . . . .
>
> In contrast to this type of disease, cerebral ischemia is characterized by a pathophysiological situation defined by an imbalance of neuronal stimulation mechanisms. In this context, the excessive inflow of calcium through NMDA receptor channels finally leads to the destruction of brain cells in specific brain areas . . . .
>
> Therefore, in order to treat or eliminate this pathological situation, an antagonistic intervention is required with regard to the NMDA receptor channels . . . .
>
> The present invention is aimed at preparing and employing compounds which can be chemically generated by simple methods, exhibiting an NMDA receptor channel-antagonistic and anticonvulsive action, for use in the prevention and treatment of cerebral ischemia.

(JA2-3 at col. 2 lines 38-68 to col. 3 lines 1-3 (emphasis added; internal citations to prior art omitted))

The main points derived from these portions of the specification are that the invention has to do with the central nervous system and not the bloodstream; the problem the invention is directed to addressing is an imbalance of neuronal stimulation mechanisms; and the invention acts on NMDA receptor channels. All of these points support the Plaintiffs' construction and detract from the proposed constructions of the Defendants.

The patent's next use of "cerebral ischmia" is in the following context:

> It has been found unexpectedly that the use of these compounds prevents an impairment or further impairment, i.e., degeneration and loss of nerve cells, after ischemia. Therefore, the adamantane derivatives of formula (I) are especially suited for the prevention and treatment of cerebral ischemia after apoplexy, open-heart surgery, cardiac standstill, subarachnoidal homorrhage, transient cerebro-ischemic attacks, perinatal asphyxia, anoxia, hypoglycemia, apnoea and Alzheimer's disease. The amount employed is a cerebral-ischemia-alleviating or preventive amount.

(JA3 at col. 3 lines 7-17 (emphasis added)) Here, one of ordinary skill in the art would note the distinction between "ischemia," which has a plain and ordinary meaning relating to an interruption in blood supply, and "cerebral ischemia," which is being used, in context, to refer to a neuronal imbalance. 4

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4 Even if, in this portion of the specification, the patentee was using "ischemia" as a shorthand for "cerebral ischemia" -- and, hence, "ischemia" should be read in this portion of the patent to refer to neuronal mechanisms and not blood supply -- that would not undermine the conclusion that "cerebral ischemia" refers to neuronal mechanisms. That is, ambiguity in the patentee's use of the term "ischemai" does not necessarily lead to the conclusion that the patentee's use of the separate term "cerebral ischemia" is ambiguous.

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The next use of the term "cerebral ischemia" appears in describing prior art in connection with reporting the results of a pharmacological test. The patent states: "PCP has been shown to prevent the destruction of brain cells after cerebral ischemia in rats (Sauer et al., Neurosci. Lett. 91, 1988, 327, 332)." (JA3 at col. 4 lines 59-62 (emphasis added)) The study being referred to is not in the record before me. On its face, I am unable to find anything in this use of the term in the specification that undermines the Plaintiffs' construction.

The specification goes on to use "cerebral ischemia" in describing two additional pharmacological tests. 5 Example E is referred to by the caption "Protection Against Cerebral Ischemia." (JA4 at col. 6 line 27 (emphasis added)) The patent describes how in Example E the carotid arteries of rats are occluded and blood is withdrawn; thereafter this "ischemia is terminated by opening the carotids and reinfusion of the withdrawn blood." (JA4 at col. 6 lines 28-33) Clearly, here "ischemia" is being used in its plain and ordinary sense -- to refer to an interruption in the supply of blood to the brains of the rats -- as Plaintiffs acknowledge. (Tr. at 177) 6 The patent goes on to state that the results of Example E "show . . . reduction of the post-ischemic neuronal brain damage." (JA4 at col. 6 lines 52-53) Again, ischemia ("ischemic") is being used here to refer to an interruption in the blood supply. Nevertheless, the discussion of Example E also notes "the results show that the compounds according to formula (I) exhibit a neuroprotective action in cerebral ischemia." (JA4 at col. 6 lines 58-60 (emphasis added)) Here, it appears that "cerebral ischemia" is being used in a manner distinct from "ischemia;" that is, "cerebral ischemia" does not refer to an interruption in blood supply, even as "ischemia" alone does.

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5 More generally, and again supportive of Plaintiffs' construction, the specification describes several "pharmacological tests" establishing "[t]he efficacy of the compounds of formula (I)." (JA3 at col. 4 lines 52-53) Each of these tests relates to NMDA receptors; none relates to the bloodstream. See A (concluding compound "binds to NMDA receptor channels at the same site as the NMDA antagonist PCP") (JA4 at col. 5 lines 6-8); B ("[D]erivatives of formula (I) are able to block the NMDA receptor channel as has been described for PCP . . . .") (JA4 at col. 5 lines 41-42); C ("[D]erivatives of formula (I) exhibit a protective effect against electrically induced convulsions.") (JA4 at col. 6 lines 12-13); D ("[T]here is a correlation between the blocking of the NMDA receptor channel and the anticonvulsive action of the adamantanes of formula (I).") (JA4 at col. 6 lines 22-25); E (showing "reduction of the post-ischemic neuronal brain damage") (JA4 at col. 6 lines 52-53); F ("[D]erivatives of the present invention are protective against the NMDA-induced mortality.") (JA5 at col. 7 lines 7-9); G (results indicate "a specific interaction with the NMDA receptor channel and predict[] neuroprotective properties") (JA5 at col. 7 lines 37-39).

6 In their briefing, Plaintiffs had argued that "ischemia" as used in Example E means "i.e. 'an imbalance of neuronal stimulation mechanisms.'" (D.I. 235 at 8) This is incorrect. "Ischemia" as so construed in the context of Example E would be nonsensical. Moreover, it would mean that "ischemia" and "cerebral ischemia" mean the same thing, which, in context, they do not. At the hearing, Plaintiffs acknowledged that "ischemia" as used in this portion of the specification's discussion of Test E refers to the interruption of blood supply. (Tr. at 177)

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With respect to Example F, the patent states: "It is well known that, subsequent to cerebral ischemia, glutamate and aspartate levels increase massively in the brain." (JA4 at col. 6 lines 66-68 (emphasis added)) Defendants suggest that in this sentence "cerebral ischemia" must refer to an interruption of blood supply; because glutamate and aspartate are neurons, taking the Plaintiffs' construction would have the sentence effectively read "subsequent to an imbalance of neuronal stimulation one

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gets an imbalance of neuronal stimulation." See Tr. at 96-97, 196. In context, however, I believe even in Example F the patentee was using "cerebral ischemia" to refer to a neuronal condition and not to an interruption of blood supply. Substituting Plaintiffs' proposed construction in this sentence yields a true, and comprehensible, sentence: "It is well known that, subsequent to an imbalance of neuronal stimulation, glutamate and aspartate levels increase massively in the brain." (Tr. at 174) As importantly, the conclusion of Example F -- "We have found that the adamantane derivatives of the present invention are protective against the NMDA-induced mortality" (JA5 at col. 7 lines 7-9) -- does not make sense if "cerebral ischemia" is referring to a blood event as opposed to a neuronal event.

In the final uses of "cerebral ischemia" (other than in the claims), the patent specification states:

It is thus seen that certain adamantane derivatives, some of which are novel, have been provided for the prevention and treatment of cerebral ischemia, and that pharmaceutical compositions embodying such an adamantane derivative have been provided for use in the prevention and treatment of cerebral ischemia, the amount of the said adamantane derivative provided in either case being a cerebral ischemia-alleviating or preventive amount.

(JA8 at col. 13 lines 34-42) In this sentence, as with the first two uses of "cerebral ischemia" (in the Abstract and at the start of the patent), there is no strong support for either side's construction. But, clearly, nothing about the use of "cerebral ischemia" here detracts from Plaintiffs' proposed construction or enhances that of Defendants.

Therefore, in the context of the specification, "cerebral ischemia" refers to a neuronal situation and not to an interruption in blood supply. As for the specific meaning that is accorded to "cerebral ischemia," I agree with Plaintiffs that it should be "an imbalance of neuronal stimulation mechanisms." In the patent specification, the patentee stated that "cerebral ischemia is characterized by a pathophysiological situation defined by an imbalance of neuronal stimulation mechanisms." (JA2 at col. 2 lines 46-48) The phrase "is characterized by" may, as here, be sufficient to call out to one of ordinary skill in the art that a claim term is being defined for purposes of the patent. See generally Agere Systems Inc. v. Atmel Corp., 2003 U.S. Dist. LEXIS 9823, 2003 WL 21652264, at *18-19 (E.D. Pa. May 27, 2003) (concluding patentee was own lexicographer where patentee wrote, "'The self-limiting effect is characterized by a tungsten formation rate at 10 minutes that is less than 10% of the initial equilibrium rate.'"). During the reexamination proceedings, the patentee expressly identified this portion of the specification as providing the proper construction of "cerebral ischemia," writing:

As defined in the '703 patent, "cerebral ischemia" refers to an imbalance of neuronal stimulation in which an excessive influx of calcium through NMDA receptor channels leads to degeneration and loss of brain cells (col. 2, lines 46-51). This imbalance can be initiated by various conditions, including Alzheimer's disease (col. 3, lines 10-16), and is characterized by a substantial increase in excitatory amino acids, which allows for an excessive influx of calcium through NMDA receptor channels leading to loss of brain cells (col. 2, lines 46-52).

(JA0760-61) Contrary to Defendants' suggestion that this statement should be accorded little significance, see Tr. at 104, 125, the reexamination proceedings are part of the intrinsic evidence on which the Court may rely. See generally Procter & Gamble Co. v. Kraft Foods Global, Inc., 549 F.3d 842, 848 (Fed. Cir. 2008) ("The district court should monitor the [reexamination] proceedings before the PTO to ascertain whether its construction of any of the claims has been impacted by further action at the PTO or any subsequent proceedings."); Alloc, Inc. v. Norman D. Lifton Co., 2007 U.S. Dist. LEXIS 52293, 2007 WL 2089303, at *11 (S.D.N.Y. July 18, 2007) ("A patent's prosecution history during a reissue or re-examination proceeding is part of the intrinsic evidence of claim meaning . . . . ."); Creo Products Inc. v. Presstek, Inc., 166 F. Supp.2d 944, 963 n.31 (D. Del. 2001) (stating request for reexamination is part of intrinsic evidence), aff'd, 305 F.3d 1337 (Fed. Cir. 2002). I find the patentee's statement important because it shows the patentee telling the PTO exactly what Plaintiffs are now advocating in Court. That the PTO issued the Reexamination Certificate for the claims without indicating any disagreement with the patentee's definition of "cerebral ischemia" is important intrinsic evidence supporting Plaintiffs' proposed construction.

Defendants raise several other objections to Plaintiffs' construction but none, individually or collectively, convince me that Plaintiffs' construction should be rejected. Defendants point to a portion of the prosecution history in which the inventors defined "ischemia" as "insufficient blood supply to an organ." (JA131) As Plaintiffs point out, this definition appears in a discussion of prior art, and there is no dispute that some of the prior art uses "ischemia" consistent with its plain and ordinary meaning. More importantly, this is a definition of "ischemia," not of "cerebral ischemia." 7 As already noted, there are places even in the patent specification where "ischemia" is used in its plain and ordinary sense as relating to an

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interruption in blood supply. But nowhere is "cerebral ischemia" used to refer to an interruption in blood supply. Defendants also contend that Plaintiffs' construction must be wrong because it is broad enough to capture all types of neuronal imbalances, including Parkinson's disease, yet the specification explicitly contrasts cerebral ischemia with Parkinson's. See JA2 at col. 2 lines 38-48. Yet this concern is eliminated if, as I recommend below, Plaintiff's construction of "imbalance of neuronal stimulation" is adopted. (Tr. at 100) (counsel for Majority Defendants conceding this point) Finally, Defendants insist that Plaintiffs' construction would result in the reexamined claims having broader scope than the original claims, which would render the claims of the '703 patent invalid pursuant to 35 U.S.C. § 305. I do not perceive a need to reach this invalidity argument at this time. See Ampex Corp. v. Eastman Kodak Co., 460 F. Supp.2d 541, 543 n.1 (D. Del. 2006) ("The validity of a claim is not an issue of claim construction . . . . I will not convert Defendants' claim construction argument into a motion for summary judgment.").

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7 The same "Definitions" page on which the definition of "ischemia" is provided goes on to state: "In connection with dementia research, animal models of cerebral ischemia have recently been introduced. By brief interruption of cerebral blood supply selective degeneration of nerve cells is induced which can be identified and evaluated microsopically about 8 days after recirculation." (JA131) This statement, which is expressly not given as a definition, does not appear to help either side's claim construction argument.

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Finally, I agree with Plaintiffs and Apotex that the destruction of brain cells that is a consequence of cerebral ischemia is not itself part of cerebral ischemia and, therefore, should not be part of the Court's construction of the term "cerebral ischemia." See JA2 at col. 2 lines 46-52 ("In contrast to this type of disease, cerebral ischemia is characterized by a pathophysiological situation defined by an imbalance of neuronal stimulation mechanisms. In this context, the excessive inflow of calcium through NMDA receptor channels finally leads to the destruction of brain cells in specific brain areas.") (emphasis added; internal citations omitted).

Thus, I recommend that the Court construe "cerebral ischemia" to mean "an imbalance of neuronal stimulation mechanisms."
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A. "Cerebral ischemia"

After considering the parties' proposed constructions, the Magistrate Judge recommended that the term "cerebral ischemia" in claims 1 and 14 be construed to mean "an imbalance of neuronal stimulation mechanisms." (D.I. 373 at 32.) The court agrees. The defendants contended in the Markman hearing, and contend now in their objections, that "cerebral ischemia" should be construed as "an acute interruption of blood supply to the brain" or "an acute interruption of blood supply to the brain characterized by the destruction of brain cells," citing the ordinary meaning of "ischemia" as referring to an interruption in blood supply. But it is clear from the language of the specification that the term "cerebral ischemia" as used in the patent refers to a neuronal imbalance. See, e.g., D.I. 243 at JA002, col. 2 lines 46-48 ("[C]erebral ischemia is characterized by an imbalance of neuronal stimulation mechanisms."); id. at col. 2 line 67 to col. 3 line 3 ("The present invention is aimed at preparing and employing compounds which can be chemically generated by simple methods, exhibiting an NMDA receptor channel-antagonistic and anticonvulsive action, for use in the prevention and treatment of cerebral ischemia."). 4

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4 As the Magistrate Judge noted, the descriptions in the specification focus on a neuronal situation, and nowhere in the specification is the term "cerebral ischemia" used to refer to an interruption in blood supply to the brain. (See D.I. 373 at 12-16.) Thus, at the very least, it is clear that the court cannot adopt the defendant's suggested construction of "cerebral ischemia" as referring to an interruption in the blood supply.

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The patentee defined "cerebral ischemia" with sufficient and "reasonable clarity, deliberateness, and precision," thereby meeting their burden of establishing that the term as used in the patent carries a meaning different than the plain and ordinary meaning of the term. See Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1354 (Fed. Cir. 2003). Furthermore, during the reexamination proceedings for the '703 patent, the patentee again expressly defined "cerebral ischemia" as "an imbalance of neuronal stimulation," thus confirming the meaning of the term in the context of this patent. (See D.I. 243 at JA00760.) Different uses of the terms "ischemia" or "cerebral ischemia" in studies and other sources cited in the patent do not override the specification's clear use of the term to refer to a neuronal situation. Thus, for the reasons set forth in the Report and Recommendation, the court will adopt the Magistrate Judge's construction. 5

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5 Some of the defendants assert that the Report "expressed the view that, since 'ischemia' alone means an interruption of blood supply, 'cerebral ischemia' must mean something completely different," citing page 13 of the Report and Recommendation for this proposition. (See D.I. 384 at 3.) Even a cursory review of the Report and Recommendation reveals this to be a gross mischaracterization of Magistrate Judge Stark's reasoning. Magistrate Judge Stark makes clear in his reasoning that the use of "ischemia" alone to mean "an interruption in blood supply" does not automatically mean that the term "cerebral ischemia" has a distinct meaning in the context of its use in the patent. (D.I. 373 at 11, 13.) At no point does the Magistrate Judge state or imply that the addition of the word "cerebral" means that "ischemia" and "cerebral ischemia" must have distinct meanings, as the defendants baldly assert in their objection. Distortions such as this of a clearly stated analysis by one of this court's judicial officers are not welcome and come very close to crossing the line that separates zealous advocacy from a failure of an attorney to properly attend the ethical responsibilities that accompany the grant of the privilege to practice law.

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Claim 1 of the '937 patent is an independent claim that provides as follows, with the court's claim construction of disputed terms bracketed and underlined:

A process for producing a moisture absorbing desiccant entrained polymer, said process comprising:

causing a polymer to assume a molten state, said polymer acting as a moisture barrier in a solidified state;

blending a desiccating agent into the polymer so that the desiccating agent is distributed within the polymer;

blending a channeling agent [a hydrophilic material (having a greater moisture transmission rate than the polymer based material) that is melted and forms passages throughout a polymer base] into the polymer so that the channeling agent is distributed within the polymer thereby creating a blended mixture; and solidifying the mixture so that the channeling agent forms passages [solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior] in the mixture through which moisture is communicable to desiccating agent entrained within the mixture.

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Claim 1 of the '255 patent is an independent claim that provides as follows, with the court's claim construction of disputed terms bracketed and underlined:

The composition having veined domains of channeling agents comprising at least three components:

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(a) wherein component A is a polyolefin;

(b) wherein component B is a channeling agent [a hydrophilic material (having a greater moisture transmission rate than the polymer based material) that is melted and forms passages throughout a polymer base] consisting of a hydrophilic material that is heated above its melt point during processing of the composition;

(c) wherein component B is substantially separate from component A and forms channels [solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior];

(d) wherein component C is a desiccating agent;

(e) wherein the volume fraction of component A represents at least about 50% by volume of the total volume of components A, B and C;

(f) wherein the preferential affinity between component B and component C is greater than between components A, and component C;

(g) wherein at least two aggregates are formed, one aggregate is composed of a majority of components A, and the second aggregate is composed of a majority of component B and a majority of component C; and

(h) wherein component B forms channels for moisture transmission through the polymer.
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4. "Characteristic of Said Allele"

GTG originally proposed the definition "capable of distinguishing at least one allele from at least one other allele. More than one amplified DNA sequence may be used for loci where alleles differ by single nucleotide substitutions that are not unique to the allele or when information regarding remote alleles (haplotypes) is desired." At the claim construction hearing, GTG modified its definition to simply "capable of distinguishing at least one allele from at least one other allele." Applera proposes "a trait, quality, or property that is unique." Following the hearing, GTG submitted a subsequent modification to its definition to: "a trait, quality, or a group of them distinguishing an individual, group, or type."

GTG is correct that the prosecution history does not limit the claims to a construction where a one-to-one correspondence has been demonstrated between the DNA sequences and the allele in question, nor does it imply "uniqueness," as Applera argues. When read in context, it is clear that the one-to-one correlation described in both the prosecution history and the specification is merely provided as an example and is not intended to limit the scope of the claims. Id.; Applera Exh. N at 19; '179 patent col. 7:24-28. However, Applera is correct that nothing in the claims or prosecution history requires that the term "characteristic" be given a construction other than its standard definition of "a trait, quality, or property or a group of them, distinguishing an individual, group, or type," as set forth in the prosecution history. Applera Exh. L at 5. GTG appears to have acknowledged this in their post-hearing proposed construction.

Accordingly, as between GTG and Applera, GTG's final proposal is the most accurate. The court thus adopts GTG's construction of the term "characteristic of said allele" as: a trait, quality or property, or a group of them, distinguishing an individual, group, or type.
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1. Claim Construction

Prior to trial, the court issued a Markman order outlining the court's claim construction. (D.I. 271) The court defined, among

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other terms, the phrase "characterizable by an efficiency equation" to mean that "the synergistic combinations are determined from the efficiency equation." (Id. at 3-4) Union Carbide argues that (1) the court erred in its claim construction, and (2) Shell improperly argued the wrong claim construction to the jury. 9

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9 Union Carbide also objects to the court's construction of the term "the same ethylene oxide production system." Because the court's definition of "characterizable" disposes of all '243 patent issues, the court will not revisit its claim construction of other terms.

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The plain meaning of the word "characterizable" means "able to be characterized or described by." However, a review of the '243 patent's claims, specification, and prosecution history dictates a different definition here. See Markman, 52 F.3d at 979. The prosecution history of the '243 patent demonstrates that in order to infringe the claims of the '243 patent, one must use the efficiency equation to determine which combinations of promoters will provide synergy. In the application leading to the '243 patent, one of the named applicants, Dr. Madan Bhasin, described his invention as being "directed to an improvement to commercial ethylene oxide production processes wherein a supported silver catalyst is characterized by, inter alia, having a certain amount of cesium and a certain relative amount of other alkali metal." (JTX 7 at 94) Unlike the prior art, the application purported to be the first to recognize that "the combination of cesium with other alkali metal could synergistically enhance the efficiency of a commercial ethylene oxide catalyst." (Id.) The examiner rejected the application as obvious in light of, among other references, U.S. Patent Nos. 4,168,247 issued to Percy Hayden et al ("Hayden '247"); 4,212,772 issued to Wolf D. Mross et al ("Mross '772"); and 3,962,136 issued to Robert P. Nielsen et al ("Nielsen '136"). The examiner noted that each of those references teaches the use of cesium and other metals in silver catalysts for the production of ethylene oxide. (Id. at 140-42)

With respect to the Nielsen '136, the examiner noted that "it would be obvious to one skilled in the art to determine at least one optimum combination of cesium and potassium amounts by routine experimentation leading to a catalyst falling within the scope of the claims." (Id. at 142) The examiner further rejected the claims as being indefinite. "The claims are directed to a process of producing ethylene oxide . . . with the improvement encompassing optimum amounts of both cesium and the other alkali metal. . . ." (Id. at 144) "The scope of the claim is incapable of being readily determined, if at all, in the absence of undue experimentation." (Id. at 145) In response, the applicants amended the claims to include the efficiency equation. (Id. at 168) The applicants commented:

Applicants' discovery of this heretofore unknown synergistic effect is applicable to any ethylene oxide production system. . . . Once the ethylene oxide production system is defined thereby fixing the various parameters to precise values, that same ethylene oxide production system is then used to prepare a composite design set of experiments from which the ultimate Efficiency Model equation is obtained. From that equation, it is a simple matter to determine the combinations of cesium and alkali metal which will provide the synergistic effects discussed and claimed herein. . . .

In other words, once the conditions and the parameters for the ethylene oxide production system are set, including but not limited to the specific reaction conditions, the specific catalyst support characteristics, the specific silver deposition method, etc., by virtue of the present invention, it is possible to determine (if it at all exists) a combination of cesium and alkali metal on a supported silver catalyst which will provide a synergistic efficiency.

(Id. at 169-70) (emphasis added).

The applicants further noted that the efficiency equation was added to the claims "such that they now contain the specific efficiency equation by which the synergistic combinations of the present invention are characterizable. . . . By means of the teachings of the present invention, applicants are able to precisely determine the amounts of alkali metal combinations which, if any, are able to produce such synergistic effects for any ethylene oxide production system." (Id. at 171-72)

After several more rejections, amendments, arguments, and an appeal, the claims were allowed with the efficiency equation in place. After reviewing the entire prosecution history, the court reaffirms its ruling that the claims at issue require that the synergistic combination of silver, cesium, and alkali metal in said catalyst is determined from the efficiency equation. The

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claims are not apparatus claims encompassing all synergistic catalysts. Rather, the claims at issue are product-by-process claims directed to synergistic catalysts with relative amounts of alkali metals which were determined from the efficiency equation. 10

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10 Mindful of the split of authority created by the Federal Circuit in Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991) and Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992), the court holds that the use of the efficiency equation is a limitation to claim 4 for both infringement and validity purposes.

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A. The '243 Synergy Patent

As discussed above, claim 4 of the '243 synergy patent is directed to a catalyst that contains a "synergistic" mixture of silver, cesium, and lithium and is "characterizable by an efficiency equation." The court construed the claim to include only those catalysts developed with the aid of the efficiency equation, and the jury found that none of Shell's accused catalysts infringed. Id. at 437. On appeal, Union Carbide argues that the district court's claim construction was erroneous. According to Union Carbide, the efficiency equation claim limitation does not require one to use the efficiency equation to develop a synergistic catalyst but rather describes the properties of the catalysts claimed by the patent. Thus, Union Carbide claims that the court's construction of independent claim 1, and therefore dependent claim 4, as a product-by-process claim unjustifiably and improperly departs from the ordinary definition of "characterizable." Additionally, Union Carbide denies that it disavowed the ordinary meaning of the claim language during prosecution of the synergy patent and instead asserts that the prosecution history supports its construction of the term. Specifically, Union Carbide states that it added the efficiency equation in lieu of claiming particular ranges of various amounts of silver, cesium, and lithium and their resulting catalyst efficiencies. Union Carbide consequently urges this court to reverse the judgment of noninfringement and grant its motion for a new trial. 3

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3 In the alternative, Union Carbide relies on Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 18 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 1991) to argue that even if claim 4 were a product-by-process claim, the judgment of noninfringement should still be reversed because the correct reading of product-by-process claims is that they are not limited to products prepared by the process set forth in the claims.

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Shell responds that the court construed the disputed claim limitation correctly, and that it properly entered judgment on the jury's verdict of noninfringement because Union Carbide failed to prove essential elements of its case. According to Shell, Union Carbide is not entitled to rely on the ordinary meaning of "characterizable" because both the patent and its prosecution history reveal that Union Carbide did not intend the term to have that meaning. Shell argues that the specification emphasizes that the relative combinations of metals in the catalysts "are derived" from "mathematical relationships," thereby indicating that the efficiency equation is to be used to determine the combinations of components necessary to make a particular catalyst synergistic. Shell also points to the patent examiner's initial rejection of Union Carbide's application on the ground that the claims lacked a readily determinable scope. The examiner approved the application only after Union Carbide added the efficiency equation, stating that "one skilled in the art could use the efficiency equation to determine the correct combinations of silver, cesium and alkali metal to prepare a catalyst with synergistic properties." Shell argues that the examiner's statements clearly indicate that claim 4 is limited to those catalysts developed with the aid of the efficiency equation. As such, Shell asserts that we should affirm the district court's claim construction and its decision to uphold the jury's finding of noninfringement.

A determination of infringement requires a two-step analysis. First, the court construes the asserted claims in order to

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determine their proper meaning and scope. Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 38 U.S.P.Q.2D (BNA) 1461, 1471, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The general rule is that the court must presume that the terms in the claims mean what they say and construe them according to their ordinary and accustomed meaning. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989, 50 U.S.P.Q.2D (BNA) 1607, 1610 (Fed. Cir. 1999). This "heavy presumption" in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence. See K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1363, 52 U.S.P.Q.2D (BNA) 1001, 1004 (Fed. Cir. 1999); Johnson Worldwide, 175 F.3d at 989, 50 U.S.P.Q.2D at 1610. Consequently, the court must examine the specification and the applicable prosecution history to determine whether a patentee has chosen to give a claim term a definition other than its ordinary meaning. See Bell Atl. Network Servs. v. Communications Group, Inc., 262 F.3d 1258, 1268, 59 U.S.P.Q.2D (BNA) 1865, 1870 (Fed. Cir. 2001); Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1301, 57 U.S.P.Q.2D (BNA) 1813, 1815 (Fed. Cir. 2001). After the court construes the claims, these claims are compared to the accused device. Id.

Claim construction is a question of law that this court reviews de novo. Bell Atl. Network Servs., 262 F.3d at 1267, 59 U.S.P.Q.2D at 1869. Determination of infringement is a question of fact, which, in the context of a jury trial, we review for substantial evidence. B. Braun Medical v. Abbott Lab., 124 F.3d 1419, 1423, 43 U.S.P.Q.2D (BNA) 1896, 1899 (Fed. Cir. 1997). A party's failure to make a motion for JMOL at the close of evidence, however, substantially narrows the scope of our review of the jury's findings. A party that does not move for JMOL before the case is submitted to the jury cannot on appeal challenge the sufficiency of the evidence underlying presumed jury findings. See Southwest Software, Inc. v. Harlequin Inc., 226 F.3d 1280, 1290, 56 U.S.P.Q.2D (BNA) 1161, 1168 (Fed. Cir. 2000); Young Dental Mfg. Co. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1141, 42 U.P.S.Q.2D (BNA) 1589, 1592 (Fed. Cir. 1997). Such a party is instead limited to challenging the judgment on the ground that the trial court committed an error of law or abused its discretion. Young Dental Mfg., 112 F.3d at 1142, 42 U.S.P.Q.2D (BNA) at 1592.

After examining the intrinsic evidence of record, we conclude that the district court erred when it construed the limitation "characterizable by an efficiency equation" to mean "determined from the efficiency equation." As the district court correctly stated, "the plain meaning of the word 'characterizable' means 'able to be characterized or described by.'" Union Carbide, 163 F. Supp. 2d at 436. The dictionary defines "characterizable" as "capable of being characterized," and defines "characterize" as, inter alia, "to describe the essential character or quality of . . . to be a distinguishing characteristic of." Webster's Third New Int'l Dictionary (1993). 4 The ordinary meaning of "characterizable by an efficiency equation" is therefore "capable of being described by an efficiency equation." This meaning controls unless the intrinsic evidence clearly redefines the claim term so as to put one reasonably skilled in the relevant art on notice that Union Carbide intended to assign the term a different meaning. See Bell Atl. Network Servs., 262 F.3d at 1268, 59 U.S.P.Q.2D at 1870 ("We have previously held that, in redefining the meaning of particular claim terms away from the ordinary meaning, the intrinsic evidence must 'clearly set forth' or 'clearly redefine' a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term." (citation omitted)). In the instant case, neither the specification nor the prosecution history justifies departing from the ordinary meaning of the claim language.

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4 Although technically a form of extrinsic evidence, dictionaries hold a special place in claim construction, and judges "may . . . rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by the reading of the patent document." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6, 39 U.S.P.Q.2D (BNA) 1573, 1578 n.6. (Fed. Cir. 1996).

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The synergy patent's specification is consistent with the ordinary meaning of "characterizable" as "capable of being described by." The specification states that the efficiency equation can be used to generate a graph, also called a contour map, which "depicts" ranges of efficiency for a particular catalyst preparation at a particular temperature. '243 patent, col. 12, ll. 21-31. Those synergistic catalysts claimed by the patent fall within certain regions of the contour map, and those not claimed fall outside them. As the Description of the Drawings clarifies:

The area [on the contour map] bound by ordinate, the abscissa and the synergism curve (curve "A") defines the area of synergism in accordance with the present invention. The area to the right of the synergism curve "A", represents the area of

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additive and antagonistic effects as described above, and thus defines mixtures not in accord with the present invention."

Id. at col. 14, ll. 15-22.

Claim 4 of the '243 patent therefore claims ethylene oxide catalysts that contain particular ratios of silver, cesium, and lithium, and the efficiency equation provides a visual and mathematical depiction of these ratios. The equation is not a patented process for developing a particular synergistic catalyst but rather a descriptive tool that defines the scope of the patented invention: silver catalysts containing cesium and lithium in a combination that provides a synergistic, rather than an antagonistic or additive, effect. See id. at col. 8, ll. 12-20. As such, "characterizable by an efficiency equation" means what the plain language says; properly construed, the claim limitation covers those catalysts that are described by the efficiency equation.

The prosecution history also supports this construction of the disputed claim term. As stated above, Shell relies heavily upon statements made by both Union Carbide and the patent examiner during prosecution of the synergy patent to support its argument that "characterizable by" should be construed to mean "determined from." A closer examination of the prosecution proceedings, however, reveals that this argument is without merit. As Shell correctly states, the patent examiner initially rejected Union Carbide's patent application under 35 U.S.C. § 112, P 2 on the ground that the scope of the claim was incapable of being determined in the absence of undue experimentation. The examiner found that "it [was] not readily apparent that only a limited number of catalysts would be encompassed and readily identified from the functional language of the claim." Union Carbide therefore added the "characterizable by an efficiency equation" limitation in order to define the scope of its claims. In other words, Union Carbide sought to overcome the § 112 rejection by limiting the field of catalysts claimed by the '243 patent to those that fall within the contour model generated by the efficiency equation, i.e., those that are "characterized" by the equation. The examiner's statements that one could use the efficiency equation to determine the necessary combinations of silver, cesium, and alkali metal to produce a catalyst with synergistic properties were therefore directed to clarifying the scope of the claim and not to rewriting it as a product-by-process claim.

Consistent with the intrinsic evidence, we construe the claim term "characterizable by an efficiency equation" to mean "capable of being described by an efficiency equation." Because the jury's verdict of noninfringement was based on an erroneous construction of that term, we reverse and remand for a determination of infringement in accordance with the correct claim construction. 5

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5 Union Carbide's argument that it is entitled to a new trial on infringement of the '243 patent because Shell tainted the verdict with irrelevant and prejudicial arguments is therefore rendered moot.

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2. "chelator of copper ions"

Genentech argues that the phrase "chelator of copper ions" does not encompass the amino acid histidine. According to Genentech, Glaxo conceded during prosecution that amino acids are not "chelator[s] of copper ions." Genentech points to the examiner's rejection of the claims as obvious in light of the '060 patent. The examiner stated that "among the various additives listed under column 38 [of the '060 patent], only citrate and EDTA belong to the chelating agents." According to Genentech, the list of additives in the '060 patent includes amino acids. Therefore, if Glaxo believed that amino acids were "chelators of copper ions," Genentech argues that Glaxo had an affirmative duty to bring that to the examiner's attention. Having failed to do so, Genentech argues that "chelator of copper ions" must be construed to exclude amino acids.

Glaxo counters that "chelator of copper ions" should be construed to include histidine. Glaxo argues that it is not estopped from claiming histidine as a "chelator of copper ions" because there were no amendments or arguments made during the patent prosecution regarding the meaning of the phrase. During oral argument, counsel for Glaxo stated that the debate between the applicants and the examiner had nothing to do with whether amino acids were chelators. Rather, counsel argued

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that the debate had to do with the examiner's rejection for obviousness. Therefore, Glaxo contends that "chelator of copper ions" includes histidine.

The specification of the '403 and '838 patents provides that the immunoglobulin composition contains "a stabilizing amount of a chelator of copper ions such as EDTA or citrate." The specification also states that EDTA is a "particularly preferred metal ion chelating agent." Therefore, it appears that the inventors did not limit the phrase, "chelator of copper ions," to EDTA or citrate.

Furthermore, the prosecution history does not support Genentech's argument that histidine is not "chelator of copper ions." Originally, the examiner objected to the phrase, "chelator of copper ions," for lack of enablement. The inventors never responded to the examiner's statement that the only chelators listed in the '060 patent are citrate and EDTA because the examiner agreed to withdraw her objection to "chelator of copper ions" following the interview with the applicants on November 9, 1995. As a result, the court finds that the phrase, "chelator of copper ions," does not exclude histidine.
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d. "chelator of copper ions sufficient . . . to protect . . . and stabilize" and "chelator of copper ions sufficient to stabilize"

Genentech argues that the phrases "an amount of a chelator of copper ions sufficient to bind the copper ions . . . protect the immunoglobulin . . . and stabilize the . . . composition" of the '403-S patent (Claims 1) and "an amount of chelator of copper ions sufficient to stabilize the . . . composition" of the '838 patent (Claim 1) require that the "chelator of copper ions" not simply bind copper ions, but also protect and stabilize the composition. That is, the chelator must compete with the antibody to bind the copper, thereby preventing the copper from binding with and eventually degrading the antibody.

Glaxo counters that the phrases convey their plain and ordinary meaning to one of skill in the art in that the chelator must be an agent added to the composition that is capable of binding the copper ions present, and must reduce, eliminate or retard copper ion-degradation of the antibody. As such, the essence of the dispute over these phrases is whether the claims require a specific method of protection and stabilization of the composition.

In support for its position, Genentech refers the court to the patent examples and expert reports. Genentech first contends that Examples 1-9 of the '403-S patent define the method of protection required by the claims. As an example, Genentech refers to the following passage form Example 1 of the '403-S patent:

The . . . table shows the approximate stoichiometry of binding of Cu.sup.2+ by mM-EDTA and 2 mM-citrate and the contributory effect of pH. 2 mM-EDTA in phosphate buffered saline, pH 7.2, is the most effective suppressing copper induced cleavage of Campath-1H. An approximate 1:1 stoichiometry of binding is indicated at pH 7.2. Copper concentrations in excess of 2mM cause cleavage of CAMPATH-1H (anti-CDw52 antibody) in 2 mM EDTA

This passage explains that EDTA, a type of chelator, effectively suppresses degradation by binding the antibody, but it does not modify or explain the nature of the binding process.

Genentech also contends that Dr. Kerr's report and the Tranter Report, two expert reports noting that antibodies are known to have several sites capable of binding copper, each with different binding affinities, support its construction that the chelator must effectively compete with copper ions present in the antibody in order to 'protect' and 'stabilize' the antibody composition. The court finds that reports do not require that it read this limitation into the phrase "chelator of copper ions."

After reviewing the proposed constructions, the court finds that the phrases should be interpreted according to their plain meaning, and therefore construes the phrases "an amount of a chelator of copper ions sufficient to bind the copper ions . . . protect the immunoglobulin . . . and stabilize the . . . composition" of the '403-S patent and "an amount of chelator of copper ions sufficient to stabilize the . . . composition" of the '838 patent to require that the "chelator of copper ions" bind copper ions, and that such bonds protect and stabilize the antibody composition.
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C. Claim 1: "A Chemical Label Further Comprising a Signalling Moiety"

Finally, the parties dispute whether the "chemical label" of Claim 1 must consist exclusively of the "signalling moiety capable of generating a soluble signal," or whether, as plaintiffs argue, the label need only include a portion that provides a signal for detection and may include other parts as well.

The patent defines the term "label" as follows:

Label - That moiety attached to a polynucleotide or oligonucleotide sequence which comprises a signalling moiety capable of generating a signal for detection of the hybridized probe and analyte. The label may consist only of a signalling moiety, e.g., an enzyme attached directly to the sequence. Alternatively, the label may be a combination of a covalently attached bridging moiety and a signalling moiety or a combination of a noncovalently bound bridging moiety and signalling moiety which gives rise to a signal which is detectable, and in some cases quantifiable.

'373 Pat. 1:45-56 (emphases supplied).

The patent defines a "signalling moiety" as "[t]hat portion of a label which on covalent attachment or non-covalent binding to a polynucleotide or oligonucleotide sequence or to a bridging moiety attached or bound to that sequence provides a signal for detection of the label." '373 Pat. 1:61-65 (emphasis supplied).

Together, the two definitions clearly show that a signalling moiety may be a part but not the whole of a label. More specifically, a label may consist of a single signalling moiety or a combination of a signalling moiety and a bridging moiety. Where the specification provides a definition of a claim term, that definition controls. See Phillips, 415 F.3d at 1316 ("The specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs.").

This reading is supported by the fact that the term "bridging moiety" is nowhere to be found in any of the claims, yet the specification defines "bridging moiety," '373 Pat. 1:57-60, and teaches methods for utilizing such a bridging moiety to join the signalling moiety to the nucleotide sequence portion of the probe, as well as the preferred bridging moieties to be used, see id. at 2:11-64. If a "label" consisted entirely of a "signalling moiety," these portions of the specification involving bridging moieties would be read out of the patent entirely.

Accordingly, the Court adopts plaintiffs' definition of "a chemical label further comprising a signalling moiety" as "a chemical label including, but not limited to, a portion that provides a signal for detection." n6

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N6 Consistent with its definition of "soluble signal," supra § IV.B, the Court also declines defendants' invitation to read the term "detectable compound" into the definition of this term.

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10) "Chemically Active Species"

MKS contends that the phrase "chemically active species" in claim 42 is "a subset of 'reactive gas' in the context of the '628 patent" and means "a species of reactive gas generated from the reactive gas in the plasma, that is itself chemically active." (D.I. 103 at 38). Advanced Energy contends that the phrase "chemically active species" means "a chemical entity in an energetically reactive state." (D.I. 110 at 30).

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A review of the specification and prosecution history reveals that neither a definition of the "chemically active species," nor an example of the phrase has been offered. Further, a plain reading of claim 42, subsection (e) reveals that MKS' proposed construction, discussing the generation of the "chemically active species," is redundant. (See D.I. 104, Ex. A col. 14, ln. 5-7). Accordingly, the Court construes the phrase "chemically active species" to mean a chemical entity in an energetically reactive state.
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1. Said film is chemically bonded with a substrate

The plaintiffs submit that "said film is chemically bonded with a substrate" should be construed as follows: "a chemical bond (i.e., the attractive force that holds together atoms in molecules and crystalline salts) is formed between at least a portion of the film and at least a portion of an adjacent, underlying material." In support of their position, the plaintiffs assert that their proposed construction reflects the ordinary meanings of the terms "chemical bond" and "substrate." A "bond" or "chemical bond" is defined as "the strong attractive force that holds together atoms in molecules and crystalline salts." McGraw-Hill Dictionary of Scientific and Technical Terms (4th ed. 1989). A "substrate" is defined as "[a]ny underlying bulk phase, layer, etc., on which something is deposited." The Compact Oxford English Dictionary (2d ed. 1989).

The defendant urges that the disputed phrase means "a chemical compound consisting of carbon and an element of the substrate that chemically bonds the nanophase diamond film to the substrate." The defendant contends that the plaintiffs' construction, which includes "crystalline salts," is improper. According to the defendant, the bonds at issue are covalent bonds, and not ionic or "salt" bonds as the plaintiffs contend. The defendant also emphasizes that carbon must be part of the chemical bond, which holds the film onto the substrate creating a carbon-substrate bond.

At issue here is whether carbon must be a part of the chemical bond and whether only covalent bonds hold the film onto the substrate. After considering the submissions of counsel and the intrinsic record, the court is persuaded that the plaintiffs are correct. Neither the claim language nor the specification require that carbon be a part of the chemical bond. There is also no support for the defendant's proposed limitation that only covalent bonds can be formed to bond the film to the substrate. The court therefore adopts the plaintiffs' construction of "said film is chemically bonded with a substrate" and construes this phrase accordingly.
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IV. "chemically embossing the portion" and "a chemically embossed portion"

The phrase "chemically embossing the portion" appears in claim 1 of the '903 patent and the phrase "a chemically embossed portion" appears in claims 1, 9, and 11 of the '008 patent. The parties dispute the meaning of these two phrases.

Mannington argues that this court should construe "chemically embossing" in claim 1 of the '903 patent to "mean[] employing an inhibitor or retarder composition to alter the decomposition temperature of a blowing agent so as to create a recessed texture in the surface of the cushioned sheet vinyl flooring when the foamable layer is foamed (or blown)." D.I. 326 at 13. Mannington asserts that "chemically embossed" as used in claims 1, 9, and 11 of the '008 patent "means that created by chemical embossing." Id. at 13. Mannington argues that the word "portion" as used in these claims is not a term "uniquely defined by the cushioned sheet vinyl flooring industry;" therefore, the word should be given an ordinary dictionary meaning referring to the part of the vinyl surface covering that is chemically embossed. Id. at 19.

Armstrong makes no argument as to claim 1 of the '903 patent as that patent is not asserted against it. Armstrong does, however, make arguments as to "a chemically embossed portion" as found in claims 1, 9, and 11 of the '008 patent. In particular, Armstrong argues that this court should not construe the process limitation "chemically embossed" as contained in the '008 patent because the '008 patent claims are "pure product" claims as opposed to product-by-process claims under

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Biacore, AB v. Thermo Bioanalysis Corp., 79 F. Supp. 2d 422, 456 (D.Del. 1999), aff'd, 30 Fed. Appx. 994, 2002 WL 418166 (Fed. Cir. Mar. 15, 2002). 3 D.I. 324 at 22.

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3 In Biacore, Judge Robinson "found that the subject claims were 'pure product' claims, notwithstanding the presence of process limitations embedded in the claims." D.I. 324 at 22.

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In the event that this court does consider the process limitations in the '008 patent claims, Armstrong argues that the claims should be limited to the preferred embodiments disclosed in the specification. Id. at 8. As provided in the art and disclosed in the specification, Armstrong asserts that "'chemically embossed' is properly interpreted as 'an embossed effect [that] is obtained chemically by the selective expansion of thermoplastic material" and "is not limited to the use of a chemical inhibitor, but can include chemical embossing using other methods, such as selective deposition of a chemical foaming agent rather than a chemical inhibitor." Id. at 24 (emphasis in original). Armstrong further argues that "portion" as used to modify this phrase refers to a "'depressed area on the sheet resulting from the chemically embossed step.'" Id. Moreover, contends Armstrong, "the specification defines the 'embossed portion,' or 'area' which corresponds to the joint or grout lines, as being 'rounded' (an embossed portion) [when referring to the chemically embossed portion]" and that this "portion" is separate and distinct from the mechanically embossed portion. Id. at 20-24.

Domco initiates its argument with respect to "chemically embossing the portion" as used in claim 1 of the '903 patent by asserting that "the design layer [as opposed to the foam layer] is chemically embossed [based upon a literal reading of the claim language]" (the "design layer argument"). D.I. 142 at 14 (emphasis in original). After presenting this argument, Domco proceeds to refer to a "modified" claim 1 4 of the '903 patent to imply that Mannington is rewriting its claim after the fact to say something different. As to this "modified" claim, Domco argues that the "modified" phrase and "a chemically embossed portion" in claims 1, 9, and 11 of the '008 patent "describe those predetermined areas of the product in which foaming of the foamable layer has been retarded." Id. at 14 (emphasis in original). Domco asserts, therefore, that "[a] proper interpretation of these terms is that the foam layer of the product is composed of depressed, chemically embossed areas and all of the complementary surface areas are raised (i.e., not chemically embossed)." Id.

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4 Domco is asserting through this line of reasoning that Mannington is writing its claim to read as follows: "Chemically embossing the portion of the foamable layer below the portion of said design layer where said printed joint or grout lines are located." D.I. 142 at 14 (emphasis in original).

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In its "modified" claim argument, Domco directs this court's attention to Becton Dickinson & Co., v. C.R. Bard, Inc., 922 F.2d 792, 799 n.6, 800 (Fed. Cir. 1990) where the Federal Circuit commented that "nothing in any precedent permits judicial redrafting of claims" to support its contention that Mannington is attempting to "modify" specific language in claim 1 of the '903 patent to avoid the consequences of poor draftsmanship. 5 This court is not of the opinion, however, as Domco asserts, that the language in claim 1 of the '903 patent referred to in its design argument is so restrictive such that it is susceptible to only one plausible interpretation. In the same breathe, this court acknowledges the dictate expressed by the Federal Circuit in Becton Dickinson & Co. and reemphasizes that a court has no power to rewrite claims, such a judicial redrafting is iniquitous.

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5 The language (claim element) Domco refers to in this line of argument is as follows: "… providing a wear layer on top of said design layer and curing said wear layer, thereby expanding said foamable layer to form a foam layer and chemically embossing the portion of said design layer where said printed joint or grout lines are located …."

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The language identified by Domco in claim 1 of the '903 patent does not force this court into such an incongruous "redrafting" situation since it is capable of an alternative interpretation consistent with the specification and understanding within the art. The claim expression "chemically embossing the portion of said design layer where said printed joint or grout lines are located" when read ex posto facto prima impressionis 6 arguably connotes Domco's proposed construction. Viewed in context, however, the phrase conveys another meaning: the foam layer corresponding to the grout or joint lines in the design layer do not expand as fully as other portions of the foam layer during curing. This court is of the opinion that this latter meaning is what the inventors embodied by their claim language and that this meaning is understood by and effectively communicated to those skilled in the art of vinyl surface coverings. 7

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6 after the event on first impression

7 In ambiguo sermone non utrumque dicimus sed id duntaxat quod volumus (When the language we use is ambiguous, we do not use it in a doubtful sense, but in the sense in which we mean it.). Note that although this Latin expression uses the word "ambiguous" there is no implication therefrom that the inventors claim language is "ambiguous" in contravention of 35 U.S.C. § 112. Instead, the expression is noted because it captures, succinctly, that all language taken out of context is vulnerable to ambiguities. The inventors of the '903 invention provided contextual support for the meaning of the words used in their claims:

"In the present invention, for purpose of creating the foamable layer, which is chemically embossed, a substrate comprising an expandable resinous layer containing a foaming or blowing agent is provided. A printed design is provided over at least a portion of the expandable resinous layer. At least a portion of this printed design comprises a retarding composition. As will be described in further detail below, once a wear layer is applied on top of the foamable layer, the expandable resinous layer (e.g., the foamable layer) is then subjected to a sufficient temperature for a sufficient time to expand the layer and thereby form an embossed region of the layer proximate the portion of the printed design that contained the foaming or blowing agent modifier or inhibitor."

'903 at 4:60-5:6.

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This being said, the issue put to this court with respect to "chemically embossing the portion" and "a chemically embossed portion" is whether chemical embossing is accomplished by "employing an inhibitor or retarder composition," as Mannington argues, or whether chemical embossing may also include the "selective deposition of a chemical foaming agent [the foam layer]," as Armstrong argues. D.I. 326 at 13; D.I. 324 at 24. Moreover, after answering this inquiry, the question must be answered as to what "portion" of the surface covering may be chemically embossed.

The '903 and '008 disclosures clearly teach that chemical embossing is carried out "by applying to the heat-expandable composition [the foam layer] a reactive chemical compound which is referred to in the art as a 'regulator,' 'inhibitor,' or 'retarder,' it is possible to modify the decomposition temperature of the catalyzed foaming or blowing agent in the area of application of the reactive compound." '903 at 4:27-34; '008 at 4:38-44. It is evident from this language that the inventors intended chemical embossing, as Mannington argues, to mean the application of a "regulator," "inhibitor," "retarder," or similar chemical compound to those areas of the vinyl surface covering in which expansion of the foam layer is to be inhibited. This court, therefore, construes "chemically embossing" accordingly.

Having construed "chemically embossing," this court now turns it attention to the phrases "chemically embossing the portion" and "a chemically embossed portion." As used in the '903 and '008 patents, these phrases refer to the depressed areas of the surface covering in which expansion of the foam layer 8 was retarded to achieve a desired texture. In the preferred embodiments, this texture was consistent with joint or grout lines thus allowing the inventors to achieve a patterned appearance. '903 at 3:42-43; '008 at 3:52-53 ("In the preferred embodiment, the chemically embossed areas are the printed joint or grout lines.").

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8 There is no support in the '903 or '008 patent records to indicate, as Armstrong argues, that the foam layer disclosed in the written description is anything but a continuous layer. This court, therefore, will not hold, as Armstrong requests, that the "chemical embossing" can also mean the selective deposition of a "selective deposition of a chemical foaming agent rather than a chemical inhibitor." D.I. 324 at 24 (emphasis in original).

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Contrary to Armstrong's assertion that the inventors limited their invention to the preferred embodiment, this court does not construe "chemically embossing the portion" and "a chemically embossed portion" to be limited exclusively to the areas of the surface covering comprising joint or grout lines. Granted, the '903 and '008 written disclosures undisputably teach a preferred surface covering with chemically embossed joint or grout lines, the inventors, though, did not limit themselves in the patents and prosecution histories of the '903 and '008 patents to this single embodiment. This court, therefore, will not so limit the inventors now but, instead, construes the phrases such that "chemically embossing the portion" and "a chemically embossed portion" refers to areas depressed after curing is completed as a result of the application of a "regulator," "inhibitor," "retarder," or similar chemical compound to those areas regardless of how patterned the appearance.
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c. "chimeric"

Genentech argues that the term "chimeric" of Claims 1 of the Page patents describes an antibody in which only the non-human constant domains have been replaced by equivalent domains of human origin. In support of its proposed construction, Genentech refers to examples of chimeric antibodies set forth in the specification as prior art consistent with its construction.

Glaxo counters that the term "chimeric" describes an antibody that derives its amino acid sequences from two genetically distinct parents. Glaxo contends that the term does not require that only the constant domains be replaced. Glaxo points to a portion of the specification stating that "chimeric antibodies may have one or more further modifications" as support for its construction. Therefore, the essence of the dispute over the term "chimeric" is whether chimeric antibodies are only those antibodies that have imported human constant domains and no other modifications.

In the context of murine cell antibody production, the specification explains that chimeric antibodies are antibodies where "the murine constant domains only are replaced by equivalent domains of human origin" (emphasis added). The specification, however, also explains that "chimeric antibodies may have one or more further modifications to improve antigen binding ability or to alter effector functioning." The court will construe the term "chimeric" so that it is consistent with both portions of the specification. Thus, "chimeric" describes an antibody in which the non-human constant domains are replaced by equivalent domains of human origin, and any additional modifications are only for the purposes of improving the antigen binding ability or altering the effector functioning.
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Chinese Hamster Ovary Cell	A cultured eucaryotic cell originating from the ovary of a Chinese hamster

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4. "wherein said cells are CHO cells"('868 Claim 2, '933 claim 8)

Amgen	Roche/Hoffmann	This Court (earlier case)
A cell derived from	A cell from the	Did not address

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the ovary of a Chinese hamster.	ovary of a Chinese hamster.

Here the dispute revolves around the term "derived." Tr. 77:4-79:10. The Court holds that Roche/Hoffmann's construction is more appropriate. The addition of "derived" as modifying "from" is unacceptable and inconsistent with this Court's previous constructions and the plain meaning of the terms.

The relevant claims language states "said host cells are CHO cells" and the "non-human mammalian cell is a CHO cell." Therefore, the plain interpretation of the claim is to assume that the cells in question "are" CHO cells, not that the cells in question "derive from" CHO cells. The Court will not read in limitations where none exist and hereby adopts the following construction:

"wherein said cells are CHO cells": A cell from the ovary of a Chinese hamster.

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C. "chromatographic separation"

The principal conflict between the parties here is whether the second phase involved in chromatographic separation should be described as "moving" or "mobile. " Axis-Shield has provided convincing evidence that chromatographic separation involves one stationary phase, through or past which another phase moves. See Axis-Shield's Opening Br. 12-16 (citing Ravindrath, Principles and Practice of Chromatography 45 (Ellis Horwood Limited 1989)). Whether a particular method, such as plaintiff's "batch chromatography," involves a "moving" phase is an infringement question that the Court need not decide at this stage. Accordingly, the Court construes "chromatographic separation" as "a method for separation of the components of a sample, in which the components are distributed between two phases, one of which is stationary while the other moves."

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Claim Construction -- "Chromosome DNA Fragment of a Donor Bacterium"

ADM challenges the district court's construction of the term "chromosome DNA fragment of a donor bacterium." ADM does not dispute that, under the district court's construction, the findings of infringement by the strains produced by ABP for ADM are supported. ADM argues, however, that the court erred in its claim construction.

The strains acquired by ADM from ABP were G472T23 (pYN8) and G472T23 (PKYN1108:6), both of which had been developed from the bacteria made by Genetika and provided to ABP. ADM states that ABP improved on the Genetika strain through spontaneously occurring mutations and by making a new hybrid plasmid. Also, ADM asked ABP to remove from pYN8 the portion of DNA that provided resistance to ampicillin, leaving the organism resistant to tetracycline only; the portion of the DNA that produced threonine was unchanged. In response to ADM's request ABP constructed two additional plasmids, which produced the bacterial strains G472T23 (pYNSTOP) and G472T23 (pYNTE2). The district court found that these bacteria differ only in their resistance to antibiotics.

ADM argues that the hybrid plasmid that ABP combined with a plasmid molecule is not a "chromosome DNA fragment of a donor bacterium" as used in the claim, stressing the importance of "a donor bacterium." ADM states that the DNA fragment that ABP used was itself derived from a hybrid plasmid, not from a donor bacterium. Thus ADM argues that this DNA fragment does not qualify as a fragment of "a donor bacterium," and that the resultant bacterial strains are not within the scope of correctly construed claims.

The district court examined the statements of the experts for both sides on the meaning of "DNA fragment of a donor bacterium" to those skilled in this field of science. The court referred to the usage by ADM of this term, referring to ADM's submission to the Japanese Ministry of Agriculture, Forestry and Fisheries wherein ADM described the threonine operon as

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"E. Coli chromosome fragments," and the usage of this term by ABP in its Owners Manual for the ADM strains. The court described the construction of the strain G472T23 (pYN8) as follows:

ABP constructed the strain G472T23 (pYN8) from G472T23 (pYN7), which it received from Genetika. ABP used the plasmid pYN7, which had an incomplete (i.e., defective) tetracycline resistant gene, from strain G472T23 in constructing the plasmid pYN8. According to expert testimony and the "owner's manual," ABP isolated the plasmid pYN7 and cut it using restriction endonucleases so as to isolate the chromosomal DNA fragment containing the threonine operon.

Ajinomoto, 1998 WL 151411 at *23. The court concluded that "the chromosome DNA fragment can be identified in the hybrid plasmid and, therefore, should be categorized as such."

There was extensive expert testimony on all of the issues and arguments raised by ADM. We discern no error in the district court's finding that the fact that a DNA fragment was subsequently inserted into a plasmid does not change its origin in a donor bacterium. The district court's claim construction and related conclusions are supported by the testimony of the experts and fully accord with ADM's and ABP's own usages, and are affirmed. Applying the district court's claim construction, the imported hybrid plasmid contains the chromosome DNA fragment of a donor bacterium, and is in infringement of claims 1 and 2. The finding of infringement is affirmed.
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"Chromium"

The parties agreed during oral argument that this term, which appears in claims from all the patents-in-suit, means "the chromium ion portion of the chemical compound chromic tripicolinate." The Court agrees and construes the term accordingly.
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A. Claim Construction

1. The parties only dispute the construction of one limitation in the '514 patent: bulk and supported chromium catalyst. (D.I. 112 at 14; D.I. 114 at 13) Plaintiff construes the limitation to cover a catalyst that uses chromium as the only catalytically active metal, but which may also contain non-catalytically active components or additives. (D.I. 73 at 2) Under plaintiff's construction, a "bulk or supported chromium catalyst" would not function in the absence of chromium. (D.I. 105 at 430-32; D.I. 112 at 15) In other words, although a "bulk or supported chromium catalyst" could contain additives, none of these additives could catalyze the reaction by themselves. (Id.) Plaintiff cites evidence that defendant's catalyst would not function in the absence of chromium. (Id.) Plaintiff also cites evidence that Agent X by itself would not catalyze the reaction for making difluoromethane. (Id.) Defendant construes "bulk and supported chromium catalyst" to cover a substance that lowers the activation energy of a chemical reaction, without itself being consumed, which only contains chromium without the addition of other metal components such as metal oxides or alkali metal fluorides or non-inert additives. (D.I. 73 at 2) In support of its construction, defendant cites several references from the '514 specification and from the '514 prosecution history where plaintiff stated that its invention does not include metal oxides or alkali metal flourides. (D.I. 115 at 9-10, 12-14)

2. Claim construction is question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc).

3. In interpreting the claims, a court should begin with the intrinsic evidence of record (i.e., the patent itself, including the claims, the specification, and the prosecution history). Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Id.

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4. First, a court should look to words of the claims themselves to define the scope of the patented invention. Id. There is a heavy presumption that the claim terms carry their ordinary and customary meanings as would be understood by one of ordinary skill in the art. Markman, 52 F.3d at 986. In other words, the court must determine how a person of experience in the field of the invention, upon reading the patent documents, would understand the words used to define the invention. Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Dictionaries and scientific treatises may help to supply the pertinent context and usage for claim construction. Tex. Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1201, 1202 (Fed. Cir. 2002).

5. Second, because a patentee may choose to be his own lexicographer and use a term in a manner either more or less expansive than its general usage in the relevant art, the court also should review the specification to determine whether an inventor has used any term in a manner other than its ordinary meaning. Vitronics, 90 F.3d at 1582. The specification may act as a dictionary when it either expressly defines terms used in the claims or when it defines terms by implication. Id.

6. Third, a court may consider the prosecution history of a patent, if in evidence. Id. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id. (quoting Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)). That is, a court must look to the prosecution history to determine if the patentee has limited the scope of the claims by disclaiming a particular interpretation during prosecution. Biodex Corp. v. Loredan Biomed, Inc., 946 F.2d 850, 862 (Fed. Cir. 1991).

7. Additionally, if the meaning of a term is not clear from the intrinsic evidence, then a court may consult extrinsic evidence, such as expert testimony, in construing claim terms as they would be understood in the relevant art. Markman, 52 F.3d at 980-81.

8. When construing the claims, courts must take great care to avoid importing unnecessary limitations into the claims from the specification. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003). "If we once begin to include elements not mentioned in the claim in order to limit such claim . . . we should never know where to stop." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (quoting McCarty v. Lehigh Val. R.R., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240, 1895 Dec. Comm'r Pat. 721 (1895)). Nevertheless, a court should look to the specification to determine whether it refers to a limitation only as a part of less than all possible embodiments or whether it suggests that the very character of the invention requires that the limitation be a part of every embodiment. It is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002). On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345 (Fed. Cir. 2001).

9. The court construes "chromium catalyst" n9 to mean a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium without the addition of metal oxides, alkali metal fluorides, or non-inert additives. A substance is catalytically active if it contributes to the catalysis of a reaction. Being catalytically active does not require a substance to catalyze a reaction on its own. n10

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n9 The language of independent claims 1, 9 and 10 of the '514 patent include as a limitation a "bulk or supported chromium catalyst." ('514 patent, col. 7 at 1. 25, col. 8 at 11. 19, 25) Furthermore, the parties purport to construe this "bulk or supported chromium catalyst" limitation. (D.I. 112 at 8-9; D.I. 114 at 14) However, the parties did not provide arguments related to construction of "bulk or supported." Furthermore, the court did not find an ordinary meaning of "bulk or supported" in the context of catalysts. As far as the court can tell, a supported chromium catalyst is "a composition in which the chromium catalyst is prepared by depositing it on a suppont - on the surface of the support [,] and the catalyst is chromium." (D.I. 103 at 92) "A bulk chromium catalyst is one in which the catalyst is also a chromium catalyst, but this time it is prepared without a support." (Id. at 93) The parties' claim construction and infringement arguments center on construction of "chromium catalyst" and have nothing to do with whether defendant's catalyst was bulk or supported. Consequently, the court will disregard this portion of the limitation and focus its analysis on construction of "chromium catalyst."

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n10 Plaintiff defines "chromium catalyst" as a catalyst where chromium is the only catalytically active metal in the claimed fluorination reaction. (D.I. 112 at 9) Plaintiff further claims that catalytically active means capable of carrying out the claimed fluorination reaction. (D.I. 105 at 430-432; D.I. 113 at 8) Thus, under plaintiff's construction, a chromium catalyst would not function without the presence of chromium and could not be carried out by another element. Plaintiff's construction would arguably cover defendant's catalyst since: (1) defendant's catalyst would not function in the absence of chromium; and (2) although Agent X plays some role in defendant's catalyst, Agent X could not carry out the catalysis on its own. (D.I. 105 at 452-53, 560-61; D.I. 108 at 1206; D.I. 109 at 1518-19) While the court agrees with plaintiff's construction of "chromium catalyst" as a catalyst in which chromium is the only catalytically active material, it rejects plaintiff's attempt to expand "catalytically active" to cover substances capable of carrying out the fluorination reaction by themselves.

Plaintiff begins its construction argument with what it claims is the ordinary meaning of chromium catalyst. However, plaintiff's sole evidence regarding the ordinary meaning of chromium catalyst comes in the form of Dr. Dolbier's testimony: Q: Could you explain what the term chromium catalyst would mean, the ordinary meaning of that term would be to a person of ordinary skill in the art in your opinion?

A: What this means is that the active catalyst in this reaction is chromium and only chromium.

(D.I. 105 at 430-31) This testimony does not indicate that "catalytically active" means capable of catalyzing a reaction on its own.

Plaintiff cites several statements in the specification and prosecution history which it claims establish that the '514 patent defined chromium catalyst to mean that only chromium is capable of catalyzing the claimed fluorination process. (D.I. 113 at 9-12) First, the '514 specification identifies the prior art "chromium-based mixed catalysts" such as "Ni-Cr/AlF[3] mixed catalysts." ('514 patent, col. 2 at ll. 17-41) Plaintiff claims that this establishes that the prior art had "two active catalysts (as opposed to the claimed 'chromium catalyst')." (D.I. 112 at 10) However, this statement says nothing about whether each of the metals in the mixed metal catalyst was capable of carrying out the reaction. At most, this statement in the specification shows that the prior art had two separate metals which contributed to the catalysis. Plaintiff also points to a specification reference which states that "usual fluorination catalysts such. as . . . Ni-Cr/AlF[3] are not stable . . . ." ('514 patent, col. 2 at ll. 51-53) Once again, this reference says nothing about both nickel and chromium being capable of carrying out the catalyzed reaction on their own. It merely shows that the prior art contained both nickel and chromium and that both of these metals contributed to the catalysis. In the prosecution history, the '514 applicants stated, "comparative examples 2 and 3 show that the use of supported catalysts (Ni/AlF[3] and Ni-Cr/AlF[3] does not make it possible to obtain the lifetime obtained on [sic] catalysts according to the invention." (PX 4 at AT000173) Like the specification references, this statement also does not indicate that the prior art contained two metals, each of which was capable of carrying out the reaction. Finally, in support of its claim construction argument, plaintiff points to arguments made before the USPTO distinguishing Cheminal from the '514 patent. The applicants for the '514 patent distinguished Cheminal by saying it "completely [taught] away from the applicants' claimed process, because it suggests to use a Cr-Ni based catalyst, where as [sic] the present catalyst is only chromium based." (PX 4 at AT000178) However, Cheminal does not indicate whether nickel is capable of catalyzing the reaction by itself. (D.I. 609)

None of the references or communications cited by plaintiff explicitly states that each metal in the prior art mixed metal catalysts could carry out the catalysis. Furthermore, plaintiff does not cite any evidence, other than the unsupported testimony of Dr. Dolbier (see D.I. 105 at 435-36), that these prior art references described catalysts in which each metal was capable of catalyzing the claimed reaction. Thus, plaintiff has failed to establish that the intrinsic evidence of record supports its definition of catalytically active (or chromium catalyst). Given that Cheminal does not disclose that both nickel and chromium are capable of catalyzing the reaction by themselves, plaintiff's construction of chromium catalyst could also encompass prior art. As a result, the court rejects plaintiff's construction of "bulk or supported chromium catalyst", and holds that catalytically active merely means contributing to the catalyzation of a reaction.

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10. The court begins by noting that the plain ordinary meaning of a catalyst is a "substance [] that accelerate[s] the rate of chemical reactions without [] being consumed during the reactions . . . ." n11 Van Nostrand's Scientific Encyclopedia 560 (8th ed. 1995). See also McGraw-Hill Concise Encyclopedia of Science & Technology 329 (3d ed. 1992) (defining "catalysis" as "the phenomenon in which a relatively small amount of foreign material called a catalyst augments the rate of

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a chemical reaction without itself being consumed."); McGraw-Hill Dictionary of Scientific and Technical Terms 307 (4th ed. 1989) (defining a catalyst as a "substance that alters the velocity of a chemical reaction and may be recovered essentially unaltered in form and amount at the end of the reaction."). A "chromium catalyst" would be a catalyst in which the only catalytically active material is chromium. Thus, a "chromium catalyst" would be a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium.

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n11 Plaintiff and defendant both agree with this plain ordinary meaning of catalyst. Dr. Dolbier, an expert for plaintiff, testified that "[a] catalyst is a material which when added to a reaction . . . will enhance the rate of the reaction by providing an alternative lower barrier pathway or mechanism for the reaction." (D.I. 105 at 428) Defendant states in its post trial brief that "to one of ordinary skill in the art, the ordinary meaning of the term 'catalyst' means 'a species that lowers the activation energy of a chemical reaction without itself being consumed.'" (D.I. 114 at 14)

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11. However, the applicants for the '514 patent made several disclaimers of claim scope in the specification and the prosecution history of the '514 patent. First, the '514 specification states that "it has now been found that there is a temperature range in which a catalyst based on pure chromium (without the addition of another metal oxide) can produce, in the presence of oxygen . . . [difluoromethane] by gas-phase fluorination . . . ." ('514 patent, col. 2 at ll. 54-58) The '514 applicants also stated to the USPTO that "as defined on page 5, lines 13-14 [of the '514 patent], pure chromium means without the addition of another metal oxide." (DX 579 at AT00207) The '514 applicants indicated to the USPTO that "the present claims exclude the utilization of an alkali metal fluoride noted in column 1, line 59 of Buckman[.]" (D.I. 579 at AT000179, AT000216) The applicants for the '514 patent state in the specification and in the prosecution history that, "it is therefore unnecessary to employ special additives to increase its selectivity; the elimination of additives employed in the mixed catalysts enables the manufacture of the catalyst to be simplified and thereby its cost to be reduced." n12 ('514 patent, col. 3, ll. 10-14; DX 579 at AT000172, AT000208) These statements constitute a clear disavowal of metal oxides, metal fluorides, and non-inert additives from the '514 patent's "bulk or supported chromium catalyst." As a result, the ordinary meaning of chromium catalyst must be construed to cover a substance that alters the velocity of a chemical reaction without itself being consumed, where the only catalytically active material is chromium without the addition of metal oxides, alkali metal fluorides, or non-inert additives.

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n12 Plaintiff argues in its post trial motion that this quote's description of additives as "unnecessary" simply means that additives are not needed, but does not mean they are prohibited. (D.I. 112 at 11) In this quote the '514 applicants were distinguishing the '514 patent from the prior art and pointing out a benefit of the invention, namely, that it was cheaper and easier to make. While "unnecessary" can be contorted to mean not prohibited, it is clear in the context of this quote that the '514 applicants did not intend their invention to include special additives.

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Having agreed with the court's definition of the term "catalyst," we also agree with its construction of "chromium catalyst" as a catalyst where the only catalytically active material is chromium without the addition of metal oxides or non-inert additives. The intrinsic record supports that interpretation. The specification states that "it has now been found that there is a temperature range in which a catalyst based on pure chromium (without the addition of another metal oxide) can produce, in the presence of oxygen," difluoromethane. '514 patent, col. 2, II. 54-59 (emphasis added). The specification further explains that "it is necessary to have a catalyst containing solely chromium." Id., col. 7, II. 7-12. In addition, the specification makes clear that it is "unnecessary to employ special additives to increase [the fluorination reaction's] selectivity; the elimination of additives employed in the mixed catalysts enables the manufacture of the catalyst to be simplified and thereby its cost to be reduced." Id., col. 3, II. 10-14. We note that the use of the term "chromium" in the patent includes chromium oxide as it refers to "solely chromium (catalysts A and B)," and catalyst A is chromium oxide. Id., col. 7, II. 8-9.

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The prosecution history confirms a construction of "chromium catalyst" that excludes metal oxides and non-inert additives. As discussed in Phillips, the meaning of the claim language may be limited by a disclaimer in the specification or prosecution history. 415 F.3d at 1316-17. Here, the applicants' statements in distinguishing their claimed "bulk or chromium catalyst" over prior art are a disclaimer of claim scope as to metal oxides and non-inert additives. The '514 claims were initially rejected on August 6, 1997, as obvious over the prior art. The applicants responded on December 30, 1997, that "the claims recited the phrase 'consisting essentially of' which would exclude the utilization of a combination catalyst, such as that taught by [the Tsuji reference, EP 629440]. Nowhere in the applicants' disclosure is there mentioned a combination of chromium and indium catalyst. Rather the applicants' disclosure in comparative examples 2 and 3 indicates the criticality of utilizing chromium catalyst alone rather than in combination with other metal components." (emphasis added).

The applicants also pointed out that contrary to what might be expected from the prior art, its chromium-based catalyst carried out the fluorination reaction without a decrease in the selectivity of the reaction and that it was "therefore unnecessary to employ special additives to increase its selectivity." The applicants repeated these assertions in their August 20, 1998, response to the PTO's second rejection. In addition, the applicants stated that "pure chromium means without the addition of a metal oxide" and that "contrary to what might be expected from the prior art, the present invention makes it possible to employ a catalyst based solely on chromium to carry out this fluorination reaction." We thus agree with the district court that the applicants' statements are a disclaimer of claim scope as to catalysts containing metal oxides and non-inert additives. Phillips, 415 at 1317 ("The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.").

The district court also interpreted "chromium catalyst" as excluding catalysts containing alkali metal fluorides. The basis for the district court's construction as to "alkali metal fluorides" is the applicants' statements in the prosecution history that "the recent claims exclude the utilization of an alkali metal fluoride noted in column 1, line 59 of Buckman, [U. S. Patent 3,644,545]." Buckman, which is entitled "Improved Vapor Phase Fluorination Procedure in the Presence of Catalyst and Alkali Metal Fluoride," discloses a fluorination reaction "in the presence of a catalyst, when such reaction is carried out in the presence of an alkali metal fluoride." '545 patent, col. 1, ll. 54-59. While the Buckman specification apparently differentiates between the catalyst and the alkali metal fluoride in naming illustrative substances that may be employed as catalysts (Cr_2O_3, CrF_3, and AlF_3) versus alkali metal fluorides (KF and NaF) that should also be present in the reaction, but perhaps not as catalysts, and the applicants may thus have not intended to exclude an alkali metal fluoride as a catalyst, we are not prepared to find error in the district court's exclusion of alka li metal fluorides from its claim construction, as an alkali metal fluoride is clearly in the reference that the applicants were distinguishing. Id., col. 2, ll. 47, 55.

We reject Atofina's argument that the district court erred in its construction of "chromium catalyst" because the applicants' statements regarding "metal oxides" were intended to distinguish only nickel-chromium catalysts, not Agent X-chromium catalysts. That the applicants only needed to surrender nickel-chromium catalysts to avoid a prior art reference does not mean that its disclaimer was limited to that subject matter. "To the contrary, it frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to." Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1361-62 (Fed. Cir. 2005) (citing Fantasy Sports Props., Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1114-15 (Fed. Cir. 2002)). Here, the patentee spoke expressly to the meaning of "chromium catalyst," both in the specification and in the prosecution history, noting that the catalyst was limited to "pure chromium (without the addition of another metal oxide)." We therefore agree with the district court that Atofina surrendered all catalysts containing non-chromium metal oxides.
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"Chromic tripicolinate" and "chromic picolinate"

The parties and the Court agree that both of these terms, which appear in claims from all the patents-in-suit, are abbreviated as "CP" and mean "a chemical compound containing one chromium ion and three picolinate ions."
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"Chromosomally Integrated"

The dispute in this case turns on the meaning of "chromosomally integrated." Essentially, does the term "chromosomally integrated" require the action of inserting a human a-Gal A gene into the host chromosome, as argued by TKT, or can it cover a gene activation technique in which only a promoter sequence is inserted into a human host cell in order to activate the a-Gal A gene already present in the host cell, as argued by Genzyme.

The district court construed "chromosomally integrated" to mean "the combining or bringing together or merging of separate elements." Further the district court reasoned: "In this case, the separate elements that are combined are the chromosome of the host cell and an exogenous nucleotide sequence encoding human alpha-galactosidase A with a promoter and selectable marker." Genzyme, 2001 WL 1530375, at *1 (emphasis added). Genzyme argues that the claims do not specify the origin of nucleotide sequences to be inserted into a target cell's chromosome. According to Genzyme, the term "chromosomally integrated" requires only that "a chromosome in the cell must contain a nucleotide sequence that encodes human alpha-Gal A enzyme." In other words, Genzyme argues, this claim term "requires the alpha-Gal A coding sequence to be located in a chromosome," regardless of whether the coding sequence originated within the cell or outside the cell. Thus, Genzyme asserts that the district court impermissibly limited the claim to the preferred embodiment of integrating an alpha-Gal A coding sequence into a host cell from an exogenous source.

The patent does not expressly define "chromosomally integrated." Rather, this court, like the district court, must derive the meaning of the term from its usage and context. A fundamental principle for discerning a term's usage is the ordinary and accustomed meaning of the words amongst artisans of ordinary skill in the relevant art at the time of invention. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). Indeed, normal rules of usage suggest a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citing Johnson Worldwide Assocs. Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). Of course, patent law has acknowledged that a patent applicant may overcome this presumption by clearly using the words in the specification, prosecution history, or both "in a manner inconsistent with its ordinary meaning." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325-26 (Fed. Cir. 2002)). In other words, a patent applicant may consistently and clearly use a term in a manner either more or less expansive than its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims. Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1361 (Fed. Cir. 2001) (noting that an applicant may disclaim claim scope during prosecution); Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) (explaining that in order to disavow claim scope, a patent applicant must clearly and unambiguously express surrender of subject matter during prosecution). In ascertaining the accustomed usage of the relevant community at the relevant time, dictionaries and treatises may serve to inform the courts. Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202-03 (Fed. Cir. 2002).

Standing alone, the words "chromosomally integrated" suggest uniting two separate portions of genetic material to form a more complete or purposeful whole. To one skilled in the art of molecular biology, "integration" generally means "insertion [of a DNA sequence] into a host genome as a region covalently linked on either side to the host sequences." Benjamin Lewin, Genes IV 812 (1990). Thus, the claim language suggests incorporation of exogenous genetic code into the chromosomal material of the host cell. In context, the asserted claims explain that the exogenous sequence has a regulatory sequence that causes the host cell to stably overexpress alpha-Gal A. The cell then secretes the excess alpha-Gal A. Again the word "integrated" suggests putting exogenous nucleotide sequences into the host cell's chromosome to facilitate this process. This word, however, does not conclusively evince whether one of skill in the art at the time of the invention would understand the exogenous sequences to come from outside the host cell, i.e., a vector, or from within the host cell but outside the critical chromosome, i.e., a transposable element. In this regard, perhaps the best tool to put the claims in proper temporal and technical context is the patent specification itself.

Throughout the '804 patent specification, the applicant consistently uses the term "integrated" to refer to a foreign gene inserted into a host cell chromosome. See, e.g., '804 patent at col. 14, ll. 14-19 (stable integration of plasmid DNA into host cell chromosomes); col. 24, ll. 42-46 (transfection of human sequences into African green monkey kidney (COS) cells); col. 24, ll. 60-64 (transfection of human sequences into Chinese Hamster Ovary (CHO) cells); col. 25, ll. 1-2 (amplification of

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integrated plasmid DNA in CHO cells); and col. 26, ll. 59-66 (transcription of stably integrated vector DNA in CHO cells). Indeed, the multitude of working examples, drawings, and diagrams of the '804 patent show the insertion of foreign alpha-Gal-A coding sequences into host cells to generate excessive expression of the protein.

Notably, the "Summary of the Invention" explicitly states that the "present invention," not merely a preferred embodiment, "involves the production of large quantities of human alpha-Gal A by cloning and expressing the alpha-Gal A coding sequence in eukaryotic host cell expression systems." '804 patent, col. 6, ll. 22-30. Likewise, the abstract of the '804 patent describes recovery in "good yield" of "recombinant alpha-Gal A" from "engineered host cells." The patent thus specifically uses "host cells" to express large quantities of alpha-Gal A. The term "host cell" means that the cell "hosts" or "receives" genetic material other than its own to perform its service. See Lewin, supra at 41 (explaining that viruses lack a cellular structure of their own, and must infect a "host cell" to effect replication); see also Bernard R. Glick and Jack J. Pasternak, Biotechnology 717 (2003) (defining a "host" to be "[a] microorganism, organism, or cell that maintains a cloning vector); Chambers Dictionary of Science and Technology 570 (Peter M.B. Walker, ed., 1999) (defining a "host" as meaning "in molecular biology that in which a plasmid or virus can replicate"). Thus, the invention involves "cloning and expressing the alpha-Gal A coding sequence in eukaryotic host cell expression systems," an explanation one of skill in the art would read as introducing exogenous cloned sequences into a host cell for expression. This definition of the invention does not embrace targeting or activation of an endogenous gene.

In reading the specification to teach that "chromosomally integrated" means introducing genetic material exogenous to a host cell, not just a chromosome, this court is aware that various portions of the patent vaguely refer to using less than the full endogenous coding sequence for expressing alpha-Gal A. In section 5.1, entitled "The alpha-Gal A CODING SEQUENCE," the patent recites:

Although portions of the coding sequences may be utilized, full length clones, i.e., those containing the entire coding region for alpha-Gal A, may be preferable for expression.

'804 patent, col. 10, ll. 61-63; see also, col. 10, ll. 51-52. In the first place, this passage does not expressly refer to activation of endogenous genes at all. Rather in context, this passage merely explains that less than the entire coding sequence may be used to express a functional alpha-Gal A protein.

Indeed, this passage in context explains that this potential abbreviated coding sequence would come from outside the host cell. Specifically, the patent proceeds to explain in section 5.2 that "in order to express a biologically active alpha-Gal A, the coding sequence for the enzyme, a functional equivalent, or a modified sequence, as described in Section 5.1., supra, is inserted into an appropriate eukaryotic expression vector, i.e. a vector which contains the necessary elements for transcription and translation of the inserted coding sequence in appropriate eukaryotic host cells." '804 patent at col. 12, ll. 35-42 (emphasis added). Once again, the specification emphasizes introduction of exogenous genetic material into host cells.

Similarly, one sentence fragment taken out of context in column 14, lines 10-14, mentions transforming a host cell with a controllable DNA, rather than the entire alpha-Gal A sequence: "Host cells can be transformed with the alpha-Gal A or DNA controlled by appropriate expression control elements (e.g. promoter...), and a selectable marker." This reference, however, falls under the heading "Construction of Expression Vectors and Preparation of Transfectants." This entire section refers to creating a vector for "expression of alpha-Gal A in the [chosen] host cell." '804 patent, col. 13, ll. 11-13; see also, col. 12, ll. 55-58. Indeed the sentence preceding the fragment out of context refers expressly to the "introduction of foreign DNA," not targeting of endogenous DNA:

For long-term, high yield production of recombinant proteins, stable expression is preferred. For example, following introduction of foreign DNA, engineered cells may be allowed to grow for 1-2 days in an enriched media, and then switched to a selective media. Rather than using expression vectors which contain viral origins of replication, host cells can be transformed with the alpha-Gal A or DNA controlled by appropriate expression control elements (e.g. promoter, enhancer, sequences, transcription terminators, polyadenylation sites, etc.), and a selectable marker. The selectable marker in the recombinant plasmid confers resistance to the selection and allows cells to stably integrate the plasmid into their chromosomes and grow to form foci which in turn can be cloned and expanded into cell lines. (Emphasis added.)

'804 patent, col. 14, ll. 4-19. The underlined sentence fragment from column 14, when read in context, does not suggest that

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gene targeting of endogenous coding sequences is possible within a host cell. Rather, the passage states host cells may be "transformed with the alpha-Gal A" (i.e. the gene in its entirety) or with "DNA controlled by appropriate expression control elements and a selectable marker." As noted in bold type above, the DNA in column 14 is foreign DNA introduced into host cells via vectors. The passage teaches that expression vectors containing viral origins of replication are not used to facilitate stable expression of alpha-Gal A. Instead, column 14 teaches the use of recombinant plasmids containing other expression control elements, such as promoters and enhancers, to continuously drive the expression of the alpha-Gal A DNA located in the plasmids for "long-term, high-yield production of recombinant proteins." '804 patent at col. 14, ll. 4-19.

Therefore, the sentence fragment in column 14, when read in context, teaches the introduction into host cells of exogenous DNA encoding alpha-Gal A, together with promoters and enhancers in recombinant plasmids. This passage does not suggest the introduction into a cell of expression control elements and a portion of a coding sequence to drive the expression of genes endogenously located within the host cell. Thus, the isolated passages in columns 10 and 14 do not even remotely suggest that "chromosomally integrated" means targeting of sequences encoding alpha-Gal A that are endogenous to a host cell.

Even if, arguendo, the cited passages did teach an example of gene targeting, such gene targeting would still require the introduction of exogenous nucleotide sequences encoding human alpha-Gal A. Gene targeting typically involves the transfection of a vector containing a gene sequence into a cell containing an endogenous form of the gene. Upon transfection, the exogenous vector targets the endogenous gene, homologous recombination occurs, and exogenous sequences become part of the genome. n1 This process requires the introduction of at least some foreign gene DNA into the host cell, and is not the same as transposable elements rearranging genes within a cell. No record evidence suggests that the specification contemplates, much less defines, the integration and expression of genes outside a chosen chromosome, but within a cell via transposable elements.

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n1 Gene targeting is described in a 1987 Cell article (Kirk Thomas and Mario Capecchi, Site-Directed Mutageneis by Gene Targeting in Mouse Embryo-Derived Stem Cells, 51Cell 503-12 (1987)) and a 1985 Nature article (Oliver Smithies, et al., Insertion of DNA Sequences Into the Human Chromosomal beta-globin Locus by Homologous Recombination, 317 Nature 230-34 (1985)), both of which are of record. The Thomas article notes: "Gene targeting-the homologous recombination of DNA sequences residing in the chromosome with newly introduced DNA sequences-provides a means for systematically altering the mammalian genome... . A desired alteration would first be introduced into a cloned DNA sequence, and gene targeting would then transfer the alteration into the genome." The Smithies article states: "the experiments reported here establish that the planned modification of a specific human gene can be accomplished in mammalian cells by homologous recombination without detectably affecting other parts of the genome."

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The prosecution history, like the specification, does not permit a broad interpretation of the claim term "chromosomally integrated." The original claims of the '804 patent recited a method of producing human alpha-Gal A protein and cells for producing this enzyme transformed with a recombinant vector encoding alpha-Gal A. The examiner rejected these claims under 35 U.S.C. § 112(1) for lack of enablement because the applicant had not deposited the claimed vector. The examiner considered the deposit "essential" to the claimed invention. The applicant conceded, and made the deposit without arguing against the requirement. Thus, during prosecution, the applicant agreed that the pending claims required a recombinant vector encoding alpha-Gal A. Later, the applicant amended the claims to remove the term "recombinant vector," but neither the examiner nor the applicant suggested that the amendment rendered the deposit unnecessary. Thus, the prosecution history shows the necessity of the deposited exogenous vector sequences to the '804 patent claims.

During prosecution, the applicant also made arguments to overcome prior art that are inconsistent with a broad interpretation of the claim term "chromosomally integrated." The examiner rejected the claims under 35 U.S.C. §§ 102 and 103 in view of prior art that allegedly taught the assembly of expression vectors containing human alpha-Gal A sequences. Specifically, the examiner rejected the pending claims over "the genomic clone containing the promoter for the human alpha-Gal A gene disclosed by Quinn, or the alpha-GalA cDNAs disclosed by Tsuji, Bishop, Coppola or Calhoun." Based on this prior art, according to the examiner, "it would have been obvious to assemble other expression vectors containing full length alpha-GalA gene sequences."

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The applicant responded by distinguishing the prior art. In particular, the applicant noted that the prior art references achieved only low level, transient, expression of human alpha-Gal A when full-length cDNA sequences were introduced into COS cells. According to the applicant, transient expression systems of Tsuji and Bishop "could not be utilized to produce alpha-Gal A, since recombinant protein could not be recovered from the system." The applicant further stated: "In contrast to the prior art failures, and to the Applicants' surprise, the human alpha-GalA gene product, when stably expressed in mammalian cell systems, is not only expressed at remarkably high levels, but is actually selectively secreted at very high levels out of the host cell so that facile recovery of the active product is finally made possible." The applicant then stressed that recovery of active alpha-Gal A was an element of the pending method claims. n2

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n2 Secretion of enzymatically active alpha-galactosidase A is an element of all of the claims issued in the '804 patent, and isolation of this active enzyme is an element of all method claims of the '804 patent.

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These arguments did not persuade the examiner, who again issued the same rejections. The examiner noted: "The selection of the appropriate plasmids, promoters, selectable markers and cell lines for proper expression of the inserted gene is merely a matter of judicious selection, within the scope of the ability of one ordinarily skilled in the art." Without further recourse, the applicant submitted an amendment after final rejection under 37 C.F.R. § 1.116. This amendment to clarify the points of disagreement with the examiner also included a declaration by Dr. Ira Mellman. In his declaration, Dr. Mellman asserted his surprise at the inventive expression scheme disclosed in the denied claims, noting the difficulty of purifying heterologously expressed recombinant proteins. By definition, a heterologously expressed recombinant protein is not naturally or normally expressed by a particular tissue or cell type. A "heterologoous protein" is recognized by those of skill in the art as being a recombinant protein "whose amino acid sequence is encoded by a cloned gene." Glick, supra at 717, 725; see also J.M. Lackie and J.A. T. Dow, The Dictionary of Cell and Molecular Biology, 212 (1999) (defining heterologous to mean "derived from the tissues or DNA of a different species"); Encyclopedia of Microbiology, 1012 (Joshua Lederberg, ed., 2000) (defining "heterologous" to mean "derived from a different source or species; not native to the host"). Dr. Mellman did not suggest that the claimed expression method embraced expression of endogenous genes.

Moreover, in its clarifying amendment, the applicant stressed again that the prior art did not teach the "stable expression of human alpha-galactosidase A and isolation of enzymatically active alpha-galactosidase A from an engineered mammalian cell system." Eukaryotic host expression systems, such as the systems delineated in section 5.2.1 of the '804 patent, have long been understood by those of skill in the art as expression vector systems that facilitate expression of eukaryotic genes. See James D. Watson, et al., Molecular Biology of the Gene, 614, 615 (1987) ("The more we learn about how gene expression is controlled in eucaryotes, the more intelligently we can develop expression vector systems ... . Several factors already encourage the development of eucaryotic systems for the expression of eucaryotic genes."); Susan Bright, et al., From Laboratory to Clinic: The Development of an Immunological Reagent, 112 Immunology Today 130-31 (1991) (discussing "eukaryotic expression systems," including CHO cells transfected with an expression plasmid for the production of recombinant antibodies); Glick, supra, at 181-87 (describing "mammalian cell expression systems" as being composed of cell lines, such as COS and CHO cells, engineered with mammalian expression vectors to express heterologous proteins). In other words, the applicant expressly confined the invention to production of proteins by introducing vectors into a mammalian host cell.

The examiner persisted in the rejection until the applicant submitted a supplemental amendment under 37 C.F.R. § 1.116. The amendment replaced the phrase "transformed with a recombinant vector which includes a nucleotide sequence encoding alpha-galactosidase A" with the phrase "chromosomally integrated nucleotide sequence encoding human alpha-galactosidase A." The examiner and applicant agreed on this language during an after-final rejection examiner interview. The record does not explain the reasons the examiner finally accepted this language.

Contrary to Genzyme's position, this eleventh-hour amendment did not operate to broaden the claims to eliminate the requirement of insertion of an exogenous gene into a host cell. In the first place, the deposit requirement, the specification, the applicant's arguments to distinguish prior art, the examiner's responses, and Dr. Mellman's declaration repeatedly stressed that the invention envisioned insertion of an exogenous gene sequence into a host cell. A clarifying amendment at

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the last moment could not negate that extensive public record.

More important, the examiner could not accept a second (supplemental) after-final amendment broadening the scope of the rejected claims without formal comment from the applicant. Under the applicable Patent Office rules, amendments to patent claims after final rejection cannot alter the substantive scope of the claims without explanation about the necessity of the amendment and without reasons for the delay in proposing the change. n3 See 37 C.F.R. § 1.116(b) (1992) ("If amendments touching the merits of the application . . . are presented after final rejection . . . they may be admitted upon showing of good and sufficient reasons why they are necessary and were not earlier presented."). If this amendment markedly broadened the claims, it satisfied neither of those requirements. The record supplies no explanation from the applicant or the examiner that these changes were both "necessary" and justifiably "not earlier presented." Thus, according to PTO rules, the examiner could not have allowed this amendment if it changed at all the scope of the claims set forth in the deposit requirement, the specification, the arguments of the applicant, and Dr. Mellman's declaration.

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n3 The dissent contends that non-compliance with a Patent Office procedural rule is of no consequence once a patent issues. Dissent, slip. op. at 8. However, this court presumes that the Patent Office complies with its own rules, a presumption overcome only upon presentation of contrary evidence. Rite Hite Corp. v. Kelley Co., Inc., 819 F.2d 1120, 1123 (Fed. Cir. 1987) ("Kelley has provided neither evidence nor inference to overcome the presumption that the PTO complied with its own rules."). Therefore, without record support, an argument alleging dereliction of duty by a patent examiner is without merit.

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The record instead suggests that the examiner felt this last-minute change did not alter the scope of the claims. The examiner's comments did not distinguish these newly amended claims from the prior art, but simply noted that the claims had to recite that the alpha-Gal A was overexpressed and secreted. Likewise, the applicant did not address any change in the scope of the claims. In any event, the examiner could not have permitted any Rule 116 amendment that expanded the claims to make the introduction of exogenous DNA into a host cell optional.

Thus, the prosecution history indicates that the term "chromosomally integrated" requires introduction of exogenous alpha-Gal A sequences into the host cell. The claims of the '804 patent recited these exogenously introduced alpha-Gal A sequences until after prosecution on the merits was closed. The record simply does not show that the examiner, contrary to PTO rules, vastly broadened these claims upon entering the supplemental after final amendment to embrace overexpression of human alpha-Gal A sequences endogenous to a host cell. The informed public could only understand this prosecution history, as well as the specification and the claim language itself, to limit Genzyme as reflected throughout the prosecution.

TKT argues that if this court reads the claims as suggested by Genzyme, they would be invalid. Indeed this court notes that the '804 specification and figures do not discuss any methods of activating endogenous alpha-Gal A gene sequences. In fact, the specification does not discuss "chromosomally integrated" sequences as endogenous alpha-Gal A genes within the host cells at all. Thus, the record would appear to raise questions of enablement. See Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996) (this court interprets claims "so as to preserve their validity" whenever "reasonably possible"). The district court, however, did not decide validity issues, and this court need not examine enablement to properly define the claim term "chromosomally integrated" in view of the specification and prosecution history.

This court also notes that this case is different from Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003), which accorded a broad reading to similar claims. This court in Amgen did not confront a prosecution history and specification that conclusively limits the scope of the disputed claim terms. In this case, both the specification and the prosecution history indicate that the patentee employed the term "chromosomally integrated" in a manner inconsistent with a broad textbook meaning that envelopes both endogenous and exogenous sources of sequences encoding genes in a host cell. See Bruce Alberts, et al., Molecular Biology of the Cell, 247-50 (1983) (discussing integration of transposable elements into the genomes of cells); Lewin, supra at 697-702 (discussing the introduction and integration of exogenous donor DNA into recipient cells in generating stably expressing host cell lines and transgenic animals). Therefore, the district court did not err in construing this claim term to require the introduction into a host cell of exogenous sequences encoding

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alpha-Gal A.
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DISSENT:

LINN, Circuit Judge, concurring-in-part and dissenting-in-part.

While I concur in the majority's construction of the claim limitations "regulatory sequence" and "stably overexpressed," I must respectfully dissent from its conclusion regarding the construction of the "chromosomally integrated" limitation. In my view, the restriction of the scope of this limitation to require the introduction into a host cell of "exogenous sequences encoding ?-Gal A," Genzyme, slip op. at 18, unadvisedly reads limitations from the specification into the claims. I can discern no proper basis to do so and would give the "chromosomally integrated" limitation the full scope of its ordinary and customary meaning.

I. CLAIM CONSTRUCTION

A. Ordinary and Customary Meaning

It is well settled in our jurisprudence that claim terms are to be given their ordinary and customary meaning to one of skill in the relevant art. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). Determining the ordinary and customary meaning of the terms of the claims is the first step in claim construction, and consultation of the written description and prosecution history before attempting to ascertain the ordinary and customary meaning of the language of the claims is premature. Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002). Where the patentee's choice of a claim term "deprives the claim of clarity,'" CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1367 (Fed. Cir. 2002), however, the court must "resort to the other intrinsic evidence," id., to determine the meaning of the claim terms.

In my view, the majority hastens too quickly past the fundamental step of determining the ordinary and customary meaning of "chromosomally integrated." It relies on a single definition of "integration," defined in the context of "viral or another DNA sequence," to import the concept of a "host genome." Genzyme, slip op. at 6; Benjamin Lewin, Genes IV 812 (1990). In light of this imported concept of a "host cell," the majority perceives ambiguity as to "whether one of skill in the art at the time of the invention would understand the exogenous sequences to come from outside the host cell, i.e., a vector, or from within the host cell but outside the critical chromosome, i.e., a transposable element." n1 Genzyme, slip op. at 6. It then turns to the specification to resolve this perceived ambiguity.

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n1 The majority's claim construction analysis frames the question as whether "chromosomally integrated" can be construed to "cover a gene activation technique in which only a promoter sequence is inserted into a human host cell in order to activate the ?-Gal A gene already present in the host cell," Genzyme, slip op. at 4, which is a description of TKT's allegedly infringing technique. I believe the question is misdirected. Our precedent informs that "claims [should] not be construed by reference to the accused device." NeoMagic Corp. v. Trident Microsys., Inc., 287 F.3d 1062, 1074 (Fed. Cir. 2002).

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With all due respect to my colleagues, there is no ambiguity here to be resolved. The majority opinion establishes that the term "chromosomally integrated" could be used in reference to the incorporation into a chromosome of either endogenous or exogenous DNA, that is to say, DNA sequences that have their origin either inside or outside the cell to which the chromosome is native. The ordinary and customary meaning of the term broadly encompasses both possibilities. It is incorrect to perceive a claim term as ambiguous merely because of its breadth and to require that the term be redefined to encompass only a portion of its ordinary meaning in the name of clarity.

Technical treatises publicly available at the time a patent is issued may be consulted as "reliable sources of information that

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would have been attributed to the terms of the claims by those of skill in the art." Tex. Digital Sys., 308 F.3d at 1202-03. See also Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1370 (Fed. Cir. 2002) ("We may look, therefore, to the dictionary definition of the claim term 'mobility' as of the date the patents issued."). A review of the relevant technical treatises contemporaneous with the issuance of the '804 patent shows that "chromosomally integrated" had a broad meaning, encompassing the integration of both exogenous and endogenous DNA. The Genes IV text that the majority cites uses the term "integrated" to describe both the incorporation of viral DNA of extracellular origin, Genes IV 674 (1990) ("One or more [viral] DNA copies become integrated into the host genome."), and the transposition of yeast transposable elements from one site to another within the same genome, id. at 681 (describing yeast Ty transposable elements as subject to "reverse transcription and integration"). Transposable elements, such as retroposons, were understood at the time to be a part of an organism's own genome. Id. at 672 ("We think of retroposons as genomic (duplex DNA) sequences that occasionally transpose within a genome; they do not migrate between cells."). Another contemporaneous leading text similarly describes both viral DNA and transposable element DNA as integrating into the chromosome. Bruce Alberts et al., Molecular Biology of the Cell 255 (1989) ("The DNA circle [of the transposable element] integrates into a randomly selected site on the chromosome.") The term "chromosomally integrated" was thus commonly understood by those of skill in the art at the time to refer to the incorporation into a chromosome of DNA that either came from another site in the same genome or from outside the cell. This is the ordinary and customary meaning of the claim term.

B. The Intrinsic Record

The next step in the claim construction process in this case, as in every case, is to examine the intrinsic evidence, comprising the claims, the written description, and the prosecution history if in evidence, to determine whether the patentee has rebutted the presumption that "chromosomally integrated" has its ordinary and customary meaning. See Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003); Tex. Digital Sys., 308 F.3d at 1204. A patentee may rebut this presumption by "defining claim terminology in a manner inconsistent with its ordinary meaning," Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1301 (Fed. Cir. 2001), or by disclaiming a particular interpretation of a claim term during prosecution, Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 863 (Fed. Cir. 1991). I find no redefinition of the claim term in the intrinsic evidence, nor do I discern any disclaimer of coverage of the integration of endogenous DNA.

The word "integrated" or "integration" appears nine times in the sixty-page '804 written description. None of these instances on its own amounts to a "special definition . . . clearly stated in the patent specification." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The majority correctly notes that "the applicant consistently uses the term 'integrated' to refer to a foreign gene inserted into a host cell chromosome." Genzyme, slip op. at 7. However, this use of "integrated" is not "inconsistent with [its] ordinary meaning," Vitronics Corp., 90 F.3d at 1582, and cannot therefore be used to show that the patentee has redefined the term "with reasonable clarity, deliberateness, and precision," In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994). As the majority demonstrates, the ordinary and customary meaning of "integrated" embraces the incorporation of both exogenous and endogenous DNA. It is immaterial to the proper construction of "integrated" that the embodiments consistently employ exogenous DNA. Absent a redefinition or disclaimer relating to a claim term, consistent use in the written description of a term in a narrower meaning cannot trump a broader ordinary and customary meaning of the term as used in a claim. Were it otherwise, the scope of claim terms would regularly be limited to the embodiments disclosed in the specification. But it is the claim language, not the embodiments, which control. See Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("The claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.").

The majority also cites the "Summary of the Invention" section, where "the present invention" is said to involve "host cell expression systems," and the abstract, which refers to "engineered host cells." '804 patent, col. 6, ll. 22-25; Abstract. The majority contends that the term "host cell" necessarily implies the introduction of exogenous genetic material, and this amounts to a "definition of the invention." Genzyme, slip op. at 8. In other words, the majority sees a redefinition of the claim term "chromosomally integrated" in the use in the specification of a term, "host cell," that appears nowhere in the claims. In my view, the majority roams too far afield in search of a redefinition of the claim term. It is clear from our precedent that any redefinition must focus on the term actually employed in the claims. See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002) ("The claim language defines the bounds of claim scope."); Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'"); Thermalloy,

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Inc. v. Aavid Eng'g, Inc., 121 F.3d 691, 693 (Fed. Cir. 1997) ("Throughout the interpretation process, the focus remains on the meaning of claim language.").

Like the written description, nothing in the prosecution history limits or redefines the scope or meaning of "chromosomally integrated." The majority stresses the fact that "during prosecution, the applicant agreed that the pending claims required a recombinant vector encoding ?-Gal A." Genzyme, slip op. at 11. However, this was predicated on the fact that the set of claims then pending explicitly required the use of a recombinant vector. The Examiner made clear that a deposit of the vector was required because the vector was present in the claims:

Since the vector(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the vector(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the vector(s).

As the majority notes, the claims were later amended to remove the term "recombinant vector," and the issued claims do not contain such a limitation.

Despite the removal of that limitation, however, the majority maintains that the deposited vector sequence remained necessary to the claimed invention, and this mandates a restriction of the scope of "chromosomally integrated." I cannot agree. The deposit of the recombinant vector was required by the Examiner to establish enablement of then-pending claims that explicitly required its use. When the use of a recombinant vector was eliminated from the claims, the predicate for the Examiner's deposition requirement evaporated. There is no reason to conclude in this case that an action taken as a result of the presence of a specific term in the claims should continue to bind the patentee when that term is removed during prosecution and does not appear in the issued claims. See Smith v. Snow, 294 U.S. 1, 16, 79 L. Ed. 721, 55 S. Ct. 279, 1935 Dec. Comm'r Pat. 757 (1935) ("It is of no moment that in the course of the proceedings in the Patent Office the rejection of narrow claims was followed by the allowance of the broader claim 1."); United States v. Telectronics, Inc., 857 F.2d 778, 783 (Fed. Cir. 1988) ("The arguments emphasizing the use of a skin electrode, which were made at the time the application claims explicitly contained such a limitation, cannot furnish a basis for restricting issued claim 1, which lacks any such limitation."); Kistler Instrumente AG. v. United States, 224 Ct. Cl. 370, 628 F.2d 1303, 1308 (Ct. Cl. 1980) ("Defendant's insistance [sic] upon this court's reading back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office cannot be permitted.").

The majority doubts, however, whether the removal of the "recombinant vector" limitation from the issued claims actually represented a broadening of the claims. Given that the amendment occurred at a late stage of prosecution, the majority states that if it were in fact broadening, the amendment would have been a violation of 37 C.F.R. § 1.116(b), because the patentee made no "showing of good and sufficient reasons why [it was] necessary and [was] not earlier presented." 37 C.F.R. § 1.116(b) (1992). A decision restricting the scope of an otherwise unambiguous claim term based on an applicant's presumed noncompliance with a procedural rule of the PTO strikes me as ill-founded. See Dethmers Mfg. Co., Inc. v. Automatic Equip. Mfg. Co., 293 F.3d 1364, 1366 (Fed. Cir. 2002) (Linn, J., dissenting from the order denying rehearing en banc) ("Once a patent issues, non-compliance with a procedural rule administered by the PTO within the scope of the agency's statutory authority and found, by virtue of the grant of the patent, to have been satisfied during prosecution is, in and of itself, of no consequence.").

The majority also relies on arguments distinguishing certain prior art references to establish that the patentee "expressly confined the invention to production of proteins by introducing vectors into a mammalian host cell." Genzyme, slip op. at 14. To establish a disclaimer or disavowal of claim scope, of course, a patentee must use "words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Tex. Digital Sys., 308 F.3d at 1204. The majority finds such a manifest exclusion of the use of a cell's own endogenous DNA in the patentee's assertions that the claimed invention was capable of recovering "recombinant protein," and that such "heterologously expressed recombinant proteins" are difficult to purify. Genzyme, slip op. at 12-13. The patentee also referred to the claimed invention's use of "an engineered mammalian cell system." Id., slip op. at 14. I see no clear disavowal of the use of endogenous DNA in these remarks. Neither Tsuji nor Bishop employed endogenous DNA. The essence of the patentee's argument was that, while the prior art employed exogenous DNA to achieve a low level of transient expression, the claimed invention was "the first demonstration of the stable, overexpression, selective secretion, and subsequent isolation of a lysosomal enzyme in a recombinant mammalian cell system." Whether the prior art references integrated the cell's own DNA into a different chromosomal site was simply not at issue.

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II. ENABLEMENT

The majority notes that "the record would appear to raise questions of enablement," although it also states that "this court need not examine enablement to properly define the claim term 'chromosomally integrated' in view of the specification and prosecution history." Genzyme, slip op. at 17. To the extent that enablement concerns underlie the majority's narrowing of the scope of "chromosomally integrated," however, I suggest that such issues are not yet ripe for consideration. The district court has not yet addressed validity, and the parties did not brief the issue on appeal. Although this court has stated that claims should be interpreted so as to preserve their validity whenever reasonably possible, Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir. 1996), it is wrong to allow enablement issues that have not yet been fully ventilated by the parties and the district court to influence a claim construction determination. I agree that all validity concerns should be left for another day.
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A. The Term "Chromosome DNA Fragment of A Donor Bacterium"

The claims of the '765 patent require that a "chromosome DNA fragment of a donor bacterium" or a "fragment of the chromosome DNA of a donor strain E. coli VNIIGenetika MG442" be used for combining with a plasmid DNA molecule to form a hybrid DNA molecule or hybrid plasmid. (D.I. 240, Ex. A, col 12, lines 1-48) According to ADM, "bacteria have two, or, at most, three types of DNA: chromosome DNA, plasmid DNA, and bacteriophage (or phage) DNA." (D.I. 240 at 7) ADM argues that chromosome DNA fragments cannot be equated with plasmid DNA fragments. (D.I. 240 at 7) ADM seeks this limitation in response to the following language from Ajinomoto's expert report:

I have also been asked to provide my opinion whether a method of making a strain in which the threonine operon-containing insert is transferred into a Mu bacteriophage which would then incorporate itself into the E. coli chromosome. As a result, the hybrid bacteriophage would no longer be present in the end product strain but would function exactly as if the plasmid were present. In my opinion, these genetic manipulations and resulting strains directly infringe or are substantially the same as the claims of the '765 patent for the following reasons. First, the feedback resistant threonine genes originate in the bacterial chromosome. Second, those genes are combined with a genetic element that, like a plasmid, is capable of amplification and replication independent of the chromosome. Finally, the hybrid is introduced into a host strain that is auxotrophic for threonine and has a mutation partly blocking a related step of metabolism.

(D.I. 240, Ex. B at P 51) ADM argues that Ajinomoto's expert equates a chromosome DNA fragment with a plasmid DNA fragment because he apparently believes that "once a chromosome fragment, always a chromosome fragement -- even when the fragment has been part of a plasmid for ten years or more." n9 (D.I. 240 at 7)

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n9 It is unclear to the court, based on the record, whether a fragment of chromosome DNA from a hybrid plasmid that was formed by combining a chromosome DNA fragment and a plasmid DNA fragment retains its identity as a chromosome DNA fragment or whether it assumes a new identity either as a hybrid plasmid DNA fragment or a plasmid DNA fragment. Furthermore, it is unclear whether the amount of time that a chromosome DNA fragment is part of a hybrid plasmid is relevant to the identification of DNA fragments from the hybrid plasmid.

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ADM supports its position that the term "chromosome DNA fragment of a donor bacterium" should not be interpreted to include the term "plasmid DNA fragment" or "bacteriophage DNA fragment" by reference to the '765 specification and definitions in a treatise on biochemistry. n10 The term "chromosome" is not defined in the '765 specification. The treatise that ADM cites defines "chromsome" as "a single large DNA molecule containing many genes and functioning to store and transmit genetic information." (D.I. 240, Ex. C at 970) The treatise defines "plasmids" as "an extrachromosomal,

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independently replicating small circular DNA molecule." (D.I. 240, Ex. C at 977) The '765 patent specification defines the term "plasmid" as "genetic elements reproducing in bacterial cells irrespective of chromosomes." (D.I. 240, Ex. A, col. 1, lines 16-17) The '765 patent also does not define the term "bacteriophage," but does make a reference to "plasmids" and "phages." The '765 patent specification states "the term vector molecules denotes DNA molecules of plasmids and phages." (D.I. 240, Ex. A, col. 1, lines 23-24). The treatise defines bateriophage as "a virus capable of replicating in a bacterial cell." (D.I. 240, Ex. C at 970) The term "virus" is defined by the treatise as "a self-replicating, infectious, nucleic acid protein complex that requires an intact host cell for its replication and that contains a chromosome of either DNA or RNA." (D.I. 240, Ex. C at 980) ADM argues that, given the discussion of phage and plasmid in the '765 patent specification and the accepted terminology provided by the biochemistry treatise, the patent applicants could not have intended that the term "chromosome DNA fragment" includes DNA fragments from plasmids or phages. (D.I. 240 at 8) ADM asserts that nothing in the specification, prosecution history, or extrinsic evidence shows that the term "chromosome DNA fragment from a donor bacterium" includes DNA fragments from plasmids or phages. (D.I. 240 at 9)

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n10 ADM cites to the following treatise: Albert L. Lehnigher, Principles of Biochemistry 969-980 (1982). (D.I. 240, Ex. C)

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Ajinomoto's expert Dr. Falkinham apparently takes a different approach in defining the term "chromosome DNA fragment of a donor bacterium strain." Dr. Falkinham defines this term by first defining "donor bacterium" as "the bacterium with which a scientist begins the experiment; it contains the genes of interest." (D.I. 240, Ex. 3 at P 30) He then defines "chromosome" as "the single DNA molecule carrying all the essential genes for the organism." (D.I. 240, Ex. 3 at P30) Finally, Dr. Falkinham defines "DNA fragment" as "a piece of DNA or genetic material that has been cut from another source using specific enzymes." (D.I. 240, Ex. 3 at P 31)

Dr. Falkinham defines "plasmid" as "a host DNA molecule with the ability to replicate independently of the chromosome; it is typically circular." (D.I. 240, Ex. 3 at P36) The term "hybrid molecule" is defined as "the resulting DNA [which] is a combination of DNA from more than one different source." (D.I. 240, Ex. 3 at P 37)

The court concludes that the term "chromosome DNA fragment" is limited to DNA from a chromosome, and does not include DNA fragments from either plasmids or bacteriophages, subject to the questions raised in footnote 9 supra.
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C. "chronic inflammatory condition"

Plaintiffs assert that the meaning of the term "chronic inflammatory condition" is plain to one skilled in the art and, therefore, needs no construction. (D.I. 64 at 27) Mylan, on the other hand, proposes that the term be construed to mean "a condition characterized by inflammation which persists for days or weeks or longer." (D.I. 55 at 15)

The '395 patent, in which this claim term is found, distinguishes between acute and chronic inflammation as follows:

Acute inflammation is generally of relatively short duration, lasting for from about a few minutes to about one to two days. Its main characteristics are increased blood flow, exudation of fluid and plasma proteins (edema) and emigration of leukocytes, predominantly neutrophils.

Chronic inflammation is of longer duration, e.g., days to weeks or even longer, and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue.

('395 patent, col. 7 lines 35-44) As can be seen, the patent distinguishes between acute and chronic conditions based on their general duration, but does so broadly, in a manner that allows for the possibility of overlap (e.g., inflammation lasting two days may be a lengthy acute condition or a short chronic condition). The patent further identifies non-temporal characteristics of acute inflammation and analogous associations of chronic inflammation.

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Because the parties dispute the meaning of "chronic inflammatory condition" and their dispute is not immaterial, it is appropriate for the Court to construe this term. See generally 02 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd., 521 F.3d 1351, 1361-62 (Fed. Cir. 2008). Given the portion of the specification quoted above, a proper construction of this disputed claim term should account for not just the temporal aspect of a chronic condition, but also its physical associations.

Accordingly, I recommend that the Court construe "chronic inflammatory condition" to mean "an inflammatory condition lasting for days to weeks or longer, and is associated histologically with the presence of lymphocytes and macrophages and with proliferation of blood vessels and connective tissue."
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3. The Meaning of "Citalopram"

The R & R construed the term "citalopram" in the '973 patent to include "the S-enantiomer, the R-enantiomer, the racemate, or any other mixture of enantiomers." 39 Defendants object to this proposed construction for several reasons.

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39 R & R at l.

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First, defendants object that the R & R did not cite to portions of the intrinsic evidence. The '973 patent refers only to "citalopram" without defining the term, but incorporates by reference two patent applications that did define the term. 40 The first is the International Patent Application 0023431 ("'431 application"), entitled "Method for the Preparation of Citalopram," which was published on April 27, 2000. 41 The second is the Italian Patent Application MI 99A 001724 ("'724 application"), which claimed a process for the preparation of an isobenzofuran derivative, an intermediate compound used in the preparation of citalopram. 42

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40 See Pl. Ex. B at col. 1:24-28 (incorporating '431 and '724 applications by reference).

41 Pl. Ex. F.

42 Pl. Ex. Gat 11:8-9.

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The defendants argue that the R & R failed to consider particular portions of the '431 and '724 applications. But the R & R considered the manner in which both of the patent applications used "citalopram" and concluded that the applications used the term to refer to citalopram's S-enantiomer, R-enantiomer, racemate, or enantiomers in any other combination. 43

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43 R & R at 6.

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This conclusion is supported by both the intrinsic and extrinsic evidence. Those skilled in the art specify particular enantiomers and the racemate by adding labels to the chemical name of the compound. 44 Both the '431 and '724 applications refer to "citalopram" as "1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-5-

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isobenzofurancarbonitrile." 45 This, the full chemical name for citalopram, does not specify a particular enantiomeric form or the racemate. 46

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44 Pl. Ex. E PP 18, 20, 27.

45 Pl. Ex. Fat 1; Pl. Ex. Gat 2.

46 Pl. Ex. E P 27; see also Pl. Ex. K at 5256 (labeling compound "racemic"); Def. Ex. H P 34 (denoting enantiomers with addition of "(S)" and "(R)" before full chemical name for citalopram).

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Both applications provide also a two dimensional figure depicting citalopram. 47 Those skilled in the art use certain conventions for indicating enantionmers in two dimensional depictions. 48 For example, a solid wedge instead of a simple line indicates atoms that extend above the plane of the paper, and a hashed wedge or line indicates atoms extending downward. 49 Neither application's depiction of citalopram indicates a specific enantiomeric form. 50 This indicates "citalopram" is used in the applications to refer to citalopram in either or both of its enantiomeric forms.

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47 Pl. Ex. F at 2; Pl. Ex. G at 2; see also Pl. Ex. E P 24.

48 Pl. Ex. E P 19; Williams Dep., Def. Ex. Q at 203:14-19.

49 Pl. Ex. E P 19.50 Pl. Ex. E P 26.

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This understanding is confirmed by plaintiff's and defendants' experts. Dr. Scott stated that, "[a]bsent definition of the three-dimensional stereochemistry via a stereochemical indicator, the chemical name or structure includes the S-enantiomer, the R-enantiomer, the racemate, or any other mixture of enantiomers." 51 Defendants' expert, Dr. Williams, testified similarly. He stated that "if the lines as drawn [in the figure of the citalopram compound] are all the same width . . . that would not tell me that that structure corresponds to S-citalopram, it would be ambiguous, and then I would assume that that structure would be corresponding to . . . either R or S or racemic citalopram." 52

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51 Pl. Ex. E P 20.

52 Pl. Ex. L at 207:11-19.

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This understanding is reinforced also by the description of the invention in the '724 application. There, it is described as one that "allows the preparation of two enantiomers of citalopram." 53 Claim 1, however, states that it is "[a] process for the preparation of citalopram and of its pharmaceutically acceptable salts." 54 Reading Claim 1 in light of this earlier description indicates that the term "citalopram" must include either or both of citalopram's enantiomers.

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53 Pl. Ex. G at 11:9.

54 Pl. Ex. Gat 20:1.

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Likewise, the '431 application states that it "relates to a method for the preparation of . . . citalopram." Later in the specification, it states that the invention described "relates to a novel method for the preparation of citalopram, its enantiomers and acid addition salts thereof." 55 This indicates that the '431 application used the term "citalopram" in its broader sense and added references to its enantiomers to clarify that the process permitted the synthesis of both the racemate and individual enantiomers.

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55 Pl. Ex. F at 3.

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Examining the applications as a whole thus demonstrates that the inventors used the term "citalopram" to refer to the compound 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-5-isobenzofurancarbonitrile generally, in any of its forms: the S-enantiomer, the R-enantiomer, the racemate, or a mixture of the enantiomers in any other combination. At other times, the applications added the term "enantiomers" in order to clarify or emphasize what was being claimed. 56 The additional clarification in places, however, cannot limit the use of the more general term "citalopram" when the applications read as a whole indicate the term was used in its broader sense. 57

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56 See, e.g., Pl. Ex. F at 18.

57 See, e.g., Bell & Howell Document Mgmt. Prods. Co. v. Altek Systems, 132 F.3d 701, 707 (Fed. Cir. 1997) ("Moreover, defining a state of affairs with multiple terms should help, rather than hinder, understanding.").

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Defendants argue that the fact that the '973 patent refers to "citalopram" as a "well known antidepressant drug" indicates that "citalopram" must refer only to the racemate because the racemic form of citalopram was the only well-known antidepressant on the market at the time the patent application was filed. 58 But, as discussed above, the term "citalopram" was used in the '431 and '724 applications in a broader sense. The term encompassed the racemate -- then and now a "well known antidepressant drug" -- as well as citalopram's other forms.

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58 Def. Obj. at 16.

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Defendants assert also that their interpretation of citalopram is supported by Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc. 59 As the R & R stated, the issue in Forest Labs was whether patent claims for substantially pure S-citalopram were invalid because they were anticipated or obvious in light of prior art that disclosed the presence of both of citalopram's enantiomers but provided the chemical structure of the R-enantiomer only. 60 The court found that the patents were valid because the process for synthesizing substantially pure S-citalopram was unknown at the time the application was filed. The court's conclusion, however, does not answer the question here, as the Forest Labs court did not interpret the use of the term "citalopram" standing on its own.

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59 438 F. Supp.2d 479 (D. Del. 2006).

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60 Id. at 486-87.

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Finally, defendants argue that the court should examine the IP Rights Agreement to shed light on the patent drafters' contemporaneous interpretation of "citalopram." 61 The contract states that Norpharma S.p.A., the applicant for the '724 patent, "is engaged in research and development on methods for manufacturing" racemic citalopram. 62 However, even if the Court assumes that Norpharma was engaged exclusively in researching and developing racemic citalopram, an IP contract presumably drafted by attorneys does not reflect the intentions or understanding of the inventors. 63 Thus, considering the balance of the evidence, most significantly the patent applications read as a whole, the Court overrules the objection and adopts the R & R's interpretation of the term "citalopram."

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61 Def. Obj. at 19.

62 Pl. Ex. K at 5256.

63 See Middleton, Inc. v. Minnesota Mining and Mfg. Co., 311 F.3d 1384, 1389 (Fed. Cir. 2002) ("If a contract supplies some insight into the understanding of skilled artisans at the time of the invention, it may have some relevance to claim construction.").

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2. Citramalic Acid

The parties raise similar arguments in relation to citramalic acid. The term "citramalic acid" is used in Claim 1, Step 2 and Claim 4(a) of the '311 Patent. Metametrix asserts that citramalic acid means only "citramalic acid, 2-hydroxy-2-methylbutanedioic acid, 2-methylmalic acid, 3-methylmalic acid, 2-hydroxy-3-methyl-butanedioic acid" since these are the only specific forms identified in the patent. Plaintiffs argue that "citramalic acid" means any form of citramalic acid, including citramalic acid, 2-hydroxy-2-methylbutanedioic acid, methylmalic, 2-methylmalic acid, 3-methylmalic acid, 2-hydroxy-3-methyl-butanedioic acid, methylmalate, 2-methylmalate, and 3-methylmalate.

* * *

With the exception of methylmalic, n1 the disputed terms are the conjugate bases of citramalic acid. Dr. Winkler's report states that the organic acid and conjugate base are two entirely different compounds. However, in Metamatrix's Organic Acid Analysis report defendant refers to citramalic acid as also citramalate. (Dkt. No. 114, Ex. 7 at MX00075). Similarly, Sigma-Aldrich, an organic chemical compounds company, refers to citramalic acid and citramalate as "synonymous." Dkt. No. 114, Ex. 5, at 4.

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n1 Based on the suffix, methylmalic is the acid form.

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Although the extrinsic evidence is helpful to the court in determining how terms may be used in the field of organic acid in general, the court returns to the patent in determining what the disputed terms mean in this context. Throughout the patent, "citramalic acid' is referred to in numerous ways including "authentic citramalic acid" (Col. 3, line 24), "citramalic acid TMS derivative"(Col. 3, line 28), "derivative of the citramalic acid" (Col. 4, line 36), "citramalic" (Col. 4, line 62), "2-methylmalic acid" (Col. 12, line 61), and "3-methylmalic acid" (Col. 12, line 62). Use of these terms should not be

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construed as limiting the scope of the claim terms but rather highlights the flexibility in meaning of citramalic acid as used in this patent.

Moreover, based on the court's understanding of the relation of organic acids and their conjugate bases, citramalate, methylmalate, 2-methylmalate and 3-methylmalate should be construed within the patent term "citramalic acid." Citramalate is the recognized conjugate base of citramalic acid, 2-methylmalate is the conjugate base of 2-methylmalic acid, and 3-methylmalic acid is the conjugate base of 3-methylmalate. Finally, methylmalic acid is recognized as another name for citramalic acid. Thus, methylmalic acid and its conjugate base fall within the scope of the term" citramalic acid" in the '311 patent. See Chemical Abstracts Service, a division of the American Chemical Society, SciFinder database available at http://www.cas.org (subscription required) (last accessed July 12, 2006) (listing the other names of citramalic acid, registry number 597-44-4).

Therefore, the court declines to import limitations from the specification into the claim language of Claims 1 or Claim 4 and adopts plaintiffs' definition of citramalic acid.
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I. INVALIDITY OF THE '358 AND '799 PATENTS

Emergency Fuel alleges that Penzoil infringes claim 1 of the '358 patent, which reads:

1. A method of using a stable emergency fuel in an internal combustion engine of a vehicle comprising the steps of:

providing a container having mineral spirits therein, the mineral spirits having a flash point of at least 100 degrees F. or higher,

safely storing the container with the emergency fuel in the vehicle for a period of at least twelve months unless needed for use prior thereto, and

pouring the mineral spirits into a fuel tank of the vehicle in the event the vehicle runs out of fuel, the emergency fuel providing clean and smooth operation of the internal combustion engine.

'358 patent, col. 10, ll. 53-65 (emphasis added).

The '358 specification states that "in order to run smoothly, the fuel must have an octane number in the same range as or higher than regular gasoline. This is typically from 86 to 88." Id. at col. 5, ll. 56-58. In light of the foregoing statement, the district court concluded that claim 1 covers an emergency fuel with an octane number of at least 86. The '358 specification also teaches that "the presence of naphthenes, aromatics and isoparaffins all help to improve the octane number." Id. at col. 5, ll. 62-64. With regard to the use of aromatics, the district court found that the '358 patent taught against using large amounts of aromatic hydrocarbons, while the more recent patents acknowledge that to fulfill the smooth and clean engine operation requirement one must increase aromatic content. Thus, the district court concluded that the '358 patent does not teach the full scope of the claimed invention, specifically, how to obtain an octane number of 86 using aromatics.

Emergency Fuel also alleges that Penzoil infringes claim 4 of the '799 patent, which reads:

4. An emergency fuel for an internal combustion engine to be stored in a vehicle and to be used when the vehicle is out of fuel, the emergency fuel comprising:

mineral spirits,

the emergency fuel having an octane number of at least 70, and

the emergency fuel having a flash point of at least 100 degrees F.

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'799 patent, col. 13, ll. 1-7.

The district court found that the '799 patent also teaches not to increase aromatic content, but incorporates by reference the entire '358 patent, including the limitation that the fuel have an octane number of 86 to 88. The court further noted that the '799 patent makes it appear that the blends described in the specification examples would achieve the claimed octane number of 70, but that the octane numbers for those blends are actually lower than 70. Accordingly, the district court concluded that the claims of the '358 and '799 patents were not enabled because if one skilled in the art does what the patents teach, he or she would not be able to obtain compositions that fall within the asserted claims without undue experimentation.

On appeal, Emergency Fuel argues that cautionary instructions in the specifications regarding the method of increasing octane by adding aromatics does not justify summary judgment for lack of enablement where those skilled in the art were aware of alterative modes of increasing octane and the specification itself discloses those alternative modes. These alternative methods are the addition of isoparaffins and napthenes. Further, Emergency Fuel contends that the district court erroneously required the '358 and '799 patent specifications to include a working example of an emergency fuel with the requisite octane rating to satisfy the enablement requirement.

Penzoil counters that the asserted claims of the '358 and '799 patents are invalid for lack of full scope enablement in light of the deficient disclosure of how to achieve an 86 octane rating in the emergency fuel by adding aromatics. Penzoil also contends that the isoparaffin embodiment cannot save the asserted claims because the claims were not restricted to that embodiment and the embodiment is not adequately enabled by the '358 specification. With regard to the '799 patent, Penzoil does not dispute that claim 4 covers an emergency fuel with an octane rating of at least 70. However, Penzoil notes that the sole support for this requirement is a table purporting to teach how various octane numbers can be achieved by varying aromatic content, which the parties do not dispute was incorrect.

A. CONSTRUCTION OF THE '358 AND '799 PATENT CLAIMS

We agree with the district court that claim 1 of the '358 patent is limited to an emergency fuel having an octane rating of at least 86. The claim recites an emergency fuel that "provides clean and smooth operation of the internal combustion engine." '358 patent at col. 10, ll. 64-65. To understand the meaning of the ambiguous claim language, "smooth operation," we must look to the specification for the meaning ascribed to that term by the inventor. See Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (stating "claims must be read in view of the specification, of which they are a part") (citations omitted); Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1339-41 (Fed. Cir. 2001) (affirming summary judgment below and reading claim in light of specification). The '358 patent specification explains that "in order to run smoothly, the fuel must have an octane number in the same range as or higher than regular gasoline. This is typically from 86 to 88." '358 patent at col. 5, ll. 56-58. Further, Mr. Hubbard and Emergency Fuel's designated expert, Richard Bechtold, confirmed that the "smooth operation" limitation of claim 1 of the '358 patent cannot be satisfied unless the emergency fuel has at least an octane rating of 86 to 88. Accordingly, the district court correctly construed claim 1 of the '358 patent as limited to an emergency fuel having an octane rating of at least 86. As to claim 4 of the '799 patent, the claim language dictates an emergency fuel having an octane rating of least 70. We next address the district court's enablement analysis.
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a. C[min]

The first claim construction dispute centers around the method for calculating C[min], the mean minimum plasma concentration. Endo contends that C[min] would be calculated by those skilled in the art by taking each patient's minimum concentration, at whatever time it was reached, totaling up those numbers for all patients, and dividing by the number of patients. Purdue, on the other hand, contends that the claims should not be limited to a particular method for measuring C[min]. It argues that C[min] could be measured as Endo contends, or it could be measured at C,[2], the end of a dosing interval during steady state for a 12-hour formulation, or C[min] could also be properly measured as the average of the plasma levels at T[0] and T[I2].

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In resolving this dispute, this Court turns first to the language of the claims themselves. The '912, '042 and '295 patents claim a mean minimum plasma concentration up to 120 ng/ml "from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions." '912 patent, claims 1-3; '042 patent, claims 1-2; '295 patent, claims 1, 8-10. This language does not provide a method for calculating C[min], although it does state in ordinary language that the range for C[min] occurs between 10 and 14 hours after achieving steady-state conditions.

Because the claim language does not provide a method for calculating C[min], we next look to the specifications in the patents in suit. Purdue contends that Example 18 of the '912 patent computed C[min] by taking the average of the plasma levels at T[0] and T[I2], which, at steady state, represent the end of two dosing intervals for a 12-hour drug formulation. However, no method for calculating C[min] is provided in Example 18 of the '912 patent, or in any other part of the specifications for the '912, '295 or '042 patents. Therefore, the specifications fail to shed light as to how to calculate C[min]. The prosecution histories are similarly devoid of any indication of how to calculate C[min].

Since neither the claim language nor the specifications nor the prosecution histories provide guidance on how to calculate C[min], this Court looks to extrinsic evidence to determine how those of ordinary skill in the art would have calculated C[min] at the time the patents were filed. See Key Pharm., 161 F.3d at 716. Endo's claim construction expert, Dr. Sanford Bolton, testified that the mean minimum plasma concentration is calculated by looking over "a dosing interval at steady state and look at the various concentrations at the blood sampling times, and for each patient or subject in the study obtain a minimum value, and then average those minimum values." Tr. 1469. Dr. Donald Stanski, Purdue's claim construction expert, and Dr. Paul D. Goldenheim, Purdue's executive vice president of research and development and chief scientific officer, both testified that C[min] could be calculated at C[12], the end of a dosing interval for a 12-hour formulation at steady state, or the average of C[0] and C[12] - both of which occur immediately before dosing at steady state. Tr. 652; Tr. 976-77. Dr. Robert F. Kaiko, a named inventor of all of the patents in suit, testified that he calculated C[min] in the same manner suggested by Dr. Bolton, namely by adding the "lowest oxycodone concentration" of each of the subjects of the study divided by the number of subjects in the study. Tr. 216. However, Dr. Kaiko utilized a different method for calculating C[min] in a 1996 published paper he coauthored which defined C[min] as the "average of the 0- and 12-hour plasma oxycodone concentrations." PTX 563, P645913.

Additionally, the FDA's July 1992 guidelines, applicable in November 1992 when Purdue filed the '912 patent, states that C[min] defined as "the drug concentrations at the end of each dosing interval during steady state." PTX 916. Consequently, pursuant to the FDA guidelines, C[min] would be C[12] for a 12-hour formulation.

This Court finds Purdue's argument persuasive. A review of the patents' claims, specifications and prosecution histories reveals only that C[min] is measured between 10 and 14 hours after achieving steady state conditions. There is no indication from the intrinsic evidence as to how C[min] should be measured. The extrinsic evidence presented by the parties indicates that one of ordinary skill in the art could use several different methods to calculate C[min] when the patents were filed. Since measurement of C[12] occurs 12 hours after dosing, and the claimed mean minimum plasma concentration is measured between the range of 10 to 14 hours, C[12] (and correspondingly T[12]) falls within the range of 10 to 14 hours - therefore, the claims do not exclude using C[I2] as C[min]. Measuring C[min] as the average of C[0] and C[12] for a 12-hour formulation also falls within the claimed range since C[0] is at the end of a dosing interval during steady state and C[12] is the end of the subsequent dosing interval. Accordingly, this Court will not "import into the claims limitations that were unintended by the patentee." Amgen, 314 F.3d at 1325; LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353-56 (Fed. Cir. 2001). One skilled in the art would not limit measurements of C[min] to the sole method proposed by Endo.

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The parties dispute the construction of the term "co-micronized". Plaintiffs argue that the term should be given its "ordinary meaning" of "micronized with or together". Defendant argues that the term should be construed narrowly to mean that "fenofibrate and a solid surfactant have been micronized together and in the absence of any other excipients".

In essence, the parties do not disagree as to the common meaning of the term "co-micronized". Both parties agree that the common meaning is construed to mean "micronized with or together". This common meaning is supported by the definitions of the parts of the word. "Co-" is defined the same as "con-" -- "a prefix meaning with or together". Dorland's

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Illustrated Medical Dictionary 368, 389 (29th ed. 2000). "Micronize" is defined as "to reduce to a fine powder; to reduce to particles a micron in diameter". Dorland's Illustrated Medical Dictionary 1112 (29th ed. 2000). Accordingly, the ordinary meaning of the term "co-micronized" would be "to reduce to a fine powder [micronize] with or together".

Defendant argues that the claim language, specification, and prosecution history support a more narrow definition to include that only fenofibrate and a solid surfactant have been micronized together in the absence of any other excipients. Plaintiff argues that Defendant is impermissibly reading a limitation into the claim from the specification.

The term "co-micronize" or a derivative thereof, i.e., co-micronizing, are used in multiple claims, including claims 1, 8, and 10. In each of these claims, a mixture of fenofibrate and a solid surfactant are micronized together. Claim 10 also refers to the micronization of a "fenofibrate/solid surfactant mixture". No other materials or excipients are identified as being part of and of these mixtures.

The term "co-micronize" or its derivatives are also used throughout the specification. For example, the specification states, in pertinent part, that it "has now been discovered that the co-micronization of fenofibrate and a solid surfactant (i.e., the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability ... than that which would be achieved either by adding a surfactant, or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant." Through this language, Plaintiff distinguished its co-micronized mixture of fenofibrate and a solid surfactant from mixtures obtained by adding a surfactant to fenofibrate, or micronizing fenofibrate by itself, and/or mixing separately micronized fenofibrate and surfactant. By distinguishing its co-micronized mixture from these types of mixtures, Plaintiff's co-micronized mixture cannot include such mixtures. See O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1581 (Fed. Cir. 1997) (description that distinguished claim over prior art narrowed construction of disputed term). In all of the examples for preparing the product, fenofibrate and a solid surfactant are the only materials micronized together. After the co-micronization, other excipients are added.

During the prosecution of the Curtet Patent and the subsequent reexamination, Plaintiff repeatedly alleged that prior art did not teach or suggest co-micronization of a mixture of fenofibrate and a solid surfactant. Furthermore, Plaintiff stated that fenofibrate in the co-micronized mixture dissolves faster than fenofibrate dissolves when micronized fenofibrate is mixed with micronized solid surfactants. The prosecution history demonstrates that Plaintiff distinguished its claims, in part, on the fact that fenofibrate and a solid surfactant would be micronized together. In every instance, no other materials are included in this co-micronization. Furthermore, fenofibrate and a solid surfactant are the only materials identified in reference to the "co-micronized mixture".

The above demonstrates that Plaintiff micronizes, together, fenofibrate and a solid surfactant. The claims, description, and prosecution history do not indicate that anything other than fenofibrate and a solid surfactant are micronized. Furthermore, the description and prosecution history indicate that one of the distinguishing elements of this Patent is the co-micronization of a fenofibrate/solid surfactant mixture. No other excipient is identified as part of this mixture.

In light of the above, one skilled in the art reading the claims, description, and prosecution history would conclude that the term "co-micronize" in claims 1 and 10 does not encompass co-microzination of excipients other than fenofibrate and a solid surfactant.

Based on the above, the term "co-micronized" is construed to mean that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients.
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Fournier and Abbott argue on appeal that the district court erred by construing the claim term "co-micronization" to require micronization of fenofibrate and solid surfactant "in the absence of other excipients." They argue that the court also erred by construing the claim phrase "mixture of" to mean "mixture wholly of," again requiring exclusion of all ingredients other than fenofibrate and solid surfactant in the mixture during co-micronization. According to the appellants, both misconstructions result from the court's having improperly imported limitations into the claims from the patent's non-limiting examples.

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We disagree, first, with the appellants' contention that the district court misconstrued the term "co-micronization." Although courts "must presume that the terms in a claim mean what they say, and unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms," Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999); see also Nike Inc. v. Wolverine World Wide, Inc., 43 F.3d 644, 646, 33 USPQ2d 1038, 1039 (Fed. Cir. 1994); E.I. du Pont de Nemours & Co. v. Phillips Petroleum, 849 F.2d 1430, 1433, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988), we have previously identified limited situations "where a sufficient reason exists to require the entry of a definition of a claim term other than its ordinary and accustomed meaning," Johnson Worldwide, 175 F.3d at 990, 50 USPQ2d at 1610. One such situation is when the patentee "has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term." Id.

The district court found that, although the term "co-micronization" was not known in the art prior to the filing date of the application that led to the '726 patent, both "micronization" and the prefix "co-" had well-known meanings as of that date, and one of ordinary skill in the art at that time therefore would have readily understood the meaning of "co-micronization." Had that term not been explicitly defined in the '726 patent specification, we might well agree with the appellants that that term could simply mean "micronized with or together" and would not necessarily exclude the presence of ingredients not specifically recited in the claim. However, the phrase "co-micronization of fenofibrate and a solid surfactant" is in fact explicitly defined at column 1, lines 35-38, of the '726 patent, as "micronization of an intimate mixture of fenofibrate and a solid surfactant." Hence, this is a case in which the patentee has "chosen to be his own lexicographer," and the district court did not err by reading the patentee's definition from the specification into the claim. Moreover, the inclusion of the word "intimate" in the definition, together with the fact that fenofibrate and SLS are the only ingredients present in every co-micronized mixture described in the '726 patent's specification, makes it abundantly clear that "co-micronization of . . . fenofibrate and a solid surfactant" should be construed as referring to co-micronization of a mixture consisting essentially of fenofibrate and solid surfactant. n2

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n2 By use of the term "essentially," we do not wish to exclude the possibility of minor impurities being present.

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O. Coagulate

Claim 1 of the '225 Patent provides that the thermal treatment is "insufficient to cause coagulation of the liquid whole egg product…." (Kempf Aff., Ex. 1, Col. 15, ll. 63-64.) However, the intrinsic evidence does not define the term "coagulation." The court therefore evaluates extrinsic evidence in construing the term. See Markman, 52 F.3d at 980. The common understanding of "coagulate" means to cause transformation into a soft, semi-solid or solid mass. The American Heritage Dictionary, Second College Edition, at 285 (1985); see also Webster's 3rd Edition at 432 (1986)(stating that coagulation means to become soft, semi-solid mass). Expert testimony shows that coagulation relates to whether the egg product is still a liquid:

Q: The next term, (gg), quote, "insufficient to cause coagulation of the liquid whole egg product," unquote, what would one of ordinary skill in the art understand that to mean?

A: He would understand that to mean that the egg is still in a liquid state and, as it says, insufficiently coagulated, or in other words it would remain in the same state as before treated.

….

Q: Would one of ordinary skill in the art understand the extended shelf life liquid whole eggs to be uncoagulated?

A: He would understand that that would certainly be the expected outcome because the liquid product should perform as a liquid instead of as a cooked product, so it should still have the same properties, same properties. Primarily you are looking

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at viscosity would be one way of measuring, has it changed.

(Kempf Aff., Ex. 15 at 93, ll. 23-25; Id. at 94, ll. 1-5; Id. at 94, ll. 23-25; Id. at 95, ll. 1-7.) Because the patent did not indicate that anything other than the ordinary and accustomed meaning of the term "coagulate" applies, the court adopts the ordinary meaning of the term, construing "coagulate" to mean to become a soft, semi-solid mass. 20

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20 The phrase "insufficient to cause coagulation of the liquid whole egg product" refers to processing which provides a product which is not coagulated by thermal treatment the product receives.

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A. Coat of Aloe Vera

For the reasons set forth below, this court interprets the claim term "coat of Aloe Vera" in the '328 patent to mean:

a coating that may include ingredients other than aloe vera but the aloe vera must account for more than 0.5% of the entire coating.

Ansell's first request regarding construction of this term is that it be interpreted to mean a coat consisting entirely of aloe vera and no other substance. (Def.'s S.J. Mem., at 4-6.) In support, Ansell relies heavily on Robie v. Carlton, 36 C.C.P.A. 739, 171 F.2d 310, 1949 Dec. Comm'r Pat. 25 (C.C.P.A. 1948), which carries precedential weight. BMW Mfg Corp. v. United States, 241 F.3d 1357, 1362 n.3 (Fed. Cir. 2001) ("Decisions of the Court of Customs and Patent Appeals are binding precedent on [the Federal Circuit].) And what Ansell alleges is Shen-Wei's disclaimer of any ingredients other than aloe vera when referring to the term "coat of Aloe Vera." This court finds neither of these contentions availing. The court in Robie explained that when a "reference is made to a coat of paint, or a coat of varnish, the meaning ordinarily intended is that the coat consists entirely of the specified material." Id. at 311. Assuming thatRobie creates a presumption that use of the term "coat" excludes the use of other ingredients, this court would still find that such a presumption would not apply in this case. To read claim 4's reference to a "coat of Aloe Vera" as excluding the use of other ingredients would render claim 1's reference to "a coat of 100% Aloe Vera" superfluous. The Court of Appeals for the Federal Circuit has made clear that the use of different terms in claims is presumed to reflect differing scopes of the claims. Forest Labs., Inc. v. Abbott Labs., 239 F.3d 1305, 1310 (Fed. Cir. 2001) (citation omitted). The use of "a coat of 100% Aloe Vera" in claim 1 indicates that the "coat of Aloe Vera" in claim 4 may include other ingredients. This court additionally agrees with Shen Wei that the reference in claim 20 to "a coating comprising Aloe Vera and no detectable oil-based substance" is not fatal to the conclusion that claim 4's reference to a "coat" includes substances other than aloe vera, because the use of the term "comprising" in claim 4 is used to identify the fact that the exclusion of "oil-based substance" did not otherwise limit the inclusion of ingredients along with aloe vera.

Contrary to Ansell's assertions, the prosecution history of the '328 Patent does not clearly indicate that Shen Wei disclaimed the use of ingredients other than aloe vera. The passage put forth by Ansell in support of disclaimer 2 explicitly focuses on claim 1, not claim 4 or any other claim, and the accompanying passage that Ansell alleges incorporates the alleged disclaimers of claim 1 into the other claims is at best ambiguous in that regard. Therefore, it is not clear from the prosecution history whether Shen Wei during the prosecution of the '328 patent disavowed the use of ingredients other than aloe vera. Even if the passage Ansell asserts as a disclaimer can be so interpreted, it is not clear whether that alleged disavowal applies beyond claim 1. 3 After carefully reviewing the prosecution history to which Ansell has referred, this court rules that Shen Wei has not disclaimed the use of ingredients other than aloe vera. Omega Eng'g v. Raytek Corp., 334 F.3d 1314, 1323 (7th Cir. 2003) (explaining that the doctrine of prosecution disclaimer is not applied where the "alleged disavowal of claim scope is ambiguous.").

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2 Ansell alleges that the following excerpt from the prosecution history of the '328 patent acts to disclaim the use of ingredients other than aloe vera:

In fact, by teaching the presence of so many ingredients that are not Aloe Vera, Buchanan actually teaches away from Claim 1's limitation of "a coat of 100% Aloe Vera". For example, Applicants note that Buchanan repeatedly stresses the importance of including an antiperspirant agent. Since Aloe Vera is not taught or known as an antiperspirant agent, Buchanan again teaches away from Claim 1's limitation of a "coat of Aloe Vera". Buchanan also stresses the importance including an antibacterial agent and lists many (about 48) different antibacterial agents without listing Aloe Vera. (See Buchanan, p. 9.) In short, Buchanan teaches the importance of including various complex ingredients other than Aloe Vera. Such teaching constitutes teaching away from Claim 1's limitation of "a coat of 100% Aloe Vera". Based on such teaching away, there would be no expectation of success for any modification of Buchanan to obtain "a coat of 100% Aloe Vera", because Buchanan teaches that Buchanan's agents are crucial and that the agents include non-Aloe Vera ingredients.

(Def.'s S.J. Mem. at 5-6) (quoting Dkt. # 12 at 38.)

3 Ansell alleges that the following excerpt from the prosecution history of the '328 patent acts to incorporate claim 1's disclaimer of materials other than aloe vera into claims 4, 12, 22, and 28:

Remaining independent Claims 4, 12, 15, 22, 28, 32, and 37 each include limitation(s) similar to limitation(s), discussed above, of Claims 1 or 20. Accordingly, Applicant respectfully submits that these remaining independent Claims are allowable under Sections 102(b)and 103(a) for at least reasons similar to those discussed above in connection with Claim 1 or 20.

(Def.'s S.J. Mem. at 6) (quoting Dkt. # 12 at 40.) The limitations "discussed above" include the fact that claim 1 is patentable over Buchanan not only because of the term "a coat of 100% Aloe Vera," but also because of the term "dehydration." Furthermore, what is "discussed above" this particular portion of prosecution history includes a discussion distinguishing claim 20 from Buchanan. Thus, it is not clear that the prosecution history incorporated claim 1's limitation of one hundred percent aloe vera into claims 4, 12, 22, and 28.

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Accordingly, this court rejects Ansell's argument that the term "coat of Aloe Vera" must be construed to exclude the use of ingredients other than aloe vera. 4

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4 This conclusion -- that "coat of Aloe Vera" need not be one hundred percent aloe vera -- becomes unnecessary to the determination of whether Ansell infringes the claim term "coat of Aloe Vera," because this court later finds that a "coat of Aloe Vera" must include more than 0.5% aloe vera. See infra Part II. Nevertheless, this issue was briefed by the parties and Ansell relies on similar arguments regarding its construction of "quantity of Aloe Vera." See infra Part I.B.

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However, in support of Ansell's second request -- that the term "coat of Aloe Vera" should be limited to a coat where the aloe vera accounts for more than 0.5% of the coating -- Ansell does point to an unambiguous disclaimer by Shen Wei in the prosecution history of the '328 patent:

No person would call the composition of Buchanan a 'coat of Aloe Vera,' as recited by Claim 4, because, quite simply, Buchanan's composition is a complicated composition that contains a mere 0.5% of aloe extract, and is described as if the aloe extract had no significant contribution to the composition.

(Def.'s S.J. Mem. at 6) (quoting Dkt. # 12 at 41). Ansell is correct to argue that this statement made to the Patent and Trademark Office ("PTO") amounts to a disclaimer as to the scope of the term "coat of Aloe Vera." Specifically, Shen Wei has disclaimed and excluded from the meaning of the term "coat of Aloe Vera" in the '328 patent any coat that contains 0.5% or less of aloe vera.

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Shen Wei does not address this specific disclaimer quoted above, but does argue that its disclaimers regarding the Buchanan patent lend nothing to the construction of "a coat of Aloe Vera" because Buchanan does not teach applying aloe vera, in any amount, to the inside of gloves. This court disagrees with Shen Wei's construction of Buchanan on this point. Buchanan mentions aloe vera in the context of a set of examples that are "set forth for the purpose[] of providing a better understanding of the composition of the . . . invention and the formulations into which it can be incorporated." (Buchanan at 13.) 5 Admittedly, the use of aloe vera appears in the Buchanan patent's example 3, which only specifically discloses that the "resulting formulation can be used by applying it to the hands prior to donning a protective medical glove" (Id. at 17.) Nevertheless, Buchanan generally teaches a "composition" that "can be applied to the hand in powder or lotion form or [that] can be applied as a coating to the interior surface of a protective medical glove." (Id. at 5.) Furthermore, the Buchanan specification explicitly notes that while the examples given "described in detail [certain] preferred embodiments [of the invention], one of ordinary skill in the art will appreciate that certain modifications can be made to the present invention without departing from its true sprit and scope." (Id. at 21.) One of these "modifications" apparent to "one of ordinary skill in the art" is the use of the disclosed examples as a coating applied to the interior of the glove, even if the specific embodiment disclosed only mentions using the composition on the hands prior to donning a glove. This conclusion is supported by the fact that Shen Wei assumed this obvious modification of Buchanan's example 3 because Shen Wei found it necessary to distinguish its invention, which only teaches a coating applied to the glove, from Buchannan by asserting that a composition containing only 0.5% of aloe vera could not be considered a "coat of Aloe Vera" as disclosed in claim 4 of the '328 Patent.

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5 As exhibit C to Shen Wei's Declaration of Thomas B. Kenworthy submission, this court was provided with a copy of the Buchanan patent granted by the World Intellectual Property Organization and designated as International Publication Number WO 94/12115. However, the entire book of exhibits is not paginated. Therefore, this court cites directly to the Buchanan patent, which is represented without challenge to be a true and accurate copy.

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This court also disagrees with Shen Wei's apparent assertion that it only disclaimed the use of 0.5% or less of aloe vera when that use also has "no significant contribution" to the coating. The excerpt of the '328 patent's prosecution history quoted above (Dkt. # 12 at 41) clearly indicates that Shen Wei did not consider the term "coating of Aloe Vera" to include coatings where aloe vera made up less than 0.5% of the composition. The scope of this disclaimer is further clarified by the fact that Buchanan does not describe the contribution of aloe vera to the coating. Therefore, Shen Wei has specifically disclaimed any right to a "coat of Aloe Vera" that includes only 0.5% or less of aloe vera.
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B. Construing the Relevant Claim Language

1. Construction Based On Intrinsic Evidence

a. Under the Patent's Intrinsic Evidence, the Claim Phrase "Physically Completely Coated" Means Entirely or 100% Coated

Proper construction turns on the "ordinary and accustomed meaning" of the claim term "as understood by one of ordinary skill in the art." See, e.g., Hockerson-Halberstadt v. Avia Group Int'l, 222 F.3d 951, 955 (Fed. Cir. 2000) (citing cases); Markman v. Westview Instrs., Inc., 52 F.3d 967, 986 (Fed. Cir. 1995) (en banc) ("The focus in construing disputed terms in claim language . . . is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). The parties have stipulated that "[a] person of 'ordinary skill in the art' relevant to the '722 patent is a cosmetic chemist, holding a bachelor's degree in chemistry or the equivalent and having several years experience in the industry." (Dkt. No. 41: JPTO Ex. 1: Joint Stip. Facts P 18.)

The relevant portion of Claim 1 of the Patent provides as follows:

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1. A cosmetic make-up composition which is a water-in-oil emulsion comprising

a) an oil phase which comprises

i) About 2 to 50% by weight of the oil phase of a coated pigment consisting essentially of finely divided particles of pigment whose surfaces are chemically bonded to, and physically completely coated by, polysiloxane which coating renders the particles hydrophobic . . . .

(Dkt. No. 1: Compl. Ex. 1: '722 Patent at Col. 9, Lns. 17-26, emphasis added.) Claims 5 and 7 contain substantially similar language. ('722 Patent at Col. 10, Lns. 26-42 & Lns. 57-60.) (See page 4 above.)

The sole claim construction dispute in this case is whether, as Estee Lauder contends, the Patent claims disclose a pigment whose surface is 100% coated by polysiloxane (Dkt. No. 49: Proposed Order; see also Dkt. No. 50: Estee Lauder Br. at 2-3), or whether, as Revlon contends, the Patent claims merely require that the pigment be coated with polysiloxane sufficiently to render the pigment "hydrophobic," as defined in the Patent (Dkt. No. 53: Revlon Proposed Order at 2; Dkt. No. 54: Revlon Br. at 3). (See also pages 4-5 above.)

As noted above, courts commonly look to dictionaries and technical treatises to determine the "ordinary meaning" of claim language. See, e.g., Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996) ("Judges . . . may . . . rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents."); see also cases cited in Point III.A.2.a above. While permitting reliance on dictionary definitions, the Federal Circuit also has cautioned about the dangers of relying on non-scientific dictionaries to define technical terms. 15

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15 See, e.g., Lizardtech, Inc. v. Earth Resource Mapping, Inc., No. 01-1343, 35 Fed. Appx. 918, 923-24, 2002 WL 1042168 at *5-6 (Fed. Cir. May 22, 2002) (district court erred by using non-technical definition for "tiling"); Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001) (the Federal Circuit has "cautioned against the use of non-scientific dictionaries 'lest dictionary definitions . . . be converted into technical terms of art having legal, not linguistic significance.'"); AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1247-48 (Fed. Cir. 2001) ("This court has repeatedly cautioned against using non-scientific dictionaries for defining technical words. . . . This case provides a good example of why definitions from general usage dictionaries may fail to provide satisfactory constructions of technical claim terms in dispute. . . . A trial court, when construing a term of art, must define the term in a manner consistent with the scientific and technical context in which it is used in the patent. Only when the context is unclear, or it appears that the term is not being used in a technical manner, should the trial court rely upon a general purpose dictionary for construing the term."); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999) ("dictionary definitions of common words are often less useful than the patent documents themselves in establishing the usage of ordinary words in connection with the claimed subject matter"); Anderson v. International Eng'g & Mfg., Inc., 160 F.3d 1345, 1348-49 (Fed. Cir. 1998) ("Dictionary definitions of ordinary words are rarely dispositive of their meaning in a technological context. A word describing patented technology takes its definition from the context in which it was used by the inventor."); Renishaw PLC v. Marposs S.p.A., 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("[A] common meaning, such as one expressed in a relevant dictionary, that flies in the face of the patent disclosure is undeserving of fealty. . . . 'Indiscriminate reliance on definitions found in dictionaries can often produce absurd results. . . .'").

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In this case, despite the Court's invitation to the parties to supply technical definitions for the claim terms "physically," "completely," and "coated" (Dkt. No. 64: 3/13/03 Order at 1-2), neither party rose to the challenge. 16 Since both parties have relied on non-technical dictionaries to aid in construction of the claim language, the Court will do so as well in conjunction with a plain reading of the intrinsic evidence. E.g. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1205 (Fed. Cir. 2002) ("By examining relevant dictionaries, encyclopedias and treatises to ascertain possible meanings that would have been attributed to the words of the claims by those skilled in the art, and by further utilizing the intrinsic record to select from those possible meanings the one or ones most consistent with the use of the words by the inventor, the full

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breadth of the limitations intended by the inventor will be more accurately determined and the improper importation of unintended limitations from the written description into the claims will be more easily avoided."), cert. denied, 538 U.S. 1058, 155 L. Ed. 2d 1108, 123 S. Ct. 2230 (2003); see also, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1344-45 (Fed. Cir. 2003) (looking to non-technical dictionary for ordinary meaning of claim term "including"); Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001) (using Random House Unabridged Dictionary to define the ordinary meaning of "portion"); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1459 (Fed. Cir. 1998) (en banc) (employing non-technical dictionary definition of "'to'" as "'in a direction toward'").

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16 As explained below at pages 41-43 & fns.21-22, discussing extrinsic evidence, Estee Lauder did supply several examples from the technical literature using the same or similar language, but did not supply technical definitions per se. Revlon did not supply any technical definitions.

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Based on dictionary definitions, the word "coat" ordinarily means, as a noun, "a layer of some substance, as paint, over a surface," and as a verb, "to cover with a layer of something." Webster's New World Dictionary Third College Edition at 267 (1994). Read in the context of the claims at issue, the term "coated" is simply the adjectival derivative of "coat," meaning the surface is covered with a layer of some substance. Id.; accord, e.g., The American Heritage Dictionary of the English Language at 354 (4th ed. 2000); McGraw Hill Dictionary of Scientific & Technical Terms (2003) (defining "coating" as "any material that will form a continuous film over a surface" and "the film formed by the material."). See, e.g., Astra Aktiebolag v. Andrx Pharms., Inc., 222 F. Supp. 2d 423, 464 (S.D.N.Y. 2002) (in chemical context, equating "coating" with "covering"). The term "physically" emphasizes the material nature of the coating. American Heritage Dictionary at 1325; Webster's New World Dictionary at 1019. Thus, the plain meaning of the phrase "physically . . . coated" means that the surfaces of the pigment particles are physically covered with a layer of polysiloxane. 17

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17 This definition of "coated," which does not appear to be disputed, is supported by the specification language: "The pigment and fluid are intimately mixed thoroughly to obtain a uniform dispersion of the fluid on the pigment, in which the fluid completely coats the particles of pigment." ('722 Patent, Col. 3, Lns. 53-56.)

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The ordinary definition of the adverb "completely" is "in a complete manner; fully, perfectly; entirely, wholly, thoroughly." The Compact Edition of the Oxford English Dictionary at 726 (1987), reproduced in Dkt. No. 51: Estee Lauder 56.1 Stmt. Ex. F; accord, e.g., III Oxford English Dictionary at 612 (2d ed. 1991); see also Estee Lauder 56.1 Stmt. Ex. E: Webster's Third New International Dictionary at 465 (1986) ("Completely adv: 1: so as to be complete: FULLY [a furnished apartment] 2: to a complete degree: ENTIRELY [the horse rolled over] [at fault]").

"Because these terms are not given any special definition in the specification, we must give them their ordinary meaning." Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1444 (Fed. Cir. 1997). Thus the phrase "physically completely coated," when read in context, means that the surfaces of the pigment particles are fully and entirely physically coated with a layer of polysiloxane. In other words, the entire surface of each pigment particle is coated with a layer of polysiloxane. Cf. Bioscan, Inc. v. United States Int'l Trade Comm'n, No. 87-1599, 847 F.2d 842 (table), 1988 WL 33816 at *1 (Fed. Cir. Apr. 18, 1988) ("The specification and prosecution history of the . . . patent do not reveal that the patentee intended the terms in dispute ["'completely enclosed chamber'"] to have something other than their plain meaning.").

Revlon argues, to the contrary, that the language at issue should be construed to mean that the pigment particles are "physically completely coated by polysiloxane so as to render the particles hydrophobic, consistent with the hydrophobicity test provided within the patent specification . . . ." (Revlon Proposed Order at 2, emphasis added.) According to Revlon, not only does the Patent not require that the pigments be 100% coated, but the degree of coating is irrelevant as long as it renders the particles hydrophobic:

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The claim language at issue . . . describes finely divided particles of pigment that have the desired property of hydrophobicity, not whether, under increasingly minute analysis, one can argue that the polysiloxane coating is something less than 100%. In other words, the key is hydrophobicity - does the pigment work for its intended purpose - not whether microscopic or even electron microscopic analysis will reveal that a certain chemical reaction between polysiloxane and pigment surface has been driven to completion.

(Dkt. No. 60: Revlon Reply Br. at 2; see also JPTO Ex. 19: Revlon Pretrial Br. at 7 (The Patent "directs all reviewers to specific commercially available coated pigments, known to cosmetic formulators, that were not evaluated on a molecular level to determine the degree of actual physical coating of the pigments [be it 1% or 50% or 99%] but were evaluated as to their hydrophobicity.") (brackets in original).)

Revlon explains away the presence of the word "completely" by asserting that, rather than looking to the definition of the adverb "completely," the Court should look to one of the definitions of the noun "complete," which means "possessing all necessary parts, items, components or elements: not lacking anything necessary." (Dkt. No. 54: Revlon Br. at 18, quoting Dkt. No. 51: Estee Lauder 56.1 Stmt. Ex. E: Webster's Third New International Dictionary at 465 (1986 ed.).) According to Revlon, this "definition inherently implies that 'completeness' is a measurement of degree for a specific purpose - so as to beg the question 'complete' for what purpose (i.e., 'not lacking anything necessary' for what purpose)." (Revlon Br. at 18.) Based on this definition, Revlon reformulates the relevant claim language as follows: "finely divided particles of pigment whose surfaces are chemically bonded to, and physically [] coated by, polysiloxane which coating [possesses all necessary parts, items, components or elements to] render[] the particles hydrophobic. . . . " (Id. at 19.) Thus, Revlon claims that the disputed language "means 'physically coated by polysiloxane so as to render the particles hydrophobic.'" (Id.)

Revlon distorts the unambiguous claim language. First, the claim provides both a structural limitation (the surfaces of the particles are "physically completely coated by" polysiloxane) and an independent functional limitation ("which coating renders the particles hydrophobic"). 18 The specification clearly supports this, as the "completely coated" structural requirement is stated as an independent conjunctive of the functional requirement that the particles be hydrophobic - the number of polysiloxane chains that are bonded must be "sufficiently high to coat the pigment completely and render it completely hydrophobic." ('722 Patent, Col. 3, Lns. 11-14 (emphasis added).) See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d at 1582 ("The specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."). In addition, the specification elsewhere states the "completely" coated limitation without mentioning hydrophobicity, further illustrating that the complete coating of the pigment is an independent structural requirement: "The pigment and fluid are intimately mixed thoroughly to obtain a uniform dispersion of the fluid on the pigment, in which the fluid completely coats the particles of pigment." ('722 Patent, Col. 3, Lns. 53-56, emphasis added.) 19 Revlon's proffered construction would eliminate the structural requirement that the pigment surface be "physically completely coated," thus violating the well-settled rule that structural limitations may not be eliminated simply on the ground that they are unnecessary to the invention's function. See, e.g., Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d at 1444 (rejecting patent holder's argument that would eliminate structural limitations that were not necessary to "meet[] the functional objective of the invention," as such a construction "would render the contested terms surplusage," effectively "eviscerating them"); K- 2 Corp. v. Salomon S.A., 191 F.3d 1356, 1360, 1363 (Fed. Cir. 1999) (in construing in-line roller skate claim which recited the "non-rigid shoe portion being permanently affixed to said base portion at least at said toe area and said heel area for substantially preventing movement therebetween at least in a horizontal plane," and thus included both structural and functional elements, the Federal Circuit refused to read the functional language "for substantially preventing movement" so as to "effectively expunge the [structural] term 'permanently' from the claim language. . . . A more natural construction reads the two clauses as complementary, recognizing that 'permanently affixed' requires an unremovable attachment, while the functional language requires that the attachment prevent sliding."); Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1582-83 (Fed. Cir. 1996) (Construing structural limitation from claim language, despite patent holder's argument that such limitation was not necessary for the successful operation of the invention: the patent holder "need not have included this limitation in its claim. Having done so, it must live with the language it chose.").

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18 See generally 2 John Gladstone Mills III, Robert C. Highley & Donald C. Reiley III, Patent Law Fundamentals, § 15:6 (2d ed. 2003) (discussing structural vs. functional limitations; "only structural language is determinative of the metes and bounds of a patent claim"); see also id. § 15:26.

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19 See also '722 Patent, Col. 7, Lns. 36-39 ("The pigment comprised an intimate blend of the five indicated components, all of which had been thoroughly coated with a polymethyl hydrogen siloxane [which is a type of "polysiloxane," see Col. 10, Lns. 37-40] coating bonded to the pigment surface.") (emphasis added). Similarly, when Claims 10 through 15 of the Patent were later amended, the "physically coated language" was added without any mention of hydrophobicity: "wherein the surfaces of the particles of pigment are chemically bonded to, and physically completely coated by, polymethyl hydrogen siloxane." (Dkt. No. 55: Estee Lauder 56.1 Obj. Ex. M: 10/9/98 Reexamination Application at 7-12, claims 1015) (See Point IV.B.2, infra.) This decoupling of the "completely coated" and hydrophobicity elements implies that the "completely coated" limitation must be independently satisfied, and cannot be reduced to the hydrophobicity requirement.

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Had Revlon's Patent drafters wanted to eliminate the "completely coated" structural requirement and replace it with a purely functional requirement, they surely were capable of phrasing the claim to read "physically coated by polysiloxane sufficiently to render the particles hydrophobic." 20 The drafters demonstrated familiarity with such functional terminology by providing in the specification that "the number of polysiloxane chains of formulas (3), (4), and (5) that are bonded to the pigment surface is not known but is sufficiently high to coat the pigment completely and render it completely hydrophobic." ('722 Patent, Col. 3, Lns. 11-14.) The specification thus expressly renders the pigment bonding as purely functional (i.e., with no set amount, but only "sufficiently high to coat the pigment completely"), and defines the function of the bonding in terms of the structural requirement that the pigment be "completely" coated. The drafters could easily have defined both the bonding and coating as purely functional (i.e., the amount of bonding and coating must be sufficiently high to render the pigment completely hydrophobic), but instead they stated "completely" coating the pigment as an independent structural requirement. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1573 (Fed. Cir. 1996) ("The claim language explicitly ties substantial part' to the height of the sidewalls, not to the overall function of the invention. The language and syntax of the claim preclude a functional definition of substantial part.' In other words, if substantial part' meant only ample height to accomplish a purpose, the claim would need to read only so much height as necessary to affix a structure against movement.' This redraft would essentially strip many words in the claim of their meaning.").

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20 See 2 John Gladstone Mills III, Robert C. Highley & Donald C. Reiley III, Patent Law Fundamentals, § 15:6 (2d ed. 2003) ("It is possible to expand or contract claim breadth by a concomitant change in the language used to express a structural element or component. One way of expressing such component is in terms of exact measurements, i.e., as an absolute numerical value. Not only is this often unduly restrictive, even when expressed as a range, it is sometimes not possible. It is not always possible or practical to ascertain the precise limits of efficacy. Under such circumstances, it may be permissible to express such limitation in 'functional terms.'"); id. § 15.34 ("Another possible technique of overcoming the absence of the existence of just the right word is with the aid of a functional expression. Rather than expressing a quantity as a numerical value, it may be possible to express it as 'an amount effective' (or sufficient or adequate) to produce a recited result.").

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Revlon's construction effectively eliminates the term "completely" - clearly violating the rules of construction. See, e.g., Elekta Instr. S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000) (avoiding claim construction which would render a term superfluous); Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d at 1444 (same). Revlon glosses over this rule by pretending that the term "completely" means something that it does not. Revlon effectively rewrites the Patent to employ the adjectival definition ("complete") rather than the adverbial ("completely"), as follows: "chemically bonded to, and physically [] coated by, polysiloxane which coating [is complete enough for the purpose of] rendering the particles hydrophobic." (Dkt. No. 54: Revlon Br. at 19.) Not surprisingly, and despite the Court's express invitation (Dkt. No. 64: 3/13/03 Order), Revlon failed to provide textual examples - either from case law or elsewhere - employing the term "completely" in this manner. 21 Estee Lauder supplied several examples from technical literature, although not from the "cosmetics field," in which "completely coated" meant entirely, i.e., 100%, coated. (Dkt. No. 65: Estee Lauder Supp. Br. at 2 n.1, citing Tabs A-E.) 22 The Court need not rely on Estee Lauder's evidence, however, as the ordinary meaning of the claim language is clear without it. Revlon's extraordinary construction could only prevail if it were supported by compelling evidence, which Revlon has failed to supply.

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21 Revlon's construction is so extraordinary that it would require strong evidence to support it. The authorities Revlon cites do not even remotely support its position. In Carnegie Mellon Univ. v. Hoffman-La Roche Inc., No. C-95-3524, 1997 WL 33152823 (N.D. Cal. Mar. 31, 1997) (cited in Dkt. No. 66: Revlon Supp. Br. at 10-11), the relevant claim language stated: "'A recombinant plasmid containing a cloned complete structural gene coding region . . . for the expression of DNA polymerase I. . . .'" 1997 WL 33152823 at *10 (ellipsis in original). The court rejected defendant's assertion that the word "complete" should be construed to mean "entire," which in this particular context meant having "no missing nucleotide bases." Id. at *11. Unlike Revlon, however, which would read the word "completely" out of the '722 Patent (or render the word meaningless), the Carnegie court rejected the "entire" construction because the "claims expressly describe the structural gene coding region only as 'complete,' not as 'entire' . . . ." Id. The court derived the correct construction of the word "complete" from the "clear" language of the specification and prosecution history: "the nucleotide sequence that expresses the complete DNA polymerase I, as opposed to only the Klenow fragment." Id. at 11-12. Thus, far from the strained construction Revlon asserts here (which, to the contrary, ignores the clear language of the specification that the pigment be both completely coated and completely hydrophobic), the Carnegie court ultimately construed the term "complete" to mean something like "entire" - as in more than a fragment - just not "entire" in the special sense asserted by the Carnegie defendants. Id.

Revlon also cites National Research Dev. Corp. v. Great Lakes Carbon Corp., 410 F. Supp. 1108 (D. Del. 1975), another patent employing the adjective "complete" rather than the adverb "completely." (Revlon Supp. Br. at 11.) The case involved a patent reciting a process for producing carbon "fibers," which included "'oxidizing an organic polymer fiber by simultaneously heating the fiber in an oxidizing atmosphere . . . for a time sufficient to permit substantially complete permeation of oxygen throughout the core of the fiber while the fiber is held under longitudinal tension . . . .'" National Research Dev. Corp. v. Great Lakes Carbon Corp., 410 F. Supp. at 1111 (emphasis added). Because "permeation is distinct from oxidation," the district court did not construe the highlighted language to mean "complete oxidation." Id. at 1115-16. Further, because the patent recited permeation "throughout the core of the fiber," it was not construed to mean "complete saturation of the fiber with oxygen," but rather "permeation of some oxygen throughout the entire cross-sectional area of the fiber." Id. at 1115-16 (emphasis added). The court also remarked that the patent's "meaning varies little if at all from the same phrase absent the term 'complete,'" id. at 1116, probably because both "permeation" and "throughout" are absolute terms, like "complete."

22 For example, one paper described mineral aggregate particles as "partially coated" if up to 99% covered, and "completely coated" if 100% covered. (Estee Lauder Supp. Br. Tab B at 8.) Revlon complains that Estee Lauder's examples are from unrelated industries and were published well after the Patent application. (Revlon Supp. Br. at 7 n.4.) See, e.g., Brookhill Wilk 1, LLC v. Intuitive Surgical, Inc., 326 F.3d 1215, 1221 (Fed. Cir. 2003) ("The district court also consulted a number of unrelated and non-contemporaneous authorities . . . . These references are dated well after the '003 patent, which was filed in March 1991 and issued in June 1993. They are not contemporaneous with the patent, do not reflect the meanings that would have been attributed to the words in dispute by persons of ordinary skill in the art as of the grant of the '003 patent, and for those reasons are not considered in our de novo claim construction analysis."). While this may be true, it assumes that the definition of the phrase "completely coated" changed over time, which seems highly unlikely. In any event, the Court need not rely on the technical literature supplied by Estee Lauder, as the ordinary meaning of the claim language is clear without it.

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Ultimately, Revlon achieves the meaning it desires by rewriting the claim so that "completely" modifies the phrase "render[] the particles hydrophobic" instead of the word "coated": "the Claim itself does not require 100% coating of the pigment, but merely sufficient coating to 'completely . . . render[] the particles hydrophobic.'" (JPTO Ex. 19: Revlon Pretrial Br. at 6 (ellipsis in original); see also Dkt. No. 54: Revlon Br. at 19.) This reformulation, however, violates both common sense and the rules of grammar, as the word "completely" immediately precedes and thus clearly modifies the word "coated." And again, Revlon's construction is contradicted by the specification, which requires both that the pigment be coated "completely" and that it be "completely" hydrophobic: "the number of polysiloxane chains of formulas (3), (4), and (5) that are bonded to the pigment surface is not known but is sufficiently high to coat the pigment completely and render it completely hydrophobic." ('722 Patent, Col. 3, Lns. 11-14.)

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Revlon also argues that the Patent does not require that the pigment particles be completely coated, but merely requires that they be completely hydrophobic, because the specification contains no test for "completely coated" but does contain a test for hydrophobicity. 23 This is nonsense. First, it makes sense that the Patent would contain a functional, rather than a structural test, because, as a practical matter, function is easier to test than chemical structure. 24 Second, Revlon has no basis for positing a rule of construction that would eliminate all structural limitations not associated with a functional test. 25

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23 "Hydrophobicity can readily be determined by placing the coated pigment into water and observing whether any becomes dispersed or suspended in the water." ('722 Patent, Col. 3, Lns. 14-17.)

24 In a pretrial brief, Revlon argued that the Patent could not be limited to particles that were 100% coated, "because there was no test in 1986 [the Patent's first submission date] to see if a particle was actually 100% physically coated." (JPTO Ex. 19: Revlon Pretrial Br. at 6.) According to Revlon, "Estee Lauder's argument that the '722 patent teaches pigments that are 100% physically coated ignores the fact that even today, let alone 1986, there is no way to determine whether such pigments are 100% coated." (Revlon Pretrial Br. at 7.) Revlon, however, has omitted this argument on the current motions, presumably because both Revlon's and Estee Lauder's experts described methods of testing for 100% coating. (Dkt. No. 60: Revlon Reply Br. Ex. T: Lochhead: Tr. 304-06; Dkt. No. 48: Estee Lauder 56.1 Stmt. Ex. H: Dahms Rebuttal Report at 9-10.) Nevertheless, it is reasonable to assume from Revlon's assertion that a functional test (i.e., determining hydrophobicity) is easier to perform than a structural test (i.e., measuring the degree of coating).

25 Revlon argues that construing the claim to require "100% coating" would read the functional hydrophobicity requirement out of the Patent:

> Estee Lauder's interpretation of "physically completely coated" requires the pigments to be absolutely 100% coated with polysiloxane. Polysiloxane is a hydrophobic compound. Were it possible for a pigment's surface to be 100% coated by polysiloxane, the pigment would be, by its very nature, hydrophobic. There would be no need to utilize the hydrophobicity test set forth in the specification to make this determination.

(Dkt. No. 54: Revlon Br. at 14-15.) As a threshold matter, Revlon fails to support these assertions with evidence. More importantly, Revlon turns the argument on its head. The Court's interpretation retains both the structural and functional limitations stated in the Patent; Revlon's construction, by contrast, would excise the structural limitation.

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One final point. The claim language leaves no room to interpret "completely coated" as a relative phrase, as, for example, "substantially completely coated." 26 The Patent, after all, speaks in terms of particles. This case does not, for example, involve a wall-painting invention, with the defendant stubbornly insisting that the wall must be covered by paint to the microscopic level. Rather, the Patent itself speaks in terms of microscopic particle-coating. It should hardly surprise Revlon that Estee Lauder insists that the claim language be analyzed in the microscopic context. 27 Moreover, Revlon has effectively disclaimed anything but a purely functional interpretation, thus waiving a relative construction such as "substantially completely coated." (See, e.g., Dkt. No. 54: Revlon Br. at 6 ("The amount of coating on the resultant pigments will fulfill the definition [in the claim] regardless of whether the polysiloxane covers 100% of the surface or some lesser amount."); Dkt. No. 60: Revlon Reply Br. at 2 ("The key is hydrophobicity - does the pigment work for its intended purpose - not whether microscopic or even electron microscopic analysis will reveal that a certain chemical reaction between polysiloxane and pigment surface has been driven to completion."); Dkt. No. 52: Revlon 56.1 Stmt. Ex. G: Lochhead Aff. P 12 ("For purposes of utility in the invention taught by the '722 patent, it is not necessary that a pigment be 100% coated by polysiloxane, rather only that the pigment be rendered hydrophobic to allow for its dispersal within the silicon oil phase of the emulsion described in the patent."); Dkt. No. 60: Revlon Reply Br. Ex. T: Lochhead Dep. 362-63 (Dr. Lochhead's "understanding is that physically completely coated by polysiloxane means that the particle is hydrophobic").)

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26 Cf., e.g., LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1354-56 (Fed. Cir. 2001) (affirming, based on intrinsic evidence, construction that "'substantially completely wetted'" means "'largely, but not necessarily wholly, surrounded by resin'"); C.E. Equip. Co. v. United States, 17 Cl. Ct. 293, 299 (1989) (discussing difference between "substantially filling" and "substantially completely filling").

27 By contrast, in Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821 (Fed. Cir. 1991), the court affirmed construction of the claim phrase "'permanently programmed' to mean 'for the useful lifetime of the . . . part under normal operating conditions.'" Id. at 835-36. The difference, of course, is that because nothing about a particular invention is truly "permanent," the term must be construed in the relative sense to mean the useful life of the device - not eternity.

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In short, the relevant claim language provides that the "surfaces" of the particles must be "physically completely coated" with polysiloxane - meaning 100% coated. Describing the surfaces of the pigment particles as "physically completely coated" with polysiloxane constitutes an independent and self-sufficient structural element. While it is true, as Revlon asserts, that a court must give a claim the full range of its ordinary meaning (Dkt. No. 54: Revlon Br. at 18, citing Johnson Worldwide Assocs. v. Zebco Corp, 175 F.3d 985, 989 (Fed. Cir. 1999); see also Revlon Supp. Br. at 1-6, 18-19), 28 Revlon's interpretation is anything but ordinary. The Court may not excise the word "completely" from the Patent merely because Revlon now finds it troublesome or inconvenient. The disputed language admits of only one reasonable unambiguous construction - that "physically completely coated" means entirely, 100% coated. See, e.g., Nichols v. Strike King Lure Co., 2000 U.S. Dist. LEXIS 15781, No. Civ. A.3:99- CV-1950-B, 2000 WL 1593616 at *2, 8 (N.D. Tex. Oct. 25, 2000) (rejecting patentee's assertion that the unambiguous claim language "entire outer surface" should be construed to mean the "greater part" of the outer surface. The claim "must be construed to mean that the outer surface of the body of the lure must be completely covered by the coating. In other words, no part of the external surface may be left uncovered by the resin coating.") (see also quotation from this case on page 2); accord, e.g., Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1349 (Fed. Cir. 2002) (The patentee "argues that one of skill in the art would understand that the term 'perpendicular' in the claim should be read to mean 'parallel.' [The patentee] stretches the law too far. It is not our function to rewrite claims to preserve their validity. We are simply tasked with determining whether the claims 'particularly point[] out and distinctly claim[]' what the inventor regards as his invention. Moreover, it is of no moment that the contradiction is obvious: semantic indefiniteness of claims 'is not rendered unobjectionable merely because it could have been corrected.'") (citations omitted); K- 2 Corp. v. Salomon S.A., 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("That the applicant could possibly have added terms other than 'permanently' to create a patentable distinction with the asserted prior art is simply irrelevant to our claim construction task. Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee."); Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed. Cir. 1999) ("We do not permit courts to redraft claims. . . . Where, as here, the claim is susceptible to only one reasonable construction, the canons of claim construction cited by [patentee] are inapposite, and we must construe the claims based on the patentee's version of the claim as he himself drafted it. . . . As a result of our claim construction, clause [d] does not make 'sense' as [patentee] itself realizes and concedes. What [patentee] fails to realize is that such a nonsensical result does not require the court to redraft the claims of the '943 patent. Rather, where as here, claims are susceptible to only one reasonable interpretation and that interpretation results in a nonsensical construction of the claim as a whole, the claim must be invalidated, thus preventing unduly burdening competitors who must determine the scope of the claimed invention based on an erroneously drafted claim."), cert. denied, 529 U.S. 1037, 120 S. Ct. 1531, 146 L. Ed. 2d 346 (2000); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("Although we construe claims, if possible, so as to sustain their validity, . . . it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims."), cert. denied, 517 U.S. 1167, 116 S. Ct. 1567, 134 L. Ed. 2d 666 (1996).

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28 Accord, e.g., Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d at 1203 ("Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor. . . . If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings.").

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b. The Patent's Preferred Embodiment Does Not Include "Commercially Available" Pigments

Revlon asserts that the following excerpt from the Patent specification is part of the "preferred embodiment": "As an alternative to synthesis, satisfactory coated pigments usable in this invention are commercially available from a variety of sources." ('722 Patent at Col. 3, Lns. 59-62.) (See Dkt. No. 54: Revlon Br. at 6.) Revlon argues that because commercially available pigments are part of the preferred embodiment, and extrinsic evidence shows that commercially available pigments cannot be entirely coated, it must follow that the Patent claims do not require that the pigments be entirely coated, as such a construction would exclude the Patent's preferred embodiment. (Revlon Br. at 12-14; Dkt. No. 60: Revlon Reply Br. at 3-4.)

Estee Lauder argues to the contrary that the "commercially available" provision constituted "merely an unclaimed satisfactory alternative to the preferred synthesized coated pigment." (Dkt. No. 57: Estee Lauder Reply Br. at 4-5 & n.5 (citing Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562-63 (Fed. Cir. 1991)). 29 Estee Lauder thus references "the well-established rule that 'subject matter disclosed but not claimed in a patent application is dedicated to the public'" and thus cannot support a finding of infringement. See Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1106-07 (Fed. Cir. 1996) (quoting Unique Concepts, Inc. v. Brown, 939 F.2d at 1562-63), cert. denied, 520 U.S. 1115, 117 S. Ct. 1244, 137 L. Ed. 2d 327 (1997). Further, the Federal Circuit recently confirmed en banc that patent owners cannot assert either literal infringement or the doctrine of equivalents "to cover . . . disclosed but unclaimed" subject matter. Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1051-55 (Fed. Cir. 2002) (en banc); accord, e.g., Maxwell v. Angel-Etts of Calif., Inc., Nos. 01-1601, 01-1647, 02-1198, 02-1219, 53 Fed. Appx. 561, 567, 2002 WL 31809442 at *6 (Fed. Cir. Dec. 13, 2002); Maxwell v. J. Baker, Inc., 86 F.3d at 1106-08.

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29 This Court would ordinarily not consider an issue raised for the first time in a reply brief. See, e.g., Playboy Enters., Inc. v. Dumas, 960 F. Supp. 710, 720 n.7 (S.D.N.Y. 1997) ("Arguments made for the first time in a reply brief need not be considered by a court.") (collecting cases), aff'd, 159 F.3d 1347 (2d Cir. 1998); see also, e.g., Fleet Capital Corp. v. Yamaha Motor Corp., U.S.A., 2002 U.S. Dist. LEXIS 18115, 01 Civ. 1047,2002 WL 31174470 at *13 n.18 (S.D.N.Y. Sept. 26, 2002) (Peck, M.J.) ("Since [plaintiff] raised the issue for the first time in its reply brief, [defendants] had no opportunity to respond. The Court therefore will not consider [plaintiff's] reply argument."); Bolanos v. Norwegian Cruise Lines Ltd., 2002 U.S. Dist. LEXIS 12227, 01 Civ. 4182, 2002 WL 1465907 at *4 n.12 (S.D.N.Y. July 9, 2002) (Peck, M.J.) (citing cases). Revlon, however, had its own subsequent reply brief in which to respond. (Dkt. No. 60.) Moreover, because of the importance of the issue, the Court ordered supplemental briefing (Dkt. No. 64: 3/13/03 Order at 2-3), affording Revlon an additional opportunity to respond.

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Courts have deemed as "disclosed but unclaimed" specification language similar to that found here, including specification verbiage describing "alternatives" that "may be used." In Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co., the Federal Circuit held that where the claim was limited to "aluminum," use of steel substrate was "disclosed but unclaimed" based on specification language providing: "'While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys may be used.'" 285 F.3d at 1055; see also id. at 1052 ("disclosed but unclaimed" doctrine is limited to where the "patent discloses an unclaimed alternative distinct from the claimed invention"). In Maxwell v. J. Baker, Inc., 86 F.3d at 1106-07, the Federal Circuit deemed the following as "disclosed but unclaimed": "'alternatively, the tabs may be stitched into a lining seam of the shoes at the sides or back of the shoes.'" See id. at 1105 ("to accept Maxwell's claim interpretation that the inside lining of the shoe is part of the tab, we would have to ignore the claim limitations that require the tab to be separate from and extend along the shoe upper, which includes the inner shoe lining."); accord, e.g., Maxwell v. Angel-Etts of Calif., Inc., 53 Fed. Appx. at 567, 2002 WL 31809442 at *6.

Under this case law, the Court finds the alternative commercially-available pigments to be disclosed but not claimed, and thus not part of the Patent's preferred embodiment. Nevertheless, as discussed in Point III.B.2.b below, even if the Court found this to be part of the Patent's preferred embodiment, that would not change the Court's claim construction.

2. Construction Based On Extrinsic Evidence

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In construing the claim language, the parties twice resort to extrinsic evidence: (1) a supposedly "related patent"; and (2) Revlon's and Estee Lauder's experts' reports.

a. Prior Art, Including the Tietjen Patent, Has No Material Effect on Construction of the '722 Patent

Estee Lauder argues that an earlier Revlon patent, U.S. Patent No. 4,578,266 (the "Tietjen Patent"; see Dkt. No. 52: Revlon 56.1 Stmt. Ex. J), should be considered intrinsic evidence when construing the '722 Patent. (Dkt. No. 57: Estee Lauder Reply Br. at 6.) The Tietjen Patent was cited as prior art 30 during the prosecution of the '722 Patent, and the two patents are both owned by Revlon, share a common inventor (Marlene Tietjen), and recite similar claim language. (Estee Lauder Reply Br. at 6, citing Tietjen Patent, claims 1, 4 & 8.)

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30 1 John Gladstone Mills III, Robert C. Highley & Donald C. Reiley III, Patent Law Fundamentals, § 2:41 (2d ed.) ("Prior art denotes knowledge that was publicly available at the time an invention was made. In terms of patent law, 'prior art' is defined by 35 U.S.C. § 102.").

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As Revlon points out, however, (1) each patent had three inventors, and Tietjen is the only inventor the two patents had in common, and (2) the two patents do not share the same file history. (Dkt. No. 60: Revlon Reply Br. at 4.) Revlon would therefore deem the Tietjen patent as extrinsic, not intrinsic, evidence.

"The prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit." Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294, 1305 (Fed. Cir. 2001) (collecting cases). The focus, however, is on whether the same claim limitation appears in the "parent" and the subsequent patents. See Masco Corp. v. United States, 303 F.3d 1316, 1324 (Fed. Cir. 2002) (prosecution history of parent patent may be considered intrinsic evidence in construing claims); Augustine Med., Inc. v. Gaymar Indus., Inc., 181 F.3d 1291, 1300 (Fed. Cir. 2000) ("the prosecution history of a parent application may limit the scope of a later application using the same claim term"); Wang Lab., Inc. v. America Online, Inc., 197 F.3d 1377, 1384 (Fed. Cir. 1999) (rejecting the patentee's argument that a statement made during the prosecution of the parent application should not apply to the continuation-in-part application); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation."), cert. denied, 529 U.S. 1066, 120 S. Ct. 1672, 146 L. Ed. 2d 482 (2000); Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995) (relevant prosecution history for estoppel purposes included not only the application upon which the patent issued but also the parent and grandparent applications), cert. denied, 516 U.S. 1115, 116 S. Ct. 917, 133 L. Ed. 2d 847 (1996); Digital Privacy, Inc. v. RSA Security, Inc., 195 F. Supp. 2d 771, 775 (E.D. Va. 2002) ("Given that the '440 and '981 patents are related, share the same priority date, and are both a continuation of the '497 patent, the disputed term must have a consistent meaning across both patents."); see also 2 John Gladstone Mills III, Robert C. Highley & Donald C. Reiley III, Patent Law Fundamentals, § 16:10 (2d ed.) ("The earlier filed application on which a continuing application may rely for its effective filing date is often referred to as the original or parent of the continuing application."). 31

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31 Estee Lauder cites Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996) (Dkt. No. 57: Estee Lauder Reply Br. at 6), for dictum that "included within an analysis of the file history may be an examination of the prior art cited therein. . . . 'In its broader use as source material, the prior art cited in the file wrapper gives clues as to what the claims do not cover.'" 90 F.3d at 1582-83 (citation omitted). Estee Lauder also cites DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1324-25 (Fed. Cir. 2001) (Estee Lauder Reply Br. at 6), in which, unlike here, the patent at issue substantively discussed the shortcomings in prior art, rendering prior art relevant to claim construction. As Revlon points out, "neither of these cases holds that an unrelated patent whose sole relationship to the patent at issue is that it was cited as prior art can then be consulted for claim construction purposes because it constitutes intrinsic evidence." (Dkt. No. 60: Revlon Reply Br. at 5.)

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Here, because the two patents do not share the same file history, the Court cannot consider the Tietjen Patent as intrinsic evidence when construing the '722 Patent's language. See Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1211 (Fed. Cir. 2002) (rejecting as irrelevant evidence of language in unrelated patent by the same inventor), cert. denied, 538 U.S. 1058, 155 L. Ed. 2d 1108, 123 S. Ct. 2230 (2003); Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1104-05 (Fed. Cir.) (relationship between two unrelated patents, although having similar subject matter, one common inventor out of three, and the same assignee, was "insufficient to render particular arguments made during prosecution of [one of the patents] equally applicable to the claims" of the other patent), cert. denied, 537 U.S. 1039, 154 L. Ed. 2d 462, 123 S. Ct. 556 (2002); cf. NCR Corp. v. Palm, Inc., 217 F. Supp. 2d 491, 519 (D. Del. 2002) ("Here, the express relationship between the '478 patent and the '845 patent is beyond dispute; aside from being filed on the same date, and sharing essentially identical disclosures, the same 'means for transferring data' limitation addressed in the prosecution history of the '478 patent appears in the claims of the '845 patent."). Accordingly, because the Court has already found the claim language at issue to be unambiguous, this Court may not resort to such extrinsic evidence as the Tietjen Patent to vary the claims. (See cases cited in Point III.A.2 above.)

Even if the Court did employ this extrinsic evidence (which the Court does not), the Court's claim construction would not be materially affected. Claim 1 of the Tietjen Patent describes a "coated pigment . . . whose surfaces are chemically bonded to, and physically completely coated by a polysiloxane which coating renders the particles hydrophobic. . . ." (Revlon 56.1 Stmt. Ex. J: Tietjen Patent, Col. 8, Lns. 29-35, emphasis added.) Claim 4 of the Tietjen Patent describes the coating more broadly as "a coated pigment . . . whose surfaces are chemically bonded to and physically coated by a polysiloxane which coating renders the particles hydrophobic. . . ." (Tietjen Patent, Col. 9, Lns. 59-63, emphasis added.) 32 Estee Lauder thus concludes that "in drafting and prosecuting the '722 patent, Revlon was fully aware of its options . . . ." (Dkt. No. 57: Estee Lauder Reply Br. at 6.) This supports the Court's conclusion that the word "completely" actually means something, and may not be excised by the Court during the process of claim construction.

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32 Claim 8 of the Tietjen patent merely requires "sufficient polysiloxane bonded to each pigment particle to render the pigment hydrophobic," but also references Claim 7 which in turn references Claim 4, thus presumably incorporating Claim 4's "physically coated" language. (Tietjen Patent, Col. 10 Ln. 45 to Col. 11 Ln. 12.)

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In its Supplemental Brief, Revlon changes positions, arguing that the Tietjen Patent "can give the Court significant guidance on the issue of 'completely coated,' though not in the manner suggested by Estee Lauder." (Dkt. No. 66: Revlon Supp. Br. at 8.) Revlon notes that the PTO originally rejected the Tietjen Patent application because, among other things, the phrases "'chemically bonded to'" and "'physically and completely coated by'" were "vague and indefinite." (Revlon Supp. Br. at 8, citing Dkt. No. 67: Brehm Aff. Ex. A: 3/7/84 Tietjen Examiner's Action at 5.) The Tietjen applicant responded that the disputed claim language was understandable to one skilled in the art, and referred to pages 7-10 of the attached Tietjen Patent specification (which is similar to the relevant specification language from the '722 Patent, discussed above). (Brehm Aff. Ex. A: 2/11/85 Tietjen Response at PP 4-5 & Specification at 9-10.) Subsequently, in an "Examiner Interview Summary Record," the examiner noted in handwriting his agreement with the Tietjen applicant that the "terms 'finely divided' and 'completely coated by' are definite. See Nasuno et al., col. 3 line 21." (Brehm Aff. Ex. A: 8/21/85 Tietjen Interview Record.) This apparently referred to U.S. Patent No. 4,390,524 (the "Nasuno Patent"), which was described as prior art in the Tietjen Patent, and states, in relevant part: "the oily material-coated pigment comprising a carrier pigment in the form of finely divided particles the surfaces of which are substantially coated with a substantially water-insoluble oily material . . . ." (Brehm Aff. Ex. B: Nasuno Patent at Col. 3 Lns. 20-23.) According to Revlon, "this reference [to the Nasuno Patent] shows that the [Tietjen] patent examiner understood what one skilled in the art knew -- that the term 'completely' did not demand 100% coating, but that it was equivalent to 'substantially' as long as the purpose of the coating was achieved." (Revlon Supp. Br. at 9.)

The Court rejects Revlon's argument for several reasons. First, the Tietjen examiner only referred to Line 21 of the Nasuno Patent, which states only "carrier pigment in the form of finely divided particles." (Brehm Aff. Ex. B: Nasuno Patent at Col.

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3 Ln. 21.) Since the examiner stated that the "terms 'finely divided' and 'completely coated by' are definite," the reference to the Nasuno Patent appears to have been solely for the purpose of explaining the Tietjen Patent's "finely divided" language.

Second, even if the Court accepted that the examiner's agreement (1) referred to Lines 20-23 and not merely Line 21, and (2) thereby explained the "completely coated" phrase and not merely the "finely divided" phrase, the examiner's agreement is far too cryptic to affect construction of the '722 Patent. The agreement may have referenced the Nasuno Patent for any number of reasons having nothing to do with construction of the terms "completely" versus "substantially." This Court would need much stronger evidence than this to support the extraordinary proposition that "completely coated" means "substantially coated."

Third, in all of its briefing, Revlon argues not that "completely" means "substantially" in the '722 Patent, but that "completely" simply means coated sufficiently to render the particles hydrophobic - a purely functional interpretation. The Nasuno Patent, however, is not purely functional, as it contains the structural requirement that the particle surface be "substantially coated." This is, of course, parallel to the '722 patent, and demonstrates that "completely," like "substantially," is a term of degree that may not be excised in favor of a functional definition. The parallel nature of the '722 and Nasuno language is shown by comparing the relevant '722 specification language ("sufficiently high to coat the pigment completely and render it completely hydrophobic"; '722 Patent, Col. 3, lines 13-14) with the Nasuno specification language ("substantially coated with a substantially water-insoluble oily material"; Nasuno, Col. 3, lines 22-23). Rather than completely coating the pigment to render it completely hydrophobic, as in the '722 Patent, the Nasuno Patent requires only substantially coating the pigment to render it substantially hydrophobic. In both cases, a structural requirement as to the degree of coating results in a functional requirement as to the same degree of hydrophobicity - i.e., completely versus substantially. Revlon's effort to excise the structural requirement as to the degree of coating, therefore, should be rejected.

In short, the Tietjen Patent and its history are not intrinsic evidence, and even if the Court employed it as extrinsic evidence, it does not change the Court's construction of the "completely coated" claim language.

b. Revlon's Impossibility Argument Based on Experts' Reports

Estee Lauder's expert, Dr. Gerd H. Dahms, opined in his rebuttal report that:

> It is my opinion that one of ordinary skill in the art would read the language 'whose surfaces are chemically bonded to and physically completely coated by polysiloxane, which coating renders the particles hydrophobic' to mean that the surfaces of the pigments be physically completely coated by polysiloxane. More specifically, one of ordinary skill in the art would understand this to mean that the entire surface area of the pigment is coated by polysiloxane.

(Dkt. No. 48: Estee Lauder 56.1 Stmt. Ex. H: Dahms Rebuttal Report at 7, fn. omitted.) Dr. Dahms then averred that Estee Lauder's products did not infringe the '722 Patent:

> It is my opinion that the methicone coated pigments used in [Estee Lauder's] accused products are not physically completely coated by polysiloxane as required by the claims of the '722 patent. My opinion is based on what is common knowledge in the industry as well as experiments performed in my laboratory.
>
> First, it is well known that the surfaces of particles are not smooth and even, but are rugged and include cracks and crevices. Furthermore, the pigments are not perfectly spherical. Accordingly, a person of ordinary skill would expect there to be uncoated surfaces - both external and internal - on these pigment particles.
>
> Second, primary pigment particles generally tend to agglomerate and, when this happens, the agglomerated primary pigment particles are coated during the coating process. Once coated, however, the agglomerates often break apart during filling, drying, packing, shipment and final use, thereby creating additional uncoated pigment surfaces.
>
> Third, technical documents from manufacturers of coated pigments recognize that the treatment process by which the pigments are coated is not complete. Revlon produced such a document from Kobo. REV 999-0042 to 999-0061. Page five of Kobo's May 2000 Treated Pigments technical brochure (REV 999-0048) discusses its technology for coating methicone-coated pigments and notes: "Kobo's proprietary technology minimizes hydrogen potential, leading to a uniform and more complete treatment of each primary particle." A coating/treatment is either complete or incomplete. Thus, the Kobo

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document shows that even the manufacturers of coated pigments recognize that the pigments are not completely coated.

(Dahms Rebuttal Report at 8-9.) 33

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33 Dr. Dahms also performed a simple experiment based on titanium dioxide's peculiar response to light. (Id. at 9-10.) Because the coated titanium dioxide pigment in the accused products demonstrated a response to light, Dr. Dahms concluded that such pigments could not have been completely coated. (Id.)

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Revlon submitted an affidavit from its own expert, Dr. Robert Lochhead, who was only too happy to concur with Dr. Dahms on this point by asserting that: (1) "one of ordinary skill would acknowledge that there would be uncoated surfaces on the molecular level"; (2) "one of ordinary skill in the art would understand that pigment particles might agglomerate and break apart, and that such actions could create uncoated surfaces on a pigment"; and (3) "technical documents from manufacturers recognize that the treatment process by which the pigments are coated does not result in 100% coated pigments, and [I] would expect one of ordinary skill in the art to have the same understanding." (Dkt. No. 52: Revlon 56.1 Stmt. Ex. G: Lochhead Aff. PP 16-18; see also Revlon 56.1 Stmt. PP 28-30.) As discussed in Point I above, while the Court has struck certain portions of Dr. Lochhead's affidavit, the Court still must discuss the extrinsic evidence issue raised by Dr. Dahms' opinions.

According to Revlon, "Dr. Dahms acknowledges that one skilled in the art would find the '100% coated' interpretation suggested by plaintiff an impossibility." (Dkt. No. 54: Revlon Br. at 8.) Revlon thus argues that

> Dr. Dahms . . . would agree that one reasonably skilled in the art would realize that the process set forth [in the Patent's preferred embodiment] would not result in 100% coated pigments.
>
> . . . .
>
> If the very process the patent exemplifies for creating pigments that are "physically completely coated by, polysiloxane which renders the particle hydrophobic" would not result in 100% coating, then the patent's preferred embodiment in the specification would not fall within the scope of the patent claim. "Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support, which is wholly absent in this case."

(Revlon Br. at 13, citations omitted.) "Only Revlon's claim interpretation would render both the patent specification and the claims internally consistent and would be in accord with the understanding of a person of ordinary skill in the art." (Dkt. No. 60: Revlon Reply Br. at 4.)

Apparently as a subset of this "preferred embodiment" argument, Revlon also asserts that Estee Lauder's "100% coating" interpretation would conflict with the "commercially available" pigment alternative in the Patent's preferred embodiment. (Dkt. No. 54: Revlon Br. at 15-16.) Specifically, the Patent specification states that "as an alternative to synthesis, satisfactory coated pigments usable in this invention are commercially available from a variety of sources." ('722 Patent at Col. 3, Lns. 59-62.) Revlon cites Dr. Dahms as allegedly acknowledging that despite testing more than 100 pigments, he found only two that currently meet the test for 100% coating and that both were either in a "pilot" stage or "confidential." (Revlon Br. at 6, 15-16; Revlon 56.1 Stmt. P 23, citing Dkt. No. 51: Estee Lauder 56.1 Obj. Ex. Q: Dahms Dep. at 335:16-341:18.) 34 Thus, according to Revlon, Estee Lauder's construction would result in a claim that excluded the patent's preferred embodiment calling for the use of "commercially available" pigments. (Revlon Br. at 15-16.)

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34 Revlon's expert also asserted that "I am not aware that there were any commercially available pigments that could be deemed 100% coated in 1986, nor am I aware of the existence of such products today." (Lochhead 2/21/02 Aff. P 19.) As discussed in Point I above, Dr. Lochhead's statement has been precluded.

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Even if the commercially available alternative pigments were part of the preferred embodiment of Revlon's Patent - which the Court has found they are not (see Point III.B.1.b above), and even if the Court were to accept Revlon's argument that those skilled in the art would know that it is impossible to entirely coat either commercially available pigments or the synthesized pigments disclosed in the Patent, Revlon's arguments still must be rejected because extrinsic evidence may not be employed to vary or contradict unambiguous claim language.

First, as noted above (Point III.B.1.a), because neither party has offered reasonable alternative technical definitions for the claim language at issue, the intrinsic evidence is entirely unambiguous: one skilled in the art would construe "completely coated" in the context of the claim language to mean entirely or 100% coated. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996) ("Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." Employing non-technical definition of term "substantially."). No alternative construction is reasonable - based on the intrinsic evidence alone, there is no inconsistency between the claim language and the preferred embodiment.

Second, the only evidence Revlon has offered to the contrary is Dr. Dahms' statement that one skilled in the art would know that it is impossible to entirely coat a commercially available pigment. This is not the kind of extrinsic evidence - involving a technical definition - that might properly be relied upon when construing a patent. See, e.g., Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1378 (Fed. Cir. 2001) ("the meaning of the claim limitation is apparent from a review of the intrinsic evidence alone, and it is improper for us to rely on extrinsic evidence other than that used to determine the ordinary meaning"). (See also Point III.A.2 above.) Indeed, Revlon has offered no case authority whatsoever for relying upon such extrinsic evidence of "impossibility." Further, it is beyond dispute that Revlon offers Dr. Dahms' statement in order to "vary or contradict" the unambiguous claim language by effectively reading out the "completely coated" structural element. Reliance upon such extrinsic evidence would therefore violate a cardinal rule of patent construction. See, e.g., CAE Screenplates v. Heinrich Fiedler GmbH, 224 F.3d 1308, 1318 (Fed. Cir. 2000) ("When the intrinsic evidence is unambiguous, it is improper for a court to rely on extrinsic evidence such as expert testimony when construing disputed claim limitations.").

Moreover, even if the Court were to accept as true the assertion - based on extrinsic evidence - that it is impossible to completely coat a pigment, 35 the claim language and other intrinsic evidence remain unambiguous that the pigment must be completely coated. One skilled in the art would conclude that: (1) the unambiguous claim language requires completely coated pigment; and (2) because, based on extrinsic evidence, it is impossible to completely coat pigment, the recited invention is inoperable - it would not work as described. The intrinsic evidence admits no other possibility; the Court may not use extrinsic evidence to rewrite unambiguous claim language. 36 See, e.g., Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1349 (Fed. Cir. 2002) (The patentee "argues that one of skill in the art would understand that the term 'perpendicular' in the claim should be read to mean 'parallel.' [The patentee] stretches the law too far. It is not our function to rewrite claims to preserve their validity. We are simply tasked with determining whether the claims 'particularly point[] out and distinctly claim[]' what the inventor regards as his invention. Moreover, it is of no moment that the contradiction is obvious: semantic indefiniteness of claims 'is not rendered unobjectionable merely because it could have been corrected.'") (citations omitted); Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1372 (Fed. Cir. 2002) ("Where claim language is clear we must accord it full breadth even if the result is a claim that is clearly invalid."); Elekta Instr. S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d at 1309 (Patentee "further argues that [alleged infringer's] interpretation would render claim 1 invalid, because [an invention with the stated limitations] would be inoperative. We do not reach the issue of invalidity [based on inoperability], and we note that the record is unclear as to whether such a device would be inoperative. Moreover, having concluded that the amended claim is susceptible of only one reasonable construction, we cannot construe the claim differently from its plain meaning in order to preserve its validity (upon which we do not opine)."); K- 2 Corp. v. Salomon S.A., 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("That the applicant could possibly have added terms other than 'permanently' to create a patentable distinction with the asserted prior art is simply irrelevant to our claim construction task. Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee."); Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed. Cir. 1999) ("We do not permit courts to redraft claims. . . . Where, as here, the claim is susceptible to only one reasonable construction, the canons of claim construction cited by [patentee] are inapposite, and we must construe the claims based on the patentee's version of the claim as he himself drafted it. . . . As a result of our claim construction, clause [d] does not make 'sense' as [patentee] itself realizes and concedes. What [patentee]

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fails to realize is that such a nonsensical result does not require the court to redraft the claims of the '943 patent. Rather, where as here, claims are susceptible to only one reasonable interpretation and that interpretation results in a nonsensical construction of the claim as a whole, the claim must be invalidated, thus preventing unduly burdening competitors who must determine the scope of the claimed invention based on an erroneously drafted claim."), cert. denied, 529 U.S. 1037, 120 S. Ct. 1531, 146 L. Ed. 2d 346 (2000); Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("We . . . have consistently employed the caveat, 'if possible,' to our instruction that claims should be construed to sustain their validity. We have also admonished against judicial rewriting of claims to preserve validity. Therefore, if the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid. In the case before us, the court misapplied the axiom and adopted a construction of 'flashlight' that is at odds with the clear language of the claim and the written description.") (citations omitted); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("Although we construe claims, if possible, so as to sustain their validity, . . . it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims."), cert. denied, 517 U.S. 1167, 116 S. Ct. 1567, 134 L. Ed. 2d 666 (1996); Texas Instruments v. United States ITC, 988 F.2d 1165, 1171 (Fed. Cir. 1993) ("To construe the claims in the manner suggested by [patentee] would read an express limitation out of the claims. This, we will not do because 'courts can neither broaden nor narrow claims to give the patentee something different than what he has set forth.'"); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 951 (Fed. Cir. 1993) ("It would not be appropriate for us now to interpret the claim differently just to cure a drafting error made by [patentee]. That would unduly interfere with the function of claims in putting competitors on notice of the scope of the claimed invention."); Becton Dickinson & Co. v. C.R. Bard Inc., 922 F.2d 792, 799 n.6 (Fed. Cir. 1990) ("Nothing in any precedent permits judicial redrafting of claims. At most there are admonitions to construe words in claims narrowly, if possible, so as to sustain their validity."); Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 2001 U.S. Dist. LEXIS 17459, 95 Civ. 8833, 2001 WL 1334997 at *3 n.5 (S.D.N.Y. Oct. 30, 2001) ("If the Court's construction demonstrably indicated that claims contained within the '277 patent were invalid, it would only be appropriate for the Court to construe the claims so as to preserve validity if it could do so without redrafting the claims.").

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35 Dr. Dahms did not say that - he merely said that commercially available pigments were not 100% coated, and he also said he knew of two pigments that were 100% coated, albeit not commercially available. (See pages 57-58 above.)

36 Were the Court to conclude that commercially available pigments could not be completely coated and that the recited invention was impossible, a finding of invalidity would be the next logical step. (See Dkt. No. 66: Revlon Supp. Br. at 18 ("Assuming, arguendo, that the term 'completely coated' required 100% coated pigments, as hypothetically proffered by the Court, the patent would have to be found invalid. It is premature, however, to reach such a conclusion where claim construction is still at issue.").) Estee Lauder did not move for summary judgment on grounds of invalidity, however, and the Court declines to raise the issue, sua sponte, because, among other things, the factual question of impossibility has not been conclusively proven. See Elekta Instr. S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1309 (Fed. Cir. 2000) (after finding noninfringement, Federal Circuit declined to "reach the issue of invalidity," "noting that the record is unclear as to whether [the patented] device would be inoperative").

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Although not cited by either party here, the Federal Circuit's decision in Aqua-Aerobic Sys., Inc. v. Aerators Inc., 211 F.3d 1241 (Fed. Cir. 2000), is on all fours, holding that expert testimony may not be used to broaden an unambiguous claim limitation by proving that the limitation would not work in actual practice:

The experts agreed that the [patented invention in actual practice] is not air-tight. However, the district court's claim construction is in accord with the teachings of the specification, which do not permit more than a negligible or minuscule amount of air to enter and pass through the mixer. The undisputed testimony that experts would understand that the described sealing system would not produce an air-tight device, does not broaden the claims to the extent [the patentee] now proposes, that its claims should be construed to reach a system that passes a significant amount of atmospheric air. This is directly contrary to the limitations in the claims and the description in the specification.

Expert testimony is often useful to clarify the patented technology and to explain its meaning through the eyes of experience, but it may not correct errors or erase limitations or otherwise diverge from the description of the invention as

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contained in the patent documents. The district court correctly rejected [the patentee's] proposal that the claim should not be limited by the amount of air that passes or flows through the system but instead should be construed to cover any downflow mixer that does not suffer cavitation at the propeller. That is not the invention described and claimed by the patentee.

Id. at 1245 (citations omitted); 37 see Williams v. General Surg. Innovs., Inc., No. 02-1474, 60 Fed. Appx. 284, 287, 2003 WL 932449 at *3 (Fed. Cir. Mar. 7, 2003) ("The '026 patent does not, on its face, disclose the removal of the tissue expander. Appellants do not contest this fact, but rather rely on expert declarations to the effect that those skilled in the art would have known that the expander could be removed as part of surgery. . . . The declarations, however, were not directed to what the patent actually disclosed, but rather what a skilled artisan could conclude therefrom.") (record cite omitted); Bioscan, Inc. v. United States Int'l Trade Comm'n, No. 87-1599, 847 F.2d 842 (table), 1988 WL 33816 at *1 (Fed. Cir. 1988) ("Where the claim is worded in such a way that the thing claimed is inoperative, the claim is invalid. . . . The administrative law judge heard testimony from several experts on whether claim 9 was enabled, and concluded that the invention set forth in claim 9 is inoperative. We agree. Although persons skilled in the art would understand what claim 9 says, as written the claim describes a device which is inoperative, and therefore the claim is invalid under 35 U.S.C. § 112."); Nichols v. Strike King Lure Co., 2000 U.S. Dist. LEXIS 15781, No. Civ. A.3:99- CV-1950, 2000 WL 1593616 at *2, 8 (N.D. Tex. Oct. 25, 2000) (Construing patent for fishing lure disclosing a "resin coating over the entire outer surface." The patentee explained that fishing lures attach accessories that "create small areas on the lure body that may not be covered by the glitter-containing coating. Thus, [patentee] argues that 'entire' cannot mean that every bit of surface area is covered by the coating; instead, it must mean that only the 'greater part' of the surface of the body is covered by the coating." The court instead construed the term "entire" "in its ordinary sense" to mean "'having no element or part left out' or 'complete in degree.'" Patentee "argues that such an interpretation creates a situation wherein a lure manufacturer may avoid infringement by simply leaving a small portion of the lure uncovered by coating material. However, the Court may not consider the fact that the patentee in retrospect would have inserted qualifying terms had he considered the implications of employing absolute language. No matter how great the temptations of fairness or policy making, courts are limited to interpreting claims, and are not permitted to redraft them."); see also Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1212-16 (Fed. Cir. 2002) (holding that district court repeatedly erred by relying on "skilled in the art" expert testimony to broaden interpretation of unambiguous claim language), cert. denied, 538 U.S. 1058, 155 L. Ed. 2d 1108, 123 S. Ct. 2230 (2003); Markman v. Westview Instrs., Inc., 52 F.3d at 983 ("The extrinsic evidence of record cannot be relied on to change the meaning of the claims. In this case, as fully discussed above, the patent and prosecution history make clear that 'inventory' in claim 1 includes in its meaning 'articles of clothing.' The district court exercised its discretion in finding unhelpful Markman's testimony that he meant 'inventory,' or that one of ordinary skill in the art would understand 'inventory,' to mean something to the contrary, and furthermore the district court rejected the testimony as conflicting with the meaning derived from the patent and prosecution history. In our construction of the claim term 'inventory,' we too find unhelpful and reject Markman's testimony."). 38

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37 Notably, the Aqua-Aerobic decision was written by Judge Newman, who generally favors the liberal use of extrinsic evidence. See, e.g., W. Thad Adams & J. Derel Monteith, Jr. The Continuing Saga of Federal Circuit Patent Claim Construction Jurisprudence: Extrinsic Evidence and Other Stories, 8 Fed. Cir. Bar J. 83, 89-91 (1999).

38 The decision in AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239 (Fed. Cir. 2001), illustrates this point. There, the Federal Circuit held that the district court erred by not considering essentially undisputed testimony of one skilled in the art that the patented invention would not run absent a particular limitation that was not clearly stated in the claim language. Id. at 1248-49 ("We can't run this product without barrier layers. I mean, it just goes whacko."). In AFG, however, unlike here, the intrinsic evidence was "vague or ambiguous," thus requiring the admission of extrinsic evidence to settle the ambiguity. Id. at 1249. Further, rather than, as here, contradicting the intrinsic evidence, the expert testimony in AFG "explained, corroborated, and reinforced the distinction recited in the written description." Id.

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The preferred embodiment decisions relied upon by Revlon are thus inapposite. The Federal Circuit has repeatedly held a claim interpretation that reads out a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996); accord, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1349 (Fed. Cir. 2003). (See cases cited at page 20 above.) Indeed, the Federal

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Circuit held that "we have done so only one time--in an instance where the patent applicant limited the full scope of the claim language to omit the preferred (and only disclosed) embodiment in order to overcome an examiner's rejection." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d at 1349 (citing Elekta Instr. S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d at 1308). In the preferred embodiment cases, however, the construction asserted by the alleged infringer would have excluded the preferred embodiment. In this case, by contrast, the unambiguous claim limitation that the pigment must be 100% coated does not inherently conflict with the preferred embodiment. 39 A conflict would arise only if the Court violated the cardinal rule of construction by venturing outside the unambiguous intrinsic evidence and relying on extrinsic evidence that Revlon construes as opining that commercially available pigments cannot be completely coated.

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39 As discussed above (Point III.B.1.b), although the alternative of commercially available pigments is not part of the preferred embodiment of the Patent, the result here would not change if the Court held otherwise.

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The Court concludes that the claim language "completely coated" means what it says - the pigment must be 100% coated.
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2. The core being coated with a rate-controlling polymer coat

Defendant proposes that "the core being coated with a rate-controlling polymer coat" should be construed to mean "a coating of polymer applied on the core that controls delivery of the active ingredient." (Id.) Defendant argues that its construction should be adopted because Plaintiffs did not provide a construction. (Def's Br. at 17; Doc. No. 29.) Plaintiffs argue that this term does not require construction because it does not have a meaning other than that of the individual words, which each have a well-understood meaning. (Joint CC Chart at 7; Doc. No. 31.)

This term does not require construction. Claim construction is not "an obligatory exercise in redundancy" and is not required where the claim terms have a well-understood meaning. O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008). Each of the words in this term has a well-understood meaning. The fact that Defendant's construction is so similar to the claim term and changes it only to use different tenses of its root words demonstrates that those words have a well-understood meaning. Thus, construing this term would be an exercise in redundancy. See O2 Micro Int'l, 521 F.3d at 1362. Therefore, the Court concludes that this term does not need to be construed.
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i. Claim Construction - First and Second Coatings

Defendants argue that the accused products do not infringe Claim 1 of the '074 Patent because coating and layers are not synonymous. Doc. No. 47 at 7. Defendants conclude that because it uses only one coating of a mixture of activated and conducting carbon, it does not meet the limitations of the '074 Patent. Id. In response, Plaintiff states that claim 1 of the ' 074 Patent is not a process claim, but a device claim. Accordingly, even if Defendants only apply its carbon slurry in one mixture, it will infringe the '074 Patent if the mixture nonetheless forms two layers, or coatings, on the aluminum current conductor. Doc. No. 66 at 3.

A review of the patent specification supports Plaintiff's construction of "coating" as including both layers and coatings. First, Plaintiff is correct that Claim 1 is a device or product claim, and not a process or method claim. The claim, for example, describes physical properties and characteristics of the device, and not a method or process of making the device. As such, Defendants' method of applying a mixture of activated and conductive carbons, instead of as layers as taught in the '074 Patent, is irrelevant if it possesses the structural limitations of Claim 1. See AFG Industries, Inc. v. Cardinal IG Co., Inc., 375 F.3d 1367, 1370 (Fed. Cir. 2004) (A product claim covers any infringing structure "however it is made or however

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it is used.").

In addition, Defendants' contention that layers are not synonymous with coatings lacks merit in light of the patent specification. Claim construction requires that a reviewing court read the claims "in view of the specification, of which they are a part." Nystrom, 424 F.3d at 1142 (Fed. Cir. 2005). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Phillips, 415 F.3d at 1316. Here, the specification repeatedly uses the terms "layers" and "coatings" interchangeably:

The first layer … is of a "conducting carbon …" '074 Patent at 7:19-20

The second layer is of an "activated carbon …" Id. at 7:32

The first layer is formed onto the surface of the current collector. Id. at 7:48

The second layer is formed onto the first layer … Id. at 7:60

The first step involves applying a first layer (or primary coating) … Id. at 9:8-9

The primary coating reduces the interfacial resistance and serves as a seed coat for a secondary coating. Id. at 9:25-26

The second layer (or secondary coating) is applied over the primary coating. Id. at 9:58-59 .

As can be seen, the first layer and the second layer are coated onto the foil, with the three lanes having been cleared of the first layer and the second layer by the set of wipers. Id. at 11:37-40.

Thus, Defendants' argument that "layers" and "coatings" are not synonymous lack merit in light of the specification's interchangeable use of the terms. Accordingly, this Court construes Claim 1 as a product claim, and the disputed term "coating" to include "coatings or layers." However, as discussed, because the record is not complete, this Court is mindful that any claim construction at this stage is preliminary and tentative.
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The parties disagree about the proper construction of the Claim 1 limitation, "coating said interior wall of said container with a Lewis acid inhibitor." (See Pls.' Resp. Def.'s Mot. Summ. J. 9; Reply Mem. Supp. Def.'s Mot. Summ. J. 5-7.) Specifically, the parties are at odds over the correct interpretation of one term: the verb "coating." (See Pls.' Resp. Def.'s Mot. Summ. J. 9; Def.'s Reply Mem. Supp. Mot. Summ. J. 5-7.)

Claim construction is a question of law to be decided by a judge. See Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). When interpreting a patent claim term, "[courts] indulge a heavy presumption that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (quotation omitted). However, courts must look to the specification, as "[t]he patentee may have acted as his own lexicographer and imbued the claim terms with a particular meaning or 'disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction.'" E-Pass Techs., Inc. v. 3COM Corp., 343 F.3d 1364, 1369 (Fed. Cir. 2003) (quoting Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002)). "[I]n determining whether a statement by a patentee was intended to be lexicographic, it is important to determine whether the statement was designed to define the claim term or to describe a preferred embodiment." Id.

Thus, when construing the term "coating," the Court must first establish the ordinary and customary meaning of the term and then determine whether Abbott attempted to define "coating" in the specification, or if it simply intended to bring forth a preferred embodiment. When construing a claim, "dictionary definitions may establish a claim term's ordinary meaning." CCS Fitness, 288 F.3d at 1366. Merriam-Webster's Dictionary defines the verb "coat" as meaning "to cover or spread with a finishing, protecting, or enclosing layer." Merriam-Webster's Collegiate Dictionary 235 (11th ed. 2004). Baxter provides no evidence of an ordinary and customary meaning contrary to the dictionary definition, whereas Abbott contends that the Court should construe "coating" to mean "covering the surface of the object." (Pl.'s Resp. Def.'s Mot. Summ. J. 12.) The

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Court construes the term "coating" according to its ordinary and customary meaning: "covering or spreading with a finishing, protecting, or enclosing layer."

Baxter objects to such a construction and argues that a reading of the '492 Patent's specification requires the Court to construe "coating" to mean "rinsing or washing." (Def.'s Reply Mem. Supp. Mot. Summ. J. 5.) Baxter points to the '492 Patent's "Detailed Description of the Invention," which states, "a container, such as a glass bottle, is first washed or rinsed with the Lewis acid inhibitor and then filled with the fluoroether compound," and "small quantities of the composition containing appropriate amounts of the Lewis acid inhibitor can be used to wash or rinse containers to neutralize any Lewis acids that might be present in the container." (App. Def.'s Mot. Summ. J., Ex. D, '492 Patent, col. 5, lines 34-37, col. 5, line 66-col. 6, line 2; see Def.'s Reply Mem. Supp. Mot. Summ. J. 5.) However, to overcome the presumption that the ordinary meaning of "coating" applies, the '492 Patent's specification must establish that the patentee sought to define "coating" as "washing or rinsing" explicitly and did not merely set out to define a preferred embodiment. See E-Pass, 343 F.3d at 1369.

A reading of the specification establishes clearly that the patentee did not intend to act as its own lexicographer by using the "washing or rinsing" language. First, in the sentence directly preceding the first instance of such language in the "Detailed Description," the patentee specifically states that "[t]he composition of the present invention can be prepared in several ways," implying that "washing or rinsing" is only one of several possible embodiments of the patented method. (App. Def.'s Mot. Summ. J., Ex. D, '492 Patent, col. 5, lines 34-35.) Second, three paragraphs later in the "Detailed Description," the patentee teaches that "small quantities of the composition . . . can be used to wash or rinse containers . . . ." (Id. at col. 5, line 66-col. 6, line 1) (emphasis added). Given this language, the Court finds that the patentee did not give a lexicographic effect to the "washing and rinsing" language but, rather, sought to describe several preferred embodiments of the patented method.

Baxter contends that this plain-meaning interpretation would render the '492 Patent invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, paragraph 1, which states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

35 U.S.C. § 112, P 1 (2009).

Baxter merely argues that because nothing in the original 1997 parent application or the issued '492 Patent indicates that the inventors had possession of any kind of solid, non-soluble Lewis acid inhibitor, a plain-meaning construction of Claim 1 would render the '492 Patent invalid for failure to satisfy the written description requirement. (Def.'s Reply Mem. Supp. Mot. Summ. J. 13.)

The Court disagrees. It is undisputed that the patentee intended a lexicographic effect when it stated in the '492 Patent's specification, "[a]s used herein, 'Lewis acid inhibitor' refers to any compound that interacts with the empty orbital of a Lewis acid thereby blocking the potential reaction sites of the acid." (Id. at col. 4, lines 51-54) Therefore, the Court construes Claim 1's "coating said interior wall of said container with a Lewis acid inhibitor" limitation to mean "to cover or spread the interior of the container with a finishing, protecting, or enclosing layer composed of any compound that interacts with the empty orbital of a Lewis acid."

Accordingly, a plain-meaning construction of coating does not necessarily require Claim 1 to encompass solid Lewis acid inhibitors. Rather, Claim 1's breadth, after this Court's construction, encompasses those Lewis acid inhibitors that interact with the empty electron orbital of a Lewis acid, regardless of the inhibitor's state of matter. Because Baxter has failed to establish by clear and convincing evidence that the '492 Patent does not satisfy the written description of section 112, the Court rejects Baxter's arguments that the '492 Patent is invalid.
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A determination of the proper construction of the term "codons preferred" will resolve the dispute about the "greater number" claim. If Mycogen is correct in its interpretation that there are 20 specific preferred codons, then DeKalb's position

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that the claim is referring to the overall distribution of all codons cannot be correct. On the other hand, if DeKalb is correct that any codon is preferred if its addition brings the codon usage frequency closer to that of the intended host, then Mycogen's position that the claim requires a simple summation of 20 specific codons would be incorrect.

The evidence relating to the proper meaning of the term "codons preferred" supports the positions of both parties. The court will discuss the relative strength of the parties' proposed constructions in light of the language of the patent, the prosecution history, and the doctrine of claim differentiation.

a. Patent language

Mycogen first points to the claim language to support its position. Under the plain meaning of the phrase "greater number," Mycogen argues, these preferred codons are something that can be counted. Its claim interpretation involves the counting of the codons most frequently used for specifying each individual amino acid. Mycogen argues that DeKalb's interpretation is not amenable to a counting of codons, because the only relevant consideration in DeKalb's interpretation is frequency of codons, not total occurrences of each codon.

DeKalb counters that the only counting technique offered by Mycogen in its specification is one for calculating the percent deviation of the frequency of preferred codon usage for a synthetic gene from that of a host cell. Col. 7, lines 15-43. This calculation does not involve simple counting, but rather sums up the differences between the frequency of each codon as used in the synthetic gene and the frequency of the same codon as used in the plant host, and divides by the total number of codons. DeKalb argues that Mycogen's suggestion that one simply add up the number of appearances of specific codons is never disclosed or described in the patent or its specification.

The patent specification uses the phrase "codons preferred" or "preferred codons" several times, and in ways that support both parties' arguments. Mycogen points to the portion which reads:
In designing a synthetic gene encoding the Bt crystal protein, individual amino acid codons found in the original Bt gene are altered to reflect the codons preferred by dicot genes for a particular amino acid.

Col. 22, lines 25-29 (emphasis added). This is followed by the statement that:
In the case of alanine, it can be seen from Table 1 that the codon GCA is used in Bt proteins with a frequency of 50%, whereas the codon GCT is the preferred codon in dicot proteins.

Col. 22, lines 32-35 (emphasis added). Table 1 indicates that GCT is used 42% of the time that alanine is specified in dicot plant genes, more often than the other three alanine-specifying codons. Thus, it would appear that the term "preferred codon" is used in this section of the specification in a way consistent with Mycogen's proffered definition.

Mycogen also cites the specification's use of the term "least preferred codon" to describe codons ending in CG (col. 4, lines 21-22) as another example that is consistent with its definition of the term "preferred codon." According to Table 1, each codon ending in CG appears least frequently for the amino acid it specifies.

DeKalb points to different sections in the specification. When explaining how to calculate the difference in frequencies of codon usage between the synthetic gene and the plant host, the specification refers to the percent deviation of the frequency of preferred codon usage. Col. 7, lines 15-16 (emphasis added). This calculation measures the difference in frequency of codon usage for every codon - not just the 20 that Mycogen claims are defined as preferred codons.

DeKalb also argues that the teaching of the specification consistently refers to the frequency of codon usage, not simply increasing the raw number of specific codons. In the very section of the specification that Mycogen quotes to support its definition, it also states that
Attention is given to maintaining the overall distribution of codons for each amino acid within the coding region of the gene. . . . Not all codons for alanine in the original Bt gene are replaced by GCT; instead, only some alanine codons are changed to GCT while others are replaced with different alanine codons in an attempt to preserve the overall distribution of codons for alanine used in dicot proteins.

Col. 22, lines 29-41.

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The patent specification contains an example of a gene produced by the patented method. In this example, of the 20 codons that Mycogen defines as preferred codons, 7 of them occur a fewer number of times in the synthetic gene than they did in the native gene prior to modification. Mycogen points out that the other 13 codons occur more frequently, and that the total number of these 20 codons is greater in the synthetic gene than in the native Bt gene. However, DeKalb claims that nothing in the teaching of the patent dictates this result.

b. Prosecution history

DeKalb also points to evidence in the prosecution history that the "greater number" claim was meant to refer to the overall codon distribution. During the application process of the '831 patent, in his declaration, Dr. Murray explains that the method taught involves modification to the Bt sequence that "will result in a frequency of codon usage that more closely reflects that of the intended plant host." Id. at P4(G). He states that by comparing the frequency of codon usage of the Bt gene and the intended plant host, one "would easily be able to determine those codons which were unfavored by the plant, and be aware of possible nucleotide substitutions which could convert selected unfavored codons into codons which are more preferred by the plant host." Id. (emphasis added). Dr. Murray also states that "there is no 'right' or 'wrong' synthetic sequence, so long as [it] more closely reflects the frequency of codon usage of the intended plant host." Thus, DeKalb argues that Dr. Murray viewed the "codons preferred" as those that most closely reflect the overall distribution of codons in plant genes.

Mycogen argues that the prosecution history supports its claim construction, and not DeKalb's. In October, 1995, during the prosecution of the '862 patent, the patent examiner suggested that the "greater number" and "frequency" claims were anticipated by two references that disclosed the truncating of the native Bt gene. Mycogen responded that a mere shortening of the Bt sequence could not possibly modify a native Bt sequence so that it would have a "greater number of codons preferred." Rather, Mycogen claimed that such a truncation could only result in a reduction in the number of plant-preferred codons or no change in the number. In response to a concern raised by the patent examiner in January, 1996, Mycogen reiterated that "while a mere truncation, not involving substitution of codons . . . could affect the frequency of codon usage, it can in no way result in an increase in the number of plant preferred codons." (emphasis in original). Mycogen argues that this is evidence that the greater number claims must refer to something different than the distribution of all codons in the gene, and evidence that the "greater number" limitation is not synonymous with the "frequency" limitation.

c. Claim differentiation

Mycogen argues that DeKalb's interpretation is contrary to the doctrine of claim differentiation, which states that:

There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.

United States v. Telectronics, Inc., 857 F.2d 778, 783 (Fed. Cir. 1988) (quoting Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987). Mycogen claims that DeKalb's interpretation of the "greater number" limitation makes claims containing the limitation superfluous, since they would then be identical in meaning to claims containing the "frequency" limitation.

DeKalb responds that the doctrine of claim differentiation is not an automatic bar to their proposed construction. It cites case language that states that "two claims which read differently can cover the same subject matter." Tandon Corp., 831 F.2d at 1017. DeKalb argues that the differently phrased limitations simply define the invention using different terminology, and that the Federal Circuit has observed that this "is not unusual." Hormone Research Foundation v. Genentech, Inc., 904 F.2d 1558, 1567 n.15 (Fed. Cir. 1990).

d. The court's construction

Neither the doctrine of claim differentiation, nor the evidence in the prosecution history that Mycogen considers the "greater number" limitation to have a different meaning than the "frequency" limitation, supports Mycogen's proposed construction of the phrase "codons preferred." The court finds that these two limitations are slightly different, consistent with Mycogen's representations in the prosecution history. The difference is demonstrated by the example of the truncated gene. Mycogen

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argued in the prosecution of the '862 patent that such a gene could not possibly contain a greater number of codons preferred by the intended plant host. This statement does not preclude DeKalb's proposed construction. It is possible that a truncation might eliminate some codons that are more frequent in the Bt gene that they are in the plant gene, and thus make the overall frequency of codon usage more like that of the plant. However, that same truncation would not add codons to the gene, and thus there would not be a greater number of any codons, including those that are "preferred."

The court finds, after considering the claims, the specification, and the prosecution history, that DeKalb's construction of the term "greater number" is correct. Mycogen can only point to a single reference in the specification to support its position that the phrase "codons preferred" refers to the group of codons that are each the most frequently used to specify one of the amino acids. The one reference in the specification is not a definition of that term, but a use of the term "preferred codon" to describe GGA, the most frequently occurring codon for alanine in dicot plants. However, the specification also uses the phrase "preferred codon" in the language explaining how to calculate the percent deviation of codon usage. In that passage, "preferred codon" apparently refers to all codons, since the frequency of every codon is included in the calculation.

The list of the 20 codons that Mycogen considers to be the "preferred codons" does not appear anywhere in the prosecution history. Mycogen does not offer any evidence that their definition of the term is a common one in the field of genetics. Patent law places upon inventors the duty of "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. If Mycogen intended that "codons preferred" have this specific definition, it could have defined the term in the specification. Thus, the court finds that the term "codons preferred" does not refer to the codons that are most frequently occurring for each individual amino acid. Rather, a codon is "preferred" if its addition to the native gene makes its frequency in that gene more like the frequency of that codon in the gene of the intended plant host.

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Mycogen contests a portion of the district court's claim construction. Specifically, Mycogen contends that the district court's definition of the "greater number of codons preferred" language in independent claims 1, 2, 13 and 14 of the '600 patent is erroneous. However, the claim construction issue here relates to both the '600 and the '862 patent, as well as the original '831 parent patent, as all three patents contain claims that use the language disputed herein. Claim 1 of the '600 patent is representative, and it reads as follows:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

'600 patent, col. 31, lines 37-57 (emphasis added).

In Mycogen, the district court held that:

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The phrase "greater number of codons preferred," is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.

61 F. Supp. 2d at 215. Thus, the district court's claim construction defines a "preferred codon" to be any codon that brings the modified Bt gene's codon frequency closer to that of the intended plant host. Mycogen argued during claim construction that the term refers to those codons that appear most frequently for each individual amino acid. Since there are 20 amino acids, exactly 20 of the 61 existing codons are "preferred" in any specific organism. See Mycogen claim construction at 18-19.

The difference between these two definitions is best illustrated by an example. GCG, GCA, GCT and GCC codons all code for the amino acid alanine. Table 1 of the '600 patent contains the following information regarding the frequency of codon usage for dicot plant proteins and Bt proteins:

	Dicot Genes	Bt Genes
GCG	0.06	0.12
GCA	0.25	0.50
GCT	0.42	0.32
GCC	0.27	0.06

'600 patent, col. 16, lines 47-50. According to the above table, the codon GCT appears most frequently in the dicot gene when coding for alanine. Thus, under Mycogen's definition of "preferred codon," only the GCT codon is a "preferred codon" for dicot plant proteins. However, under the district court's definition, both an addition of GCT and an addition of GCC would bring the Bt gene closer to the codon frequency of the dicot gene, and thus either one of these codons would be considered a "preferred codon."

When defining a claim term, we look first to the words of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1576 (Fed. Cir. 1996). Mycogen's proffered definition of "preferred codon" specifies that only the most preferred codon is considered "preferred." This definition appears to read an additional limitation into the term "preferred codon" that is not evident from the plain meaning of the phrase. However, a patentee is free to be his own lexicographer, so long as the special definition of a term is made explicit in the patent specification or file history. Id. Thus we must examine whether these additional sources of intrinsic evidence shed further light on the definition.

The term "preferred codon" is never explicitly defined in the '600 patent specification. However, the written description uses the terms "codons preferred" and "preferred codons" multiple times. For example, the '600 written description states:

In designing a synthetic gene encoding the Btt crystal protein, individual amino acid codons found in the original Btt gene are altered to reflect the codons preferred by dicot genes for a particular amino acid. . . For example, in the case of alanine, it can be seen from Table 1 that the codon GCA is used in Bt proteins with a frequency of 50%, whereas the codon GCT is the preferred codon in dicot proteins.

'600 patent, col. 22, lines 25-35 (emphasis added). This statement tends to support Mycogen's definition that there is only one preferred codon per gene for each type of amino acid. However, this same passage goes on to state:

In designing the synthetic Btt gene, not all codons for alanine in the original Bt gene are replaced by GCT; instead, only some alanine codons are changed to GCT while others are replaced with different alanine codons in an attempt to preserve the overall distribution of codons for alanine used in dicot proteins.

Id., col. 22, lines 35-41. This statement supports the district court's construction because it explains that not all Bt gene alanine codons are replaced with GCT, but other alanine codons may also be used so long as the resulting distribution of codons more closely resembles the dicot distribution (the intended plant host). This implies that GCT is not the only

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preferred codon in this example. The '600 written description also states:

The percent deviation of the frequency of preferred codon usage for a synthetic gene from that employed by a host cell is calculated first by determining the percent deviation of the frequency of usage of a single codon from that of the host cell followed by obtaining the average deviation over all codons.

Id., col. 7, lines 15-20. Again, this statement supports the district court's claim construction. The specified calculation for preferred codon usage measures the difference in frequency of codon usage for each single codon - not just the 20 codons that Mycogen's definition would consider "preferred." Thus, the '600 patent's written description does not provide an explicit definition of the term "preferred codon" that would supersede the plain meaning of the claim terms.

The patent prosecution history is similarly unhelpful in specifying the definition of "preferred codon." During the prosecution of the '862 patent, the patent examiner stated that a reference disclosing the truncation of native Bt genes anticipated a gene with either the "frequency of codon usage" limitation or the "a greater number of codons preferred" limitation. In response, the prosecuting attorney pointed out: "By simple truncation it is impossible to modify a native Bt sequence to yield a truncated sequence that has 'a greater number of codons preferred by a host plant cell.'" (emphasis in original). However, this example would be applicable for either definition of the "greater number of codons preferred" limitation, and thus does not shed additional light on the issue.

Thus, we rely on the plain meaning of the claims. Mycogen chose to use the term "codons preferred" in its claims. Had Mycogen meant the claims to refer to the "most preferred codon" it could have and should have included this limitation in the claims themselves. Furthermore, Mycogen did not indicate or specify in the written description that an individual protein may have only 20 preferred codons, or that a particular protein may have only a single "preferred codon" for each type of amino acid.

Mycogen further argues on appeal that the district court's definition of "greater number of codons preferred" cannot stand because it renders this phrase synonymous with the "frequency of codon usage" limitation in independent claims 7, 8, 19 and 20 of the '600 patent, thus rendering these two sets of claims identical. Under the doctrine of claim differentiation, "there is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023, 4 U.S.P.Q.2D (BNA) 1283, 1288 (Fed. Cir. 1987). Claim 7 of the '600 patent, set forth in its entirety below, is representative of the set of claims at issue:

7. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes a pesticidal protein toxin;

(b) modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed than did said coding sequence prior to modification, said modification comprising reducing the number of codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

(c) inserting said modified sequence into the genome of a plant cell; and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

'600 patent, col. 32, lines 18-41 (emphasis added).

The doctrine of claim differentiation cannot be used to overcome the plain language of the claims themselves. Claims 1 and 7 are separate, independent claims. "It is not unusual that separate claims may define the invention using different

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terminology, especially where (as here) independent claims are involved." Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1567 n.15, 15 U.S.P.Q.2D (BNA) 1039, 1047 n.15 (Fed. Cir. 1990).

Additionally, the gene truncation example provided in the prosecution history of the '862 patent demonstrates that it would be possible to satisfy independent claim 7 while not satisfying claim 1. The simple truncation of a Bt gene could theoretically "yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant" (the limitation of claim 7) if certain non-plant-like codons were removed. However, such a truncation could not satisfy the district court's definition of the claim 1 "greater number" definition, because it would not result in a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host. This supports the proposition that there is a distinction between the claim constructions given to these two limitations.

Furthermore, the actions of the district court demonstrate that these two claim sets (claims 1 and 7 and their respective dependent claims) were not construed to be identical. For instance, the district court stated in the claim construction decision, "The court finds that these two limitations are slightly different, consistent with Mycogen's representations in the prosecution history." Mycogen claim construction at 25. The proceedings at trial support the premise that the two sets of claims were treated as having separate limitations. For example, all of the claims were submitted separately to the jury; there was no "grouping" of synonymous claims on the jury verdict sheet. Furthermore, the two claim limitations of "greater number of codons preferred" and "frequency of codon usage" were considered separately by the district court in evaluating Monsanto's genes and gene products for infringement in granting Mycogen's motion for JMOL. See Mycogen, 61 F. Supp. 2d at 246-51. In the section of the district court's opinion where these two limitations were analyzed together, any potential error was harmless, as explained in section VI of this opinion. Thus, the district court's claim construction regarding the "greater number of codons preferred" limitation was correct.
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The court heard oral argument on the issue of claim construction in order to better understand the extent of the parties' disagreement about the construction of the claims. During oral argument, both parties focused primarily on the '273 patent. Since neither party has distinguished the facestock claims of the '273 patent from the facestocks claimed as part of the process patents, the court's reasoning in this opinion regarding construction of the '273 patent should be considered applicable to the '532 and '669 patents.

When considering the claims, the "terms of a claim will be given their ordinary meaning, unless it appears that the inventor used them differently." ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579 (Fed. Cir. 1988) (citation omitted). Claim 19 of the '273 patent provides:

19. A multilayer facestock for use in pressure-sensitive label, tape or sign applications comprising a coextrudate of cojoined layers comprising a relatively thick core or base layer of polymeric film material of a stiffness of between 10 and 100 Gurley and which contributes the majority of the dimensional stability and stiffness of labels or signs cut or formed from the facestock, and at least one relatively thin skin layer, said skin layer being on the face side of the coextrudate and having an ink-printable surface, and a pressure-sensitive adhesive layer combined at the side of said coextrudate opposite said face side.

Claims 20 and 21 are dependant on claim 19 and necessarily incorporate by reference all the elements of claim 19. Claims 19-21 cover a plastic multilayer facestock or film. Claim 1 of the '532 patent provides:

1. A method of economically manufacturing die-cut labels or signs using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate comprising a relatively thick core layer and at least one relatively thin skin layer, the former layer providing the majority of the dimensional stability and stiffness of the construction, preselecting the charge for said core layer, as by selection of density or flex modulus, to provide a degree of stiffness suitable for the label or sign application, preselecting the charge for said skin layer to provide a skin adapted to the intended decorating process, such as printability, or surface performance characteristics, such as weatherability of the facestock, and combining said extrudate with a pressure-sensitive adhesive layer to form label or sign facestock, combining said facestock with a liner, die-cutting

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said facestock to form a label or sign releasably adhered to said liner and surrounded by a matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away from the die-cut label or sign.

Claims 3 and 8 are dependent on claim 1 and claim 9 is dependent on claim 8. Claim 14 of the '532 patent provides:

14. A method of economically manufacturing die-cut labels or signs using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate having a face side and a back side, said multilayer extrudate including stiffening layer means which contributes the majority of the stiffness of the construction, preselecting at least one of the charges, as by selection of density or flex modulus, to provide said stiffening layers means with a degree of stiffness suitable for the label or sign application, and combining said multilayer extrudate with a pressure-sensitive adhesive layer and release liner to form linered label or sign facestock, die-cutting said facestock to form a label or sign releasably adhered to said liner and surrounded by a matrix of excess facestock material, and stripping said matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away form the die-cut label or sign.

Claim 16 is dependent on claim 14. Claim 1 of the '669 patent provides:

1. A method of economically manufacturing die-cut labels using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate comprising a relatively thick core layer and at least one relatively thin skin layer, preselecting the charge for said core layer, as by selection of density or flex modulus, to provide said facestock with a degree of stiffness suitable for the label application, preselecting the charge for said skin layer to provide a skin adapted to the intended decorating process, or surface performance characteristics, of the facestock and combining said extrudate with a pressure-sensitive adhesive layer to form label facestock, combining said facestock with a liner, die-cutting said facestock to form a label releasably adhered to said liner and surrounded by a matrix of excess facestock material, and stripping said matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away from the die-cut label.

Claims 2, 3, 7, 8 and 9 are dependent on claim 1. Claim 11 of the '669 patent provides:

11. A method of economically manufacturing die-cut labels using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate comprising a relatively thick core layer and at least one relatively thin skin layer, preselecting the charge for said core layer, as by selection of density or flex modulus, to provide said facestock with a suitable degree of stiffness and sufficient body and strength for the label application, preselecting the charge for said skin layer to provide a skin adapted to the intended decorating process, or surface performance characteristics, of the facestock, hot-stretching and combining said extrudate with a pressure-sensitive adhesive layer to form label facestock, combining said facestock with a liner, die-cutting said facestock to form a label, releasably adhered to said liner and surrounded by a matrix of excess facestock material, and stripping said matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away from the die-cut label.

The construction of the facestock claims' terms and phrases desired by the parties, especially "coextrudate of cojoined layers" and "comprising a relatively thick core or base layer," require the court to look beyond the language of the claims. To aid in construction of the claims, the court must look at the patent specifications. "The specification acts as a dictionary when it defines terms used in the claims or when it defines terms by implication." Vitronics at 1582. The patent inventor is his or her own "lexicographer." ZMI at 1580. Therefore, "the specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification." Id. (citation omitted).

The patent specifications for the '273 patent offer several illuminating claim descriptions. The specifications for the facestock offer two prototypical examples in Figures 5 and 6. The coextrudates in these examples "comprise polymeric film materials, are formed by simultaneous extrusion from a suitable know type of coextrusion die, and are adhered to each other in a permanently combined state to provide a unitary coextrudate." Patent '273, Column 9, Lines 21-26. The elements of the facestock, as described in the specifications, are as follows: "a relatively thick core layer of polymeric film material . . .

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having a cojoined, relatively thin, ink-printable skin layer at least at the face side of the construction, and having a pressure-sensitive adhesive layer combined at the sides of the construction opposite the face side." Patent '273, Column 10, Lines 59-66. The facestock is produced "by coextruding a plurality of at least two charges of film-forming resin to form a coextrudate having a relatively thick core layer and at least one relatively thin skin layer . . . and combining the coextrudate with a pressure-sensitive adhesive layer." Patent '273, Column 10, Lines 67-68; Column 11, Lines 1-8.

The prosecution history of the patents provides similarly helpful evidence for this court. A patent's "prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985). The prosecution history reveals that in the application for the '273 patent, Serial No. 06/853,772, the inventor, Melvin S. Freedman, distinguished his facestock from a product which is "formed by adhering preformed layers." The patent examiner issued a restriction requirement on October 17, 1986 stating: "the product as claimed can be made by a materially different process such as by adhering pre-formed layers." Def's Resp. Ex. W. In an amendment filed October 27, 1986, Freedman responded: "The process pointed out by the Examiner, namely adhering preformed layers, cannot be used to form the claimed coextrudate, since if the layers were preformed they would not have been coextruded and would not constitute a coextrudate as called for in [the] independent product claims." Def's Resp. Ex. X.

Based upon a review of the entirety of the patent, including the claim language, specifications and prosecution history, the court concludes that claims 19-21 of the '273 patent should be plainly construed to cover a coextrudate which is a facestock, or plastic film, formed solely by simultaneous, or joint, extrusion of several materials through a die. The immediate result of this simultaneous extrusion, or coextrusion, is a multilayer film wherein the layers are firmly adhered to one another in a permanently combined state, i.e., the patented coextrudate. A facestock formed by adhering preformed layers is not within the scope of claims 19-21 of the '273 patent. Further, in claim 19, the coextruded product must have (1) a thick core or base layer (with a stiffness of between 10 and 100 Gurley); (2) at least one thin ink-printable skin layer on the face side of the product; and (3) a pressure-sensitive adhesive layer on the side opposite the face side. In claim 20, the product is the same as in claim 19 with the addition of a second skin layer between the core or base layer and the adhesive layer. In claim 21, the product is the same as in claim 19 with the addition of a releasable liner on the adhesive.

The parties, especially UCB Films, have also devoted substantial time to arguing that the phrase "core or base layer" in the claims must mean "core layer or base layer" (meaning the core must be made up of only one layer) and not, as Avery argues, "core" (which could have one or more layers) or "base layer." However, the court finds that the patent specifications, on which UCB Films primarily relies, use both the term "core" (e.g. '273 Patent; Column 10, Line 46) and the phrase "core layer" (e.g. '273 Patent, Column 10, Line 60). This court is thus unwilling to apply UCB Films' reading to the claims and cannot find on the basis of this argument that the claims are limited to a core composed of a single layer.

As stated previously in this opinion, the court's construction of the claims of the '273 patent is largely applicable to the facestock portions of the process patents. In light of the above claim construction, this court finds that there are disputed issues of material fact as to whether UCB Films infringed the patents and that infringement remains a question of fact to be submitted to a jury. The motions for summary judgment [154-1, 250-1] are therefore denied.
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5. a first [or second] collection of labeled nucleic acid is construed to mean multiple nucleic acid molecules labeled with a first [or second] label.

Affymetrix contends that this term means multiple nucleic acid molecules labeled with a first [second] label. Hyseq contends that this term means multiple non-identical nucleic acid molecules labeled with a first [second] label.

Incyte originally did not propose a construction of this term.

The Court finds that the plain and ordinary meaning of a "collection of labeled nucleic acid" is merely an aggregation or accumulation of nucleic acid and does not, as Hyseq suggests, require the labeled nucleic acids to be non-identical. Although the examples from the specification that are cited by Hyseq may reflect embodiments where "collection of labeled nucleic acid" refers to non-identical molecules, the Court finds that these usages do not in any way disclaim the

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conventional meaning of the word "collection." Hyseq's definition would impermissibly import an extraneous limitation from the specification into the plain meaning of "collection." For the reasons discussed above, the Court cannot rewrite the claims based on asserted non-enablement. The Court thus adopts the construction recited above.
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E. "Colloidal Gold Particles Coupled to the Bound Target Compound"

Claim Term	Eppendorf's Construction	Nanosphere's Construction
"colloidal gold particles coupled to the bound target compound"	one or more gold nanoparticles directly or indirectly linked to the target compound bound to the capture molecule	colloidal gold particles directly attached by a chemical bond to a bound "target compound"

Claim 4 of the '829 Patent describes the method of identifying and quantifying a target compound as involving the chemical reduction of silver in the presence of "colloidal gold particles coupled to the bound target compound." '829 Patent, col. 12, II. 3-4. The Court has determined that Eppendorf's proposed language is consistent with the intrinsic evidence, and is the appropriate construction.

First of all, the parties have agreed that "colloidal gold particles" means "gold nanoparticles or 'nanogold.'" (Supp. Markman Letter, App'x at 1.) As for the "coupl[ing]" of those particles to the target compound, the "preferred embodiment" of the '829 Patent illustrates that this can be accomplished either directly or indirectly:

> Direct labelling of the target molecules with gold is possible by usinggold-labelled antigens, antibodies or nucleotides.
>
> An alternative is to avoid any labelling of the target molecule, and then a second nucleotide sequence is used which is labelled. They then formed a sandwich hybridisation or a sandwich reaction with the capture molecule fixing the target and the labelled nucleotide sequence ….

Id. at col. 4, II. 55-63. Because the specification provides examples in which colloidal gold particles can be "coupled to the bound target compound" directly or indirectly, restrictively construing "coupled" to include only "directly attached," "the term 'coupled to' is entitled a broader scope" which encompasses indirect linking. Bradford Co. v. ConTeyor N. Am., Inc., 603 F.3d 1262, 1271 (Fed. Cir. 2010); see also id. at 1270-71 (construing "coupled to" to allow for both direct and indirect attachments in a collapsible shipping containers patent, because the claim terms provided examples of indirect attachments).

Turning next to "bound target molecule," Nanosphere again repeats the words themselves in its proposed construction, without explaining what "bound target molecule" means. Eppendorf's definition, in contrast, provides context for the words, by providingthat a "bound target molecule" is "the target compound bound to the capture molecule." This definition is consistent with the "Summary of the Invention" section of the specification, and claim 1, which explain that the method described in the '829 Patent "put[s] into contact the target compound with a capture molecule in order to allow a specific binding between said target compound with a (corresponding) capture molecule," '829 Patent, col. 2, II. 44-48; col. 11, II. 47-49; see also id. col. 12, II. 5-7, 9-11, & 13-15 (describing the "binding between the target compound and its corresponding capture molecule"). Thus, Eppendorf's construction of "colloidal gold particles coupled to the bound target compound" has been adopted.
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3. "Colloidal silica sol." Consistent with the plain meaning of the terms and the intrinsic evidence, the term "colloidal silica sol" shall mean "a dispersion of silica particles, as defined above, in a liquid."
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2. "Colloidal silicic acid." Consistent with the plain meaning of the terms and the intrinsic evidence, the term "colloidal silicic acid" shall mean "a dispersion of silica particles, as defined above, or polysilicic acid in liquid."
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a. Claim Construction

To determine the "true meaning" of a disputed claim, a Court must examine: 1) the claim at issue; 2) the specification, and 3) the prosecution history. ZMI Corp., 844 F.2d at 1579; Loctite, 781 F.2d at 867; American Standard, 722 F. Supp. at 92. The threshold requirement in claim construction is an examination of the language of the claim itself. McGill, Inc. v. John Zink Co., 736 F.2d 666, 672 (Fed. Cir.), cert. denied, 469 U.S. 1037, 83 L. Ed. 2d 404, 105 S. Ct. 514 (1984). In this regard, the "terms of a claim will be given their ordinary meaning, unless it appears that the inventor used them differently." ZMI Corp., 844 F.2d at 1579. A court must construe the claim as it would be construed by one who is skilled in the art. Loctite, 781 F.2d at 867. To this end, the court could consider the testimony of experts; "such testimony is evidence of construction of the claims as they would be construed by those skilled in the art." McGill, 736 F.2d at 675; American Standard, 722 F. Supp. at 92.

Thus, in this case, to determine the scope of Claim 5 of the Burlone patent, the Court must resort to the language of the claim itself, the specification, and the prosecution history. In construing the claims, the Court will consider the trial testimony of the various experts.

1) Claim Construction -- The Claim Language

A patent claim typically has three parts: 1) the preamble; 2) the transition; and 3) the body. 2 Donald S. Chisum, Patents § 806[1][b] (1994). The preamble is "an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties." Id. It may also constitute a limitation on a claim. Id. The transition is a phrase containing a term such as "comprising" that serves to connect the preamble to the body of the claim. Id. The third part of a patent claim, the body, is composed of the recitation of the elements and limitations that "define the product or process to be encompassed within the patent monopoly." Id.

In this case, the Burlone patent is entitled "Polymeric Color Concentrates for Thermoplastic Polymeric Materials." (JTX 1). Claim 5 of the Burlone patent recites: "The color concentrate of claim 2 . . . " Claim 2 in turn recites: "The color concentrate of claim 1 . . . " Claim 1, the only independent claim of the Burlone patent, begins with the following preamble: "A color concentrate for coloring thermoplastic polymeric materials . . ." One of the fundamental disputes between the parties in this case revolves around the meaning of the term "color concentrate" and the effect that should be given to the language of the preamble: "color concentrate for coloring thermoplastic polymeric materials."

DuPont contends that: 1) the ordinary meaning of "color concentrate" is a blend of a carrier polymer and a concentrated amount of pigment that is used to color something else, a host polymer, and 2) the language of the Burlone patent supports this ordinary construction of the term. Based upon the language of the claims and, particularly, the language of the preamble of Claim 1 as incorporated into Claim 5, DuPont contends that the Burlone patent relates to "a specific kind of material, a polymer-based 'color concentrate' for coloring other polymeric materials." (D.I. 278 at 2). In other words, DuPont contends that the preamble -- "a color concentrate for coloring thermoplastic polymeric materials" -- is a limitation on the claims of the patent, and that LUMENA does not infringe the Burlone patent because LUMENA does not meet this limitation.

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According to DuPont, LUMENA is not a "color concentrate" as the term is understood both in the art and in the Burlone patent, and it is not used to color thermoplastic materials. Rather, LUMENA is an already-colored host polymer that is not used to color any other material.

BASF contends, on the other hand, that the preamble of the claims does not impose any such end-use limitation on the color concentrate described in Claim 5. Rather, according to BASF, "if a composition contains the components described by the claims of the Burlone patent, that product is a 'color concentrate,' and is covered by the patent, no matter what name or label may be applied to it by someone else, or how it may be used." (D.I. 273 at 23). In other words, the Burlone "color concentrate" must be interpreted as Dr. Burlone defined it in his patent, and if a composition contains the two components recited by the claims of the Burlone patent, catdye nylon and colored pigment, then that product is a Burlone "color concentrate," regardless of whether it is ultimately used to "color thermoplastic polymeric materials."

Thus, the first issue to be resolved in construing Claim 5 of the Burlone patent is whether the preamble recitation, "a color concentrate for coloring thermoplastic polymeric materials", is a limitation on the claim. It is well-settled that the "preamble of a claim does not limit the scope of the claim when it merely states a purpose or intended use of the invention." In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). Nevertheless, "terms appearing in a preamble may be deemed limitations of a claim when they 'give meaning to the claim and properly define the invention.'" Id. (quoting Gerber Garment Technology, Inc. v. Lectra Systems Inc., 916 F.2d 683, 688 (Fed. Cir. 1990)). There is, however, no "litmus test" to determine when the introductory words of a claim, the preamble, constitute an additional limitation of the claim, or when the words represent mere introductory language. Id.; Corning Glass Works v. Sumitomo Electric, Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). Rather, the issue of whether a preamble constitutes a claim limitation must be determined on the facts of each case in light of the claimed invention as a whole. In re Stencel, 828 F.2d 751, 754 (Fed. Cir. 1987). The effect that should be accorded to the words contained in a preamble "can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works, 868 F.2d at 1257. The terms of a claim must be given their ordinary meaning, unless it appears that the inventor used them differently. ZMI Corp., 844 F.2d at 1579. In this regard, the Federal Circuit has recently stated that:

The focus in construing disputed terms in claim language is not the subjective intent of the parties to the patent contract when they used a particular term. Rather the focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995).

DuPont's expert, Dr. Cohen, testified as to his pre-lawsuit understanding of what a color concentrate is:

[A] color concentrate is a concentrated mixture, blend, of a pigment or colorant, it could be a dye, in a carrier vehicle. A small amount of that is usually added to a material to be colored. And when you do that, you impart a predetermined color to that material to make a final product.

(D.I. 294, Cohen, Tr. at 472). With regard to the amount of colorant by weight that is typically contained in commercial color concentrates, Dr. Cohen testified that such commercial color concentrates typically contain "ten, fifteen percent or greater", but in any event, "as much [colorant] as possible." (D.I. 294, Tr. at 472, 494-95). Dr. Cohen also testified that his understanding of color concentrates was consistent with the definition provided by Robert A. Charvat in an article entitled "Introduction to Color Concentrates For Plastics" that appeared in the July/August 1968 issue of Color Engineering. In that article, Mr. Charvat defined a color concentrate as:

[A] resin in which a high concentration of a single pigment or combination of pigments has been dispersed. When a specified quantity of the concentrate is mixed with a specified quantity of natural (uncolored) resin, a predetermined color should be produced. Pigment colors may be as low as 10 percent or as high as 70 percent with the remaining portion being a polymer designed to work with a specific polymer family.

(DTX 250; D.I. 204, Tr. at 473-74). A "resin" is a polymer. (D.I. 293, Tr. at 207). According to Dr. Cohen, color concentrates are typically mixed with a fiber-forming host polymer, and then the mixture is spun into fiber. (D.I. 294, Tr. at 473). Based upon his review of the Burlone patent and the prosecution history, Dr. Cohen opined that Dr. Burlone used the term "color concentrate" in his patent as the term had been understood by those skilled in the art. (See, e.g., D.I. 294, Tr. at 480).

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Like DuPont's Dr. Cohen, BASF's witnesses, Dr. Burlone and Dr. Harris, each testified as to his understanding of the term "color concentrate" in 1979, prior to the Burlone invention. According to them, the two basic components of a color concentrate as understood in the art were: 1) a colorant, i.e., a pigment or dye, and 2) a vehicle polymer to disperse and carry that colorant. (D.I. 293, Tr. at 50; D.I. 294, Tr. at 395). With regard to the level of pigment that was typical of color concentrates in the art, Dr. Burlone testified that the lower limit on pigment levels in traditional color concentrates was typically about 25% or 35%. 4 (D.I. 293, Tr. at 53). It is BASF's position that, in contrast to these lower levels of pigment that were typical of traditional color concentrates (i.e., 25% to 35%), Claim 5 of the Burlone patent discloses a composition containing pigment levels from 1% to 70%. According to BASF, traditional color concentrates that are intended for use in adding color to other materials are not typically sold at the level of 1% pigment; rather, such 1% blends are typical in the art of blends that are spun directly into fiber. (D.I. 293, Tr. at 54, 255; D.I. 287, at 4). Thus, BASF argues, because the Burlone patent specifically claims pigment levels at 1%, it follows that Dr. Burlone did not use the term "color concentrate" in his patent as the term had been understood by those skilled in the art. (E.g., D.I. 293, Tr. at 284; D.I. 294, Tr. at 392). Instead, Dr. Burlone defined his color concentrate in a different way than had been understood in the art, and DuPont's LUMENA infringes the color concentrate as defined in the patent. 5 According to BASF, because Dr. Burlone specifically described his "color concentrate" as having pigment levels from 1% to 70%, his claimed color concentrate, unlike traditional color concentrates that may have been limited in use to coloring other materials, is capable of being spun directly into fiber at its lower pigment levels. (D.I. 293, Tr. at 186, 286). In support of this contention that the Burlone color concentrate is not limited to "coloring thermoplastic polymeric materials" and, in fact, can be spun into fiber at claimed 1% pigment levels, BASF points to the trial testimony of Dr. Burlone and Dr. Harris. (See, e.g., D.I. 293, Tr. at 73-74, 284; D.I. 294, Tr. at 384, 392). BASF also points to several places in the text of the patent wherein pigment levels from 1 to 70 percent are described. 6 (D.I. 273, at 11; JTX 1, col. 3, 11. 28, 34,; col. 10, 1. 16).

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4 Dr. Harris testified that he did not know whether anyone had ever specified what the pigment level in a color concentrate is. (D.I. 294, Tr. at 394). 5 Dr. Harris testified at trial that the level of pigment recited by Claims 1, 2, and 5 of the Burlone patent is satisfied by the pigment content in the LUMENA, DSDN, and Berber blends. (D.I. 293, Harris, Tr. at 284).6 The "1 to 70 percent pigment" language is found in at least four places in the Burlone patent. First, the specification provides: "very beneficial results are obtained when the coloring agent is a pigment, which is present in the color concentrate in an amount sufficient to provide from about 1 to 70 percent by weight thereof . . . " (JTX 1, Tab 1, col. 3, 11. 26-30). The specification also states that "equally beneficial results are achieved, moreover, if the coloring agent is a dye, which is present in the color concentrate in an amount sufficient to provide about 1 to 70 percent by weight thereof . . . " (Id., 11. 31-34). Third, Claim 3 of the patent recites: "The color concentrate of Claim 2, wherein the coloring agent is a pigment, which is present in the color concentrate in an amount sufficient to provide from about 1 to about 70 percent by weight thereof . . . " (Id., col. 10, 11. 13-16). Claim 4 also includes the "1 to about 70 percent" pigment language. (Id., col. 10, 1. 21). In addition to the patent text itself, the patent examiner stated in his reasons for allowance of the Burlone patent that "Component B (1-70 wt%) consists of a non-reactive dye . . . " (JTX-2-C, P3).

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After careful consideration of the language of the claims and the testimony of the experts at trial, the Court finds that the phrase in the preamble of Claim 1 of the Burlone patent as incorporated through Claim 5, "a color concentrate for coloring thermoplastic polymeric materials", is not merely introductory in nature but rather, "breathes life and meaning into the claims and, hence, is a necessary limitation to them." See Loctite, 781 F.2d at 866. The testimony of DuPont's Dr. Cohen demonstrates that the way he understood the term "color concentrate" prior to this lawsuit was as a mixture of a high concentrate of pigment and another substance that is used to color something else. The express language of the Burlone claims reveals that Dr. Burlone did not ascribe a different meaning to the term "color concentrate" than that which had been understood by those in the art, such as Dr. Cohen. In particular, the preamble is entirely consistent with Dr. Cohen's testimony regarding the ordinary construction of the term "color concentrate" because the preamble discloses a color concentrate "for coloring thermoplastic polymeric materials." That the preamble breathes life into the claims of the patent is evident in subpart (A)(4) and part (B) of Claim 1. Subpart (A)(4) imposes the limitation that the claimed concentrate must be capable of being "melted with the thermoplastic material to be colored without substantial degradation or reaction . . . " Clearly, the preamble language is absolutely necessary to give meaning to subpart (A)(4) of Claim 1 because, if the preamble language were not present, then the "thermoplastic material to be colored" in subpart (A)(4) would be meaningless. In other words, if the preamble did not disclose a color concentrate for coloring thermoplastic polymeric

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materials and, if such an end-use were not, in fact, built into the claim, then the property described in subpart (A)(4), capable of being "melted with >the thermoplastic material to be colored", would make no sense; if there were no material to be colored, then there would be no way to test the property that is recited in subpart (A)(4). Said yet another way, subpart (A)(4) of Claim 1 cannot be read independently of the preamble; the preamble is essential to give definition to subpart (A)(4) of Claim 1. In short, every element of a claim is "material and essential" and, in Claim 1, the preamble is necessary to give meaning and effect to subpart (A)(4). 7 See Environmental Instruments, Inc. v. Sutron Corp., 877 F.2d 1561, 1564 (Fed. Cir. 1989) (words of a claim "have meaning and must be given effect."); Lemelson v. United States, 752 F.2d 1538, 1551 (Fed. Cir. 1985) ("each element of a claim is material and essential").

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7 In this regard, Dr. Burlone's testimony that the limitation described in subpart (A)(4) is not always important and need not be met in every application of his invention is not credible. (D.I. 293, Tr. at 209-10). Dr. Burlone testified that if his claimed color concentrate is not going to be used to color anything else, then the limitation described in subpart (A)(4) of Claim 1, "capable of being melted with the thermoplastic polymeric material to be colored without substantial degradation or reaction . . . ", is a non-issue. Similarly, BASF's Dr. Harris testified that elements (A)(1) through (A)(4) of Claim 1 are properties of the invention that need not be utilized in every application. (D.I. 294, Tr. at 294). Both witnesses opined that the claimed invention need only have the capability of interacting with the thermoplastic material to be colored in the ways specified in subpart (A)(4) and part (B). The Court rejects this testimony.

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Similarly, the preamble is necessary to give meaning to part (B) of Claim 1. Part (B) defines the second essential component of the Burlone color concentrate: "a heat-stable, chemically-inert coloring agent . . ., the coloring agent causing no visible chemical reaction with the thermoplastic material to be colored . . . " Again, as in subpart (A)(4), the language of the preamble is necessary to breathe life into this claim because, without the preamble, the language of part (B) is meaningless. Like subpart (A)(4), part (B) cannot be read independently of the preamble. Furthermore, the language of part (B) makes clear that component (A) of the claimed color concentrate is separate from, and does not include, the material to be colored. Part (B) provides in part: "the coloring agent causing no visible chemical reaction with the thermoplastic material to be colored or the . . . [polymer defined in part (A)]." (emphasis added). The "or" in Part (B) separates the thermoplastic material to be colored from the polymeric component (A), evidencing that the two materials are distinct from each other; to satisfy part (B), the coloring agent must not cause a visible chemical reaction with either one. (See D.I. 294, Tr. at 499). Even BASF's Dr. Harris conceded that such a distinction exists in part (B). (D.I. 294, Tr. at 402). Moreover, unlike elements (A)(1) through (A)(5) of Claim 1, the limitation described in part (B) does not follow the "capable of" language of part (A), and so, BASF's argument that the claimed invention need only have the capability of meeting the described limitations is unavailing as to part (B). (See supra note 7). In this regard, the Court rejects Dr. Harris's testimony that the limitation described in part (B) recites merely a capability of the claimed invention. (See D.I. 294, Tr. at 392).

At trial, Dr. Cohen testified that subpart (A)(4) and part (B) of Claim 1 of the Burlone patent would make no sense without the preamble. (D.I. 294, Tr. at 482-83). The Court agrees. Consequently, the Court finds that, based upon, inter alia, the testimony of Dr. Cohen, which the Court finds to be credible on this point, and the language of subpart (A)(4) and part (B) of Claim 1 of the Burlone patent, the preamble of Claim 1 as incorporated into Claim 5 gives meaning to the elements of the claim and is a necessary limitation to the claim. See Schering Corp. v. Precision-Cosmet Co., Inc., 614 F. Supp. 1368, 1375 (D. Del. 1985) (introductory phrase was a claim limitation because the phrase was essential to point out the subject matter defined by the claims).

In reaching this conclusion, the Court rejects BASF's argument that the phrase "for coloring thermoplastic polymeric materials" merely describes one possible usage of the claimed color concentrate. 8 Although a phrase in a preamble that merely states an intended use of the claimed invention is not a claim limitation, the language of the claims in the Burlone patent, particularly the language of subpart (A)(4) and part (B), unequivocally makes clear that the phrase "for coloring thermoplastic polymeric materials" is more than a mere intended use. The phrase is necessary to define the claimed invention because it is only by reference to the preamble that the elements of the claim have meaning. Thus, notwithstanding the "1 to 70 percent pigment" language, subpart (A)(4) and part (B) of Claim 1 expressly define the claimed invention in terms of its properties in reference to the "thermoplastic material to be colored" of the preamble. Accordingly, based upon the claim language taken as a whole, the Court is unpersuaded by BASF's argument that the "1 to 70 percent pigment" language compels a finding that the disputed preamble phrase is merely an intended use and not a claim limitation.

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8 According to BASF, the Burlone color concentrate is not limited by the preamble because the concentrate need not be used to color another material; rather, it can be spun directly into fiber at its lower pigment levels. On this point, BASF relies principally upon the testimony of Dr. Harris and Dr. Burlone wherein they assert that, as evidenced by the specification and by the language of Claim 3, see supra note 6, the color concentrate claimed in the Burlone patent covers blends with pigment levels of about 1% to 70%.

To be sure, Claim 3 is not asserted against DuPont in this case; nevertheless, Dr. Harris testified at trial that the pigment levels recited in Claim 3 are useful to understand the pigment levels of the color concentrate recited by Claim 1. (D.I. 293, Tr. at 319). Accordingly, he testified that the pigment levels of the color concentrate described in Claim 1 are also about 1% to 70%.

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The Court's conclusion in this regard is supported by the testimony of Dr. Cohen. Dr. Cohen testified that, although color concentrates in the art typically contained at least 10-15% pigment, it was his opinion that, based upon the claims and prosecution history of the Burlone patent, Dr. Burlone was claiming a color concentrate for coloring thermoplastic polymeric materials containing, at the extreme, pigment levels of 1%. 9 (D.I. 294, Tr. at 583-86). In other words, the fact that the Burlone patent recites pigment levels below 10% does not necessarily mean that Dr. Burlone used the term color concentrate in a different way than had been understood in the art, nor does it mean that the claimed color concentrate would be incapable of coloring thermoplastic polymeric materials at its lower pigment levels. 10 In short, the determination of the effect of the preamble can be resolved only on review of the entirety of the patent, and it is upon this basis that the Court rests its decision with regard to the effect of the Burlone preamble.

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9 On this point, the Court finds the testimony of Dr. Cohen to be credible, and the Court rejects the testimony of Dr. Burlone and Dr. Harris. 10 In fact, Dr. Burlone conceded that his claimed color concentrate would be capable of coloring an uncolored polymer at its 1% pigment level. (D.I. 293, Tr. at 258; see also Harris, Tr. at 329).

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The cases cited by BASF do not change this analysis. For example, BASF relies on Funnelcap, Inc. v. Orion Industries, 421 F. Supp. 700 (D. Del. 1976). There, the preamble of the patent at issue ("the Nowak patent") claimed:

1. A funnel, for use on a container, said container having a circular upper surface, a container flange upwardly directed from the periphery of the upper surface, and a container lip extending radially from the upper edge of the container flange, comprising:

[elements a through f].

Id. at 703. In support of its argument that the Nowak patent was not anticipated by the prior art, Funnelcap argued that its patent claim was limited in its preamble to "funnels", and the term "funnel" necessarily connotes a conically-shaped device. Id. at 707. According to Funnelcap, the prior art device did not constitute such a structure, and therefore, the Nowak patent was not anticipated. The Court rejected the patentee's argument, reasoning that a patentee is his own lexicographer, and Mr. Nowak defined his funnel in his patent as a "device comprising" elements (a) through (f). Because the prior art device read on all of those claim elements, the prior art device was a funnel within the meaning of the preamble of the Nowak patent. Id.

Based upon Funnelcap, BASF argues that whether a given composition is a "color concentrate" as defined by Dr. Burlone can only be determined by comparing the chemical components of that composition with the two essential components of the blend described in Claim 5 of the Burlone patent. If the components of the blend in question conform to the components recited by that claim, then the blend is the "color concentrate" within the meaning of the Burlone patent.

The Court observes that Funnelcap does not hold that a term in a preamble of a claim can never be a claim limitation. Rather, the Funnelcap Court rejected the patentee's attempt to construe the preamble term "funnel" as a claim limitation

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because this construction was inconsistent with the patent specification, which revealed that the device was not limited to a conically shaped instrument. Similarly, in this case, the Court's construction of the preamble term "color concentrate" is completely consistent with Dr. Burlone's use of the term in his specification. (See infra section (D)(1)(a)(2)).

BASF also cites Kropa v. Robie, 38 C.C.P.A. 858, 187 F.2d 150, 152 (C.C.P.A. 1951), for the proposition that a preamble is denied the effect of a limitation when it merely states a purpose or intended use of the invention. However, as discussed above, the preamble in this case does not merely state a purpose or intended use of the invention; rather, the preamble is necessary to define the invention. Moreover, according to the Kropa Court, a preamble is denied the effect of a limitation where the "portion of the claim following the preamble [is] a self-contained description of the structure not depending for completeness upon the introductory clause". Id. at 152. In contrast, the invention claimed by the Burlone patent most certainly depends upon the preamble for completeness and is "necessary to give life, meaning and vitality to the claims." Id.

None of the other cases relied upon by BASF compels a conclusion contrary to the Court's conclusion that the language of the Burlone patent claims supports a construction of the preamble as a limitation on the claims. 11 Nevertheless, the ordinary meaning of claim language does not end the inquiry. The Court must still resort "to the specification and prosecution history to determine if the inventor used the disputed terms differently than their ordinary accustomed meaning." ZMI Corp., 844 F.2d at 1580.

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11 BASF also relies upon Marston v. J.C. Penney Company, 353 F.2d 976 (4th Cir. 1965), cert. denied, 385 U.S. 974, 17 L. Ed. 2d 437, 87 S. Ct. 515 (1966), where the Court held that the preamble of the claim did not limit the claims because, inter alia, the preamble was "not essential to a reading and understanding of the claim." Id. at 986. Thus, Marston is distinguishable from the Burlone preamble which is essential to a reading and understanding of subpart (A)(4) and part (B) of Claim 1. BASF cites In re Sinex, 50 C.C.P.A. 1004, 309 F.2d 488 (C.C.P.A. 1962), where the Court held that the phrase "for reconcentrating liquid dehydrating agents" was merely a statement of intended use and not a claim limitation. Id. at 492. However, every patent must be considered on an individual basis, and In re Sinex does not change this Court's finding that the Burlone preamble is a claim limitation. BASF's citations to Data Line Corp. v. Micro Tech., Inc., 813 F.2d 1196, (Fed. Cir. 1987), DeGeorge v. Bernier, 768 F.2d 1318 (Fed. Cir. 1985), In re Lundberg, 47 C.C.P.A. 1140, 280 F.2d 865 (C.C.P.A. 1962), and Dotolo v. Quigg, 1989 U.S. Dist. LEXIS 13984, 12 U.S.P.Q.2D (BNA) 1032 (D.D.C. 1989), are similarly unavailing.

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2) Claim Construction -- The Specification

It is well established that "patent law allows an inventor to be his own lexicographer." ZMI Corp., 844 F.2d at 1580. Thus, "'the specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification.'" Id. (quoting Autogiro Co. of America, 384 F.2d 391, 397 (Ct. Cl. 1967)); see also McGill, 736 F.2d at 674. Accordingly, the Court must ascertain how Dr. Burlone used the term "color concentrate" in the specification of his patent.

In the specification, Dr. Burlone repeatedly used the term "color concentrate" in reference to the coloring of thermoplastics. For example, in the Abstract of his patent, he described his invention as:

> A color concentrate for coloring thermoplastic polymeric materials, which is prepared from a blend of a . . . polymer and a . . . coloring agent . . . .

(JTX 1 at 1) (emphasis added). In delineating the field of his invention, Dr. Burlone stated that his invention

> relates generally to the coloring of thermoplastics. In particular, it relates to the coloring of thermoplastics by the incorporation of color concentrates therein.

(JTX 1, col. 1, 11. 11-14) (emphasis added). In discussing the prior art, he stated:

> However, coloring of fibrous materials through the use of color concentrates is a less common practice. . . . The majority

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of color concentrates available today contain vehicles which are not totally compatible with, for instance, nylon, since nylon is one of the fibers which is less commonly colored by the addition of color concentrates.

Described here is the preparation of pigment or dye concentrates in vehicles which are compatible with common fiberforming thermoplastic materials, in particular nylon.

(JTX 1, col. 1, 11. 21-23, 30-38) (emphasis added). In the summary of the invention, Dr. Burlone stated:

Concentrates according to the present invention are utilized with especially advantageous results in coloring thermoplastic materials which are employed in the production of synthetic textile fibers.

(JTX 1, col. 3, 11. 36-39) (emphasis added). Similarly, in the 18 examples provided in his patent, Dr. Burlone uniformly described the use of his color concentrate in coloring another polymer, and consistently distinguished his color concentrate from the material to be colored. For instance, Example 1 provides in part:

One part of the solid color concentrate was blended with 29 parts of uncolored nylon-6 polymer . . . . This mixture was extruded into yarn . . . . Deeply colored blue fiber containing 1% pigment was obtained.

(JTX 1, col. 4, 11. 6-16) (emphasis added). Example 6 provides in part:

One part of the solid color concentrate was blended with 39 parts of uncolored nylon-6 polymer . . . . The mixture was extruded into fiber as in Example 1 to obtain deeply colored golden fiber containing 1% colorant.

(JTX 1, col. 5, 11. 6-10) (emphasis added). Example 7 states that "One part of the solid color concentrate was blended with 24 parts of uncolored nylon-6 polymer . . . " (Id., 11. 25-27). Example 10 provides: "One part of the color concentrate of Example 2 was blended with 29 parts of uncolored poly(ethylene terephthalate) . . . " (Id., 11. 54-56). All of the remaining examples in the patent employ similar language and, significantly, none of the examples refers to the final colored product containing 1% pigment as a color concentrate. (See D.I. 293, Tr. at 224; D.I. 294, Tr. at 414-15; JTX 11). Instead, each of the examples refers to the final colored product as "colored fiber". 12

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12 According to the evidence presented at trial, Example 17 of the Burlone patent, in which the carrier polymer is plain Nylon-6, is not within the scope of Claim 1. (D.I. 294, Harris, Tr. at 373-74).

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The repeated reference in the specification of the Burlone patent to the claimed "color concentrate" as a substance used to color another material indicates that Dr. Burlone did not employ the term "color concentrate" in a manner different from that which Dr. Cohen testified was understood in the art. (See D.I. 294, Tr. at 480). Rather, the specification patently demonstrates that the claimed color concentrate, a blend of pigment and carrier polymer, is directed to the use of color concentrates as that term had been used before in the art, i.e., to color another material. 13 What is absent from the specification is any meaningful indication that the host polymer, that is, the material to be colored, was within the scope of Dr. Burlone's claimed invention.

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13 See D.I. 294, Cohen, Tr. at 477 ("every single example [of the Burlone patent] is directed toward the production of a color concentrate and its use.").

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Nevertheless, BASF maintains that the specification of the Burlone patent supports its construction of Claim 5 as covering a blend having pigment levels of 1% to 70%, which, at the 1% level, can be spun directly into fiber. (See, e.g., D.I. 293, Tr. at 186). According to BASF, such 1% blends are literally embraced by Claim 5, which recites no numerical limit for the level of pigment in the blend. 14 (See, e.g., D.I. 293, Tr. at 86-88, 319). In support of this contention, BASF argues that the examples in the patent expressly describe blends having 1% pigment levels. For instance, BASF cites to Example 1, where

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"One part of the solid color concentrate was blended with 29 parts of uncolored nylon-6 polymer . . . The mixture was extruded . . . Deeply colored blue fiber containing 1% pigment was obtained." (JTX 2, col. 4, 11. 6-16). BASF argues that Example 1 describes a 1% blend that is "made by diluting the initial blend with nylon-6 in an extruder." (D.I. 273, at 11; D.I. 293, Tr. at 70).

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14 In contrast, DuPont contends that the claims of the Burlone patent have an "expressly-stated one-percent lower limit." (D.I. 294, Tr. at 495).

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The Court disagrees with BASF's construction of the patent examples. BASF argues that the examples in the specification disclose a Burlone color concentrate containing 1% pigment that is "made by diluting the initial blend" with the nylon-6 in the extruder. (See D.I. 293, Tr. at 79-81). Thus, it is BASF's position that the claimed color concentrate covers the initial blend of pigment and catdye polymer, and it covers the final blend after one part of the initial blend is "diluted" with 29 parts of the uncolored nylon. 15 (See, e.g., D.I. 293, Tr. at 57, 73-75, 79-81; D.I. 294, Tr. at 412-13). This argument, that Burlone Claim 5 covers the final colored blend that is spun directly into fiber, is essentially an attempt to argue that the claimed color concentrate covers the "thermoplastic polymeric material to be colored" of subpart (A)(4) and part (B) of Claim 1. Such an argument is completely inconsistent with the patent specification, which repeatedly distinguishes between the "color concentrate" and the uncolored nylon, or polymer to be colored. 16 BASF cannot now rewrite the Burlone patent. The specification makes clear that the claimed "color concentrate" is a substance that is separate from the thermoplastic polymeric material to be colored. 17 The Court, therefore, rejects BASF's argument, as well as the supporting testimony of Dr. Burlone and Dr. Harris, as inconsistent with the patent specification.

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15 At trial, BASF characterized the claimed color concentrate as having two stages. At the "first blend" stage, the color concentrate is composed of catdye polymer and 25-35% pigment; at the "second blend" stage, the initial color concentrate is "diluted" with uncolored nylon to the level of 1% pigment. (E.g., D.I. 293, Tr. at 74, 78-81; D.I. 294, Tr. at 335-36). 16 See, e.g., JTX 1, Example 1 ("One part of the solid color concentrate was blended with 29 parts of uncolored nylon-6 polymer . . . "). Moreover, at trial, Dr. Cohen testified that "these colored products, or these final colored materials, are excluded [from the scope of the claims of the Burlone patent]." (D.I. 294, Cohen, Tr. at 488). In support of his assertion that the final colored products are not included within the scope of the Burlone color concentrate, Dr. Cohen discussed an entry in the 1968 Kirk-Othmer Encyclopedia of Chemical Technology wherein "very clear distinctions" are made among carrier polymers, host polymers to be colored, and final colored products. (D.I. 294, Tr. at 491-493; DTX 251 at 589-90).17 See also part (B) of Claim 1 ("the coloring agent causing no visible chemical reaction with the thermoplastic material to be colored or the . . . [carrier polymer defined in part (A)].") (emphasis added). At trial, Dr. Harris conceded that in part (B) of Claim 1, the (A) polymer and the thermoplastic material to be colored are two different materials. (D.I. 294, Harris, Tr. at 402).

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Furthermore, the language in the specification and in Claim 3, wherein Dr. Burlone describes pigment levels from about 1 to 70 percent, does not change this Court's conclusion with regard to the effect of the preamble in this case. Notwithstanding the "1 to 70 percent pigment" language, all of the examples contained in the patent teach the addition of "one part of the solid color concentrate" to anywhere from 21 to 39 parts of an uncolored material. As discussed supra, subpart (A)(4) and part (B) of Claim 1 expressly define the claimed invention in terms of its properties in reference to the "thermoplastic material to be colored" of the preamble. Thus, based upon the entirety of the patent and its specification, and notwithstanding the "1 to 70 percent pigment" language, which the Court finds to be inconsistent with the patent claims and specification, the Court is unpersuaded by BASF's argument that the disputed preamble phrase states merely an intended use and not a claim limitation. Instead, the Court concludes that the specification of the Burlone patent supports a construction of the preamble as a limitation on the patent claims. See In re Walles, 54 C.C.P.A. 710, 366 F.2d 786, 790 (C.C.P.A. 1966) (introductory phrase "a composition for setting hair" was a claim limitation where the patent specification, including the discussion of the prior art and the examples, indicated that the invention was directed solely to compositions for setting hair).

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3) Claim Construction -- The Prosecution History

To interpret disputed claim language, the Court must also resort to extrinsic evidence, such as the prosecution history. ZMI Corp., 844 F.2d at 1580. The "'prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.'" Id. (quoting Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985)). Like the specification, the prosecution history of the Burlone patent reveals that Dr. Burlone repeatedly distinguished his color concentrate from the host polymer to be colored. For example, in the August 1981 request for reconsideration, Dr. Burlone's representative distinguished the Burke reference as follows:

As is clear from a study of the instant claims and the supporting specification, the polymeric component A of the present invention is merely a carrier for the introduction of coloring component B into a host polymer. Accordingly, when introduced into the host polymer to be colored, polymeric component A of the instant color concentrate dissolves or disperses in the host polymer leaving the coloring component B in a state identical to that in which it would be found if it were dispersed directly into the host polymer.

(JTX 2, at 51) (emphasis added). Further, in distinguishing his invention over the Kazenas reference, Dr. Burlone's representative argued that:

Kazeras [sic] describes the synthesis of a melamine-sulfonamide-formaldehyde resin and the coloring thereof. The final product, which is a colored resin containing 1-2% coloring agent, cannot be employed as a coloring agent such as that of the instant claims, wherein up to 70% of coloring agent is present for the purpose of combination with a virgin thermoplastic to produce a colored final product. In fact, if the pigments of Kazeras are to be used to color plastics, a method must be found for dispersing them in the host polymer.

(JTX 2, at 52) (emphasis added). During BASF's summary in the same August 1981 Amendment, it explained:

It is consequently impossible to arrive at applicant's invention as claimed by combining the non-reactive dyes of the primary reference with anything taught therein or in the secondary reference, in order to prepare a color concentrate for coloring thermoplastic polymeric materials . . . . What is lacking everywhere is any suggestion of a color concentrate, especially one which is prepared in accord with the recitations in applicant's claims.

(JTX 2, at 54) (emphasis added). In its June 28, 1982 Brief on Appeal, BASF distinguished the McIntosh reference, arguing that:

A color concentrate for coloring thermoplastic polymeric materials is neither taught nor suggested.

(JTX 2, at 81) (emphasis added). In distinguishing the Industrial Colours reference, Dr. Burlone's representative argued:

Industrial Colours describes the preparation of a liquid coating composition (ink, varnish, etc.) and not a color concentrate to be used for coloring thermoplastic materials, as recited in the instant claims.

. . .

That the colored resins of Industrial Colours are not meant to be color concentrates for thermoplastic polymeric materials is clear from an observance of the colorant level of the resin, which at 5% is too low to be useful in the coloration of a host polymer. Moreover, the resins specified by Industrial Colours could not be melted with a thermoplastic material to be colored without substantial degradation or reaction and without any visible separation therefrom on a microscopic scale.

(JTX 2, at 53-54, 86) (emphasis added).

The prosecution history of the Burlone patent, like the specification, demonstrates that the claimed invention is limited to a color concentrate for coloring thermoplastic polymeric materials. Although BASF repeatedly objects to DuPont's use of the carrier/host distinction because the terms "carrier" and "host" do not appear in Claim 5, the prosecution history of the patent reveals that Dr. Burlone's representative repeatedly described the Burlone invention to the PTO as a carrier polymer for

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introducing pigment into a host polymer. Dr. Burlone's representative expressly used the terms "carrier" and "host". Thus, BASF's objections to the use of the terms are foreclosed by its own use of the terms before the PTO.

The Court finds that the prosecution history of the Burlone patent supports a conclusion that the preamble of the claim, "color concentrate for coloring thermoplastic polymeric materials", is a claim limitation because BASF repeatedly characterized it as such before the PTO to distinguish its invention over the prior art. The prosecution history indicates that: 1) BASF specifically referred to its sulfonated component (A) as a carrier polymer for introducing the pigment component (B) into a host polymer, and 2) BASF repeatedly distinguished its claimed "color concentrate" from the host polymer to be colored. In addition, BASF expressly relied upon the limitation described in subpart (A)(4) of Claim 1 of the Burlone patent to overcome the prior art Industrial Colours reference. See JTX 2 at 53-54 ("the resins specified by Industrial Colours could not be melted with a thermoplastic material to be colored without substantial degradation or reaction and without any visible separation therefrom on a microscopic scale."); see also D.I. 293, Tr. at 207-14. Thus, BASF is estopped from now asserting that Burlone Claim 5 is not limited to a "color concentrate for coloring thermoplastic polymeric materials" and that subpart (A)(4) is not always important and need not be met in every application of the invention. As stated above, BASF's argument that the preamble is not a claim limitation because the Burlone color concentrate need not be used to color another material and, in fact, it can be spun directly into fiber, appears to be an attempt to argue that Burlone Claim 5 covers the "thermoplastic material to be colored" of subpart (A)(4) and part (B) of Claim 1. In light of the prosecution history, this argument is untenable. 18

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18 In this regard, the Court finds unpersuasive the testimony of BASF's Dr. Harris, wherein he testified that the above-quoted excerpts from the Burlone prosecution history are taken out of context. (See, e.g., D.I. 294, Tr. at 404-06). Similarly, the Court rejects BASF's characterization of the excerpts as "selective quotes." (D.I. 273, at 23).

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4) Claim Construction -- Conclusion

Based upon its review of the entirety of the patent, including the language of the claims and the specification, the entire prosecution history, and the evidence presented at trial, the Court concludes that the preamble recites a limitation on Claim 5 of the Burlone patent, which is directed to color concentrates for coloring thermoplastic polymeric materials.
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g. "water based acrylic colorant" and "colorant" Claims 1, 3, 4, 5, 7, and 8

The term "water based acrylic colorant" is defined as "a water-based substance having both a pigment and an acrylic component." This definition comes from the patent itself, which specifies that "[t]he colorant used to color the rubber particles, shreds, granules, and/or chips can be selected from a variety of different coloring systems, as long as the colorant is available in at least earth tone colors, readily adheres to rubber, and does not wash off the rubber when contacted by water." ('514 Patent, col. 4, ln. 66 through col. 5, ln. 3) The term "colorant" means "a substance used for coloring a material: dye, pigment." Merriam-Webster Online Dictionary (visited May 15, 2007) <http://www.m-w.com/dictionary/colorant>. While Defendants Rubber Mulch and Rubber Resources maintain that such colorant cannot have a binding agent, inherent in the coloring process is the fact that the colorant adheres to the rubber to form a coating. Thus, the Court will not adopt Rubber Mulch's definition that the colorant does not contain a binder.
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6. Colorant

Dependent claims three and six of the '793 patent and three and seven of the '622 patent provide for the inclusion of a colorant in the invention described in claims one and four, respectively, in order "to provide visual aid in applying the

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composition to a surface." Once again, the parties differ concerning this term, their disagreement centering upon whether the colorant must be a separately added ingredient, or instead can be inherent in one of the other prescribed constituents.

According to one authoritative chemical dictionary, the term "colorant" is described as a "substance that imparts color to another material or mixture. Colorants are either dyes or pigments and may be (1) naturally present in a material . . . (2) admixed with it mechanically . . . or (3) applied to it in a solution". Hawley's at 322. As can be seen, this definition does not appear to limit the term to color additives, but instead is sufficiently broad to allow for inclusion of pigmented or dyed materials already included within the formulation.

To be sure, there is some facial appeal to the argument that use of the phrase "further includes" in the relevant claims suggests that the addition of a separate colorant as an ingredient was envisioned by the inventors. This proffered interpretation, however, is belied by the illustrations given in the patent. Certain of the examples cited in the '793 patent describe materials which are in some way colored in appearance without the introduction of a separate ingredient to instill color. While in examples I and II a colorant (Caramel YT25) is added, example III describes a solution, with high maltose corn syrup and industrial grade magnesium chloride solution as the key ingredients, which has an appearance described as "[c]lear, light brown" without the addition of any separate colorant.

Based upon the cited examples, the stated objective of including a colorant, and the Hawley's definition of the term, in Cargill I defined the term "colorant" to include "a substance or material, whether inherent in or separately added to the specified composition, which imparts color to the composition," rejecting the restrictive reading of the term "further" which would exclude the possibility of a colorant already inherent and present in the solution described in claims one and four of the '793 patent. Because the ADM defendants raise no arguments not previously considered in connection with my Cargill interpretation of this term, I will adhere to that construction.

* * *

ORDERED as follows:

1) The disputed terms of the '793 and '622 patents are hereby construed by the court as follows:

Terms	Construction
*	*
"colorant"	a substance or material, whether inherent in or separately added to the specified composition, which imparts color to the composition

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Claim 36, which is representative of the other independent claim, reads:

A pharmaceutical composition of matter for use in the treatment, management or mitigation of the pain component of cough, cold, cold-like and/or flu symptoms in a mammalian organism, said composition comprising[:]

a sympathomimetically, analgesically and anti-inflammatorily effective amount ranging from 25 mg to 600 mg of ibuprofen or pharmaceutically acceptable salt thereof,

in combinatory immixture with 5 mg to 120 mg of pseudoephedrine or pharmaceutically acceptable salt thereof, and wherein the ratio by weight of said NSAID (i) to said sympathomimetic amine (ii) ranges from about 1.5:1 to about 8:1.

Thus, claim 36 defines a cough and cold medication comprising two ingredients--ibuprofen and pseudoephedrine--in "combinatory immixture." (As earlier noted, claim 37, which depends from claim 36, further limits the amount of ibuprofen to 200 mg and to 30 mg of pseudoephedrine; claim 48 claims a method of treating cough and cold symptoms using the claimed combination of claim 36, while claim 49 is a similar method claim incorporating claim 37.) The question then is

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whether this composition would have been obvious in view of the prior art. Since the patentee RVI does not argue the validity of the dependent claims separately, their validity will stand or fall with independent claim 36. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1536, 218 U.S.P.Q. (BNA) 871, 877 (Fed. Cir. 1983).

The trial court reviewed the claims, the written description, and the prosecution history, and concluded that the phrase "combinatory immixture" required "the two ingredients in a single form such as a tablet or elixir." Neither party seriously disputes this definition. Having conducted a similar review of the evidence relevant to claim construction, we find no error in this definition and adopt it as our own.

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5. Construction Of "Comparison Of Said Plurality Of Probe Intensities To Each Other"

Affymetrix's proposed construction of "comparison of said plurality of probe intensities to each other" is "an examination of the detectable signals of two or more probes in relation to each other." (D.I. 243 at 36.) Illumina's proposed construction is "ranking of probe intensities from a hybridization experiment." (D.I. 240 at 36.) The dispute here is whether the "comparison" must be a "ranking." The Court concludes that the "comparison" need not be a ranking.

The specification teaches several methods of comparison including the Intensity Ratio Method ('716 patent, col. 7, l. 34 - col. 10, l. 39), the Reference Method (Id., col. 10, l. 40 - col. 17, l. 44), and the Statistical Method (Id., col. 17, l. 45 - col. 22, l. 34). None of these methods can accurately be characterized as simply a "ranking of probe intensities." Thus, Illumina's proposed construction would exclude these embodiments. A proposed construction that excludes an embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support . ." Vitronics, 90 F.3d at 1583. The Court finds no such support here. Therefore, the Court construes "a comparison of said plurality of probe intensities to each other" to mean "an examination of the probe intensities of two or more probes in relation to each other."

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C. "competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-[alpha]"

Claim term, phrase or clause	Centocor's Proposed Construction
"competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-[alpha]"	"Competes with A2 (ATCC Accession No. PTA-7045) for binding to human TNF-[alpha]"

Claim term, phrase or clause	Defendants' Proposed Construction
"competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-[alpha]"	"ATCC PTA-7045 is a hybridoma deposited with the American Type Culture Collection. The product of the ATCC PTA-7045 includes the A2 antibody, which binds to human TNF [alpha]. An antibody 'competitively inhibits' A2 if, in a standard ELISA or equivalent assay: (i) the antibody blocks binding of the antibody product of ATCC PTA-7045 to human TNF [alpha] at least as well as the hybridoma product blocks itself; AND (ii) the blocking of the ATCC PTA-7045 product is due to the test antibody binding the same epitope of

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TNF-[alpha] as the antibody product of ATCC PTA-7045. An 'epitope' consists of amino acid residues on the antigen to which an antibody binds."

Within the '775 patent, the above phrase appears in independent claims 1 and 13 and dependent claims 4, 5, and 6. Within the '239 patent, the term appears in independent claim 9 and dependent claims 10-16.

In defining the above phrase, the defendants propose a construction that addresses "competitively" and "inhibits" separately. In defining "competitively," the defendants seek to require the A2 murine monoclonal antibody and the disclosed anti-TNF-[alpha] antibody to compete for the same epitope. In defining "inhibits," the defendants seek to require a definite quantitative level of inhibition.

1. "competitively"

Regarding "competitively," the defendants rely on the specification and the prosecution history for support. The specification's only specific example of competitive inhibition testing occurs between A2, the murine antibody, and cA2, an embodiment of the patent; the test involves a competition assay in which A2 and cA2 bind to the same epitope. See '775 Patent, col. 48, l. 58-col. 49, l. 67. Contrary to the defendants' assertion, however, the specification also allows for competitive inhibition between A2 and other "antibod[ies] having substantially the same specific binding characteristics." Id. at col. 12, ll. 4-8. Whether or not the experts agree on what a "similar epitope" is, the above cited passage implicitly allows for something more than a competition between A2 and an anti-TNF-[alpha] antibody for the same epitope. 8 Both the Harlow Laboratory Manual, incorporated by reference in the patents, and the prosecution history also teach against such a limitation. The manual states, "if the sites of interaction are identical or overlapping, the unlabeled antibody will compete." '775 Patent, col. 10, ll. 52-57; see ED HARLOW & DAVID LANE, ANTIBODIES: A LABORATORY MANUAL 567 (Cold Spring Harbor Laboratory 1988) (Ex. 17 to Pl.'s Reply Claim Construction Brief). Within the prosecution history, in response to an obviousness rejection, the patentee stated, "[t]hus, the claimed monoclonal antibodies, in their ability to inhibit A2 binding, must also bind to the same or similar epitope." U.S. Patent Application No. 08/192,093 ("the '093 application") at 7 (Ex. 17 to Defs.' Opening Claim Construction Brief). Accordingly, the weight of the support in both the specification and the prosecution history guides the court away from strictly defining the term as requiring competition for the same epitope. Contrary to the defendants' arguments, "overlapping," "similar," and "substantially the same" do not denote two epitopes that are identical.

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8 It is noteworthy that the Harlow Laboratory Manual also discloses a method "to test whether antibodies recognize similar sites on protein antigens." ED HARLOW & DAVID LANE, ANTIBODIES: A LABORATORY MANUAL 590 (Cold Spring Harbor Laboratory 1988) (emphasis added).

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2. "inhibits"

Regarding "inhibits," the defendants argue that without a quantitative level of inhibition, the claim is indefinite as written. The defendants suggest that, because the only competition assay disclosed in the specification requires competition between A2 and cA2, and A2 and cA2 share the same variable region, then the level of inhibition between A2 and cA2 would be the same as an assay that measured inhibition of an antibody against itself. Contrary to such logic, however, the specification incorporates by reference strategies and techniques for determining whether antibodies competitively inhibit binding to an antigen. See HARLOW & LANE at 567, 569. As suggested by the Harlow reference, competitive inhibition is characterized by whether the level of inhibition continues to increase as more of the competing antibody is added. Id.

For all the above reasons, the court adopts the plaintiffs' construction.

The court defines "competitively inhibits binding of A2 (ATCC Accession No. PTA- 7045) to human TNF-[alpha]" as "competes with A2 (ATCC Accession No. PTA-7045) for binding to human TNF-[alpha]."
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(10) Is complementary to a ribonucleotide sequence transcribed from said gene . . . The Court concludes that the non-naturally occurring RNA sequence described in elements (8) and (9) must be complementary to a naturally occurring RNA sequence produced by the gene. However, necessary to a complete construction of this claim is the meaning of the term "complementary," which is disputed by the parties. Enzo claims that the specification of the '931 Patent defines the term "complementary" as "capable of hybridizing." For example, in column 2, lines 63-66 of the '931 Patent, it states that the DNA construct is "transcribed to produce an mRNA (micRNA) which is complementary to and capable of binding or hybridizing with the mRNA transcribed by the gene to be regulated."

In interpreting a patent claim, a court generally gives the words in a claim their ordinary and customary meaning. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). However, "a patentee may be his [or her] own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Id. (citations omitted) (emphasis added). In reviewing the patent specification in this case, the Court concludes that the specification fails to clearly define the term "complementary." It is the Court's view that the use of the word "and" in the specification's references to the term "complementary" and the phrase "capable of hybridization" suggest that the specification is referring to two different characteristics of the RNA. While complementarity may be necessary for hybridization, the Court is not persuaded that the concepts are synonymous, such that one term defines the other. Accordingly, the Court rejects Enzo's contention that the patent defines the term "complementary."

Because the Court concludes that the term "complementary" is not given a special meaning in the '931 Patent, the Court must turn to the ordinary and customary meaning of the term. Ordinarily defined in the context of genetic technology, the term "complementary" means ". . . the capacity for the precise pairing of. . . bases between strands of DNA and sometimes RNA such that the structure of one strand determines the other." Webster's Ninth Collegiate Dictionary 269 (1983) (emphasis added).

Relying in part on this definition, Calgene contends that the term complementary should be narrowly construed to require complete complementarity. In response, Enzo maintains that complementary means "capable of hybridizing" and that there are no degrees or percentages of complementarity. Based on the record in this case, including the testimony of Dr. Knauf, which the Court finds credible, the Court rejects Enzo's argument and concludes that an appropriate definition of the term "complementary" requires quantification.

To the extent that Enzo's definition of complementary as "capable of hybridizing" suggests that the '931 Patent permits any degree of complementarity, the Court rejects Enzo's contention as contrary to the evidence and to existing precedent. Every example of operable antisense constructs in the specification of the '931 Patent involves a gene, or a portion of a gene, which is removed and inverted in the opposite orientation in a plasmid, and which thus, has complete complementarity with a single segment of the transcribed RNA. Indeed, because there are only four nucleotides which make up RNA, every RNA strand will have individual nucleotides and short sequences of nucleotides which are complementary to another RNA and thus, there would always be a theoretical possibility of hybridization. 9 However, if this were the case, and the Court were to accept Enzo's contention that complementary means "capable of hybridizing," and as such, any degree of complementarity is sufficient under the '931 Patent, then the "complementary" limitation would be meaningless.

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9 While the Court understands this to be an extreme example, it underscores the problem of accepting a definition of the term "complementary" which fails to quantify how much complementarity is required.

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In addition, the Court finds this issue to be analogous to the issue before the Court of Appeals for the Federal Circuit in Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed Cir. 1994). In Genentech, the phrase at issue was "human tissue plasminogen activator" ("t-PA"). In interpreting this phrase, the Court rejected the broad definition sought by the patentee, which would include proteins whose amino acid sequences were not identical to natural t-PA, so long as they

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included important segments of the sequence or were capable of serving the same function as natural t-PA. In rejecting this broad definition, the Federal Circuit noted that the definition would cover "an infinite number of permutations," many of which would be inoperable, and that there was "no basis provided in the specification for determining which of these permutations are operative and which are not." Id. at 1564 (citing Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212-14 (Fed. Cir. 1991)).

Similarly, in this case, the Court notes that the specification for the '931 Patent provides no guidance for determining when less than complete complementarity would make an operable antisense construct. Moreover, as discussed earlier, the specification only provides examples of operable antisense constructs that had complete complementarity with a single segment of transcribed RNA. Following the Genentech decision, the Court will reject the broad definition Enzo seeks, because the specification provides no basis for determining when less than complete complementarity would be successful. The Court concludes that this element of the claim requires the bases of the two RNA strands to precisely or exactly pair together according to the base pairing rules for RNA, such that complete complementarity exists between the two strands.

Also of importance to the interpretation of this claim is the meaning of the phrase "said gene" in element (10). In interpreting this language, the Court construes element (10) to require that the complementary RNA sequence must be transcribed from the gene described in element (3).
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Claim 23

The process according to claim 1, wherein the ladle metallurgy additive is a completely mixed granular material that is predominantly no larger than material that passes through a screen having one-inch square openings and no smaller than that which is retained by a 20-mesh screen. (emphasis added)

The key dispute here is with the phrase "a completely mixed granular material." Defendant's position is that this means a solid material with a mixture of recycled slag and raw material, each in the form of granules uniformly mixed together. Defendant says "completely" means "all" or "uniformly." Plaintiff's position is there is no mention of the particles being uniform. In other words, completely does not mean uniformly. Also, uniformly is used elsewhere in the patent, but not here.

Defendant again refers the Court to the specification which discusses "uniformly mixed granular material." But the specification never uses the word "completely" (Tr. 53-54). Defendant also argues that "if you go to the dictionary definition of completely, it says fully" (Tr. 54). The Court does not agree that the word "uniformly" is what is meant by "completely." Those two words have different meanings and are used in different places in the patent documents to convey specific, not synonymous, meanings.
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A. Claims 1, 12, and 13 and the definitions of "complex," "hexamer," and "formulation"

Lilly argues that "complex" (claims 1 and 12) 13 means "an equilibrium of association species and their free constituents in solution." Docket Item ("D.I.") 156 at 2. It then argues that the terms "complex is a hexamer" (claim 1) and "LysPro-human insulin is a hexamer" (claim 13) mean "nearly all of the human insulin analog in the solution are in the hexameric association state." 14 D.I. 156 at 2. Lilly also maintains that the term "formulation" does not have any meaning independent of the term "pharmaceutical," see Transcript ("Tr.") at 390:24-391:16, and that the phrase "pharmaceutical formulation" (claim 13) means "an aqueous solution formulated to be of appropriate safety and efficacy for treatment of patients." 15 D.I. 156 at 2.

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13 Since claims 1 and 12 are identical, except for the use of "comprises" in claim 1 and "consisting of' in claim 12, the

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meaning of "complex," "hexamer," and "formulation" will be identical for purposes of both claims. See Digital Biometrics Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998) (general rule is that same words in claims should be given same meaning). Therefore, for the remainder of the discussion of "complex," "hexamer," and "formulation," unless otherwise indicated, claim 1 will be used as the representative claim for claims 1 and 12. However, the Court notes that it departs from this general rule, as discussed infra, because the term "hexamer" means something different in claim 13 than it does in claims 1 and 12.

14 Lilly's exact argument is that "such that the insulin analog complex is a hexamer" means "an equilibrium of association species and their free constituents in solution where nearly all of the human insulin analog in the solution are in the hexameric association state." D.I. 156 at 2. When one removes the part of the definition that is identical to the definition of "complex," one is left with the definition of "hexamer" quoted in the text.

15 The term "pharmaceutical" is discussed in Part IV.C, infra.

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Novo first argues that "human insulin analog complex" (claim 1) means "a distinct arrangement of individual human insulin analog molecules that are associated or grouped together, with other individual components, all of which are in fixed numerical proportions with respect to each other." D.I. 154 at 25. It then argues that "complex" means "that the individual molecules come together or associate with each other to form a distinctive composition of matter or chemical species, also called an 'association state.'" D.I. 154 at 25. Novo contends that "hexamer" means "a distinct association of six molecules of one of the specified human insulin analogs, together with the specified two zinc ions and the specified at least three phenolic molecules, in a hexamer structure." 16 D.I. 154 at 28. Novo maintains that "pharmaceutical formulation" means "a composition that contains a medicinal drug or a biologically active agent and is suitable for administration to an animal." D.I. 154 at 33. However, Novo also implies that "formulation" alone refers to the equilibrium state. First, Novo argues that "complex" does not mean an equilibrium state because "complex is distinguished in the patent from formulations containing the complex." D.I. 172 at 7. Moreover, at the Markman hearing, Novo argued that "formulation" means "the equilibrium solution" or "putting it together in a solution or mixture," Tr. at 391:23-24.

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16 Novo further argues that the term "hexamer" contains a limitation that it is "not analogous to the R[6] hexamer of human insulin" ("the R[6] limitation"). D.I. 154 at 28. This limitation is discussed in Part IV.D, infra.

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Before discussing the merits of the respective definitions, it is helpful to discuss where the parties agree, and to define some short hand terminology that will make the discussion more concise. The following chemical equation summarizes how the individual molecules (or free constituents) of hIA, zinc, and phenolics come together to form a hexamer association state and shows the equilibrium between the individual molecules and the hexamer association state:

6 hIA + 2 Zn<+2> + 3 (or more) phenolic < -> (hIA)[6](Zn<+2>)[2](phenolic)[3] [(or more)]

[the individual molecules or free constituents] [the hexamer association state]

For convenience, the entire equilibrium between the individual molecules and the hexamer association state will be referred to as the "equilibrium," while each individual molecule or free constituent will be referenced by the general term "molecule." The term "molecular structure" will refer generally to any type of individual chemical association state of two or more molecules held together by non-covalent bonds. Finally, the individual molecular structure of six hIA molecules, two zinc ions, and at least three phenolics will be referred to as the "Zn-hIA structure."

Using this shorthand, Novo essentially argues that the term "complex" (claim 1) is a general term referring to any molecular structure and that "hexamer" (claims 1 and 13) refers to the Zn-hIA structure. Lilly agrees that individual molecules, molecular structures and Zn-hIA structures do exist. 17 However, Lilly argues that the term "complex" refers to the equilibrium containing molecules and molecular structures and that "complex is a hexamer" (claim 1) and "LysPro-human

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insulin is a hexamer" (claim 13) means that most of the species in the equilibrium are Zn-hIA structures. Novo agrees that an equilibrium exists and that the Zn-hIA structures exist as part of a larger equilibrium. 18 Indeed, Novo argues that "formulation" (claims 2-11 and 13) refers to the equilibrium containing the Zn-hIA structures. Thus, the parties agree that the molecular structures, Zn-hIA structures, and equilibrium exist. The dispute centers around whether the claim language is directed to a molecular structure or to an equilibrium.

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17 For example, Lilly's own definition of "is a hexamer" states that "most of the analog are in the hexameric association state" meaning that most of the hIA molecules are bound together with one another in Zn-hIA structures. D.I. 156 at 3. Also, Lilly's definition of "complex" as "equilibrium of association species and their free constituents in solution" means that the equilibrium contains many molecular structures. D.I. 156 at 2. In addition, in its Opening Brief Lilly argues that in the equilibrium, "nearly all the insulin analog molecules come together in six molecule units," which refers to molecular structures bonding together in Zn-hIA structures. See D.I. 156 at 8. Although Lilly argues that these structures exist nowhere in isolation, Lilly does not dispute that they do exist.

18 For example, Novo's attorneys admitted that the Zn-hIA structures exist as part of a larger solution or equilibrium. See Tr. at 347:22-348:9.

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The Court essentially adopts Novo's definition of "complex" and holds that the term "complex," as used in the claims (claims 1 and 12), is an individual molecular structure, i.e., "a chemical association state of two or more molecules held together by non-covalent bonds." 19 Next, the Court essentially adopts Novo's definition of "formulation" and holds that "formulation," in claims 2-11 and 13, means "an equilibrium containing molecules and molecular structures." Finally, the Court essentially adopts both Novo's and Lilly's definitions of "hexamer," holding that the term "hexamer" means different things in different contexts so that "complex is a hexamer" in claims 1 and 12 and "Lys<B28>Pro<B29>-human insulin is a hexamer" in claim 13 mean different things. 20 In claims 1 and 12, because it is being used in the context of individual molecules and their structure, the term "hexamer" refers to the Zn-hIA structure, i.e. "a type of complex where six molecules of human insulin analog are held together in a single structure." In claim 13, because it is being used in the context of a "formulation," which is an equilibrium, the phrase "LysPro-human insulin is a hexamer" is shorthand meaning "in the equilibrium, most of the LysPro-human insulin molecules are in Zn-hIA structures." Interestingly, at the Markman hearing Lilly's expert, Dr. Weiss stated that the term "hexamer" has these two competing definitions, depending on the context. 21

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19 As set forth in the text, infra, 1999 U.S. Dist. LEXIS 18690 *33-37, in the specification, complex refers to both a molecular structure and equilibrium, dependent upon the context. Because of the context of claims 1 and 12, complex refers to a molecular structure.

20 The Court recognizes that having two different definitions for "hexamer" violates the general rule of claim construction that the same word should be interpreted to have the same meaning throughout the claims. See Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1310 (Fed. Cir. 1999). However, "where the language of the written description is sufficient to put a reader on notice of the different uses of a term, and where those uses are further apparent from publicly available documents referenced in the patent file, it is appropriate to depart from the normal rule of construing seemingly identical terms in the same manner." Id. at 1311. When a term has different meanings in different contexts, "the term must be read to correspond only to the plausible meaning in each context." Id. As discussed in the test, infra, the claim language, the specification and the prosecution history fully support the two meanings of hexamer.

21

THE WITNESS [Dr. Weiss]: In general the word hexamer is used in two senses in this patent. It refers, if it's not modifying anything, hexamer by itself, it refers to the hexameric self association unit. . . . If it's modifying hexamer, if it's modifying complex either in the phrase hexamer complex or such that complex is a hexamer in this adjunct title sense, then it means that the equilibrium is such that nearly all the molecules are participating in one of the hexameric self association

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states.

Tr. at 80:19-81:7. The Court does not rely on this extrinsic evidence in resolving the issues. Nonetheless, it takes some comfort in Dr. Weiss' testimony.

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1. The Claim Language

The starting point for claim construction is the plain language of the claims. See Smiths Indus. Medical Systems, 183 F.3d at 1357. The claim language provides support for the Court's definitions of "complex," "hexamer," and "formulation."

First, claim 1 defines "complex" in terms of the number of molecules of hIA, the number of ions of zinc, and the number of molecules of phenolic. Because claim 1 refers only to eleven molecules, the term "complex" must refer to only an individual molecular structure, not to an equilibrium. If "complex" referred to an equilibrium, it would have to contain some of the individual molecules of hIA, zinc, and phenolics and some of the Zn-hIA structures. That is, the equilibrium would have to contain more than simply the eleven molecules listed in the claim. 22 It would not make sense for an equilibrium state to contain only the eleven molecules listed as part of the "complex."

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22 Lilly argues that the use of the term "comprising" in claim 1 means that the "complex" contains more than the listed eleven molecules in the equilibrium. This argument is unpersuasive for two reasons. First, as discussed in Part IV.C, infra, the term "comprising" means that the "complex" can contain other types of molecules not listed, but that it can contain six, and only six, hIA molecules and two, and only two, zinc ions. Second, claim 12 has the exact same claim language as claim 1 except that it uses the closed ended "consisting of" instead of "comprising." This language means that the "complex" in claim 12 contains only the eleven listed molecules. These eleven claimed molecules by themselves could not be an equilibrium between individual molecules and the Zn-hIA structures.

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Lilly also argues that the eleven molecules listed in claim 1 refer to the relative stoichiometric proportions of the molecules in the equilibrium. However, if this argument is correct, then Lilly's other definition of "complex is a hexamer" meaning that most of the molecules in the equilibrium are be in Zn-hIA hexamers cannot also be correct. To illustrate, accept for the moment that Lilly is correct. According to Lilly's definitions, claim 1 would then claim an equilibrium having hIA molecules and Zn ions in a 6:2 ratio where most of the molecules in the equilibrium are in Zn-hIA hexamers. However, the patent specification teaches a wide range of ratios of hIA molecules to zinc ions in the equilibrium, 23 while also teaching that in each individual hexamer structure there are exactly 6 hIA molecules and exactly two zinc ions. 24 The fact that the claim recites a whole number ratio of 6:2, as opposed to some fractional ratio, strongly indicates that the claim is directed to the structure, not the equilibrium. Moreover, the most preferred embodiment in the specification teaches that in order to achieve a solution of mostly hexamers, there must be more than two zinc ions for every six molecules of hIA. 25 Therefore, the list of the eleven molecules in claim 1 does not refer to the stoichiometric ratios of these molecules in an equilibrium. Rather, it refers to the number of molecules in the structure.

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23 The specification recites a sliding scale range of the preferred concentrations of hIA molecules to zinc ions in order for the solution to have mostly hexamers. See '978 Patent at 4:60-67. The preferred range of hIA is from 1.2 mg/mL to 17.5 mg/mL. See id. The preferred concentration of zinc is 14 [mu] g/mL to 35 [mu] g/mL. Converting these weights to moles reveals a wide range of ratios of zinc ions per hIA molecules. For these calculations the molecular weight of hIA is estimated at 6000 mg/mmol, see 8 McGraw-Hill Encyclopedia of Science and Technology, 264 (8th ed. 1997), and the molecular weight of zinc is 65.4 mg/mmol, see 19 McGraw-Hill Encyclopedia of Science and Technology, 699. The following calculations illustrate the point:

Smallest Ratio of hIA to Zn:

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hIA: (1.2 mg/mL)(mmol/6000 mg) = 2.0 x 10<-4> mmol/mL

Zn: (35 [mu] g/mL)(mg/1000 [mu]g)(mmol/65.4 mg) = 5.35 x 10<-4> mmol/mL

Ratio: 2.0 hIA:5.35 Zn = 6.0 hIA:16.0 Zn

Largest Ratio of hIA to Zn:

hIA: (17.5 mg/mL)(mmol/6000 mg) = 29.0 x 10<-4> mmol/mL

Zn: (14 [mu] g/mL)(mg/1000 [mu] g)(mmol/65.4 mg) = 2.14 x 10<-4> mmol/mL

Ratio: 29.0 hIA:2.14 Zn = 6.0 hIA:0.4 Zn

24 See '978 patent at 4:67-5:1.

25 Figure 3 illustrates that in order to achieve mostly hexamers, there must be an hIA concentration of 3.5 mg/mL. In this solution, the ratio of Zn ions to hIA molecules is 0.5. See '978 Patent at 3:37-38. Thus, the ration of hIA to Zn is 6.0 hIA:3.0 Zn, which is more than 2 zinc ions for every six molecules of hIA.

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In contrast, claim 13 defines a "formulation" in terms of the concentrations of the hIA, zinc, and phenolics in solution. Because claim 13 refers to the concentrations in solution, and not the number of molecules, the term "formulation" must refer to the equilibrium containing molecules and molecular structures. Moreover, the proportion of the hIA molecules to zinc ions is not the 6:2 ratio of these species in a single Zn-hIA structure. 26 Therefore, the term "formulation" must refer to more than just a molecular structure; it must refer to the overall equilibrium.

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26 Claim 13 claims a ratio of roughly 2.5 zinc ions to 6 hIA molecules.

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Because claim 1 claims a "complex," i.e., a molecular structure, the term "hexamer" is used in the structural sense to mean a single Zn-hIA structure. It would make no sense for the claim to read that most of the complexes are in the Zn-hIA molecular structure because the claim only lists the exact number of molecules needed to form one Zn-hIA molecular structure. It follows that "hexamer" is being used in the structural sense.

Because claim 13 claims a "formulation," i.e., an equilibrium, the phrase "Lys<B28>Pro<B29>-human insulin is a hexamer" means that most of the Lys<B28>Pro<B29>-human insulin molecules are associated into Zn-hIA molecular structures. It would make no sense for "hexamer" to have a structural meaning in this claim because it claims 3.5 mg/mL Lys<B28>Pro<B29>-human insulin, or about 3.5 x 10 <17> molecules per mL of solution. It would be absurd to say that this number of molecules "is a molecular structure." Rather, in the context of a "formulation" or equilibrium, it makes more sense for "hexamer" to have its shorthand meaning as most of the LysPro-human insulin molecules are in Zn-hIA structures.

Lilly counters that, in claim 1, the term "hexamer" cannot refer to a single Zn-hIA structure because the term "hexamer" would be superfluous. It further argues that "hexamer" cannot mean an individual molecular structure of six hIA molecules, two zinc ions, and at least three phenolic molecules because the "complex" is already defined as a molecular structure containing these eleven components. However, Lilly's position cannot withstand close scrutiny because "complex" is a general term referring to all types of molecular structures, including monomers, dimers, tetramers, and hexamers (Zn-hIA structures). As such, the term "hexamer" refers to a specific type of complex where six of the hIA molecules are bound together in a single structure. The term "hexamer" is not superfluous because a "complex, which comprises: six molecules of human insulin analog" could be a complex of three dimers or one hexamer. Therefore, "hexamer" has independent

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meaning as a complex where the six hIA molecules are bound together in a single structure.

Lilly further argues that "complex" must refer to the equilibrium state because claim 10 claims using a "complex" to treat a patient and a patient can only be treated with an equilibrium solution. 27 However, claim 10 actually claims using a "formulation" containing the "complex" to treat the patient. Since the "formulation" is the equilibrium, the Court's definitions of "complex" and "formulation" are fully consistent with the use of these terms in claim 10.

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27 Claim 10 actually recites using the "composition" of claim 1 to treat the patient. However, since the "complex" recited in claim 1 is the only composition of matter recited in claim 1, the term "composition" means a "complex."

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For the reasons stated above, the claim language supports the Court's definitions of "complex," "hexamer," and "formulation."

2. The Specification

The above discussion of the meaning of the claim terms is further supported by the specification. The specification supports how the Court interprets the use of "complex," "formulation," and "hexamer" in the claims, including the two meanings of the term "hexamer" dependent on the context in which it is used.

At the outset, the specification uses the term "complex" by itself as a noun, uses the term "hexamer" by itself as a noun, and uses the phrase "hexamer complex" where "hexamer" is an adjective and "complex" is a noun. Much like the term "hexamer," the specification uses the term "complex" to mean either an equilibrium or a structure, depending on the context in which it is used. 28 In the context of describing the behavior of an equilibrium, and the associated properties of stability and fast action, "complex" is used as shorthand to describe an equilibrium and the term "hexamer" is used as shorthand for the equilibrium where most of the insulin or insulin analog species are aggregated into Zn-hIA structures. 29 When used outside the context of an equilibrium and in the context of individual molecules and their structures, the term "complex" refers to an individual molecular structure and the term "hexamer" refers to a particular type of molecular structure, the Zn-hIA structure. 30 Only one sentence in the specification is ambiguous as to whether "complex" and "hexamer" refer to the equilibrium or the molecular structure. 31 Since claims 1 and 12 only refer to "complex" in the context of individual molecules, the term "complex" is only used in the structural sense in the claims. Thus, the specification fully supports the Court's definitions of "complex" and "hexamer" in the claims.

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28 See n. 19.

29 See '978 Patent at 2:47-50 ("Brange et al. . . . disclose that when insulin is administered as a hexamer. . . the hexamer must be sterically more hindered" -- in the Brange et al. reference, the authors are discussing the properties of solutions of human insulin where most of the insulin molecules in the solution are in hexamer structures); id. at 62-63 ("The present formulation is a zinc-phenolic induced hexamer complex" -- this means that most of the insulin analogs in the formulation are in Zn-hIA structures); id. at 63-65 ("The rate of absorption for the hexamer complex is at least two times that observed with insulin" -- this clause describes the "formulation" and its rapid action); id. at 65-66 ("when the hexamer complex is formulated, it is equally stable" -- this describes stability of the equilibrium); id. at 3:3-5 ("when formulated, this hexamer complex retains the fast acting properties" -- this describes the rapid action of the equilibrium); id. at 3:30-41 ("FIG. 3 is a graphical representation of Lys<B28>Pro<B29>-human insulin in a hexamer complex. The graph is the in vitro dissociation of formulated insulin [degree]; Lys<B28>Pro<B29>-human insulin formulated as a hexamer complex. . ." -- this paragraph describes the behavior of equilibrium formulations of hIA so that hexamer complex is used in the equilibrium sense.); id. at 4:33-34 ("Both the zinc and phenolic derivative are critical to achieve a complex that is stable and capable of rapid dissociation and onset of action" -- this refers to the properties of the equilibrium); id. at 5:16-20 ("it is quite surprising that the formulated hexamer analog brings a rapid onset of action. Unlike insulin, the formation of an insulin analog hexamer complex does not adversely effect the time required to achieve peak serum insulin analog concentration" -- these sentences

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refer to the properties of the equilibrium state.); id. at 5:21-31 ("FIG. 1 demonstrates, in human patients, the mean glucose infusion rate response to a formulation containing monomeric Lys<B28>Pro<B29>-hI (formulated without zinc); a formulated Lys<B28>Pro<B29>-hI hexamer; and human regular insulin. The formulated hexamer complex retains the rapid action of monomeric Lys<B28>Pro<B29>-hI The absorption rate is significantly more rapid than regular human insulin. Thus, the results in FIG. 1 illustrate: First, hexamer Lys<B28>Pro<B29>-hI and monomeric Lys<B28>Pro<B29>-hI have similar rates of absorption; second, both hexameric and monomeric Lys<B28>Pro<B29>-hI have faster rates of absorption than insulin" -- this paragraph refers to the rapid action and stability of the equilibrium.); id. at 5:32-33 ("The formulation comprising the insulin analog complex as hexamer is stable" -- this refers to the properties of the equilibrium); id. at 5:40 ("Formulated Lys<B28>Pro<B29>-hI, as a hexamer complex, exhibits diminished rate of higher molecular weight polymer formation" -- this refers to the equilibrium and its stability.); id. at 5:67-6:2 ("Samples of Lys<B28>Pro<B29>-hI as a hexamer complex were prepared in an identical fashion except 19.7 [mu] g/ml zinc was added" -- this sentence refers to preparation of a solution that is in equilibrium); id. at 6:16-23 ("Degradation is initiated by incubating formulated and unformulated preparations of insulin and monomeric and hexameric Lys<B28>Pro<B29>-hI at 30 [degrees] C. The formulated insulin and hexamer Lys<B28>Pro<B29>-hI contained: 3.5 mg/ml protein, 16 mg/ml glycerol, 7 mM dibasic sodium phosphate heptahydrate, 1.25 mg/ml m-cresol, 1.09 mg/ml phenol, and 0.0245 mg/ml zinc oxide at a pH of 7.3 to 7.4" -- this refers to the composition of a solution in equilibrium.); id. at 6:44-45 ("The in vitro dissociation properties of monomeric Lys<B28>Pro<B29>-hI, Lys<B28>Pro<B29>-hI as a hexamer complex, and insulin are probed using static light scattering." This refers to experiments with a solution in equilibrium.); id. at 7:12-20 (" FIG. 3 discloses the results of the light scattering study. The in vitro dissociation profile of Lys<B28>Pro<B29>-hI as a hexamer complex and insulin are quite different. . . . the formulations are equally stable against chemical degradation, hexamer Lys<B28>Pro<B29>-hI has a greater propensity to dissociate than insulin" -- this refers to experiments with equilibrium solutions).

30 See id. at Abstract ("The present invention discloses a human insulin analog complex and formulations" -- differentiates the structure from the equilibrium); id. at 1:61-63 ("The addition of certain metal ions, primarily zinc [to the solution containing insulin], enhance the chemical stability by driving the insulin to form hexamers, specifically Zn(II)-T6 conformations" -- First, this language differentiates "hexamers" from the equilibrium solution. Also, the plural on the word "hexamer" implies that the hexamer is a single structure and that the solution contains multiple hexamers. Finally, the Zn(II)-T6 conformation is a way of describing the structure of an individual molecular structure.); id. at 1:64-66 ("phenolics have been shown to specifically bind to the insulin hexamer and induce an allosteric conformational change" -- refers to phenolic molecules binding to the insulin hexamer structure.); id. at 2:5-6 ("insulin, in the presence of zinc, aggregates to form a well defined zn-hexamer structure" -- this teaches that the hexamer complex is a type of structure.); id. at 2:13-14 ("the highly stable Zn-hexamer complex" -- this refers further to the Zn-hexamer structure.); id. at 2:26-28 ("The association that is observed with these analogs is. . .distinct from the predominate, well-defined, Zn-insulin hexamers." -- the use of the plural on "hexamer" indicates that "hexamer" is a single structure); id. at 2:31-41 ("In view of the published literature, it is surprising that the present invention affords monomeric insulin analogs in a well defined, stable zinc-phenol hexamer complex. This hexamer complex is uniquely different from those complexes observed with insulin under identical conditions. Insulin complexes with zinc and phenol are in a Zn(II)-R[6] conformation. The hexamer complex of the present invention is not identical to this conformation. Also quite remarkably, the insulin analog hexamer complex has a much greater propensity to dissociate than insulin." -- This paragraph discusses the structure of the hexamer complex of the present invention as distinguished from the R[6] structure observed in the prior art complexes containing insulin. Because the R[6] notation and the term "conformation" refer to structure of a single hexamer complex of insulin, see Tr. at 197:18-203:23; 209:13-210:4, the patent teaches that "complex" and "hexamer complex" refer to a single structure); id. at 2:45-46 ("the obvious route to creating a fast-acting insulin is to prevent dimer or hexamer formation" -- this indicates that the goal is to avoid the formation of individual hexamer structures in the equilibrium.); id. at 2:58-59 ("efforts to chemically stabilize the monomeric insulin analog with zinc by forming a well defined, hexamer complex," referring to forming a molecular structure.); id. at 3:11-16 ("This invention provides a human insulin analog complex, which comprises: six molecules of a human insulin analog, two zinc ions, and at lease three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol, or a mixture of m-cresol and phenol; such that the analog complex is a hexamer." -- This sentence defines the "complex" as a molecular structure by defining it in terms of the molecules that are part of the structure. It defines "hexamer" as a particular type of molecular structure.); id. at 3:16-17 ("The invention further provides parenteral formulations comprising the hexamer complex" -- differentiating between the formulation, i.e., the equilibrium, and the hexamer complex in the equilibrium); id. at 3:45-46 ("the invention provides a monomeric human insulin analog complex as a hexamer" -- refers to a single molecular structure.); id. at 4:30-33 ("The insulin analogs of the present invention complex with zinc ions and a phenolic derivative to form a stable, hexamer conformation" -- here, the term "hexamer" is used to describe the conformation, which generally refers to a molecular structure.); id. at 4:60-61 ("The

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hexamer complex may be formulated into stable, rapid acting parenteral formulations" -- differentiates the molecular structure from formulating it into an equilibrium.); id. at 4:67-5:1 ("two zinc ions are bound to each hexamer" -- in this phrase "each hexamer" refers to each of the individual molecular structures in the equilibrium.); id. at 5:1-3 ("the hexamer complex binds as many as seven phenolics. Generally, when formulated, six phenolics are bound to the hexamer." -- Here, "complex" and "hexamer" refer to the individual molecular structure because it lists the number of molecules bound to the hexamer structure.); id. at 7:17-18 ("both preparations contain hexameric association states" -- the use of the plural indicates that the hexameric association states refer to individual molecular structures in the solution).

31 Id. at 4:34-35 ("The hexamer complex consists of two zinc ions per hexamer of human insulin analog and at least three molecules of a phenolic derivative selected from the group consisting of m-cresol, phenol, or a mixture of m-cresol and phenol.") One could argue that "hexamer complex" refers to the equilibrium and that the second instance of "hexamer" refers to the structure because the "hexamer complex" is composed of "two zinc ions per hexamer of human insulin analog," implying that the "complex" contains multiple "hexamers." However, the sentence also states that the "hexamer complex" is composed of "at least three molecules of phenolic derivative," but not per hexamer, implying that there are only three molecules of phenolic in the complex and that the complex refers to the structure. Given the ambiguities in the drafting of this sentence and the clear drafting throughout the rest of the specification, the language of this sentence will be ignored for purposes of claim construction.

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The specification also supports the Court's definition of "formulation" as the equilibrium. When the specification uses the terms "formulation" or "formulated" it refers to the equilibrium or the rapid action and stability of the equilibrium. 32 Therefore, as defined above, the "formulation" refers to the equilibrium state.

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32 See id. at Abstract ("invention discloses a human insulin analog hexamer complex and formulations" -- differentiates between structure and the equilibrium "formulation"); id. at Abstract ("formulation [not complex or hexamer] provides rapid onset of action" -- discusses the rapid action of the equilibrium); id. at 1:14-15 ("various formulations with different time-actions have been developed"); id. at 1:28-31 ("Recently, considerable effort has been devoted to create insulin formulations and insulin analog formulations that alter the kinetics of the subcutaneous absorption process" -- discusses the rapid action properties of the equilibrium.); id. at 1:24-32 ("all commercial pharmaceutical formulations of insulin contain insulin in the self associated state and predominantly in zinc-hexamer form." -- this sentence states that "formulations" are equilibria which contain the free constituents, insulin and zinc, and the hexamer complexes.); id. at 2:65-67 ("when the hexamer complex is formulated, it is equally stable" -- discusses stability of equilibrium) id. at 3:2-5 ("when formulated this hexamer complex retains the fast acting properties" -- discusses stability of equilibrium); id. at 3:15-16 ("the invention further comprises parenteral formulations of the hexamer complex" -- the formulation is the equilibrium that contains the complexes); id. at 3:36-41 ("formulated samples contained [concentrations of solutions]" -- the "formulation" is the equilibrium state because it is defined in terms of solution concentrations); id. at 3:30-41 ("FIG. 3 is a graphical representation of Lys<B28>Pro<B29>-human insulin in a hexamer complex. The graph is the in vitro dissociation of formulated insulin [degree]; Lys<B28>Pro<B29>-human insulin formulated as a hexamer complex. . ." -- This paragraph describes the behavior of equilibrium formulations of hIA.); id. at 4:60-61 ("the hexamer complex may be formulated into stable, rapid, acting parenteral formulations," discussing the equilibrium); id. at 5:3 ("when formulated, six phenolics are bound to the hexamer" -- teaches that the formulation is the equilibrium solution which contains multiple hexamers); id. at 4:67-5:1 ("in the formulation . . . two zinc ions are bound to each hexamer" -- teaches that the formulation is the equilibrium solution which contains multiple hexamers); id. at 5:8-13 ("An isotonicity agent, preferably glycerin, may be added to the formulation. The concentration of the isotonicity agent is in the range known in the art for insulin formulations, preferably about 16 mg/ml. The pH of the formulation may be buffered with a physiologically tolerated buffer, preferably a phosphate buffer, like sodium phosphate" -- this paragraph discusses other ingredients that can be added to the equilibrium.); id. at 5:17-18 ("formulated hexamer brings on rapid onset of action" -- discusses the rapid action of the equilibrium); id. at 5:40-44 ("formulated Lys<B28>Pro<B29>-hI, as a hexamer complex, exhibits a diminished rate of higher molecular weight polymer formation" -- refers to the rapid action of the equilibrium); id. at 5:33-34 ("the formulation comprising the insulin analog complex is stable"); id. at 6:16-23 ("Degradation is initiated by incubating formulated and unformulated preparations of insulin and monomeric and hexameric Lys<B28>Pro<B29>-hI at 30 [degrees] C. The formulated insulin and hexamer Lys<B28>Pro<B29>-hI contained: 3.5 mg/ml protein, 16 mg/ml glycerol, 7 mM dibasic sodium phosphate heptahydrate,

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1.25 mg/ml m-cresol, 1.09 mg/ml phenol, and 0.0245 mg/ml zinc oxide at a pH of 7.3 to 7.4." -- This refers to the composition of a solution in equilibrium.); id. at 7:12-20 ("FIG. 3 discloses the results of the light scattering study.. . . the formulations are equally stable against chemical degradation, hexamer Lys<B28>Pro<B29>-hI has a greater propensity to dissociate than insulin" -- this refers to experiments with equilibrium solutions.).

The term "formulated" refers to a "formulation" where most of the species are in hexamer structures, while the term "unformulated" refers to a "formulation" where most of the species are not in hexamer structures. See id. at 30-41 ("FIG. 3 is a graphical representation of the dissociation of Lys<B28>Pro<B29>-human insulin in a hexamer complex. The graph is the in vitro dissociation of formulated insulin; Lys<<B28 Pro<B29>-hI formulated as a hexamer complex; unformulated insulin; and monomeric Lys<B28>Pro<B29>-hI monitored by static light scattering at 488 nm at a 90 [degrees] angle. The formulated samples contained 0.5 mol Zn per mol protein, 1.25 mg/ml m-cresol and 1.09 mg/ml phenol, 7 mM sodium phosphate and 16 mg/ml glycerol. The unformulated and monomeric samples contained no additional excipients." -- This paragraph illustrates how the words formulated and unformulated are used to refer to hexameric and monomeric solutions, respectively); id. at 5:36-40 ("Unformulated human insulin undergoes a slower rate of polymer formation of 0.61% per week. Upon formulation, however, the rate of high molecular weight polymer formation is reduced to 0.095% per week for insulin"); id. at 5:17-18 ("formulated hexamer brings on rapid onset of action"); id. at 5:40-44 ("formulated Lys<B28>Pro<B29>-hI, as a hexamer complex, exhibits a diminished rate of higher molecular weight polymer formation"); id. at 5:62-6:2 ("Unformulated samples of insulin and Lys<B28>Pro<B29> -hI were prepared at 3.5 mg/ml in 7 mM sodium phosphate, and with or without 1.25 mg/ml m-cresol, 1.09 mg/ml phenol and 16 mg/ml glycerol, depending on the experiment performed. Samples of Lys<B28>Pro<B29>-hI as a hexamer complex were prepared in an identical fashion except 19.7 mu g/ml zinc was added."); id. at 6:16-23 ("Degradation is initiated by incubating formulated and unformulated preparations of insulin and monomeric and hexameric Lys<B28>Pro<B29>-hI at 30 [degrees] C. The formulated insulin and hexamer Lys<B28>Pro<B29>-hI contained: 3.5 mg/ml protein, 16 mg/ml glycerol, 7 mM dibasic sodium phosphate heptahydrate, 1.25 mg/ml m-cresol, 1.09 mg/ml phenol, and 0.0245 mg/ml zinc oxide at a pH of 7.3 to 7.4."); id. at 6:48-50 ("Three formulated and unformulated protein stock solutions are prepared as described except that the unformulated protein stock solutions did not contain zinc, glycerol, or preservatives [i.e., they do not form hexamers]").

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Thus, the specification validates the Court's definitions of "complex," "hexamer," and "formulation."

3. The Prosecution History

The next step is to turn to the prosecution history to help understand the terms in the claims. See Multiform Desiccants, 133 F.3d at 1478. The prosecution history provides support for the Court's definitions of "complex," "hexamer," and "formulation."

First, the arguments in the prosecution history support that the terms "complex" and "hexamer" have different meanings in different contexts. In the context of describing the behavior of a "formulation," or equilibrium, and the associated properties of stability and fast action, the terms "complex" and "hexamer" are used as shorthand for the equilibrium where most of the insulin or insulin analog species are aggregated into Zn-hIA structures. 33 When used outside the context of an equilibrium and in the context of individual molecules, the terms "complex," "hexamer," and "hexamer complex" refer to the Zn-hIA structure. 34 Therefore, the prosecution history supports the two definitions of "complex" and "hexamer." Second, the arguments in the prosecution history support the definition of "formulation" as an equilibrium. 35 The prosecution history, like the claim language and specification, confirms the Court's definitions of "complex," "hexamer," and "formulation."

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33 See Amendment and Remarks of March 14, 1995, Novo Ex. D at A-370 ("when phenol or m-cresol is added to a zinc solution of a monomeric analog, the monomeric analog forms a well ordered, hexamer association state" -- refers to the equilibrium solution.); id. ("the hexamer association state retains a rapid profile of action" -- refers to the properties of the equilibrium.").

The following passage also illustrates how the word "hexamer" is used in the equilibrium sense, to distinguish the prior art based on the predominance of hexamers structures in the equilibrium and the rapid time action of this equilibrium:

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Therefore, in view of Brems et al., one skilled in the art would predict that a monomeric analog would remain predominantly monomeric and any association monomeric and any association observed would be to a mixture of aggregates. Thus Brems et al. suggest that the present invention would fail -- the zinc-phenolic induced association of monomeric analogs into a hexamer is most unexpected. The present invention demonstrates that the claimed analogs form a well ordered, zinc/phenol hexamer. . . Most significantly, the association of the monomeric analog into a hexamer does not change the time action.

Id. at A-375.

34 See id. at A-370 ("The addition of zinc. . . does not induce aggregation to well, defined hexamers of the analog" -- the plural of hexamers indicates that these are the structures in the equilibrium); id. ("the present invention claims the hexamer analog complex, formulations, and methods" -- distinguishes the molecular structure from the equilibrium.); id. at A-372 ("Clearly, Wollmer et al. do not disclose an analog containing 2 Zn ions and at least 3 phenol derivative in a hexamer conformation." -- This sentence defines "complex" as a structure by referring to the number of molecules in the complex, and defines "hexamer" as a structure by referring to its conformation.); id. at A-373 ("the present monomeric analogs complexes and formulations" -- distinguishes the structure from the equilibrium.); id. at A-374 ("Wollmer et al. study. . . structural transformations of insulin hexamers. . . [and] the 2 Zn to 4 Zn transition of insulin is a property of hexamers" -- refers to structures); id. ("Wollmer et al. do not disclose des(B26-B30)-insulin in a hexamer conformation" -- refers to the structure); id. ("because the CD-spectral effects observed with des(B26-30)-insulin are different and opposite than those observed with insulin hexamers, one of ordinary skill in the art would conclude that the hexameric complex could not be formed with the monomeric insulin analog." -- In this section, Lilly is referring to the structure of the hexamers.).

Moreover, the following passage illustrates how Lilly attempted to distinguish the structure of the claimed hexamer complex from prior art hexamer complex:

Insulin in the presence of zinc is in a T[6] hexamer association state. When phenol is added, the conformation changes to a R[6] hexamer association. Brems et al. report that monomeric analogs do not form a hexameric T[6] association state with zinc. In view of Brems et al., it logically follows that one of ordinary skill in the art would predict that the monomeric analog would not change its conformation to an R[6]-like hexameric association state with zinc and phenol. . . The present invention demonstrates that the claimed analogs form a well ordered, zinc/phenol hexamer. However, this association state is not analogous to the R[6] association state observed with insulin.

Id. at A-375.

35 See id. at A-370 ("the present invention claims the hexamer analog complex, formulations, and methods" -- distinguishes the equilibrium from the molecular structures.); id. at A-373, A-375 ("The novelty of the present invention lies in the zinc-phenolic induced association and the subsequent rapid time action of the formulation" -- refers to the rapid time action of the equilibrium.); Office Action of Jan. 27, 1995, Novo Ex. D at A-353 ("formulations are disclosed which. . . are intended to provide rapid onset of action combined with improved stability." -- Lilly did not dispute this use of the term "formulation" by the Examiner).

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4. Extrinsic Evidence

Both parties invite the Court to examine reams of extrinsic evidence, including dictionary definitions, prior art, expert testimony, and inventor testimony. Because the definitions of "complex," hexamer," and "formulation" are clear from the intrinsic evidence of the patent, it is not necessary, and indeed improper, to examine the extrinsic evidence proffered by the parties. See Pitney Bowes, 182 F.3d at 1309. Therefore, the Court declines the invitation to examine the extrinsic evidence.

However, in the interests of judicial caution, in light of recent Federal Circuit law, the Court notes that the dictionary definitions are in accord with the Court's definitions. 36 First, the dictionaries validate that "complex" means a molecular structure. 37 The dictionary definitions do not illuminate the meaning of the term "hexamer." 38 The parties submitted no dictionary definitions of "formulation." Therefore, the dictionary definitions do not contradict the Court's definitions of

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"complex," "hexamer," and "formulation."

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36 Prevailing Federal Circuit law has always held that dictionaries are extrinsic evidence. See, e.g., Vitronics, 90 F.3d at 1584-85. However, in a recent non-precedential decision, a diminished panel of the Federal Circuit held that "dictionary definitions are considered to be intrinsic evidence." Antonious v. Spalding & Evenflo Cos., Inc., 1999 U.S. App. LEXIS 22984, 1999 WL 777450, *3 (Fed. Cir. 1999). Moreover, in several other cases, the court seems to have employed a dictionary as part of its intrinsic analysis of the plain meaning of the claim language. See, e.g., Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971 (Fed. Cir. 1999) (using dictionary definitions as part of the intrinsic evidence analysis of the claim language); Desper Products, Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1333 (Fed. Cir. 1998) (same). Nonetheless, absent explicit precedential authority to the contrary, this Court will consider dictionaries as extrinsic evidence. Whether the dictionaries are intrinsic or extrinsic evidence does not affect the outcome of claim construction in this case.

37 See Oxford Dictionary of Biochemistry & Molecular Biology -- (2d ed. 1989) ("an aggregate of two or more molecules, particularly macromolecules, held together by non-covalent forces in a definable structural relation and as a result of particular interactions"); Grant & Hackh's Chemical Dictionary (1987) ("ion or compound, which in solution dissociates reversibly into its component parts" or "ion or compound which is sufficiently stable to retain its identity in solution"); Merriam-Webster's New Collegiate Dictionary (1998) ("a chemical association of two or more species (as ions or molecules) joined usu. by weak electrostatic bonds rather than covalent bonds"); Merriam-Webster's New Collegiate Dictionary (1993) (1. "a whole made up of complicated or interrelated parts" -- referring in general to a type of structure; 2. "a complex substance (as a coordination complex) in which the constituents are more intimately associated than in a simple mixture"); Webster's Third New Int'l Dictionary (1981) ("a conjunction of varied contributing or interacting factors, elements, or qualities: as a complex substance (as a coordination compound, an ion containing several atoms, or an adsorption compound -- usu. distinguished from mixture"); Random House Dictionary (1987) (Lilly Ex. 26) ("10. a compound in which independently existing molecules or ions of a non-metal form coordinate bonds with a metal atom or ion; 11. an entity composed of molecules in which the constituents maintain much of their chemical identity: receptor-hormone complex, enzyme substrate complex").

38 Only the roots of the word "hexamer" actually appear in the dictionary. See Webster's New Collegiate Dictionary (1989) ("hexa-" = "six; containing six atoms, groups, or equivalents"; "mer" = "member of a specified class (monomer)"); Random House Dictionary (1987) (Lilly Ex. 26) ("hexa-" = "a combining form meaning six"; "-mer" = "a combining form meaning member of a particular group").

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The Court has construed the limitations of Claim 1, in relevant part, as follows:

"Active" means producing an intended action or effect: active ingredients.
"Pharmacologically effective" means an amount that is medically effective.
"Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate 1, dermatan sulfate, keratan sulfate and acemannan, for example.
"Amount effective" means a quantity that produces a result.
"Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
"Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.

1 Chondroitin sulfate is the complex carbohydrate at issue in this case.
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1. "component"

The claims at issue, excepting claims 32 and 33, teach providing a "dispersion containing components A and B" and exposing that dispersion to radiation to form an alloy. Aeromet argues in its summary judgment motion that it did not infringe the '875 patent when it used Ti-6-4 and other "single powdered alloys" because those alloys do not contain the required "components." ImageCube responds that Ti-6-4 does contain the necessary "components" in the form of alpha and beta "phases" and thus even the irradiation of single powdered alloys infringes its patent. The parties are well aware that the construction of "components" bears significantly on the disposition of the summary judgment motion and the proposed definitions are framed accordingly. However, the Court is equally aware that it cannot construe claims with reference to the accused device or process (see SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed. Cir. 1985)) and therefore will disregard Aeromet's process when construing "components."

ImageCube explicitly includes "phase" in its otherwise broad construction of "components" as "a metal, polymer or ceramic, or a combination of any of the foregoing, including an alloy, in liquid, solid, gas, or particulate form, such as a phase. When two components are present, they must differ in some physical or chemical property." Aeromet asks the Court to define "components" more narrowly as "discrete polymers, metals, ceramics, or combinations of these materials, that are present in a dispersion, that are capable of forming an alloy upon exposure to radiation, and that are not already alloyed with one another."

Both parties propose that "components" include "polymers, metals, ceramics, or combinations of these materials." That language is supported by the patent and will be adopted. See, e.g., '875 Patent, Col. 17, ll. 12-13; Col. 2, ll. 23-24. However, there is no reason to include the superfluous language that they can "include an alloy" when that possibility is encompassed by "combinations of these materials." The second half of ImageCube's proposed first sentence was slightly altered between its opening and response brief. It originally stated that a "component" could be "in liquid, solid, or particulate form." ImageCube cites to examples in the patent where "components" take these forms and Aeromet did not object. See id., Col. 17, ll. 25-28. However, in its reply brief, ImageCube added "gas" to this list. Aeromet was not given an opportunity to respond to this change. And, equally important, ImageCube does not indicate where the patent teaches "components" in gaseous form. Therefore, only the original statement that the listed materials can be in "liquid, solid or particulate form" will be included in the definition. Before proceeding, it is important to note that the second part of ImageCube's proposed first sentence depends on the first. In other words, "components" must first be a metal, polymer, ceramic, or alloy of those materials - liquid, solid and particulate are merely forms that those materials can take.

Aeromet objects to the explicit reference to "phase" in the definition, but ImageCube argues that one skilled in the art would understand "components" to include "phases" and submits that both the intrinsic and extrinsic record support that contention. Whether a "component" encompasses "phases" can be more effectively and efficiently addressed once the proper boundaries of "component" are defined. 6 Therefore, the Court will address the remainder of the parties' construction arguments before turning to the specific question of "phases."

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6 It is unclear to the Court, and neither party makes a point of distinguishing, whether the "phase" question should be addressed as a claim construction question or whether, once construed, the Court should determine whether "phase" is encompassed within that definition. The issue is further confused by ImageCube's inclusion of "phase" in its proposed definition. The issue ultimately is irrelevant because ImageCube's argument fails either way.

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The second half of ImageCube's proposed definition would require "components" to possess different chemical or physical properties from each other. The patent does contain dependent claims that teach "components" with different melting points (claim 16) and a process where one of the "components" is in an above solidus state (claim 23). '875 Patent, Col. 17, ll. 43-47; Col. 18, ll. 14-16. Although Aeromet does not argue otherwise, it contends that differences in physical and/or chemical properties are insufficient as the sole basis for defining "component." A quick glance at the first sentence of ImageCube's

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proposed construction reveals the Aeromet is correct -- more is required. The claims cited by ImageCube further support that conclusion. Claim 16 teaches the "process as claimed in claim 1, wherein component A has melting point MpA, component B has a melting point MpB, and MpA is higher than MpB, and wherein homogenization forms an alloy having an euctetic which is different from MpB." Id., Col. 17, ll.43-47. Compare that language to claim 4, which teaches the "process as claimed in claim 1, wherein components A and B are polymers, metals or ceramics." Id., Col. 17, ll. 12-13 (emphasis added). While claim 4 describes what "components" are, claim 16 describes characteristics of the permissible "components." As a final note, the '875 patent is concerned more with differences between the components that make up the dispersion and the alloy formed from those components, not the distinction between the components themselves. Nonetheless, the Court agrees that "components" must "differ in some chemical or physical property" as it is supported by the above claim language and the repeated use of A and B signifying a difference between "components." To determine whether additional limitations are proper, the Court turns to Aeromet's proposed definition.

ImageCube does not contest the proposition that "components" must be "present in a dispersion" (see, e.g., '875 Patent, Col. 16, ll. 60-63) or that they must be "capable of forming an alloy upon exposure to radiation" (see, e.g., id., Col. 16, ll. 58-67; Col. 17, ll. 1-5). Therefore, as it currently stands, a "component" is a "polymer, metal, ceramic or combination of those materials; in liquid, solid, or particulate form; that differs in some chemical or physical property from the other component(s) present in the dispersion; and is capable of forming an alloy upon exposure to radiation." The dispute can be narrowly focused -- disregarding the specific "phase" question for now -- to the question of whether "components" have to be "discrete" materials and are precluded from being "already alloyed with one another."

2. "not already alloyed with one another"

As always, claim interpretation begins with the actual words of the claims. Bell Commc'ns. Research v. Vitalink Commc'ns. Corp., 55 F.3d 615, 619-620 (Fed. Cir. 1995). Claim 1, which is similar to the other claims at issues, excluding claims 32-33, teaches:

A process for producing a homogenized, three dimensional, integral object by imagewise thermal radiation of a dispersion, the dispersion containing components A and B, comprising the steps of:

a) providing the dispersion containing components A and B;

b) forming the dispersion into a layer;

c) homogenizing the dispersion by applying imagewise thermal radiation to form an alloy of components A and B; * * *

'875 Patent, Col. 16, ll.58-67. Under the ordinary meaning of that language, one starts with two things (A and B) and through the process of thermal radiation, creates a third (the alloy). If that is the proper reading, the components cannot be previously alloyed; if they were, then no alloy would be "formed." However, the Court is not the intended audience and the Court must determine how one skilled in the art would read this claim. ImageCube has not presented any evidence that one skilled in the art would read it any other way. 7

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7 ImageCube reserves its "one skilled in the art" argument for the question of whether "phases" are "components."

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Aeromet argues that absent the limitation noted above, the patent claims would teach a process in which there is no difference between the dispersion and the completed alloy -- the process could begin and end with the same alloy. And if that were the case, so the argument goes, then no alloy would be "formed" as the claims requires. ImageCube responds that the patent does not require that a new alloy be formed. According to ImageCube, alloy formation merely requires changes in physical or chemical properties subsequent to radiation. That interpretation rests on language in the specification stating that "the alloyed (homogenized) material has a different melting point than the dispersion of components A and B, and thus, the alloyed three-dimensional article can be separated from the surrounding dispersion based on the difference in melting

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point." '875 Patent, Col. 3, ll. 3-7. 8 However, the sentence preceding that embodiment reveals that the difference in melting point permitting separation is founded on the distinction between non-alloyed and alloyed. See id., Col. 2, ll. 66-67; Col. 3, ll. 1-2 (the "difference in properties of the alloy is preferably sufficient in itself to permit separation of the alloyed components from non-alloyed, surrounding regions of the dispersed components following imagewise exposure"). The difference in melting points thus is the result of the distinction between the non-alloyed region and the alloyed components. The melting point change is simply a characteristic of the alloyed material -- the patent still requires the formation of an alloy that is distinct from the "non-alloyed" material.

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8 ImageCube also points to this line in the specification to argue that the patent provides examples supportive of its position that the dispersion can be distinguished from the end product, not solely on the basis of unalloyed versus alloyed, but also through changes in properties. The Court rejects the argument in that context for the same reason.

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Following the same line of argument that forming an alloy merely requires a change in properties, ImageCube cites the specification which states that "[t]he components A and B are capable of alloying, when exposed to imagewise radiation, to form an alloy of the two components A and B which is characterized by physical and/or chemical properties which are distinct from the physical and/or chemical properties of the dispersion of components A and B." '875 Patent, Col. 2, ll. 24-29. ImageCube's example fails to persuade the Court. The patent teaches that (a) an alloy be formed, and (b) the alloy possess attendant changes in physical or chemical properties. Simply because the second step is met does not mean that an alloy necessarily has been formed. By focusing on the results of irradiation, ImageCube reads out the step required to get to those results. It may be true that irradiation of a single material, without introducing a second "component," may alter the material's properties. But that is not the process that the patent teaches. If the same alloy exists before and after applying radiation, nothing has been formed -- at most, the alloy has been altered. ImageCube's interpretation would expand the patent to cover a dispersion with only one "component" as long as irradiation of that single "component" resulted in a change in some property of that material. The Court cannot so easily read out the requirements that (a) an alloy be formed (b) by using two "components." The Court concludes that the claim language supports a construction that the "components" constituting the dispersion cannot be alloyed prior to homogenization.

That conclusion also is convincingly supported by the specification which draws a distinction between the "unalloyed" dispersion (containing the "components") not treated by the laser and the resultant homogenized alloy formed upon subjection to radiation. Specifically, the patent includes statements that "the alloy of A and B should preferably be separable from the unalloyed dispersion of A and B based on the difference in physical and/or chemical properties" '875 Patent, Col. 3, ll. 24-26 (emphasis added), and "[t]he difference in properties of the alloy is preferably sufficient in itself to permit separation of the alloyed components from non-alloyed, surrounding regions of the dispersed components following imagewise exposure" Id., Col. 2, ll. 66-67 and Col. 3, ll. 1-2 (emphasis added). Those statements certainly suggest that only through the imagewise radiation of the dispersion do the "components" become alloyed -- and therefore they cannot be alloyed prior to radiation.

ImageCube counters that Aeromet fails to read the specification as a whole. According to ImageCube, when viewed in context, the portion of the specification on which Aeromet relies requires "components" A and B to satisfy three conditions, none of which is that they be unalloyed with each other:

> Choice of the particular material combinations to be used depends on the nature and intended us[e] of the three-dimensional part or object being produced. From within these classes of materials, the components A and B should be selected so as to be: capable of alloying under the exposure of imagewise radiation within a practical range of intensity; the alloy must have physical and/or chemical properties distinct from the properties of an intimate dispersion of A in B or B in A; and the alloy of A and B should preferably be separable from unalloyed dispersion of A and B based on the difference in physical and/or chemical properties.

'875 Patent, Col. 3, ll. 16-26. However, ImageCube does not say what three conditions should be gleaned from this section. As the Court reads it, there actually are two statements requiring that the "components" be unalloyed with each other before the laser is applied. First, they must be capable of alloying, which, as discussed above, suggests that they cannot previously

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have been alloyed. Second, and more importantly, the "context" of the preceding sentences does nothing to diminish the fact that the patent distinguishes the unalloyed dispersion from the alloy formed by imagewise radiation. ImageCube persists that the use of "preferably" in the last sentence acts as a qualifier that "provides latitude." But even if that were the case, "preferably" is used in reference to the separability of the alloy. The distinction between unalloyed and alloyed exists regardless of the preferred separability. ImageCube's concluding statement that "preferably unalloyed" is not limiting is a red herring; that phrase does not appear in the patent.

Aeromet's proposed limitation also is consistent with the embodiments contained in the '875 patent. Despite the numerous examples provided in the specification, nowhere does the patent teach the inclusion of an alloy in the dispersion unless a separate material is introduced prior to irradiation. When the patent provides examples in which alloys act as a "component," it is merely one "component" of the dispersion. ImageCube itself states that "the defendants agree that a 'component' can itself be an alloy, and that this alloy can be combined, with another component, into still another alloy." ImageCube's Memo. Re Component [172] at 4. (emphasis added). The patent provides an example of powdered aluminum, S(A), dispersed with an alloy of gallium and aluminum, A1B1, to form a different alloy of A2B2. '875 Patent, Col. 6, ll. 25-41. The irradiation process always results in the formation of a third object. The Court is aware that it cannot necessarily limit claims to the embodiments contained in the specification. See Phillips, 415 F.3d at 1323. However, the examples in the patent merely buttress the claim language and the remainder of the specification discussed above and therefore provide further support for the Court's conclusion that a new alloy must be formed. And because a new alloy must be formed, the components cannot be alloyed with other prior to homogenization.

Finally, ImageCube argues that even if its other arguments fail and an express description is required, the patent does specify the use of pre-alloyed "components." In support of that contention, ImageCube looks to the following language:

> Furthermore, the liquid phase need not be comprised of a pure component B or a pure component A. The liquid phase may be comprised of, for example, an alloy of component A and component B at a euctetic point such that upon heating above the euctetic isothermal line EuB temperature the liquid phase does not have crystalline components AB or [beta]. Such a condition ensures a greater amount of liquid to solid particle ratio and also reduces the amount of homogenization required to change the composition to a higher melting alloy.

'875 Patent, Col. 11, ll.37-46. But when read in the context of the embodiment, that passage does not support ImageCube's position. The embodiment begins with the addition of a material "component" A to a liquid phase "component" (L)A1B1. Id., Col. 10, ll. 35-38. A new alloy of (S)A2B2 is then formed where the component A is placed. Id., ll. 39-41. Therefore, when the specification later states that the (L)A1B1 can be an alloy, there still is another "component" added, material "component" A, prior to homogenization. As the language cited by ImageCube states, "[s]uch a condition ensures a greater amount of liquid to solid particle ratio * * *" (id., ll.43-44) -- the liquid being (L)A1B1 and the solid being material "component" A. This example does not teach homogenizing an alloy alone and the Court comes to the same conclusion -- the "components" cannot be alloyed prior to irradiation.

3. "discrete"

The parties agree that, given the A and B nomenclature employed to identify them and other references throughout the patent, the "components" must differ from each other in some way. However, the parties disagree on whether they need to be "discrete" -- that is, different -- materials. The use of A and B to distinguish components does not necessarily require that result -- it simply requires that two (of something) exist and that they differ in some regard. In the same vein, the references to "individual" "components" are not necessarily determinative.

Again, we begin with the claim language, which states that "components A and B are polymers, metals or ceramics." '875 patent, Col. 17, ll. 12-13. Those are all individual, discrete, materials. Nothing in the patent claims suggests that a component can be any division or subset of a material or anything non-material. That reading is borne out by the specification, which similarly limits its discussion of components to discrete materials. The "Summary of the Invention" states that "Components A and B may be polymers, metals, ceramics, or combinations of these materials." Col. 2, ll. 23-24. In reality, whether it is implied that the "components" be different materials or explicitly spelled out in the definition ultimately is of no consequence.

ImageCube advances several arguments in support of its view that components are not limited to polymers, metals,

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ceramics, or "materials" generally. Initially, ImageCube maintains that "components" cannot be limited to the listed materials because of the inclusion of "may be." The Court disagrees and interprets "may be" not to expand upon the universe of materials that may comprise a component, but simply to indicate that a component could be any one of those materials, alone or alloyed. 9 ImageCube's interpretation would improperly expand the scope of the patent. Every example contained in the patent teaches a dispersion of at least two discrete materials. At no point does the specification describe irradiating an alloy alone, much less suggest that doing so would satisfy the requirement that two "components" be homogenized. In those instances where one of the "components" is an alloy, there always is a separate discrete "component" added to the dispersion. See Patent '875, Col. 6, ll. 25-27 (50 parts of component B (Alloy A1B1 containing 30% gallium and 70 % aluminum) 50 parts of solid component A (powdered aluminum)). Again, the Court is aware that it cannot necessarily limit claims to the embodiments. See Phillips, 415 F.3d at 1323. Yet, examples constitute further evidence that the patent only disclosed material "components."

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9 This actually is consistent with ImageCube's brief which, after suggesting that "may be" requires that "components" not be limited to the listed materials, provides a list of all possible combinations of components and only references those materials.

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Beyond the claim terms and summary of the invention, which limit "components" to the listed materials that happen to be "discrete," there are other helpful clues to meaning in the patent itself. The formation of an alloy is described as taking place "between the substances which are homogenized." Col. 2, ll. 59-66 (emphasis added). Although "substances" are not explicitly equated with "components," that result can be easily derived. The patent teaches a process of homogenizing a dispersion; the dispersion contains "components" A and B; therefore, the "substances which are homogenized" must be "components." The "components" in the dispersion also are described as different "material combination[s]," the selection of different combinations governed by the intended use of the object being produced (Id., Col. 3, ll. 16-17), and "material pairs" (Id., Col. 5, ll. 6).

ImageCube maintains that there is no requirement that each "component" consist of only one material. To the extent that the patent permits alloys and polymers to act as "components," ImageCube is correct. However, to the extent ImageCube argues that a single material can contain the sufficient "components," the Court must disagree. ImageCube contends that because Example 1 of the specification includes three materials -- polyethylene oxide, trimethylolpropane triacrylate and graphite -- there is no one-to-one "material" to "component" requirement. It is unclear how this example supports ImageCube's position. To the extent that ImageCube believes that these three materials are one "component," ImageCube's reading is incorrect. They are three separate materials mixed in the dispersion and constituting individual components. And that example is entirely consistent with the requirement that "components" be discrete materials of the metal, ceramic, polymer or combination thereof variety.

Finally, and related to the previous limitation, the patent only encompasses "components" that are capable of forming an alloy with each other and eventually are alloyed through the homogenization process. ImageCube does not suggest that non-material or non-discrete "components" would be capable of forming a new alloy. As discussed above, a mere change in properties of an existing alloy is not the "formation of an alloy" as taught by the patent, which is one final reason to permit the limitation that the "components" be discrete.

In short, ImageCube argues that the construction should not include "discrete," "not already alloyed with one another," or any other language that is not contained in the claims. However, "in clarifying the meaning of claim terms, courts are free to use words that do not appear in the claim so long as the resulting claim interpretation * * * accord[s] with the words chosen by the patentee to stake out the boundary of the claimed property." Pause Tech. LLC v. Tivo Inc., 419 F.3d 1326, 1333 (Fed. Cir. 2005) (internal quotations omitted). Both limitations are supported by the words chosen by the patentee in setting the borders of the invention. Therefore, the Court construes "component" as a "discrete polymer, metal, ceramic or combination of those materials; in liquid, solid, or particulate form; that differs in some chemical or physical property from the other component(s) present in the dispersion; is capable of forming an alloy upon exposure to radiation; and is not already alloyed with the other component(s)."

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d. Are "phases" "components"?

The inquiry into whether "phases" are "components" must begin with the recognition that the patent does not directly state that "components" can include "phases" -- as it expressly does for polymers, metals and ceramics. In fact, the only mention of phases in the patent is in reference to a completed alloy. See '875 Patent, Col. 4, ll. 30-33 ("It should be noted that homogenization does not require complete mixing. It is recognized, for example, that solidified alloys may contain crystals or phases of varying composition"). ImageCube acknowledges this fact and makes two arguments for its inclusion -- first, there was no need to include phases specifically because one skilled in the art would understand that "phases" can be "components" and second, "phases" fall within the definition of "components" that ImageCube proposed. The Court will address these arguments in reverse order.

ImageCube notes numerous property differences between the alpha and beta phases of Ti-6-4 and alpha and beta phases generally. It then asserts that "[e]ach phase can be a solid or a liquid, depending on the temperature. * * *. The physical or chemical properties of each phase differ from the properties of another phase. A component therefore cannot be construed to exclude a phase." 10 If viewed within the boundaries of the construction adopted by the Court, a "phase" certainly can be excluded from the umbra of "components."

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10 ImageCube also states "[e]ach phase has at least one metal" but there is no citation to the record to support that statement. See [172], pg. 6.

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ImageCube's argument for encompassing "phases" is contrary to the Court's construction of a "component" as one of, or a combination of, a metal, ceramic, or polymer. ImageCube does not argue that "phases" fall into any of those categories. Instead, ImageCube argues that "phases" need not fit within those categories, a position that the Court has rejected. The Court also has rejected ImageCube's contention that no new alloy need be formed and that a change in some property of the "component" is all that the patent requires when it teaches forming an alloy. Differences between "phases" of an alloy are simply irrelevant if the other requirements of a "component" are not met -- and they are not met by "phases."

This "change in property" as a basis for "component" argument appears to provide the foundation for ImageCube's analogy to H[2]O. Beyond a basic tutorial in how the same elements can align themselves in different ways and exist in different states, it is not clear how this example is applicable to the '875 patent or would support the notion that "phases" can be "components." To the extent that ImageCube seeks to argue that because (a) components" can exist in different states and (b) "phases" exist in different states, therefore (c) "phases" can be "components," the Court already has concluded that different states do not a component make. The component first must satisfy the requirement that it be a metal, polymer, ceramic, or alloy of those materials. If that requirement is met, then the "components" may exist in different forms including solid, liquid and particulate. And to the extent that ImageCube references its water analogy to argue that changes can occur in both "phases" and "components," the Court notes that "homogenization" as it used in the patent means something specific -- "formation of an alloy." Water does not form an alloy when it changes states from solid to liquid and to gas.

Perhaps recognizing that the most natural construction of "components" would preclude "phases" of an alloy, ImageCube argues that one skilled in the art would understand otherwise. In support, ImageCube cites several extrinsic references, including the inventor's declaration and a various assortment of definitions and advertisements. Because the Court finds that the intrinsic evidence unambiguously describes the scope of the patented invention, it would be improper to proceed to the extrinsic evidence. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). However, for the sake of completeness, the Court will address the extrinsic evidence.

ImageCube cites two definitions of "phase" from the same dictionary. One definition provides that a "phase" is one of the three states or conditions in which a substance can exist -- solid, liquid, or gas. Hawley's Condensed Chemical Dictionary, 11th ed. The other states it is:

A physically distinct and mechanically separable portion of a dispersion or solution. Phases may be either solid, liquid, or gaseous (vapor). In any mixture or solution the major component is called the continuous or external phase, and the minor

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component the dispersed or internal phase. The latter may or may not be uniformly dispersed in the continuous phase.

Id. From those definitions, ImageCube argues that a "phase" can be both a "component" and part of a dispersion. Although the second definition uses "component" and "dispersed," it still is not clear that "component" is being used in the same sense as in the patent. "The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of the words rather than on the meaning of claim terms within the context of the patent." Phillips, 415 F.3d at 1321; see also Cabell v. Markham, 148 F.2d 737, 739 (L. Hand, J.) ("But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of a dictionary * * *"). The Federal Circuit also has voiced concern that it often is possible to find extrinsic evidence of at least some marginal relevance that might support either side's position (or both sides' positions). See Phillips, 415 F.3d at 1318.

Those concerns are validated in this case, for Aeromet has countered with a quotation that differentiates "components" and "phases": "The substances in alloys might be two metals * * * or several metals, such as aluminum, magnesium, and manganese. These substances constitute the components comprising the system and should not be confused with the various phases found within the system." "Introduction to Alloy Phase Diagrams", Baker, Ed., Section 1 of ASM Metals Reference Book, ASM Int'l, Materials Park, OH (1993). ImageCube replies by rephrasing the reference to say that "'substances' should not be confused with 'phases'" and therefore it "does not preclude a component from being a phase."

If read correctly, and substances and components are equated, the reference explicitly precludes a "component" from being a "phase." But the larger point illustrated by the dualing dictionary definitions is that definitions can be found to support both parties' constructions. And, like most extrinsic evidence, those definitions can be unhelpful or even misleading unless they are placed in context -- and, even then, often have limited utility where the intrinsic record is robust. Here, for the reasons explained above, the Court is not persuaded to deviate from the meaning of "component" established by the ample intrinsic evidence presented by the parties in this case.

In regard to the declarations submitted by Lawton, the Court notes that there certainly are instances where a declaration, even if created during the course of litigation, may be helpful to a proper construction. For example, in Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 716-718 (Fed. Cir. 1999), the Federal Circuit approved the trial court's acceptance of an expert's testimony applying a specific number to the generic claim term "pharmaceutically effective amount." At the same time, many courts have sounded words of caution when evaluating the "after-the-fact" testimony of the inventor, and have noted that such testimony must be viewed in light of the generally more reliable intrinsic evidence in the case, including the patent disclosure itself. See, e.g., Bell & Howell Document Management v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997); Amazin' Raisins Int'l, Inc. v. Ocean Spray Cranberries, Inc., 2007 U.S. Dist. LEXIS 60808, 2007 WL 2386360, at *13 (D. Mass. Aug. 20, 2007).

Aeromet contends that the Court should not give credence to the Lawton declaration at all because it is litigation driven and attempts to impart new meaning that is contrary to the original specification. While the Court has considered the declaration, it is in some respects "at odds with the claim construction mandated by the claims themselves, [and] the written description * * *, in other words, with the written record of the patent." Key Pharms., 161 F.3d at 716 (citing Markman, 52 F.3d at 981; Vitronics, 90 F.3d at 1584). Moreover, here -- in contrast to Key Pharms. (see id. at 718), there is a substantial amount of intrinsic evidence to aid the Court in defining the pertinent claim terms. In these circumstances, Lawton's declaration cannot be given much weight and will not be used to trump the meaning of the terms that is evident from the intrinsic record.
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1. Can the Claimed Coating "Composed of" Five Layers Read on a Device Containing Interlayers in Addition to Five Metallic Layers?

Cardinal argues that AFG's patent claim only reads upon coatings containing five metallic layers, and does not cover coatings that contain other layers or interlayers. Cardinal notes that claim 1 of the '532 patent recites a coating "composed of" five alternating metallic layers. Cardinal argues that "composed of" is a closed transition phrase, and therefore that this claim is limited to a coating containing five, and only five, layers of zinc oxide and silver. Cardinal points out that its accused windows have coatings that contain a thin deposit of titanium dioxide in addition to other layers of silver and zinc oxide, and thus contends that its coatings cannot infringe AFG's claim.

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We refer to claim terms like "composed of" as "transition phrases." When a claim uses an "open" transition phrase, its scope may cover devices that employ additional, unrecited elements. See Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271, 229 U.S.P.Q. (BNA) 805, 812 (Fed. Cir. 1986). We have consistently held that the word "comprising" is an open transition phrase. See id.; see also Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 977, 52 U.S.P.Q.2D (BNA) 1109, 1112 (Fed. Cir. 1999). In contrast, "closed" transition phrases such as "consisting of" are understood to exclude any elements, steps, or ingredients not specified in the claim. See PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354, 48 U.S.P.Q.2D (BNA) 1351, 1354 (Fed. Cir. 1998); see also Ex parte Davis, 80 U.S.P.Q. (BNA) 448, 449-50 (Pat. Off. Bd. App. 1949).

We identify little precedent defining the term "composed of." In 1942, the Court of Customs and Patent Appeals stated that "'composed of' should be regarded as synonymous with 'consisting of.'" In re Bertsch, 30 C.C.P.A. 813, 132 F.2d 1014, 56 U.S.P.Q. (BNA) 379 (CCPA 1942). The CCPA qualified this statement, however, by remarking that "the words 'composed of' may under certain circumstances be given, in patent law, a broader meaning than 'consisting of.'" Id. In the decades since the CCPA set forth this rather equivocal characterization of "composed of," this transition phrase appears to have acquired a meaning somewhat more expansive than "consisting of." The Manual of Patent Examining Procedure ("MPEP"), for example, contrasts "composed of" with "consisting of," and states that "transition phrases such as 'composed of' . . . must be interpreted in light of the specification to determine whether open or closed claim language is intended." MPEP § 2111.03 (7th ed. rev.1 Feb. 2000). While we owe no deference to the authors of the MPEP regarding the definition of claim terms, and we decline to assign such a broad and flexible meaning to this term, we do agree based on the specification and other evidence before us that the term "composed of" in this case is not completely closed. Rather, we think that "composed of" in this case should be interpreted in the same manner as "consisting essentially of." Under this approach, the transition phrase "composed of" "excludes ingredients that would materially affect the basic and novel characteristics of the claimed composition." Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1574, 224 U.S.P.Q. (BNA) 409, 412 (Fed. Cir. 1984). The phrase is open to "unlisted ingredients that do not materially affect the basic and novel properties of the invention." PPG, 156 F.3d at 1354, 48 U.S.P.Q.2D (BNA) at 1354.

The invention in this case is a product comprising a coating, which is itself "composed of" various layers. It appears, from a reading of the patent specification and from the testimony elicited during the Markman hearing, that interlayers are important to facilitate the process of manufacturing the claimed coatings, but are not themselves significant in the final, claimed product. The patent specification states that interlayers, although optically insignificant, are useful to protect the explicitly claimed layers: "For the purpose of improving the adhesion or durability of the coating layers, an interlayer having a thickness not to substantially affect the optical properties may be inserted at the interface with the substrate or at the interface between adjacent layers or at the interface with air." Col. 4, ll. 63-68.

Moreover, the parties presented essentially undisputed evidence that persons of ordinary skill in the art understand that interlayers (or "barrier layers") are routinely, and often necessarily, present in low-emissivity coatings that contain silver. The testimony at the Markman hearing makes clear that barrier layers may be vitally important in the process of producing low-emissivity coatings, but that in the final product (as is claimed in this case), they may be disregarded. For example, during the Markman hearing, Cardinal presented live testimony of its president, Roger O'Shaughnessy, who appears to be a person of ordinary skill in the art. 1 On direct examination, O'Shaughnessy stated that Cardinal's products would be "black and totally unusable" if titanium barrier layers are not applied:

My understanding is that when the silver comes out of a zone which has just sputtered the silver and if no titanium metal were applied, then the resulting zinc oxide would be formed on the silver and would literally ruin the silver; so the coating comes out extremely ugly. It's very black and totally unusable.

AFG also presented deposition testimony of O'Shaughnessy. When asked whether a Cardinal coating referred to in an internal document contained barrier layers in addition to other recited layers, O'Shaughnessy replied:

A. Absolutely. We can't run this product without barrier layers. I mean, it just goes whacko. It's impossible to --

Q. Okay, but it's not referred to in the, in the document; is that correct?

A. No, it's not, nor is the top layer broken into its components; so I think, again, someone is just communicating

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fundamental basic layer structures; oxide, metal, oxide, metal, without going into the detail of the actual layers that exist.

Q. But even though it's not specified, it's your understanding that a barrier layer is included?

A. Absolutely. That may be the source of the confusion here. It -- because we can't run without it, we just always know it's there, so internally everybody just assumes the barrier is there.

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1 Because O'Shaughnessy has been president of Cardinal since 1967, and his testimony provided a detailed technical description of Cardinal's products, it appears that O'Shaughnessy's testimony can be interpreted as that of a person of ordinary skill, and that his testimony provides a reliable indication of how people in his field refer to the terms "layer" and "barrier layer."

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O'Shaughnessy's testimony further indicates that when describing their layered coatings, Cardinal personnel generally omit reference to the barrier layers. During the Markman hearing, O'Shaughnessy referred to a Cardinal product sheet that had been written for its production line operators and that contained the following description of one of its coatings:

E5 Lo E has a shading coefficient of 5.5

This coating is made up of 5 layers:

1) zinc oxide

2) metal (Silver, ti barrier)

3) zinc oxide

4) metal (Silver, ti barrier)

5) top oxide (zinc and ti)

O'Shaughnessy acknowledged that this internal Cardinal document describes the coating as a "5 layer coating," despite the presence of several barrier layers in addition to the five primary metallic layers. 2 In his deposition, O'Shaughnessy testified, moreover, that he generally omits reference to the barrier layers when describing coatings. He testified: "That's pretty common to drop the reference [to barrier layers]. It just gets sort of clumsy to put them in. . . . I would always assume that the barriers are in there." 3

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2 Although internal production documents might not in some cases accurately reflect the understanding of persons of ordinary skill, this document is entirely consistent with the other testimony presented by the parties as to how skilled artisans refer to the terms "layer" and "barrier layer."

3 Although this testimony was not read during the Markman hearing, it is contained in a deposition transcript that appears to have been admitted into evidence during the hearing.

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The patent specification and the testimony presented during the Markman hearing indicate that the importance of the interlayers (or barrier layers) arises only in the process of fabricating the coatings, and that once the claimed product is formed, the presence of the interlayers may be insignificant. It appears that the interlayers may be an artifact of the manufacturing process, rather than a material component of the claimed coating itself. Whether they are, indeed, immaterial

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in the final product is a question of fact. See PPG, 156 F.3d at 1357, 48 U.S.P.Q.2D (BNA) at 1357 (determining that a claim to a glass product could read on the accused glass containing iron sulfide, and stating that it is the province of the jury to determine whether the iron sulfide had a material effect on the basic and novel characteristics of the glass). Thus, in light of the specification and of the essentially undisputed testimony of persons of ordinary skill, we think it is reasonably clear that the claimed coating may include interlayers, insofar as they "do not materially affect the basic and novel properties of the invention." PPG, 156 F.3d at 1354, 48 U.S.P.Q.2D (BNA) at 1354. We set forth a more explicit definition of "layer" and "interlayer" below.

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II. "Composite Composition"

Some of the claims of the Group I patents describe a composite that is comprised of a composite pellet, and other claims describe a composite that comprises a linear extrudate. The remainder of the claims in the Group I patents claim a "composite composition, capable of extrusion into a dimensionally stable structural member." ('607, c. 13, 11: 32-33 & '611, c. 12, 11: 52-54; see also '334, c. 14, 11: 12-13 & '612, c. 11, 11: 50-51 (using slightly different language).) The parties disagree about whether this "composite composition" is limited to a particular form. Fiber Composites proposes that the term is "limited to a composite composition which is used to make structural parts, and [it does] not cover the structural part itself." (Fiber Composites' Proposed Claim Construction Order at 1.) Fiber Composites also argues that the term is limited to a "composite composition in the form of a solid pellet or a solid linear extrudate from which pellets can be cut." (Id.) Andersen proposes that the term means "a mixture of polymer and wood fiber, which if thermoplastic, can be melted, shaped, remelted and reshaped." (Andersen's Proposed Claim Constructions and Br. in Supp. at 14.) Andersen states that the term "is directed to a composite material without a particular form." (Andersen's Proposed Claim Construction Order at 3.) Furthermore, in response to Fiber Composites' proposed claim construction, Andersen argues Fiber Composites' proposed construction would make the claim-at-issue equivalent to the other independent claims in the Group I patents. (Andersen's Markman Br. at 6-7.)

The Court first looks to the claim language itself to construe the term "composite composition." 6 See Itron, 169 F. Supp. 2d at 1081. In the independent claims-at-issue, the composite composition is defined as a composite composition that is "capable of extrusion into a dimensionally stable structural member, which composition comprises a thermoplastic material." ('607, c. 13, 11: 32-34 (emphasis added).) The "capable of" formation language describes the product itself, the "composite composition" which is a thermoplastic material capable of being formed into a structural member. Thus, the composite composition of the Group I patents is the material, the intermediate solid in the form of either a pellet or linear extrudate, that is used to form a structural member (the subject of the Group II patents). It is important to note that it is the intermediate solid that is the subject of the Group I patents, not the structural member. In addition, the composite composition of the claims-at-issue must have "a Young's modulus of greater than 600,000 psi." 7 (Id., c. 14, 11: 23.) Thus, the intermediate material is a solid due to the required Young's modulus value. Finally, the claims-at-issue claim an "intentionally recycled impurity" limitation and a different percentage of water than can be found in the other independent claims of the Group I patents. (Id., c. 14, 11: 4-5, 8.) Thus, contrary to Andersen's assertions, the claim language reveals that Fiber Composites' proposed construction does not render the claims-at-issue equivalent to the other independent claims because they contain an "intentionally recycled impurity" limitation and a different percentage of water.

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6 When the claims-at-issue use the same or similar language, reference will be made to only one of the Group I patents.7 Young's modulus is a measure of strength and stiffness of a solid material. (Affidavit of R.J. Zayad ("Zayad Aff.") Ex. 38.); see also Fiber Composites Final Markman Br. at 6.)

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The Court next looks at the specification. Itron, 169 F. Supp. 2d at 1081. The specification confirms that the composite composition of the invention is either a pellet or linear extrudate intermediate solid that is used to form the structural member. The specification states "this invention relates to composite thermoplastic materials used for the fabrication of structural members." ('607, c. 1, 11: 13-14.) It teaches that the "pellets or linear extrudate of the invention are made by

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extrusion of the . . . composite through an extrusion die resulting in a linear extrudate that can be cut into a pellet shape." ('607, c. 4, 11: 44-48 (emphasis added).) Moreover, repeated references are made to pellets or the linear extrudate (which can be cut into small pieces to form pellets) in the specification. (See e.g., '607, c. 4, 11: 6-7 ("moisture control is an important element of manufacturing a useful linear extrudate or pellet"); c. 3, 11: 1-7 ("the successful manufacture of structural members requires the preliminary manufacture of the polyvinyl chloride wood fiber composite in the form of a pellet wherein the materials are intimately mixed and contacted in forming the pellet prior to the extrusion of the members from the pellet material"); c. 4, 11: 66-68-c. 5, 11: 1 ("physical properties of an extruded member are improved when the polymer melt during extrusion of the pellet or linear member").) Finally, the specification teaches that the wood fiber used is often the "by-product of sawing or milling soft woods commonly known as sawdust or milling tailings" (id., c. 6, 11: 55-56) and that sometimes the "sawdust material can contain substantial proportions of waste stream by-products." (Id., c. 7, 11: 20-21.) Thus, the specifications teach that the invention is a product made with or without "intentionally recycled impurities," which shows that the claim-at-issue differs from the other independent claims.

Fiber Composites contends that because the specifications disclose only how to manufacture a "useful linear extrudate or pellet," the composite composition "can only cover a composite material in the form of solid pellets or solid linear extrudate from which pellets are cut." (Fiber Composites' Markman Br. at 7, 9.) Andersen argues that imposing such a limitation on the claims is unfounded and contrary to law. Citing to the specification, Andersen admits that the composite composition "can be in the form of either (1) a linear extrudate, or (2) a thermoplastic pellet, either of which is used to manufacture composite structural members." (Andersen's Proposed Claim Constructions and Br. in Supp. at 14.) Andersen, however, defines linear extrudate as "simply extruded material (i.e., material that does not go through a pelletizing step)." (Andersen's Post Markman Br. at 9.) Thus, Andersen contends that linear extrudate can be material made through a direct extrusion process.

Andersen's definition of "linear extrudate" is not supported by the patent, the specification, or the prosecution history. Andersen relies on sections of the specification that discuss the use of the linear extrudate after it has been formed and is being used "to make a structural unit." (Id. at 8 (citing '334, c. 1, 11: 40-44).) Andersen points to the following language to support its argument: "Alternatively, the extruded thermoplastic mass, in the form of an elongated linear extrudate without a pelletizing step, can be immediately directed after formation into an extruder or injection molding apparatus." (Patent '334, col. 1, line. 40-44; (emphasis added).) In this section, the specification teaches how to make the structural member, which can be made using the linear extrudate that already has been formed but not cut into pellets. This alternative method of forming a structural member does not teach a method of direct extrusion of the pellet or linear extrudate itself. Rather, it teaches an alternative method in which the linear extrudate (the subject of the Group I patents) can be directly placed into an extruder to make a structural member (the subject of the Group II patents). Therefore, the section Andersen relies on actually supports Fiber Composites' proposed definition because it confirms that a useful structural member is made from using an extruded pellet or linear extrudate that is then re-extruded to form the structural member. It does not support a theory that the Group I patents cover a directly extruded composite structural member.

The Court's construction is confirmed in another section of the specification, which teaches that "in the manufacture of the composition and pellet of the invention, the manufacture and procedure requires two important steps. A first blending step and a second pelletizing step." ('607, c. 7, 11: 43-45.) The specification teaches how to form the "composition and pellet of the invention." (Id., c. 7, 11: 46-68, c. 8, 11: 1-68.) The material is first blended by heating the polymer and wood fibers, and then the material is placed in an extruder device from which the linear extrudate is formed. (Id.) If desired, the linear extrudate can then be cut into pellets. (Id.) Therefore, the specification reveals how to manufacture the subject of the Group I patents, which is the pellet or linear extrudate made from the composite material.

Finally, the Court looks to the prosecution history. Itron, 169 F. Supp. 2d at 1081. The prosecution history confirms the Court's construction. The parties spend significant time discussing the impact of the prosecution history on the construction of "composite composition." Fiber Composites contends that the prosecution history supports its proposed construction because during the prosecution Andersen disclaimed anything but pelletizing. (Fiber Composites' Final Markman Br. at 9-12.) Conversely, Andersen contends that the "patent examiner clearly understood that the pellet was merely an embodiment, but one that was patentably distinct from the composite composition form of the invention." (Andersen's Reply Brief at 7.) Andersen contends that the prosecution history, in context and in total, establishes that Andersen distinguished its claims by citing several references and that it never limited its composite composition claims to a particular form. (Andersen's Final Markman Br. at 11-12.)

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"Arguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." Southwall, 54 F.3d 1570 at 1579. To the extent that the prosecution history is helpful to the Court, it confirms the Court's conclusion that the composite composition is either a pellet or linear extrudate because no other form was contemplated in the prosecution history.

All of the Group I patents are continuations on two abandoned applications, the '364 Application and the '396 Application. Representations made to the Patent Office during these applications are part of the prosecution history of the Group I patents. Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990). For example, one of the Patent Office's bases for rejecting Claims 1-20 of the '365 Application was that the claims were anticipated, in part, by the Miani patent, U.S. Patent No. 4,915,764. (Zayad Aff. Ex. 31.). In response, Andersen states that in the Miani patent "the composite is directly extruded and kept hot during the entire operation . . . This type of composite is not the composite taught in the present invention. In contrast, the presently claimed composite is prepared by mixing the melted polymer and wood pulp, forming pelletized material, cooled, and then extruded." (Zayad Aff. Ex. 32 (emphasis added).) Thus, it is evident that the composite that is the subject of Andersen's invention is the pellet or linear extrudate of the pelletizing step, not the final structural member made through direct extrusion.

The prosecution of the '364 Application also reveals the invention covers a pellet or linear extrudate. The Abstract in the '364 Application states, "The invention relates to a composition . . . in the form of a linear extrudate or thermoplastic pellet." (Skeynon Decl., Ex. 8 (emphasis added).) The original '364 Application had thirty claims. (Id.) Claims 1-11 claimed a composite in the form of a pellet, claims 12-21 claimed a composite in the form of a linear extrudate, and claims 22-30 claimed a composite without an enumerated form. (Id.) The claim language for the independent claims in the '364 Application is nearly identical to that found in the Group I patents. The Patent Office responded to the '364 Application by rejecting all 30 of the claims "as being unpatentable over Hamed 3943079 in view of Maldas, Journal of Vinyl Technology; v. 11, no. 2." (Skenyon Decl., Ex. 9, p.2.) The Hamed patent and the Maldas article both taught a composite material comprised of wood or cellulosic fiber and some type of a polymer. (Id.)

In responding to the Patent Office rejection of all 30 claims, Andersen referred to the invention as a pellet or the pelletizing process no less than 13 times. (Id. Ex. 10.) In so doing, Andersen never attempted to limit its references to the pellet or pelletizing process only to independent claims 1 and 12 nor to differentiate between the pellet and the composite. The response specifically stated:

> Applicant's invention comprises a pellet . . .
>
> * * *
>
> Further, Maldas does not teach the pelletizing of the composite material.
>
> * * *
>
> In contrast, Applicant first pelletizes the thermoplastic composite material, and then, manufactures a structural member from the pelletized materials by melting and extruding the composite. Thus, Maldas does not teach or suggest the manufacture or composition of the thermoplastic pellet materials of Applicant's invention.
>
> * * *

(Id. (emphasis added).) Thus, Andersen's response that the "invention comprises a pellet" and Andersen's references to the "composite material" are relevant to an understanding of the term as used in the Group I patents and help to show that the invention is the intermediate solid used to form the structural member, not the final product.

Therefore, the Court concludes that the term "composite composition," when viewed in light of the claim language, the specification, and the prosecution history, means as a solid pellet or a solid linear extrudate, which may subsequently be remelted and extruded to make a structural member.

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Construction of Claim 1

The district court construed claim 1 to include "compositions" formed by the spaced, sequential application of the two ingredients to a tuber in storage, even though the two ingredients are not physically combined, as long as they work together to inhibit sprouting on the tuber. Markman Order at 10. The interpretation of that term forms the heart of the parties' claim construction dispute on appeal.

PIN/NIP argues that the term "composition," as a term of art in both the fields of patent law and chemistry, requires a physical mixture of the constituents. PIN/NIP also argues that the '912 patent uses the terms "composition" and "mixture" synonymously, and that the only embodiment described in the specification involves a pre-mixture of CIPC with either DMN or DIPN. Platte responds that the court properly gave the term the full breadth of its ordinary meaning, so as to include the ordering or arranging of materials that do not physically come into contact with each other. Platte also has a different reading of the specification from PIN/NIP, asserting that one skilled in the art would not conclude that the specification discloses only a pre-mixture of the constituents.

We agree with PIN/NIP concerning the interpretation of the disputed claim language. The term "composition" in chemistry is well-established. It generally refers to mixtures of substances. 2 It cannot be construed by analogy to a painting. We have previously construed the term "composition" in the context of a particular patent claim. In Exxon Chemical Patents, Inc. v. Lubrizol Corp., we equated a "composition" with a "mixture," stating:

[A] chemical composition exists at the moment the ingredients are mixed together. Before creation of the mixture, the ingredients exist independently. . . . Consequently, as properly interpreted, Exxon's claims are to a composition that contains the specified ingredients at any time from the moment at which the ingredients are mixed together. This interpretation of Exxon's claims preserves their identity as product claims, and recognizes as a matter of chemistry that the composition exists from the moment created.

64 F.3d 1553, 1558, 35 U.S.P.Q.2D (BNA) 1801, 1804 (Fed. Cir. 1995) (emphases added). Although the construction of a term in a patent claim is a highly contextual exercise that is dependent upon the content of the particular patent in which the term appears, and one cannot always apply the construction of a claim term from one patent to an unrelated patent in an unrelated lawsuit, the basic definition of the term "composition" is well-established, was well-expressed in Exxon, and is applicable to this case. The principle that a composition is indeed a mixture in which the components are present together at some point in time is even more true in this case, in which the specification of the '912 patent teaches only the mixture of the two ingredients. In fact, that is the invention; use of the materials separately was in the prior art. Although the specification uses various terms to describe the invention -- "composition," see, e.g., '912 patent, Title; "mixture," id. at Abstract; "combination," id. at col. 3, l. 9; and "conjunction," id. at col. 5, ll. 43-49 -- they all mean essentially the same thing. The described invention is clear; it is a mixture of the two chemicals together. The written description of the invention is typified by the following sentence from the specification: "However, what was unexpected, and is summarized above in Table II, the application of a mixture of CIPC and DIPN to the tubers to obtain [results], which were substantially greater than the sum of [the results] of each treatment separately." Id. at col. 5, ll. 4-11 (emphasis added). One skilled in the art of tuber sprout suppression would read this sentence, and the specification as a whole, to mean that CIPC and DIPN were mixed together, and that the resulting mixture was applied to the tubers, as opposed to separate applications with each chemical alone. Moreover, as indicated, separate use of the component chemicals was known before the invention, as the '912 patent acknowledges that prior art practitioners applied CIPC, DMN, and DIPN separately for the same purpose as the invention -- sprout suppression. In fact, allowance of the '912 patent was based upon the unexpected results of the combination of CIPC and DMN or DIPN.

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2 The term "composition of matter" is within the definitions of patentable inventions in 35 U.S.C. § 101. It is the principal rubric under which chemical compounds are patentable (arguably, they can also be "manufactures").

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The district court interpreted claim 19 differently from claim 1 based upon the presence of the term "providing," but we do not see a sufficient distinction. Claim 19 recites two steps: "providing a composition comprising CIPC and a substituted naphthalene to form a sprout inhibiting composition" and "applying [the] composition to the outer surface of the tubers." The court reasoned that the first step results in a unitary, pre-mixture of the two chemicals. We do not disagree. Instead, we conclude that the nearly identical words of claim 1 also refer to a unitary mixture of the two chemicals. The absence of the step of "providing" a composition does not lead us to distort the meaning of the term "composition" in claim 1 as not requiring a mixture of CIPC and a substituted naphthalene.

We therefore construe the term "composition" in claim 1 to mean a physical mixture of CIPC and a substituted naphthalene existing together at approximately the same time. The mixture may be a pre-mixture, i.e., a mixture that comes into being well before being used for sprout suppression, or a mixture that is formed at any time during use, such as through simultaneous application of the constituent chemicals, as long as a mixture is indeed formed.
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E. "composition"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, n10 is as follows:

An immediate-release fenofibrate composition comprising:

(a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 [mu] m, a hydrophilic polymer and a surfactant; and

(b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

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n10 I note, however, what appears to be an inconsistency in the prosecution history of the '405 and '881 patents. Claim 1 of the '405 patent, as originally submitted to the patent and trademark office, and claim 1 of the '881 patent, as issued, are identical. (D.I. 170, Ex. 7 at 055, C.A. 03-120-KAJ, Response and Amendment, date stamped Jan. 26, 2001; '881 patent, col. 10, ll. 44-65.) In the prosecution history of the '405 patent, the examiner required, and the applicants acquiesced in, adding the term "hydrosoluble carrier" to the claim in order to clearly define the composition. (D.I. 235, Ex. 7 at 118, C.A. 02-1512-KAJ, Interview Summary dated Mar. 21, 2001 (stating that "to clearly define the composition ... [it] must comprise the micronized fenofibrate and a hydrosoluble carrier to give the claimed dissolution profile [and that] without the hydrosoluble carrier (i.e. drug alone), the dissolution profile would be different.") However, in prosecuting the '881 patent, a second examiner allowed claim 1 without requiring the addition of the "hydrosoluble carrier" term. ('881 patent, col. 10, ll. 44-65.) This would suggest that the term "composition," as used in claim 1 of the '405 patent, was understood by at least one examiner to include a hydrosoluble carrier. Thus, there seems to be an inconsistency in the decisions rendered by the two examiners, because claim 1 of the '405 patent and claim 1 of the '881 patent each claim the same dissolution profile, yet the applicants were not required to amend claim 1 of the '881 patent to include the hydrosoluble carrier as well.

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1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "composition" to mean "a combination of various elements or ingredients." (D.I. 238 at 8, C.A. 02-1512-KAJ; D.I. 167 at 6, C.A. 03-120-KAJ.) Abbott argues that this meaning comports with "its ordinary

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meaning to a person of skill in the art." (D.I. 237 at 14, C.A. 02-1512-KAJ.) Teva proposes that I construe "composition" to mean "a fenofibrate composition, wherein the inert carrier (as described above) is a support for the micronized fenofibrate (as described below) and hydrophilic polymer (as described above), and which can take the form of granulates, tablets and capsules." (D.I. 238 at 8, C.A. 02-1512-KAJ.) Teva makes the same argument in support of its proposed construction for "composition" that it made for its proposed construction of "granulates," see supra Part IV.D.1., namely, that it must be construed to cover the coated-core structure. (D.I. 223 at 34-36.) Impax proposes that I construe "composition" to mean "a structure wherein an inert hydrosoluble carrier is coated with micronized fenofibrate and a hydrophilic polymer or (the remnants of) some solvent for fenofibrate." (D.I. 167 at 6, C.A. 03-120-KAJ.) Impax makes the same argument in support of its proposed construction for "composition" as it made for its proposed construction of "granulates," see supra Part IV.D.1., namely, that it must be construed to include the structural limitation of a coating. (D.I. 169 at 12-13, C.A. 03-120-KAJ; D.I. 205 at 11-14; C.A. 03-120-KAJ.)

2. The Court's Construction

For the same reasons expressed in construing the term "granulate," see supra Part IV.D.2., I find that the term "composition" should be construed according to its ordinary meaning and thus means "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients." Webster's Third New International Dictionary 466 (3d ed. 1986). As seen in claim 1 of the '670 patent, the elements which combine to form the "composition" are specifically identified. Thus, I agree with Abbott that "composition," is used "as a general descriptive term" (D.I. 270 at 6, C.A. 02-1512-KAJ) and thus I give it the ordinary meaning of "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients."

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A. "potassium bromate replacer composition"

Sara Lee contends that the phrase "potassium bromate replacer composition" must be construed to refer to a premixed composition of ingredients for addition to a dough. (Sara Lee's Claim Construction Brief, at 3). 5 Kim argues that "potassium bromate replacer composition" must be interpreted as applying "to a bread that contains the claimed proportions of ingredients at any time during the mixing, fermentation, or forming stages of the breadmaking process." (Plaintiff Yoon Ja Kim's Claim Construction Brief, at 7-8).

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5 Sara Lee also contends that the phrase must be construed as a combination of ascorbic acid and food acid -- and optionally, a phosphate -- that has a proven effect of prolonging oxidation. (Sara Lee's Claim Construction Brief, at 3). According to Sara Lee, "without proof that the action of ascorbic acid has been slowed down by the food acid and is effective and functional during mixing, proofing, and baking' the claims cannot be infringed." (Sara Lee's Claim Construction Brief, at 14). As noted earlier, however, the court must construe the claims independent of the accused product. Embrex, Inc. v. Service Eng'g Corp., 216 F.3d 1343, 1347. Only after claim construction does the fact finder compare the properly construed claims to the accused device or process to resolve the issue of infringement. Catalina Marketing International, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 812 (Fed.Cir. 2002). As such, Sara Lee's contentions on what might be necessary to prove infringement have no import in this Markman proceeding.

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We begin claim construction with the ordinary and customary meaning of the term. Teleflex, Inc., 299 F.3d at 1325. Here, in this context, "composition" has the ordinary and customary meaning of "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, at 466 (4a) (1986). The Federal Circuit has discussed "composition" as a term of art in patent law, which must be interpreted as "containing the specified ingredients at any time from the moment the ingredients are mixed together." Mars, Inc. v. H.J. Heinz Co., L.P., 377 F.3d 1369, 1374 (Fed. Cir. 2004); PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235, 1243-44 (Fed. Cir. 2002); Exxon Chemical, 64 F.3d at 1557-1558 (Fed. Cir. 1995). Before the creation of the mixture, according to the Federal Circuit, the ingredients exist independently. Mars, Inc., 377 F.3d at 1374; PIN/NIP, Inc., 304 F.3d at 1244; Exxon

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Chemical, 64 F.3d at 1558. Accordingly, the composition claimed in the 355 patent must refer to the specific ingredients -- here, ascorbic acid, food acid, an optional phosphate, and flour -- at any time from the moment they are mixed together.

This construction of the claim term leaves open the question of whether the "composition" requires that the ingredients be premixed before introduction to the dough. In Exxon Chemical, the court rejected an interpretation of a claimed composition that was limited to a final, stand-alone product made and ready for use. The court found that the specification contained no such temporal limitation to the term "composition" that would support an interpretation dependent upon the time at which one views the composition. 64 F.3d at 1558. Here, the court finds nothing in the ordinary and customary meaning of the term to require that the "composition" occur at a given time or location, as would a limitation requiring the ingredients to be premixed apart from the bread mix or dough. Furthermore, the patent specification refers to the addition of a food acid to a bread mix or dough already containing ascorbic acid. ('355 patent, 5: 15-19; 6: 3-5; 6: 66-7: 25). Accordingly, the "composition" may occur within the dough, with the result meeting the requirement that it "contain[] the specified ingredients at any time from the moment the ingredients are mixed together."

Sara Lee's argument that the claim can only be interpreted as a stand-alone, pre-mixed composition, relies almost entirely on the prosecution history. According to Sara Lee, the prosecution history indicates that Kim can claim only that the potassium bromate replacer is a separate composition. Because Kim originally filed a patent application for a dough product and a method of making that dough product that was rejected, Sara Lee submits that the present "composition" cannot be read to cover a dough product. (Sara Lee's Claim Construction Brief, at 8-10; Sara Lee's Response to Plaintiff Yoon Ja Kim's Claim Construction Brief, at 5). In this manner, Sara Lee supports its construction requiring that the composition be a pre-mixed, stand-alone product. The court's review of the prosecution history, however, does not suggest that such a construction is demanded.

The Examiner did, indeed, reject Kim's application, explaining that prior art showed:

> bread doughs containing the combination of ascorbic acid with organic acids . . . As far as the claim is understood, the reference shows the same combination claimed. In any event the selection of a functioning amount of additive for the functionality of the reference would have been a routine matter and well within the ordinary skill of one in the art.

(Sara Lee's Claim Construction Brief, Ex. 6, at 91). After a few fits and starts, (Sara Lee's Claim Construction Brief, at 9), Kim then drew claims toward a method of preparing potassium bromate replacer. (Sara Lee's Claim Construction Brief, Ex. 7, at 74-5). The Examiner then allowed the claims, providing these reasons for allowance:

> None of the prior art of record teaches or suggests either an ascorbic acid consisting of the specific components, ascorbic acid, a food acid and a phosphate in the specific amount or that such ascorbic acid composition would be effective as a slow-acting oxidizing agent so that it would effectively replace a slow-acting oxidizing agent such as potassium bromate, because ascorbic acid had been known as a fast-acting oxidizing agent.

(Sara Lee's Claim Construction Brief, Ex. 7, at 89). Similarly, the Examiner's reasons for allowing the reissue patent were:

> a composition, which has use as a potassium bromate replacer when combined with flour, consisting essentially of 0.001 to 0.03 parts ascorbic acid per 100 parts by weight flour and 0.015 to 0.2 parts food acid per 100 parts flour.

(Sara Lee's Claim Construction Brief, Ex. 8, at 177). The Examiner's allowance, then, was in both instances dependent on two departures from prior art: (1) the specific components in the specific amounts; and (2) efficacy as a slow-acting oxidizing agent. There is nothing to suggest it must be a pre-mixed, stand-alone product, as long as it is used as a slow-acting oxidizing agent, and is made up of the specific ingredients in the specific amounts. The prosecution history does not disavow the addition of those ingredients to a bread mix or dough in sequence, nor does it disavow the use of the invention in dough or dough products.

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II. Test Results and Interpretation of Claims

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Claims 1 and 2 of the '791 patent state the following:

1. A two-phase porcelain composition comprising a leucite crystallite phase dispersed in a feldspathic glass matrix, a maturing temperature of from about 750 [degrees] to about 1050 [degrees] C. and a coefficient of thermal expansion of from about 12x10<-6>/ [degrees] C. to about 17.5x10<-6>/ [degrees] C. (room temperature to 450 [degrees] C.), said porcelain composition comprising:

Component	Amount (wt. %)
SiO[2]	57-66
Al[2]O[3]	7-15
K[2]O	7-15
Na[2]O	7-12
Li[2]O	0.5-3
CaO	0-3
MgO	0-7
F	0-4
CeO[2]	0-1

wherein the leucite crystallites possess diameters not exceeding about 10 microns and represent from about 5 to about 65 weight percent of the two-phase porcelain composition.

2. The two-phase porcelain composition of claim 1 further comprising at least one component selected from the group consisting of opacifying agent, pigment and fluorescing agent.

('791 Patent, Col. 6, Claims 1, 2.)

Jeneric's expert witness, Richard D. Sisson, Ph.D., conducted a variety of tests to determine the physical properties of Sensation and Cerpress. Professor Sisson is the Program Head of the Materials Science and Engineering Program at Worcester Polytechnic Institute in Worcester, Massachusetts. The tests conducted on samples of Sensation and Cerpress included: (1) x-ray diffraction and scanning electron microscopy to determine the presence of leucite crystals in the glass matrix; (2) scanning electron microscopy and quantitative image analysis to determine the percent and size of leucite crystals in the glass matrix; (3) wet chemical analysis to calculate the chemical composition of the two products; (4) thermal expansion coefficient measurement to ascertain the respective coefficients of thermal expansion; and (5) quantitative image analysis and digital x-ray maps to identify the amount of cerium oxide ("CeO[2]") inside and outside of the two-phase composition. (Pl.'s Mem. Supp. at 2-3; Exs. 15-51B.) The parties do not dispute the results of Professor Sisson's testing of samples of Sensation and Cerpress. A chart comparing Professor Sisson's test results to claim 1 of the '791 patent is reproduced below:

* * * [SEE TABLE IN ORIGINAL]

(Pl.'s Mem. Supp. at 6-18, 26; Sisson Decl. at 12-17; Defs.' Mem. Opp. at 10-11.) In addition to the chemical elements comprising Cerpress listed above, tests showed that Cerpress contained 1.02% of Barium Oxide ("BaO") and 1.93% of Boron Oxide ("B[2]O[3]"). (Id.)

Both sides agree that most of the elements of claim 1 read on Sensation and Cerpress. For example, Sensation and Cerpress constitute a two-phase porcelain composition having a leucite crystallite phase dispersed in a glass matrix, with leucite crystal sizes "not exceeding about 10 microns," as provided in claim 1. In addition, the leucite crystals in the two products comprise 25 to 40 weight percent of the two-phase composition, well within the range of "from about 5 to about 65 weight percent" established by claim 1. Next, Professor Sisson calculated the coefficients of thermal expansion for Sensation as 13.5x10<-6>/ [degrees] C. and for Cerpress as 14-16x10<-6>/ [degrees] C., clearly within the range of "12x10<-6>/ [degrees] C. to about 17.5x10<-6>/ [degrees] C." established by claim 1. Finally, the maturing temperatures of Sensation and Cerpress fall within claim 1's range. However, the defendants argue that the chemical compositions of Sensation and Cerpress, as measured in weight percentage, do not fall within the ranges stated in claim 1. Indeed, Professor Sisson's tests revealed that: (1) Sensation contained 1.61% of CeO[2]; and (2) Cerpress contained 15.97% of Alumina ("Al[2]O[3]") and .041% of Lithium Oxide ("Li[2]O").

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Jeneric contends that Sensation literally infringes claims 1 and 2 of the '791 patent. It acknowledges that Sensation contained 1.61% of CeO[2], more than the range of 0-1% specified in claim 1. However, Jeneric asserts that claim 2 covers the addition of an "opacifying agent, pigment and fluorescing agent" to the composition of claim 1. ('791 Patent, Col. 6, Claim 2.) The specification of the '791 patent lists CeO[2] as a fluorescing agent. (Id., Col. 5, Lines 45-48.) Professor Sisson's tests showed that of the 1.61% of CeO2 in Sensation, .92% was present in the glass matrix as an antigreening agent, while .69% was present as a fluorescing agent or additive outside of the two-phase matrix. (Sisson Decl. PP 20-21; Pl.'s Mem. Supp. P 14.) Jeneric proposes that the .92% of CeO[2] satisfies the range limitation in claim 1, and the .69% of CeO[2] is permitted by claim 2 as a fluorescing agent or additive. (Pl.'s Prop. Find. Fact Concl. Law PP 54, 58, 163, 164.)

Jeneric also maintains that Cerpress infringes claim 1 of the '791 patent under the doctrine of equivalents. Once again, Jeneric acknowledges that Cerpress contained .041% of Li[2]O, less than the 0.5-3% range established by claim 1. However, it states that 1.02% of BaO, 1.95% of B[2]O[3], and sodium oxide ("Na[2]O have been added as a substitute for the range of Li[2]O in claim 1 to perform the same function, in the same manner, and to achieve the same result. (Pl.'s Mem. Supp. PP 16, 18, 20.) Li[2]O performs the function of a "flux modifier" in a ceramic material, controlling the viscosity and the fusion temperature or melting point. (Sisson Test.; Panzera Test.) According to Professor Sisson, the elements of Na[2]O, BaO, and B[2]O[3] found in Cerpress also act as a flux and are well-known substitutes in the art. (Sisson Decl. PP 8, 24, 26; Pl.'s Prop. Find. Fact Concl. Law PP 63-65.) Jeneric also acknowledges that Cerpress contains 15.97% of Al[2]O[3], greater than the 7-15% range established by claim 1. However, it explains that "a portion of the Alumina (Al2O3) was added as an additive." (Pl.'s Mem. Supp. at 27.) In turn, Professor Sisson states that:

A portion of the Alumina (Al[2]O[3]) either was added as a substitute for one of the glass modifying or glass forming oxides or resides outside of the two phase glass-leucite matrix and thus this component is within the range of claim 1. The additional Alumina may also have been added to increase the coefficient of thermal expansion of the two phase glass-leucite matrix to counteract the reduction caused by the addition of the Boron Oxide (B[2]O[3]), and thus this component is within the range and intent of claim 1.

(Sisson Decl. P 25.) Jeneric suggests that at least .97% of the Al[2]O[3] in Cerpress exists outside of the two-phase matrix. (Pl.'s Mem. Supp. at 17, 27; Pl.'s Prop. Find. Fact Concl. Law PP 62, 166.)

STANDARD OF REVIEW FOR PRELIMINARY INJUNCTION

Injunctive relief in patent cases is authorized by 35 U.S.C. § 283. A moving party in a patent infringement suit must establish its right to a preliminary injunction in light of four factors: (1) whether the movant has demonstrated a reasonable likelihood of success on the merits; (2) whether the movant will suffer irreparable harm if the injunction is not granted; (3) whether the balance of the hardships tips in favor of the movant; and (4) the impact of the injunction on the public interest. See Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367 (Fed. Cir. 1996); Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993). Courts must consider all four factors before granting a preliminary injunction. See Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1555 (Fed. Cir. 1994). In contrast, courts may decline to issue a preliminary injunction if the movant fails to prove either of the first two factors. See Polymer Tech., Inc. v. Bridwell, 103 F.3d 970, 973 (Fed. Cir. 1996). The burden of persuasion always remains on the movant to establish entitlement to a preliminary injunction. See Reebok Int'l, 32 F.3d at 1555.

To demonstrate a reasonable likelihood of success, the movant must show clearly that it owns the patent at issue, the patent is valid and enforceable, and the defendant infringed the patent. See Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir.), cert. denied, 522 U.S. 963, 139 L. Ed. 2d 310, 118 S. Ct. 397 (1997); Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1219 (Fed. Cir. 1996). More specifically, in light of the presumptions and burdens that will inhere at trial, the patentee must establish a reasonable likelihood of success that: (1) the defendant infringed its patent; and (2) the defendant's challenges to validity and enforcement probably will not succeed at trial. See Bell & Howell Document Management Prod. Co. v. Altek Sys., 132 F.3d 701, 705 n.4 (Fed. Cir. 1997); New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed. Cir. 1992); Genentech, 108 F.3d at 1364.

A patent is presumed valid and this presumption exists throughout every stage of litigation. See 35 U.S.C. § 282; PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996). The Federal Circuit has explained the different effects of the presumption of validity at trial and the presumption of validity at the preliminary injunction stage:

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The presumption [of validity] acts as a procedural device which places the burden of going forward with evidence and the ultimate burden of persuasion of validity at the trial on the alleged infringer . . . . However, the presumption does not relieve a patentee who moves for a preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all the disputed liability issues at trial, even when the issue concerns the patent's validity. At this preliminary stage, the trial court does not resolve the validity question but rather must . . . make an assessment of the persuasiveness of the challenger's evidence, recognizing that it is doing so without all of the evidence that may come out at trial.

New England Braiding, 970 F.2d at 882-83 (emphasis added). At the preliminary injunction stage, the defendant must carry its burden of production by coming forward with evidence of invalidity. See Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc., 134 F.3d 1085, 1088 (Fed. Cir. 1998). If the defendant "fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies the patentee's burden on the validity issue." Id.; accord New England Braiding, 970 F.2d at 882-83. When the defendant offers proof of invalidity, the patentee must submit sufficient evidence to rebut this showing. See Canon Computer, 134 F.3d at 1088. In sum, the patentee must show that the alleged infringer likely will not prove that the patent is invalid at trial. See Nutrition 21 v. United States, 930 F.2d 867, 869-70 (Fed. Cir. 1991); Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir. 1983).

Where a patentee demonstrates a reasonable likelihood of success regarding patent validity and infringement, along with continuing infringement by the defendant, the owner obtains a rebuttable presumption of irreparable harm. See Polymer Tech., 103 F.3d at 973; Reebok Int'l, 32 F.3d at 1556. Alleged infringers may rebut the presumption that the patentee will suffer irreparable harm with evidence that: (1) the defendant has or will soon cease the infringing activities, thus making a presumption unnecessary, see Reebok Int'l, 32 F.3d at 1557-59; (2) the patentee engaged in a pattern of granting licenses under the patent, making it reasonable to expect that the invasion of its patent right can be recompensed by royalties-type damages rather than an injunction, see High Tech. Med. Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1557 (Fed. Cir. 1995); (3) the patentee unduly delayed in bringing suit, thereby negating the idea of irreparability, see T.J. Smith & Nephew Ltd. v. Consolidated Med. Equip., Inc., 821 F.2d 646, 648 (Fed. Cir. 1987); Nutrition 21, 930 F.2d at 872; (4) the patentee actually does not practice the patent, see Rosemount, Inc. v. United States Int'l Trade Comm'n, 910 F.2d 819, 821 (Fed. Cir. 1990); and (5) the patentee maintains a large market share in comparison with the alleged infringer. See Bell & Howell, 132 F.3d at 708; Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 683 (Fed. Cir. 1990).

DISCUSSION

I. Reasonable Likelihood of Success
A. Infringement

A determination of patent infringement requires a two-step analysis. First, courts must construe the asserted claims of the patent to determine their proper scope and meaning. See Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1443 (Fed. Cir. 1997); Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993). Claim construction is a question of law for the Court. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Second, courts must determine whether the properly construed claims read onto the accused structure. See General Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 981 (Fed. Cir. 1997). This is a question of fact. See id.

1. Claim Construction

A patent does not protect everything it describes, but rather only the innovations set forth in its claims, which provide the metes and bounds of the invention. The claims of a patent, as distinguished from the specification and drawings, define the invention protected by the patent. See Smith v. Snow, 294 U.S. 1, 11, 79 L. Ed. 721, 55 S. Ct. 279 (1935); Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 419-20, 52 L. Ed. 1122, 28 S. Ct. 748 (1908); Novo Nordisk of N. Am., 77 F.3d at 1369. Courts may consult both intrinsic and extrinsic evidence as aids in construing patent claims. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Intrinsic evidence consists of the patent itself, the claim or claims at issue, the specification, and the prosecution history. See id. Extrinsic evidence includes expert testimony, inventor testimony, dictionaries, technical treatises, and prior art not cited in the prosecution history. See Markman, 52 F.3d at 980.

Under established rules of claim construction, intrinsic evidence of a patent constitutes "the most significant source of the

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legally operative meaning of disputed claim language." Vitronics, 90 F.3d at 1582. The claims, specification, and prosecution history constitute the public record of a patentee's claim, upon which competitors may rely. See Markman, 52 F.3d at 978-79. Allowing a clearly drafted claim to be altered by extrinsic evidence would destroy the rights of competitors to rely on the public record and design around the claimed invention. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995). Thus, reliance upon extrinsic evidence is improper where the intrinsic evidence unambiguously describes the scope of the patented invention. See Markman, 52 F.3d at 978-79, 986; Bell & Howell, 132 F.3d at 705-06.

In construing patent claims, the Court must first consider the words of the claims themselves, both asserted and unasserted. See Vitronics, 90 F.3d at 1582-83; SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 882 (Fed. Cir. 1988). These words generally should be given their customary and ordinary meaning to one of skill in the art. See Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1580 (Fed. Cir. 1995). However, a patentee may be his own lexicographer provided that he or she delineates any special definitions in the specification or the file history. See Hoechst Celanese, 78 F.3d at 1578; Markman, 52 F.3d at 980.

Next, the Court must review the patent specification to determine if the inventor used any terms in a manner inconsistent with their ordinary meaning. 2 See Vitronics, 90 F.3d at 1582. The specification contains a description of the invention, and the manner and process for making and using it in such full, clear, and exact terms as to enable any person skilled in the art to make and use it. See 35 U.S.C. § 112. In addition, the specification must explain the best mode or preferred embodiment for carrying out the invention, 3 see id., and thus can serve as a dictionary for defining terms in the claims. See Markman, 52 F.3d at 979. However, a patented invention is defined by its claims, which may be broader in scope than the specification. See Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277 (Fed. Cir. 1995) (instructing that courts may not incorporate features of preferred embodiments or examples used in the specifications into claim definitions); Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1566 (Fed. Cir. 1992) (holding that courts may not read into a claim a limitation that appears in the specification, but not in the claim); SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121-22 (Fed. Cir. 1985) (same).

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2 Under 35 U.S.C. § 113, a patent also may contain drawings. Courts may utilize drawings to help construe claims "in the same manner and with the same limitations as the specifications." Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 398 (Ct. Cl. 1967).

3 35 U.S.C. § 112's disclosure requirement functions as part of a contract. The government grants a monopoly to inventors in exchange for disclosing the invention's best mode or optimal embodiment. See Construction Tech., Inc. v. Cybermation, Inc., 965 F. Supp. 416, 431 (S.D.N.Y. 1997).

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The Court also may examine the prosecution history of the patent, if in evidence. See Graham v. John Deere Co., 383 U.S. 1, 33, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). The prosecution history includes a "complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Vitronics, 90 F.3d at 1582. These representations may include amendments and arguments made to convince the patent examiner that the claimed invention complies with the statutory requirements of novelty, utility, and nonobviousness. See Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985). In addition, courts may review the prior art cited within the prosecution history to gain a general idea of what the claims do not cover. See Autogiro, 384 F.2d at 399. While the prosecution history should be used to construe claim language, it cannot "enlarge, diminish, or vary" the limitations in the claims. Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149 (1880); Markman, 52 F.3d at 980.

Extrinsic evidence such as expert testimony, inventor testimony, dictionaries, technical treatises, and prior art provides a final source for claim interpretation when needed to explain scientific principles, technical terms, and terms of art. See U.S. Indus. Chems., Inc. v. Carbide & Carbon Chems. Corp., 315 U.S. 668, 678, 86 L. Ed. 1105, 62 S. Ct. 839 (1942); Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995). Extrinsic evidence also may demonstrate the state of the art at the time of the invention. See Brown v. Piper, 91 U.S. 37, 41, 23 L. Ed. 200 (1875); Markman, 52 F.3d at 980. While experts may testify concerning the meaning of claim language from which the Court can then determine claim construction,

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experts cannot provide testimony that alters the actual claim language or that contradicts the import of other parts of the specification. See Vitronics, 90 F.3d at 1584. Moreover, the testimony of an inventor and his attorney concerning claim construction is entitled to little or no weight. See Bell & Howell, 132 F.3d at 706. Lastly, courts may admit prior art not cited in the patent or prosecution history to show how a disputed term is used by those skilled in the art. See Vitronics, 90 F.3d at 1584.

Applying these principles to the present case, the Court may utilize Professor Sisson's test results to compare the physical properties of Sensation and Cerpress to claims 1 and 2 of the '791 patent. The Court also may consider Professor Sisson's declaration and testimony to the extent that they explain scientific principles and technical terms of art. However, claim construction remains the exclusive province of the Court, and the claims in this case prove relatively unambiguous. As a result, those portions of Professor Sisson's declaration and testimony that attempt to vary or contradict the plain meaning of claims 1 and 2 will not be considered.

Claims can either be independent or dependent. An independent claim does not refer to any other claim of the patent and is read separately to determine its scope. See Baracuda Int'l Corp. v. Hoffinger Indus., Inc., 4 F. Supp. 2d 1188, 1193 (N.D. Ga. 1998); Johns Hopkins Univ. v. Cellpro, 894 F. Supp. 819, 832 (D. Del. 1995). A dependent claim refers to at least one other claim in the patent, includes all of the limitations of the claim to which it refers, and specifies a further limitation on that claim. See Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989); Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1107-08 (Fed. Cir. 1987).

35 U.S.C. § 112 provides in relevant part:

[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

By definition, a dependent claim must be narrower than the independent claim upon which it relies. See Quantum, 65 F.3d at 1579. One may infringe an independent claim and not infringe a claim dependent upon that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependent on, and thus containing all the limitations of, that claim. See Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994); Teledyne McCormick Selph v. United States, 214 Ct. Cl. 672, 558 F.2d 1000, 1004 (Ct. Cl. 1977). In other words, "the dependent claim tail cannot wag the independent claim dog." North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993). 4

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4 One court pondered the purpose of dependent claims if the patent holder must be able to recover on the independent claim before it can recover on the dependent claim. It provided the following answer:

Dependent claims may serve as an aid in construing the language in the independent claims that they incorporate . . . . The court can look to one claim in an attempt to interpret the terms of another claim -- indeed the doctrine of claim differentiation requires that to be done.

Perhaps more importantly, a dependent claim can save a patent if the independent claim fails. Independent claims are generally drawn as broadly as possible so as to include all possible embodiments of the invention, including those that exist and those that are yet to be conceptualized. That attempt to maximize the breadth of an independent claim may later cause it to be held to be obvious from or anticipated by the prior art. Dependent claims could save the day, however, if the additional limitations included in a dependent claim would meet the otherwise unsatisfied test of nonobviousness or nonanticipation.

Zip Dee, Inc. v. Dometic Corp., 931 F. Supp. 602, 614-15 (N.D. Ill. 1996) (citations omitted).

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The Court disagrees with Jeneric's proposed construction of claims 1 and 2 of the '791 patent as a matter of law. In essence, Jeneric argues that the elements comprising claim 1 are not limited to the ranges set forth therein. With regard to Sensation,

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Jeneric acknowledges that Sensation contains 1.61% of CeO[2], more than the range of 0-1% specified in claim 1. However, it maintains that of the 1.61% of CeO[2], .92% is present in the glass matrix as an antigreening agent, while .69% is present as a fluorescing agent or additive outside of the glass matrix. (Sisson Decl. PP 20-21; Pl.'s Mem. Supp. at 15, 27.) Claim 2 covers the addition of an "opacifying agent, pigment and fluorescing agent" to the composition of claim 1. ('791 Patent, Col. 6, Claim 2). Jeneric correctly points out that the specification of the '791 patent lists CeO[2] as a fluorescing agent or additive, (id., Col. 5, Line 38), and other patents confirm that CeO[2] may function in such a manner. (U.S. Pat. No. 4,170,823, Col. 1, Lines 22-42.) Jeneric contends that the .92% of CeO[2] satisfies the range limitation in claim 1 as an antigreening agent, and the .69% of CeO[2] is permitted by claim 2 as a fluorescing agent or additive. (Pl.'s Mem. Supp. at 15, 27; Pl.'s Prop. Find. Fact Concl. Law PP 54, 58, 163, 164.)

Jeneric attempts the same construction regarding its theory of how Cerpress infringes claim 1. Jeneric acknowledges that Cerpress contains 15.97% of Al[2]O[3], more than the range of 7-15% specified by claim 1. Yet, it maintains that a portion of the Al[2]O[3] "was added as an additive" and "is not within the matrix forming the leucite crystallite phase dispersed in a glass matrix." (Pl.'s Mem. Supp. at 17, 26-27.) Similar to its explanation concerning the amount of CeO[2] in Sensation, Jeneric proposes that at least .97% of the Al[2]O[3] in Cerpress exists outside of the two-phase matrix, thus allowing for infringement of claim 1. (Pl.'s Prop. Find. Fact Concl. Law PP 62, 166.) To accept Jeneric's theories of infringement, one would have to construe claim 1's components as not being limited to their weight percentage ranges. The Court refuses to do this for three reasons.

First, the language of claim 1 clearly indicates that the invention's chemical components should be limited to the precise ranges set forth therein. Claim 1 uses the word "about" to modify the stated range of the maturing temperature, the coefficient of thermal expansion, the leucite crystallite sizes, and the weight percentage of the leucite crystals. ('791 Patent, Col. 6, Claim 1.) The descriptive word "about" avoids a strict numerical boundary to the specified parameter, and its range must be interpreted in its technologic and stylistic context. See Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995). "About" is neither broad nor arbitrary, but rather serves as a flexible term with a meaning similar to "approximately." See Syntex (U.S.A.) Inc. v. Paragon Optical Inc., 1987 U.S. Dist. LEXIS 14544, 7 U.S.P.Q.2D (BNA) 1001, 1038 (D. Az. 1987). As a matter of law, the term "about" gives a "clear warning that exactitude is not claimed but rather a contemplated variation." Kolene Corp. v. Motor City Metal Treating, Inc., 307 F. Supp. 1251, 1258 (E.D. Mich. 1969), aff'd, 440 F.2d 77 (6th Cir. 1971).

However, claim 1 does not use the word "about" to modify the specific weight percentage ranges of its chemical components. Where an inventor restricts claims to a precise range of ingredients, he or she ordinarily is limited to those precise ranges. See 3 Anthony W. Deller, Patent Claims § 476 (2d ed. 1971); Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed. Cir. 1995). The purposeful use of the word "about" elsewhere in claim 1, while omitting it from the component ranges, yields strong evidence that the chemical elements must be limited to the exact weight percentage ranges set forth in the claim. In addition, the specification and claim 6 of the '791 patent both indicate that claim 1 represents the outer range of protection for the invention because they refer to a preferred composition within the scope of broader claim 1. ('791 Patent, Col. 3, Lines 10-20; Id., Col. 6, Claim 6.)

Second, evidence shows that claim 1 needed to be written narrowly to avoid being anticipated or rendered obvious by Jeneric's United States Patent No. 4,798,536 (" '536 patent"). The '791 patent states that "the second porcelain component of this invention is preferably produced in accordance with the teachings of commonly assigned U.S. Pat. No. 4,798,536 . . . ." ('791 Patent, Col. 4, Lines 34-37.) The '536 patent and the '791 patent utilize many of the same components with similar ranges, such as SiO[2], Al[2]O[3], CaO, MgO, Li[2]O, Na[2]O, and K[2]O. ('536 Patent, Cols. 3-4, Lines 63-6.) Moreover, claim 8 and example 2 of the '536 patent refer to a composition where the leucite crystallites in a final dental restoration exhibit a size of less than 5 microns. (Id., Col. 10, Claim 8; Id., Col. 9, Line 12 et seq.) Because the inventors likely claimed narrowly to distinguish from the prior art, this strengthens the conclusion that claim 1 does not encompass ranges greater than those plainly stated. See North Am. Vaccine, 7 F.3d at 1577 (holding that a "patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue that the claims should be construed to cover that which is neither described nor enabled in the patent"); Smith v. Magic City Kennel Club, Inc., 282 U.S. 784, 790, 75 L. Ed. 707, 51 S. Ct. 291 (1931).

Finally, claim 1's precise weight percentage ranges may not be modified by claim 2, because claim 2 is in dependent form. Claim 2 states the following:

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The two-phase porcelain composition of claim 1 further comprising at least one component selected from the group consisting of opacifying agent, pigment and fluorescing agent.

('791 patent, Col. 6, Claim 2.) (emphasis added). Quite obviously, claim 2 is dependent upon claim 1, and therefore incorporates all of the limitations contained in claim 1. See 35 U.S.C. § 112; Wahpeton Canvas, 870 F.2d at 1553; Hartness Int'l, 819 F.2d at 1107-08. As provided in section 112, dependent claims must be narrower and protect less subject matter than the independent claims upon which they rely. See Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 685-86 (Fed. Cir. 1990). Dependent claims limit independent claims by adding an additional element or elements. See Zip Dee, 931 F. Supp. at 614. As such, the additional limitations of a dependent claim cannot be read or implied into an independent claim to help it cover an accused device, see D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1573-74 (Fed. Cir. 1985), to allow it to survive a charge of invalidity, see Wolens v. F.W. Woolworth Co., 703 F.2d 983, 988 (7th Cir. 1983), or to permit it to escape infringement. See Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 770 (Fed. Cir. 1983).

The mere fact that claim 2 allows for the addition of an opacifying agent, pigment, or fluorescing agent cannot alter claim 1's limitations. "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend" have been found infringed. Wahpeton Canvas, 870 F.2d at 1553. To prove infringement of a dependent claim, the patent holder must prove each of the elements of the incorporated independent claim, as well as the added elements of the dependent claim. See North Am. Vaccine, 7 F.3d at 1577; Wolverine World Wide, 38 F.3d at 1199; Wilson Sporting Goods, 904 F.2d at 685-86. Where an accused device avoids the elements of the independent claim, a fortiori the device does not infringe a dependent claim that incorporates the independent claim. See, e.g., Wolverine World Wide, 38 F.3d at 1199-1200; North Am. Vaccine, 7 F.3d at 1577; Wilson Sporting Goods, 904 F.2d at 685-86; Wahpeton Canvas, 870 F.2d at 1552 n.9; Hartness Int'l, 819 F.2d at 1108; Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987); Teledyne McCormick Selph, 558 F.2d at 1004; Baracuda Int'l, 4 F. Supp. 2d at 1193; Zip Dee, 931 F. Supp. at 614.

As a result of the preceding discussion, the Court construes claim 1 as being limited to the exact weight percentage ranges for its chemical components. The proper construction of claim 1 reveals that there must be a maximum of 1% of CeO[2] and 15% of Al[2]O[3] in the composition of the accused devices in order to find literal infringement. Because claim 2 as a dependent claim incorporates all of the limitations of claim 1, claim 2 also permits a maximum of 1% of CeO[2] and 15% of Al[2]O[3] in the composition of the accused devices in order to find literal infringement. Even though claim 2 covers the addition of an opacifying or fluorescing agent or additive, if CeO[2] or Al[2]O[3] are selected, their total weight percentages must be less than 1% and 15% respectively, regardless of whether they exist "inside or outside" of the two-phase matrix. 5

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5 The Court notes that neither claim 2 nor any other section of the '791 patent mentions the possibility of the invention covering anything beyond a two-phase composition. To the contrary, claim 2 incorporates by reference the "two-phase porcelain composition of claim 1." ('791 Patent, Col. 6, Claim 2.) Hence, Jeneric's argument that some amounts of CeO[2] in Sensation and Al[2]O[3] in Cerpress exist outside of the two-phase matrix, possibly in a third phase, proves disingenuous. If Sensation or Cerpress truly contained a third phase, then they would not infringe claim 1 or claim 2.

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1. The Smith Patents

a. "immunoglobulin composition of IgG 1 containing copper ions . . . comprises" and "composition comprising IgG 1 and copper ions"

Genentech contends that the phrases "immunoglobulin composition of IgG 1 containing copper ions . . . comprises" of the '403-S patent (Claim 1) 9 and "a starting composition comprising: i) IgG 1 and ii) copper ions" of the '838 patent (Claim 1) 10 describe a mixture containing a substantial portion of IgG 1 immunoglobulin, which may include other substances such as proteins (including other immunoglobulin types), other organic cell-derived components and non-organic substances.

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9 Claim 1 of the '403-S patent claims:

In an immunoglobulin composition of IgG 1 containing copper ions in an amount sufficient to degrade the immunoglobulin, wherein the improvement comprises the addition of an amount of a chelator of copper ions sufficient to bind the copper ions present in the composition and protect the immunoglobulin from degradation by the copper ions and thus stabilize the IgG 1, composition

10 Claim 1 of the '838 patent claims:

A method of making a stabilized IgG 1 composition comprising adding to a starting composition comprising:

i) IgG 1

ii) copper ions in an amount sufficient to degrade said IgG 1, an amount of a chelator of copper ions sufficient to stabilize said IgG 1 against copper ion mediated degradation, so that said IgG 1 composition is made

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In support of its construction, Genentech points to the plain meaning of the claims, arguing that the terms "composition," "comprises" and "comprising" are open-ended terms indicating that the immunoglobulin mixture could include other substances. As intrinsic evidence of the open-ended nature of the terms, Genentech refers the court to certain passages from the '403-Sspecification, which it argues, make clear that other substances can be included in the mixture. Genentech also refers the court to Genentech, Inc. v. Chiron Corp., 112 F.3d 495 (Fed. Cir 1997), and Landis on Mechanics of Patent Claim Drafting as extrinsic evidence defining the term "comprising." Finally, as evidence of the plain meaning of the term "composition," Genentech urges the court to consider the Oxford English Dictionary, which defines "composition" as "a substance or preparation formed by combination or mixture of various ingredients."

Glaxo counters that the phrases convey a different plain and ordinary meaning to one of skill in the art. That is, they describe a composition containing only IgG 1 immunoglobulin. As support for its construction, Glaxo points to the prosecution history. In particular, Glaxo argues that when the applicants amended the phrase "composition comprising an IgG 1 immunoglobulin" to read "composition of IgG 1," they reduced the parts of the composition from plural to singular. Glaxo contends that claims cannot be construed to include subject matter surrendered by limiting claim amendments, and thus, Claim 1 of the '403-S patent and all dependant claims require that the "composition of IgG 1 " contain only IgG 1 immunoglobulin. As such, the essence of the dispute over these phrases is whether the immunoglobulin composition can contain other substances in addition to IgG 1 .

As a preliminary matter, the court finds that the term "comprises" in Claim 1 of the '403-S patent refers to the "improvement," not the "immunoglobulin composition." As such, "comprises" cannot possibly indicate whether the composition can include substances other than IgG 1 . The terms "comprising" and "composition," however, do relate to the immunoglobulin composition.

When interpreting the plain meaning of the phrases, the court looks to the traditional meanings of their terms. In construing such terms, the court recognizes that "comprising" is traditionally "a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Chiron, 112 F.3d at 497. The court further recognizes that a "composition" is traditionally a combination of two or more substances, and that IgG 1 is a protein constituting a single substance. See e.g. Diamond v. Chakrabarty, 447 U.S. 303, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980).

The inventors did not set forth alternative definitions for these terms in the specifications or prosecution histories of the '403-S or '838 patents. Furthermore, the fact that the inventors removed the term "comprising" from Claim 1 of the '403-S patent does not change the plain meaning of the term "composition," which remains in the final version of the claim. Moreover, if the court were to adopt the construction of the '403-S claims put forth by Glaxo, Claim 1 would contradict Claim 1 of the '838 patent, which retains the term "comprising" and claims the process for producing the compositions

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described in '403-S patent. Such a construction would be inconsistent.

In light of these findings, the court concludes that the terms "comprising" and "composition" must be construed according to their plain meanings. See Vitronics, 90 F.3d at 1582 (holding that words in claims are generally given their ordinary and customary meaning unless the patentee clearly sets forth a different in the specification or file history). As a result, the phrases "immunoglobulin composition of IgG 1 containing copper ions" of the '403-S patent and "a starting composition comprising: i) IgG 1 and ii) copper ions" of the '838 patent describe a mixture containing IgG 1 immunoglobulin that can include other substances.
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B. "A Compound"

Here, Aventis, the owner of the '722 patent, maintains that "a compound" in claim 1 refers to one of the three types of claims in the pharmaceutical field: compound claims, formulation claims, and methods-of-use claims. Pl.'s Pre-Trial Claim Construction Brief at 5. Moreover, it also maintains that "[c]ompound claims are the broadest [and] they cover the drug compound itself." Id. n2 Lupin, on the other hand, construes "a compound" in claim 1 to mean "a singular molecular entity with the chemical formula set for in claim 1, that further has the so-called (S,S,S,S,S) configuration." Def.'s Pre-Trial Claim Construction Brief at 1. In Lupin's view, claim 1 is "directed to a single isomer of a compound that corresponds to the listed structure." The distinction between the parties' constructions appears to be this: Aventis maintains that the term "a compound" is being used in a broad and more general sense, while Lupin urges that, in the context of claim 1, "a compound" refers only to ramipril itself and that this version of ramipril includes only a single isomer of the compound. However "a compound" is read, the parties seem to agree that the term is used to refer to ramipril in the context of claim 1.

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n2 At the hearing, Aventis described claim 1 as a "genus" claim, stating that the compound described in claim 1 is a specific entity that "covers more than one compound." (Markman Hearing Trans. 20: 14). Indeed, looking at the '722 patent in its entirety, it appears that this is the case as subsequent claims 2 and 3 seem to provide for alternative versions of claim one. Aventis described these claims as "species claims," which relate to a "particular molecule." Id. 20: 19. As MOY'S WALKER ON PATENTS explains:

Two patent claims can be dominant and subservient to each other by being drawn respectively to a genus and an included specie. This relationship broadly resembles the taxonomic organization employed in fields such as zoology. A generic claim uses terms that define the invention to include a class of individual embodiments, each of which shares one or more characteristics in common. A specific claim defines its invention as one of the embodiments in the class.

1 MOY'S WALKER ON PATENTS § 4:27 (4th ed.). The fact that claim 1 is a "genus claim," however, does not change this Court's view that claim 1 uses the term "a compound" broadly and that claim 1 goes on to define the term in the context of the claim as the chemical compound that is ramipril. To be sure, Aventis does not appear to make a contrary argument, as it has said that compound claims "cover the drug compound itself." Pl.'s Pre-Trial Claim Construction Brief at 5 (Doc. 85).

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As the parties do not spend a lot of time on this point, the Court will try not to belabor this issue either. In this Court's view, the plain language of claim 1 uses the term "a compound" like it uses the word "formula" -- as a fairly broad term. The substance recited in the claim has to be called something, and what it is called is "a compound." In Schering Corp. v. Geneva Pharmaceuticals, the United States Court of Appeals for the Federal Circuit described compound claims as "encompass[ing] compounds defined by structure only." 339 F.3d 1373, 1375 (Fed. Cir. 2003) (also describing claims listing "a compound" followed by the formula of the compound as "compounds" and going on to read compound claims broadly). In this Court's view, this indicates that the term "a compound" refers to a "structure" made up of specific chemical constituents. In Ortho-McNeil Pharmaceuticals, 348 F. Supp. 2d at 728, the district court provided a definition that conforms with this understanding, defining "compound" as that which is "a chemically distinct substance formed by union of two or more ingredients (as elements) in definite proportion by weight and definite structural arrangement." n3 (quoting

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WEBSTER'S THIRD NEW INT'L DICTIONARY 466 (2002)). The Court adopts this definition for the purposes of this case.

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n3 The district court went on to say that molecules may also be compounds, as a "molecule is a unit of matter that is the smallest particle of an element or chemical combination of atoms (as a compound) capable of retaining chemical identity with the substance in mass." Ortho-McNeil Pharmaceuticals, 348 F. Supp. 2d at 728 (internal quotations omitted). In this case, neither party appears to argue that "a compound" in this case refers only to a portion or particular molecule of the ramipril drug; consequently, this Court will not do so either.

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The Court observes that, contrary to what Lupin seems to argue, the fact that claim 1 goes on to give content to what compound is involved in the claim does not narrow the plain meaning of the word "compound" or the term "a compound." Rather, the term is used to indicate a "chemically distinct substance" -- what that substance consists of must be explained in the formula provided and in the rest of the claim. The Court therefore FINDS that the term "a compound" is a fairly broad term meaning "a chemically distinct substance formed by union of two or more ingredients (as elements) in definite proportion by weight and definite structural arrangement." Id.
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2. The Levofloxacin "Compound"

Claims 2 and 5, by incorporating the term from claims 1 and 4, respectively, refer to a "compound" with the structure S(-)-9-Fluoro-3-methyl-10-(4-methyl-l-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid. In its March 31, 2003 Order, the Court equated the term "compound" with "a pharmaceutical preparation" or drug. In reaching this conclusion the Court relied on the specification and the prosecution history, which referred to the properties of the compounds, not to confirm this limitation, but as its source. In light of the Federal Circuit's recent decision in SmithKline Beecham v. Apotex, 365 F.3d 1306 (Fed. Cir. 2004), the Court is compelled to revisit its conclusion that claim 2, although used as a drug, has been claimed as anything more limited than a compound defined solely by chemical structure.

Mylan maintains that the word "compound" and the accompanying chemical formula comprise a broad compound claim to even a single molecule with that chemical structure. To the contrary, Daiichi/Ortho argues that claim 2 must be construed to cover more than a single molecule of ofloxacin because the specification and prosecution history contain the additional limitation that the claimed compound be pharmaceutically effective. n9 It emphasizes that a single molecule would be neither optically active nor pharmaceutically effective.

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n9 In the previous claim construction, the Court identified the specific language in the specification and prosecution history that it found to support the requirement of the identified properties. The Court relies on the same language as factual support for its findings herein.

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At trial, Daiichi/Ortho and Mylan presented conflicting expert testimony as to how one of ordinary skill in the art would understand the term "compound." Mylan's expert on Patent and Trademark Office ("PTO") procedures, George M. Gould, opined that a compound claim is the broadest possible claim. (Gould Tr. at 227.) Specifically, a "compound claim is directed to the molecule itself." (Gould Tr. at 228.) This opinion was echoed by Dr. Mitscher, who stated that claim 2 "identifies a particular molecule." (Mitscher Tr. at 728.)

To the contrary, Daiichi/Ortho's expert, Dr. Klibanov, maintained that the term "compound" as used in claim 1 of the '407 patent (and as otherwise incorporated therein) indicates that the patent is not referring to a "molecule or couple of molecules

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sitting somewhere." (Klibanov Tr. at 1881). Under his definition of compound, the patent claim unambiguously refers to a drug: "The use of the word compound here implies that we are talking about a sizeable quantity of a material, a quantity that has certain properties, physical properties, chemical properties, and pharmacological properties." (Id.)

In support of its single molecule definition of "compound," Mylan cites multiple cases in which a compound has been construed to refer a single molecule. See, e.g., Dow Chem. Co. v. Am. Cyanamid Co., 816 F.2d 617, 618 (Fed. Cir. 1987) ("A nitrile is an organic compound containing a carbon-to-nitrogen triple bond and, depending on the rest of the molecule, can be classified as either aromatic or aliphatic"); Studiengesellschaft Kohle mbH v. Eastman Kodak Co., 616 F.2d 1315, 1320 (5th Cir. 1980) ("The simplest hydrocarbon molecule is a compound of one carbon atom and four hydrogen atoms and is commonly known as methane, represented by the chemical symbol CH 4.").

Most prominently, Mylan relies on the Federal Circuit's recent decision in SmithKline Beecham v. Apotex, 365 F.3d 1306 (Fed. Cir. 2004). As in the case at bar, Apotex involved a pharmaceutical patent. Engaging in a analysis similar to the one this Court followed in its prior order, the district court concluded that what appeared to be a claim defined only by chemical structure should be construed to cover only "commercially significant" quantities of that compound. Id. at 1310. On appeal, the Federal Circuit reversed this claim construction, holding that it improperly looked beyond the claim language because the "language [was] not ambiguous, but rather describe[d] a very specific compound." Id. at 1313.

Mylan further cites Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 1381 (Fed Cir. 2003), as evidence of the Federal Circuit's approach to compound claims. Although Schering involved an agreed claim construction, the unambiguous language employed by the Court suggests that the Federal Circuit will read compound claims broadly: "Compound claims . . . broadly encompass compounds defined by structure only. Such bare compound claims include within their scope the recited compounds as chemical species in any surroundings, including within the human body as metabolites of a drug." Id.

Daiichi/Ortho does not cite any case law supporting a contrary construction of the term "compound." Rather, the plaintiffs argue that, unlike the patentee in Apotex, they relied on unexpected results as the basis for establishing levofloxacin's patentability over prior art ofloxacin, and thus clearly disavowed a claim to levofloxacin that did not demonstrate those unexpected results.

Under a standard dictionary definition, "compound" means "a chemically distinct substance formed by union of two or more ingredients (as elements) in definite proportion by weight and with definite structural arrangement <water is a [compound] of oxygen and hydrogen>." Webster's Third New Int'l Dictionary 466 (2002). A "molecule" is "a unit of matter that is the smallest particle of an element or chemical combination of atoms (as a compound) capable of retaining chemical identity with the substance in mass." Id. at 1455. Therefore, Mylan's proposed definition of "compound" appears consistent with Apotex, Schering and the dictionary definition. The Court's construction of the disputed claims, however, does not end with that term.

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II.
Claim Construction of the '499 Patent

Astra was granted U.S. Patent No. 4,255,431 in 1981. The patent claims a chemical compound called omeprazole, whose basic structure is 2-pyridyl methylsulfinyl benzimidazole, and its oral administration for inhibiting gastric acid secretion. Astra's scientists had found that when omeprazole was ingested by a human, the enzyme responsible for gastric acid secretion in the stomach lining, H<+> K<+> ATPase, was inhibited.

The '499 patent, granted in 1987, claims a class of substances called sulphenamides, and also the administration of the claimed sulphenamides to effect gastric acid inhibition. Astra argues that Genpharm and Cheminor's proposed practice of the oral administration of omeprazole, as described in the soon to be expired '431 patent, will infringe the '499 patent because when a patient takes the Genpharm and Cheminor products, sulphenamides will form in the patient's body.

In the first of the two steps necessary to the infringement analysis the Court construes the allegedly infringed patent claims

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to establish their meaning and scope. See Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The primary claim construction dispute between the parties turns on the meaning of the word "compound" as used in claims 1, 2, and 3 of the patent. 2 Astra argues that the term refers to both sulphenamides made synthetically outside the body as well as those produced by the in vivo conversion of omeprazole. Genpharm and Cheminor argue that the inventors of the '499 patent intended to claim only synthetically produced sulphenamides when they used the term "compound." Astra concedes that if the '499 patent is construed to claim only synthetic sulphenamides, the defendants' products will not infringe it. See May 10, 2001 Tr. at 23 ("we have not developed evidence of infringement by synthetic production against the defendants in the first wave of cases.").

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2 Claim 1 reads: "A compound according to the formula IIIa wherein" and goes on to describe the various components of the sulphenamide. Importantly, the claim ends "and X<-> is a pharmaceutically acceptable anion." Claims 2 and 3 depend upon claim 1, and claim variants of the formula set forth therein. For example, claim 2 claims "[a] compound according to claim 1 wherein the pharmaceutically acceptable anion is Cl<->, Br<->, I<->, BF[4]<->, PF[6]<->, AuCl[4]<->."

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Astra relies heavily on the Federal Circuit's opinion in Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994), for the proposition that "when a patent claims a compound by its chemical formula (as the '499 patent does), the patent covers that compound regardless of whether it is made synthetically or is produced in the body after ingestion of a different compound." Genpharm and Cheminor in turn rely on Marion Merrell Dow, Inc. v. Baker Norton Pharmaceuticals, Inc., 948 F. Supp. 1050 (S.D. Fla. 1996).

In Marion Merrell Dow, the Court declined to find a per se rule in Zenith which would require "that all claims which describe a compound be construed as covering both the metabolically produced and synthetically produced forms of the compound, without regard to the language of the claims, the specification of the patent or the prosecution history." Id. at 1054 n.4. Instead, the court held that it should construe the claims pursuant to the Markman procedure. This Court agrees.

It cannot be that a claim to a "compound" covers the compound whether it is made synthetically or produced in vivo, regardless of whether such a construction is supported by the evidence intrinsic to the patent. As in Marion Merrell Dow, the Court construes the claims of the '499 patent according to the hierarchy of evidence articulated in Markman, looking first to the intrinsic evidence of the patent:

The court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim. As such, "[a] patent covers the invention or inventions which the court, in construing its provisions, decides that it describes and claims." … "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history."

52 F.3d at 979 (citations omitted).

A. The Claim Language

In construing the patent, the Court looks first to the language of the disputed claims. See Autogiro Co. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 395-96 (C.C.P.A. 1967) ("the claims of the patent provide the concise formal definition of the invention"). While Astra notes 3 that no language in claims 1, 2 or 3 explicitly limits those claims to sulphenamides in their synthetic or pre-ingested form, neither can Astra point to any language explicitly claiming sulphenamides formed in vivo. Genpharm and Cheminor, however, do point to specific language in claims 1-3 which support their argument that the '499 patent does not claim sulphenamides formed in vivo.

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3 Because the briefs submitted by the parties on these motions for summary judgment did not sufficiently address the issue of claim construction, the Court requested additional briefs from all of the parties to the consolidated litigation specifically addressing claim construction and held a hearing pursuant to Markman on May 10, 2001.

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Claim 1, referring to the drawing at the top of column 21 of the patent, describes the general formula of sulphenamides and notes that the X<-> shown in the drawing represents "a pharmaceutically acceptable anion." See U.S. Patent No. 4,636,499 at Col. 21 line 1 to Col. 22 line 1. Genpharm and Cheminor argue that because in vivo the sulphenamides exist as a free amine base without an anion component, the inclusion of the term "pharmaceutically acceptable anion" demonstrates that the '499 patent claims a pharmaceutically prepared stable sulphenamide salt. See Defs. Consol. Claim Cnstr. Memo. at 6-7.

Astra counters that sulphenamides are permanent cations which are always associated with an anion, whether they are found in vivo or in pharmaceutical preparations. See May 10, 2001 Markman Hearing Tr. at 58. Even accepting Astra's assertion that in vivo sulphenamides are always associated with an anion, "in vivo sulphenamides do not incorporate an anion that has been selected on the basis of its pharmaceutical acceptability." Defs. Consol. Claim Cnstr. Memo. at 7. By describing the invention in terms of an anion chosen pursuant to pharmaceutical standards, the inventors of the '499 patent suggested a degree of control over the formulation of the sulphenamide; such control is available only in the synthetic context and is nonsensical in the in vivo context. See Marion Merrell Dow, 948 F. Supp. at 1055 (finding that inventors' use of term "pharmaceutically acceptable" in the patent at issue constituted "further evidence that the inventors sought a patent on chemical formulations of TAM only.").

Moreover, Astra admits that some of the anions listed in claim 2 as "pharmaceutically acceptable" do not occur in vivo, further supporting the defendants' arguments that those claims refer to synthetic sulphenamides only. See 5/10/2001 Tr. at 59. 4 Accordingly, the primary intrinsic evidence, the language of the claims at issue, supports defendants' contentions that the inventors of the '499 patent intended to claim synthetic sulphenamides only.

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4 Although counsel for Astra said "admittedly, the list of cations include things that are not naturally within the body" it is clear from the context that he meant that the listed anions, rather than cations, are not naturally within the body. Opposing counsel had earlier argued that tetraflourobromide, or BF[4]<->, one of the anions listed in claim 2, is not found in vivo. See 5/10/2001 Tr. at 32.

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Defendants' claim construction is also supported by the language of the '499 patent claims not in dispute. Aside from claim 8 and claims 12-14, which Astra concedes are directed to sulphenamides in their pre-ingested form only, the defendants note that other claims demonstrate similar limitations. Claims 4 and 5 refer to "a compound according to claim 1" but require that the compound include chemical components not found in vivo, and thus must also refer only to synthetic sulphenamides. See Defs. Claim Cnstr. Memo. at 8; see also id. at 10 (claims 9-11 also must claim synthetic sulphenamides because they describe processes for preparation of the compound and refer to "isolating" sulphenamides, which according to the specification cannot be done in vivo).

Astra argues in response that because the claims not in dispute clearly and explicitly claim sulphenamides in their synthetic pre-ingested form while claims 1-3 are silent with respect to form, pursuant to the doctrine of claim differentiation the limitations to synthetic sulphenamides expressed in claim 8 and claims 12-14 should not be read into claims 1-3. See Pl.'s Opp. to Defs.' MSJ at 28-29. Astra is correct that where some claims are broad and others narrow, the narrow claim limitations should not be read into the broad. See DMI, Inc. v. John Deere, Inc., 755 F.2d 1570, 1574 (Fed. Cir. 1985). In this case, however, the limitation to pre-ingestion synthetic sulphenamides advanced by the defendants is not imported from narrower claims within the patent but rather evidenced within the disputed claims themselves by the language "pharmaceutically acceptable." The patent claims not in dispute simply provide further evidence of the meaning of the "pharmaceutically acceptable" limitation contained in the disputed claims.

Astra also argues that the doctrine of claim differentiation demands that the Court read claims 1-3 as encompassing in vivo sulphenamides because to read them as only encompassing pre-ingestion sulphenamides would render the language "in solid form" contained in claim 8 5 superfluous. However, the defendants correctly note that the language "in solid form" may be interpreted not to distinguish synthetic sulphenamides from those formed in vivo, but rather to distinguish

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sulphenamides contained in a pharmaceutical preparation that takes a solid form from a pharmaceutical preparation that takes a liquid, or parenteral form. See U.S. Patent No. 4,636,499 at col. 5 lines 34-36 ("for clinical use the compounds of the invention are formulated into pharmaceutical formulations for oral, rectal, parenteral or other mode of administration …. The carrier may be in the form of a solid, semisolid or liquid diluent"); see also 5/10/2001 Tr. at 42-43. Accordingly, construing claims 1-3 as claiming only synthetic sulphenamides does not render the "in solid form" language in claim 8 superfluous and thus does not invite application of the doctrine of claim differentiation.

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5 Claim 8 reads "[a] compound according to one of the claim 1-6 wherein compound III(a) is in solid form."

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B. The Specification Language

Having determined that the language of all of the claims of the '499 patents substantiates the defendants' construction, the Court next directs its analysis to the specification of the '499 patent. Astra argues that the '499 patent specification expressly discloses in col. 1, line 56 to col. 2, line 18 that the claimed sulphenamides may be formed in the body and that the specification describes the in vivo conversion of omeprazole to sulphenamides in col. 4 lines 3-49. The first portion of the specification cited by Astra reads:

BACKGROUND OF THE INVENTION

….

The in vivo inhibiting effect of the compounds with the general formula I [omeprazole] is not, however, exerted by the compounds as such but by one or more degradation products.

OUTLINE OF THE INVENTION

According to the present invention, it has now been surprisingly found that the above mentioned degradation reaction of the sulphoxides with the general formula I is a complicated transformation reaction to the new sulphenamides with the general formula III …"

U.S. Patent No. 4,636,499, Col. 1 lines 56-68 (emphasis added).

Clearly these portions of the specification, which begin under the heading "Background of the Invention" and continue into the "Outline of the Invention" reveal that sulphenamides are formed in the body when omeprazole is ingested. This reference to omeprazole's in vivo conversion to sulphenamides, however, merely provides a description of the prior art which gives the context for the discovery of the claimed invention. If anything, it is an implied admission that the sulphenamides formed in vivo are inherent in the prior omeprazole art.

Furthermore, another portion of the "Outline of the Invention" section of the specification cited by Astra does not support its claim construction. It begins with the language "compounds of the general formula IIIa above [sulphenamides] may be prepared by the following method," followed by a drawing. See U.S. Patent No. 4,636,499, at col. 4, lines 3-5. The words "prepared by the following method" connote at the outset that a pharmaceutical preparation, rather than an in vivo transformation, is being described. The specification then reads "the transformation reaction probably goes via the sulphenic acid IIa, which may also be an in vivo inhibitor, when a sulphoxide with the general formula Ia [such as omeprazole] has been administered." Col. 4 lines 41-45 (emphasis added). The Court reads this portion of the "Outline of the Present Invention" section cited by Astra only as a further reference to the "Background of the Invention" portion of the patent noting that an omeprazole degradation product, rather than omeprazole itself, is responsible for the acid inhibiting effect attributed to omeprazole.

The detail of the description of the processes for the. synthesis of the claimed sulphenamides contained in the patent also demonstrate an intention to teach and claim those synthetic processes that is absent from the description of the in vivo

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formation of sulphenamides. The language "probably goes via" describing the in vivo pathway lacks the detail and certainty of the claimed synthetic processes, and reveals on its face no intent to claim and teach sulphenamides formed in vivo. Moreover, directly following the vague language Astra relies upon, the specification reads "especially preferred acids for preparation of the compounds with the general IIIa are …." and begins a detailed description of methods for the in vitro synthesis of sulphenamides. See U.S. Patent No. 4,636,499, col. 4 lines 51-53. Accordingly, the specification language cited by Astra does not persuade the Court that the '499 patent claims encompass sulphenamides formed in vivo.

C. The Prosecution History

The final source of intrinsic evidence the Court examines to determine the meaning of the disputed claim language is the prosecution history of the patent. Each side argues that its claim construction is supported by the same exchange between Astra and the patent examiner during the prosecution of the '499 patent. The examiner initially denied Astra's claims to. sulphenamides because he determined that European patent 05129 disclosed them. The examiner noted "no distinction can be seen between the compounds of formula III [sulphenamides inherent in omeprazole European patent 05129] and formula III(a) [those claimed in the '499 patent]" and rejected them under 35 U.S.C. § 103. See Exh. 17 to Decl. of David M. Conca. This finding that the claims were invalid due to obviousness leads the defendants to argue that the examiner must have read the patent to claim only synthetic sulphenamides, because in light of the prior disclosures that sulphenamides operated to inhibit gastric acid secretion in vivo, creating synthetic sulphenamides would be obvious and thus unpatentable. Had the examiner thought that Astra intended to claim in vivo sulphenamides, presumably he would have declared the claim invalid due to anticipation either instead of or in addition to obviousness. See 35 U.S.C. § 102.

After the examiner's initial rejection Astra reasserted the validity of the claims and persuaded the patent examiner to allow them to stand, citing Ex Parte Biel, Patent Appeal No. 223-47 (Oct. 14, 1964). The defendants argue that in light of the examiner's initial rejection on obviousness grounds, when Astra persuaded the patent examiner to allow the claims to stand by citing Ex Parte Biel, the examiner was allowing them to stand as claims to synthetic sulphenamides only. See Defs.' Claim Cnstr. Memo. at 17-21. Since the examiner cites Biel without any analysis or explanation, this interpretation is uncertain.

What is clear is that nothing in the prosecution history explicitly demonstrates that the examiner recognized that the claims of the '499 patent covered sulphenamides in their in vivo form. Astra cites nothing more in support of its position than the examiner's response "Claims 1-7, 9 and 18-27 are allowed in view of the Ex Parte Biel decision cited by Applicants." Exh. 17 to Decl. of David M. Conca, '499 file history 136-137. These different conclusions and arguments by the parties highlight the ambiguity of the exchange but do not favor either party's claim construction. The Court thus accords no weight to the prosecution history in determining the scope and meaning of the claims.

In light of the language of the claims in dispute and those not asserted, in conjunction with the specification of the patent, the Court is persuaded that the inventors of the '499 patent claimed only synthetic sulphenamides in claims 1-3 of that patent. Accordingly, disputed claims 15 & 16 are also construed to cover only synthetic sulphenamides, because those claims refer to "a compound according to claim 1." See U.S. Patent No. 4,636,499 at col. 24 line 66 - col. 25 line 7.

In the second phase of the patent infringement analysis, the factfinder compares the properly construed claims against the allegedly infringing devices. See Carroll Touch, Inc. v. Electro Mechanical Sys., 15 F.3d 1573, 1576 (Fed. Cir. 1993). In this case, however, as previously noted no such comparison is necessary because Astra concedes that if the '499 patent is construed only to cover synthetic sulphenamides the defendants will not infringe it. Defendants' motions for summary judgment of non-infringement are therefore granted.

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1. The Claims

"The claims of the patent provide the concise formal definition of the invention. . . . Although courts are confined by the language of the claims, they are not, however, confined to the language of the claims in interpreting their meaning." Autogiro Co. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 395-96 (C.C.P.A. 1967). MMD alleges in its complaint that claims 1, 6, 8 and 11 of the '129 Patent will be infringed by Baker Norton's proposed course of conduct. The asserted claims

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are as follows:
We claim:
1. A compound of the formula wherein R[1] represents hydrogen or hydroxy; R[2+] represents hydrogen; or R[1] and R[2] taken together form a second bond between the carbon atoms bearing R[1] and R[2]; n is an integer of from 1 to 5; R[3] is --COOH or --COOalkyl wherein the alkyl moiety has from 1 to 6 carbon atoms and is straight or branched; each of A and B is hydrogen or hydroxy; with the proviso that at least one of A or B is hydrogen; and pharmaceutically acceptable salts and individual optical isomers thereof.
6. A compound of claim 1 of the formula wherein R[4] is hydroxy and R[5] is hydrogen, or R[4] and R[5] taken together form a second bond between the carbon atoms bearing R[4] and R[5]; n is the integer 3; and R[3] is -- COOH or a pharmaceutically acceptable salt thereof.
8. A compound of claim 1 which is 4-[4- [-4-(hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]-[infinity], [infinity]-dimethylbenzeneacetic acid or a pharmaceutically acceptable salt thereof. 11. A method of treating allergic reactions in a patient in need thereof which comprises administering to said patient an effective amount of a compound of claim 1.

U.S. Patent No. 4,254,129, issued Mar. 3, 1981.

First, the Court need only focus on claim 1, because if it is infringed, all of the others are infringed as well. Claim 1 appears to claim the novel chemical compound commonly known as "terfenadine acid metabolite" or TAM. The crux of the dispute between the parties is focussed upon the meaning of the word "compound" as used in claim 1. MMD insists that the term refers to the compound TAM regardless of whether it is created by the liver's metabolism of terfenadine (inter vivo conversion) or by synthetic means. n4 Baker Norton argues that the inventors of the '129 Patent meant only synthetically produced TAM when they used the term "compound." Although there is no language within the claim which would explicitly limit the meaning of the term "compound" to exclusively TAM synthetically produced, there is no language within the claim which refers in any way to the inter vivo manufacture of TAM either. The process of construing the claim does not end with consideration of the explicit language of the claims, however. As the Autogiro court noted,

the fact that claims are free from ambiguity is no reason for limiting the material which may be inspected for the purpose of better understanding the meaning of claims. . . . Claims cannot be clear and unambiguous on their face.

384 F.2d at 396 (citations omitted).

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n4 In its briefs, MMD relies heavily on the Federal Circuit's opinion in Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir.), cert. denied, 130 L. Ed. 2d 409, 115 S. Ct. 500 (1994), for the proposition that "when a patent claims a compound by its chemical formula (as the '129 Patent does), the patent covers that compound regardless of whether it is made synthetically or is produced in the body after ingestion of a different compound." Plaintiff's Supplemental Brief, Sept. 13, 1996, at 4. In Zenith, the alleged infringer argued that a patent containing only one claim should be construed as limited to chemical compound it described in its pre-ingested form. The court construed the claim and determined based upon its language and prosecution history that it should not be so limited. The Court declines to find a per se rule in Zenith which requires that all claims which describe a compound be construed as covering both the metabolically produced and synthetic produced forms of the compound, without regard to the language of the claims, the specification of the patent or the prosecution history. Instead, the Court will conduct the construction pursuant to Markman, and as will be demonstrated infra, the reference points for construction in this case are much more replete with evidence that a different interpretation of the term "compound" is appropriate here than was the case in Zenith.

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Next, the Court notes that claim 10, though not asserted in this action, claims the pharmaceutical composition of TAM in unit dosage form. As a result, clearly claim 10 can be limited to synthetically produced TAM reduced to tablet form. In addition, claim 10 claims the combination of an effective amount of TAM with a "significant amount of a pharmaceutically acceptable carrier" in order to produce the "unit dosage form" to be administered. Baker Norton persuasively points out that if as MMD suggests the term "compound" refers to impure TAM created in the body by metabolism, claim 10 could be construed as the removal of impure TAM from human bodies to then be combined pharmaceutically with a synthetic, or pure, carrier, which as a practical matter the Court finds to be a tenuous assertion leading to an absurd result. n5 Further,

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each of the unasserted claims 6 through 9 specify the inclusion of "pharmaceutically acceptable salts" in the variations of the TAM compound described in those claims. The Court finds this inclusion further evidence that the inventors' sought a patent on chemical formulations of TAM only.

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n5 Indeed, at oral argument counsel for MMD suggested somewhat disingenuously that "if it was economic you could extract [TAM] from people who had metabolized terfenadine." Transcript, at 67. Counsel further stated that "there was a comment about oh, I don't know how I'd get it out of the liver. I guess there isn't a practical way. Patents don't have to be practical." Transcript, at 67.

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Finally, the claims are organized such that claims 1 through 9 claim the compound TAM and various chemical variations thereof, with claim 10 claiming TAM in "unit dosage form" and Claim 11 claiming administration of TAM in effective amounts. The Court finds that the structure of the claims provides some evidence in favor of a construction of the term "compound" as used in claim 1 as covering only TAM which is synthetically produced.

2. The Specification

"Claims must be read in view of the specification of which they are a part." Markman, 52 F.3d at 979 (citing Autogiro, 384 F.2d at 397). See also Vitronics, 90 F.3d at 1582 ("specification acts as a dictionary . . . when it defines terms by implication. . . . It is the single best guide to the meaning of a disputed term (citations omitted)). "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it." Vitronics, 90 F.3d at 1582.

The specification accompanying the claims of the '129 Patent exhaustively discusses and gives examples of the chemical formulations of TAM, the usefulness of TAM as an antihistamine, and the modes for administering TAM in effective amounts. See generally U.S. Patent No. 4,254,129. By contrast, the specification contains no reference whatsoever to TAM created inter vivo by metabolism. The Court finds that the lack of such a reference in what is otherwise a comprehensive description of TAM and its administration gives further support for Baker Norton's position that the term "compound" as used in claim 1 refers only to synthetically produced TAM.

3. The Prosecution History

Far more compelling than the language of the claims themselves and of the specification, however, is the history of the prosecution of the '129 Patent before the U.S. Patent Office. Markman, teaches that the prosecution history of the alleged infringed patent is of "primary significance" in the Court's infringement inquiry. 52 F.3d at 980 (citing Autogiro, 384 F.2d at 397).

The Court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims: "The construction of the patent is confirmed by the avowed understanding of the patentee, expressed by him, or on his half [sic], when his application for the original patent was pending."

Markman, 52 F.3d at 980 (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149 (1880)) (alterations in the original). See also Vitronics, 90 F.3d at 1582 ("[The prosecution] history contains the complete record of all the proceedings before the [Patent Office], including any express representations made by the applicant regarding the scope of his claims"); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir.) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution"), cert. denied, 133 L. Ed. 2d 424, 116 S. Ct. 515 (1995); Senmed, Inc. v. Richard-Allan Medical Indus., Inc., 888 F.2d 815, 818-20 (Fed. Cir. 1989) (same); ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1580 (same). Further, "claims may not be construed one way in order to obtain allowance and in a different way against accused infringers." Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991).

At the time that MMD prosecuted the '129 Patent before the Patent Office, it submitted claim 1 as it appears in the '129

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Patent and a "claim 2," which was identical to claim 1 except in that it specified the compound as "an essentially pure compound of the formula [that is TAM]." By notice of January 14, 1980, the examiner rejected both claims 1 and 2, stating that "in view of the nature of the instant disclosure, n6 no proper distinction is seen in scope between claims 1 and 2 . . . based upon the additional recitation in claim [] 2 of "essentially pure." By submission dated May 1, 1980, MMD canceled claim [] 2 stating, "with the cancellation of claim[] 2 . . ., the rejection of claim[] 1 . . . on the basis that there is no proper distinction from claim[] 2 . . ., is no longer applicable." By letter of July 9, 1980, claim 1 was allowed absent the "essentially pure" language and prosecution of the patent closed, the '129 Patent being formally issued on March 3, 1981.

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n6 The disclosure of which the patent examiner spoke was the patent specification, which as the Court noted above, contains no reference to TAM produced by metabolism.

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When it canceled claim 2 in response to the examiner's rejection of it as identical to claim 1, MMD necessarily adopted the examiner's interpretation of "compound" as limited to that formed by synthetic means. In Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994), the Federal Circuit approved such a result when it stated that "an appropriate method for resolving the [problem of diverse definitions of a claim term] is to avoid those definitions upon which the PTO could not reasonably have relied when it issued the patent." Therefore, the Court finds that the prosecution history provides further support for limitation of the meaning of the language of claim 1 to synthetically produced TAM.

That metabolically produced TAM is excluded under the "essentially pure" construction is confirmed by the ordinary meaning of those words to one skilled in the art. The former head of clinical pharmacology at MMD testified at deposition to this effect, stating that

in my wildest dreams I wouldn't think of [contemplating that the claims of the '129 Patent application could cover the swallowing of terfenadine and the subsequent conversion to TAM] because I was aware that terfenadine has been swallowed for many, many years and that its action was known . . . There was nothing I could see invented of utility. . . . And for that reason I didn't conceive that the well-known product terfenadine could come under a patent for something into which it is converted in the body.

Deposition of Murray Weiner, M.D., July 7, 1995, at 317-18. The after the fact assertions to the contrary by the inventors of the '129 Patent n7 submitted by MMD, are "of little weight compared to the clear import of the patent disclosure itself." North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, (Fed. Cir. 1993) (citing Senmed, 888 F.2d at 819 n.8), cert. denied, 128 L. Ed. 2d 365, 114 S. Ct. 1645 (1994). Further, by repeatedly asserting that MMD's patent attorney did not agree with the examiner's finding that claim 1 and claim 2 were equivalent in scope and so instead canceled claim 2 in favor of the "broader claim," MMD itself argues by implication that the claim as finally allowed is limited to synthetically produced TAM. n8 To construct a claim as encompassing a different scope than that contemplated by the examiner when she allowed the claim effectively allows an end run by MMD around the authority of the Patent Office in its role as executor of Congress' mandate as expressed in the laws governing the issuance of patents. The Court cannot sanction such activity by construing claim 1 in any other fashion. As stated by the Genentech court, such a result is appropriate,

because it avoids the possibility of an applicant obtaining in court a scope of protection which encompasses subject matter that, through the conscious efforts of the applicant, the PTO did not examine. An applicant should not be able to deliberately narrow the scope of examination to avoid during prosecution scrutiny by the PTO of subject matter with the objective of more quickly obtaining a patent (or avoiding the risk of an estoppel), and then obtaining in court, either literally or under the doctrine of equivalents, a scope of protection which encompasses the subject matter.

Genentech, 29 F.3d at 1564 (omitting footnote) (emphasis added). See also North Am. Vaccine, Inc., 7 F.3d at 1577 (stating that "[a] patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent").

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n7 See, e.g., Deposition of Albert A. Carr, Feb. 8, 1995, at 142-47; Deposition of Joseph Dolfini, January 25, 1995, at 87; Deposition of George J. Wright, Ph. D., May 18, 1995, at 50-52.

n8 The MMD attorney who prosecuted the '129 Patent before the patent examiner stated at deposition that he disagreed with the examiner's statement because he felt that there was a difference between the claim including the "essentially pure" language and the claim without such language. Deposition of John Kolano, Feb. 23, 1995, at 55. When asked "why did you cancel claim 2 if you disagreed with what the examiner stated in her office action," Kolano stated: "Because I was satisfied that we would be obtaining protection on claim 1 and the question of how readily it would have been possible to overcome the examiner's rejection." Kolano Deposition, at 56.

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B. "Mixing" and "Compression mixture"

Claim 5 recites the method of:
c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a compression mixture; then d) pressing the compression mixture to form a solid oral dosage form.

(Emphasis added.) Plaintiffs define "mixing" as "combining two or more ingredients into one mass," and "compression mixture" as "one mass containing two or more ingredients that are compressed into a tablet." Plaintiffs' construction of these terms is sufficiently broad to encompass both one-layer and two-layer coated granule tablets. Defendants propose the following alternative construction of "mixing" and "compression mixture": "Effecting a uniform dispersion of liquid, semi-solid or solid ingredients of a mixture by means of a mechanical agitation." (Emphasis added.) Defendants' construction would purportedly encompass only a one-layer tablet because the famotidine and antacids would not be "uniformly dispersed" if they are separated into two layers.

This Court must "determine the ordinary and customary meaning, if any, that would be attributed to the terms by those skilled in the art." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1346 (Fed. Cir. 2003). None of the parties have submitted a proposal for the qualifications and experience required of a person skilled in the art. Nevertheless, this Court concludes that one of skill in the art would have a Ph.D in chemistry, organic chemistry, pharmaceutics or pharmaceutical microbiology, or a B.S. or M.S. with several years of work experience in pharmaceutics or pharmaceutical microbiology, or an M.D. with several years of clinical experience in administering H2 blockers or antacids. See, e.g., Astrazeneca Pharms., LP v. Mayne Pharma (USA) Inc., 352 F. Supp. 2d 403, 411-12 (S.D.N.Y. 2004); Bayer AG v. Carlsbad Tech., Inc., No. 01 Civ. 867 (LSP), 2001 U.S. Dist. LEXIS 24487, 2001 WL 34125673, at *3 (S.D. Cal. Oct. 24, 2001).

1. Specification

This Court must examine the specification to determine a construction that is consistent with the spirit of the claimed invention. Phillips, 415 F.3d at 1315-17. The specification favors Plaintiffs' broad construction of "mix" and "compression mixture" in two ways. First, Examples II and III each contemplate a dual-layer coated granule tablet. ('340 Patent col. 10, ln. 63 - col. 12, ln. 51.) Example II requires that the "famotidine [be] layered on top of [the] antacid blend" and compressed into a bilayer tablet. ('340 Patent col. 11, ln. 39.) Likewise, Example III expressly involves a "bilayer tablet." ('340 Patent col. 11, ln. 58.) "[I]t is . . . well established that a claim construction that excludes a preferred embodiment is 'rarely, if ever, correct.'" Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1378 (Fed. Cir. 2001) (quoting Vitronics, 90 F.3d at 1583); see also Burke, Inc. v. Bruno Ind. Living Aids, Inc., 183 F.3d 1334, 1341 (Fed. Cir. 1999) (holding that a claim interpretation excluding the preferred embodiment was improper). This is because "it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way." Hoechst Celanese Corp., 78 F.3d at 1581.

Second, Example II describes a two-layer tablet comprised of "coated famotidine granules admixed with granules of an

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antacid and formed into a solid oral dosage form." ('340 Patent col. 10, ll. 63-66 (emphasis added).) Defendants concede that the term "admixed" means "to mix with." (Kiel Decl. Ex. 11 PP 64-65.) Thus, Example II implicitly defines "mix" to include a dual-layer embodiment. Phillips, 415 F.3d at 1321 (the specification "acts as a dictionary when it . . . defines terms by implication").

Perrigo responds by contending that portions of Example II were copied from McNeil's United States Patent 5,679,376 (the "'376 patent"), which claims a single-layer tablet comprised of loperamide and simethicone. (Defendants' Claim Construction Exhibit ("Defs. Cl. Constr. Ex." H: '376 Patent col. 10, ln. 40 - col. 11, ln. 55.) According to Defendants, the word "admixed" was mistakenly used in Example II because of this copying error, and for that reason should not be considered in connection with the two-layer embodiment. This Court disagrees. Extrinsic evidence such as the '376 patent cannot be used to contradict the unambiguous intrinsic evidence. See Vitronics Corp., 90 F.3d at 1584. Moreover, the relevant language of the '376 patent is different from its alleged counterpart in the '340 patent. Defendants offer no testimonial or documentary evidence demonstrating that the latter is derived from the former. Finally, Plaintiffs' proposed constructions of "mixing" and "compression mixture" broadly cover both a one-layer and a two-layer coated granule embodiment. (Tr. at 49, 88.) These constructions are entirely consistent with Plaintiff's use of the term "admixed" to describe a one-layer embodiment in the '376 patent and, later, a two-layer embodiment in the '340 patent.

2. Prosecution History

The prosecution history also supports Plaintiffs' construction. A court must consider the prosecution history of the patent "to determine whether the applicant clearly and unambiguously 'disclaimed or disavowed [any interpretation] during prosecution in order to obtain a claim allowance.'" Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985)) (alteration in original). Disclaimer during prosecution of the patent may include instances where "the patentee distinguished [a] term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2002). Prosecution disclaimer must be narrowly tailored, however, to exclude only claim scope that has been "clearly and unmistakably" disclaimed. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324-26 (Fed. Cir. 2003) ("For prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable."); accord Sunrace Roots Enter., Co. v. SRAM Corp., 336 F.3d 1298, 1306-07 (Fed. Cir. 2003). "Where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of surrender." Omega Eng'g, 334 F.3d at 1324; accord Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310 (Fed. Cir. 2003).

Significantly, Perrrigo identifies no statement made by McNeil disclaiming the dual-layer coated granule embodiment. Perrigo instead asserts that the scope of claims allowed on the basis of unexpected results cannot exceed the parameters of those results, and therefore, the '340 claims must be limited to the single-layer tablets tested by Roche. It is true that a patent applicant using unexpected results to show non-obviousness must provide data commensurate in scope with the claims which the evidence is offered to support. See In re Grasselli, 713 F.2d 731, 743 (Fed. Cir. 1983); In re Tiffin, 58 C.C.P.A. 1420, 448 F.2d 791, 792 (C.C.P.A. 1971). However, that does not mean that courts mechanically import limitations from the test results into the claims. See, e.g., In re Cescon, 474 F.2d 1331, 1334 (C.C.P.A. 1973) (allowing "broadly drawn" claims even though "not all compounds encompassed by the claims [were] tested"). Moreover, the Federal Circuit has held that claims allowed based on "surprising results" may be construed more broadly that the results themselves. Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1135-37 (Fed. Cir. 2006). In Purdue Pharma, Plaintiff Purdue Pharma ("Purdue") alleged that Defendant Endo Pharmaceuticals Inc. ("Endo") infringed various Purdue patents by filing an ANDA for a generic version of Purdue's OxyContin, a pain relief tablet comprised of a controlled release oxycodone product. After the examiner rejected the OxyContin patents as obvious, Purdue distinguished the prior art using "surprising results" allegedly observed in a specific dosage range of oxycodone. Purdue Pharma, 438 F.3d at 1130. Thereafter, Purdue relied on these "surprising results" as a "prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of the claims." Purdue Pharma, 438 F.3d at 1130 (internal quotations omitted). Construing the term "controlled release," the district court found a prosecution disclaimer of claims to oxycodone outside the range detailed in the extraordinary results.

Sitting en banc, the Federal Circuit reversed the district court's construction of the claim. Purdue Pharma, 438 F.3d at 1135-37. The panel:

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agreed with Purdue that it made no such disclaimer or disavowal . . . While it is true that Purdue relied on its 'discovery' of the . . . dosage range to distinguish its claimed oxycodone formulations from other prior art . . ., Purdue's statements do not amount to a clear disavowal of claim scope.

438 F.3d at 1136. By restricting the claims in accord with the alleged test results, "the trial court [had] impermissibly imported a limitation [from the prosecution history] into the claims." Purdue Pharma, 438 F.3d at 1136-37. Perrigo urges this Court to make precisely the same error of law. See also Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1220 (Fed. Cir. 1996) (refusing to import limitations from the prosecution history into the claims). The submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims.

Absent evidence of a clear disavowal in the prosecution history, this Court will not deviate from the claim meanings compelled by the remainder of the intrinsic evidence. See, e.g., Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 908 (Fed. Cir. 2005); Cordis Corp. v. Medtronic Ave, Inc., 339 F.3d 1352, 1359-62 (Fed. Cir. 2003). Here, there is no incontrovertible evidence that McNeil disavowed the two-layer embodiment during the prosecution of the '340 patent. McNeil's initial claims were rejected by the Patent Office. Following the submission of the Roche declaration, the examiner found McNeil's claims "persuasive as to unexpected results . . . over the prior art for the dosage form tested therein, i.e. coated granule solid dosage form." The Patent Office accepted application claims 9, 10 and 27, each of which was sufficiently broad to encompass a dual-layer coated granule embodiment.

Again, there is no record evidence of an express disclaimer of the dual-layer coated granule embodiment. Purdue Pharma, 438 F.3d at 1135-37. Perrigo focuses on statements made by the examiner following the submission of the Roche declaration. As an initial matter, "unilateral statements by an examiner do not give rise to a clear disavowal of claim scope by an applicant." Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347-48 (Fed. Cir. 2005). To the extent the examiner's statements are relevant, they are, at most, ambiguous. After McNeil submitted the Roche declaration, the examiner noted that the unexpected results were sufficient to allow the "dosage form tested therein." (Kiel Decl. Ex 2: Paper No. 33, at 2.) Perrigo asserts that the singular "form" refers only to the single-layer embodiment tested by Roche. Yet the examiner explained that the phrase "dosage form tested therein" broadly referred to the "coated granule solid dosage form." (Kiel. Decl. Ex. 2: Paper No. 33, at 2.) Having failed to distinguish between one-layer and two-layer embodiments, the examiner apparently was persuaded as to all coated granule embodiments. This interpretation of the examiner's statement is consistent with the specification's description of the preferred embodiment, in which the singular "form" expressly refers to both one-layer and two-layer tablets. ('340 Patent col. 9, ll. 12-14.)

Likewise, in explaining her reasons for allowing claims 9, 10 and 27, the examiner expressed her approval of claims that "limited allowed claims to coated granules. Other barrier means, e.g., the barrier sandwich, have not been allowed." (Kiel Decl., Ex. 2: Paper No. 36.) Defendants contend that the dual-layer coated granule embodiment is one of the "other barrier means" that, in addition to the barrier sandwich, was disallowed. Yet the quoted passage does not distinguish between one-layer and two-layer coated granule embodiments in describing the allowed application claims. The better reading of the passage is that both one-layer and two-layer coated granule embodiments were allowed, and the remaining embodiments--the barrier sandwich and the core embodiments--were rejected. At the very least, the examiner's statement is open to more than one reasonable interpretation, meaning there has been no demonstration of a "clear and unmistakable" disclaimer. Sandisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1287 (Fed. Cir. 2005); Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed. Cir. 2004).

Perrigo's contentions are further weakened by the nature of the unexpected results. Perrigo asserts that its proposed constructions are necessary because the 25-70% degradation Roche observed in uncoated famotidine can be achieved only by mixing the ingredients into a single layer coated granule tablet. But Perrigo offers no evidence demonstrating that the same results would not be achieved using a two-layer tablet. Perrigo admits that the examiner did not review the results of a test exploring the degradation in a two-layer embodiment. (Tr. at 65.) Nor can Perrigo identify any such test that was completed prior to the allowance of the '340 patent. (Tr. at 66.) Regardless, there is no record evidence showing that either the examiner or McNeil viewed the unexpected results as narrowly as the Defendants submit.

Perrigo also notes that the examiner rejected application claim 24. (Kiel Decl. Ex. 2: Paper No. 36.) That claim, as amended February 27, 1998, recites:

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An oral dosage form . . . comprising: a first portion containing a therapeutically effective amount of famotidine granules; a second portion containing a therapeutically effective amount of [antacid]; and barrier means between said first and second portions for separating the [antacid] from the famotidine, wherein the barrier means is a coating disposed on the famotidine granules which prevents the famotidine from degrading more than an additional 1% by weight of the famotidine as compared to an identically formulated dosage form not containing an antacid . . .

(Kiel Decl. Ex. 2: Paper No. 34, at 3.) Defendants contend that this claim was rejected because it encompassed a two-layer coated granule embodiment. However, the examiner explained her rejection of this claim as follows: "Claim 24 is indefinite as to how the absence of 'an antacid' broadly . . . would be relevant to the construction of the dosage form." (Kiel Decl. Ex. 2: Paper No. 36, at 1.) This explanation has nothing to do with the inclusion of a two-layer embodiment in the claim. Application claim 24 also contains the quoted "1% by weight" language which is irrelevant to the number of layers in the tablet and which references the data the examiner had found to be insufficient on several occasions during the prosecution history. n4 (Kiel Decl. Ex. 2: Paper Nos. 16, at 6; 20, at 3; 29, at 4.) No clear disavowal arose from the rejection of application claim 24.

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n4 The inclusion of the "1% by weight" language in application claim 32 would explain why the examiner rejected that claim as well.

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3. Other Evidence

As a final matter, this Court may consult dictionaries, encyclopedias and treatises to develop an understanding of the disputed terms. Phillips, 415 F.3d at 1324. Here, the dictionary definitions of the word "mix" are inconclusive. Webster's Third New International Dictionary, at 448 (3d ed. 1986), provides a variety of definitions. One is "to stir, shake, or otherwise bring together (different substances) with a loss of separateness of identity" and to "cause to be scattered or diffused throughout." This definition supports Defendants' proposed construction. However, Webster's also defines "mix" to mean: (1) to "combine . . . in one mass," (2) to "put as an ingredient," (3) to "bring together in . . . close association," and (4) to "combine with or introduce into a mass already formed." These constructions are sufficiently broad to encompass a two-layer tablet.

Technical dictionaries can also assist claim construction by showing how persons skilled in the art define a particular term. Dow Chem., 257 F.3d at 1375. Defendants cite the portion of Hawley's Condensed Chemical Dictionary that defines "mixing" as "[e]ffecting a uniform dispersion of liquid, semi-solid or solid ingredients of a mixture by means of a mechanical agitation. " However, an alternative definition in Hawley's also supports Plaintiff's construction: "A heterogeneous association of substances which cannot be represented by a chemical formula. Its components may or may not be uniformly dispersed . . ." These conflicting dictionary definitions do not aid this Court's construction of the claims.

Based on the intrinsic evidence, this Court adopts McNeil's proposed definitions and construes "mixing" to mean "combining two or more ingredients into one mass," and "compression mixture" to mean "one mass containing two or more ingredients that are compressed into a tablet."
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As to DDI's second argument, we acknowledge that the term "comprising" raises a presumption that the list of elements is nonexclusive. See Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997). However, "'[c]omprising' is not a weasel word with which to abrogate claim limitations." Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1380 (Fed. Cir. 1998). "Comprising" appears at the beginning of the claim-"comprising the steps of"-and indicates here that an infringing process could practice other steps in addition to the ones mentioned. Those six enumerated steps must, however, all be practiced as recited in the claim for a process to infringe. The presumption raised by the term "comprising" does not reach into each of the six steps to render every word and phrase therein open-ended-especially where, as here, the patentee has narrowly defined the claim term it now seeks to have broadened. The district court's limitation of the claim scope to exclude

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processes that produce some irregularly shaped particles is correct.
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1. Claim Construction

Claim 1 of the '827 patent includes the transition term "comprising." Medichem argues that this term is open-ended and that, as a result, additional material elements or method steps may be included in the claimed process. According to Medichem, the absence of a tertiary amine in Rolabo's claims is therefore irrelevant. Rolabo's claim encompasses not only any improved processes for the manufacture of Loratadine that do not include tertiary amines, but also, because of the open-ended transition term, processes like Medichem's that do include tertiary amines. Consequently, Medichem asserts, the district court misconstrued the subject matter claimed by the '827 patent by reading the absence of a tertiary amine requirement as excluding tertiary amines from the Rolabo process. Had it wanted to, Medichem continues, Rolabo could have drafted its claim to exclude the presence of tertiary amines by using the transition phrase "consisting of" rather than "comprising." Rolabo does not dispute Medichem's argument regarding claim construction, and, in fact, admitted its correctness during the district court proceedings.

We agree with Medichem in its urged construction. "The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368 (Fed. Cir. 2003) (citations omitted). In the course of its analysis, the district court apparently assumed that the absence of an affirmative claiming of tertiary amines excluded them from its scope. See District Court Opinion, 2002 U.S. Dist. LEXIS 27086, slip op. at 9 ("The test . . . is whether someone reasonably skilled in the art would find the elimination of a tertiary amine obvious or anticipated in light of the prior art at the relevant time." (emphasis added)). The assumption that tertiary amines were excluded from the claims of the '827 patent is consistent throughout the district court's opinion. As drafted, however, the process described in the '827 patent includes not only the steps listed in the claim, but also any additional steps that may be added. Invitrogen, 327 F.3d at 1368. The addition of a tertiary amine to the process described by the '827 patent is an indisputable possibility, as demonstrated by both the '100 patent itself and Rolabo's concession at oral argument. Thus, while the process described by claims 1 and 17 of the '827 patent does not require the presence of a tertiary amine, it certainly cannot be read to exclude it. n3

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n3 This is consistent with the conclusion reached by the Board of Patent Appeals and Interferences. Stampa, 65 U.S.P.Q.2d at ___, 2002 Pat. App. LEXIS 191 at *14-*15.

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Georgia Pacific argued at trial that the terms "comprise" and "consist" have different meanings; the appellee is correct in this contention. The Manual of Patent Examining Procedure explains the difference between "comprise" and "consist" in patent law as follows:

The transitional term "comprising" . . . is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. 4

The transitional phrase "consisting of" excludes any element step, or ingredient not specified in the claim. 5

Patent and Trademark Office, Department of Commerce, Manual of Patent Examining Procedure, § 2111.03 (6th ed. 1997). From these definitions it is clear that "comprise" is a broader term than "consist." The set of mats that are "comprised" of glass fibers includes the subset of mats that "consist" of glass fibers and also includes mats made up of glass fibers and other substances. Whereas, mats that "consist" of glass fibers are made up of glass fibers and nothing else. In this case, claim 1 of

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the earlier '569 patent uses the broader term "comprise," while claim 1 of the later '989 patent uses the narrower term "consist." Thus, any mat that meets the "consist" requirement of the '989 patent would also meet the "comprise" requirement of the '569 patent. In effect, the invention claimed in the '989 patent is, with respect to the glass mats, merely a subset of the invention claimed in the '569 patent.

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4 For this definition, see Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 U.S.P.Q. (BNA) 805 (Fed. Cir. 1986), and In re Baxter, 656 F.2d 679, 210 U.S.P.Q. (BNA) 795 (CCPA 1981).

5 For this definition, see In re Gray, 19 C.C.P.A. 745, 53 F.2d 520, 11 U.S.P.Q. (BNA) 255 (CCPA 1931), and Ex parte Davis, 80 U.S.P.Q. (BNA) 448, 450 (Bd. App. 1948).

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The dispute here centers on the construction of the word "comprising." Tr. 79:10-91:23. Amgen asks the Court to construe the term "comprising" as meaning "containing at least." Further, Amgen argues that its interpretation would mean that any additional steps would be included in the claim. Roche/Hoffmann, on the other hand, wants the Court to construe the term "comprising the steps of" as meaning that any other additional step is outside the claim. It therefore argues that only the two mentioned steps are included in these claims.

The grounds for the disagreement are already reasonably clear. Apparently, Roche/Hoffmann's product includes the addition of a step or more in the process of making the accused composition. Therefore, if the Court construes the claim narrowly, it will potentially prevail on its 35 U.S.C. § 271(g)(1) argument that its product does not infringe because it is "materially changed by subsequent processes." Amgen, of course, benefits from the opposite argument. Should the Court construe "comprising" to mean "containing at least," other products that are obtained by the same plus additional elements could potentially fall within the ambit of these patent claims.

There are two important points to make. First, at this point, the Court is only construing the claims, not ruling on infringement. See Amgen, 126 F.Supp. 2d at 80-81. Second, as the Court made clear at oral argument, construing the term "comprising" as "containing" leaves open for later the discussion and argument to determine whether the additional steps Roche/Hoffmann apparently uses "materially change" the accused product. See Biotec Biologische Naturverpackungen GmbH v. Biocorp, Inc., 249 F.3d 1341, 1351-52 (Fed. Cir. 2001) ("Whether a change in a product is material is a factual determination, and is properly for the trier of fact.").

Therefore, following the common understanding of the words, the Court determines that "comprising" means "containing the named elements."
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Claim 1 of the '721 patent is representative of the claims at issue in both patents with regard to the limitation in dispute. That claim reads as follows:

A biodegradable high molecular polymer useful as an excipient in producing a pharmaceutical preparation comprising a copolymer or homopolymer of about 50-100 mole percent of lactic acid and about 50-0 mole percent of glycolic acid having a weight average molecular weight of about 2,000 to 50,000 and wherein the content of water-soluble low molecular compounds, as calculated on the assumption that each of said compounds is a monobasic acid, is less than 0.01 mole per 100 grams of said high molecular polymer.

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The language in dispute for purposes of OWL's appeal on claim construction is "comprising a copolymer ...of lactic acid and ...of glycolic acid." OWL argues that the reference to copolymers of lactic acid and glycolic acid requires that the copolymers be made from lactic acid and glycolic acid as starting materials. The district court, however, construed that language to include "copolymers composed of lactic acid and glycolic acidmers produced by any method, including the use of lactide and glycolide."

Under OWL's construction, the claimed copolymers would have to be made by direct polymerization from lactic acid or glycolic acid. Under the district court's construction, the claims were not limited to copolymers made by direct polymerization. Instead, under the district court's construction, the claimed polymers could be made by a different method such as the "ring-opening" method in which lactic acid and glycolic acid are first converted into cyclic dimers, known as lactide and glycolide. The rings of those dimers are then opened by a catalyst, after which they react to form copolymer chains consisting of repeating units of lactic acid and glycolic acid.

We uphold the district court's claim construction, which was the product of a careful analysis of the claim language, the specifications of the two patents, the prosecution history, and the extrinsic evidence provided to the court. As the district court observed, neither the language of the claims nor the specification of either patent explicitly sets forth the starting materials for making the copolymers, nor do the claims or the specification require that the copolymers be produced by direct polymerization. To the contrary, while the common specification of both patents lists examples of polymerization by using lactic acid and glycolic acid as the starting materials, the specification explicitly provides that the biodegradable high molecular polymer that serves as the starting material for performing the method of the invention "may be produced by any method." '721 patent, col. 1, ll. 63-65.

The district court based its claim construction in part on treatises that recognize that copolymers of lactic acid and glycolic acid can be made either by direct polymerization or by ring opening. Based on that evidence, the district court concluded that one of ordinary skill in the art would consider the terms "copolymer of lactic acid and glycolic acid" to be synonymous with the term "copolymer of lactide and glycolide." Indeed, OWL's expert, Dr. Colin Pitt, testified that at the time the patent application was filed, a person of ordinary skill in the art would use the terms "lactic acid" and "glycolic acid" interchangeably with the terms "lactide" and "glycolide" because "the language was relatively loose at that point in time" with respect to the use of those terms.

As to the prosecution history of the two patents, OWL argues that because the prosecution files contained statements regarding the preparation of the polymers by combining lactic acid and glycolic acid, the examiner intended to exclude the use of other compounds as the appropriate starting materials for the claimed high molecular polymer. The prosecution history, however, does not exclude the use of other compounds, such as lactide or glycolide, to make the copolymer.

Finally, OWL argues that the prosecution history of the European application corresponding to the '721 patent excludes copolymers made from lactide and glycolide because TAP stated to the European examiner that the invention did not include a polymer made from lactide or glycolide. As the district court explained, however, while the applicant for the European patent characterized the claims in that manner, the European patent examiner rejected that characterization, stating that the applicant "does not appear to be correct in saying that the polymer of the present application is different from polymerized glycolide and/or lactide." In light of the European examiner's rejection, it is reasonable to conclude that TAP receded from that characterization of its claims, which it did not repeat in the course of the prosecution of its U.S. patents. It was therefore proper for the district court to attribute little weight to the statements made to the European examiner.
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F. "Ethylene Polymer . . . Comprising A Linear Polymer Fraction"

Dow's Construction	NOVA's Construction
Ethylene polymer means a polymer made from ethylene. A linear polymer fraction is a fraction that is neither	A heterogeneously branched ethylene polymer containing a polymer fraction that is neither branched nor highly

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highly branched nor medium branched but is linear.
branched.

This claim term appears only in the '023 patent and is used to refer to the "(B)" component of the claimed polymer blends. The disputes between the parties are (1) whether the phrase "ethylene polymer" should be limited to heterogeneously branched polymers (NOVA's position) or not (Dow's position) and (2) whether the phrase "linear polymer fraction" permits some small amount of branching (Dow's position) or not (NOVA's position).

As to the first dispute, NOVA contends that the "SUMMARY OF THE INVENTION" portion of the specification describes the overall invention as including two components: a homogeneously branched polymer and a heterogeneously branched polymer. (See D.I. 127 at 2 (citing '023 patent at 2:25-67.) According to NOVA, the specification then consistently describes the invention itself as including these two specific components, failing to set forth an embodiment in which the second component is a generic ethylene polymer rather than a heterogeneously branched polymer. Indeed, NOVA notes that the specification even includes a section specifically entitled "THE HETEROGENEOUSLY BRANCHED ETHYLENE POLYMER." (Id. at 24-25.) There, the specification explains that "[t]he ethylene polymer to be combined with the homogeneous ethylene/[alpha]-olefin interpolymer is a heterogeneously branched (e.g., Ziegler polymerized) interpolymer of ethylene . . . ." ('023 patent at 8:14-18.) The Court further notes that the Abstract explains generally that "[t]he ethylene polymer compositions have at least one homogeneously branched substantially linear ethylene/[alpha]-olefin interpolymer and at least one heterogeneously branched ethylene polymer." (Id. at Abstract.) Likewise, the "BACKGROUND OF THE INVENTION" attributes the "surprising" physical properties of the new polymer compositions specifically to the combination of a homogeneously branched polymer and a heterogeneously branched polymer. (See '023 patent at 2:4-8 ("Surprisingly, we have now discovered that film can have synergistically enhanced physical properties, when the film is made from a blend of at least one homogeneously branched ethylene/a-olefin interpolymer and a heterogeneously branched ethylene/a-olefin interpolymer.").)

"Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term." C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 864 (Fed. Cir. 2004). On reviewing the specification, the Court agrees with NOVA that it characterizes the invention as a whole as including (1) a homogeneously branched polymer, and (2) a heterogeneously branched polymer. In particular, as NOVA notes, the "SUMMARY OF THE INVENTION" explains in general terms that the invention pertains to novel polymer compositions, and then sets forth two distinct aspects of the invention. In both aspects, the polymer compositions comprise a "(B)" component that is a "heterogeneously branched ethylene polymer." (See '023 patent at 2:25-67.) Although, as Dow notes, this portion of the specification does not use the term "the present invention," the Court assigns this fact little weight given that the patentee has explicitly labeled this portion of the specification as "THE SUMMARY OF THE INVENTION." Furthermore, as noted above, the Abstract includes an additional statement of general applicability in which the polymer compositions are characterized - as a whole - as including a "heterogeneously branched ethylene polymer." On reviewing the remainder of the specification, the Court sees no evidence - and Dow does not cite any - suggesting that the patentee contemplated any embodiment in which the "(B)" component was something other than a heterogeneously branched polymer. On the contrary, as noted above, the specification includes a section specifically detailing "THE HETEROGENEOUSLY BRANCHED ETHYLENE POLYMER" that is part of the inventive compositions. (See '023 patent at 8:14 - 9:12.) Likewise, all embodiments disclosed in the specification include a heterogeneously branched ethylene polymer.

Dow attempts to rebut this evidence in the specification largely through the prosecution history. In particular, Dow notes that prior to examination, Dow deleted the words "heterogeneously branched" from the claims in favor of broader generic language, and that the examiner thereafter acknowledged the broader scope of the claims. (See D.I. 148 at 34 (citing D.I. 129, Exh. F at F-091).) However, in the Court's view, this aspect of the prosecution history does not overcome the patentee's clear characterization in the specification of the overall invention as specifically including a heterogeneously branched polymer. Indeed, "the claims cannot be of broader scope than the invention that is set forth in the specification." On Demand Mach. Corp. v. Ingram Indus., 442 F.3d 1331, 1340 (Fed. Cir. 2006). Dow does not cite any authority, and the Court is not aware of any, suggesting that the prosecution history can be used to broaden the scope of claims beyond that which is supported by the specification.

With respect to whether the phrase "linear polymer fraction" should be understood to allow some small amount of branching, the Court refers to the portion of the specification, noted above, specifically directed to "THE

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HETEROGENEOUSLY BRANCHED ETHYLENE POLYMER" used in the claimed polymer compositions. There, as Dow notes, the specification describes linear low density polyethylene ("LLDPE") as an exemplary heterogeneous polymer that may be used in the invention, noting further that LLDPE contains a "highly branched portion," a "medium branched portion," and an "essentially linear portion." ('023 patent at 8:19-27.) In connection with this description, the specification refers to a figure depicting the results of a temperature rising elution fractionation ("TREF") study on Dowlex(R) 2045, a type of heterogeneously branched LLDPE. (Id. at 8:38-44.) The specification explains that this figure graphically depicts the relative amounts of each polymer fraction in Dowlex(R) 2045. In so doing, it refers to a distinct peak in the TREF study appearing at 98[degree]s C (i.e., the rightmost peak in the figure), explaining that this is "the 'linear' fraction of the whole polymer." (Id. at 8:59-62.) Thus, the specification correlates the 98[degree]s C "'linear fraction" with the least branched "essentially linear portion" of LLDPE. In other words, in describing the heterogeneously branched ethylene polymers used in the claimed invention, the specification confirms that the term "linear" may be used to refer to polymers that include some small degree of branching. (See also D.I. 132 P 7 (Dow's expert, Dr. Joao B.P. Soares, confirms that the 98[degree]s C peak in Dowlex contains molecules with some short chain branches).) Because Dow's construction of the phrase "linear polymer fraction" properly permits some degree of light branching, the Court will adopt it.

Accordingly, the Court will construe the term "ethylene polymer . . . comprising a linear polymer fraction" to mean "a heterogeneously branched ethylene polymer containing a polymer fraction that is neither highly branched nor medium branched."

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(7) a DNA segment comprising a segment of said gene . . . The Court construes this element to require that the nonnative DNA construct must contain a DNA segment which includes a portion of the targeted gene.

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BACKGROUND

The claimed invention relates to purified DNA molecules having promoter activity for the human involucrin gene (hINV). The outermost layers of the skin and other stratifying squamous epithelia are composed of dead cells densely packed with a fibrous protein called keratin. Involucrin is a protein that interacts with keratin and other intracellular proteins to form a cross-linked envelope within the dead cells to strengthen the plasma membrane of the cells.

As the name indicates, the involucrin gene contains the DNA sequence that codes for involucrin. Crish's application discloses that Crish has isolated and sequenced the promoter sequence of hINV from plasmid pSP64 [lambda] I-3 H6B using standard molecular biology techniques. 1 Crish determined that the hINV promoter sequence was approximately 2.5 kb (kilobases) in size. Crish's application also identified and numbered each nucleotide in the hINV promoter sequence and designated it as SEQ ID NO: 1.

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1 Inasmuch as the language of molecular biology has been known for many years and described in several decisions of this court, familiarity with such subject matter is presumed and we will not go into detail except as necessary to understand this appeal.

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Claims 53-55 on appeal are all independent and read as follows:

53. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO: 1, wherein said portion consists of the nucleotide sequence from 521 to 2473 of SEQ ID NO: 1, and wherein said portion of the nucleotide sequence of SEQ ID NO: 1 has promoter activity.

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54. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO: 1, wherein said portion consists of the nucleotide sequence from 1141 to 2473 of SEQ ID NO: 1, and wherein said portion of the nucleotide sequence of SEQ ID NO: 1 has promoter activity.

55. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO: 1, wherein said portion consists of the nucleotide sequence from 1488 to 2473 of SEQ ID NO: 1, and wherein said portion of the nucleotide sequence of SEQ ID NO: 1 has promoter activity.

During prosecution, the examiner rejected claims 53-55 under 35 U.S.C. § 102(b) as being anticipated by a Crish publication 2 and a Welter publication. 3 The Crish publication lists James Crish, coinventor on the '509 application, as a coauthor. The Crish publication analyzed the phenotype (physical appearance) of mice pups that had hINV (including the promoter region) microinjected into them at the embryonic stage. The microinjected hINV was isolated from the same plasmid pSP64 [lambda] I-3 H6B referenced in Crish's patent application. The Crish publication also disclosed the complete structure of hINV (the promoter region of hINV used in the Crish publication, however, was not sequenced), including the approximate size (2.5 kb) of the promoter region, and referenced an earlier publication 4 disclosing how the plasmid pSP64 [lambda] I-3 H6B was obtained.

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2 Crish et al., Tissue-Specific and Differentiation-Appropriate Expression of the Human Involucrin Gene in Transgenic Mice: An Abnormal Epidermal Phenotype, 53 Differentiation 191-200 (1993).

3 Welter et al., Fos-related Antigen (Fra-1), junB, and junD Activate Human Involucrin Promoter Transcription by Binding to Proximal and Distal AP1 Sites to Mediate Phorbol Ester Effects on Promoter Activity, 270 J. Biol. Chem. 12614-22 (1995).

4 Robert L. Eckert and Howard Green, Structure and Evolution of the Human Involucrin Gene, 46 Cell 583-89 (1986) ("Eckert publication").

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The Welter publication, which also lists James Crish as a coauthor, identified five protein-binding sites on the promoter region of hINV. The publication also confirmed that protein binding on two of those sites was necessary for the cell to begin transcribing the DNA coding region. The hINV that was used for this study was from plasmid pSP64 [lambda] I-3 H/Hc. Although plasmids pSP64 [lambda] I-3 H6B and pSP64 [lambda] I-3 H/Hc are not identical, the PTO contends that the promoter regions of hINV contained in both plasmids are identical.

In reply to the examiner's rejection, Crish argued, inter alia, that even if the Crish and Welter publications used the same plasmid as Crish's application, other workers have sequenced plasmid pSP64 [lambda] I-3 H6B and have obtained promoter sequences different from SEQ ID NO: 1. Crish relies primarily on a Lopez-Bayghen 5 publication that sequenced the hINV promoter sequence using the plasmid pSP64 [lambda] I-3 H6B. In a declaration submitted to the PTO, Crish noted that Lopez-Bayghen sequenced a promoter region having 74 nucleotides different from SEQ ID NO: 1 and that the Lopez-Bayghen promoter region was 17 nucleotides longer than SEQ ID NO: 1. Accordingly, Crish asserted that the same starting plasmid does not necessarily possess the same DNA sequence. Crish also argued that a person of ordinary skill in the art would not have recognized SEQ ID NO: 1 in view of differing promoter sequences obtained by other workers. Finally, Crish contended that claims 53-55 used the transition phrase "consists" and were, therefore, limited to only the recited numbered nucleotide sequences of SEQ ID NO: 1. Because neither the Crish nor the Welter publication specifically disclosed the nucleotide sequence of SEQ ID NO: 1, according to Crish, those publications could not be anticipatory.

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5 Lopez-Baygen et al., Transcription Analysis of the 5'-Noncoding Region of the Human Involucrin Gene, 271 J. Biol. Chem. 512-20 (1996).

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The Board affirmed the examiner's final rejection. The Board first rejected Crish's argument that the claims were limited to only the portions of SEQ ID NO: 1 specified in the claims and not the entire sequence. The Board held that the transition language "comprising" allowed the claims to cover the entire involucrin gene plus the other portions of the plasmid, as long as the gene contained the specific portions of SEQ ID NO: 1 recited by the claim. The Board also agreed with the examiner's 35 U.S.C. § 102(b) rejection based on the Crish and Welter publications. Crish's application disclosed that SEQ ID NO: 1 was obtained by sequencing the same plasmid disclosed in the cited prior art references. Although the plasmids used in the prior art were not sequenced, the Board found that the plasmids used in the prior art would have necessarily possessed the same DNA sequence as Crish's claimed oligonucleotides.

Although Lopez-Bayghen obtained a promoter sequence different from what Crish claims, the Board found that Crish failed to demonstrate that the plasmids used in the Crish and Welter publications had a nucleotide sequence different from that in the plasmid used in his application. Moreover, Crish did not provide any evidence demonstrating that the DNA sequence differences found in Lopez-Bayghen's promoter sequence were not the result of mere experimental error.

Crish now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

A determination that a claim is anticipated under 35 U.S.C. § 102(b) involves two analytical steps. 6 First, the Board must interpret the claim language, where necessary. Because the PTO is entitled to give claims their broadest reasonable interpretation, our review of the Board's claim construction is limited to determining whether it was reasonable. In re Morris, 127 F.3d 1048, 1055 (Fed. Cir. 1997). Secondly, the Board must compare the construed claim to a prior art reference and make factual findings that "each and every limitation is found either expressly or inherently in [that] single prior art reference." Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998). We review those factual findings for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (holding that factual determinations underlying an obviousness rejection under 35 U.S.C. § 103 are reviewed for substantial evidence). Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion, id. at 1312 (quoting Consol. Edison Co. v. NLRB, 305 U.S. 197, 229-30, 83 L. Ed. 126, 59 S. Ct. 206 (1938)), and "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence," id. (quoting Consolo v. Fed. Mar. Comm'n, 383 U.S. 607, 620, 16 L. Ed. 2d 131, 86 S. Ct. 1018 (1966)). We agree with the PTO that the claimed nucleotides were anticipated by the Crish publication.

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6 Crish does not dispute that the Crish (1993) and Welter (1995) publications qualify as prior art under 35 U.S.C. § 102(b). Both references were published more than one year prior to the '509 application's filing date of March 27, 1997.

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I. Claim Construction

At the outset, Crish challenges the Board's decision affirming the PTO's construction of the pending claims as expanding the scope of the claims to allow nucleotides in addition to the specified portions of SEQ ID NO: 1. Crish alleges that in affirming the PTO's construction, the Board ignored the claims' second transition term, "consists." Crish argues that during prosecution, the term "consists" was added to limit the claimed oligonucleotide to a specific DNA sequence in the promoter region, as opposed to the entire SEQ ID NO: 1. The parties do not otherwise dispute the construction of any terms of the pending claims.

We affirm the PTO's claim construction. During prosecution, as indicated above, the PTO gives claims their broadest reasonable meaning in light of the specification. Morris, 127 F.3d at 1053-54. Moreover, it is well-established that "'comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997). Following these principles, the Board's construction that does not limit the pending claims to the recited

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portions of SEQ ID NO: 1 is surely reasonable. Each pending claim contains the open-ended transition term "comprising." Moreover, the language requiring "at least a portion" of SEQ ID NO: 1 implies that the pending claims contemplate additional nucleotides. Crish's principal argument here that the claims also contain the closed-ended transition term "consists," and that that term narrows the entire claim, is unpersuasive. The reasonable interpretation of the claims containing both of the terms "comprising" and "consists" is that the term "consists" limits the "said portion" language to the subsequently recited numbered nucleotides, but the earlier term "comprising" means that the claim can include that portion plus other nucleotides. 7 Read in context, the claims thus do not preclude a DNA sequence having additional nucleotides.

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7 Crish has not argued that the portions of the plasmid not consisting of the involucrin gene are not nucleotides, nor has he argued that the preamble term "purified" has any operative meaning in this appeal.

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3. "Comprising Incorporating an Admixture Comprising Mixtures of"

The "admixture clauses" of claim 20 explain that, during or after the sequential addition into the mixer of cement, aggregate, and water, the process for accelerating the hardening of the cement mix "comprises incorporating an admixture comprising mixtures of" certain substances. Euclid asserts that this phrase is so indefinite and ambiguous that it is incapable of construction, especially because it confuses the particular order suggested by the prior "sequentially adding" clause -- that is, Euclid complains there is no claim or explanation of when, in the mixing sequence, the admixture is added. Put differently, Euclid asserts this language is "indefinite in that it is unclear as to when the admixture is incorporated into the cement mix." MBT responds that "one of ordinary skill in the art would immediately understand that the admixture could be incorporated into the cement mix at any time before hardening of the cement mix in which it is included." Thus, MBT asserts the phrase "comprising incorporating an admixture comprising mixtures of" should take its ordinary meaning, and needs no special construction by the Court.

As discussed above in the "sequentially adding" discussion, one skilled in the art would easily understand the language in question to mean that: (1) the claimed process is essentially comprised of mixing cement, aggregate, water, and an admixture; (2) the admixture, in turn, is comprised of certain components; and (3) the mixing order of the four ingredients (cement, aggregate, water, and admixture) is sequential, as the Court has already construed that term.

Euclid again argues that: (1) the claimed mixing order of the concrete ingredients is definite; (2) this otherwise-definite order of mixing is made indefinite because the claim language does not state when the admixture must be added; and (3) thus, the phrase at issue is incapable of definition. But, as noted in section B.2 above, the claimed mixing order is not definite, other than non-simultaneous. In sum, the language of claim 20 is not indefinite for failure to recite when, in the mixing sequence, the admixture must be added to the cement mix. On the other hand, Euclid is correct that the phrase in question is very unwieldy. It is fair to say that the phrase in question "must be translated into plain English so that a jury will understand." Control Resources, 133 F. Supp. 2d at 127. Here, the essence of the claim is that the invention is a process involving the sequential mixing (as that term was construed above) of cement, aggregate, water, and an admixture, and the admixture is made up of substances from three component groups. Accordingly, in the context of claim 20 of the '194 patent, the Court concludes that the phrase "comprising incorporating an admixture comprising mixtures of" must be construed to remove ambiguity, as follows: "and also an admixture including, but not limited to." This construction ensures that the jury will better understand the claimed process.

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c. "fraction comprising sucrose"

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The next disputed term is "fraction comprising sucrose." Defendants submit that the phrase means "a fraction produced by the second separator that is sufficiently high in concentration of sucrose (also known as purity) so that it is at least ready for refinement into a commercial product." The court finds that the limitations in Defendants' proposed definition are not required by the claim language. The claim only requires that the second fractionator fractionate "a stream comprising said dissolved component from the first fractionator" into "a fraction comprising sucrose and another fraction comprising a greater percentage of said dissolved component than each of said fractions from said first fractionator." (DTX 3, Col. 15). Thus, so long as the "fraction comprising sucrose" includes sucrose and that the fraction separated from the "fraction comprising sucrose" has a greater percentage of said dissolved component than the fractions from the first fractionator, the requirements of the claim language have been met. The court construes "fraction comprising sucrose" to mean "a fraction that includes sucrose and may also include other dissolved components." (Joint Stmt. p. 16).
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At issue is the proper construction of the following limitation: "skin medication . . . comprising two gels adapted to be simultaneously applied and mixed in situ and to adhere on the skin or lesion surface to be treated . . . comprising said first gel being an aqueous gel comprising sodium chlorite and said second gel being an aqueous gel comprising lactic acid." '531 Patent, col. 6, ll. 20-27. Claims must be construed in light of the specification and the prosecution history. See Grain Processing, 840 F.2d at 908, 5 U.S.P.Q.2D (BNA) at 1793. "Claim terms are given their ordinary and customary meaning in the field of the invention, unless a special definition is clearly stated in the specification." Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1443, 43 U.S.P.Q.2D (BNA) 1837, 1840 (Fed. Cir. 1997).

The district court construed the "comprising two gels" element as referring to two separate gels, each of which contains one of the two critical chemicals, sodium chlorite and lactic acid, and each of which is capable of being applied to the skin, being mixed on the skin, and adhering to the skin before mixing. We agree that the plain language of Claim 1 requires the presence of two distinct gels. The term "comprising two gels" means two separate and distinct gels, and not the intimate combination of two gels after mixing. The term "adapted to be" describes the product in a pre-mixing condition. The plain language requires that before mixing, each gel must be individually capable of being applied to the skin, being mixed on the skin, and adhering to the skin.

The prosecution history bolsters a claim construction requiring two distinct gels prior to mixing. Initially the Patent and Trademark Office rejected Claim 1 of the '531 patent as obvious in light of United States Patent No. 4,101,190 (Hartshorn) and United States Patent No. 3,843,548 (James). Alcide distinguished Hartshorn as not disclosing a two-component gel system comprising sodium chlorite and lactic acid. Alcide further responded that James did not disclose a gel diluent for an acid and a gel diluent for an "analogous" hypochlorite. The non-obvious point of difference between the prior art and the claims of the '531 patent was the use of two distinct gels. In light of the prosecution history, the district court properly construed the term "comprising two gels" to mean two separate and distinct gels prior to mixing.
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II. Ward Patents
A. '767 and '824 Patents, Claim 1: "A comprises at least three carbon atoms and represents at least one component of a signalling moiety capable of producing a detectable signal" and "signalling moiety"

The '767 and '824 patents claim: "A method of detecting the presence or absence of a nucleic acid in sample which comprises the steps of (a) contacting under hybridizable conditions said sample with at least one compound comprising the structure [DIAGRAM] . . . wherein A comprises at least three carbon atoms and represents at least one component of a signalling moiety capable of producing a detectable signal. . . ." '824 Pat. 30:49 - 31:29. Plaintiffs construe this term such that A may constitute, in some instances, the whole signaling moiety (a chemical entity) capable of direct and indirect detection. See Expert Report of Richard Sinden, Def. Ex. 12, at 25 ("I understand the claims of the '824 and '767 Patents as requiring that the A moiety (i) have at least three carbon atoms and (ii) form one or more parts of a signalling moiety capable of producing a detectable signal.").

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Plaintiffs argue that "at least one component" can mean "from one to all of the component parts of the signalling moiety," because scientists recognize the existence of single-component systems. (See Pls.' Claim Constr. Mem. at 16.) Further, they point out that dependent Claims 67, 68 and 70 of the '767 patent and Claims 18, 19 and 21 of the '824 patent specifically provide that "A comprises an indicator molecule," n4 and argue that it would be impermissible to construe the independent claim more narrowly than the dependent claims.

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n4 '767 Patent, Claim 67: "An oligo- or polynucleotide of claim 1 or 48 wherein A comprises an indicator molecule."

'767 Patent, Claim 68: "An oligo- or polynucleotide of claim 67 wherein said indicator molecule is fluorescent, electron a dense, or an enzyme capable or depositing insoluble reaction products."

'767 Patent, Claim 70: "An oligo- or polynucleotide of claim 68 wherein fluorescent indicator molecule is selected from the group consisting of fluorescein and rhodamine."

'824 Patent, Claim 18: "The method of claim 1 wherein the moiety A comprises an indicator molecule."

'824 Patent, Claim 19: "The method of claim 18 wherein said indicator molecule is fluorescent, electron dense, or is an enzyme capable of depositing insoluble reaction products."

'824 Patent, Claim 21: "The method of claim 19 wherein fluorescent indicator molecule is selected from the group consisting of fluorescein and rhodamine."

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Additionally, plaintiff's expert, Dr. Richard R. Sinden, testified at the Markman hearing that the specification includes an example of direct detection. Examples 1-6 of the patents describe indirect detection, where biotin or iminobiotin is complexed with detectable polypeptide, and Examples 7 and 8 merely suggest the use of a NAGE linker arm between the nucleic acid and A, which was well known in the art. However, Example 9 describes use of successive chemical reactions, involving covalent bonds, that would only function using direct detection with fluorescent labels.

Defendants construe Claim 1 as precluding the possibility of A being the whole signalling moiety. They primarily rely on the specification, which states several times in each patent that "A represents a moiety consisting of at least three carbon atoms which is capable of forming a detectable complex with polypeptide when the compound is incorporated into" DNA or RNA. Defendants argue that because this specification does not teach a directly detectable moiety, Claim 1 must not do so. Defendants also argue that because the specification states that A is "formed," A must have multiple components and cannot itself be the directly detectable complex. Additionally, they rely on competing dictionary definitions that differ from plaintiffs', as well as that the six articulated "essential criteria" for A listed in the specifications, which, they argue, require that, among other properties, A be able to "react specifically with chemical or biological reagents to provide a sensitive detection system," '824 Pat. 6:35-37, and that the "detection system" be able to react with A, '824 Pat. 6:55-57, suggesting that A itself is not directly detectable.

The Court finds that the plain language and structure of the '824 and '767 Patents indicate that these patents cover both direct and indirect detection. Plaintiffs acknowledge that dependent claims 2-11 of the '824 Patent, and dependent claims 3, 54-59 and 61 of the '767 Patent, teach indirect detection. They teach that A is a "ligand" that is capable of binding with a detectable polypeptide, and therefore that A is not itself detectable. However, another chain of dependent claims in each patent teaches direct detection, with A comprising an indicator molecule." '767 Patent, Claims 67, 68, 70; '824 Patent, Claims 18, 19, 21; see also supra note 4.

"[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Thus, the presence of dependent claims in both patents that teach both direct and indirect detection creates a presumption that Claim 1, the independent claim, is not limited to either. The specifications do not alter this conclusion. While "claims must be read in view of the specification," Phillips, 415 F.3d at 1315, and the specification is "the best source for understanding a technical term," id., courts are also to "avoid

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importing limitations from the specification into the claims." Id. at 1323. It is true that in the two Ward patents at issue, the specifications largely focus on indirect detection. However, the expert evidence indicates that Example 9 could involve direct detection. See Reply Expert Report of Richard R. Sinden, Def. Ex. 13, 56, 57 (citing Kricka Report, Def. Ex. 10, 30). Thus, importing into Claim 1 only the examples of indirect detection from the specification would skew the full illustrative range of all examples, resulting in utilization of the specifications as "limitations" on Claim 1 rather than as aids for understanding technical terms.

Defendants argue that the term "comprise" in the dependent claims asserted to teach direct detection implies that the indicator molecule is only a part of a multi-component system. The dependent claims, however, utilize "is" and "comprises" interchangeably. For example, Claim 67 of the '767 Patent teaches that " A comprises an indicator molecule," and Claims 68 and 70 teach that "An oligo- or polynucleotide of claim 67 wherein said indicator molecule is fluorescent, electron dense, or an enzyme capable or depositing insoluble reaction products," or "is selected from the group consisting of fluorescein and rhodamine." The drafting of this claim language is less than clear, but in the context of all the dependent claims taken together, the Court sees no basis for inferring from the word "comprise" in certain claims that A must have more than one component, as opposed to suggesting that A may have more than one component. See infra § I.F.

The Court therefore finds that A may be a part of or the entire signalling moiety. For this reason, it declines to limit Claim 1 only to indirect detection, and adopts plaintiffs' construction of the disputed Claim 1 language in the '824 and '767 Patents: "A comprises at least three carbon atoms and is one or more parts of a signalling moiety, which includes, in some instances, the whole signalling moiety."

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Disputed claim language	Plaintiffs' construction	Defendants' construction
concentrate	A compound extracted from the leaves of the Banaba plant (Lagerstroemia speciosa, Linn. or Pers.).	A substance which is extracted from the leaves of the Lagerstroemia Speciosa, Linn. or Pers., and which is concentrated.

There is essentially no dispute about the meaning of this term. At the hearing, Plaintiffs agreed that the words, "which is concentrated," should be included in the construction. In addition, for ease of reference, the parties agreed that the words "Banaba plant" should be used in addition to the plant's Latin name, "Lagerstroemia speciosa, Linn. or Pers." Further, there is no meaningful difference between "compound" and "substance," and at the hearing, the parties agreed to the use of the word "substance." Accordingly, the Court adopts Defendants' construction of this term as modified: "A substance which is extracted from the leaves of the Banaba plant (Lagerstroemia speciosa, Linn. or Pers.) and which is concentrated."

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The first step in determining whether Actagro raised a substantial question concerning validity is to determine the meaning and the scope of the claims to the best of our ability on the preliminary record before us. See Nat'l Steel Car, 357 F.3d at 1334 (citing Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1206 (Fed. Cir. 1992)); Amazon.com, 239 F.3d at 1351. The '200 patent has two essential features, both of which are at issue here. First, the invention of the '200 patent is a concentrated phosphorus fertilizer; and second, it must buffer at a foliage-acceptable pH when diluted with water.

Actagro contends that the limitation "a concentrated phosphorus fertilizer" essentially means a "concentrated fertilizer that contains phosphorus." The Regents, on the other hand, argue that the limitation means "a fertilizer where phosphorus is concentrated." The meaning of the phrase may not be perfectly clear from the claim language itself. However, the specification indicates that the limitation is properly read as "a concentrated fertilizer that contains phosphorus." For

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example, when discussing the possible dilution ratios of the concentrated phosphorus fertilizer to water, the specification explains the ratios in terms of concentrate to water, not in terms of concentrated phosphorus. '200 Patent at col. 3, lines 15-19 ("The concentrated phosphorus fertilizer can be diluted with water . . . at ratios of concentrate to water at about 1:40 to about 1:1600 to result in a fully solubilized fertilizer having a pH in a range acceptable for foliar uptake of phosphorus."). Similarly, the specification states that "it is also an object that the phosphorus fertilizer formulations be conveniently formulated in concentrated solutions that are stable during storage and shipping," Id. at col. 2, ll. 65-67 (emphases added), and "the highly concentrated fertilizers of the present invention, which can be diluted with water . . . ." Id. at col 4, line 67-col. 5, line 1 (emphasis added). These excerpts indicate that it is the fertilizer that is concentrated, not the phosphorus. Finally, nowhere in the specification can we find reference to "concentrated phosphorus" as opposed to a "concentrated phosphorus fertilizer."

Nothing The Regents offer compels us to find otherwise. For example, claim 9 simply states the percentage of the phosphorus fertilizer that must be phosphorous-containing acid. This sheds no light on whether the fertilizer is concentrated or the source of the phosphorus is concentrated - or even what "concentrated" might mean in the context of referring solely to the phosphorus source. The Regents' reference to the prosecution history's treatment of the Offenlegungsschrict 3,417,133 ("Offen. '133") reference also does not help its position. The '200 patent applicant's statement that "Offen. '133 does not teach or suggest a concentrated phosphorus fertilizer as required by the claims" (emphasis in original) suggests nothing other than that the fertilizer must be concentrated. The rest of the discussion simply refers to the weight percent of phosphorous-containing acid present in the fertilizer. This discussion, as explained above, says nothing that suggests it is not the fertilizer itself that is concentrated. During the reexamination, The Regents explained that the SSP reference taught a 13 weight percent of phosphorous acid and that this was "even less concentrated than the other phosphorous acid-containing formulations that were mentioned in col. 4 lines 60-65 of the captioned patent which contain approximately 16% phosphite." The relevance of this text is doubtful, as the referenced section of the specification was deleted in a Certificate of Correction because "Applicant's attorney, believed that [it was] inaccurate and was perhaps originally made based on misinformation or a misunderstanding of information." The statement in the reexamination could arguably be said to mean that "concentrate" as used in that sentence refers to the amount of a compound contained in a composition. However, this does not illustrate that "concentrated" in the phrase "a concentrated phosphorus fertilizer" used throughout the specification is intended to refer both to the fertilizer and to the phosphorus.

Turning to the limitation that the composition be "buffered," both parties appear to agree on the general meaning of this term: "a material is said to be buffered if it resists changes in pH when either an acid or a base is mixed with it." (Grech Supp. Decl. P4). Therefore, in the context of the claims, the composition should be buffered "such that when said composition is diluted with water, there is formed a substantially fully solubilized use-dilution fertilizer having a foliage-acceptable pH for phosphorus uptake." '200 Patent, col. 8, lines 53-56. The specification defines "foliage-acceptable pH for phosphorus uptake" to mean: "a pH that allows phosphorus to be absorbed by the plant without causing damage to the foliage[; a] foliage-acceptable pH for phosphorus uptake usually ranges between about 5.0 to 7.0, and preferably between about 5.5 to about 6.5." '200 Patent at col. 4, lines 19-24. In other words, the claimed composition, when diluted, should buffer in the range of about 5.0 to 7.0, and preferably between about 5.5 to about 6.5. 2

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2 We make no determination of what "about" and "preferably between" precisely mean.

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Therefore, based on the preliminary record before us, "a concentrated phosphorus fertilizer" as used in the '200 patent is best described as a "concentrated fertilizer that contains phosphorus." When diluted, this fertilizer should buffer in the range of about 5.0 to 7.0, and preferably between about 5.5 to about 6.5.
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12. "concentration"

Plaintiff's proposed construction of "concentration"is: "the act of process of concentrating a chemical compound (or group

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of chemical compounds) in relation to other chemical compounds (or groups of chemical compounds)." Defendant argues the term is indefinite as a matter of law, because the term does not appear in the specification or the file history.

Plaintiff argues a person of ordinary skill in the art would understand the term "concentration" to have the same meaning, with simply a different tense, as the term "concentrated," which is used in the specification. Defendant did not dispute this. Plaintiff's proposed construction will be adopted.
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II. "(1) an upper concentration limit for the catalyst which is capable of producing the desired performance from the FCC unit" and "(2) a lower concentration limit for the catalyst which is capable of producing the desired performance from the FCC unit" '236 patent, col. 15, ll. 52-54, 55-57.

Plaintiff construes each of these phrases separately. It contends that the first defines "a concentration [area] within an upper boundary which is capable of producing the desired performance from the FCC unit. It need not be the maximum tolerable value." 28 It contends that the second defines "a concentration [area] within a lower boundary which is capable of producing the desired performance from the FCC unit. It need not be the minimum (or lowest) tolerable value." 29

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28 (Pl.'s Claim Construction Br. at 20.)

29 (Id. at 24.)

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Defendants combine the two phrases and contend that together they define "a particular range of concentrations for the catalyst that has a defined upper limit and a defined lower limit (each expressed as weight percentage) and that is capable of producing or maintaining a desired level of performance from that FCC unit." 30

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30 (Defs.' Opening Claim Construction Br. at 20.)

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Before addressing the areas of disagreement, it should be noted that there are at least two general areas of agreement. First, the parties agree that the "upper concentration limit" and the "lower concentration limit"--whatever those phrases mean--denote catalyst concentration "that is capable of producing a desired level of performance from the FCC unit." 31 Second, they agree that "upper" and "lower" require no construction, as both of their proposed constructions leave those words unchanged. Thus, the main disagreements are over "concentration" and "limit."

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31 While Defendants would substitute "the FCC unit" with "that FCC unit," there is no support for the substitution of "the" for "that." See supra Analysis Part I.E.

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A. "concentration"

As an initial matter, the parties agree that "concentration" requires no construction--Plaintiff asserts that the word needs no further definition, while Defendants' proposed construction leaves "concentration" undefined. 32

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32 (Pl.'s Claim Construction Br. at 20; Defs.' Opening Claim Construction Br. at 20.)

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But the parties disagree on how the "concentration" must be expressed. Defendants contend that it is "expressed in percentage by weight." 33 Plaintiff objects to such a narrow construction. 34

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33 (Defs.' Opening Claim Construction Br. at 18, Ex. 7 at WRG-51152, 51917 (Webster's Third New International Dictionary (1986)).)

34 (Pl.'s Rebuttal Br. at 6.)

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The Court finds that although concentration may be expressed in percentage by weight, nothing in the intrinsic record requires such an expression. The claim does not express concentration as a weight percentage. And the specification repeatedly refers to a catalyst "amount, percentage or concentration." See, e.g., '236 patent, col. 8, ll. 38-61 (emphasis added). By distinguishing between "percentage" and "concentration," the specification reveals the patentee's intent not to categorically express concentration as a weight percentage. Although the prosecution history expresses catalyst concentration as a weight percentage, there is no clear disclaimer that a weight percentage is required or that other expressions of concentration are forbidden. See Brookhill-Wilk 1, 334 F.3d at 1301 ("Absent a clear disclaimer of particular subject matter, the fact that the inventor anticipated that the invention may be used in a particular manner does not limit the scope to that narrow context." (citations omitted)).

B. "limit"

Before addressing the areas of disagreement over "limit," it should be noted that there are three areas of agreement. First, there appears to be no dispute that "limit" denotes a "boundary"--Plaintiff defines "limit" as "the place of area enclosed within a boundary: bounds," while Defendants define "limit" as, among other things, "something that bounds, restrains, or confines." 35

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35 (Pl.'s Claim Construction Br. at 20, Ex. E at I-31089 (Webster's Third New International Dictionary (1993)); Defs.' Opening Claim Construction Br. at 18, Ex. 5 at WRG-51164-65 (Merriam Webster's Collegiate Dictionary (10th ed. 1995)).)

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Second, there appears to be no dispute that the claim depicts a concentration "range"--Plaintiff consistently referred to a "concentration range" at oral argument and Defendants' final proposed construction refers to a "range of concentrations." 36

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36 (See Pl.'s Markman Presentation at 53-59; Defs.' Opening Claim Construction Br. at 20.)

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Finally, there appears to be no dispute that the upper and lower boundaries can change over time. Plaintiffs argue that the boundaries can change and Defendants agreed at oral argument. 37 Nothing in the claim language or in the rest of the intrinsic record indicates that the boundaries are immutable. In fact, the claim speaks of upper and lower boundaries which are capable of producing a "desired" performance from the FCC unit. '236 patent, col. 15, ll. 53, 56. As the "desired"

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performance changes, so may the boundaries.

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37 (Pl.'s Rebuttal Br. at 3-4; Markman Hr'g Tr. at 8, 41, 43, 48, 52, 95, 106-07.)

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But there is a dispute over whether the "upper" and "lower" boundaries denote absolute maximum and minimum catalyst concentration levels that a FCC unit can tolerate. Defendants assert that "upper concentration limit" means "a higher, maximum weight percentage of the catalyst as expressed as the percentage of overall FCC unit inventory." 38 They make similar arguments with respect to "lower concentration limit." 39 Plaintiff rejects any argument that the "limit" is the absolute maximum or minimum or the only possible limit. 40

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38 (Joint Claim Construction Br. at 13.)

39 (Id. at 15.)

40 (Id. at 21.)

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Nowhere in the claim do the words "maximum" or "minimum" appear. Instead, the claim introduces "an upper concentration limit" and "a lower concentration limit" which is capable of producing "the desired performance." '236 patent, col. 15, ll. 52-57. It does not state that these are the maximum or the minimum limits that can be tolerated by a FCC unit. Similarly, while the specification and prosecution history refer to "maximum" and "minimum" "amounts," these are the maximum and minimum concentrations for "desired" or "acceptable" performance. See id., col. 8, ll. 40-44; (Defs.' Opening Claim Construction Br. Ex. 4 at I-3151). Absent a clear disclaimer to the contrary, "the fact that the inventor anticipated that the invention may be used in a particular manner does not limit the scope to that narrow context." Brookhill-Wilk 1, 334 F.3d at 1301 (citation omitted); see Texas Digital, 308 F.3d at 1204.

C. Summary

Accordingly, the Court concludes that "(1) an upper concentration limit for the catalyst which is capable of producing the desired performance from the FCC unit" means "(1) an upper boundary (but not necessarily the maximum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) that is capable of producing the desired performance from the FCC unit." Similarly, the Court concludes that "(2) a lower concentration limit for the catalyst which is capable of producing the desired performance from the FCC unit" means "(2) a lower boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) that is capable of producing the desired performance from the FCC unit."
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II. "concomitant administration" and its permutations 9

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9 The term "concomitant administration" and its permutations are contained in claims 1, 2, 3, 5-8, and 9-27 of the '499 patent and claims 1, 2, 5, and 6-24 of the '458 patent.

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The '499 and '458 patents both contain the claim terms "concomitantly administering," "concomitantly administered," and "concomitant administration." In order to fully assess the context in which "concomitant administration" and its permutations is presented, theCourt assesses the term separately as it is used in each patent.

A. The '499 Patent

Plaintiff's Proposed Construction	Defendants' Proposed Construction
Simultaneous administration; or administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount; or administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12-24 hours after the onset of migraine or onset of precursor symptoms of a migraine.	Putting into a patient two (or more) compositions (i.e., drugs) such that: a) the drugs are put into a patient at the same time; or b) the second drug is put into a patient while the first drug is present in the patient in a therapeutically effective amount, or c) putting into a patient a 5-HT agonist and NSAID such that effective plasma levels of the NSAID will be present in a subject from about one hour to about 24 hours after the onset migraine or onset of precursor symptoms of a migraine.

Pozen and Defendants present the same arguments discussed in the previous section as to disputed claim term "administering" and its permutations. Having already provideda construction for this term in section I, supra, the Court incorporates the foregoing discussion and now turns to the meaning of "concomitantly."

Pozen contends that the inventor acted as his own lexicographer in the '499 patent specification and defined "concomitant administration" as "simultaneous administration," "co-timely administration," or "coordinated administration." OPENING at 12 (citing '499 patent at 7:37-8:5). Pozen also suggests that the language in the specification aligns with the ordinary and customary meaning of the term, namely "simultanelous administration."

Defendants generally "agree with Pozen that the proposed construction for this term should be nothing more than the express definition of 'concomitant administration' from the '499 patent specification," but Defendants dispute whether Plaintiff accurately characterizes the specification. RESPONSE at 11-12. Defendants maintain that to have a concomitant administration, there must be at least two drugs administered. After the Provisional Claim Construction Order was issued, Defendants moved the Court to clarify that "simultaneous administration" should alternatively mean "administration of a second drug for migrainerelief," with the requested construction designating the combination of therapeutic agents and the time required to alleviate symptoms. (Doc. No. 204).

As suggested by both parties, the '499 patent specification recites an express definition that describes the drug administration: "For convenience, the term 'concomitant administration' shall refer to 'simultaneous administration,' 'co-timely administration, or 'coordinated administration.'" See '499 patent at 8:1-5. Since this is an instance where the inventor has clearly defined his own terms, the inventor's lexicography will govern the construction provided for "concomitant administration." Phillips, 415 F.3d at 1316. The '499 patent prosecution history is also consistent as to the explicit definition. Accordingly, the Court finds that "concomitant administration" means "simultaneous administration," and further extrapolating "concomitantly" in the context of the '499 specification, the Court finds "concomitantly" to mean "simultaneously."

Alternatively, the Court adopts additional language 10 proposed first by Pozen at the Markman hearing, and then by Defendants in the Motion to Clarify the Provisional Claim Construction Order (Doc.No. 204). The '499 patent specifications supports a broad understanding of "simultaneously" that includes a "co-timely" or "coordinated" administration. See '499

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patent at 7:37-40, 46-51. It necessarily follows that a "simultaneous administration" would include the limitations provided for in "co-timely" 11 and "coordinated" 12 administrations, such as the administration of a second drug. Therefore, the administration details disclosed in the '499 patent specification are incorporated as an alternative construction for "simultaneous." The proper construction of the term "concomitant administration" and its permutations in the '499 patent is "simultaneous administration," or "administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount," or "administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12-24 hours after the onset of migraine or onset of precursor symptoms of a migraine."

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10 This additional language reads: "or administration of a second drug for migraine relief while a first drug for migraine relief ispresent in a therapeutically effective amount or administration of a 5-HT agonist and NSAID such that the effective plasma levels of the NSAID will be present in a subject from about one hour to about 12-24 hours after the onset of migraine or onset of precursor symptoms of a migraine." (Doc. No. 225 at 2, n. 1).

11 "Co-timely" is described in the'499 patent specification as: "administration of a second drug for migraine relief while a first drug for migraine relief is present in a therapeutically effective amount." '499 patent at 7:37-40.

12 "Coordinated" is described in the '499 patent specification as: "administration of an NSAID such that effective plasma levels of the NSAID will be present in a subject from about one hour to about 12-24 hours after the onset of migraine or onset of precursor symptoms of a migraine." '499 patent at 7:46-51.

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"Condensation of water vapor on the other oxides"

The parties dispute whether "condensation" requires the formation of a "liquid film of water" on the non-native oxides, or whether it only requires the formation of liquid. Genus' expert, Oldham, states that in the context of the claim, "condensation" means the formation of a liquid from vapor. (Brown Decl., Ex. E, Oldham Expert Report at 10.) Under some conditions, that condensation can coalesce into a film. (Id.) Condensation can also form as droplets. (Id. at 11.)

ASM's expert, Hammond, concedes in his rebuttal report that Oldham's statement is correct. (Brown Decl., Ex. I, Hammond Rebuttal Report at 2.) Nonetheless, he states that ASM's construction is more accurate in the context of the patent, because the patent addresses condensation on silicon oxide surfaces. (Id. at 2.) "Because silicon oxide is a hydrophilic surface, any condensation of water vapor onto its surface may initially take the form of tiny droplets; however, these will soon coalesce and form a film of water." (Id.) As Hammond concedes that condensation may initially take the form of tiny droplets, the Court rejects ASM's construction of "condensation," which requires the formation of a liquid film. Nothing in the patent even suggests that a liquid film must form. At the claim construction hearing, however, the parties agreed that any condensation of droplets of water on a hydrophilic surface such as a silicon oxide wafer will quickly coalesce and form a film of water.

ASM also argues in its brief that defining "condensation" as a "film" is necessary to avoid confusing laypersons (presumably, the jury) into thinking that molecules of water that adsorb on a surface during a phenomenon known as "enhanced adsorption" might fall within the definition of "liquid." This argument is not addressed in the expert reports, however, and there is no other information about "enhanced adsorption" provided in the parties' briefing. As there is no evidentiary basis for this argument, the Court disregards it.

ASM also asserts an entirely new argument, not contained in the parties' joint claim construction statement, that condensation should be defined "as the formation of a liquid film from the vapor phase, as described in the phase diagram of Figure 13." This argument also does not appear in the parties' expert reports, other than as a single line in the Hammond report. Genus complains that the argument was not raised until a few days before the opening brief was due, and was not the

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subject of expert discovery. Figure 13 is "a graph of H[2]O partial pressure plotted against HF partial pressure to show the H[2]O and HF partial pressure ranges for H[2]O condensation for various temperatures." ('568 patent 3:52-55.) As already noted, however, nothing in the specification requires the formation of a liquid film. Moreover, if ASM is concerned about confusing laypersons, using Figure 13 as a definition of condensation will surely not help avoid juror confusion. It also appears that there is some doubt that the graph that appears in Figure 13 is entirely accurate, as inventor Bruce Deal testified at deposition that there are some discrepancies between when Figure 13 would predict condensation to occur and when a similar figure in a published scientific article that he co-wrote would predict condensation to occur. (Brown Supp. Decl., Ex. D, DealDep. 110:18-112:25; id. Ex. F.) Most importantly, nothing in the specification even suggests that the inventors are attempting to define the meaning of condensation by reference to Figure 13. Instead, Figure 13 shows how changes in partial pressure affect condensation at various temperatures. The Court declines ASM's invitation to use Figure 13 as part of the definition of condensation.

Accordingly, the Court construes "condensation" in accordance with its ordinary meaning of "the formation of liquid from vapor." On silicon oxide wafers, condensation begins with tiny droplets that soon form a film of water.
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2. The phrase concerning the SMB system

The next dispute concerns many of the separate terms in the phrase "a chromatographic simulated moving bed system having at least three chromatographic columns connected in series and adapted for the flow of liquids in a single direction." (DTX 2, Col. 10). Defendants propose separate definitions for the terms "a chromatographic simulated moving bed system," "a system having at least three chromatographic columns connected in a single series for the flow of liquids in a single direction," and "connected in series." (Joint Stmt. pp. 5-6). However, the court agrees with Plaintiff that a separate definition is not needed for each disputed term because examining the phrase as a whole automatically resolves the ambiguity resulting from viewing each disputed term independently. Therefore, the court will interpret the phrase as a whole.

The main issue of dispute concerning the aforementioned terms is how a simulated moving bed ("SMB") system operates as it is described in the claim. (Markman Hearing Tpt. pp. 32-34; Joint Stmt. pp. 5-6). As previously discussed, a SMB system involves the simulation of a moving bed to allow for a continual feed operation by utilizing multiple columns, and necessarily multiple resin beds, and valve switching. The simulation of the moving of the resin bed is accomplished by changing the pattern of where the molasses is fed into the columns and where the fractions are removed. Essential to the SMB system is the use of multiple columns. As described in the claim, the columns are "connected in series and adapted for the flow of liquids in a single direction through the columns." (DTX 2, Col. 10). As explained by Dr. W. Roy Penney (Plaintiff's Expert), "the loop [in a SMB system] is formed by piping successive columns in series to form a closed circuit containing all the columns in series." (Penney Decl. P 16).

With this background in mind, the court construes the phrase "a chromatographic simulated moving bed system having at least three chromatographic columns connected in series and adapted for the flow of liquids in a single direction through the columns" to describe "multiple columns that form a SMB system as it is used in the claim such that all the columns in the system are connected in series so as to form a loop." A separate definition for each of the aforementioned terms is not necessary. This construction is reinforced by the specification, wherein, regardless of the number of columns depicted in the examples, the examples illustrate that all the columns are connected in series to form a SMB system. (DTX 2, Fig. 1 (example of a SMB system having four columns connected in series); DTX, Fig. 2 (example of a SMB system having eight columns connected in series). Furthermore, this construction is consistent with how one with ordinary skill in the art would interpret columns connected in series in a SMB system. (Penney Decl. P 16).
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Challenging the district court's finding of a lack of literal infringement, UC argues that the district court incorrectly interpreted the claims. Specifically, UC argues that the use of the term "comprising" in the claims indicates that a transfer vector such as that used by Lilly will infringe the claims as long as it includes the inserted cDNA encoding human PI,

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irrespective of the presence of other elements such as the DNA encoding the remainder of Lilly's fusion protein. Lilly responds that the district court correctly interpreted the claims in light of the prosecution history. Lilly argues that a prior art rejection was based on the examiner's conclusion that the prior art taught how to make recombinant insulin as part of a fusion protein and that UC therefore obtained allowance of the claims by specifically disclaiming transfer vectors that encode fusion proteins.

A determination of infringement requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1576, 27 U.S.P.Q.2D (BNA) 1836, 1839 (Fed. Cir. 1993). The first step, claim construction, is a question of law which we review de novo; the proper construction of the claims is based upon the claim language, the specification, the prosecution history, and if necessary to aid the court's understanding of the patent, extrinsic evidence. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81, 34 U.S.P.Q.2D (BNA) 1321, 1329-31 (Fed. Cir. 1995) (in banc), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461 (1996). The second step, determining whether a particular device infringes a properly construed claim, is a question of fact which we review for clear error on appeal from a bench trial. See Fed. R. Civ. P. 52(a); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 U.S.P.Q. (BNA) 1137, 1140 (Fed. Cir. 1983). In order to prove infringement, a patentee must show that "the accused device includes every limitation of the [asserted] claim or an equivalent of each limitation." Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 397, 29 U.S.P.Q.2D (BNA) 1767, 1769 (Fed. Cir. 1994).

We agree with Lilly that UC surrendered coverage of DNA that encodes a fusion protein. The district court correctly interpreted the asserted claims to be limited to genetic constructs and microorganisms that do not include DNA coding for a fusion protein. UC argues that the direct expression of human PI and the expression of human PI via a fusion protein are both described in the patent as part of the invention of the '740 patent, but that fact doesn't change the prosecution history which indicates that UC surrendered coverage of the latter in order to overcome prior art.

This surrender is best exemplified by the prosecution history relating to the claims that ultimately issued as claims 2 and 5. These claims as originally filed were directed, with varying degrees of specificity, to a DNA transfer vector comprising a DNA sequence coding for human PI. The word "comprising," as UC argues and as is well-established, permits inclusion of other moieties. However, during the prosecution of the patent, the examiner rejected these claims as unpatentable based on, inter alia, Ullrich et al., 196 Science 1313 (June 17, 1977) and Villa-Komaroff et al., 75 PNAS 3727 (August 1978). n5 The district court, essentially repeating the statements made by the patent examiner during the prosecution of the patent, found that these references taught, n6 respectively, the need "to combine the genetic information for the eukaryotic insulin gene with prokaryotic regulatory sequences, to obtain expression of insulin in bacteria," and "a general method for the expression and secretion of any eukaryotic protein [such as human PI] provided another protein . . . will serve as a carrier [as part of a fusion protein], by virtue of its leader sequence." 39 U.S.P.Q.2D (BNA) at 1232. The examiner thus rejected the claims because he believed that the prior art taught the use of recombinant eukaryotic/procaryotic fusion proteins for the production of a eukaryotic protein, including insulin, in a recombinant bacterium.

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n5 Several other publications of record before the PTO were found by the district court to teach the use of fusion proteins in the production of human PI. See 39 U.S.P.Q.2d (BNA) at 1231 n.12. For the sake of brevity, we do not discuss them here.

n6 UC also appears to argue that the district court clearly erred in finding that these references taught the production of human PI via a fusion protein. This argument misses the point of the analysis of prosecution history. As the Supreme Court recently noted, the question of the correctness of the examiner's rejection is "properly addressed on direct appeal from the denial of the patent, and will not be revisited in an infringement action." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 137 L. Ed. 2d 146, 117 S. Ct. 1040, 1051 n.7, 41 U.S.P.Q.2D (BNA) 1865, 1872-73 n.7 (1997). In construing the claims in view of prosecution history or in deciding whether to estop a patentee from asserting a certain range of equivalents, a court may only explore "the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." Id. Thus, the district court properly accepted the examiner's arguments for the purpose of construing the claims in view of the prosecution history.

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In an effort to overcome the rejection based on these references, UC first amended claim 2 to read, in pertinent part: "A DNA transfer vector comprising an inserted cDNA having a [DNA] sequence coding for human [PI] . . . ." The word "having" still permitted inclusion of other moieties. When again confronted by a rejection based upon the same references and a later requirement that the word "having" be changed to "consisting essentially of," a narrower term, UC ultimately complied by amending claim 2 to its present form, viz., "A DNA transfer vector comprising an inserted cDNA consisting essentially of a [DNA] sequence coding for human [PI]." Similarly, UC amended claim 5 to its present form, which reads, in pertinent part: "A DNA transfer vector comprising a [DNA] sequence coding for human [PI] consisting essentially of a plus strand having the sequence . . . ." (emphasis added). The examiner allowed these claims, noting that the required "consisting essentially of" language "excludes from the cDNA the presence of sequences other than [those coding for PI]." We agree with the district court that UC thus narrowed its claims in response to a prior art rejection to exclude the materials producing a fusion protein, as Lilly now does. UC urges us to read the examiner's statement on allowance of the claims narrowly as pertaining only to claim 2 and to exclude only DNA other than naturally-occurring human cDNA. However, that statement is not so limited; it expressly applies to claim 5 and, moreover, reflects the examiner's consistent requirement, acquiesced in by UC, that the DNA inserted in the claimed vectors code only for PI, not for a PI-containing fusion protein. n7

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n7 UC's later-filed amendment pursuant to 37 C.F.R. § 1.312 (1983) ("Amendments after allowance"), in which it argued that the claims as allowed would not necessarily encompass the "trivial" oligo-dC and oligo-dG ends actually used to construct the plasmid of the '740 patent, also supports this broader reading of the examiner's statement.

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We have considered all of the other arguments made by UC, including its assertion that the examiner's rejections were based on a distinction between tailored and non-tailored cDNA, but find them to be unpersuasive. In light of the prosecution history, we agree with the district court that claims 5 and 6, which contain the language added during prosecution, cannot be construed to literally cover Lilly's expression of human PI via a fusion protein. Furthermore, UC has stated in its appeal brief that, for purposes of the analysis of literal infringement, the scope of claims 8-10 is no broader than that of claims 5 and 6, and that it does not appeal the court's finding with respect to claims 8-10. Accordingly, we affirm the district court's construction of claims 5-6 and 8-10; its factual finding that Lilly does not literally infringe claims 5-6 is not clearly erroneous and is therefore also affirmed.

Regarding the district court's application of the doctrine of equivalents, UC argues that the district court improperly interpreted the prosecution history to indicate that UC had disclaimed vectors encoding fusion proteins instead of to indicate, as properly interpreted, that the claims were limited to "tailored" cDNA inserts. However, as indicated above, we find no error in the district court's interpretation of the claims and the prosecution history and hence its conclusion that Lilly does not infringe the asserted claims under the doctrine of equivalents.

When a claim has been narrowed by amendment for a "substantial reason related to patentability," such as to avoid a prior art rejection, the patentee may not assert that the surrendered subject matter is within the range of equivalents. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 137 L. Ed. 2d 146, 117 S. Ct. 1040, 1049-51, 41 U.S.P.Q.2D (BNA) 1865, 1871-73 (1997); Insituform Techs., Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1107, 40 U.S.P.Q.2D (BNA) 1602, 1609 (Fed. Cir. 1996), cert. denied, 137 L. Ed. 2d 703, 117 S. Ct. 1555 (1997); ("Prosecution history estoppel bars the patentee from recapturing subject matter that was surrendered by the patentee during prosecution in order to promote allowance of the claims."). "The application of prosecution history estoppel is a question of law subject to de novo review." Id.; see also Warner-Jenkinson, 117 S. Ct. at 1049-51, 41 U.S.P.Q.2D (BNA) at 1871-73.

As the district court properly concluded, the above-described prosecution history estops UC's '740 patent from dominating Lilly's expression of its fusion protein. As a matter of law, the material used by Lilly for expressing its fusion protein is not equivalent to that of the above-analyzed claims, or to the materials of the other asserted claims, i.e., claims 2-3 and 13-14, for such an application of the doctrine of equivalents would allow UC to recapture subject matter it surrendered during the prosecution of the '740 patent. Accordingly, UC cannot meet its burden of establishing infringement under the doctrine of equivalents. The district court did not clearly err in determining that Lilly did not infringe the '740 patent, either literally or under the doctrine of equivalents.

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D. Consisting essentially of

The term "consisting essentially of" appears in several asserted claims of the '324 Patent. Claims 9 and 13, quoted above, provide examples. Plaintiffs assert that the claim should be construed as "whole beta-glucan and any other components which do not affect the novel properties of whole beta-glucans." Immudyne contends that the claim should be construed as "consisting entirely of whole beta-glucans and without any non-whole beta-glucans."

Immudyne's proposed construction conflicts with the meaning accorded "consisting essentially of" by the Federal Circuit. See W.E. Hall Co. v. Atlanta Corrugating, LLC, 370 F.3d 1343, 1353 (Fed. Cir. 2004); AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1245 (Fed. Cir. 2001); PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). "'Consisting essentially of' is a transition phrase commonly used to signal a partially open claim in a patent." PPG Indus., 156 F.3d at 1354. The phrase typically precedes a list of ingredients in a composition claim or a series of steps in a process claim. Id. Use of the phrase signals that "the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." Id.; see AFG Indus., 239 F.3d at 1245. A claim that uses "consisting essentially of" "occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." PPG Indus., 156 F.3d at 1354; see W.E. Hall, 370 F.3d at 1353.

Immudyne's proposed construction also conflicts with the '324 Patent's specification. See PPG Indus., 156 F.3d at 1355-56. For example, the specification states that the occurrence of non-glucan components is minimized:

> [beta] - glucans obtained using this process are also very pure. The occurrence of other cell wall components, including glycogen, protein and chitin, is minimized when this process is used. Glycogen, protein and chitin are undesirable as the presence of these components tend to reduce the water holding capacity and the effective dietary fiber content of [beta] - glucans.

'324 Patent, col. 4, ll. 18-24. Similarly, the specification notes that "[t]he [beta] - glucan product obtained from this process is typically about 96-99% pure." '324 Patent, col. 4, ll. 39-40. The specification also states that "[t]he composition of the present invention can optionally include, in addition to whole [beta] - glucan, other components, which will be determined primarily by the manner in which the composition is to be administered." '324 Patent, col. 7, ll. 11-14.

In short, the Court rejects Immudyne's proposed construction of "consisting essentially of." Consistent with the specification and the cases of the Federal Circuit, the Court construes "consisting essentially of" to denote that the claim necessarily includes the listed ingredients or steps and is open to unlisted ingredients or steps that do not materially affect the basic and novel properties of the claim.

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Disputed claim language	Plaintiffs' construction	Defendants' construction
consisting essentially of	The invention necessarily includes the listed components and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim.	The transitional phrase, "consisting essentially of," signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim. Thus, as used in

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this claim, the transitional phrase should be read so as to exclude any ingredients that affect the ability of the claimed composition to prevent blood glucose level from rising above a normal level, or to lower blood glucose level to a normal level.

There is essentially no dispute as to the meaning of this phrase. The phrase "consisting essentially of" is a middle ground transitional phrase used to signal a partially open claim in a patent. PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998) (A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format."). At the hearing, the parties agreed that the first sentence of Defendants' proposed construction and Plaintiffs' proposed construction were essentially the same and constituted an accurate statement of the law. The second sentence of Defendants' proposed construction unduly restricts this transitional phrase and incorporates the flaws in its proposed construction of the first disputed term. Therefore, the Court adopts the following construction of "consisting essentially of:" "the invention necessarily includes the listed components and is open to unlisted ingredients that do not materially affect the basic and novel properties of the claim."
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"Consisting essentially of"

The parties agreed during oral argument that this term, which appears in claims from the '624 and '156 Patents, means "containing no matter other than chromium picolinate that materially affects the basic and novel characteristics of the claimed method." The Court agrees and construes the term accordingly.
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A. The '135 Patent

AK Steel argues that the district court erred in interpreting the phrase "consisting essentially of aluminum" in the '135 patent claims to permit only up to about 0.5% silicon. Rather, according to AK Steel, the correct interpretation permits silicon in an amount up to but not including 10%, as the intrinsic evidence shows that about 10% silicon materially changes the novel characteristics of the invention. AK Steel contends that the court read the specification's statement that "silicon should not exceed about 0.5%" out of context. That statement, which advanced a theory that the applicants expressly stated was not binding on them, relates to reactivity, according to AK Steel, not to the critical characteristic of the claimed invention -- good wetting.

Sollac responds that the specification clearly states that the invention is to be used with pure or nearly pure aluminum and should not be used with Type 1 aluminum. Sollac further contends that the prosecution history also contains statements expressing that view. Finally, Sollac contends that, given the choice between a broader and narrower construction, and the enablement concerns raised by the broader one, the narrower one should prevail.

We agree with the district court's construction of the disputed claim language. The phrase "consisting essentially of" in a patent claim represents a middle ground between the open-ended term "comprising" and the closed-ended phrase "consisting of." In view of the ambiguous nature of the phrase, it has long been understood to permit inclusion of components not listed in the claim, provided that they do not "materially affect the basic and novel properties of the

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invention." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998); In re Janakirma-Rao, 50 C.C.P.A. 1312, 317 F.2d 951, 954, 1963 Dec. Comm'r Pat. 578 (CCPA 1963). Thus, the claim construction issue presented by the '135 patent in this case is whether an amount of silicon in excess of 0.5% in the aluminum coating materially affects the basic and novel properties of the invention.

To determine those properties, we need look no further than the patent specification. The specification clearly states that good wetting is the goal of the invention as well as what distinguishes it from the prior art. See '135 patent, col. 2, ll. 66-68 ("It is a principal object of this invention to form hot dip aluminum coated ferritic chromium alloy steels having enhanced wetting by the coating metal."). The specification also clearly states that Type 1 aluminum containing "about 10%" silicon contains too much silicon and does not achieve that goal, id. at col. 5, ll. 23-29, whereas Type 2 or nearly pure aluminum does and is therefore preferred, id. at col. 5, ll. 35-40. Furthermore, the specification draws a precise line between those two materials, demarking the exact percentage of silicon that the inventors considered to be too much silicon, when it states, "silicon contents in the coating metal should not exceed about 0.5% by weight." Id. at col. 5, ll. 33-34. On the basis of that statement, we conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention, and that the claims of the '135 patent must therefore be interpreted to permit no more than 0.5% silicon by weight in the aluminum coating.

AK Steel's attempt to distance itself from the clear limiting statements in its specification is unavailing. While it is true that statements in a specification explaining a scientific theory by which an invention is believed to operate should seldom, if ever, be treated as a limitation on a claimed invention, e.g., Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570 (Fed. Cir. 1983), the district court did not do so here. There is a distinction between an inventors' theory as to the reason for a limitation and the meaning of that limitation. By its very terms, the specification here expresses the inventors' desire not to be bound by the reactivity theory they present to explain why aluminum with more silicon does not wet well. See '135 patent, col. 5, ll. 29-34 ("While not being bound by theory . . . ."). However, no such disclaimer attaches to the following conclusion that silicon should not exceed 0.5%. That conclusion is not a theory; it is an expression speaking to the conditions under which the invention will or will not operate properly. As such, AK Steel cannot escape its impact upon the meaning of the claim phrase "consisting essentially of aluminum."

Nor are we persuaded by AK Steel's arguments that the determination whether more than 0.5% silicon materially alters the basic and novel properties of the invention is a question of fact that must be answered by the jury. While "consisting essentially of" language in a patent claim can at times blur the distinction between the separate steps in an infringement analysis (claim construction and comparison of the construed claim to the accused device or method), the distinction is clear enough in this case. AK Steel cites PPG Industries to support its position that that determination is a factual one for the jury. Indeed, we held in that case that "the court properly left it to the jury to determine whether the amounts of iron sulfide in [the accused] SMG glass have a material effect on the basic and novel characteristics of the glass." Id. However, we so held there because, as we stated in the immediately preceding sentence, "The district judge properly recognized that the patent is silent about iron sulfide and about what constitutes a material effect on the properties of the glass." Id. In this case, quite differently, the specification is far from silent regarding silicon and its material effect on the properties of the aluminum coating bath and the resultant coated steel; as explained above, the specification directly speaks to and conclusively answers that question. Therefore, it is as a matter of claim construction that we hold that the claims of the '135 patent do not encompass steel coated with aluminum containing more than about 0.5% silicon. The only factual issue that remains is the simple one whether the claims, so interpreted, read on Sollac's steel strips coated with aluminum containing 8.0% silicon. They do not, and no reasonable juror could conclude otherwise, given the fact that 8.0% is far in excess of 0.5%. We therefore affirm the court's grant of summary judgment of noninfringement of the '135 patent.

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3. "consisting essentially of iron"

Bayer contends that the phrase "consisting essentially of iron" does not refer to a particular percentage of iron. Rather, Bayer contends that as long as iron makes up more than half of the metal content of the powder, then the powder consists essentially of iron.

In response, the Sony Defendants contend that the phrase "consisting essentially of iron" is a term of art signaling that the

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invention necessarily includes the listed ingredient, but excludes additional ingredients that would affect the basic and novel properties of the claimed invention. Applying this definition in the context of the '799 Patent, the Sony Defendants contend that the materials must be at least 90% reduced from iron oxide to elemental iron. According to the Sony Defendants, more than 10% iron oxide would have a material effect on the basic and novel properties of the claimed invention and would produce an inferior product. Further, the Sony Defendants contend that the prosecution history of the '799 Patent indicates that the claimed metal powder cannot contain more than 7% of other metal additives.

The phrase "consisting essentially of iron" is not defined in the '799 Patent. However, the Court of Appeals for the Federal Circuit has concluded that the drafter's use of the phrase "consisting essentially of" signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do no materially affect the basic and novel properties of the invention." PPG Industries v. Guardian Industries Corp., 156 F.3d 1351 (Fed. Cir. 1998).

Although the patent does not expressly quantify the amount of iron which must be present for the claimed invention to "consist essentially of iron," the Court concludes that the amount can be discerned from the specification. Specifically, the specification explains that Figure 3 depicts the prior art in which the dissociation of metal particles "is lower commensurate with the degree of reduction of only 80-90%." ('799 Patent at col. 2, l. 39). In contrast, the specification explains that in the claimed invention, "the product is reduced throughout." ('799 Patent at col. 6, l. 46). Thus, to be distinguishable from the inferior prior art product depicted in Figure 3 of the patent, the claimed invention must necessarily contain material which is more than 90% reduced from iron oxide to elemental iron.

The Court's conclusion regarding the percentage of elemental iron reduced from iron oxide is supported by the testimony of the inventor of the '799 Patent. During his deposition Mr. Schroder was asked the following question and gave the following answer:

Q: And what percentage of iron is required in order for you to conclude that the particles consist essentially of iron?

A: In the area of above 90 percent, depending on the multiplicity of the treatment and the preliminary steps, where the optimal reduction lies.

(Schroeder 9/30/96 Dep. 237). Further, the Court observes that there is no support in the specification for Bayer's counter definition that the phrase "consisting essentially of iron" means that the claimed invention contains more than half iron. Accordingly, the Court concludes that the phrase "consisting essentially of iron" means that the claimed invention necessarily includes iron and is open to unlisted ingredients that do no materially affect the basic and novel properties of the invention and that the claimed invention must necessarily contain material which is more than 90% reduced from iron oxide to elemental iron.

The Sony Defendants also urge the Court to include as part of its claim construction the quantities and types of unlisted ingredients which do not materially affect the basic and novel properties of the invention. Relying on the prosecution history of the '799 Patent, the Sony Defendants contend that the claimed metal powder cannot contain more than 7% of other metal additives Further, the Sony Defendants contend that Bayer disclaimed coverage of particles containing cobalt, nickle or tin, because they distinguished their invention from the prior art in the prosecution history by saying that the claimed invention "shows very good magnetic properties without being doped with expensive elements, as for example Co, Ni or Sn." (D.I. 477 at 44, citing DX 28 at 2).

The Court is only required to define a claim "with whatever precision is warranted by the language of the claim and the evidence bearing on the proper construction …" Id. at 1355. The Court may not, under the rubric of claim construction, give a claim "whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," because claim construction is a legal question and infringement is a factual question. In the Court's view, the amount of other metal additives which would affect the basic composition of the claimed invention is not readily apparent in the claim language or specification, and is a factual question relevant to the infringement analysis. Accordingly, the Court declines to address the quantity or types of other additives that would have a material effect on the basic properties of the claimed invention in the context of its claim construction.
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1. Claim Construction

The operative claim language of claim 7 is "consisting essentially of. . . one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25 [degrees] C and an atmospheric humidity of 50% for one year." At issue is whether that language should be construed to exclude the eight lactam-promoting adjuvants referenced in the specification as adjuvants that "reduce the stability" of gabapentin compounds and "should be avoided." ('482 Patent, Col. 5, ll. 5-10). Ivax urges a construction of claim 7 excluding the eight adjuvants, basing that on the patent specification and prosecution history. n5

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n5 Ivax adopts and incorporates the arguments advanced on behalf of other generic drug manufacturers in this multidistrict patent litigation for summary judgment of noninfringement of claims 7-11.

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Warner-Lambert responds that claim 7 broadly covers any "pharmaceutically acceptable adjuvants," including titanium dioxide, provided that their use meets the 0.2% limitation on lactam formation. Warner-Lambert further argues that "adjuvant" refers to ingredients that are intimately mixed with the gabapentin, and not those used solely for purposes of encapsulation.

For reasons discussed more fully in this Court's Memorandum and Order granting Apotex Corp., Apotex, Inc., and TorPharm, Inc. summary judgment of noninfringement based on use of adjuvants, the Court construes clause (ii) of claim 7 to exclude the eight lactam-promoting adjuvants listed in the specification as those that should be avoided. n6 In summary, the Court reasoned that while the plain language of the claim does not refer to useable and non-useable adjuvants, the written description and prosecution history require the interpretation of that claim to exclude particular adjuvants listed in the written description as those that should be avoided due to their negative effect on stability of the compounds.

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n6 The Court acknowledges language to the contrary in its October 13, 2004 bench opinion denying Warner-Lambert's application for preliminary injunctive relief directed to Purepac's entry into the market for AB-rated gabapentin capsules. The Court stated that it was inclined, at that time, to agree with Warner-Lambert's claim construction arguments. Now, having had an opportunity to consider the record in more depth, the Court concludes otherwise. Findings of fact and conclusions of law made in the context of a preliminary injunction, let alone observations, do not foreclose conclusions to the contrary at later stages of the litigation. See New Jersey Hosp. Ass'n v. Waldman, 73 F.3d, 509, 519 (3d Cir. 1995).

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a. Construction of '046 Patent Claims - Regarding the Exclusion or Non-Exclusion of Particles With Sizes Below 355 [mu]m.

Claim 1 of the '046 patent recites a composition "consisting essentially of" particulate glass, which glass has individual particle sizes in the range of "from about 355 to about 710 [mu]m." The parties agree that in order for Claim 1 to be infringed, particles in this range must be present; however, they disagree over whether or not the existence of smaller particles in the particulate glass composition would prevent a finding of infringement. It is the Defendants' position that the proper construction of Claim I is that all particles must be within the cited range, while Plaintiffs contend that Claim I should be read in conjunction with dependant Claim 4 to permit infringement when there is the presence of particles below

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the cited range. This distinction is extremely important as the BioGran (R) product indisputably contains particles which are smaller than 355 [mu]m regardless of whether traditional sieving or scanning electron microscopy is utilized to determine particle size. In order to determine the proper scope of the '046 patent claims, the Court will consider the language of the claims in conjunction with the patent specification and prosecution history.

i. The Claim Language and Specification

a. Does Claim 1 Exclude Particles Smaller Than 355 [mu]m

Claim 1 of the '046 patent identifies a composition adapted for the repair of periodontal osseous defects "consisting essentially of" particulate glass, said glass having particles within a cited range of sizes. The phrase "consisting essentially of' was deliberately inserted by the patent applicants to replace the phrase "comprised of' which was used in Claim 1 of the original patent application in an effort to narrow that broader application claim. See Application for Patent, June 19, 1985, at p.22 (Doc. 106, Exh.5). An 'essential' ingredient is one which is indispensable or fundamental. Plaintiffs contend that this language is intended to allow the presence of items which do not materially affect the basic characteristic, or "essence" of the composition. See Transcript of Feb. 6, 1998 hearing (Doc. 125 at 10). The Court agrees. See Water Technologies v. Calco Ltd., 850 F.2d 660, 666 (Fed. Cir. 1988).

With regard to the language of Claim 1, the Court concludes that in order to be infringing, a composition must, at a very minimum, contain glass particles within the cited particle size range; however, the claim language does not preclude the existence of other materials which do not materially affect the essential characteristics of the composition of Claim 1. Yet the question remains, can those "other materials" be particulate glass with particle sizes below 355 [mu]m? In other words, does the presence of particles smaller than 355 [mu]m, materially affect the essential characteristics of the invention claimed in the '046 patent? In order to answer these questions, the Court must determine what the essential characteristics of the claimed invention are.

The Plaintiffs' claimed invention is a powder comprised of bioactive and biocompatible glass particles within such a range of particle sizes with the following essential characteristics: that when it is combined with an aqueous solution, it not only promotes bone growth, stops the invasion of soft tissue into the periodontal osseous defect, and helps control bleeding, but it also forms a paste that is cohesive, is easily manipulable, and which resists breakdown when subjected to irrigation or suction. See '046 Patent, col. 4, lines 23-68 (Doc. 106, Exh. 1). These characteristics are based upon the improved performance of the claimed invention over prior art in the same field. The patent specification suggests that the most advantageous composition is one with the widest range of particle sizes, i.e. 90 to 710 [mu]m, and more specifically, the specification notes that the most superior performance resulted from testing a hypothesized formulation containing particles in equal thirds, each third having particles within the three ranges cited in Claim 4. The characteristics of three compositions of differing size ranges are summarized in column 5, table 1 of the '046 patent, 7 the relevant portions of which provide:

[SEE TABLE IN ORIGINAL]

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7 This table lacks any indication of the performance characteristics which result from the use of particles either largely or solely within a range similar to that used in Defendants' product, i.e. 300 to 355 [mu]m or within the range of Claim 1, i.e. 355 to 710 [mu]m.

8 The optimal characteristics of the composition, with particles in the range of 90 to 710 [mu]m, are predicated upon the use of glass particles within the each of the three size ranges set forth in dependant Claims 4 and 5.

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Plaintiffs argue that the evidence confirms that the additional presence of particles sized below 355 [mu]m in a composition under Claim 1, does not affect the basic characteristics of the composition, but rather only affects the degree of resultant cohesiveness of the composition, i.e. its performance. However, it was the improved performance of a broader range of particle sizes cited in the '046 patent claims which served as the impetus for the patent application, and which has been cited as the distinguishing characteristic of Plaintiffs' product over the prior art. See United States Patent No. 4,851,046, col. 3,

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11. 58-68, col. 4, 11. 1-45. The improved performance derives from the use of particles in the ranges cited in Claim 5, i.e. one which contains no more than one-third of its particles in the 90 to 355 [mu]m size range. It, therefore, seems apparent that the basic characteristics of the claimed invention are inextricably intertwined with the degree of performance associated with the use of particles within the cited ranges.

Defendants likewise contend that the presence of a greater number of the smaller glass particles does affect the characteristic of the composition, and they point to the existence of smaller particles in Plaintiffs' own product PerioGlas TM 9 and the Patent Office's subsequent issuance of the Schepers patent as evidence of the same. Defendants do agree that the smaller particles which are present in the BioGran (R) product affect the performance of the composition, but unlike Plaintiffs, they contend that the marked difference in performance brought about by the inclusion of a greater percentage of smaller particles does materially alter the characteristics of the composition at issue. They cite to the Patent Office's issuance of a separate patent to Schepers et al., for a composition restricted solely to particles of a smaller range than that of the '046 patent, 10 and which restricted size range and smaller particle characteristics "result[] in a quantitatively greater amount of bone formation than the particles as disclosed by [the '046 patent]." See (Doc. 126, Attach. B) (citing to Patent Office's reaffirmation of patentability of the claims in the Schepers patent). Defendants contend this is evidence that, by increasing the amount of bone formation, the presence of a greater number of smaller particles does change the basic characteristics of the composition in Claim 1 of the '046 patent.

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9 Defendants have properly noted that there is no evidence of any composition being produced with particles solely within the range cited in Claim 1 of the '046 patent, i.e. from about 355 to 710 [mu]m. In fact, analysis using a Microtrac Particle Size Determination method ("Microtrac"), which Plaintiffs contend is equivalent to Scanning Electron Microscopy ("SEM"), reveals that Plaintiffs' own PerioGlas TM is composed of a percentage of particles smaller than 355 [mu]m, as high as 57.83%. See Corning Analysis (Doc. 88, Exh. 12 at p. 4).

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Thus, Defendants argue that the "consisting essentially of" language, which Plaintiffs have argued only excludes from Claim 1 those other materials or particles which materially affect the essential characteristic of the claimed invention, does in fact exclude the smaller sized glass particles found in the BioGran (R) product from the scope of Claim 1, since BioGran's smaller particles appear in much larger quantities than those contemplated by the '046 patent claims, and because, according to the Patent Office's holding in the Schepers patent, the presence of the greater number of smaller particles changes the characteristics of the '046 claimed invention. Defendants' argument relies on the Patent Office's conclusions regarding the Schepers patent, which patent and the resultant product characteristics cited therein, are based on the presence of particles which are solely within a smaller particle size range, and which does not deal with smaller particles co-existing with larger sized particles, as would be required under the '046 patent claims. However, this Court agrees with Defendants, and with the Patent Office's conclusion in the Scheper's patent, that the presence of a greater number of smaller particles does affect the performance of the composition to the point that it alters its basic characteristics, especially in light of the fact that the characteristics of the claimed invention are based upon its improved performance over prior art in the field. And while the claims within, and the findings of the Patent Office with regards to the Schepers patent, do not qualify as being part of the '046 patent, its patent specification, its prosecution history, or the relevant prior art which this Court can properly consider when construing the meaning and scope of the terms thereof, this Court finds them to be instructive in determining what amount of smaller particles are anticipated by Claim I of the '046 patent. Accordingly, the Court concludes that a larger presence of particles smaller than the range cited in Claim 1, especially where the percentage thereof is greater than the one-third fraction cited in Claim 5, could easily lead to the conclusion that the basic characteristic of the claimed invention would be altered by the variance in performance brought about by their inclusion. Indeed, were a hypothetical composition to be comprised of more than two-thirds of its particles below 355 [mu]m, it would be difficult to argue that the composition consists "essentially of" particles within the range of 355 to 710 [mu]m.

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10 Claim 1 of the Schepers patent calls for a composition in which at least 95% of the particles are within the particle size range of from between 280 and 425 [mu]m. Dependant Claim 2 requires the composition of Claim 1 wherein 2/3 of the particles are between 300 and 360 [mu]m, and dependant Claim 3 requires a composition of Claim 2 wherein at least 90%

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of the particles are between 300 and 360 [mu]m. See United States Patent No. 5,204,106, column 8, lines 56-61.

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This Court, therefore concludes that the basic characteristics of a composition consistent with Claim 1 of the '046 patent, i.e. a composition of particles with sizes in the range of from about 355 to 710 [mu]m, may not be altered by the inclusion of smaller particles in an potentially infringing composition. Thus, Claim 1 is amenable to infringement actions against compositions which not only contain particles within the size range of 355 to 710 [mu]m recited in Claim 1, but which also contain particles with sizes smaller than 355 [mu]m. However, the Court also concludes that the presence of substantially more than one-third of a composition's particles below the range cited in Claim 1 would very likely affect the performance in a manner sufficient to alter the basic characteristics of the composition claimed in the '046 patent, and therefore, would remove the composition from infringement of Claim 1, which, though it allows for and even anticipates the presence of smaller particles, does not anticipate the presence of smaller particles in much greater a quantity than the one-third weight percentage cited in Claim 5 thereof. The inclusion of particles smaller than 355 [mu]m in compositions alleged to infringe upon '046 patent Claim 1 must remain subject to the limitations of dependant Claims 4 and 5, which narrow the scope of Claim 1 by allowing the additional presence of up to one-third of the particles in the size range of 90 to 355 [mu]m.

b. Does Claim 4 Permit the Presence of Particles Smaller Than 355 [mu]m

In order to determine whether the '046 patent, and specifically Claim 1, can be interpreted to allow for compositions which include other glass particles sized below 355 [mu]m, Plaintiffs suggest that the Court look to the dependant Claim 4. The fourth claim is for the composition of Claim 1, wherein that composition is defined as consisting "essentially of' a mixture of particulate glass within the following three, separately delineated particle size ranges: (I) from about 90 to 350 [mu]m, (2) from about 355 to 500 [mu]m, and (3) from about 500 to 710 [mu]m. Under 35 U.S.C. § 112, a dependant claim "shall be construed to incorporate by reference all the limitations of the claim to which it refers." Id. Additionally, a dependant claim shall specify a further limitation on the subject matter of the claim to which it is referenced. See id. Dependant Claim 4 adds a limitation to independent Claim 1, by requiring not only the presence of particles in the size range contained in Claim 1, but also the presence of particles in the 90 to 350 [mu]m range. Claim 4 further requires that the particles within the 355 to 715 [mu]m range of Claim 1 be comprised of particles from the two more specific ranges already claimed in dependant Claims 2 and 3, i.e. the 355 to 500 [mu]m and 500 to 710 [mu]m ranges. Plaintiffs contend that, by implication, Claim 1 must be sufficiently broad to accommodate the further restriction of dependant Claim 4. Indeed, the Patent Examiner specifically approved of the revised text of Claim 1 knowing that the dependant Claim 4 was based upon it. In doing so, the Examiner implicitly found that the scope of Claim 1 does not exclude the presence of particles smaller than 355 [mu]m.

It is axiomatic in patent law that all patent claims, be they independent or dependant in nature, are presumed to be valid regardless of the validity of other claims. See Applied Materials, Inc. v. Advanced Semiconductor Materials, 98 F.3d 1563, 1569 (Fed. Cir. 1996), cert. denied 520 U.S. 1230, 117 S. Ct. 1822, 137 L. Ed. 2d 1030 (1997); see also, 35 U.S.C. § 282. Furthermore, the presumption of validity of patent claims is based upon the presumption of administrative correctness associated with the actions of an agency which is charged with patentability evaluation. See Applied Materials, 98 F.3d at 1569. Accordingly, this Court must give due weight to the presumption of validity of the patentability determinations of the United States Patent Office as manifested by its approval of dependant Claim 4 in conjunction with Claim 1 of the '046 patent. See id. (citing Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1139 (Fed. Cir. 1985)).

The Court concludes that based upon the claim language as interpreted by the Patent Office, the presumptively valid dependent Claim 4 could not exist but for the amenability of Claim 1 to the inclusion of compositions that contain particles below 355 [mu]m, so long as the composition in question also contains those essential particle sizes in the range of 355 to 710 [mu]m. Claim 1 is sufficiently broad to include particle sizes smaller than 355 [mu]m, especially when, as required by Claim 4, the smaller particles co-exist in a mixture with particles that have sizes in the range of 355-500 [mu]m, and with particles that have sizes in the range of 500-710 [mu]m. Furthermore, as stated above, the Court agrees that the basic characteristics of the patented invention would not be altered by the presence of additional smaller particles below the range state in Claim 1, so long as those smaller particles were subject to the limitations of dependant Claims 4 and 5 which allow for the presence of up to one-third of the composition's particles in the range below 355 [mu]m.
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a. "Consisting of"

First, EEI alleges that the patentee's use of "consisting of" limits the scope of the '937 patent to exclude products performing only the recited steps of the patent "and nothing else." EEI contends that the district court erred by allowing the accused process's suspension medium to include MIBK, a non-alcohol, in spite of the limitation that the suspending medium consist of water or a water-alcohol mixture.

Transitional phrases, such as "comprising," "consisting of," and "consisting essentially of," are terms of art in patent law that "define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim." MPEP § 2111.03; accord Vehicular Techs. Corp., 212 F.3d at 1382-83. The phrase "consisting of" signifies restriction and exclusion of unrecited steps or components. MPEP § 2111.03. Although "consisting of" is a term of restriction, the restriction is not absolute. The Patent Board of Appeals has interpreted "consisting of" to "close[] the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith." Ex parte Davis, 80 U.S.P.Q. 448, 450 (Pat. Office Bd. App. 1948); see also Bethell v. Koch, 57 C.C.P.A. 1233, 427 F.2d 1372, 1373-74 (C.C.P.A. 1970) (noting the parties' concession of a similar meaning of "consisting of").

We have explained that "consisting of" does not exclude additional components or steps that are unrelated to the invention. See Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331-32 (Fed. Cir. 2004). In Norian Corp., the District Court for the Northern District of California found as a matter of law that a product containing an unrecited element did not infringe U.S. Patent No. 6,002,065 ("the '065 patent") because the transitional phrase "consisting of" excluded the additional element from the protection of the patent. Id. at 1331. Specifically, the '065 patent taught a kit containing specified chemicals; the infringing kit contained all the recited elements of the '065 patent, but added one element unrelated to the invention disclosed in the '065 patent--a spatula. Id. The district court held that adding the spatula to an otherwise infringing product avoided infringement of the '065 patent.

On appeal, we reversed the district court's holding and explained,

> "Consisting of" is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while "consisting of" limits the claimed invention, it does not limit aspects unrelated to the invention. It is thus necessary to determine what is limited by the "consisting of" phrase.

Id. at 1331-32 (citation omitted). We held that the invention disclosed in the '065 patent was directed to a kit containing specified chemicals, and although the claims explicitly recited that no other chemical could be included in the composition, a competitor could not avoid infringement by adding a component unrelated to the invention. Id.

Similarly, impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the "consisting of" list do not exclude the accused product or process from infringement. EEI contends that MIBK is not an impurity because it was purposely added to the alcohol to denature it. However, the intentional addition of a component does not change its status as an "impurity ordinarily associated therewith." See Davis, 80 U.S.P.Q. at 450.

MIBK is a common impurity in industrial alcohols in order to prevent a liquor tax from being applied. If, however, MIBK had been added to adjust the stability of the suspending medium or prevent agglomeration of polymer, it may not have been an impurity and therefore EEI would most likely not infringe. Thus, impurities normally associated with the component of a claimed invention are implicitly adopted by the ordinary meaning of the components themselves. 5 See Phillips, 415 F.3d 1303 at 1312-13 ("The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art . . . .").

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5 We are not presented with the question of whether impurities not normally associated with a component would exclude the accused process from infringement; however, as in Norian Corp., the additional component must be related to the invention. 363 F.3d at 1331-32.

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The district court found as a matter of fact that Alfol-2 consisted of water and alcohol and that any non-alcohol and non-water components, such as MIBK, were impurities. This conclusion was based on the testimony of EEI's expert, who acknowledged that the small amounts of ammonia and heptane in the suspension were impurities and was impeached by prior testimony indicating MIBK was also an impurity. The court's findings were based on the testimony of persons of ordinary skill in the art who testified that MIBK has little to no effect on the present invention and is normally associated with industrial alcohols to reduce tax liability. Accordingly, there was substantial evidence to support the district court's findings that the MIBK and the other non-alcohol/non-water components were impurities, and the district court did not clearly err by finding that Alfol-2 met the claim limitations of the suspending medium.
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The parties do not dispute that the BoneSource (R) kit contains all of the elements set forth in claims 8-10 of the '065 patent, plus a spatula. The district court held that the claim signal "consisting of" means that nothing can be included in the kit beyond what is claimed, and therefore that Stryker's kit cannot infringe as a matter of law. "Consisting of" is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. See Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1382-83 (Fed. Cir. 2000). However, while "consisting of" limits the claimed invention, it does not limit aspects unrelated to the invention. It is thus necessary to determine what is limited by the "consisting of" phrase.

"Consisting of" as used in claim 8 limits the kit to the claimed chemicals and no other chemicals; that is, the kit "consists of" only the chemicals described as contained in the kit:

8. A kit for preparing a calcium mineral, said kit consisting of:

at least one calcium source and at least one phosphoric acid source free of uncombined water as dry ingredients; and

a solution consisting of water and a sodium phosphate, where the concentration of said sodium phosphate in said water ranges from 0.01 to 2.0 M and said solution has a pH in the range of about 6 to 11.

The invention is a kit containing specified chemicals, and the claims are explicitly limited in that no other chemical can be included in the composition. See In re Gray, 19 C.C.P.A. 745, 53 F.2d 520, 521, 1932 Dec. Comm'r Pat. 85 (CCPA 1931) (because the chemical composition claim used the term "consists" it was "therefore drawn to an alloy of silver and indium without other elements"). While the term "consisting of" permits no other chemicals in the kit, a spatula is not part of the invention that is described. Cf. Mannesmann Demag Corp. v. Engineered Metal Prods., 793 F.2d 1279, 1282-83 (Fed. Cir. 1986) ("The presence of additional elements is irrelevant if all the claimed elements are present in the accused structure.").

It is undisputed that the BoneSource (R) kit contains the same chemicals as set forth in claims 8-10 of the '065 patent. Infringement is not avoided by the presence of a spatula, for the spatula has no interaction with the chemicals, and is irrelevant to the invention. The summary judgment is reversed. We remand for further proceedings with respect to the '065 patent.
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D. "consisting of"

Lilly argues that "consisting of" indicates "closed claim language. It closes the claim to the inclusion of materials other than those recited, except for components ordinarily associated therewith." D.I. 156 at 3 (emphasis added) (citing Sakano v. Rutemiller, 158 U.S.P.Q. 47, 51 (Bd. Pat. Interf. 1968); Ex Parte Davis, 80 U.S.P.Q. 448, 450 (Bd. App. 1948)). Novo urges that "consisting of" means that "the claim is closed to additional components . . . [and] the claimed complex can include

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only the named components in the named amounts." D.I. 154 at 35 (citing Schering v. Amgen Inc., 18 F. Supp. 2d 372, 382 (D. Del. 1998)). 43

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43 Novo also cites PPG Industries v. Guardian Industres, 156 F.3d 1351 (Fed. Cir. 1998). However, that case construes the meaning of "consisting essentially of," not "consisting of" and, therefore, is not applicable.

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Both parties are partially correct. Sakano and Davis, both chemical cases, hold that "consisting of" closes the claim "except for impurities ordinarily associated therewith." See Sakano, 158 U.S.P.Q. at 51; Davis, 80 U.S.P.Q. at 450 (emphasis added). Therefore, in the context of chemical patents, "consisting of" indicates closed claim language and closes the claim to the inclusion of unrecited elements, except for impurities ordinarily associated therewith.
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B. "consisting of a cyclic peptide"

Claim 1 states that the claimed antigen consists of a cyclic peptide. '724 Patent col.15 l.23. The parties dispute whether this language limits the claim to exactly one cyclic peptide. The Court concludes that it does. The phrase "consisting of" is "a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331 (Fed. Cir. 2004) ("Norian I") (citation omitted). For example, the Norian I court held that, where a patent claimed a kit for preparing a calcium mineral "consisting of" several chemicals, the kit was limited to the claimed chemicals and no other chemicals. Id. Because a spatula was not part of the described invention, its presence in such a kit was irrelevant. Id. at 1332.

Plaintiff argues that, because claim 1 refers to "a cyclic peptide," it is limited to only one such peptide. In patent construction, the "question whether 'a' or an' is treated as singular or plural depends heavily on the context of its use." TiVo, Inc. v. Echostar Commc'ns Corp., 516 F.3d 1290, 1303 (Fed. Cir. 2008). The Federal Circuit typically interprets "a" in its singular sense when "used in conjunction with the closed transitional phrase 'consisting of.'" Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1359 (Fed. Cir. 2005) ("Norian II"); see also Abbott Labs v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1281 (Fed. Cir. 2003) ("[A]lthough 'a' without more generally could mean one or more in an open-ended patent claim, 'a' with 'consisting of' in this case indicates only one member of a Markush group."). In Norian II, the Federal Circuit held that "the claim language 'consisting of . . . a sodium phosphate,' on its own, suggests the use of a single sodium phosphate." Norian II, 432 F.3d at 1359. Here, the '724 Patent claims an antigen "consisting of a cyclic peptide." col.15 l.23. As in the Norian cases, this language suggests the use of a single cyclic peptide as the invention itself. Defendant has not shown why a deviation from this convention is warranted in this case.

Defendant argues that the claim language and specification of the '724 Patent show that "a peptide" refers to one or more peptides. (Def.'s Br. at 9, Def.'s Resp. Br. at 9.) As Defendant points out, the specification states that "two or more peptides according to the invention may be part of one oligopeptide." '724 Patent col.3 l.42-44. However, the fact that an oligopeptide is created from the combination of two peptides does not mean that, once formed it is two peptides. Instead, the specification's reference to "one oligopeptide" suggests that it is still one peptide; the "oligo-" prefix designates the origin of the molecule, not its nature. Accordingly, the specification language relied upon by Defendant does not support its argument that claim 1 is not limited to one peptide.

Defendant further argues that, because the peptide of claim 1 is a fragment, and the fragment can be made up of multiple peptides, claim 1 is not limited to one peptide. (Def.'s Br. at 9-10.) However, the Court does not agree that the fragment of claim 1 can be multiple peptides.

The parties agree that a "cyclic peptide" is a peptide that includes one or more bonds contributing to looped structures in the chain. (Doc. No. 105 at 2.) The parties dispute the nature of the bonds that form these loops. Plaintiff argues that these must

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be covalent bonds, while Defendant objects to such a limitation. (Pl.'s Br. at 14; Def.'s Br. at 10.) Declining to import this limitation into the claim, the Court agrees with Defendant.

Plaintiff points out that the specification of the '724 Patent describes only cyclic peptides containing covalent bonds -- specifically, disulfide bridges between cysteine side chains. 1 col.2 l.25-27; col.5 l.60-63. However, it is improper to confine patent claims to the preferred embodiment. Phillips, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."). Moreover, the specification of the '724 Patent states that bond between cysteine residues is provided as an example. col. 2 l.25-27 ("According to a favourable embodiment the peptide is a cyclic peptide, for instance, due to the presence of a cysteine residue.") In prosecuting the '724 Patent, the patentee intended that claim 1 encompass "a cyclic peptide, regardless of the means of its cyclization" stating that "the important aspect here is that a cyclic peptide is formed, not how it is formed." (Aannestad Decl. ISO Def.'s Br. Ex. C at 31.)

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1 Covalent bonds involve the sharing of electrons between atoms, as opposed to hydrogen bonds (interaction between positively charged hydrogen atoms and atoms with a negative charge) and van der Waals interactions (caused by temporarily uneven charge distributions).

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"Even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope." Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1332 (Fed. Cir. 2007). Here, in light of the open language of the specification and prosecution history, the patentee has not demonstrated a clear intention to require covalent bonds. The Court concludes that, "after reading the entire patent," an ordinary artisan in the relevant field would construe the ordinary meaning of "cyclic peptide" as a sequence of amino acids, that includes one or more bonds that form one or more looped structures in the peptide. Phillips, 415 F.3d at 1321.

The parties also dispute whether the cyclizing bonds "form one or more looped structures" or "cause the peptide to form one or more looped structures." (Doc. No. 105 at 2.) Defendant objects to Plaintiff's use of the word "cause," arguing that this construction improperly requires that the bond initiate the looping process. (Def.'s Br. at 12-13.) However, Plaintiff disclaims any temporal aspect to its construction. Accordingly, this dispute turns on a distinction without a difference. The parties agree that the cyclizing bonds keep the loops in place, and the Court's construction conveys this idea.
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D. "CONSISTING OF" ('939 PATENT).

King asserts that "the first layer consisting of the opioid antagonist" in claim 1 should be construed as limitingthe first layer to that which is specifically recited and nothing more. In other words, the first layer is made solely of an opioid antagonist. Purdue counters that, "consisting of" is a term of art that has already been defined by the Federal Circuit and should be given its ordinary meaning. I agree with Purdue.

While King is correct that the term "consisting of," as opposed to comprising or containing, "is a term of restriction, the restriction is not absolute." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1360 (Fed. Cir. 2006). "'Consisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331 (Fed. Cir. 2004) (citation omitted). Therefore, the ordinary meaning of "the first layer consisting of opioid antagonist" is "the first layer contains only the opioid antagonist and other ingredients unrelated to the invention." Because nothing in the patent or its prosecution history shows that the inventors departed from this customary definition, it is the proper way to construct the term.
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Claim 6 of BASF's '545 patent is the only claim at issue in this case. Claim 6 claims a process for the catalytic rearrangement of EpB to DHF

which consists essentially of the rearrangement being catalyzed by a system which contains components A and C from 60 [degrees] to 200 [degrees] C where A is an onium halide, which is substantially soluble in the reaction medium, and C is a Lewis acid or elemental iodine with the proviso that at least one of the components A or C is an iodide.

BASF and Eastman dispute the meaning of two phrases of claim 6. They dispute the meaning of "consists essentially of," and "substantially soluble in the reaction medium."
1. What Does "Consists Essentially Of" Mean?

BASF argues that the phrase "consists essentially of" means virtually solvent free, and therefore, a small amount of component B, solvent or solubilizer, can be present in the reaction. Eastman argues that "consists essentially of" precludes the use of component B, solubilizers.

BASF argues that the terms solvent and solubilizer are synonymous, that component B includes both terms, and that claim 6 permits the addition of small amounts of either. Eastman distinguishes between the terms, arguing that solvents and solubilizers perform different functions, that component B encompasses solubilizers only, and that claim 6 excludes the addition of component B. Accordingly, before the court construes whether the phrase "consists essentially of" permits the addition of component B, the court must determine whether component B includes both solvents and solubilizers.

The patent describes component B as an organic solubilizer. At column 2, lines 61 to 66, the patent specification explains that because the only requirements that component B has to meet are "bringing about the dissolution of component A and otherwise being stable and inert under the reaction conditions, a large number of substances can be used as component B." Column 2, line 66 to column 3, line 50 of the '545 patent gives examples of solubilizers that can be used in the catalyst system, including dioxane, tetrahydrofuran, and certain podands. Thus, the patent defines a solubilizer as an element which dissolves component A.

Column 3, line 68, of the patent discusses certain inert solvents, explaining that specific solvents can be used "for diluting the reaction mixture." The patent specification also gives examples of solvents that can be used for this purpose, including toluene and xylene. Thus, the patent defines a solvent as an element which dilutes the reaction mixture. Accordingly, the patent distinguishes between solubilizers and solvents, teaching that a solubilizer makes component A more soluble in the reaction medium, while a solvent dilutes the reaction medium.

Furthermore, during the prosecution of the '545 patent, BASF's patent attorney specifically distinguished between solubilizers and solvents, emphasizing that "organic solubilizers" are distinct from solvents. The attorney wrote to the PTO:

The term "organic solubilizer" is also carefully defined by the Fischer ['545] specification as being 'complexing agents for the salts A' or closely equivalent complexing solvents. This "organic solubilizer" is not an "inert solvent" such as those listed in col. 3, lines 64-68, including xylene and toluene, etc. Fischer makes it quite clear that such "inert solvents" are not suitable as an organic solubilizer but may be optionally added as a diluent.

Thus, the court concludes that solvents and solubilizers have distinct meanings and that component B, an "organic solubilizer," includes solubilizers only.

The court must now determine what the phrase "consists essentially of" means, and whether it permits the addition of component B. The phrase "consists essentially of" is not unique to the '545 patent. The Federal Circuit has stated that the "limited phrase 'consisting essentially of'" does not "exclude the addition of another ingredient which does not materially affect the characteristics of the invention." Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 666 (Fed. Cir. 1988). The Federal Circuit has also stated that "consists essentially of" does "close the claims to other ingredients that do alter the basic and novel characteristics of the invention." Neville Chem. Co. v. Resinall Corp., 915 F.2d 1584, 1990 WL 135903, at *1 (Fed. Cir. 1990).

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The '545 patent originally included six claims. Claims 1 to 5 all included component B, an organic solubilizer, as an essential element of the catalyst system. Component B's role in the catalyst system was to bring component A into solution. Claim 6, however, covered a catalyst system in which component A, an onium halide, is "substantially soluble," thereby eliminating the need for an organic solubilizer. The patent specification refers to onium halides as having an "intrinsic solubility." If something is intrinsically soluble, it is inherently capable of dissolving and does not need an additional component to put it into solution. Because the court defines solubilizer as an element that makes component A soluble, it follows that something that is intrinsically soluble does not need a solubilizer to help it dissolve.

The patent specification also states that certain onium halides are soluble enough such that "virtually no addition of solubilizer B is necessary." BASF argues that "virtually no addition" means that some solubilizer B can be added. However, this statement must be read in connection with the following sentence which states that "[a] procedure of this type [with virtually no addition of solubilizer] is equivalent to the claimed process." This language was part of the patent specification prior to the addition of claim 6. Thus, the "claimed process" referred to is the process covered by claims 1 to 5, in which the addition of solubilizer, regardless of how little, constituted a basic and novel characteristic of the process.

During the prosecution of the original '545 patent application, which included claims 1 to 5 only, the patent examiner relied on the specification language when he noted that solubilizer may not be necessary when certain halides are used as component A. On November 6, 1990, the examiner suggested what eventually became claim 6 of the '545 patent when he wrote that "this 'no solubilizer' embodiment is intended to be covered by the claims."

As noted above, one of the "basic and novel characteristics" of claim 6 is that component A is "intrinsically soluble." Because it is "intrinsically soluble" component B does not need to be added to make it soluble. In fact, the reason BASF eventually added claim 6 was because of the patent examiner's recognition that certain onium halides do not need the addition of component B to bring them into solution. BASF even admits this, stating in their argument that "[a] basic and novel characteristic of claim 6 is that it is a catalytic process for converting EpB to DHF which can be carried out virtually neat." Therefore, the addition of component B, a solubilizer, is not necessary and would alter this inherent trait.

Accordingly, the court concludes that the phrase "consists essentially of" excludes the addition of any component B, a solubilizer.
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D. "Consists of All or a Fragment of an HPV DNA"

Plaintiff maintains that it is not necessary to construe this claim, which is found in independent claims 8, 18, 21, 24 and 26. Plaintiff is technically correct, only because the term depends on the construction of HPV DNA that I determined earlier. Incorporating that construction, I construe this term as meaning "all or a fragment of one HPV DNA that does not contain any other DNA." As discussed earlier, "an" means "one" and only one. Adding "that does not contain any other DNA" makes this explicit.
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B. "HPV 52 DNA consists of all or a fragment of an HPV DNA"

Objecting to the construction of this term as meaning that "the HPV 52 DNA consists of all or a fragment of one HPV DNA and does not contain any other DNA," plaintiff seeks reconsideration out of concern that the jury will be confused if the construction does not acknowledge the inevitable mutations and variability that are present in any DNA sequence. Plaintiff fears that in the absence of such acknowledgment, the jury may focus on the exactness of the match between the HPV DNA nucleotide base sequence and a known sequence of HPV DNA, rather than on whether cross-hybridization occurs under moderately stringent conditions.

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Plaintiff's fears are unfounded. Nothing in the court's construction suggests or requires exclusion of mutations or subtypes. If the HPV genome from which the HPV 52 DNA must come contains mutations, those mutations will be found in the HPV 52 DNA and will be covered by the claim.

Plaintiff challenges the construction on another ground, arguing that it might suggest to the jury that the HPV 52 DNA of the claims cannot be linked to any other DNA. This, it maintains, runs counter to claims 1-7, in which the patent makes it clear that HPV 52 DNA can be connected to other DNA as part of recombinant DNA of HPV 52 comprising a cloning vector and HPV 52 DNA. This challenge is a chimera. The construction does not apply to the cloning vector in claims 1-7 of the patent. The cloning vector is listed explicitly as a claim limitation and is not modified by the term "consists of all or a fragment of an HPV DNA."

Finally, plaintiff contends that the construction may lead the jury to think that the HPV 52 DNA cannot be connected to or include even a single oligonucleotide other than a known sequence of HPV 52 DNA. This, it says, would be a mistake in light of claims 18 and 21, which are directed to HPV 52 hybridization probes comprising a member selected from the group consisting of either HPV 52 DNA or HPV 52 RNA, labeled with a detectable label. Plaintiff seizes on the word comprising to assert that the elements specified in the claim do not limit the probe itself, which must comprise HPV 52 DNA labeled with a detectable label but can also include other DNA sequences not meeting any of the limitations of HPV 52 DNA.

Ordinarily, the word comprising is "understood to signify that the claims do not exclude the presence in the accused apparatus or method of factors in addition to those explicitly recited." Vivid Technologies, Inc. v. American Science and Engineering, Inc., 200 F.3d 795, 811 (Fed. Cir. 1999). However, the word does not affect the scope of the structure recited within the steps, Moleculon v. CBS, Inc., 793 F.2d 1261, 1271 (Fed. Cir. 1986), or allow the patentee to ignore explicit limitations that follow the word. If, as plaintiff would have it, other DNA sequences were to be "comprised" by claim 18, they could change the nature of the elements that must be present to meet the claim terms by extending the length of the probes beyond 8000 bases or by affecting the hybridization ability of the probe. In this instance, therefore, it would not be logical or consistent with principles of claim construction to read the term comprising as permitting other DNA sequences within the claim.

Plaintiff challenges this conclusion as conflicting with this court's decision in Promega v. Applera Corp., 2002 U.S. Dist. LEXIS 26927, 2002 WL 32359938 (W.D. Wis. Jan 2, 2002) (Promega II), granting the plaintiff's motion for reconsideration of the interpretation given to term in a patent claim. Beyond the fact that both cases involve motions for reconsideration and a patent claim including the word comprising, the cases have no apparent similarities. In Promega II, I concluded that it was error to read a claim to require that the selections in a "set" for amplification could not include other "loci." This conclusion rested on the prosecution history, the wording of the claim term "wherein the at least four loci in the set" and the rule that a product cannot infringe a dependent claim without infringing the independent claim from which the claim depends. Promega II offers no assistance in construing the disputed terms in claims 18 and 21 of the '715 patent.
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We also agree with Third Wave that the district court correctly construed "consists of all or a fragment of an HPV DNA" to mean "consists of all or a fragment of one HPV DNA that does not contain any other DNA." As the district court correctly noted, "[i]t is a canon of construction that 'a' or 'an' following the phrase 'consisting of' is generally read as meaning one." Claim Construction Opinion, 2007 U.S. Dist. Lexis 53882, *14 (citing Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1359 (Fed. Cir. 2005) ("In particular, this court has interpreted the word 'a' in its singular sense when, as in this case, it has been used in conjunction with the closed transitional phrase 'consisting of.'")). Digene argues that the transitional phrase for the entire claim is "comprising," so the open transitional phrase should govern the claim term's meaning, and the word "an" should be construed to mean "one or more." Digene points to Mannesman Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1282-83 (Fed. Cir. 1986), and In re Crish, 393 F.3d 1253, 1257 (Fed. Cir. 2004), for support. In both cases we held that a claim with the overall transitional phrase "comprising," containing a limitation with the transitional phrase "consisting of," allowed for the addition of other elements to the overall claim. However, neither case opened the individual elements limited by the term "consisting of." If the term "consists of" appears in the body of a claim, it does not limit the entire claim as such, but it does limit the clause for which it acts as a transition to only those elements found in that particular clause. Thus, the clause "consists of" generally requires that the word "an" following it be limited to one and only one. Because the "HPV 52 DNA consists of all or a fragment of an HPV DNA," the term "an HPV DNA" cannot be

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expanded to include fragments of DNA that come from multiple HPV types. We therefore affirm the district court's construction of "consists of all or a fragment of an HPV DNA" as meaning "consists of all or a fragment of one HPV DNA that does not contain any other DNA."

We finally agree with Third Wave that the district court's claim constructions do not exclude possible mutations or subtypes. As the district court stated, "[i]f the HPV genome from which the HPV 52 DNA must come contains mutations, those mutations will be found in the HPV 52 DNA and will be covered by the claim." Opinion Denying Reconsideration, 2007 U.S. Dist. Lexis 73010, *15-16.
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3. "fraction which consists principally of betaine"

Next, the parties dispute the meaning of "fraction which consists principally of betaine." (Joint Stmt. p. 3). Plaintiff interprets the phrase to mean that "a commercially significant component of the fraction is betaine." (Joint Stmt. p. 3). Defendants disagree and submit that the phrase means "a fraction of sufficiently high purity of betaine on a dry solids concentration basis that it is ready for commercial crystallization." (Joint Stmt. p. 3). For support, Defendants refer to the specification which describes the process as illustrated in Figure 1. (Markman Hearing Tpt. pp. 220-22; DTX 1, Col. 3/ln. 39-41). Figure 1 diagrams the production of betaine and illustrates the fraction characterized as the "fraction which consists principally of betaine" to undergo crystallization. (DTX 1, Fig. 1). However, Defendants are attempting to insert a limitation on the claim that is not required by the claim language. It does not necessarily follow that because Figure 1 portrays the betaine fraction undergoing crystallization that the fraction must be "a fraction of sufficiently high purity of betaine on a dry solids concentration that it is ready for commercial crystallization." (Joint Stmt. p. 3) (Emphasis added). So long as the "fraction which consists principally of betaine" can undergo crystallization and produce anhydrous betaine crystals by the process described in the specification, Plaintiff's construction conforms with the claim language and is not varied by the specification. Thus, the court defines the phrase to mean "a fraction consisting of a commercially significant amount of betaine such that the fraction will not materially affect the characteristics of processes described in Figure 1 of the '430 patent."
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8. Constituents

Although one might anticipate that the term "constituents" would be relatively non-controversial, taking on its ordinary meaning as the functional equivalent of "elements" or "ingredients", the parties also differ as to its meaning. At the heart of their disagreement is a dispute over whether the term denotes the ingredients of the de-icing and anti-icing composition, as Sears argues, or instead the aqueous solution, a position espoused by the defendants.

Ordinarily, unless compelling circumstances dictate otherwise, a term of common usage such as "constituents" should be given its ordinary and customary meaning when used in a patent claim. See Kegel Co. v. AMF Bowling, 127 F.3d 1420, 1427 (Fed. Cir. 1997) (noting that absent "an express intent to impart a novel meaning to a claimed term, the term takes on its ordinary meaning"); CCS Fitness, 288 F.3d at 1366 (stating that a court construing patent terms should "indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning"). While the term "constituents" does not appear to be susceptible to widely varying definitions from a lay point of view, the appropriate point of reference is a person of ordinary skill in the art. That the term "constituents" is no more controversial or ambiguous among those of ordinary skill in the art than with the lay population, however, is confirmed in this case by the declaration of Dr. Bruce Nauman. See Nauman Second Decl. (Dkt. No. 183-2) P 7.

The rub comes with the question, as squarely presented by the parties, of whether the term "constituents" relates to the "aqueous solution" specified in the two patents in suit, or instead the entire composition. I find it unnecessary to resolve this issue, since the question was laid to rest with the earlier determination of the meaning of the term "balance". Addressing that term in Cargill, I essentially found that although the composition specified in the '793 patent -- a circumstance which would

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apply with equal vitality to the '622 patent -- was in fact the aqueous solution specified, when addressing the definition of the term "balance" I concluded that in addition to the carbohydrates, chloride salts, water, colorants and thickeners as specified, the composition could also include "incidental impurities or harmless ingredients associated with the commercial sources of the key components in the invention . . . ." Cargill, 334 F. Supp. 2d at 220-21. Accordingly, I will define constituents in accordance with its ordinary meaning, to include ingredients of the deicing and anti-icing composition specified.

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7. "Contacting Said Assay Device In A Predetermined Order With: (A) A Solution Of A Sample Suspected Of Containing Said Analyte; And (B) A Solution Of Components Of Said Signal Producing System . . . ."

The parties' disagreement concerning this claim language revolve around whether if there is one solution, whether the components of solutions (a) and (b) must remain distinguishable or whether they can essentially become one component. Dade Behring contends that solutions (a) and (b) can form a homogeneous solution, while Biosite asserts there may be one solution, but that solution has to be heterogeneous in that there has to be two distinct components in the solution.

Starting with the language of the claim, the claim provides for two solutions with different components to be contacted with the assay device. Claim 2, a dependent claim, adds: "A method according to claim 1, wherein said signal label-mip conjugate is contacted with said assay device in a solution not earlier than concurrently with said sample solution." See Col. 41, lines 11-14. It is therefore also clear that the two solutions can be applied to the assay device concurrently, i.e., at the same time or in conjunction with one another. See Webster's at 472. Not surprisingly, therefore, there is no dispute between the parties that one solution may be used. However, "concurrently" does not mean that the two components have to combine into one component so that a homogeneous solution is formed. As an analysis of the relevant claim language proves inconclusive in this respect, it is necessary to consider the relevant portions of the patent specification.

Dade Behring, in order to support its construction that one homogenous solution is possible, points to that part of the specification which states that "while the device may be contacted with only one solution, usually it will be contacted with at least two solutions." See Col. 10, lines 30-32. However, this language must be read in the context of the whole specification. The specification clarifies what it means by this sentence when it states:

Normally, after contacting the device with the signal label-mip conjugate, a subsequent contact with a wash solution containing reagents, such as enzyme substrates will often be employed. In this way, one can ensure the substantial absence of nonspecific binding and occlusion of the signal label-mip in the immunosorbing zone.

See Col. 10, lines 32-38. Thus, the second solution referred to in this passage is a reagent wash. This passage illustrates that the two solutions set out in the claim language, i.e., the test solution and signal solution, and the two solutions referred to in this portion of the specification, i.e., a signal solution and a reagent wash, do not correspond. This suspicion is later confirmed by specification language which states that the assay device always must come into contact with solution containing signal label-mip conjugate and solution containing the analyte sample. There, the specification reads:

By employing two steps, first contacting the assay device with the sample, followed by contacting the assay device with the signal label-mip conjugate, the amount of signal label-mip conjugate greater than a predetermined minimum will not significantly affect the assay result, when a subsequent step is employed to reduce occluded and non-specifically bound signal label-mip.

See Col. 11, lines 12-19 (emphasis added). This "subsequent step" refers to the language cited above by Dade Behring for the proposition that a second washing step is usually employed, but need not be. However, whether the assay is conducted with this subsequent washing step or not, the fact remains that the assay device must be contacted by two separate components. In fact, the competition assay would not work properly if the labeled analyte and the sample analyte were to become one component; two different components could no longer compete for the limited number of antibody binding sites in the immunosorbing zone as a competition assay requires.

Dade Behring also directs the Court's attention to a sentence in the specification which states, "protocols having various

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number of steps, including as few as one can be employed for a determination of analyte." Col. 40, lines 31-33. Protocol 2, disclosed in the specification, in fact "involves combining the sample and mip components of the signal producing system and contacting the assay device with the resulting solution." Col. 8, lines 2-4. This part of the specification just makes clear that the solution of labeled analyte and solution of sample analyte may be mixed together before adding the combined solution to the assay device. However, there is no intrinsic evidence that the two components become indistinguishable from one another in the process. In fact, for reasons elucidated above, the two components' separateness within the same solution seems crucial for the competition assay to work properly.

Finding nothing in the intrinsic record that the immunoassay method described in Claim 1 could be performed with a homogeneous solution, i.e., containing one component, the Court construes "contacting said assay device in a predetermined order with: (a) a solution of a sample suspected of containing said analyte; and (b) a solution components of said signal producing system . . . ." as requiring the immunoassay to be contacted with at least two separate components, though those two components may be combined in one solution.
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B. "contacting said sample with a homocysteine converting enzyme and at least one substrate for said enzyme other than homocysteine"

Axis-Shield's proposed construction is "any joining of said sample with a homocysteine converting enzyme [and at least one substrate for said enzyme other than homocysteine]." General Atomics' construction is "adding from an external source a homocysteine converting enzyme and a substrate for the enzyme other than homocysteine to the sample prior to the conversion of homocysteine." Thus the principal contentions are "any joining" versus "adding from an external source," and General Atomics' specification that the contact occur "prior to the conversion of homocysteine."

1. "Any joining" versus "adding from an external source"

Axis-Shield argues that "adding from an external source" is too narrow, and would preclude one of the contacting techniques disclosed in the patents. Because the preferred enzyme, SAH-hydrolase, tends to become inactive during storage, the patents describe a method by which inactive SAH-hydrolase, already combined with the sample, can be activated by a reducing reagent, in this example DTT. See Patent '127, 7:42-67. An ordinary reading of "contacting" is broad enough to include a method such as this, where the contact occurs through the addition of an activating agent, albeit from an external source. "Contacting" does not require, as General Atomics' construction suggests, that the enzyme be added, in active form, from an external source.

2. "prior to the conversion of homocysteine"

If the homocysteine converting enzyme is to convert the homocysteine in the sample being assayed, as discussed supra, then naturally the contact between the sample and the enzyme must occur prior to the conversion of the homocysteine by the enzyme. Moreover, this construction is consistent with the fact that "contacting" is "step (i)" of the claimed method.

Accordingly, the Court construes "contacting said sample with a homocysteine converting enzyme and at least one substrate for said enzyme other than homocysteine," as "joining the sample with a homocysteine converting enzyme and a substrate for the enzyme other than homocysteine prior to the conversion of homocysteine by said enzyme." "Joining" includes the activation of an inactive homocysteine converting enzyme already present with the sample.
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A. "Containing a Mixture of Lipid and Solid Ingredients" (Claims 1. 17, 25, 78, and 89)

Plaintiff argues that this phrase means a composition that includes lipids and solids. That is, the composition must contain a mixture of lipids and solids, but the composition can also contain additional ingredients. Defendants argue that the phrase is

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not open-ended, and means a composition wholly of lipid and solid ingredients, in varying proportions, that retain their own properties. 1

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1 Defendants also contend that Plaintiff expressly disclaimed any such mixture that has added water, an aqueous phase, water-added ingredients, or moisture control ingredients. However, it is unclear whether Defendants seek to incorporate this assertion into their proposed construction of the claim term.

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Whether the phrase "containing a mixture of lipid and solid ingredients" is exclusive or inclusive of ingredients other than lipids and solids turns on the definition of the term "containing." The ordinary meaning of the term, as articulated by Webster's Dictionary, is "comprising, including." See Webster's Ninth New Collegiate Dictionary 282 (9th ed. 1990); see also Bell Atlantic Network Servs., Inc. v. Covad Comm. Group Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001) (dictionaries, while technically extrinsic evidence, may be considered along with the intrinsic evidence when determining the ordinary meaning of claim terms). This definition may be interpreted as either open-ended or closed-ended.

However, a review of the claim language indicates that the term is meant to be closed-ended, and exclusive of ingredients other than lipids and solids. First, the claim language shows that, where Plaintiff meant to write an open-ended limitation, it did so. For example, in each of the asserted claims of the patent-in-suit, Plaintiff uses the term "containing" twice. Claim 1, which uses the language that is representative of all the claims at issue, states:

1. A dual texture pet or animal food product comprising:

a soft inner component of a dual texture . . . containing a mixture of lipid and solid ingredients . . .

a cereal based shell component . . . containing at least one ingredient comprising a carbohydrate . . .

See Joint Appendix to Opening Briefs ("Jt. App."), Exhibit A, at col. 18, lines 12-22. Plaintiff's failure to use a qualifier, such as "at least," when referring to the soft inner component, yet including such a qualifier when referring to the cereal based shell component, indicates that Plaintiff meant for the inner component to be exclusive of ingredients other than lipids and solids.

Second, the patent specification describes the embodiment of the soft inner component as being a mixture that may vary in its percentage of lipids and solids, but in all cases, should not exceed 100 wt%. Furthermore, the written description states that the most preferred embodiment comprises "about 60 wt% solids and 40 wt% lipids." Jt. App., Exhibit A, col. 6, lines 4-13. This statement provides further evidence that Plaintiffs intended the claim term to comprise only lipids and solids.

In support of its position to the contrary, Plaintiff cites to the patent wherein the claim states: "a soft inner component . . . containing a mixture of lipid and solid ingredients, the first component having a water activity, a[w], less than about 0.65 and a total moisture content less than about 15 wt%." Jt. App., Exhibit A, col. 18, lines 13-17. Plaintiff asserts that the express claim language above shows that the soft, or first, component is composed of ingredients other than just lipids and solids because of the defined amounts of water that are also included in the component. However, the Court does not read the claim language in the same manner. Based on the Court's interpretation of the claim, the term "first component" (which has a water activity less than . . .) is referring to the lipid ingredient. Therefore, the claim language indicates that any amount of water activity or moisture content found within the soft inner component would be present by virtue of the lipid content.

The written specification supports this Court's interpretation. In the "Summary of the Invention" section, Plaintiff writes, "the inner component is a mixture of lipids and solids which forms a soft cream-like matrix. Since this soft matrix is formed without needing any added water, it has minimal water content and very low water activity levels." Jt. App., Exhibit A, col. 3, lines 31-35 (emphasis added).

Plaintiff also asserts that the specification expressly teaches that additional ingredients, such as nutritive or non-nutritive compounds, can be included in the inner component. See Jt. App., Exhibit A col. 5, lines 38-40. However, there is no

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indication that these additional ingredients are neither lipids or solids. Additionally, Plaintiff states that such ingredients as anti-inflammatory agents and natural colorants are not necessarily solids, and are available in liquid form. However, this statement is not convincing or instructive, as the fact that the ingredients are available in liquid form does not preclude its availability and use in solid form.

As to Defendants, in addition to arguing that the phrase "mixture of lipid and solid ingredients" is close-ended, they also argue that Plaintiff expressly disclaimed any such mixture that has added water, an aqueous phase, water-added ingredients, or moisture-control ingredients. In support of their contention, Defendants assert that (1) the written specification clearly describes what the inner component does not contain, which are water-added ingredients and moisture-control ingredients, and (2) that the specification is replete with representations that added water, water-added ingredients, and moisture-control ingredients are undesirable and to be avoided. However, Defendants' arguments are not well-taken by this Court. While the aformentioned statements and representations in the specification may serve as further limitations on the patent, they do not operate to redefine, deviate or limit the meaning of the claim term.

Based on the forgoing analysis, it is clear from the intrinsic evidence that the term "containing" is meant as an exclusive term. The other terms within the phrase, as used in the relevant claims of the patent, are terms that are commonly understood by those of ordinary skill in the art, and require no further elaboration by this Court. As such, the claim limitation, "containing a mixture of lipid and solid ingredients" means "a composition wholly of lipids and solid ingredients."

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A

The appellant first contends that the district court erred in holding that the term "ingredients" in the phrase "a mixture of solid and lipid ingredients" refers only to starting materials. We agree that the claims are not so limited.

The parties direct us to Webster's Third New International Dictionary (2002) ("Webster's"), which provides that an "ingredient" is "something that enters into a compound or is a component part of any combination or mixture." Id. at 1162. So too, the Oxford English Dictionary 2d ed., vol. 7 (1989) ("OED"), defines "ingredient" as "something that enters into the formation of a compound or mixture; a component part, constituent, element." Id. at 963. These definitions indicate that the ordinary meaning of "ingredients" can refer to either starting materials (e.g., as in a recipe) or to the components of a mixture after they have been combined.

Here, the term "ingredients" must be read in context of the claims' reference to "a mixture of lipid and solid ingredients." The parties agree that "mixture" means "a portion of matter consisting of two or more components in varying proportions that retain their own properties." (J.A. at 1224); see also Webster's at 1449 (defining "mixture" as "a product of mixing: COMBINATION," or more specifically as "a combination of several different kinds of some article of consumption"). The claims at issue are for "a mixture . . . of ingredients." This strongly suggests that "ingredients" refers to the components after they have been combined to form that "mixture." 2

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2 It may be that the use of the word "ingredients" standing alone - in the absence of anything contrary in the intrinsic record - could be entitled to the full range of both dictionary definitions. See Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1379 (Fed. Cir. 2002). However, given the use of "mixture" in conjunction with "ingredients," that is not the case here.

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Our decisions in PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235 (Fed. Cir. 2002) and Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed. Cir. 1995), support this construction. In those cases "we equated a 'composition' with a 'mixture'" and construed the term "composition" to refer to the claimed ingredients after they were joined together. PIN/NIP, 304 F.3d at 1244. We explained that:

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[A] chemical composition exists at the moment the ingredients are mixed together. Before the creation of the mixture, the ingredients exist independently. . . . Consequently, as properly interpreted, [the patentee's] claims are to a composition that contains the specified ingredients at any time from the moment the ingredients are mixed together.

Id. (emphasis added); see also Exxon Chem., 64 F.3d at 1558. So too, in this case the ordinary meaning of the phrase "a mixture of lipid and solid ingredients" refers to the components of the inner component "at any time from the moment at which the ingredients are mixed together." 3 See id.

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3 We agree with the parties that regulations issued by regulatory agencies can be helpful to a claim construction analysis if they are probative of an industry-specific meaning for a disputed claim term. See E-Pass Techs., Inc. v. 3COM Corp., 343 F.3d 1364, 1368 (Fed. Cir. 2003). The FDA and USDA regulations cited by the parties however do not address the meaning of the phrase "a mixture . . . of ingredients." See id. (rejecting the use of industry standards to provide the ordinary meaning of claim terms because "there was no suggestion in the . . . standards that . . . either was intended to define [the claim terms in dispute]"). Nor is the use of the term "ingredients" in the cited regulations inconsistent with the dictionary definitions. See 7 C.F.R. § 205.2 (2003) (stating that an "ingredient" is "any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed") (emphases added); 21 C.F.R. § 501.4 (2003) (stating that "ingredients [must be listed] in descending order of predominance in the finished food").

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The specification does not, as Heinz contends, provide a basis for deviating from this ordinary meaning. The mere fact that the patent examples appear to use the term "ingredients" to refer to starting materials is not a sufficient reason, in and of itself, to deviate from the ordinary meaning of claim language. See Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 (Fed. Cir. 2004). Moreover, Heinz's argument that the specification in other respects uses the term "ingredients" to refer only to starting materials 4 fails for at least two reasons. First, these statements do not provide the "clear definition" required by our precedent to show that the patentee has acted as a lexicographer in redefining a claim term. See, e.g., Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004). Second, these statements refer only to "ingredients," and not to "a mixture of . . . ingredients" as required by the claims. The specification therefore provides no basis for deviating from the ordinary meaning of the phrase "a mixture of solid and lipid ingredients," and Heinz does not argue that the prosecution history suggests otherwise.

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4 For example, the specification teaches that "in general, it is recommended that the dry mean component of the inner [component] be added to the mixer first, followed by the tallow and other fat and oil ingredients during a batch operation process." '746 patent, col. 9, ll.7-10 (emphasis added). There is also a reference to "the safe handling of the softer core ingredients" prior to production of the finished product. Id. at col. 8, l. 62 (emphasis added).

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For these reasons we hold that the term "ingredients," as used in the phrase "a mixture of lipid and solid ingredients," refers to the components of the inner component at any time after they have been mixed together. This would include, but is not limited to, the ingredients as found in the final food product.

B

The next question is the meaning of the terms "containing" and "mixture" in the phrase "containing a mixture of lipid and solid ingredients." We hold that neither term requires that the ingredients be limited only to those ingredients listed in the claim itself. In other words, like the term "comprising," the terms "containing" and "mixture" are open-ended.

The general purpose dictionary teaches that "containing" is synonymous with "comprising" and "including." See Webster's at 491 (defining "contain" as "to consist of wholly or in part: COMPRISE, INCLUDE"). Moreover, the Manual of Patent

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Examining Procedure ("MPEP") is helpful for determining the meaning of "containing" in the context of a patent application. See Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1425 (Fed. Cir. 1988); Application of Kaghan , 55 C.C.P.A. 844, 387 F.2d 398, 401 (CCPA 1967) ("An applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provisions of the MPEP in the prosecution of his patent application."). The MPEP specifically provides that "the transitional term 'comprising,' . . . is synonymous with 'including,' 'containing,' or 'characterized by,' [and] is open-ended and does not exclude additional, unrecited elements or method steps." MPEP, 8th ed., rev. 1 § 2111.03 (2003); see, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."). Thus, neither the dictionary nor the MPEP provides a definition for "containing" that excludes additional, unnamed ingredients.

The use of the term "mixture" does not exclude additional, unnamed ingredients. As noted above, the parties agree that "mixture" means "a portion of matter consisting of two or more components in varying proportions that retain their own properties." (J.A. at 1224.) Heinz argues that this definition bars the addition of ingredients other than lipids or solids because "a mixture of three classes of ingredients . . . [would] not [be] the same mixture[]" as one consisting of only lipids and solids. (Br. of Defs.-Appellees at 17 (internal quotation marks omitted).) This argument misses the point. A mixture with lipids, solids and a third ingredient is a different mixture than one containing only lipids and solids, but both are still "mixtures of lipid and solid ingredients" as required by the claims. There is nothing within the ordinary meaning of "mixture" that bars additional, unnamed ingredients. 5

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5 We did not hold otherwise in Abbott Laboratories v. Novopharm Ltd., 323 F.3d 1324 (Fed. Cir. 2003). There, we construed the claim language "containing a co-micronized mixture of particles of fenofibrate and a solid surfactant" to be close-ended, i.e., to exclude ingredients other than fenofibrate and a solid sufactant. Id. at 1327. That construction however was based on the meaning of "co-micronization," as opposed to the meaning of "containing" or "mixture." Id. at 1330. Moreover, the patentee in Abbott acted as "his own lexicographer" and specifically defined "co-micronization of fenofibrate and a solid surfactant" as a "micronization of an intimate mixture of fenofibrate and a solid surfactant." Id. Our decision in Abbott was based on a specialized meaning attributed to the term "co-micronization," and not on the broader, ordinary meaning of the terms "containing" and "mixture" at issue here.

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The district court erred in concluding that the specification was inconsistent with the ordinary, open-ended meaning of the terms "containing" and "mixture." The portion of the specification that describes "preferable" amounts of lipids and solids in the inner component states:

It is preferable for the inner portion or component to comprise about 40-90 wt % solids and about 10-60 wt % lipids; more advantageous for the inner portion or component to comprise about 50-80 wt % solids and about 20-50% lipids; and still more advantageous for the inner portion or component to comprise about 55-65 wt % solids and about 45-35 wt % lipids, with the sum of the wt % of solids and lipids, in all cases, [does] not exceed 100 wt %.

'746 patent, col. 6, ll.4-11 (emphasis added). This passage does not, as the district court concluded, bar a sum weight percentage of solids and lipids less than 100%. The mere fact that the sum of the minimum and maximum values of the stated ranges equals 100%, does not suggest that the sum of the percentage of solids and lipids must always equal 100%. To the contrary, the specification recites a range of values in which the weight percentage of lipids and solids may vary given the presence of additional, unnamed ingredients. See Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 717 (Fed. Cir. 1998) (refusing to limit the claims based on a combination of minimum values from ranges stated in the specification because "there was no suggestion to use the lowest stated flux rate with the smallest stated preferred patch size").

Likewise, Heinz's argument that Mars narrowed the scope of its claims during prosecution to require an inner component made wholly of lipid and solid ingredients fails. During prosecution of a related application, Mars replaced claims requiring an inner component "containing at least an ingredient comprising a lipid, wherein said [inner] component has a total moisture content less than about 25 wt%," (J.A. at 342), with claims requiring an inner component "containing a mixture of lipid and solid ingredients forming a cream-like matrix . . . and a total moisture content less than about 15 wt%." (J.A. at

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398.) While it is conceded that this amendment narrowed the total moisture content limitation (from 25% to 15%), the extent to which additional subject matter, if any, has been surrendered is ambiguous. "It is inappropriate to limit a broad definition of a claim term based on prosecution history that is itself ambiguous." Inverness, 309 F.3d at 1382; see also Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Thus, we decline to limit the ordinary meaning of the claims at issue here.

Finally, we reject the argument that using the term "containing" to describe the inner component, as opposed to "containing at least," which was used to describe the outer shell, "indicates that [Mars] meant for the inner component to be exclusive of ingredients other than lipids and solids." Mars, slip op. at 4. The phrase "at least" is not required to make the outer shell limitation open-ended. Instead it was included to make clear that not all, but "at least" one, of the listed ingredients must be present in the outer shell. The phrase "at least" does not appear in the inner component limitation because that limitation, as the parties admit, is drafted to require the presence of both lipid and solid ingredients. Thus, the use of the phrase "at least" to describe the outer shell does not suggest that the term "containing" is close-ended.

As such, we conclude that, like the term "comprising," the claim term "containing" is open-ended. Since the term "mixture" is entirely consistent with this construction, we hold that the "containing a mixture of lipid and solid ingredients" limitation does not exclude the presence of additional, unnamed ingredients in the inner component of the claimed invention. The district court's construction to the contrary was erroneous.
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"Treating Composition Containing the Materials Released by Platelets During the Platelet Release Reaction"

The term "treating composition containing the materials released by platelets during the platelet release reaction" should be construed to mean "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components." First, the language of the claim supports this conclusion. The ordinary meaning of the term "composition" is "a product of mixing or combining various elements or ingredients." Webster's Ninth New Collegiate Dictionary 270 (1990). Courts have recognized that the ordinary meaning of "composition" is open-ended and includes mixtures having the recited ingredients and other substances. See e.g., Glaxo Wellcome Inc. v. Genentech, Inc., 136 F. Supp. 2d 316, 334-35 (D. Del. 2001). The term "contain" means "to have within . . . comprise, include." Webster's Ninth New Collegiate Dictionary 282 (1990). The term "include" means to contain within as part of a whole" and "suggests the containment of something as a constituent, component, or subordinate part of a larger whole." Webster's Ninth New Collegiate Dictionary 609 (1990). Thus, the ordinary meaning of a "treating composition containing the materials released by platelets" encompasses compositions containing substances in addition to the materials released by platelets. The phrase does not recite a composition containing only those materials, and claims should not be rewritten to add words not present. Panduit, 810 F.2d at 1576.

The patent specification supports the conclusion that the term should be construed as "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components." The specification does not demonstrate that the patentee deviated from the customary, open-ended nature of the phrase "composition containing." In the "Summary of the Invention" section, the patent emphasizes the discovery that activated platelet-enriched plasma ("PRP") contains platelet-derived angiogenesis factor ("PDAF") and growth factor ("PDGF") which may be used to speed the healing of wounds. The specification refers repeatedly to applying "activated PRP" to wounds as a healing agent, without mention of removal of platelet ghosts (the residual platelet body that remains after a platelet releases all of its alpha-granule contents during the platelet release reaction) from the activated PRP. Also, the specification of the '938 patent includes the nineteen originally filed application claims directed to treating compositions and methods for their preparation and use. Only one of those original claims requiring isolating PDAF and PDGF from activated PRP, which further demonstrates that the disclosed invention is not limited to using platelet derived factors isolated from platelet ghosts. Because specification simply does not indicate that the patentee restricted its claims to any preferred embodiment, the treating compositions of the claims are not limited to compositions free of platelet ghosts or other non-related materials.

Finally, the prosecution history supports the construction that the treating composition can have all of the various materials released by activated platelets. The PTO rejected application claims on the basis of prior art references disclosing that

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isolated PDGF may be beneficial in wound healing. In a Response dated November 18, 1989, the term "material released from platelets" was distinguished from isolated growth factor as follows:

This phrase refers to the actual physical stuff or soup in its entirety which is released by platelets -- without further processing or isolation of factors contained therein. This material is very complex, admittedly containing PDGF but also containing platelet-derived angiogenesis factor and many other growth factors and inhibitors including fibroplast growth factor ("FGF"), epidermal growth factor ("EGF"), TGF-d, TGF-B, platelet factor 4, and many others.

After the PTO Examiner maintained the position that "material released by platelets" was broad enough to cover isolated PDGF, the pending claims were amended to replace that phrase with the expression "the materials released by platelets during the platelet release reaction." The patentee emphasized that the substituted expression refers to "all of the various components" released and not just "one or more of the materials released." (emphasis in original) The patentee consistently applied this meaning to the term in distinguishing the issued claims from the prior art. The Examiner eventually recognized this distinction, and indicated in the Notice of Allowability that "the materials released by platelets during the platelet release reaction" referred to "materials more complex than PDGF." Because the patentee expressly defined the term "the materials released by platelets during the platelet release reaction" during prosecution to require all of the various components released, the claimed treating composition must include all of the various released components. Honeywell Inc. v. Victor Co. of Japan, Ltd., 298 F.3d 1317, 1323-24 (Fed. Cir. 2002) (definition of term offered during prosecution relevant to intended meaning of term).

Defendants argue that the term "treating composition" should be construed as the union of a "biologically compatible macromolecular substance" to the "platelet-free supernatant," i.e., "the materials released by platelets," and that "containing the materials released by platelets during the platelet release reaction" should be construed to mean "platelet-free supernatant." However, limiting the phrases as such would contradict the ordinary meanings of the terms "composition" and "containing," namely that both terms are by nature open-ended and permit inclusion of other components. The patent claims nowhere indicate that platelet ghosts or other non-related substances must be removed to make the compositions of the invention effective healing agents.

Defendants' proposed construction is also not supported by the specification. The specification includes the nineteen originally filed application claims directed to treating compositions and methods for their preparation and use. The majority of those claims described preparation methods and resulting compositions which included platelets as well as released materials. Defendants attempt to suggest that the invention is limited to platelet-free supernatants and a carrier by focusing on parts of the preparation methods described elsewhere in the patent specification. These preparation methods, however, only serve to illustrate preferred ways of making embodiments in accordance with the invention. The law is clear that claims are not limited to a preferred embodiment disclosed in the specification. Transmatic, 53 F.3d at 1277. But even if the specification did contain some limitations, limitations appearing only in the specification cannot be read into the claims. Howes, 992 F. Supp. at 961.

Finally, the prosecution history does not support the Defendants' construction of this term. Defendants argue that the applicant disavowed the scope of coverage of the claims directed to the use of activated platelet-rich plasma applied to a wound. Contrary to this assertion, however, the applicant never gave up on claims directed to the use of activated platelet-rich plasma applied to a wound, i.e., what Defendants call "one centrifuge cycle" claims.

The original application for the '938 patent contained fifteen claims as filed, which were directed to various treatments and methods of the invention. For example, the initial claims covered methods for producing wound healing substances through platelet activation with thrombin and the use of a carrier, methods for extracting PDAF and PDGF from blood, and platelet-derived compositions for the treatment of wounds. Application claim 13 described a treatment composition comprising PDAF and PDGF in a platelet-rich plasma also containing thrombin. As acknowledged by Defendants, the initial claims included broad claims directed to the use of the activated platelet-rich plasma applied to a wound; the claims were not limited to a platelet-free supernatant and a carrier.

Following the Examiner's rejection of the claims, the initial application was abandoned in favor of a related application. The new disclosure included additional information summarizing results of clinical trials with diabetic patients. This application presented nineteen claims for consideration, many of which were claims carried over from the original parent application.

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Application claims 1-19 were thereafter cancelled and replaced with claims 20-65. Newly presented claims 47-56 were directed to treatment methods involving topical application to tissue of material released from platelets. Thus, as shown by application claims 47-56, the applicant continued to pursue claims directed to the use of activated platelet-rich plasma applied to a wound. Contrary to Defendants' argument, nothing in the prosecution history suggests that claims 47-56 "inherently required two centrifuge cycles." Applicant subsequently cancelled claims 20-65 and replaced them with application claims 66-90. Claims 76-86 recited a method for treatment of tissue "comprising applying materials released from platelets topically onto tissue." There was no requirement of a carrier or of a platelet-free supernatant. Thus, in pursuing claims 76-86, the applicant did not limit itself to a platelet-free supernatant and a carrier, i.e., what Defendants call a "three centrifuge cycle."

In a series of communications with the PTO addressing claims 76-89 and successor claims, the applicant clarified the meaning of the phrase "materials released by platelets," which was later replaced by the phrase "the materials released by platelets during the platelet release reaction." The applicant explained that this phrase was directed to methods and treatments containing all of the materials released by platelets during the platelet release reaction after activation and not to any one isolated component of these materials. These exchanges between the applicant and the Examiner show that both the applicant and Examiner understood the phrase to have this meaning.

Furthermore, the Examiner's statements from the Notice of Allowability show that the Examiner allowed the claims based on this clarification of "materials released by platelets during the platelet release reaction." The Examiner allowed the claims because the prior art did not show the use of all the materials released by activated platelets, which "are materials more complex than PDGF" alone. The Examiner therefore allowed the claims because applicant was not seeking claim coverage of any one released factor, such as PDGF, alone. The Examiner's understanding of the claims, as stated in his reasons for allowance, should be considered in construing the claims. Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (7th Cir. 1999).

Significantly, the applicant made no effort to distinguish the prior art by limiting the claims to a platelet-free supernatant and a carrier. In addition, there is no indication in the prosecution history that the Examiner required such an implicit limitation as a condition for allowance. The applicant cannot be said to somehow have incorporated the requirements of a platelet-free supernatant and a carrier.

Defendants argue that the applicant narrowed the definition of the claimed treating composition to include only the "supernatant" remaining after a "third centrifugation cycle." They quote a passage from an amendment to support their argument that the applicant expressly limited its treatment method to compositions containing the supernatant and not compositions containing the supernatant plus additional materials. This argument, however, is not supported by the very amendment they quote. First, the passage from the specification describing preparation of a platelet-free supernatant was referred to by the applicant only to show that the claims were adequately supported by the specification, and not to define the phrase now at issue. Moreover, the full text of the applicant's remarks shows that the applicant was emphasizing an intent to claim "all of the various components" of the materials released during the platelet release reaction, not just "one or more of the materials released." To further emphasize this point and to show that the claim was adequately supported, the applicant referred to a preferred embodiment in the specification describing the preparation of a platelet-free supernatant:

P. 5, lines 15-34 [of the specification] set forth the procedure for preparing the materials released by platelets. After the release reaction the platelet ghosts and fibrin are removed by centrifugation (see p. 5, lines 24-26). The resultant "supernatant" is what is applied to a wound in toto (see p. 5, lines 33-35). Applicant does not isolate individual factors from this supernatant and does not otherwise process this supernatant in ways that would affect the bioactivity of the multitude of factors contained therein. Applicant "names" this supernatant "the materials released by platelets in the platelet release reaction" . . . This phrase refers to the actual physical stuff or soup in its entirety which is released by platelets - without further processing or isolation of factors contained therein.

(emphasis in original). Viewed in the proper context, this passage emphasized: (1) that the claim was adequately supported by a preferred embodiment of the specification in which the materials released by platelets were in the form of a platelet-free supernatant; (2) that the disclosed supernatant was not further separated into isolated factors; and (3) that the specification therefore supported a definition of the materials released by platelets as all of the various components released. The concluding sentence of the applicant's remarks reiterated the salient point that the "material released from platelets" refers to the "actual physical stuff or soup in its entirety which is released by platelets - without further processing or

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isolation of factors contained therein." A person of ordinary skill would not conclude from this exchange that the claims were limited to compositions free of platelet ghosts.

Furthermore, the prosecution history in its entirety shows just the opposite of what Defendants contend. At one point during prosecution the patentee introduced independent claims 76 and 87. Claim 76 was directed to a method for treatment of tissue "comprising applying material released from platelets topically onto tissue." Independent claim 87 more narrowly recited a composition comprising a carrier and the material released from platelets, and also required that the composition be "substantially free of (i) blood or plasma contaminants and (ii) platelet ghosts or other material found in human platelets but not released by said platelets." Application claim 89 recited a treatment method comprising topically applying the composition of claim 87 onto the tissue. Application claims 76 and 87-89 were later cancelled and replaced with claims similar to the broader claim 76, which later issued as claims 1 and 12. Thus, the narrower claim scope of claims 87-89 was abandoned in favor of the broader issued claims 1-12, which does not require the absence of non-released materials in the treating composition.
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C. Treating Composition

Harvest argues that the phrase "the materials released by platelets during the platelet release reaction" in the '938 patent should be interpreted to be the supernatant free of platelets, cells, and fibrin. (Kuter Decl. at P 25.) Under this interpretation, SraartPReP does not infringe since those elements remain in the APC after centrifuging. Harvest does not argue that the dictionary meanings of the terms require this interpretation, but rather argues that the inventor disclaimed coverage of products including those factors in prosecuting his patent to overcome prior art. Cytomedix responds that those statements were either taken out of context or directed to another, later--canceled claim.

"Arguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1155 (Fed. Cir. 1997) (quoting Southwall Techs. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995)). See also Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990) (holding that statements about a term made in separate but related patent served to define and limit term in patent at issue, despite otherwise different claim language); Watts v. XL Sys., 232 F.3d 877, 883 (Fed. Cir. 2001) ("It is irrelevant in this case whether Watts' prosecution history remarks were directed to claim 18 specifically because there is no clear indication that they were not."). "Arguments made during the prosecution of a patent application are given the same weight as claim amendments." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999) (noting that "it is . . . irrelevant whether Elkay emphasized this argument at the time, or indeed whether Elkay had to relinquish an interpretation"). But see Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 832 (Fed. Cir. 2003) ("While on its face this statement appears to limit claim scope, it cannot do so absent some claim language. . . . The applicants' inaccurate statement cannot override the claim language itself, which controls the bounds of the claim."); Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053-54 (Fed. Cir. 1989) (noting that erroneous remark by attorney would not change scope of patent, for "the claims themselves control").

"The scope of the disclaimer must be determined by what a competitor would reasonably believe that the applicant had surrendered.'" Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1361 (Fed. Cir. 2001) (holding that statements made to distinguish certain claims of parent application from prior art limited scope of patent issuing from separate claims where statements spoke generally of "the present invention"). However, "the alleged disavowing statements [must] be both so clear as to show reasonable clarity and deliberateness, . . . and so unmistakable as to be unambiguous evidence of disclaimer." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325 (Fed. Cir. 2003) (citations omitted).

The Court starts, as it must, with the language of the claims themselves. Claim 1 reads: "a treating composition containing the materials released by platelets during the platelet release reaction." Nothing in the plain language of this claim suggests that the composition must contain only these materials. See Cytomedix, Inc. v. Little Rock Foot Clinic, P.A., 2004 U.S. Dist. LEXIS 4804, No. 02-4783, 2004 WL 609330 (N.D. Ill. March 24, 2004) (interpreting the same claim language).

Harvest's principal argument is that Knighton, the inventor of the '938, specified that his invention was of the supernatant free of platelets, cells and fibrin in prosecuting the patent. Harvest points to several passages from the prosecution history,

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the strongest three of which are quoted below.

After the Patent Office stated that the prior art showed that platelets contain wound healing substances and it would be obvious to combine platelets and a carrier, namely collagen, to produce a wound-healing composition, Knighton argued:

Claim 64 is allowable over Antoniades because the composition, containing material released from the granules, is substantially free of other material found in platelets outside of the granules. In contrast, in Antoniades, the platelets are lysed . . . with the result that extra-granular platelet material is mixed with the contents of the granules. This might not matter for Antoniades because PDGF is later separated by precipitation, gel electrophoresis, or other means from the lysed cellular material. In the case of applicant's invention, only the contents of the granules are used in the composition.

(Mesiti Decl. Ex. I, Amendment and Response of Jan. 19, 1988 at 28.) Although Harvest argues that the term "applicant's invention" refers to the entire patent, see Ballard, 268 F.3d at 1361, the passage expressly states that this argument is intended to apply only to claim 64, which read:

A topical therapeutic composition for application to tissue for the purpose of forming granulation tissue and/or capillaries and/or epithelial tissue, said composition being in the form of an ointment, salve, cream or solution and comprising

(i) the material released from the alpha granules of human platelets; and

(ii) a pharmaceutically acceptable carrier or diluent therefore

wherein said composition is substantially free of (i) blood or plasma contaminants or (ii) other material found in human platelets outside of said alpha granules.

(Id. at 7-8 (emphasis added).) Claim 64 excludes extra-granular platelet material, unlike Antoniades' composition. Therefore, there was a clear indication that this argument was specific to one claim. CVI/Beta, 112 F.3d at 1155.

In response to another prior art rejection, Knighton again amended his claims and argued:

-- MOST IMPORTANT

[The specification] sets forth the procedure for preparing the materials released by platelets. After the release reaction the platelet ghosts 2 and fibrin are removed by centrifugation. . . . The resultant "supernatant" is what is applied to a wound in toto. Applicant does not isolate individual factors from this supernatant and does not otherwise process this supernatant in ways that would affect the bioactivity of the multitude of factors contained therein. Applicant "names" this supernatant "the materials released by platelets in the platelet release reaction." This expression is well known in the art as evidenced by the excerpts from the text on hematology and applicant should not have its claims limited to a centrifugation process for manufacturing the supernatant. Finally, even though the Examiner has asserted that the previous claims could be read broadly, applicant has consistently used "material released" in the claims to mean "the materials" released. . . . This phrase [materials released from platelets] refers to the actual physical stuff or soup in its entirety which is released by platelets -- without further processing or isolation of factors contained therein.

(Mesiti Decl. Ex. R, May 18, 1990 Preliminary Amendment at 5-6 (second emphasis added).) The context of this passage was the rejection by the Examiner on the grounds that prior art disclosed that isolated platelet-derived growth factor ("PDGF") may be beneficial in wound healing. The patentee therefore explained that the invention referred to all of the components released, not just PDGF.

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2 Platelet ghosts are the bodies of the activated platelets.

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Harvest underscores the express definition of "the materials released by the platelet reaction" as the supernatant from which

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the platelet ghosts and fibrin have been removed by centrifuge, and argues that this sentence is a clear disavowal of a composition containing other blood components. If this definition stood alone, Harvest may well have a prevailing argument. However, later in the passage, the inventor states that "materials released from platelets" refers to the "actual physical stuff or soup in its entirety which is released by platelets -- without further processing or isolation of factors contained therein." In this latter definition, there is no reference to the fibrin-free or platelet-free limitation on the contents of the stew. The two definitions in the same passage must be read in sync; accordingly, in light of Knighton's motive in writing the passage--he was attempting to include components, namely all of the materials released instead of one isolated material, PDGF, not to exclude components -- and the word "soup" in the definition, the Court does not read the passage as a clear "disavowal" of the plain meaning of Claim 1.

Finally, in arguing for claims 76-86 and 89 of a parent application, Knighton stated:

Regarding the 102 rejection, claims 76-86 and 89 do not "read on" the Annals of Surgery article because as discussed more completely below the "injection" into the cornea was not "topical application." Furthermore . . . the . . . article suggests platelets play a role along with other cell types in natural wound healing. Applicant's present discovery is that platelet released material alone is sufficient to heal wounds without the concurrent activity of macrophages and other cell types present in natural wound healing.

. . .

The examiner has yet to address the first reason for nonobviousness. Why is it obvious that platelet released material "alone" could heal wounds when the point of the Annals of Surgery article was to show that platelets at least participate in natural wound healing along with macrophages and other cell types.

(Mesiti Decl. Ex. P, Response of Nov. 20, 1989 at 8, 9.)

This passage is not a clear disavowal of coverage such as to limit the claims, for it does not define specific terms in the claims and does not require the invention to be free of other components. Knighton did not state that his "composition" could not include other components, but rather that it did not have to. In the context of the prosecution history, Knighton made the same argument with respect to claims 87 and 88, which required a composition "substantially free of (i) blood or plasma contaminants and (ii) platelet ghosts or other material found in human platelets but not released by said platelets." (Id. at 13.) Knighton noted that these claims, which were ultimately canceled, showed his "preferred" embodiment (id.), but he did not state that they represented the only embodiment. 3

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3 Cytomedix's expert recently mentioned in his own patent application that the '938 patent requires isolating the platelets from red blood cells, plasma, and white blood cells. The Court declines to rely on this extrinsic evidence.

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Accordingly, the Court adopts Cytomedix's claim construction that the term "treating composition containing the materials released by platelets during the platelet release reaction" means "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components."
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Specifically, the parties dispute the meaning of the phrase: "the phenyl group contains at least one substitutent chosen from the group consisting of: [...]." According to Dow, the disputed phrase means that the phenyl group contains at least one substituent (and up to five), all of which must be chosen from the enumerated group (a)-(k). Defendants, on the other hand, contend that the "language of the asserted claims ... is clear on its face to one of ordinary skill in the art." Thus, someone with a bachelor's degree in Chemistry n6 would immediately understand the disputed phrase to mean that only one substituent must be selected from the list (a)-(k), but that any other substituents are unlimited and unbounded. Because Dow offered credible expert evidence to rebut Defendants' contention, and because the grammar of the language at issue is

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susceptible to two plausible interpretations, we disagree with Defendants that the claim language is clear on its face and undertake the following claim construction analysis.

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n6 In this case, the parties agree that one of ordinary skill in the art means a person with a bachelor's degree in Chemistry. Def.'s Resp. Br. at p.17 (citing Pl.'s App. D at P33).

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The enumerated list (a)-(k) in Column 2 of each specification constitutes a "Markush group." We accept the well-known use of that term to mean that "members of the Markush group are ... alternatively usable for the purposes of the invention." In re Driscoll, 562 F.2d 1245, 1249 (C.C.P.A. 1977). Moreover, "[a] Markush group, incorporated in a claim, should be 'closed,' i.e., it must be characterized with the transition phrase "consisting of," rather than "comprising" or "including."" Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1280-81 (Fed. Cir. 2003) (citing Stephen A. Becker, Patent Applications Handbook § 2:17 (9th ed. 2000)).

Generally, "members of the Markush group are used singly." See Meeting Held to Promote Uniform Practice In Chemical Divisions, 28 J. Pat. & Trademark Off. Soc'y 757, 849, 852 (1946) (listing practices approved by the primary examiners of the USPTO's chemical group). If a patentee desires to use or to combine multiple members of the Markush group, then he or she must add qualifying language to the claim. Abbott Labs., 334 F.3d at 1281 (citing Meeting Held to Promote Uniform Practice In Chemical Divisions, supra, at 852). An example of such qualifying language is "at least one member of the group." Id. Therefore, in our case, the language "at least one" and "chosen from the group consisting of" in our judgment modifies the word substituent, allowing the patentee to select more than one substituent from among the Markush group.

Next, we examine the meaning of the pivotal word, "contains." Defendants argue that "contains," like the transitional term, "containing," "is inclusive or open-ended and does not exclude additional, unrecited elements or method steps." Manual of Patent Examining Procedure ("M.P.E.P.") § 2111.03; Defs.' Resp., Ex. 1, Forstner Decl. PP47-48. Thus, Defendants contend that "a recitation in a claim that a compound 'contains' a substituent means that the presence of that substituent with or without any other substituent(s) meets the requirement of the claim." Defs.' Resp. at p. 18, n. 7. Dow, on the other hand, asserts that "contains" should be read together with "at least one" to modify "only the word substituent, thus signifying that the number of substituents is open, i.e., that there could be as few as one substitution and as many as five." Dow then goes on to reason that the language "group consisting of" is drafted in the standard closed language of a Markush group, signifying "that the identity of any and all substituents is closed. 'Contains at least one,' under this interpretation, does not serve to make open-ended what is otherwise understood to be a closed group." Pl.'s Reply Br. on Claim Constr. at p.7.

Dow's construction of the disputed language gives meaning to all of the words in Column 2 of the common specification, including the numerical ranges for the substituents listed at a, b, and e of the specification. See Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991) (adhering to the rule that "all the limitations of a claim must be considered meaningful"); see also Advanced Communication Design, Inc. v. Premier Retail Networks, Inc., 46 Fed. Appx. 964, 980-81 (Fed. Cir. 2002) ("The construction of any legal document--like a statute, contract or patent--should try to give meaning to every term in that document; otherwise, a lawyer or court will have erred by reading the chosen words of the document into oblivion."). Because of this, we find Dow's reasoning compelling.

To say, as Defendants do, that the definition of R[2] is so broad as to include a substituted phenyl group with 4-5 halogen atoms even though the specification explicitly provides for the substitution of only 1-3 halogen atoms renders the "1-3" limitation surplusage. See Forstner Dep. at 139-41. Where, as here, the specification assigns significance to the numerical delineation of possible substituents, we import these numerical delineations into the claims as limitations. See Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1339 (Fed. Cir. 2001) (citing Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1367-69 (Fed. Cir. 2000) (indicating that the claim term "protecting back panel" was limited to a "relatively stiff" panel because, in addition to other intrinsic evidence, the specification's text described the back panel in the patent's drawings as being "constructed of a relatively stiff material")); see also Eutectic Corp. v. Metco, Inc., 579 F.2d 1, 5-6 (2nd Cir. 1978), cert. denied, 439 U.S. 867, 58 L. Ed. 2d 177, 99 S. Ct. 192 (1978) (noting that the extent to which a court may look to specifications or examples to limit claim is to be determined on facts in each patent case). n7

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n7 We find unpersuasive the parties' arguments based on the prosecution history and litigation involving a predecessor patent to those in suit. Dow asserts correctly that the Philips Group, the patentee, has previously taken Dow's position when interpreting a specification identical to the one in suit: "Duphar interprets the phrase in the specification "If R sub2 is a substituted phenyl group, the phenyl group contains at least one substituent chosen from the group consisting of [groups (a)-(k)]:" to mean that the enumerated substituents in groups (a)-(k), none of which include -OCF sub3, are the only possible substituents for the phenyl group. Bayer Aktiengesellschaft v. Duphar Intern. Research B.V., 738 F.2d 1237, 1243 (Fed. Cir. 1984). However, the district court disagreed with the Philips Group's interpretation of the specification and the Federal Circuit failed to reach the issue. We also find unconvincing the parties' contentious views regarding German Patent No. 2,123,236.

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IV

On appeal, Crompton argues that the district court improperly construed the claim language in two respects. First, Crompton argues that the phrase "If R[2] is a substituted phenyl group, the phenyl group contains at least one substituent chosen from the group consisting of: . . ." does not require that all of the substituents on the phenyl group be from the enumerated list. Rather, Crompton argues that only one of the substituents on the phenyl group must come from the enumerated list and that all other substituents are unbounded. It is undisputed that other than the substituted alkoxy groups, all the substituents on the phenyl groups of hexaflumuron and noviflumuron are on the enumerated list. Thus, Crompton argues that under its claim construction, both compounds literally infringe the patent.

Second, Crompton argues that the term "alkoxy" refers to both substituted and unsubstituted alkoxy groups. As such, Crompton argues that the substituted alkoxy groups on each compound are "alkoxys" as referred to on the enumerated list. Again, because it is undisputed that the remaining substituents on the phenyl groups of hexaflumuron and noviflumuron are on the enumerated list, Crompton argues that under its claim construction, both compounds literally infringe the patent.

However, we agree with the district court with regard to both claim construction issues. First of all, the phrase "the phenyl group contains at least one substituent chosen from the group consisting of: . . . " requires that all substituents on the phenyl group be chosen from the enumerated list. Crompton itself proffered this construction in connection with the similarly phrased provisos of the claim. The proviso of claim 1 of the '044 patent serves to exclude certain compounds from the claim language, stating that a compound is not included in the claim if "R[2] is a phenyl group substituted at least one position with a moiety selected from the group consisting of . . . ." Crompton argued before the district court that this meant "compounds wherein all moieties substituted onto the R[2] phenyl group are selected from the group consisting of . . . ." First Claim Construction Order, slip op. at 21-22.

Further, as the district court noted, this construction gives meaning to the numerical limitations on substituents contained within the enumerated list. Id., slip op. at 19-20. The relevant language states that "the phenyl group contains at least one substituent chosen from the group consisting of: (a) 1-3 halogen atoms, (b) 1-2 alkyl groups . . . (e) 1-2 nitro groups or cyano groups or alkoxy groups . . . ." '044 patent, col. 2, ll. 30-49. Under Crompton's proposed construction, a compound would infringe if the phenyl group was substituted with four or five halogen atoms, even though the enumerated list limits the number of halogen substituents to three. Because at least one of the substituents (the first halogen atom) would be on the enumerated list, it would not matter that two of the other substituents (the fourth and fifth halogen atoms) are not on the enumerated list. As a result, Crompton's proposed claim construction would render the "1-3" limitation on halogen atoms surplusage. As such, we agree with the district court that phrase "the phenyl group contains at least one substituent chosen from the group consisting of: . . . " requires that all substituents on the phenyl group be chosen from the enumerated list.
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I. Background

The larger context of this matter is an action brought by Ortho alleging that Barr's generic version of Ortho Tri-Cyclen Lo, which is the subject of an Abbreviated New Drug Application pending before the U.S. Food and Drug Administration, infringes claims 1 and 4 of the '815 patent. Claims 1 and 4 are recited below, with the two pertinent claim terms highlighted:

1. A method of contraception which comprises administering for 21 successive days to a female of childbearing age a combination of 17a-ethinylestradiol and norgestimate for the first 7 days in a daily dosage corresponding to 25 [mu]g of 17a-ethinylestradiol and 0.180 mg of norgestimate, for the succeeding 7 days a daily dosage equal to 25 [mu]g of 17a-ethinylestradiol aid [sic] 0.215 mg of norgestimate; and for the next 7 days a daily dosage equal to 25 [mu]g of 17a-ethinylestradiol and 0.250 mg of norgestimate; followed by 7 days without estrogen and progestogen administration.

4. A triphasic oral contraceptive unit having 21 separate dosage units, adapted for successive daily oral administration comprising: 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, 25 [mu]g of 17a-ethinylestradiol and 0.180 mg of norgestimate, 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, 25 [mu]g of 17a-ethinylestradiol and 0.215 mg of norgestimate; and 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, 25 [mu]g of 17a-ethinylestradiol and 0.250 mg of norgestimate; and optionally containing 7 additional dosage units free of estrogen and progestogen.

Plaintiff's Exhibit ("Plt. Ex.") 1 (the '815 patent). The parties agree on the ordinary meanings of the terms at issue. 1 The crux of this dispute is whether, in the context of the patent as a whole, the disputed terms incorporate additional characteristics. See Barr's Opening Claim Construction Brief ("Def. Mem.") at 9; Ortho's Opposition to Barr's Opening Claim Construction Brief ("Plt. Opp.") at 2.

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1 See Ortho's response to Barr's second set of interrogatories, interrogatory nos. 9, 10 ("Ortho relies upon the ordinary dictionary definitions for the terms in the phrases as well as their ordinary and customary usage . . . Consequently, a 'method of contraception' is defined as a means or manner of procedure that is designed for an intended to prevent conception or impregnation. . . . 'contraceptive' in the phrase 'oral contraceptive' is an adjective defined as 'capable of preventing contraception' . . . The term 'oral' is defined as '[u]sed in or taken through the mouth.'") (citing The American Heritage Dictionary of the English Language 409, 1135 (3d ed. 1992)).

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It is undisputed that in the course of seeking the '815 patent, Ortho advised the Patent and Trademark Office (PTO) that its Ortho Tri-Cyclen Lo invention was an independently patentable species of the genus that had previously been disclosed in the Pasquale Patents. See Plt. Ex. 2, Petition to Make Special, August 30, 1999 at 5 ("The ['839 and '006 Pasquale] patents disclose and claim a genus of triphasic regimens which is generic to the inventive triphasic regimes of the present invention."). The Patent Examiner initially rejected this petition on "obviousness" grounds, but later permitted the '815 patent because Ortho had demonstrated that its claimed species had unexpected properties over the Pasquale genus: The Patent Office "Amendment" explains that

[t]he cycle control of a 35 [mu]g EE daily dose triphasic regimen is compared to the same regimen containing 25 [mu]g EE daily dose. In this comparison, the commensurate or expected drop in cycle control is not seen. Thus . . . Applicants have found that the EE dose can be substantially reduced . . . with surprisingly little or no significant loss of cycle control.

Plt. Ex. 4, Amendment, February 22, 2000. "One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). Here, it is undisputed that the '815 patent was ultimately allowed because the applicant demonstrated the unexpected result of "excellent cycle control" comparable to prior-art, higher-dose methods.

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The core of the matter before the court is whether this fact--that "excellent cycle control" is the characteristic that made the '815 invention patentable--necessarily implies that the characteristic is a limitation on the disputed terms in claims 1 and 4. 2 Ortho maintains that it does, and that an oral contraceptive regimen will prevent pregnancy only if the steroid doses are (1) sufficient to produce contraceptive effects and, (2) are administered as part of a regimen in which there is good or excellent cycle control, i.e., relatively little unscheduled bleeding or spotting (the primary reason why women discontinue oral contraceptive therapy). See Ortho's Memorandum Regarding Claim Interpretation ("Plt. Mem.") at 2 (citing the '815 patent, col. 1, ll. 25-38, noting that cycle control in the form of unscheduled bleeding and spotting is common in products in which the dosage of the estrogen component has been reduced). Thus, Ortho proposes that the disputed terms should be construed as follows:

. "method of contraception" refers to a regimen that effectively prevents conception (with contraceptive efficacy comparable to approved or potentially approvable oral contraceptive products) and delivers excellent cycle control; and

. "oral contraceptive unit" refers to an oral contraceptive product that effectively prevents conception and delivers excellent cycle control.

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2 Ortho argues that rather than seeking to "limit" claims 1 and 2, it seeks only to define the disputed terms in those claims. Transcript of Oral Argument, March 31, 2005 ("Transcript") at 30, ll. 1-3; 72, ll. 16-18. This characterization unconvincing--the construction sought by Ortho would necessarily limit the scope of the claims, to call it anything other than a limitation is disingenuous.

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Barr agrees that the ordinary meanings of "method of contraception" and "oral contraceptive unit" include that the regimen effectively prevent pregnancy. See Def. Mem. at 7, 10-11; Def. Reply at 14. Barr asserts, however, that "delivers excellent cycle control" should not be read into the terms "method of contraception" and "oral contraceptive unit." Barr maintains that the PTO's decision to allow the '815 patent on the grounds of "excellent cycle control" does not preordain that "excellent cycle control" is a limit on the claims. The legal authority marshaled on both sides is discussed in detail below.

II. Legal Standard

The court may utilize numerous sources for guidance in determining the proper construction of a claim. It is well-settled, however, that the Court should first consult the claim language, the patent specification and the prosecution history on record, which together constitute the "intrinsic evidence." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Id. As a general matter, moreover, "claims should be read in a way that avoids ensnaring prior art if it is possible to do so." Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1153 (Fed. Cir. 1997).

Thus, the Court must look to the words of the claims themselves to define the scope of the patented invention, and to the extent that "it expressly defines terms used in the claims or when it defines terms by implication," the specification acts as a dictionary. Vitronics, 90 F.3d at 1582. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it." Aventis Pharmaceuticals, Inc. v. Barr Labs., Inc., 341 F. Supp. 2d 502, 507 (D.N.J. 2004) (citing 35 U.S.C. § 112). "Thus, the specification is always highly relevant to the claim construction analysis. 'Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Id. (citing Vitronics, 90 F.3d at 1582).

The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Vitronics, 90 F.3d at 1582. "As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims." Id. at 1582-83; Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.") (citations omitted)). In addition, an analysis of the file history may include an examination of the prior art cited therein. Id.

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(citing Autogiro Co. of America v. United States, 384 F.2d 391, 399, 181 Ct. Cl. 55 (Fed. Cir. 1967) ("In its broader use as source material, the prior art cited in the file wrapper gives clues as to what the claims do not cover.") (citations omitted)).

"Relying on extrinsic evidence to construe a claim is proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." Interactive Gift Exp., Inc. v. Compuserve Inc., 256 F.3d 1323, 1332 (Fed. Cir. 2001) (citations omitted). "Such instances will rarely, if ever, occur." Id. Thus, while dictionaries, "are a form of extrinsic evidence, [which] hold a special place and may sometimes be considered along with the intrinsic evidence," the court should only do so where "the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Id. at 1332 n.1.

II. Discussion

Because it is undisputed that the ordinary meanings of the terms "method of contraception" and "oral contraceptive unit" do not include "excellent cycle control," in order to determine whether "excellent cycle control" nevertheless limits those terms, the patent specification and prosecution history must be considered. Where the patentee has clearly narrowed the scope of the claims in the patent specification and during prosecution, the court must construe the claims accordingly. See C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004). Dictionary definitions can be limited or overcome where the patentee has clearly set forth an explicit definition of the term different from its ordinary meaning, or otherwise disavowed or disclaimed the claim scope. Id. at 862.

A. The '815 Patent Specifications

First, the '815 patent's specification must be considered. Ortho argues that because the specification consistently describes the invention as providing "excellent cycle control," and unexpectedly so, comparable to the higher-dose prior art, claims 1 and 4 must be construed to include this function. Specifically, Ortho cites the "Background" and "Summary of the Invention" sections which, inter alia, describe the necessity of meeting the need for a low dose (less than 30 [mu]g of estrogen) oral contraceptive unit "having cycle control equivalent to an OC [oral contraceptive] of higher estrogen content." See the '815 patent, col. 2, ll. 21-23. In addition, the "Background" section notes that inventors recognized past efforts to reduce total monthly steroid dose, but nevertheless identified a continuing need "for a combination type oral contraceptive, which contains even lower total monthly steroid doses, particularly of estrogen yet is still effective for the prevention of pregnancy and maintains a high level of cycle control" and for a triphasic contraceptive regimen "with substantially lower doses of estrogen . . . [that] does not exhibit a substantial loss of cycle control." Id., col. 3, ll. 6-13. 3

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3 Other references to good or excellent "cycle control" in the specifications include:

(1) further statements in the "Summary of the Invention" section that "[a]pplicants have surprisingly discovered for this triphasic regimen, . . . that the reduced level of estrogen administration does not result in a commensurate reduction of cycle control," Id., col. 3, ll. 41-45; and

(2) with respect to only one embodiment (the regimen disclosed in claims 1 and 4), the inventor explained that "the incidence of irregular bleeding for this 25 [mu]g EE triphasic regimen is unexpectedly comparable to the incidence of irregular bleeding for the 35 [mu]g EE triphasic as described in Comparative Example 1 [the Ortho Tri-Cyclen regimen]," Id., col. 12, ll. 27-30.

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Ortho posits that in light of these references, patent claims 1 and 4 should be interpreted consistently with the stated purpose of the invention--"effective cycle control." In support, Ortho cites SuperGuide Corp. v. DirecTV Enters. Inc., 358 F.3d 870, 893-95 (Fed. Cir. 2004), which consults the stated purpose of an invention in defining claim terms, and Altiris, Inc. v. Symantec Corp., 318 F.3d 1363 (Fed. Cir. 2003) for the same proposition. Ortho additionally points out that "[a]lthough words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.

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Cir. 1996).

But as Barr points out, to rely on the specification for guidance as to the meaning of claim terms, references must be clearly and deliberately linked to particular claim terms. As stated in Johnson Worldwide Associates, Inc. v. Zebco Corp.,

> . . . "a party wishing to use statements in the written description to confine or otherwise affect a patent's scope must, at the very least, point to a term or terms in the claim with which to draw in those statements." . . . That is, claim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources. . . . In other words, there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction.

175 F.3d 985, 989-90 (Fed. Cir. 1999) (citations omitted) (emphasis added).

In particular, the Federal Circuit has only reluctantly imported, from specifications or prosecution history, language that limits a claim. See e.g., E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed Cir. 1988) ("[T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'"); Bayer AG. v. Biovail Corp., 279 F.3d 1340, 1348 (Fed. Cir. 2002) (citing DuPont); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed. Cir. 1993) (same); Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (same).

Specific examples mentioned in Johnson, moreover, where reference to the specification or prosecution history was "clearly invited," include patent applicants who have explicitly chosen to be their own lexicographer and cases where the "the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used." Johnson, 175 F.3d at 989-90. In this case, there is no claim that the patentee acted as his own lexicographer. Nor do the disputed terms "so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used," as evidenced by the fact that the agreed upon ordinary meanings of the terms--if that were the end of the story--leave the scope of the claims readily ascertainable.

Nor do the '815 patent specifications, in any other manner, disavow the scope of claims 1 and 4. The passages quoted above from the patent specifications indeed make repeated reference to "excellent cycle control," but nowhere do these references clearly or consistently set out to limit or define the terms "method of contraception" or "oral contraceptive unit." If anything, these references merely offer a more detailed description of the embodiment disclosed in claims 1 and 4--they do not go so far as to define, in particular, the "method" or the "unit" set forth in those claims. If the Court applied Ortho's logic, then the whole of the specification, to the extent that it describes the functions and benefits of the claimed invention, would be incorporated by reference into the more precise, limited language of the claims. This logic would obviate the need to draft claims at all and cannot be adopted.

The specifications remain relevant, lastly, to the extent that they "consistently and clearly use a term in a manner either more or less expansive than its general usage in the relevant community, and thus expand or limit the scope of the term in the context of the patent claims." ResQNet.com v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003). Here, if anything, the term "contraceptive" and "method of contraception" are consistently used in the specifications in a manner that is more expansive than Ortho's suggested construction. A particularly pertinent example is the discussion of prior-art, low-dose regimens which prevent pregnancy without providing excellent cycle control. Despite the fact that they fail to achieve what Ortho claims is the sine qua non of the invention, these regimens are referred to throughout the '815 patent as "oral contraceptives." See also the '815 patent, claims 2 & 3 (disclosing an embodiment with, inter alia, different progesterones and different "pill free" intervals than claims 1 and 4, as well as potentially different side effect profiles, while still using the terms "oral contraceptive unit" and "method of contraception"). As Johnson teaches, "varied use of a disputed term in the written description demonstrates the breadth of the term, rather than providing a limited definition." Johnson, 175 F.3d at 991. By way of contrast to this case, in Bard, where the dispute was whether "pleats" were an unstated, limiting characteristic of the claimed invention, the specifications were clear that all possible embodiments of the patented structure, all "included a pleated surface." See Bard, 388 F.3d at 865.

B. The '815 Patent Prosecution History

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Since claims 1 and 4 clearly do not incorporate language regarding "excellent cycle control" from the specifications, the Court must next look to the prosecution history. As discussed above, the prosecution history of a patent is a primary source in the intrinsic record for construing the claims: A dictionary definition will be overcome where the patentee has clearly set forth an explicit definition of the term different from its ordinary meaning, or otherwise disavowed or disclaimed claim scope. Bard, 388 F.3d at 861, 863. "Unless altering claim language to escape an examiner rejection, [however] a patent applicant only limits claims during prosecution by clearly disavowing claim coverage." York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1575 (Fed. Cir. 1996) (emphasis added).

In Bard, the patentee of an internal hernia plug distinguished the claimed invention over the prior art based on, among other things, the use of a pleated outer layer--the patent was allowed on the basis of this distinction. Bard, 388 F.3d at 863-67. Here, Ortho argues that the Examiner's initial, obviousness-based rejection, together with the ultimate allowance of the patent because of unexpectedly good cycle control, amount to a clear disavowal of claim coverage.

Bard, however, did not construe the claims as including pleats merely because the invention was distinguished from the prior art based upon its pleating. See Bard, 388 F.3d at 867 (noting that the applicant's reliance on pleats, among other things, in the initial PTO examination was insufficient to read that limitation into all of the claims). Rather, it was the applicant's unequivocal statement, upon reexamination, that the "the surface of the inventive plug is pleated" that amounted to a clear disclaimer of claim scope: "Bard clearly defined the plug in claim 20 as having pleats." In other words, in Bard, the applicant clearly disclaimed the scope of the invention proper. 4 Unlike Bard, here, the prosecution history of the '815 patent at most disclaimed a function or secondary effect of the invention. Here, there has been no disavowal of the scope of the invention itself (which invention, it is clear from the '815 patent, is a contraceptive method and contraceptive unit not merely a function or secondary effect 5).

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4 The parties dispute whether Bard construes the claim term "plug"--the invention proper-- or the functional claim terms "conformable" and "pliable." Judge Michel's Opinion and Judge Prost's Concurrence are both clear, however, that while there was an effort made to infer that the inventive plug was not pleated based on the terms "conformable" and "pliable," the dictionary definitions of these terms did not have to be consulted because the intrinsic record demonstrated that claim scope turned most directly on construction of the term "plug." See Id. at 863; Id. at 870 (Prost, C.J., concurring).

5 There has been some effort on the part of Ortho to define the '815 patent's "invention," as effective cycle control achieved through the "method" described in claim 1 and use of the "unit" described in claim 4. See Transcript at 72, ll. 17-18 (Ortho: "We are saying that cycle control is the invention."). Specifically, Ortho advances the following troublesome argument: Without excellent cycle control, the resulting unscheduled bleeding and other side effects cause women to stop taking the "contraceptive unit," and discontinuance of the regimen disables its contraceptive function.

But the court takes note that it is the "method" and the "unit" that are patented here--and any attempt to present "effective cycle control" as just another a step in the patented method, runs into difficulty. This attempt to shoehorn "cycle control" into the inventive terms "contraceptive" or "contraceptively effective" is futile: Not only does the ordinary meaning of the term "contraceptively effective" belie such a definition, but besides that, Ortho makes no effort to suggest that the method disclosed would fail to prevent pregnancy in the cases of women who continue the regimen despite poor cycle control.

Without evidence of a physical effect arising from "excellent cycle control," or lack thereof, a method that prevents conception or impregnation must be considered contraceptively effective without regard to side effects. Any number of factors lead women to discontinue their birth-control regimens, ranging from weight gain to moral strictures--by Ortho's logic, the '815 regimen would have to control for all of these in order to be contraceptively effective--and as Barr emphasized in their Reply, "[t]o state the argument is to see its absurdity." Def. Reply at 16.

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A more apt comparison can be drawn to E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430 (Fed. Cir. 1998). In DuPont the Federal Circuit held that the district court erred when it concluded that the "essence of the invention"--the superior results achieved by the invention's copolymers when compared with the prior art--must be read into the claim

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terms. See E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1432-33 (Fed. Cir. 1998). DuPont's teaching is clear: While unexpected or superior results may be considered the "essence of the invention" by the PTO and the patentee, and while the invention may be patentable on that basis alone, those unexpected or superior results are not necessarily included within the patent claims. Id. at 1432-33 (citing United States v. Adams, 383 U.S. 39, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293 (1966)); see also Intervet America Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (citing DuPont with approval).

In short, this case most closely parallels DuPont. Ortho cites no cases which suggest that the "unexpected results" that make an invention patentable become, on that ground alone, an implied limitation on the patent claims. Bard only goes so far as to demonstrate that there are circumstances where the features that distinguish an invention from the prior art may be implicit in the claims. DuPont complements Bard by showing that such features indeed may, but need not, be implied in claim language. Not only is there no case law to support Ortho's position, but--insofar as the standards applied by the patent office to determine the patentability of an invention remain distinct from the standards applied by courts to determine what has been patented--logic and restraint suggest that courts ought not conflate these distinct inquiries.

For all of these reasons, the patent prosecution history does no more to incorporate "excellent cycle control" into claim terms 1 and 4 than did the specifications. Ortho's proffered construction must be rejected. In construing patent claims, we are not at liberty to resort to an "Alice-in-Wonderland" lexicon:

"When I used a word," Humpty Dumpty said in a rather scornful tone, "it means just what I choose it to mean--neither more nor less."

"The question is," said Alice, "whether you can make words mean so many different things."

L. Carroll, Alice's Adventures in Wonderland and Through the Looking Glass 169-71 (1981) (emphasis in original). The answer to Alice's question, and to that raised by this case, is decidedly no, you cannot make words mean so many different things.

III. Conclusions

The term "method of contraception" in claim 1 of the '815 patent shall be construed in all future proceedings, pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), as a means or manner that effectively prevents conception or impregnation (with contraceptive efficacy comparable to approved or potentially approvable oral contraceptive products).

The term "oral contraceptive unit" in claim 4 of the '815 patent shall be construed in all future proceedings, pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), as a plurality of oral contraceptive pills assembled in a package that will allow women of child bearing ability to effectively prevent conception for at least a four week interval or one cycle.

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With respect to the term "control region," which appears in the representative claims of all three asserted patents, the district court originally propounded the following construction:

"a piece of DNA, containing at least a promoter, an operator, and a ribosome binding site, that is the part of the recombinant DNA cloning vehicle that directs and regulates expression of the structural gene. The control region must be taken from a single operon; it may not be constructed from control elements derived from various operons."

Id. at 24. Judge Smith further found that "DNA [comprising the control region] may be 'taken from' the listed sources: it may be physically obtained, cloned, partially chemically synthesized or totally chemically synthesized." Id. at 37-38.

Nevertheless, in his summary judgment ruling, Judge Alsup interpreted Judge Smith's claim construction to include a limitation on the method of obtaining the control region. In confirming that the definition of "ribosome binding site"

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necessarily includes the linker DNA, Judge Alsup stated that "were the term 'ribosome binding site' reduced to the Shine-Dalgarno sequence and the start codon ATG, it would be impossible to determine whether a ribosome binding site was derived from the same operon as the promoter and the operator, a requirement of the term 'control region.'" Amended Summary Judgment Order at 14. Judge Alsup assumed that the control region must possess control elements that correspond to one and only one operon. Hence, Judge Alsup concluded that Amgen's ribosome binding site DNA was not physically "taken from" the bacteriophage lambda. Id.

Genentech asserts that by this language, Judge Alsup misapprehended the meaning of the claim term "control region" by requiring (1) that the method used to construct the control region use only one operon, and (2) that to prove this single operon source requirement was satisfied, the sequence of each control element must correspond to a control element found in one, and only one, operon. 2

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2 Amgen responds that the district court did not limit the claims to a particular method of constructing an operon, but instead properly construed the "control region" limitation to require that the control elements be endogenous to the host cell. This court cannot accept Amgen's interpretation of the Summary Judgment Order, as Judge Alsup's rejection of Genentech's proposed construction of the term "ribosome binding site" on the basis of inability to determine from which operon the ribosome binding site was derived necessarily limits the methods by which a control region is constructed.

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This court agrees with Genentech on this point. 3 The district court did not appreciate the distinction between the content (sequence) of the control region and the method by which one constructs the control region. Genentech does not argue that the patent supports an interpretation of "control region" that includes so-called hybrid control regions in which the operator, promoter, and ribosome binding site sequences do not correspond to the three control elements' sequences found in a single operon. Rather, it argues that as long as the sequence of the control elements correspond to the sequence of the control elements found in a single operon, the "control region" limitation is satisfied, irrespective of whether a single operon was used to construct it. 4

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3 It appears that the confusion between the sequence of the control region and the method for constructing it arose from the original claim construction's requirement that the control region "be taken from a single operon." This construction is only correct to the extent that it is understood to refer to a control region containing a sequence that corresponds to the sequence of the control elements in a single operon, so that it is not a hybrid control region.

4 The district court (Judge Smith) rejected Amgen's contention that the control region must be intact, i.e., identical to a control region native to the untransformed host. Judge Smith found that the specification and file history in fact refuted Amgen's proposed limitation requiring the use of a single operon "taken intact" to construct the control region. Rather, she noted: "What these examples disclosed in the patent suggest is that some variation from the native control region of the untransformed host is permissible as long as the control region remains operable. In short, the control region need not be 'intact.'" Id. at 19-20.

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In the context of the patented invention, the term "control region" describes functional control elements involved in the production of a protein and is directed to a sequence of DNA, not a method for constructing such a sequence. Rather than requiring a limitation on the method of constructing a control region, the patent appears to preclude one. In the section titled "The Control Elements," the specification discloses using a control region comprising "control elements" derived from a bacteriophage infective for E. Coli. '362 Patent, col. 8, ll. 45-48. The specification further suggests obtaining control elements from "other operons or portions thereof." Id. at col. 8, ll. 56-60.

Likewise, the prosecution history shows that a control region may be constructed portion-by-portion. In an amendment submitted to the PTO on January 11, 1996, the patentee explained: "The specification quite clearly supports the preparation

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of expression control regions wherein the elements are taken from various sources, including partial or total synthesis, and operatively linked by generally well-known ligation means to provide functional, homologous expression control region as such." Amendment submitted to U.S. Patent and Trademark Office, U.S. Application Serial No. 08/434,321, at 6 (Jan. 11, 1996).

Thus, all the control elements of a single operon need not be derived from a single operon to comprise a control region in the context of the patented invention, and the district court's contrary conclusion was in error. For purposes of satisfying the control region limitation, some control elements may be physically derived from an operon and other control elements may be chemically synthesized or physically derived from a different operon, as long as the sequence of the three control elements in the control region correspond to the sequence found in a single operon. This court thus finds error in the district court's requiring that each control element be unique, so as to make it possible to determine whether it was derived from the same operon as the other control elements. Simply put, the method by which the control region is constructed and the sources from which it is derived are inapposite, thus negating any requirement that such methods or sources be discernable from the sequence of the control elements.
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Controlling the Amount of Said Protic Material
The Amount of Protic Material in Step(b) is Controlled

The parties also seek construction of two similar terms: "controlling the amount of said protic material in step (a) or (b) to provide a selectivity of at least 0.97, wherein the selectivity is the molar ratio of 4-ADPA intermediates" and "the amount of protic material in step (b) is controlled." The Court agrees with Defendants that these terms have been used interchangeably with "controlled amount of protic material," and are entitled to a similar construction.

The Federal Circuit gives like treatment to terms that are used within the specifications interchangeably. In Terhani v. Hamilton Med. Inc., the court applied the same interpretation to the terms "indicative of" and "representing" because "the intrinsic evidence indicates that the patentee meant for these two terms to be interchangeable and to carry the same meaning within the claims." 331 F.3d 1355, 1361 (Fed. Cir. 2003). Similarly, in Tate Access Floors, Inc v. Maxcess Techs., the court construed the terms "inner layer" and "inner body portion" in the same manner because "they are used interchangeably in the specification." 222 F.3d 958, 968 (Fed. Cir. 2000).

Turning to the specifications for the patents-in-suit, it is clear that Flexsys never drew a distinction between the terms "controlled amount," "controlling the amount," and "is controlled." For example, the specifications provide: "[c]ontrol of the amount of protic material present in the reaction is important" ('063 patent, col. 4, ll. 30-32;' 111 patent, col. 5. 11. 27-28 and col. 10, ll. 30-31); "[a] 'controlled amount' of protic material is an amount up to that which inhibits the reaction […]" ('063 patent, col. 4, ll. 48-52; '111 patent, col. 5, ll. 43-47); "[t]he present invention relates to methods for preparing 4-aminodiphenylamine […] wherein the amount of protic material, e.g., is controlled, to produce a mixture […]" ('063 patent, col. 4, ll. 48-52; '111 patent, col. 1, ll. 15-22); and "the continuous distillation of protic material is the currently preferred method for controlling the amount of protic material […]." 16 ('111 patent, col. 6, ll. 40-44) (emphasis added).

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16 In addition, Dr. Maleczka testified that the terms "controlled" and "controlling" were used in an interrelated way. (TR at 179.)

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As for the claims, it is clear in claim 7 of the '111 patent that the phrase "the amount of protic material in step (b) is controlled" is referring to the "controlled amount of protic material" that is identified at column 21, lines 4-5, and has been previously defined by the Court. The same analysis applies to claim 11. As for claim 23, "controlling the amount of said protic material in step (a) or (b) to provide a selectivity of at least 0.97, wherein the selectivity is the molar ratio of 4-ADPA intermediates" also corresponds to the "controlled amount" of protic material that is critical to the reaction and has previously been defined.

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Thus, the Court construes "the amount of protic material in step (b) is controlled" to mean "the amount is controlled so that it is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent." The phrase "controlling the amount of protic material" in claim 23 also has the same meaning as "is controlled" and "controlled amount." As for the second half of the term, "to provide a selectivity of at least 0.97, wherein the selectivity is the molar ratio of 4-ADPA intermediates to undesired products," the Court finds that a person of ordinary skill in the art is readily familiar with the formula set forth in this phrase and, therefore, no construction is necessary.
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The main issue on appeal is the meaning of the claim term "controlled amount." The parties here agree that "controlled amount" does not have any well-accepted meaning in the field of chemistry. Sinorgchem contends that the ITC misconstrued the term "controlled amount" and on that basis erred in finding infringement. Claim construction is a question of law which we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

Our opinions have repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification. See, e.g., CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("[A] claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in . . . the specification . . . ."); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.").

The approach of those cases was endorsed in Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). In Phillips, we described the specification as "the single best guide to the meaning of a disputed term." Id. at 1315 (citing Vitronics, 90 F.3d at 1582). We confirmed that "our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Id. at 1316.

Here, the drafters have done just that. The specification states:

A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent.

'063 patent col.4 ll.48-52. The term "controlled amount" is set off by quotation marks--often a strong indication that what follows is a definition. See, e.g., Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) (finding that the claim term "water-soluble polydextrose" was expressly defined in the specification). Moreover, the word "is," again a term used here in the specification, may "signify that a patentee is serving as its own lexicographer." Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1210 (Fed. Cir. 2007). As such, the patentee must be bound by the express definition. See Durel Corp. v. Osram Sylvania Inc., 256 F.3d 1298, 1303-04 (Fed. Cir. 2001). Here the drafter clearly, deliberately, and precisely defined the term "controlled amount" of protic material as "an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent." 1 Elsewhere in the same paragraph, the specification again refers to the 4% limit. 2

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1 Flexsys cites Conoco, Inc., v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1358 (Fed. Cir. 2006), Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998), and Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996) for the proposition that a claim construction should not import numerical limits into a claim that does not contain such limits. But cases like these have no application here, where the numerical limit is included within an express definition set forth in the specification. 2 The specification states:

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Control of the amount of protic material present in the reaction is important. Generally, when the reaction is conducted in aniline, water present in the reaction in an amount greater than about 4 H[2]O, (based on volume of the reaction mixture) inhibits the reaction of the aniline with the nitrobenzene to an extent where the reaction is no longer significant. Reducing the amount of water to below the 4 level causes the reaction to proceed in an acceptable manner. When tetramethylammonium hydroxide is utilized as a base with aniline as the solvent, as the amount of water is reduced further, e.g., down to about 0.5 based on the volume of the reaction mixture, the total amount of 4-nitrodiphenylamine and 4-nitrosodiphenylamine increases with some loss in selectivity so that more 2-nitrodiphenylamine is produced but still in minor amounts. Thus, the present reaction could be conducted under anhydrous conditions. A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4 H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent. The upper limit for the amount of protic material present in the reaction varies with the solvent. For example, when DMSO is utilized as the solvent and tetramethylammonium hydroxide [TMAH] is utilized as the base, the upper limit on the amount of protic material present in the reaction is about 8 H[2]O based on the volume of the reaction mixture. When aniline is utilized as a solvent with the same base [TMAH], the upper limit is 4 H[2]O based on the volume of the reaction mixture. In addition, the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used in the various solvent systems. However, it is within the skill of one in the art, utilizing the teachings of the present invention, to determine the specific upper limit of the amount of protic material for a specific solvent, type and amount of base, base cation and the like. The minimum amount of protic material necessary to maintain selectivity of the desired products will also depend on the solvent, type and amount of base, base cation and the like, that is utilized and can also be determined by one skilled in the art.

'063 patent col.4 l.31--col.5 l.4 (emphases added).

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The ITC agreed that the patentee had expressly defined the term "controlled amount" in the specification but held that the language "e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent" should not be considered part of that definition for two reasons. Neither of these reasons is persuasive. First, the ITC dismissed the 4% limit as merely an example that did not apply to all situations in which aniline was used as the solvent. The ITC relied particularly on the emphasized language in the following passage:

When aniline is utilized as a solvent with the same base [TMAH], the upper limit is 4% H[2]O based on the volume of the reaction mixture. In addition, the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used in the various solvent systems. However, it is within the skill of one in the art, utilizing the teachings of the present invention, to determine the specific upper limit of the amount of protic material for a specific solvent, type and amount of base, base cation and the like.

'063 patent col.4 ll.58-68 (emphasis added). The ITC found that this language made clear that the "e.g., up to about 4% H[2]O" language was used in the specification as an example and not a definition of the amount of water permitted when aniline is the solvent. 3

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3 On appeal, the ITC relies on expert testimony that "a person of skill in the art would recognize the example of 4 water to be limited to the conditions of room temperature and ambient pressure." Br. of Appellee at 22. We attribute no weight to that testimony because the experts did not identify any evidence that those skilled in the art would recognize that "controlled amount," or any term used in the specification, has an accepted meaning in the field of chemistry. Under such circumstances, testimony as to how one skilled in the art would interpret the language in the specification is entitled to little or no weight.

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We disagree. This vague language cannot override the express definitional language. We have frequently found that a definition set forth in the specification governs the meaning of the claims. See, e.g., Cultor Corp., 224 F.3d at 1330. "When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to

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search further for the meaning of the term." Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998). When aniline is used as the solvent, the express definition is neither ambiguous nor incomplete--the "controlled amount" is "up to about 4% H[2]O based on the volume of the reaction mixture"--and we need look no further for its meaning. Nor is the specification passage relied on by the ITC inconsistent with the express definition of "controlled amount," since the passage refers generally to at least six different solvents while the definition refers specifically to reactions in which aniline is the solvent. Moreover, the specification sets forth a different limit of "about 8% water" for the "controlled amount" of protic material when DMSO is the solvent. Quite tellingly, aniline and DMSO were the only two solvents of the six solvents mentioned in the specification for which an express numerical limit was given for the "controlled amount." The quoted "will vary" language appears to refer to the four other solvents for which a specific percentage was not provided.

Second, the ITC found that the 4% language was inconsistent with Example 10 (which appears identically in both the '063 and the '111 patents), a "preferred embodiment," which uses more than 10% water in a reaction where aniline is the solvent. Despite the high level of water used in Example 10, the reaction yields a high percentage (92.8%) of 4-ADPA intermediates. On appeal, both the ITC and Flexsys support the ITC's decision by relying on statements in our case law that we do "not normally interpret a claim term to exclude a preferred embodiment," Primos, Inc., v. Hunter's Specialties, Inc., 451 F.3d 841, 848 (Fed. Cir. 2006), as would be the case if the 4% limit were applied to the claims. This rule has particular force where the claims as construed do not encompass any disclosed embodiments. See Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1355 (Fed. Cir. 1998) ("A patent claim should be construed to encompass at least one disclosed embodiment in the written description portion of the patent specification.") (emphasis added). This is not the case here. Example 10 is merely one of twenty-one distinct examples set out in the two specifications, all of which are described as "preferred embodiment[s]." '111 patent col.8 ll.5-8.

Where, as here, multiple embodiments are disclosed, we have previously interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history. Telemac Cellular Corp. v. Topp Telecom, lnc., 247 F.3d 1316, 1326 (Fed. Cir. 2001); see also N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335 (Fed. Cir. 2005). In Telemac, the district court looked to the specification to determine the meaning of the claim term "communication means," since that term was written in the claim in "means-plus-function" form. 247 F.3d at 1324. Telemac challenged the district court's construction on the basis that it left certain embodiments inoperable. Id. at 1326. We held that the description of those embodiments did not call for a different construction. Id. Instead, we held that those embodiments "could not provide the structure or equivalent structure for performing the claimed function" and were therefore outside of the scope of the claims. Id. See also Rheox, Inc. v.
Entact, Inc., 276 F.3d 1319, 1327 (Fed. Cir. 2002) ("where the prosecution history requires a claim construction that excludes some but not all of the preferred embodiments, such a construction is permissible") (emphasis added).

It is moreover significant that Example 10 does not specifically disclose the amount of water used in the reaction. Instead, the amount of water used in that reaction can only be determined by a complex calculation. 4 In stark contrast, the patentees in Tables 2 and 6, accompanying Examples 3 and 8 respectively, specifically disclose the amount of water used in those reactions. '063 patent col.9 ll.32-48, col.11 ll.25-33. In Example 3, for example, the amount of water added to the reaction where aniline is the solvent ranges from 2.2 to 4.7%, and illustrates the effect of water on the yield of 4-NDPA and p-NDPA. Table 2 shows that the yield dropped from 0.18 mmole to 0.05 mmole, an unacceptably low level, as the amount of water added was increased from 3.45 to 4.7%. Similarly, Example 8 illustrates the effect of the amount of water added to a reaction where DMSO is the solvent. Water added there ranged from 2.3 to 14.7%, and again shows that the yield dropped to an unacceptably low level when more than 8% water is added. Significantly, Example 10 is not even directed toward illustrating the control of the amount of protic material to be used in the reaction. Rather, its stated purpose is to illustrate "the reaction of aniline, nitrobenzene and tetramethylammonium hydroxide dihydrate under anaerobic conditions at 50 degrees C." '063 patent col.11 ll.61-63. Examples 3 and 8, on the other hand, are explicitly directed toward the control of the amount of protic material:

"[Example 3] illustrates that control of the amount of protic material present in the reaction is important."

. . .

"[Example 8] illustrates the effect that the amount of protic material present in or added to the reaction has on the extent of conversion and yields of 4-NDPA and p-NDPA."

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Id. at col.9 ll.20-21, col.11 ll.10-13. Under these circumstances, the fact that the calculated amount of water in Example 10 exceeds 4% where aniline is used as the solvent is entitled to little weight, and cannot override the clear definitional language set forth in the specification. 5

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4 Flexsys's supplemental filing in response to a question raised at oral argument described how the calculation is conducted. Letter from Mark G. Davis, Sept. 14, 2007. First, one determines the total volume of the reaction mixture from the known volumes of aniline, nitrobenzene, water added, and base. Next, one determines the total mass of water in the base and converts that number to volume of water. By summing the volume of the water added to the volume of water in the base, one can determine the total volume of water in the reaction. Water volume percentage is thus determined by dividing the total amount of water in the reaction by the total volume of the reaction mixture.

5 All parties agreed before the ITC that the disputed term "controlled amount" must be construed to mean the same thing in the claims of the '111 patent as in the '063 patent. Additional examples included in the specification of the continuation-in-part application that led to the '111 patent cannot alter the meaning of the term as it appears in the '063 patent.

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Flexsys further argues that the doctrine of claim differentiation supports the ITC's refusal to read into the claims the 4% water limit. We have characterized the doctrine of claim differentiation generally as the "presumption that each claim in a patent has a different scope." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006) (internal citation omitted). Flexsys points out that independent claim 30 of the '063 patent does not specify a numerical limit for "controlled amount of protic material," while dependent claim 41 recites "up to about 4 v/v % water." 6 Claim 30 states:

30. A method of producing 4-aminodiphenylamine (4-ADPA) comprising the steps of:

a) bringing aniline and nitrobenzene into reactive contact in a suitable solvent system;

b) reacting the aniline and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and controlled amount of protic material to produce one or more 4-ADPA intermediates; and

c) reducing the 4-ADPA intermediates under conditions which produce 4-ADPA.

'063 patent col.14 ll.16-26 (emphases added). Claim 41 states:

Method of claim 30 wherein said solvent system includes aniline and up to about 4 v/v % water based on the total volume of the reaction mixture.

Id. at col.14 ll.50-52 (emphasis added).

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6 Flexsys also points to the same relationship between non-asserted independent claims 1 and 61 and dependent claims 12 and 72 of the '063 patent. For the reasons described in the text, the existence of these dependent claims is also not persuasive.

Flexsys, but not the ITC, relies in passing on claim 29 of the '111 patent, which, in addition to specifying that the process involves "reacting" in the presence of a "controlled amount" of protic material, states that "the amount of protic material present at the beginning of the reaction is up to about 13.8 volume water based on the total volume of the reaction mixture." Flexsys has not explained how the presence of 13.8% water at the beginning of the reaction is necessarily inconsistent with a "controlled amount" of 4% during the operative part of the reaction.

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Thus, according to Flexsys, interpreting "controlled amount" in claim 30 to have an upper limit of "e.g., up to about 4% H[2]O . . . when aniline is utilized as the solvent" would render the scope of the independent claim and the dependent claim identical. Flexsys's argument might have some merit if claim 30 referred only to aniline solvents. But it does not. Claim 30 refers generally to "a suitable solvent system," which, as the specification indicates, can include "dimethylformamide, aniline, pyridine, nitrobenzene, nonpolar hydrocarbon solvents such as toluene and hexane, ethyleneglycol dimethyl ether, diisopropyl ethylamine, and the like, as well as mixtures thereof." '111 patent col.4 ll.24-27. Because claim 41 refers merely to a subset of the solvent systems described in claim 30, and is significantly narrower in scope, the claims are not rendered identical and present no claim differentiation problem. Therefore, Flexsys's claim differentiation argument is without merit.

For these reasons, we hold that the correct claim construction of the term "controlled amount" is that defined expressly in the specification, namely: "an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent."
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I do not join the panel majority in its reversal of the Commission's finding of literal infringement. No error of fact or law has been shown in the Commission's determination; indeed the Commission's findings are scarcely mentioned. Instead, my colleagues have made findings contrary to the detailed and unchallenged text of the patent specifications, and have construed the claims so that they exclude a major part of the invention described in the patents. I must, respectfully, dissent.

The basic principle of determining the scope of patent claims is that the claims provide the legal definition of the invention that is patented, based on the descriptive text and controlled by the prosecution history, with cognizance of the prior art. A patentee can reduce or disclaim claim scope to cover less than what is described in the specification. Here, however, there was no disclaimer of the scope set forth in the patent specifications and claims; there is no prior art to limit the claims in the way selected by the panel majority; and there is no reason to insert an absolute numerical limit of "about 4%" protic material into the claims that do not contain a numerical limit, when the specifications of both patents demonstrate significantly higher percentages. There was no evidence contradicting the evidence of the experts concerning the range of protic material set forth in the specifications' text and illustrated in the specific examples.

The Commission correctly construed the "controlled amount of protic material" to match the content of the specifications and claims. The Commission's findings concerning the amount of protic material shown in the specifications are supported by substantial evidence, the statutory standard for review of the agency's findings, 19 U.S.C. §1337(c), and its claim construction is in accordance with law. The panel majority has seriously erred in discarding the Commission's findings and conclusions, for they are not only supportable on the required standard of review, but they also are correct.

The products at issue are N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6-PPD) and 4-aminodiphenylamine (4-ADPA), from which 6-PPD is derived. The complaint charged that the 4-ADPA and 6-PPD are produced using a process that is covered by claims 30 and 61 of Patent No. 5,117,063 and claims 7 and 11 of Patent No. 5,608,111. The '111 patent issued from a continuation of an application that led to Patent No. 5,453,541 (not in suit here), which was a continuation-in-part to the application that led to the '063 patent. The patents describe and claim conducting the process by the direct reaction of aniline and nitrobenzene in the presence of a solvent, a base and a "controlled amount" of protic material as set forth in step (b) of the overall process. Claim 61 of the '063 patent is representative:

61. A method of producing alkylated p-phenylenediamines comprising the steps of:

a) bringing aniline and nitrobenzene into reactive contact in a suitable solvent system;

b) reacting the aniline and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and controlled amount of protic material to produce one or more 4-ADPA intermediates;

c) reducing the 4-ADPA intermediates under conditions which produce 4-ADPA; and

d) reductively alkylating the 4-ADPA of Step c).

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The patents explain that the presence of a controlled amount of protic material produces the environmental advantage of avoiding halide waste products, and reduces manufacturing and material costs because it permits the direct reaction of aniline and nitrobenzene, instead of requiring the preparation of intermediate compounds as in the prior art.

The claims in suit do not include numerical limits for the "controlled amount" of protic material, and the specifications define the amount as varying with the solvent, base, base cation, and the like. The '063 patent states (with emphases added):

A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent. The upper limit for the amount of protic material present in the reaction varies with the solvent. For example, when DMSO is utilized as the solvent and tetramethylammonium hydroxide is utilized as the base, the upper limit on the amount of protic material present in the reaction is about 8% H[2]O based on the volume of the reaction mixture. When aniline is utilized as a solvent with the same base, the upper limit is 4% H[2]O based on the volume of the reaction mixture. In addition, the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used in the various solvent systems. However, it is within the skill of one in the art, utilizing the teachings of the present invention, to determine the specific upper limit of the amount of protic material for a specific solvent, type and amount of base, base cation and the like.

Id., col. 4, lines 48-68. The "teachings of the present invention" are extensive and detailed. The Commission defined "controlled amount" as "an amount up to that which inhibits the reaction of aniline and nitrobenzene." This definition is in accord with the patent specifications, but it is rejected by the panel majority, who limit "controlled amount" to the part of the patentee's statement about using up to 4% water where there is excess aniline and no other solvent, and exclude all of the other variables that affect the amount of water, as demonstrated in the specifications' text and specific examples. The panel majority promotes the number that is described for one condition, to a limit under all conditions, contrary to the specifications. It is not the judicial role to change the invention. Although the panel majority acknowledges that limits above 4% "could be found in the specification" and were so found by the Commission, the panel majority discards this undisputed fact.

The patents describe the conditions in which 4-ADPA intermediates are produced by the direct reaction of aniline and nitrobenzene. The '063 patent specification includes twelve specific examples, varying the amount and nature of the base, the solvent, the cation, the protic material, and the reaction conditions. Additional examples are in the continuing '111 patent, illustrating further variation in the protic material. In the '063 patent, Example 1 was conducted at room temperature, using tetramethylammonium hydroxide (TMAH) dihydrate 1 as the base. Example 2 shows the effect of varying the temperature. Example 3 shows varying the amount of water from 2.2 to 4.7%, and also uses methanol as the protic material. In Example 3, water in amounts of 0, 10, 50 and 100 L is added to the reaction. The percentage of water in the reaction includes both this added water and the water introduced by the TMAH dihydrate. See '063 patent, col. 9, tbl.2 note. The other Examples show that the amount of water present in the dihydrate is part of the protic material that is present and is calculated as such. See id. col. 11, lines 14-18 & tbl.6.

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1 TMAH dihydrate contains two molecules of water per molecule of tetramethylammonium hydroxide. The specific Examples in the patents variously add water in liquid form, or as the dihydrate, or both together.

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Example 4 shows the use of various solvents; Example 5 is directed to various bases; Example 6 is a comparison with a prior art method; Example 7 varies the ratios of the reactants; Example 8 shows varying the total amount of water in steps of 2.3%, 3.5%, 6%, 9.75%, and 14.7%; Example 9 shows varying the amount of the TMAH dihydrate base while maintaining the amount of added protic material constant at 4.7%. Example 10 shows anaerobic conditions at 50EC and contains 10% water 2 from the dihydrate; the Commission describes this example as a preferred embodiment. Example 11 demonstrates the production of the tetramethylammonium ion salt of 4-NDPA and p-NDPA; Example 12 illustrates the conversion of 4-ADPA to produce 6-PPD.

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2 My colleagues call it a "complex calculation" to calculate the percentage of water in the total volume of reactants, maj. op.

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n.7, and decline to consider this evidence; the ALJ, the Commission, and everyone else in the record and briefs treat this calculation as routine. In response to a question from the bench during oral argument, counsel submitted the following explanation:

Specifically, the question was asked of how one skilled in the art would be able to calculate the percentage of water in the reaction disclosed in Example 10 of the patents-in-suit.

Example 10 discloses "the reaction of aniline, nitrobenzene and tetramethylammonium hydroxide dihydrate ("TMAH dihydrate") under anaerobic conditions at 50 degrees C." JA 000269. Col. 11, line 64-Col. 12, line 1. The term "dihydrate" means that there are two water molecules for each molecule of TMAH. JA 000561, lines 13-22. Example 10 discloses that 0.42 moles of TMAH dihydrate are present in the reaction. Because there are two moles of water (dihydrate) for one mole of TMAH, there are .84 moles of water in the reaction. JA 000567, lines 4-20. Because the amount of water and of aniline and nitrobenzene and TMAH are disclosed in Example 10, the percentage of water in the reaction can be calculated using the method described at JA 000568, line 6 through JA 000569, line 21. The method of calculating the amount of water in a reaction where the amount of TMAH dihydrate, aniline and nitrobenzene are known is also found in the prosecution history of the '111 patent, as is discussed in the Final Initial and Recommended Determination at JA 000137-138. Sinorgchem's experts agreed that Example 10 has 9 to 10 percent water, and that it could be calculated. JA 000151.

Letter from counsel Mark G. Davis dated September 14, 2007. The experts were in agreement that Example 10 shows the presence of 9-10% water.

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In the '111 patent, additional examples, particularly Examples 13 and 15, again show the presence of significantly more than 4% water. The panel majority declines to consider the additional examples, which show 10.8% water for Example 13 and 13.8% water for Example 15. The Commission had no need to rely on the additional examples because it found the '063 examples sufficient. Nor is the issue one of "new matter," in using the continuation-in-part to construe claims of an ancestor patent, for the charge is infringement of both or either patent.

The specifications explain the effect of each variable, and state that "the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used n the various solvent systems." '063 patent, col. 4 lines 61-63. The specifications further explain that "[T]he reactions can be successfully performed by conventional modifications known to those skilled in the art, e.g., by appropriate adjustments in temperature, pressure and the like, by changing to alternative conventional reagents such as other solvents or other bases, by routine modification of reaction conditions, and the like, or other reactions It is undisputed that a person of ordinary skill in the field of the invention can readily calculate the amount of water. disclosed herein or otherwise conventional, will be applicable to the method of this invention." Id. col. 6, lines 35-43.

The panel majority, in discussing some of the examples, ignores the dihydrate that is present throughout the examples, and finds that only Example 10 of the '063 patent can be viewed as having more than 4% water. The majority's complaint that Example 10 "is not even directed toward illustrating the control of the amount of protic material to be used in the reaction," maj. op. at 13, is inapt, for Example 10 shows 92.8% yield of the desired 4-ADPA intermediates in conditions that include 9-10% of protic material. '063 patent, col. 12, lines 11-13. Thus my colleagues find "clear definitional language [of a 4% limit] set forth in the specification" although that number is in a sentence with the signal "for example," and ignore the text and examples showing a higher range. These erroneous appellate findings of scientific fact directly contradict the findings of the Commission, made upon extensive and detailed evidence and argument on the content of the specifications, including the variables discussed and exemplified in the '063 and '111 patents. Instead, the panel majority selects the parts of the specifications that show water in the 4% range, and ignores the description and examples that show other amounts of water. The majority's de novo ruling is contrary to the testimony of experts for both sides, contrary to Commission expertise, and contrary to the rules of claim construction. The Commission's finding warrants appropriate deference. See, e.g., Federal Power Comm'n v. Fla. Power & Light Co., 404 U.S. 453, 466, 92 S. Ct. 637, 30 L. Ed. 2d 600 (1972) ("The court may not . . . ignore the conclusions of the experts and the Commission and put itself in the absurd position of substituting its judgment for theirs on controverted matters of hydraulic engineering." (quoting United States ex rel. Chapman v. Fed. Power Comm'n, 191 F.2d 796, 808 (4th Cir. 1951), aff'd, 345 U.S. 153, 73 S. Ct. 609, 97 L. Ed. 918 (1953))).

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Claims are construed as they would be understood by persons in the field of the invention, for those are the persons by and for whom patents are written. Such persons are charged with the specification, the prosecution history, and general knowledge in the field of the invention. Phillips v. AWH Corp., 415 F.3d 1303, 1316-17 (Fed. Cir. 2005) (en banc). It is beyond debate that the entire specification must be consulted in construing the claims. Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1373 (Fed. Cir. 2005) ("It is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent."); Slimfold Mfg. Co. v. Kinkead Industries, Inc., 810 F.2d 1113, 1116 (Fed. Cir. 1987) ("Claims are not interpreted in a vacuum, but are part of and are read in light of the specification.").

When the entire specification including the specific examples is consulted, rather than selected snippets, the correct claim scope is apparent from the specifications. Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1210-11 (Fed Cir. 2007) (declining to limit claim term to description following the word "is" in the specification where to do so would exclude disclosed examples); Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1305 (Fed. Cir. 2007) ("We normally do not interpret claim terms in a way that excludes disclosed examples in the specification."); Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1369 (Fed. Cir. 2003) (district court's claim construction erroneously excluded an embodiment described in an example in the specification); Budde v. Harley- Davidson, Inc., 250 F.3d 1369, 1379-80 (Fed. Cir. 2001) (the specification should be considered as a whole and read "if possible, in a manner that renders the patent internally consistent").

The labored justification by the majority of its ruling that "about 4%" is the maximum amount of protic material permitted by the specifications does not suggest how the Commission erred, or explain a claim construction that excludes much of the content of the specifications and is contrary to the expert testimony. For example, expert witness David Crich testified, without dispute, that a person of ordinary skill would recognize that the description of 4% water is directed to reactions with aniline as the solvent at conditions of ambient temperature and pressure. The panel majority inexplicably attributes "no weight" to this expert testimony by arguing that since "controlled amount" has no universal meaning in chemistry, the court can ignore how persons skilled in this field of chemistry would understand the term as applied in this field. As resolved in Phillips, 415 F.3d at 1313, "[t]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. That starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art." (Citations omitted.)

The cases on which the majority relies do not support, and indeed contravene the majority's approach to claim construction. In Durel Corp. v. Osram Sylvania, Inc., 256 F.3d 1298, 1303-04 (Fed. Cir. 2001) the court held that the entirety of the specification, including the specific examples, must be considered in determining the scope of the term "oxide coating," and not a single broader statement. In Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998) the court stated that the patentee's lexicography could not be enlarged by resort to extrinsic dictionary definitions, when the intended scope was clearly set forth in the entirety of the specification "without ambiguity or incompleteness," a sound rule that emphasizes the controlling role of the specification. These cases support the Commission's holding, not that of the panel majority. Equally inapplicable is the majority's citation of Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1327 (Fed Cir. 2002), for unlike Rhoex, here the prosecution history does not require exclusion of preferred embodiments.

The majority also relies on Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316 (Fed. Cir. 2001) and North American Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335 (Fed. Cir. 2005) as supporting its claim construction. These are cases where the construction of claims is narrower than the breadth of the specification, on specific facts where such narrowing was required, such as by "means-plus-function" construction, or by an express disclaimer during prosecution as in North American Container, 415 F.3d at 1345-46, 1348. In contrast, in the present case the words "controlled amount" do not have an unambiguous meaning that dictates the exclusion of disclosed embodiments, nor is there any suggestion of disclaimer. These decisions do not support the majority's arbitrary appellate limitation of claim scope, contrary to the content of the specifications. See, e.g., Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1358 (Fed. Cir. 2006) (it is generally improper for courts to import a numerical limitation into a patent claim that contains no numerical limit); Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996) ("Ordinarily a claim element that is claimed in general descriptive words, when a numerical range appears in the specification and in other claims, is not limited to the numbers in the specification or the other claims.") The patents' teachings that the amount of protic material can vary with the reaction conditions, teachings heavily reinforced by actual experimental examples, were readily understood by the Commission to show, as the patentee stated, that the invention can be practiced over a range of

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conditions. The extensive data in the patent specifications were not challenged. No error has been shown in the Commission's conclusion that "controlled amount" is not limited to 4%.

Our appellate obligation is to impart consistency, predictability, and guidance to patent claiming, whereby the patent-user community can rely on a technologically correct and legally consistent interpretation of patent claims. The health of innovative technology requires confidence in objective rules of claim construction, and in uniform judicial application of the rules. The panel majority adds inconsistency and unpredictability by arbitrarily limiting the scope of the claimed invention in a way that conflicts with the teachings of the specifications and the knowledge in the field of the inventions. I respectfully dissent.

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B. Infringement

On cross-appeal, Endo challenges the trial court's finding that Endo's generic controlled release oxycodone formulations would infringe the asserted claims of Purdue's patents. Because we are vacating the trial court's unenforceability judgment, it is necessary for us to address Endo's cross-appeal.

The trial court construed the claims to require acceptable pain control for 90% of patients over a four-fold dosage range. Despite the absence of an express claim limitation to that effect, the trial court held that the "invention itself," i.e., the "controlled release oxycodone formulation," was limited to a four-fold dosage range that controls pain for 90% of patients. The court then found that Purdue's own OxyContin(R) product satisfied the four-fold dosage range limitation based on NDTI usage data relating to OxyContin(R) dosing patterns. Because Endo's proposed generic drug is bioequivalent to OxyContin(R), the trial court found that Endo's product also met the four-fold dosage range limitation. The trial court further found that Endo's product satisfied the remaining limitations in the claims asserted by Purdue and therefore would infringe.

Endo's only argument on appeal is that the trial court correctly construed the claims to include the four-fold dosage range limitation but that the court improperly relied on OxyContin(R) data to show that Endo's proposed generic drug would meet that limitation. Endo does not dispute the trial court's finding that the other claim limitations read on its product.

Purdue contends that the trial court erred by importing the four-fold dosage range limitation into the claims and that, if the claims do not include that limitation, we should affirm the trial court's infringement determination because Endo does not dispute that its product satisfies the remaining claim limitations. Even if the trial court correctly construed the claims, Purdue argues, the court properly based its infringement finding on the NDTI data and the bioequivalence of OxyContin(R) and Endo's generic drug.

Reviewing the trial court's claim construction without deference, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc), we begin with the claim language itself, Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). As the trial court correctly determined, the claims contain no language limiting their scope to controlled release oxycodone formulations that acceptably control pain in 90% of patients over a four-fold dosage range. Endo had argued that the term "controlled release" should be interpreted as including the four-fold dosage range limitation, but the trial court properly held that the term should be given its customary and ordinary meaning--that oxycodone is released in a controlled manner over an extended period of time. The trial court also correctly held that nothing in the written description common to the patents-in-suit uses the term "controlled release" in a manner inconsistent with that ordinary meaning.

Next we look to the prosecution history to determine whether it contains statements that narrow the scope of the claims. Id. at 1317. Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear

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and unmistakable disavowal of scope during prosecution. See Seachange Int'l, Inc. v. C-COR Inc., 413 F.3d 1361, 1372-73 (Fed. Cir. 2005); Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-26 (Fed. Cir. 2003). This may occur, for example, when the patentee explicitly characterizes an aspect of his invention in a specific manner to overcome prior art. See Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004) (interpreting "sending," "transmitting," and "receiving" limitations as requiring direct transmission over telephone line when patentee stated that invention transmits over a standard telephone line, thus disclaiming transmission over a packet-switched network).

In this case, the trial court concluded that during prosecution Purdue "deliberately and clearly relinquished, disclaimed and surrendered controlled release oxycodone formulations that do not control pain relief in approximately 90% of patients with an approximately four-fold dosage range." Purdue Pharma, 2004 U.S. Dist. LEXIS 10, 2004 WL 26523, at *14. We agree with Purdue that it made no such disclaimer or disavowal, and the trial court's holding to the contrary was in error. While it is true that Purdue relied on its "discovery" of the four-fold dosage range to distinguish its claimed oxycodone formulations from other prior art opioids, Purdue's statements do not amount to a clear disavowal of claim scope. Rather than presenting the four-fold dosage range as a necessary feature of the claimed oxycodone formulations, Purdue described it as a property of, or a result of administering, the oxycodone formulations characterized by the in vivo blood plasma concentrations set forth in the claims. As Purdue stated during prosecution of the '912 patent, "by choosing the above-identified parameters [i.e., the claimed blood plasma concentrations] in the controlled-release formulation, it is possible to acceptably control pain over a substantially narrower dosage range than through the use of other opioid analgesics of similar chemical structure."

It important to note that the claims contain no limitations relating to the effectiveness of dosages in controlling pain in patients, and it is the claims ultimately that define the invention. See Phillips, 415 F.3d at 1312. The trial court correctly determined that it would be improper to construe the claim term "controlled release" to require acceptable pain control in approximately 90% of patients over a four-fold dosage range. The only way the trial court could hold that the four-fold dosage range was a claim limitation, then, was to state that the "invention itself" controlled pain in approximately 90% of patients with a four-fold dosage range. Without any specific claim language to interpret, however, the trial court impermissibly imported a limitation into the claims. See Bayer AG v. Biovail Corp., 279 F.3d 1340, 1348 (Fed. Cir. 2002) ("Extraneous limitations cannot be read into the claims from the . . . prosecution history.").

We therefore conclude that the patent claims asserted by Purdue do not include a limitation requiring acceptable pain control in approximately 90% of patients with a four-fold dosage range. Accordingly, Endo's argument that the trial court improperly relied on the NDTI data to show that its generic product satisfies that limitation is moot. Because Endo does not challenge the trial court's finding that the other claim limitations are met, we affirm the trial court's infringement determination.

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1. "controlled release formulation 1"

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1 In their joint claim construction chart, the parties indicated that the phrase "controlled release formulation" was in dispute. Both Plaintiffs and KV provided proposed constructions, however, neither Barr nor Sandoz provided their own constructions. During oral argument, the parties agreed that the dispute revolves around the meaning of the term "formulation" and not the entire phrase "controlled release formulation." Tr. p. 19:18-20:19. As such, the Court focuses its analysis on the term "formulation" and not the entire phrase.

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This disputed phrase appears in claim 1 of the '559 Patent. Plaintiffs' proposed construction for this phrase is as follows: "a pharmaceutical composition for oral administration in which the release profile of the active ingredient includes a component that is not released immediately." KV, on the other hand, argues that the term should be construed as: a "component of a dosage form that provides a release of an active ingredient, which is altered from the release provided by an immediate release formulation."

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The difference between the two suggested constructions is whether "formulation" refers to the entire dosage form administered to the patient or whether it refers to only a portion of the dosage form. Plaintiffs claim that formulation "encompasses the dosage form as a whole that is administered to the patient," whereas KV argues that the term "formulation" "refers to part of a full dosage form, such as a pellet in a capsule (the pellet is the formulation and the capsule is the dosage form)." Pl.'s Opening Brief at 10 ("Pl's Brief"); KV's Opening Brief at 11 ("KV's Brief").

In support of its proposed construction, Plaintiffs first look to the plain meaning of the term "formulation". According to Plaintiffs, formulation "refers to that which is formulated" meaning the pharmaceutical composition in its entirety, rather than a portion of the dosage form. Pl.'s Brief at 10-11. However, the ordinary meaning does not necessarily control if the specification provides otherwise. Phillips, 415 F.3d at 1315-17. Here, the specification states: "Dosage forms comprising a therapeutically effective amount of said controlled release formulations can be administered orally to a patient once daily." '559 patent at 2:46-48. As such, the patent itself makes clear that "dosage form" does not equate with "formulation," rather the controlled release formulation is a component of the dosage form.

Defendants' construction is further bolstered by the prosecution history. For instance, application claim 16, in the initial claims submitted to the PTO, states: "A dosage form comprising a therapeutically effective amount of the controlled release formulation of any claims 1 to 15." Decl. Lynn Ulrich, Def.'s Joint Ex., Tab 18, June 21, 2001 Prelim. Am. at 8, App. Claim 16. It would be redundant if formulation meant dosage form. As such, Plaintiffs must have contemplated a difference between the terms "dosage form" and "formulation" in their initial application.

Furthermore, the claims themselves support Defendants' construction. Specifically, KV cites to claim 15 which states: "[a] formulation according to [c]laim 1, wherein the particles are filled in a hard-gelatin capsule." '559 patent 16:4-5. KV argues that formulation cannot be the entire drug product, as Plaintiffs claim, because claim 15 requires the formulation to be filled into the capsule, i.e. the finished drug product. KV's Brief at 12. According to KV, if "formulation" is construed according to Plaintiffs' construction it would have two contrary meanings - particles to be filled into a capsule and a finished drug product. Id. KV argues that since claims must be construed consistently throughout the patent, Plaintiffs' interpretation cannot stand. Phillips, 415 F.3d at 1314.

On the other hand, Plaintiffs contend that several claims support their construction. For instance, they argue that the use of the term formulation in claim 11 - "[a] formulation according to claim 1 providing a mean maximum plasma concentration of galantamine from 10 to 60 ng/ml and a mean minimum plasma concentration from 3 to 15 ng/ml after repeated administration every day through steady-state conditions," '559 patent at 14:52-6 - must refer to the entire dosage because steady-state plasma concentrations cannot stem from only a part of the entire dosage. Similarly, Plaintiffs assert that claim 13 refers to the entire dosage form. Claim 13 provides: "comprising administering to a human in need of such treatment, a therapeutically effective amount of galantamine in a controlled release formulation as claimed in claim 1, said amount being sufficient to alleviate said Alzheimer's dementia, but insufficient to cause said adverse effects." '559 patent at 14:65-16:6. Plaintiffs argue that Alzheimer's disease cannot be treated through the administration of only a portion of the drug, so formulation must refer to the entire dosage form. However, the Court is not persuaded by this argument because Plaintiffs' interpretation of claims 11 and 13 directly contradicts the plain language of claim 15 as well as the specification and the prosecution history.

Considering the plain language of claim 1 as well as the specification of the '559 Patent, and the patent prosecution history, the Court shall construe "controlled release formulation" consistent with KV's proposed construction as follows: "component of a dosage form that provides a release of an active ingredient, which is altered from the release provided by an immediate release formulation."

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b. Controlled release

The second claim construction dispute centers around the meaning of the term "controlled release." Endo contends that "controlled release" should be construed to require reduced dosage range and easier titration. Purdue contends that "controlled release" means that the dosage form is designed so that the active ingredient - oxycodone - releases in a controlled manner over an extended period of time, in contrast to "immediate release" where the release rate of the active

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ingredient is not controlled.

Looking to the claim language itself, the term "controlled release" oxycodone formulation is used in Claims 1 and 2 of the'912, '042 and '295 patents to describe formulations that result in a mean maximum plasma concentration between 2 and 4.5 hours after administration and a mean minimum plasma concentration from 10 to 14 hours after repeated administration every 12 hours through steady-state conditions. See also the '295 Patent, Claims 3, 8-10. None of the bodies of the claims disclose a reduced dosage range or easier titration. Accordingly, as inferred from how the term is used in the claims, the ordinary meaning of "controlled release" is consistent with Purdue's interpretation - that is, "controlled release" is the release of oxycodone in a controlled manner over an extended period of time.

The preamble to Claim 8 of the '295 Patent reads, "[a] method for substantially reducing the range in daily dosages required to control pain in human patients, comprising …" and the preambles to the '042 patent claims both read, "[a] method for reducing the range in daily dosages required to control pain in human patients, comprising …." However, Endo does not contend that the preambles should be read as imposing limitations on either the claims generally or on the specific term "controlled release." Accordingly, this Court shall not revisit its earlier finding in Purdue v. Boehringer - made in the context of granting a preliminary injunction - that the preambles in the patents in suit do not state independent limitations of the claimed inventions. See Boehringer, 98 F. Supp. 2d at 377. Some of the claims do set forth a range of dosages, see, e.g., Claim 1 of the '912 patent, which states "[a] controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 to about 40 mg oxycodone or a salt thereof," but this language merely states a dosage range, not a reduced dosage range. Therefore, according to the customary and ordinary language of the claims, "controlled release" does not require reduced dosage ranges or ease of titration limitations.

Turning to the specifications of the patents in suit, the term "controlled release" is used consistent to how it is used in the claims - specifically, "controlled release" is described as the release of oxycodone in a controlled manner over an extended period of time. For example, Examples 1-4 of each of the patents in suit describe "controlled release" tablets in the context of the dissolution rates of oxycodone over an extended period of time. See the '912, '295 and '042 Patents, Tables 2, 4, 6 and 8. Similarly, Figure 5 of the patents in suit charts the plasma concentration over "time from last dose" and is described as a graph "showing the mean plasma concentration for a 10 mg controlled release oxycodone formulation …." '912 and '295 Patents, Cols. 3:27-30; '042 Patent, 3:31-34.

However, as this Court previously noted in Boehringer, the specifications also "repeatedly refer to a reduction in the range of daily dosages." 98 F. Supp. 2d at 377. For example, the section of the specifications entitled "Detailed Description" opens with the following passage,"it has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold (10 to 40 mg every 12 hours - around-the-clock-dosing) in approximately 90% of patients for opioid analgesics in general." '912 patent, 3:34-41; '042 Patent, 3:38-45; '295 Patent, 3:34-41. See also '912 Patent, 3:67 to 4:8, 1:10-45; '042 Patent, 2:16-20, 3:5-22; '295 Patent, 2:3-17, 3:1-18. The specifications also state that "the use of from about 10 mg to about 40 mg of 12-hourly doses of controlled-release oxycodone to control pain in approximately 90% of patients … is an example of the unique characteristics of the present invention." '912 Patent, 3:42-46; '042 Patent, 3:46-51; '295 Patent, 3:42-47. Further on, the specifications state that,

> the clinical significance provided by the controlled release oxycodone formulations of the present invention at a dosage range from about 10 to about 40 mg every 12 hours for acceptable pain management in approximately 90% of patients with moderate to sever pain, as compared to other opioid analgesics requiring approximately twice the dosage range provides for the most efficient and humane method of managing pain requiring repeated dosing.

'912 Patent, 4:51-57; '042 Patent, 4:53-60; '295 Patent, 4:51-58.

When read in their entirety, the specifications of the patents in suit indicate that the invention itself - the controlled release oxycodone formulation - may be limited to a four-fold dosage range that controls pain for 90% of patients, but it does not indicate that the specific term "controlled release" by itself should be construed to require reduced dosage and ease of titration, especially when the customary and ordinary meaning of the term clearly does not include or even suggest these limitations.

Finally, we turn to the prosecution history of the patents in suit to ascertain whether that history is consistent with our

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interpretation of the disputed claim language. Endo contends that Purdue successfully convinced the PTO that the reduced dosage range and easier titration features distinguished the patent claims from the prior art, and therefore cannot now disavow construing the term "controlled release" as requiring reduced dosage range and ease of titration. Purdue contends that the references in the prosecution histories to reduced dosage range and ease of titration relate to benefits of the inventions rather than to claim limitations.

"An inventor may use the specification and prosecution history to define what his invention is and what it is not - particularly when distinguishing the invention over prior art. 'Just as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under § 112, P 6.'" See Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1359 (Fed. Cir. 2001) (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998)). "That explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations makes sense, because 'the public has a right to rely on such definitive statements made during prosecution.'" Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378-79 (Fed. Cir. 1998) (quoting Digital Biometrics v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998)). "Prosecution history may limit claim scope if the patentee disclaimed or disavowed a particular interpretation of the claims during prosecution. This principle does not, however, mean that any words appearing in the prosecution history but not in the issued claims are forever banished. The prosecution history inquiry asks not what words the patentee discarded, but what subject matter the patentee relinquished or disclaimed." Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1372 (Fed. Cir. 2002); Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1313 (Fed. Cir. 2002) ("the prosecution history limits even clear claim language so as to exclude any interpretation surrendered during prosecution, but only where the accused infringer can demonstrate that the patentee surrendered that interpretation with reasonable clarity and deliberateness"). Accordingly, at issue is whether or not Purdue clearly and deliberately disclaimed or surrendered controlled release oxycodone formulations that do not reduce the dosage range and ease titration such that the term "controlled release" must be construed to require reduced dosage range and ease of titration.

In addition, the Federal Circuit has repeatedly emphasized that claim language is to be interpreted in light of the "fundamental purpose and significance" of the invention, Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1566-67 (Fed. Cir. 1992) and in a manner "consistent with and further[ing] the purpose of the invention," CVI/Beta Ventures. Inc. v. Tura LP, 112 F.3d 1146, 1160 (Fed. Cir. 1997), cert. denied, 522 U.S. 1109, 118 S. Ct. 1039, 140 L. Ed. 2d 105 (1998). 4 Courts must review the entire prosecution history in construing claims. See Eagle Comtronics, Inc. v. Arrow Commun. Labs., Inc., 305 F.3d 1303, 1315 (Fed. Cir. 2002).

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4 Purdue cites to several Federal Circuit cases for the supposedly contrary proposition that it is error for this Court to consider the disputed issues in a lawsuit based on the differences between the claimed invention and the prior art. See Jones v. Hardy, 727 F.2d 1524, 1528 (Fed. Cir. 1984) ("in determining the obvious/nonobviousness issue, it is improper (even if erroneously suggested by a party) to consider the difference [between the invention and the art] as the invention"); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986); Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n.5 (Fed. Cir. 1986). See also Para-Ordnance Mfg., Inc. v. SGS Importers Int'l Inc., 73 F.3d 1085, 1087 (Fed. Cir. 1995) (stating, in the context of an obviousness analysis, that "there is no legally recognizable 'heart' of the invention") (citing W.L. Gore & Asoc., Inc. v. Garlock, Inc., 721 F.2d 1540, (Fed. Cir. 1983), cert, denied 469 U.S. 851, 83 L. Ed. 2d 107 (1984)). However, these cases only state that, for purposes of a 35 U.S.C. § 103 obviousness analysis, it is inappropriate for a court to consider the difference between the invention and prior art as the invention itself - here, this Court is construing claims and, accordingly, must consider assertions Purdue made before the PTO to distinguish its invention from prior art. See, e.g., Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 956 (Fed. Cir. 2000).

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After reviewing the prosecution history of the '331 parent patent and the patents in suit, this Court finds that Purdue surrendered, with deliberateness and clarity, controlled release oxycodone formulations that do not control pain over an approximately four-fold dosage range for approximately 90% of patients; in other words, we conclude that reduced dosage range is a claim limitation. The PTO initially rejected the '331 patent claims pursuant to 35 U.S.C. § 103 because "it would have been obvious to one of ordinary skill in the art to use oxycodone" in place of the hydromorphone in the 4,990,341 patent (the "'341 patent") in view of the 4,861,598 patent (the "'598 patent"). DX 2008, EN205614, EN205615. In Purdue's

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response to the PTO's rejection, Purdue distinguished the '331 invention by stating that (1) prior art controlled release opioid analgesics had a wide range of dosages that "makes the titration process particularly time consuming and resource consuming," (2) but "it has now been surprisingly discovered" that the oxycodone formulation of the '331 patent "acceptably controls pain over a substantially narrower, approximately four fold (10 to 40 mg every 12 hours - around-the-clock dosing) in approximately 90% of patients," (3) "the opioid analgesic titration process" of the '331 invention is "substantially reduced through the efficiency of the controlled release oxycodone formulations of the present invention," and (4) that

it is respectfully submitted that one skilled in the art having knowledge of the controlled release oxycodone formulations of Goldie, et al. [the '341 patent] would not be motivated to prepare controlled release oxycodone formulations in a dosage range from about 10 mg to about 40 mg, which formulations thereby acceptably control pain over a substantially narrower, approximately four-fold range in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients utilizing controlled release hydromorphone, or controlled release opioid analgesics in general. One skilled in the art would certainly not arrive at this surprising result without the benefit of hindsight.

DX 2008, EN205621 dated October 22, 1992 - entitled "The Results Obtained by the Present Invention are Not Obvious From the Prior Art" (italics added).

In other words, Purdue admitted to the PTO that the cited prior art would teach a controlled release oxycodone formulation, but the particular controlled release oxycodone formulation of the '331 invention would, in contrast to other controlled release opioid drugs -and in contrast to the controlled release oxycodone formulations of the cited prior art - control pain over a four-fold dosage range for most patients. Purdue distinguished the claimed '331 invention over the prior art by setting forth what the invention did not cover - specifically, controlled release oxycodone formulations that did not control pain over a four-fold dosage range for most patients.

After the relevant claims of the '331 patent were again rejected for obviousness, the PTO scheduled an interview with Purdue after which the examiner noted that they "discussed nature of dissolution rate with regard to prior art. Applicant will submit proposed declaration supporting unobviousness and unexpected results. Terminal disclaimer will be filed. Favorable consideration will be given for the proposals discussed regarding allowability." PTX 2008, EN205626. Purdue subsequently submitted a proposed declaration prefaced with a remarks section written by Harold Steinberg, Purdue's outside patent prosecuting attorney for the '331 patent, who wrote that "as was pointed out to the Examiner at the conference, it is totally impossible to predict what dissolution rates for any particular drug will give rise to an extended duration of action." DX 2008, EN205630. In the declaration, Dr. Kaiko stated that one skilled in the art with knowledge of the controlled release hydromorphone formulation as set forth in the '341 patent could not predict whether a controlled release oxycodone formulation having a "T[max] in 2-4 hours would also provide a duration of therapeutic effect of at least 12 hours." PTX 2008, EN205635. With respect to the '598 patent, Dr. Kaiko stated that one skilled in the art with knowledge of the "teaching of a controlled-release matrix formulation of oxycodone with accompanying in vitro dissolution data" in the '598 patent could not predict "the T[max] and the duration of effect which would be achieved with such a formulation in vivo." Id. Therefore, one skilled in the art could not combine the '341 patent and the '598 patent to make the '331 invention. Id. at EN205637. Dr. Kaiko also attached an exhibit to the declaration that, under the title "INVENTION," stated that

[the invention] acceptably controls pain over a substantially narrower, approximately four-fold (10 to 40 mg q 12h around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general …. Regardless of the fact that both controlled-release oxycodone and control release morphine administered q12h around-the-clock possess qualitatively comparable clinical pharmacokinetic characteristics, [the invention] can be used over approximately 1/2 the dosage range as MS Contin [a morphine-based opioid drug for pain relief also manufactured by Purdue] to control 90% of patients with significant pain.

Id. at EN205639-41.

In sum, Purdue responded to the PTO's initial rejection by distinguishing the '331 invention from prior art by noting its particular analgesic effect over a four-fold dosage range, and after another rejection, subsequently distinguished it again by stating that (1) one skilled in the art could not simply replace hydromorphone with oxycodone, (2) that in vitro controlled release oxycodone formulation data did not provide a predictable correlation to in vivo data and (3) repeated the distinction raised in response to the earlier rejection, namely that the invention -in contrast to prior art - acceptably controlled pain over

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a four-fold dosage range for most patients.

With respect to the '912 patent, the PTO rejected certain claims pursuant to 28 U.S.C. § 102(b) as being anticipated by the '341 patent because the '341 patent "teaches opioid analgesics with the claimed rate of release." DX 2033, P 000170. Purdue responded to the rejection with an "Amendment" that stated, in a section titled "The Invention," that

Applicants have surprisingly found that even in the case of controlled-release opioid formulations having a similar in-vitro release profile, a much wider range of dosage of drug must be administered to the patient in order to achieve a satisfactory analgesic response over the requisite period of time. This is set forth, e.g., in the Specification at page 6, line 30, through page 7, line 3.

DX 2033, P 000177-78 - Amendment, dated February 22, 1995 (the "Amendment").

The referenced portion of the specification states, in part, that "the oxycodone formulations of the presently claimed invention can be used over approximately 1/2 the dosage range as compared with commercially available controlled release morphine formulations [previously set forth in the specification as an eight-fold range] to control 90% of patients with significant pain." DX 2033, P 000106-107. In the following section of the Amendment, titled "The Rejection under 35 U.S.C. § 102(b)," Purdue continued to respond to the patent examiner's rejection by stating that one of ordinary skill in the art could not have predicted from the disclosure of the '341 patent concerning hydromorphone formulations that oxycodone - a different opioid - would have the particular plasma concentration profile set forth in the '912 patent, and that "in view of the '341 patent's lack of disclosure concerning oxycodone and further in view of the lack of predictability among opioid analgesics, it is respectfully requested that the Examiner reconsider and remove the rejection under 35 U.S.C. § 102(b)." See DX 2033, P 000178, P 000181.

With respect to the '042 patent, the patent examiner initially rejected the claims pursuant to 35 U.S.C. § 112 due, in part, to deficiencies in the specification. DX 2009, EN205729-30. After an interview between Purdue and the examiner, Purdue deleted the term "substantially" from the claims "to bring into condition for allowance." Id. at EN205733. Subsequently, the PTO issued a Statement of Reasons for Allowance for the '042 patent claims that stated that "none of the references of record singly anticipate or in combination motivate one with ordinary skill in the art to formulate the particular method for reducing the dosage of oxycodone as set forth in the claims." DX 2009, EN 205735. As explicitly and definitively stated by the examiner, the '042 patent claims were allowed because the invention - in contrast to prior art -set forth a method for reducing dosage ranges for oxycodone. 5

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5 Neither party cites to the patent prosecution history of the '295 in support of their respective claim construction contentions.

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Reviewing the prosecution history of the '331, '912 and '042 patents, this Court finds that Purdue clearly and deliberately distinguished the claimed invention over the prior art by "indicating what the claims do not cover" - specifically, controlled release oxycodone formulations that do not control pain over a four-fold dosage range for most patients. See Spectrum, 164 F.3d at 1378-79 ("by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover") (quoting Ekchian v. Home Depot, Inc., 104 F.3d 1299,1304 (Fed. Cir. 1997)); Hockerson-Halberstadt, 222 F.3d at 956 ("The inventor then distinguished the prior art by arguing that the claimed invention "provides a much narrower groove for a totally different purpose …. Flowing from this statement is the inventor's clear disavowal of footwear having a groove width greater than that disclosed in the prior art"); Lemelson v. General Mills, Inc., 968 F.2d 1202, 1206 (Fed. Cir. 1992) ("Prosecution history is especially important when the invention involves a crowded art field, or when there is particular prior art that the applicant is trying to distinguish.").

During the prosecution history of both the '331 and '912 patents, Purdue distinguished the invention on additional grounds other than just reduced dosage range. However, that Purdue set forth alternative grounds for the PTO to admit the claims does not mean that it disclaimed its earlier explicit distinction of the invention from prior art based on its reduced dosage range, especially given that it continued to assert the reduced dosage range as a reason for allowing the claims. See

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Hockerson-Halberstadt, 222 F.3d at 957 (citing Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999) ("it is the totality of the prosecution history that must be assessed, not the individual segments of the presentation made to the Patent and Trademark Office by the applicant"); Ekchian, 104 F.3d at 1303-04 (absent an indication by the examiner to the contrary, an examiner will consider all parts of the prosecution history); Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985).

As well, that the PTO rejected Purdue's initial attempt to distinguish the '331 invention on the basis of reduced dosage range does not render the distinction invalid or irrelevant. See Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 996 (Fed. Cir. 2003) (citing Laitram Corp. v. Morehouse Indus., Inc., 143 F.3d 1456, 1462 (Fed. Cir. 1998) ("The fact that an examiner placed no reliance on an applicant's statement distinguishing prior art does not mean that the statement is inconsequential for purposes of claim construction."). This Court will not "erase from the prosecution history" Purdue's clear and deliberate disavowal of controlled release oxycodone formulations that do not control pain over an approximately four-fold dosage range for approximately 90% of patients. Hockerson-Halberstadt, 222 F.3d at 957 ("Such an argument is inimical to the public notice function provided by the prosecution history. The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct.").

Accordingly, this Court finds that Purdue deliberately and clearly relinquished, disclaimed and surrendered controlled release oxycodone formulations that do not control pain relief in approximately 90% of patients with an approximately four-fold dosage range. See Ballard, 268 F.3d at 1359. However, Purdue's contention to the PTO that the patents eased titration - which, as discussed previously, is the method by which dosages are adjusted in order to provide acceptable pain control without unacceptable side effects - is not a claim limitation. Any ease of titration is due, in part, to the reduced dosage range and is a benefit of the invention rather than a structural feature of the claims.

Moreover, it would be a rather strained claim construction that would result in construing the term "controlled release" with a plain and ordinary meaning - the release of an active ingredient in a controlled manner over an extended period of time - to require reduced dosage range and ease of titration. It is the invention itself, the "controlled release oxycodone formulation," that Purdue claims will control pain relief in approximately 90% of patients with an approximately four-fold dosage range. Accordingly, this Court will construe the terms "controlled release oxycodone formulation" and "controlled release dosage formulation" to require controlling pain relief in 90% of patients with a four-fold dosage range.

As it is clear from the intrinsic evidence that Purdue deliberately and with clarity limited the scope of its invention, this Court will not address the generally unpersuasive extrinsic evidence both parties have presented in support of their respective claim constructions of the term "controlled release." 6

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6 In Boehringer, this Court found, in the context of determining whether to grant a motion for a preliminary injunction, that the preambles to the '042 and '295 claims that refer to a reduction in the range of daily dosages were "not structural feature[s] of the administration of the oxycodone formulations set forth but rather simply [] a benefit of the administration of those formulations." Boehringer, 98 F. Supp. 2d at 377. Not only was this conclusion made, as noted, in the context of a preliminary injunction hearing, but also without analysis of the patent prosecution histories. Here, unlike in Boehringer, the Court is able to "construe the asserted claims based upon a final and complete record in the case." CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1160 (Fed. Cir. 1997).

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1. Independent Claims 3, 6, 7, 13-15

Independent claims 3, 6, 7, and 13-15 all describe a controlled sustained release tablet comprising an admixture of bupropion hydrochloride and HPMC. (Brief Supp. Def.'s Mot. Summ. J., Ex. A.) To interpret the scope of these claims, they "must be read in view of the specification, of which they are a part." Markman, 52 F.3d at 979. The specification provides

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the following guidance:

In order to prepare the controlled sustained release (SR) tablets of this invention, particles of bupropion hydrochloride are preferably blended with microcrystalline cellulose and hydroxypropyl methylcellulose (Methocel(R)) to form an admixture of blended powders.

(Specification 2:40-46.) This indicates that the admixture described in claims 3, 6, 7, and 13-15 refers to a blend of bupropion hydrochloride and hydroxypropyl methylcellulose ("HPMC"). The specification also provides guidance as to the purpose of this admixture: "This invention is directed to control sustained release (SR) tablets containing bupropion hydrochloride (as the active drug or active ingredient), [and] preferably hydroxypropyl methylcellulose (Methocel(R)) for controlling drug release rate ...." (Specification 1:67-2:2.) Thus, the language of these claims, read in view of the specification, clearly indicates that the claims contemplate the use of HPMC to control the release rate of bupropion hydrochloride into the bloodstream.

The prosecution history confirms the significance of HPMC to these claims. Claims 13-15 as originally written did not contain the HPMC limitation. (Brief Supp. Def.'s Mot. Summ. J., Ex. B.) The examiner rejected claims 13-15, noting that "[HPMC] is considered critical for controlled and/or sustained release and should be incorporated into the independent claims." (Id., Ex. C.) The patentee opted not to contest this determination and accordingly amended claims 13-15. The examiner's rejection of the claims that did not originally include the HPMC limitation confirms the significance of this limitation to the '798 patent.

Finally, an affidavit submitted by one of Glaxo's experts provides guidance in construing these claims. Anthony M. Lowman, an Associate Professor in Drexel University's Department of Chemical Engineering, indicates that claims 14 and 15 "recite the release profiles over time in blood plasma, i.e., bioavailability, of bupropion active drug after administration of a tablet comprising HPMC and ... bupropion hydrochloride." (Lowman Decl. P 16.) n9 This interpretation is consistent with the language of claims 14-15 and with the specification of the '798 patent. Moreover, this affidavit proves useful to interpreting the language in the other claims containing the HPMC limitation.

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n9 Claim 13 is identical to claims 14 and 15 except that it varies in the dosage of bupropion hydrochloride contained within the tablet. See infra note 16.

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Thus, having considered the language of the claims, patent specification, prosecution history, and extrinsic evidence, the court construes claims 3, 6, 7, and 13-15 as describing a specific polymer, HPMC, that is blended with bupropion hydrochloride to form an admixture. The addition of HPMC serves to retard the release of bupropion hydrochloride into the bloodstream.
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This court reviews the district court's claim construction of the '630 patent without deference. See Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1330, 52 U.S.P.Q.2D (BNA) 1590, 1597 (Fed. Cir. 1999). "In claim construction the words of the claims are construed independent of the accused product, in light of the specification, the prosecution history, and the prior art. . . . The construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims." Scripps Clinic v. Genentech, Inc., 927 F.2d 1565, 1580, 18 U.S.P.Q.2D (BNA) 1001, 1013 (Fed. Cir. 1991) (internal quotations omitted).

The preamble to independent claim 1 recites a method "for controlling an immunizable disease . . . in an avian species comprising [several steps]." This language calls on this court to determine whether "controlling an immunizable disease" requires inoculation of an entire population of birds and effective immunization of a high percentage of treated birds. The

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district court read claim 1 to simply describe the purpose of the claimed method, namely to control a disease by preventing or managing the disease in individual birds.

The language of the claims supports the district court's interpretation. The claims describe the process of immunizing a single egg. For example, claim 1 calls for "injecting a vaccine . . . into the egg embodying the embryo . . . wherein said injection is made during the final quarter of the incubation period whereby the embryo has developed immunologic competence." '630 patent, col. 9, ll. 28-33. With this language, the claim calls for a process involving immunization of an individual egg, rather than a process for entire populations of birds.

The claims also speak of a "vaccine effective for inducing immunity." Id. at col. 9, ll. 28-29. This phrase does not require that the method be effective for all birds or any threshold percentage of birds. In context, the word "effective" modifies the word "vaccine," not the claimed method as a whole. The claim requires no more than a vaccine effective to inoculate an individual chick. Thus, the district court correctly construed this part of the claim to require only that the vaccine injected is known to be effective, but not that every inoculation into an egg actually confers immunity.

The written description accompanying the claims also supports the trial court's construction of the claims. The specification repeatedly refers to the immunization of single eggs. For example, the summary of the invention states: "It is essential that the egg be injected during the final quarter of the incubation period, and . . . under these conditions, the embryo will favorably respond." Id. at col. 2, ll. 2-6. Similarly, the detailed description of the invention explains: "A 1-inch needle when fully inserted from the center of the large end will penetrate the shell, the outer and inner shell membranes enclosing the air cell, and the amnion. Depending on the precise stage of development and position of the embryo, a needle of this length will terminate either in the fluid above the chick or in the chick itself." Id. at col. 3, ll. 51-58. In these instances, the inventor refers to a single egg, chick, and injection. Thus, the specification also supports the district court's interpretation that injection of a single egg is all that is required by the claims. While use of the singular form of a word does not preclude a meaning which includes the plural, see Elkay Mfg. Co. v. Ebco. Mfg. Co., 192 F.3d 973, 977, 52 U.S.P.Q.2D (BNA) 1109, 1112 (Fed. Cir. 1999), these descriptions of the singular injections into individual eggs, without more, do not limit the claims to cover only inoculations of an entire flock of birds. Logic precludes reading a rule that permits singular usage to encompass the plural to require instead the plural meaning.

In addition to the descriptions of individual processes, the written description also reports the results of efficacy tests performed in multiple animals. These reports, however, do not limit the claims to processes performed only on populations of birds. For reliability, biological tests generally demand study of groups of many animals to ensure accurate and reproducible results. Reporting such data in the written description does not operate to import a limitation into the claims. In sum, the claims do not cover only the inoculation of entire flocks of birds. The district court correctly construed this claim.
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10. The court construes the term "copolymer" to mean either poly(alkyl vinyl ether/maleic acid) copolymer or poly (alkylvinyl ether/maleic acid anhydride) copolymer, but not the salt form thereof. While the written description sets forth a variety of copolymers, including ones with mixtures of anionic monomers, 12 cationic monomers, and amphoteric monomers, plaintiffs opted to narrowly define the term copolymer in claim 1 as being either the acid or anhydride form of poly (alkyl vinyl ether/maleic acid) by stating "said copolymer is a poly (alkyl vinyl ether/maleic acid) copolymer or a polyalkylvinyl ether/maleic anhydride) copolymer." ('382 patent, col. 13 at 11. 6-8) The court declines to broaden the plain language of the claim by reading a salt limitation into it, especially since a salt copolymer is a distinct chemical entity from both an acid copolymer and an anhydride copolymer.

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12 The specification specifically recites maleic acid as one type of anionic monomer, stating "acrylic acid (AA), methacrylic acid (MA), maleic acid, itaconic acid and the like, which are unsaturated carboxylic acid monomers or their anhydrides or their salts." ('382 patent, col. 2 at 11. 25-28)

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11. The prosecution history of the '382 patent supports the court's construction of the term "copolymer." Claim 1 of the '382 patent originally was written to cover only maleic acid and maleic anhydride, not the salt form. To this end, claim 1 originally recited "a copolymer comprising an alkyl vinyl ether and maleic acid or an anhydride on said substrate." Claim 1 later was amended to recite "monomer units comprising an alkyl vinyl ether and a monomer selected from the group consisting of maleic acid or an anhydride thereof." (PX 41 at 116-177; 141) This claim did not contain any express or inherent recitation of a salt form. Plaintiffs ultimately amended this language to eliminate the terms "monomer units" pursuant to an interview with the examiner wherein he specifically limited the claims to maleic acid/methyl vinyl ether and maleic anhydride/methyl vinyl ether. (See id. at 248-249) Subsequently, plaintiffs filed the '719 patent with claims specifically directed to salts of the copolymers claimed in the '382 patent. If applicants had intended the claims of the '382 patent to include these salt forms, then there would have been no need to file the '719 patent as a continuation of the '382 patent. Otherwise, the '719 patent would contain claims to an invention previously claimed in the '382 patent.
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The disputed language arises from Claims 1 & 2 of the '721 patent, which are as follows:

1. A biodegradable high molecular polymer useful as an excipient in producing a pharmaceutical preparation comprising a copolymer or homopolymer of about 50-100 mole percent of lactic acid and about 50-0 mole percent of glycolic acid having a weight average molecular weight of about 2,000-50,000 and wherein the contents of water-soluble low molecular weight compounds, as calculated on the assumption that each of said compounds is a monobasic acid, is less than 0.10 mole per 100 grams of said high molecular polymer.

2. The biodegradable high molecular polymer according to claim 1, wherein the molecular polymer has an inherent viscosity of about 0.05-.5 di/g as determined with a 0.5 weight percent chloroform solution thereof and a weight average molecular weight of about 5,000-35,000. ('721 patent Claims 1-2).

The most significant dispute arises over whether the claim language calling for "a copolymer or homopolymer...of lactic acid and...glycolic acid" includes polymers which were formed using monomers of lactide and/or glycolide. This issue was addressed by Judge Oliver in the Oakwood litigation who found that the claim language was inclusive of polymers formed by lactide and/or glycolide. See TAP Pharm. Prod. Inc. v. OWL Pharm., LLC., No. 99 CV 2715 (N.D. Ohio Sept. 4, 2002). After reviewing the relevant evidence, I find that Judge Oliver's interpretation is the correct one and base much of my reasoning on his careful and detailed analysis.

Like Judge Oliver, I look first to the claim language itself. As seen above, the claim language references only lactic acid and glycolic acid, not lactide or glycolide. Similarly, the patent specifications and examples refer only to lactic acid and glycolic acid. However, the specification states that "the biodegradable high molecular polymer to serve as the starting material in performing the method of the invention may be produced by any method." (emphasis added). TAP argues that one of ordinary skill in the art would have known that lactide and glycolide could be used to make that biodegradable high molecular polymer.

According to TAP, copolymers of lactic acid and glycolic acid were known by those of ordinary skill in the art n2 to be made by two different methods: direct polycondensation, using lactic acid and glycolic acid, and ring-opening polymerization, using lactide and glycolide. In the direct polycondensation polymerization process, lactic acid and glycolic acid are heated, while water, which is generated during the reaction by the release of one oxygen and two hydrogen atoms, is rapidly removed. In the ringopening polymerization process, lactide and glycolide, which are cyclic dimers formed by a condensation reaction occurring between two lactic acid or two glycolic acid molecules, n3 are opened, usually in the presence of a catalyst, and become pairs of mers that react with each other to form a polymer.

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n2 One with ordinary skill in this art in 1985, the parties seem to agree, would have worked for at least two years as a researcher in the field of biodegradable polymers and drug delivery systems on a Ph.D. level in industry, a research institute, or in a university.

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n3 There was some discussion at the Markman hearing as to whether the dimerization necessary to form the lactide and glycolide should be considered as a step in the ring-opening polymerization process. Defendants argue that it should not be because they tend to purchase the already formed cyclic dimers of lactide and glycolide instead of performing the dimerization themselves. I find this line of thinking to be largely irrelevant. There is no dispute that lactide and glycolide are made from lactic acid and glycolic acid molecules respectively. Whether the dimerization was performed at a different time than the polymerization makes no difference in my construction of the claims.

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TAP argues further that one skilled in the art would not differentiate between polymers formed through the ring-opening method and direct polycondensation method. These methods, TAP contends, could each be used to generate the copolymers of lactic acid and glycolic acid that are the subject of the '721 patent. As evidence of the interchangeability of the direct polycondensation and ring-opening methods, TAP points to prior art cited by the '721 patent, which references both methods and shows that each can be used to create copolymers of lactic acid and glycolic acid. n4 (See U.S. patent 3,565,869, col. 1, ln. 49-54; U.S. patent 3,890,283, col. 1, ln. 33-36). n5

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n4 See Kumar v. Ovonic Battery Co., 351 F.3d 1364, 1368 (Fed. Cir. 2003) ("our cases establish that prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence").

n5 In making their respective arguments, both parties have referenced published statements made by the other's experts and scientists over the course of the last decade. For the reasons I outlined at the Markman hearing, I give these statements very little, if any, weight in making my decision.

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TAP also points to a number of treatises which recognize that copolymers of lactic acid and glycolic acid can be made by both direct polycondensation or ring-opening. It appears from these treatises and peer-reviewed articles, that scientists in the industry frequently use the term copolymer of lactic acid and glycolic acid when referring to a polymer that was synthesized using lactide and glycolide. See Donald L. Wise et al., "Lactic/Glycolic Acid Polymers," in Drug Carriers in Biology and Medicine 237, 241-45 (Gregory Gregoriadis, ed., Academic Press 1979) ("lactic acids and glycolic acids may be polymerized directly from the linear monomer or oligomers...For most applications it will be preferable to prepare the polymer or copolymer using the cyclic dimers as the starting material.); D.K. Gilding and A.M. Reed. "Biodegradable polymers for use in surgery: polyglycolic/poly(lactic acid) homo-and co-polymers," 20 Polymer 1459, 1459 (1979) (The preferred method for producing high MW polymers is the ring-opening polymerization of the cyclic diester, glycolide (lactide) using antimony, zinc, lead, or preferably tin catalysts."); Robert Langer and Nikolaos Peppas, "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents," C23 Journal of Macromolecular Science-Reviews of Macromolecular Chemistry and Physics 61, 90 (1983) ("Polymers and copolymers of lactic acid and glycolic acid can be polymerized directly by a polycondensation mechanism. This method is limited to lower molecular weights so the preferred method is catalytic ring-opening polymerizations of the corresponding cyclic dimers.); Cowsar, Tice and English, "Chapter 8: Poly(lactide-co-glycolide) Microcapsules for Controlled Release of Steroids," in Drug and Enzyme Targeting Part A 101-116 (Widder & Green, eds., 1985 at 102-03).

To rebut TAP's arguments, Defendants rely primarily on statements made by TAP during the prosecution of the European counterpart to the '721 patent. However, to the extent that I can consider the European patent prosecution, I, like Judge Oliver, find that it supports TAP's interpretation, not the Defendants. During its prosecution of the European counterpart to the '721 patent, TAP's attorneys argued that the European claims did not include polymers made from lactide and glycolide. This statement, however, was rejected as erroneous by the European patent examiner who found that "the Applicant does not appear to be correct in saying that the polymer of the present application is different from the polymerized glycolide and/or lactide." (TAP Ex. 14 '065 PH, office action of 2/8/1991). The Federal Circuit has consistently held that "incorrect statement[s] in the prosecution history do [] not govern the meaning of...claims." Rambus Inc. v. Infineon Tech. Ag, 318 F.3d 1081, 1090 (Fed. Cir. 2003); see also Intervet America, Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989) ("When it comes to the question of which should control, an erroneous remark by an attorney in the course of prosecution of an application or the claims of the patent finally worded and issued by the Patent and Trademark Office as an

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official grant, we think the law allows for no choice. The claims themselves control...It is not for the courts to say that they contain limitations which are not in them.") Since the European examiner's interpretation is consistent with TAP's position that copolymers of lactic acid and glycolic acid include those made from lactide and glycolide, I find that whatever weight it carries favors TAP.

I also disagree with Defendants' argument that TAP expressly disavowed claim coverage of copolymers made from lactide and glycolide by making these statements to the European patent office. In Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1374 (Fed. Cir. 2005), the primary case cited by Defendants, the Court relied on the patent holder's statements in a foreign prosecution to support a broader reading of the patent claim at issue. While the Court did consider statements made during the prosecution of a foreign counterpart to the patent in suit, it did not suggest that those statements would create the sort of prosecution history or file wrapper estoppel Defendants are seeking to apply here. n6

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n6 I also find that the other cases cited by Defendants do not support their prosecution estoppel argument. In Tanabe Seiyaku Co. v. ITC, 109 F.3d 726 (Fed. Cir. 1997), the Court relied on the statements made in a foreign prosecution in determining whether the doctrine of equivalents would apply, not during claim construction. Even in that context, the Court found that "representations to foreign patent offices should be considered . . . when [they] comprise relevant evidence" but declined to recognize any "estoppel related to the prosecution of foreign counterparts." Id. at 733. (citing Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1116 (Fed. Cir. 1983)). Similarly, in Caterpillar, the Court found that while statements made in a foreign patent prosecution relevant to determining the application of the doctrine of equivalents, those statements could not "serve as a basis for reading a limitation" into the claim. Caterpillar, 714 F.2d at 1116.

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The second dispute arises over whether and to what extent the copolymer of lactic acid and glycolic acid could contain additional monomers and other compounds or elements. In their reply brief, TAP agreed that the copolymer of lactic acid and glycolic acid could contain other monomers. TAP, however, does not agree that the copolymer of lactic acid and glycolic acid could include the open-ended array of compounds, elements, and macromolecules suggested by Defendants. n7 TAP would limit the compounds and elements to initiator compounds, including various alcohols, and catalysts generally associated with direct condensation and ring-opening polymerizations. I find that TAP's interpretation is the more reasonable of the two. Allowing the basically unlimited combination of macromolecules, compounds, and elements suggested by the Defendants, would effectively swallow the '721 patent. The additional compounds, elements, and macromolecules should be limited to those things that a person skilled in the art would expect to be present in a polymer of this sort.

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n7 Defendants spent much of their time at the Markman hearing and much of their Surreply brief suggesting that TAP has taken a position different from the one argued in the Oakwood case. As I stated at the Markman hearing, I find that it is perfectly acceptable for TAP to make new or slightly different arguments in this case so long as they are not fundamentally inconsistent with arguments relied upon by Judge Oliver. From what I have seen so far, I do not believe that any such inconsistencies have arisen.

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The third dispute between the parties has arisen over whether the preamble, which describes the patented polymer as "a biodegradeable high molecular polymer useful as an excipient in producing a pharmaceutical preparation," should constitute a claim limitation. As a general rule, "a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quotation omitted). However, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Id.

TAP argues that the statement in dispute was added to the claim in an amendment dated May 11, 1987 in order to

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distinguish two pieces of prior art dealing with similar polymers used as sutures. Defendants disagree claiming that TAP distinguished the prior art on other grounds. After reading the relevant communication with the examiner, I find that TAP sought to distinguish its polymer on many grounds-including its use as a "biodegradable high molecular polymer useful as an excipient." First, the author of the letter states that, unlike the disclosed polymers, which are homopolymers of glycolic acid, the proposed polymer is a homopolymer of lactic acid or a copolymer of lactic acid and glycolic acid. Second, the author argues that the two prior art references do not suggest that treating the lactic acid and glycolic acid copolymers would increase their usefulness as sutures, i.e., improve their extrusion and strength properties or their strength retention. Essentially, the author is arguing that when removed of impurities, the polymers described by the prior art and the proposed polymer differ in their usefulness as sutures. Moreover, it was easy to see that this is a crowded field even in the early nineteen eighties, making it entirely reasonable for the patentee to differentiate its polymer by its use. I do note, however, that the preamble may well play little or no role in the ultimate resolution of this case, at least as it currently appears to me.

For the reasons stated above, I adopt the following claim construction: "a copolymer, useful as an excipient in producing pharmaceutical preparation, comprised of lactic acid and glycolic acid mers produced by any method, including the use of lactide and glycolide."
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1. Core

Plaintiffs propose that "core" should be construed to mean "an inner portion," while the Defendant's construction is "an inner portion of the particle not including the polymer coating." (Joint CC Chart at 7; Doc. No. 31.) The dispute is over whether Defendant's additional limitation, which excludes a polymer coating from the core, should be part of the definition of the term "core." The Court construes this term to mean "an inner portion," because it is in line with the ordinary meaning of the term, and, while Defendant is correct that the specification does not expressly or impliedly disclose a polymer coating within the core, Defendant's construction imports a limitation from the specification into the claim.

The Court construes "core" as "an inner portion" because that construction gives full breadth to the ordinary meaning of the term. See NTP, Inc, 392 F.3d at 1346 (there is a presumption that terms are given the full breadth of their ordinary meaning). "Core" certainly does not disclose the contents of the core, only its location — it is inside something. This ordinary meaning is supported by the term's context in the claim. The claim states that the core is "coated with a rate-controlling polymer coat," placing the core inside a polymer coat. ('339 patent, 20:62-64; see also '339 patent, 5:63-67.)

The Defendant is correct that the specification discloses no polymer coat in the core. The most complete description of the core (the "specific description"), cited by both parties, does not point to the possibility of an internal coating. That portion states:

> The core, herein referred to as applied beads or IR beads, can be formed by building up the morphine active agent, osmotic agent, and, if desired, any pharmaceutically acceptable excipient(s) such as binders, surfactants and lubricants on an inert core. The inert core is preferably a non-pareil seed of sugar/starch having an average diameter in the range 0.2-1.4mm, more especially, 0.3-0.8mm, most especially 0.5-0.6mm.
>
> The morphine active agent, the osmotic agent and, if desired, pharmaceutically acceptable excipient(s) are blended to form a homogenous powder herein referred to as the active blend. This blend can then be applied to the inert core using an application solution.

('339 Patent, 5:19-31 (emphasis added); see also '339 patent, 7:64-67, 10:37-50, 14:39-53, 8:65-67, 9:57-59 (the patent's examples do not have polymer coatings within the core).) The excipients mentioned in the description are substances used to aid medical delivery of an active agent and could include polymers such as those that make up the coating. (See, e.g., '339 Patent, 7:49-59 (listing the polymer coating as an excipient in an example).) Thus, the first paragraph implies that the polymer could be one of the layers that are built up on the core. However, when read in context with the second paragraph, this description requires the excipients to be blended with the active agent to form a homogenous powder before they are built up. Consequently, this portion of the specification does not disclose a coating because the layers could only be built with a homogenous mixture that includes the active ingredient and the polymers.

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Despite this language, Defendant's construction improperly imports a limitation of the specification into the claim. See Phillips, 415 F.3d at 1323. This conclusion is supported both by the specification, which in other passages describes "core" more broadly, and the claim language itself, which provides limits on the core that suggest that when the drafter intended to limit the core, he did so using the claim language itself and not the written description.

Several portions of the specification disclose a core without the limitations contained in the specific description. The specification describes the core as "a core of water soluble morphine and optionally an osmotic agent" ('339 patent, 3:38-42) and as "a core containing water soluble morphine and an osmotic agent[.] (Id. at 2:60-61.) These passages, while short, do not imply that a polymer coating could not be present; they are inclusive, not exclusive. The claim mirrors this inclusive language. (Id. at 20:60-67.) Thus, the Defendant's proposed limitation, which may be implied in the specific description, is far from omnipresent in the specification as a whole.

Further, to the extent the drafter intended to put limitations on the type of "core" he claimed, he put those limitations in the claims themselves. ('339 patent, 20:60-67.) This is demonstrated by the fact that some but not all of the limitations that are present in the specific description are present in the claims. Claim 1 provides that each sustained release particle has:

a core containing water soluble morphine and an osmotic agent, the core being coated with a rate-controlling polymer coat comprised of ammonia methacrylate copolymers in an amount sufficient to achieve therapeutically effective plasma levels of morphine over at least 24 hours in the patient wherein the said osmotic agent is an organic agent.

('339 patent, 20:60-67.) Thus, the claim itself puts limits on the core — it contains water soluble morphine and an osmotic agent, and that agent is an organic acid. This strongly suggests that, to the extent that the drafter intended limits to be placed on the term "core," he put them in the claim following the term itself. Because the claim language surrounding the term "core" sets forth the type of core the patentee intended to claim, there is no reason the Court should import other limitations into the term itself. Consequently, this Court rejects Defendant's construction because it imports a limitation from part of the specification into the claims. See Phillips, 415 F.3d at 1323.

Thus, the Court construes "core" to mean "an inner portion" because it is in line with the full breadth of the term's ordinary meaning and the specification provides no reason to narrow that construction.

The Court also notes that, despite Defendant's concern, its construction of "core" as "an inner portion" is not the same as construing it "an inner portion, including an internal polymer coat." Rather, the Court's construction gives a basic meaning to the term and allows the surrounding limitations in the claim to further limit the type of core that is claimed. The determination of whether the claims read on a product with a polymer coating in its core is a question of infringement and is not before the Court.
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1. The Terms "Core" and "Core Region"

The court finds that the terms "core" and "core region" are synonymous in the context of the '505 and '230 patents; thus, the court construes the term "core region" to have the same meaning as the term "core." This construction is apparent from the language of the claims themselves. The term "core region" does not appear anywhere in either patent except in certain claims, including claims 1 of the '505 and '230 patents. In those claims of the '505 and '230 patents where the terms "core region" and "core" appear, they are used interchangeably. For example, claim 1 of the '505 patent requires "an oral pharmaceutical preparation comprising (a) a core region." (Pl, col. 16:42-43 (emphasis added).) Claim 5 of the '505 patent, however, requires "[a] preparation according to claim 1 wherein the alkaline core comprises . . . ." Claim 5 depends from claim 1 and references "the alkaline core." (Pl, col. 16:65-66 (emphasis added).) Thus, the term "core" in claim 5 must be referring to the "core region" in claim 1. Claim 12 of the '505 patent also refers back to the "core region" in claim 1 when it requires "[a] preparation according to claim 1, wherein the core comprises . . . ." (Pl, col. 18:4-5 (emphasis added).) Similar examples occur in the claims of the '230 patent. Indeed, the only place where the term "core region" appears in the '230 patent is in element (b) of claim 1, where the term "core region" is preceded by the word "said," which in patent claim drafting indicates that the specific claim term "core region" has been previously introduced. Manual of Patent Examining

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Procedure, 7th ed., § 2173.05(e), at 2100-168. Since the phrase "said core region" in claim 1(b) has no antecedent basis and refers back to the term "alkaline reacting core" in element (a), the term "core region" in element (b) must be referring to the term "core" in element (a). Finally, there is no language in the specification or the claims of either patent to suggest what, if anything, beyond the core region would be encompassed by the term "core"; accordingly, "core" must be defined to be synonymous with the term "core" because "a patent claim may be interpreted only as broadly as its unambiguous scope." Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1581 (Fed. Cir. 1996) (citations omitted). 12

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12 Although the court need not address extrinsic evidence to determine whether the terms "core" and "core region" are synonymous, the court notes that the extrinsic evidence confirms the court's construction. Dr. Lovgren, one of the inventors of the two patents, testified that the term "core region" as used in claim 1 of the '505 patent refers to "the core." Indeed, Dr. Lovgren stated that the term "alkaline reacting core" in the claims of the '230 patent means the same thing as the term "core region" in the claims of the '505 patent. (Lovgren Tr. 1862:5-18, 1863:20-1864:3.)

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The court defines the terms "core" and "core region" to mean the portion of the patented preparation that lies beneath the subcoating and contains the active ingredient and, in the case of omeprazole as the active ingredient, an ARC. The claim language itself expressly states that the "core region" is the portion of the formulation that lies beneath the inert subcoating, which is "disposed on" the core region. (Pl, col. 16:48-50; P2A, col. 13:10-11.) Also, the discussion of the subcoating in the patents makes it clear that the entire mixture, whether called the "alkaline core" or the "alkaline reacting core" is the core to which the subcoating is applied. (Pl, col. 4:3-58, see particularly col. 4:4, 13, 31; P2A, col. 8:66 - col. 9:52, see particularly col. 8:67, col. 9:6-8.)

The court's construction of the terms "core" and "core region" includes cores made by conventional pharmaceutical procedures. (See Pl, col. 3:1-11, col. 16:43-47.) The primary dispute concerning these terms is whether they encompass cores wherein the active substance is coated or sprayed onto a sugar seed. Based on the briefing submitted on claim construction as well as the evidence introduced at trial, the court finds that, in the abstract, a person of ordinary skill in the art could consider the sugar sphere itself to be a "core," but that same person could also consider the sugar sphere plus the active layer sprayed onto it to be a "core." 13 Defendant Genpharm's construction for the term "core," which would exclude cores made by layering onto sugar spheres, incorrectly focuses attention on this abstract situation and away from the meaning a person of ordinary skill in the art reading these two patents would attach to the term "core." For example, Genpharm cites to a definition for the term "core" in a non-technical dictionary. Cf. Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1580-81 (Fed. Cir. 1986) (finding general dictionary definition secondary to specific meaning of technical term as used and understood by those of ordinary skill in the art). Even though the term "core" when applied to coated sugar spheres might be limited to the sphere itself in the abstract, the court finds that in the context of these two patents a person of ordinary skill in the art would understand the term "core" to encompass not only the sugar sphere but also the active layer sprayed or coated onto the sugar sphere.

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13 A summary review of patents in this field demonstrates this point. Compare U.S. Patent No. 4,808,416, at 1 (Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 41) (identifying cores as including the sucrose granule, or sugar seed, and the active layer), with EP 0 013 262 (G707, at 3) (describing the use of a "core made up of pharmaceutically indifferent material" that is then coated with the active drug).

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The patent specifications expressly state that cores may be made "by conventional pharmaceutical procedures," (Pl, col. 3:66-68; P2A, col. 8:62-64), and some of the conventional pharmaceutical procedures that may be used to prepare cores are expressly disclosed in the patent specifications and file histories. Conventional pharmaceutical procedures for making cores may include, but are not necessarily limited to, cores formed by extrusion and spheronization, cores made by layering on sugar seeds, and cores made by tabletting techniques. (See, e.g., Pl, col. 1:57 - col. 2:4, col. 3:1 - col. 4:2, col. 16:43-47 (the powder mixture is formulated into pellets, tablets or capsules, which are used as cores for further processing, such as

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applying the subcoat) (emphasis added); see also Story Tr. 3737:10-13 (testifying that the technique of layering active drug on sugar sphere seeds was known prior to 1986); P921 at 12:3-4, 14:20-15:3.) Tablet cores are found in Example 1 of the '505 patent. (Pl, col. 6:29-65.) Extruded and spheronized cores are described in Example 2. (Pl, col. 7:55 - col. 8:34.) The '505 patent specification also expressly references active-coated sugar seeds as "cores." The '505 patent specification states that WO No. 85/03436 (the "'436 application") describes pharmaceutical preparations containing cores, (Pl, col. 3:1-2), and the '436 application, a part of the prosecution history, acknowledges that active coated sugar seeds are a type of core "widely used in the known art." (Astra's Cl. Constr. Mem., Ex. 4, '436 application at 12:4-19; App. 1, '505 Prosecution History at 166.)

Contrary to arguments made by Second Wave Defendants Mylan and Eon, Astra's citation to the '436 application in the '505 and '230 patents and their file histories does not serve as a disclaimer of a sugar core with a layer of the active ingredient. The '505 and '230 patents never explicitly adopt an active-coated sugar core as part of one of the examples or preferred embodiments for the claimed invention described in the specification; however, the specification need not describe every possible way of making the product. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121-22 (Fed. Cir. 1985). Far from expressly disclaiming the method of laying the active ingredient on a sugar sphere that is described in the '436 application cited in the patents, Astra claimed cores formed by that method in its patent by claiming any formulation with cores made by conventional pharmaceutical techniques.

Defendant Genpharm would graft onto the claims a requirement of homogeneity in order to exclude a core that is built on a sugar seed. (See Story Tr. 3712:4-18, 3719:7-3720:5, 3725:2-13, 3720:12-3721:5 (testifying that one of ordinary skill in the art would conclude that "core" as used in the '505 and '230 patents is a homogenous mixture of omeprazole, alkaline compounds, and excipients, with the omeprazole uniformly distributed throughout the core).) For intrinsic support within the '505 patent, Genpharm relies on the sentences bridging columns 3 and 4 of the '505 patent, which describe using a mixture of omeprazole and other materials to form "small beads" by conventional procedures, which are "used as cores for further processing." (See P1, col. 3:66 - col. 4:2; see also P2A, col. 8:62-65.) The flaw in Genpharm's logic is reading the reference to a powder mixture "formulated into small beads" as excluding a mixture coated onto sugar seeds. There is no question that coating a sugar seed with an active substance is a conventional procedure, and nothing in the language Genpharm highlights excludes coating the mixture onto sugar seeds to form the small beads.

Genpharm also relies on references in the patents to the subcoating as the "first layer." (See, e.g., P2A, col. 8:1-3.) Those references, however, concern the first layer of the invention--the subcoating. They do not exclude making small beads using the conventional sugar seed process before applying the "first layer" of the invention, which is the subcoating. 14 Genpharm's definition is also based on consideration of a subset of the examples included in the '505 patent specification. By requiring a homogenous core, Genpharm adopts a definition for "core" and "core region" that is limited to those cores made by particular processes, which do not include cores made by spraying active ingredients onto a sugar seed. Since it is improper to read a limitation from the specification into the claims or to limit the claims to examples in the specification, see Tate Access Floors, Inc. v. Maxcess Techs., Inc., 222 F.3d 958, 966-67 (Fed. Cir. 2000); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997), the court will not limit the definition of the terms "core" and "core region" to exclude cores made by spraying or coating a sugar seed. The claims themselves do not contain any process limitations, and, as such, cores produced by any "conventional pharmaceutical procedure" are covered by claim 1.

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14 This misreading infects Genpharm's arguments based on the testimony of the inventors--the court finds that the inventors' testimony does not support Genpharm's claim construction.

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Genpharm's construction is not only inconsistent with the intrinsic evidence but also with the testimony of those skilled in the art, who testified, both at the trial and throughout discovery, that the terms "core" and "core region" mean the portion of the pharmaceutical preparation that lies beneath the subcoat. Dr. Auslander, KUDCo's expert, understood the term "core region" to refer to "everything under the subcoat . . . It contains all the omeprazole plus the alkaline-reacting compound." (Auslander Tr. 2687:23-2688:14.) Likewise, in an opinion based on his experience as a formulator for the past thirty years, Cheminor's expert Dr. Porter recognized that the term "core region" refers to the "material under the sub coating." (Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 34, Porter Dep. Tr. 45:4-14.) Cheminor's formulators identified the core of a

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formulation in its development reports as "core (sucrose, drug and meglumine)." (Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex 39, Omeprazole Capsules - Development Report at 5; see also Ex. 40, portion of Development Report of Omeprazole Capsules 10, 20 & 40 mg at CD-V-00065-68, 70, 75, 77.) Andrx's former President and Chief Formulator, Dr. Chen, similarly referred to his layered sugar seed pellet as a core. 15 (P1312, Chen Dep. Tr. 347:7-18.)

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15 Dr. Chen testified as follows at his deposition, which was admitted into evidence and watched on video tape during the trial:

Q. Is it your understanding that the term "core" means the sugar sphere with the omeprazole on it?

A. Two together it is a core. The carrier is meaningless because it's just a carrier, inactive.Q. So the core means the active material on the pellet?A. Together.

Q. Sir, is that definition your understanding of the common meaning of a core?

A. That's my understanding, yes.

(P1312, Chen Dep. Tr. 347:7-18.)

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Genpharm's own Development Report refers to the nonpareil sugar seed together with the active, omeprazole-containing drug layer and HPMC subcoating as the "protected core." (P20 at G13549; P19 at G13038.) Even Dr. Story, Genpharm's expert, admitted at trial that he had used the word "core" to refer to a sugar seed that is layered with active ingredients during his testimony in Australia concerning a foreign counterpart to the '505 patent. (Story Tr. 3736:2-4, 3805:12-3806:12.) The process Dr. Story was describing in his Australian testimony is the process used by Genpharm to build up the active material on its sugar seeds. (Story Tr. 3805:12-3806:12.) Dr. Story agreed that formulation scientists, including those who worked with him, would interpret the term "core" to mean an inner seed with an active coating. (Story Tr. 3803:13-18.) Dr. Story further agreed that the term "core" in column 3 of the '505 patent refers to the portion of the formulation where the omeprazole is mixed with the ARC, (Story Tr. 3800:20-3801:2; see P1, col. 3:20-26), and that the reference to a "powder mixture" in that same column is a mixture of omeprazole and the ARC and other excipients, which can be formulated into, among other things, "pellets," (Story Tr. 3801:6-19; see P1, col. 3:66-68). In the context of the '505 patent, "pellets" means "cores." (Story Tr. 3801:20-22.) Finally, Genpharm's own purported person of ordinary skill in the art, Dr. Marshall, when preparing the expert reports Genpharm submitted, identified the ingredients of a "Formulation of cores/granules" to include both "Omeprazole" and the "Sucrose [sugar] spheres." (P1299, Marshall Report No. 3, at 4.) In summary, Dr. Story's testimony at trial in support of Genpharm's claim construction is outweighed by the intrinsic evidence and the testimony of those skilled in the art, including Dr. Story himself. Accordingly, the court declines to adopt Genpharm's proposed claim construction, which would graft onto the core a requirement for complete homogeneity and unnecessarily limit the conventional pharmaceutical processes by which the core could be created by excluding the process of layering the drug substance onto sugar spheres.

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Claim 1(a) of the '505 Patent identifies: "a core region comprising an effective amount of a material selected from the group consisting of omeprazole plus an alkaline reacting compound, an alkaline omeprazole salt plus an alkaline reacting compound and an alkaline omeprazole salt alone." (PSWTX 1A 16:44-47.) Similarly, '230 Patent claim 1(a) identifies: "an alkaline reacting core comprising an acid-labile pharmaceutically active substance and an alkaline reacting compound different from said active substance, an alkaline salt of an acid labile pharmaceutically active substance, or an alkaline salt of an acid labile pharmaceutically active substance and an alkaline reacting compound different from said active substance." (PSWTX 2A 13:1-9.)

The terms "core or core region" are defined as "the portion of the patented preparation that lies beneath the subcoating and

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contains the active ingredient and, in the case of omeprazole as the active ingredient, an ARC." Astra v. Andrx, 222 F. Supp. 2d at 447. "[T]he terms 'core' and 'core region' are synonymous in the context of the '505 and '230 Patents." Id.
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2. "cores"

The term "cores" is used in the context of "metal cores." Bayer contends that the term "core" was not understood in the art at the time the '799 Patent was developed and that the inventors explicitly defined metal core in the patent specification as follows:

In the context of the invention, a metal core is understood to be a geometric subregion of an acicular particle which is formed by the merging of several individual pores which are thus no longer separated by matter. Needles dissociated into metal cores are formed, for example, when the metal needles are produced from acicular a-Fe[2]O[3] by reduction, as a result of the fact that, dependent on the decrease in crystal volume during reduction, the pores increase in volume so that they ultimately overlap.

('799 Patent, col. 2, ll. 42-51). Thus, Bayer contends that the inventors defined "core" in terms of a metal needle (acicular particle) whose parts have become separated or dissociated from other regions of the needle. According to Bayer, under the patent's definition of "core," an acicular particle which has not dissociated or separated into two or more different geometric subregions consists of one core. The presence of different geometric subregions is detected by light colored gaps in the TEM image which indicate an absence of matter. Bayer contends that these subregions may have the same or different crystallographic orientation and areas of different crystallographic orientation do not qualify as cores unless they are separated from each other by light colored gaps as viewed by the TEM image at a magnification of about 120,000:1.

In response, the Sony Defendants contend that the term "core" is defined in the patent with reference to crystallographic orientation, which is omitted in the Bayer definition. Specifically, the Sony Defendants highlight that part of the specification which contrasts "metal core" from the prior art "chain of spheres." In this regard, the specification states:

The expression "chain of spheres" is known from the literature for structures which have a similar appearance in photographs taken through a microscope. However, these structures are formed by agglomeration or growth of individual metal particles. The individual "spheres" consist predominantly of differently oriented crystallographic regions. By contrast, the expression "metal core" as used herein is intended to designate a structure which may be imagined to have been formed from originally coherent material, the various metal cores of a needle having substantially the same crystallographic orientation.

('799 Patent col. 2, ll. 51-62). According to the Sony Defendants, the definition of a "metal core" as a "subregion" of a certain crystallographic orientation is evident from the comparison between the prior art particles with "differently oriented crystallographic regions" and the "subregions" of the claimed invention with "substantially the same crystallographic orientation."

After reviewing the claim language in light of the specification, the Court agrees with the Sony Defendants. Bayer's definition of "core" overlooks the remaining portion of the specification which elaborates on what is meant by the term "metal core" and includes as an essential element of that term "substantially the same crystallographic orientation." The specification explicitly explains that, as used in the patent, the term "metal core" is designated to have a structure formed "from originally coherent material, the various metal cores of a needle having substantially the same crystallographic orientation." ('799 Patent, col. 2, ll. 60-62). That the crystallographic orientation is important to the definition of metal core is, in the Court's view, highlighted by the comparison to the prior art "chain of spheres," which consisted mainly of differently oriented crystallographic regions.

Bayer contends that the appropriate focus is not on the crystallographic regions, but on the lack of dissociation in the claimed invention as compared with the prior art. With regard to the prior art, Bayer explains:

As used in the '799 Patent, the terms "dissociated" and "dissociation" regarding the prior metal needles (which the patent

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seeks to avoid) mean that the needle form has been separated or divided into separate parts or subregions.

(D.I. 476 at 22-23, P 39). In contrast, Bayer contends that the invention of the '799 Patent seeks to produce acicular (needle like) particles having a "coherent, non-dissociated external needed form" as depicted in Figure 1. According to Bayer, it is this "non-dissociated" form that makes the claimed invention different from the prior art needles which have "dissociated into a plurality of individual metal cores" as depicted in Figures 2 and 3. The Court disagrees with the distinction Bayer seeks to make between the claimed invention and the prior art. In the Court's view, the specification contradicts Bayer's position by highlighting the difference in crystallographic orientation as the key difference between the prior art and the claimed invention. That this is an important distinction between the claimed invention and the prior art was confirmed by one of the inventors of the '799 Patent, Dr. Schroeder, who testified as follows:

Q: So … it's a logical conclusion from the preparation process of the particle that you would expect a single core to have a uniform crystallographic orientation?

A: Correct. In the literature the contrasting … conclusion was arrived at with regard to the spheres. And subsequent to that we did our considerations for our particles.

(Schroder 9/28/96 Dep. 178-179).

In addition to the language of the specification, the Court's definition of the term "core" is supported by a certified translation of a counterpart patent to the '799 patent. Both the English translation and the original German text were submitted to the PTO in connection with the '799 Patent to give Bayer the benefit of its German filing date under 35 U.S.C. § 119. In relevant part, the English translation of the counterpart patent provides:

From the literature, the phrase "chain of spheres" has been used to describe structures having a similar appearance to these clusters when viewed under a microscope …. The individual "spheres" are predominately made up of regions with different crystallographic orientations. Contrary to this, the expression "metallic core" shall be used herein to describe a structure that originates from an originally coherent material. The metallic cores in the needle generally all exhibit the same crystallographic orientation.

(DX 699). Accordingly, the Court concludes that the term "core" is defined as a geometric sub-region of an acicular particle which is formed by the merging of several individual pores which are no longer separated by matter, but which have substantially the same crystallographic orientation.

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2. Correlating

The term "correlating" appears in the final step of Claim 1 of the '311 patent. The relevant language states that "correlating the quantity of said at least one compound with an autism condition or lack thereof in said patient" (Pltf. Exh. 2, at 39, Col. 17, lines 8-9). Metametrix argues that "correlating" means establishing a definite mutual or reciprocal relationship for predictive or diagnostic purposes. Plaintiffs argue that "correlating" means associating, relating, or co-relating one variable or factor with another, either positively or negatively. In support of their definitions, both parties cite Metabolite Labs., Inc. v. Laboratory Corp. of America Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

In Metabolite, the court examined claim terms relating "to a method of detecting a deficiency of cobalamin or folate in warm-blooded animals." Id. at 1362. The inventor had included this description of the patent in the preamble. Id. The original patent in Metabolite did not include a correlating step. Id. Rather, the patent examiner suggested a correlation requirement for the patent to be approved. Id. The inventor in Metabolite included the correlation step and received a patent. Id. Using the prosecution history, the Federal Circuit in Metabolite concluded that the prosecution history tied the preamble directly to the correlating step. Id. It found that the word "detecting" in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. Id. The Circuit noted that the assaying step identified an elevated or unelevated level of total homocysteine and the correlating step identified in elevated cases a relationship or lack thereof to a vitamin deficiency. Thus, the Circuit found that the preamble supported the district court's construction of

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correlating to include either a mutual or reciprocal relationship. Id.

Next, the Metabolite court looked at the specification and found that it did not require a confirmatory step, as advocated by the defendant. Id. at 1362-63. The court in Metabolite rejected the addition of a diagnostic criterion in correlating and limited the definition of correlating as "to establish a mutual or reciprocal relationship between." Id. at 1364.

The court finds Metabolite instructive. Much as in Metabolite, the '311 patent did not include a correlating step. Dr. Shaw only included the correlation step after the examiner said such a step would be needed for the patent to be approved. Much as in Metabolite, the parties before this court dispute whether the correlation requirement includes a diagnostic element. Here, although the preamble described the patent as a method for diagnosing the likelihood of autism in a patient, the claim describes the patent as a method of detecting. Based on the claim language (or even the preamble), the diagnosis of autism appears to be a separate step from the correlation of a quantity of a particular compound for an autism condition or lack thereof. It is only if the quantities of one or more compounds are abnormally high that there may likely be an ultimate diagnosis of autism. Thus, correlating and diagnosing appear to be separate steps. The court finds that a diagnostic element should not be added to the term "correlating."

Plaintiffs' definition appears to be unnecessarily repetitive in its description of correlating as "associating, relating or co-relating." Further, the comparison of one variable or fact with another appears to be already described in the claim language so that adding this descriptive language creates redundancy. Finally, the prospect that the correlation may be positive or negative also appears to be accounted for in the claim language. In the final step of Claim 1, the claim language indicates that the examiner correlates "at least one compound with an autism condition or lack thereof in said patient."

Metametrix's definition also adds unnecessary language. The use of the word "definite" is too strong as the nature of the detection of certain organic compounds appears to be delicate as one or more compounds may correlate with an autism condition. Correlation by its very nature creates an associational relationship rather than a definite relationship. Next, the use of "predictive or diagnostic purposes" appears to be too heavy-handed. The claim language attempts to correlate the presence of compounds with a condition. Thus, the court adopts a modified version of defendant's definition. Correlating means "establishing a mutual or reciprocal relationship."

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III.

Infringement

The primary challenge to the jury's indirect infringement verdict requires this court to review the district court's construction of the claim term "correlating." The infringement inquiry is a two-step process. This court construes the disputed claim terms and then compares the properly construed claims to the accused device. Cybor Corp., 138 F.3d at 1454. Thus, this court first reviews the district court's claim construction.

As always, the claim language itself governs its meaning. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). This court construes the meaning of claim language according to its usage and context. ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003). The touchstone for discerning the usage of claim language is the understanding of those terms among artisans of ordinary skill in the relevant art at the time of invention. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). Indeed, normal rules of usage create a "heavy presumption" that claim terms carry their accustomed meaning in the relevant community at the relevant time. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citing Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). Thus, this court sets the meaning of claim terms by ascertaining their technological and temporal context.

In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention. In addition to providing contemporaneous technological context for defining claim terms, the patent applicant may also define a claim term in the specification "in a manner inconsistent with its ordinary meaning." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing Teleflex, 299 F.3d at 1325-26). In other words, a patent applicant may define a term differently from its general usage in the relevant

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community, and thus expand or limit the scope of the term in the context of the patent claims. Id. Therefore, the primary aids to supply the context for interpretation of disputed claim terms are in the intrinsic record. Vitronics, 90 F.3d at 1582 (Fed. Cir. 1996).

Another tool to supply proper context for claim construction is the prosecution history. As in the case of the specification, the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term. Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) (a patent applicant may "clearly and unambiguously" disavow claim scope during prosecution).

This court also acknowledges the relevance of extrinsic evidence, often presented in the form of expert testimony. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999) ("Consultation of extrinsic evidence is particularly appropriate to ensure that [the court's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art."); Vitronics, 90 F.3d at 1585. Another excellent source of context for disputed terms is dictionary definitions and treatises. See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002) ("Dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms.").

As noted before, these claim construction aids inform the court's task of ascertaining the meaning of the claim terms to one of ordinary skill in the art at the time of invention. Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed. Cir. 2003) ("Moreover, as this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); Ferguson Beauregard v. Mega Sys., LLC, 350 F.3d 1327, 1338 (Fed. Cir. 2003) ("The words used in the claims must be considered in context and are examined through the viewing glass of a person skilled in the art."); Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1332 (Fed. Cir. 2001) ("It is important to bear in mind that the viewing glass through which the claims are construed is that of a person skilled in the art."); Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995) (en banc) ("The focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). In this case, as evidenced by the jury instruction, the parties agreed that the level of ordinary skill in this field of invention was "a person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases."

The disputed term "correlating" appears in the second step of claim 13, which states: "Correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." In its Markman brief below, LabCorp urged the district court to construe "correlate" according to its dictionary definition as a verb meaning "to establish a mutual or reciprocal relation of" an elevated level of homocysteine. LabCorp further argued that the district court should construe the "correlating" step as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropyschiatric abnormality," or "[a] deficiency of folate which causes a hematologic abnormality." The district court adopted LabCorp's dictionary definition by construing "correlating" to mean "to establish a mutual or reciprocal relationship between," but declined to "include a reference to hematologic or neuropsychiatric abnormality" in order to avoid impermissibly importing a limitation from the specification.

On appeal, LabCorp argues that claim 13's correlating step should be construed as establishing that an elevated level of homocysteine is caused by a "shortage of cobalamin which causes a hematologic or neuropsychiatric abnormality," or a "deficiency of folate which causes a hematologic abnormality." LabCorp interprets the specification to clearly define a "deficiency of cobalamin" as the presence of a clinical or hematologic syndrome or both that responds to cyano-cobalamin treatment, and to acknowledge that some clinical or hematologic syndrome or neuropsychiatric abnormality must be present. Thus, LabCorp contends that the correlation step of claim 13 should be construed to require a showing of a separate hematologic or neuropsychiatric symptom to confirm the "correlation."

The claim states that the method must correlate "an elevated level of total homocysteine . . . with a deficiency of cobalamin or folate." This language does not require a further association between the level of total homocysteine and either a hematologic or neuropyschiatric abnormality or both. The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies. The claim simply says nothing about a confirmatory step or a further correlation beyond the stated relationship.

The preamble further supports the district court's reading of the claim: "A method for detecting a deficiency of cobalamin or

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folate in warm-blooded animals." This language restates that the invention detects vitamin deficiency. This introductory language does not relate those deficiencies to any particular abnormality. A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history. Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002) (in rare circumstances, a preamble's recitation of intended use may serve to distinguish the prior art).

An examination of the prosecution history of this patent brings the meaning of the preamble into focus. As originally filed, claim 13 did not contain the "correlating" step. The examiner rejected claim 13 under 35 U.S.C. § 112 because it did not "recite discrete, sequential process steps, for example, obtaining a sample, contacting the sample with, etc. The final step should be clearly related to the preamble of the claim." Rather than add a second step as the examiner suggested, however, the applicant responded: "As applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, not limited to any particular steps or methods." After this response, the examiner dropped the § 112 objection, but rejected claim 13 under § 102: "In the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the invention. The claim lacks a positive limitation for correlating to a particular condition and has only one method step recited." At that point, the applicant added the recommended "correlating" step. The examiner then allowed claim 13.

This prosecution history ties the preamble directly to the "correlating" step. Specifically, the recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency. "Detecting" in the medical context requires evaluation of all test results, both positive and negative, to evaluate a patient's condition. For example, the results of a pregnancy test can either be positive or negative. Either result is informative to the patient. Similarly, in this case, the assaying step can identify an elevated or an unelevated level of total homocysteine. Then the "correlating" step can identify, in cases of elevated levels, a relationship or not to vitamin deficiency. The results in either the assaying or correlating steps are informative. Thus, the preamble supports the district court's construction that "correlating" includes ascertaining either a mutual or reciprocal relationship between total homocysteine and a vitamin deficiency. The preamble does not require this invention to show a further association with an abnormality.

The specification confirms that the claim language does not require as part of the method a confirmation that the elevated level causes some deleterious symptoms or abnormalities. LabCorp points to portions of the specification that discuss the relationship between the elevated levels and either clinical or hematologic symptoms. See, e.g., '658 patent, col. 10, ll. 56-61; col. 12, ll. 8-15. LabCorp would expand those references to require some confirmatory step in the claim. The specification, however, does not require such a confirmatory step. Rather, the specification at one juncture acknowledges that the method can show vitamin deficiency without any clinical symptoms: "These findings led us to conclude that large numbers of patients with cobalamin deficiency lack the 'typical' clinical and hematologic features usually expected to be present in cobalamin deficiency . . . ." Id. at col. 11, ll. 40-45. In other words, the specification shows that the method can show an association between elevated levels and vitamin deficiency without any further clinical symptoms. Thus, the district court properly refused to import into the claims LabCorp's proposed limitation from the specification. The specification itself does not support such a limitation on the meaning of the claims.

As noted earlier, the district court construed "correlating" to mean a "mutual or reciprocal relationship between" the elevated levels and the vitamin deficiencies. The inventors discovered that assaying total homocysteine correlated with (or predicted relatively accurately) whether a patient had a deficiency of cobalamin or folate. Id. at col. 4. ll. 17-23; col. 10, ll. 35-42. The specification explains that an elevated level of total homocysteine often indicates a deficiency, while a non-elevated level indicates no deficiency. For example, the overview of the invention notes: "This invention pertains to . . . methods for determining whether said warm-blooded animal has a cobalamin deficiency, a folic acid deficiency, neither, or both." Id. at col. 1, ll. 13-15 (emphasis added). Next, in the summary of the invention, the patentee stated: "Accordingly, assays for homocysteine can be used to determine the presence or absence of cobalamin and/or folic acid deficiency in warm-blooded animals." Id. at col. 5, l. 66 - col. 6, l. 1 (emphasis added). This court observes that the perfect symmetry between "mutual or reciprocal" and "presence or absence" shows that the district court correctly placed the term "correlating" in its proper context with its proper meaning.

Finally, the patentee explained:

Once folate and/or cobalamin deficiency has been determined, the progress of treatment can be monitored by repeating the assays periodically during and after treatment. A drop in the level of homocysteine in the serum and/or urine after oral or

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parenteral adminstration of cobalamin and/or folate as the case may be confirms the diagnosis.

Id. at col. 10, ll. 18-24. This recitation confirms that the patentee anticipated assays without an elevated level of total homocysteine, i.e., the reciprocal relationship, would further confirm the diagnosis by showing an improvement trend after a physician prescribed treatment.

Taken in the context of the entire specification, "correlating" means relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither. In essence, "correlating" means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship). The claim, in other words, provides that if the assay discloses "an elevated level of total homocysteine," the physician determines whether there is a cobalamin or folate deficiency by "correlating," i.e., comparing the elevated level with the normal homocysteine level. In sum, the specification and prosecution history confirm that the claim language "correlating," in the understanding of one of ordinary skill in this art field at the time of invention, includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency. Further, the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms. The district court correctly construed the claim.

LabCorp also raises claim construction arguments in its challenge to the trial court's assessment of damages. Specifically, LabCorp contends that only twenty percent of the assays have elevated levels of homocysteine and therefore only this percentage could form the basis for a damages award. As noted earlier, LabCorp itself urged the district court to define "correlating" to include either a mutual or a reciprocal relationship. In the damages calculation, however, LabCorp prefers to restrict the claim to correlations that yield mutual relationships while excluding any reciprocal relationships. This court declines the invitation to apply a different claim construction for computation of damages than for infringement liability.

As explained above, the mutual relationship is established when an elevated homocysteine level is present, whereas a reciprocal relationship is established when an elevated homocysteine level is absent. LabCorp's new damages argument, in essence, attempts to change its claim construction position to read out the reciprocal relationship that it initially urged. This court, as it does now, has previously declined such invitations. Interactive Gift Express, 256 F.3d at 1346 (Fed. Cir. 2001) ("[A] party will be judicially estopped from asserting a position on appeal that is inconsistent with a position it advocated at trial and persuaded the trial court to adopt."). For all purposes in this litigation, this court affirms the district court's construction of the "correlating" step.

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D. "Correlating the Presence and Quantification of the Precipitate(s) at the Discrete Region(s) with the Identification and/or Quantification of Said Target Compound" 4

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4 This is the sole disputed claim term for which the parties were not "amenable" to the Court's tentative construction, and for which they subsequently submitted alternative constructions. (See Supp. Markman Letter 1-2.)

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Claim Term	Eppendorf's Construction	Nanosphere's Construction
*3*Initial Proposed Constructions (Markman Briefs)		
"correlating the presence and quantification of the precipitate(s) at the discrete region(s) with the identification and/or	associating a species of capture molecule with the presence	correlating both the presence and specific amount of the metallic precipitate(s) with the presence and/or amount of target compound using a

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quantification of said target compound"	of precipitate(s) in one or more discrete regions of the test array and performing mathematical comparison(s) of the value(s) determined by the quantification of precipitate(s) in the aforementioned discrete region(s) to one or more reference(s) or standard(s) to determine if the target compound is present and/or to determine the amount of target compound in the sample	standard concentration curve that plots the specific amount of metallic precipitate versus the amount of "target compound"

*3*Alternate Proposed Constructions (Supplemental Markman Letter)

	associating a species of capture molecule with the presence of precipitate(s) in one or more discrete regions of the test array and comparing the quantification of the precipitate(s) with the identification and/or quantification of the target compound	associating the presence and specific amount of the precipitate in one or more discrete regions of the test array with the identification and/or quantification of the target compound

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Claims1 and 31 include in their description of the '829 Patent's method, "correlating the presence and quantification" of the precipitate(s) at the "discrete region(s) with the identification and/or the quantification" of the "target compound." '829 Patent, col. 11, II. 59-62; col. 14, II. 25-27. Eppendorf's initial proposed construction described "performing mathematical comparison(s)" determined by "one or more reference(s) or standard(s)" to determine the "amount of target compound in the sample." Nanosphere, however, initially defined the disputed claim term as involving the use of a "standard concentration curve."

The Court has determined that both initial constructions improperly seek to "give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," PPG Indus., 156 F.3d at 1355, and are also overly wordy and cumbersome. The patent does not use the words "mathematical comparison(s)," but the specification does explain that quantification "allow[s] a statistical comparative analysis" to be performed," '829 Patent, col. 8. II. 29-30, and that "[u]nexpectedly … a concentration curve could be obtained" for agold-labelled nucleotide sequence, id. col. 5, II. 8-11. Similar to preferred embodiments, see Phillips. 415 F.3d at 1323, a permissive measurement should not be used be restrict, or impose an unintended limitation upon, the construction of a disputed claim term.

As between the parties' alternative proposed constructions, the Court finds Eppendorf's to be more comprehensible and supported by the intrinsic evidence. Eppendorf's alternative proposal explains not only that the precipitate is associated with the target compound, but that "a species of capture molecule" is associated with "precipitate(s)," which in turn is compared with the target compound. Such a definition is helpful at explaining the relationships among the capture molecule, precipitate, and target compound, because the method described by the '829 Patent involves "putting into contact the target compound with a capture molecule," and a "reaction leading to a precipitate formed at the location of the binding," '829 Patent Abstract, without clarifying how the precipitate relates to the binding between the target compound and the capture molecule. Accordingly, the Court has adopted Eppendorf's straightforward alternateproposed construction.
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9. The court construes the term "cosmetic article" to mean a liquid, semi-solid, or dried preparation used to beautify the body by application. At the outset, the court observes that the adjective "cosmetic" means "a preparation, such as skin cream, designed to beautify the body by direct application." American Heritage Dictionary 328 (New College Ed. 1976). Thus, the use of this term imparts the idea that an "article" is applied to the skin for purposes of beautification. While defendants contend that the "article" is limited to liquid and semi-solid preparations based upon the use of the terms "pack" and "poultice" in the specification, the court notes that the specification, through the use of the term "may," offers these two formulations as examples only. "The keratotic plug remover according to this invention may take a form of a poultice … beside pack preparations." ('382 patent, col. 5 at 11. 19-22)(emphasis added) This permissive "may" language does not restrict the claimed invention to a particular formulation, but instead expressly leaves open the possibility of other formulations. Further, the court declines to limit the claimed invention to a liquid formulation based upon the examples alone, despite the fact that each example discloses either expressly or implicitly a liquid formulation. Indeed, the Federal Circuit has cautioned against restricting the claims based upon the embodiments described in the specification, stating "even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting Teleflex, 299 F.3d at 1327). The court, therefore, concludes that it would be improper to limit plaintiffs to a liquid formulation, particularly since the prosecution history reveals that plaintiffs submitted data for dry formulations; i.e., in amending claim 1 to include the wetting language, plaintiffs argued that the "the addition of the wetting step is not further limiting since the wetting step was implied in the previously submitted claim." (PX 41 at 260)
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Cotransformed Eucaryotic Cell	A eucaryotic cell that has undergone a genotypic change as a result of the introduction into the cell of more than one

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	different or distinct genes
Cotransforming	Process for carrying out transformation of a recipient cell with more than one different or distinct gene. Cotransformation includes both simultaneous and sequential changes in the genotype of a recipient cell mediated by the introduction of DNA corresponding to either unlinked or linked gene

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D. "COTTRELL CURRENT"

The third term of the 268 patent in dispute is "Cottrell current." Roche avers that "Cottrell current" means "diffusion controlled current which decays substantially in accordance with one over the square root of time." Roche Reply Br. at 28-31. Roche argues that the intrinsic evidence establishes that the current measured by the method must be "diffusion controlled." Id. at 28 (citing 268 Reisuee Patent, col. 3, l. 52). Moreover, the patent provides that "Cottrell current" should decay in accordance with the square root of time. See id. at 29 (citing 268 Patent, col. 8, ll. 9-12). But, not all the conditions for application of the Cottrell equation are necessary for the current to be "Cottrell current" in the context of the 268 patent. According to Roche, only these requirements are consistent with the statements of Dr. Weber during prosecution of the 268 patent application. Id. (citing Defs.' Joint App. at 72, 76).

Generally, the defendants assert that the patent specification requires Cottrell current to vary in accordance with the Cottrell equation; therefore, Cottrell current is produced only if the method employed controls all the variables in the Cottrell equation including: (1) a planar electrode; (2) the only available approach to the surface of the electrode is from the front; (3) the chemical entities must move by diffusion only; (4) there must be no movement of the fluid; (5) the concentration of the analyte in the solution when the potential is applied must be uniform; and (6) there must be no wall opposite the electrode. See Bayer Br. at 25 (citing Lowe Report P 29; Weber Report, at 7); see also Inverness Br. at 51; Inverness Surreply, at 23. Based on this understanding, Bayer argues that "Cottrell current" should be construed to mean "a current that conforms to the Cottrell equation and is measured under the six conditions required by Cottrell[,] including being measured in a solution in which the concentration of the reduced oxidant is wholly unchanging when the measurement begins." Bayer Br. at 25 (citing Defs.' Joint App. at 73, 82). Bayer avers that Roche's definition truncates the Cottrell equation and modifies the degree of compliance with the equation required by the 268 patent and its prosecution history. Id. (citing 268 Patent, col. 8; Defs.' Joint App. at 73, 82; Jeneric/Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377, 1381-82 (Fed. Cir. 2000)).

Similarly, Inverness argues that "Cottrell current" means "the measured current conforms to the Cottrell equation and that the conditions of the Cottrell equation are satisfied." Inverness Br. at 47. Inverness points to the 268 patent's disclosure of the entire Cottrell equation in its specification as evidence that the patent calls for strict adherence to the conditions for use of the Cottrell equation. Id. at 47-48 (citing 268 Patent, col. 3, ll. 43-66; id. col. 3, ll. 44-57; id. col. 3, ll. 51-57). Further, Inverness cites to passages in the prosecution history that suggest that the term contemplates strict compliance with the requirements of Cottrell equation behavior, particularly the requirements that the reaction in the solution have stopped and that the ferrocyanide concentration in the sample be constant or homogeneous. Id. at 48-50 (citing Inv. App. 8, Protest, Oct. 27, 1995, at 6-7; id. Exh. B, at 6; id. at 10, 15; Inv. App. 9, Office Action, Jan. 22, 1996, at 5).

In the context of the 268 patent, the specification and the prosecution history, the Court finds that "Cottrell current" means the rate of charge flow of a diffusion controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to t<-1/2> within experimental error.

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The Court notes at the outset that apparently there is no "plain meaning" for the phrase "Cottrell current." However, based on the background information on electrochemistry supplied by the parties, equally apparent are two things: that "Cottrell" refers to Frederick Cottrell, an electrochemist who determined the mathematical equation for predicting the current in a reaction controlled by diffusion at a planar electrode when a controlled potential, or a step potential, is applied, Roche Br. at 7-8; Pl.'s Exh. 12, PETER J. KISSINGER & WILLIAM R. HEINEMAN, LABORATORY TECHNIQUES IN ELECTROANALYTICAL CHEMISTRY 57-58 (Marcel Dekker, Inc., 1984) ("KISSINGER & HEINEMAN"), and that "current" has the plain meaning of "the amount of electric charge flowing past a specified circuit point per unit of time." AMERICAN HERITAGE DICTIONARY. See also KISSINGER & HEINEMAN, at 57 ("Current is physically defined as the rate of charge flow . . . ."). Arguably then, a simple grammatical construction for the phrase "Cottrell current" leads to a definition where Cottrell's equation defines the amount of electric charge flowing past a specified circuit point per unit of time. Or, "Cottrell current" could mean the amount of electric charge at a planar electrode in a diffusion controlled reaction that varies with time according to the Cottrell equation. But, the parties argue that the Court must make the definition of Cottrell current more specific with respect to how closely the current must follow the Cottrell equation.

Starting with the claim language, all of the independent claims of the 268 patent refer to measurement of the "Cottrell current" after the oxidation reaction has been "substantially completed" or has gone "substantially to completion." 268 Patent, col. 13, ll. 66-67 to col. 14, ll. 1-5; id. col. 14, ll. 60-67; id. col. 16, ll. 5-12; id. col. 16, ll. 64-67 to col. 17, ll. 1-4; id. col. 18, ll. 9-12; id. col. 18, ll. 44-47. That current then either "determines," "is correlated to," or "is proportional to" the amount of biologically significant compound in the sample. Id. col. 14, ll. 3-5; id. col. 15, ll. 1-2; id. col. 16, ll. 13-14; id. col. 17, ll. 5-6; id. col. 18, ll. 11-15; id. col. 18, ll. 47-49. Two of the claims refer to the concept that the Cottrell current is proportional to the concentration of the biologically significant compound. Id. col. 18, ll. 11-15 ("measuring the resulting Cottrell current, said current being proportional to the concentration of the reduced electron acceptor and the selected compound in the blood sample"); id. col. 18, ll. 47-49 ("measuring the Cottrell current through the cell, the Cottrell current being proportional to the glucose concentration in the blood"). This proportionality is confirmed for glucose in the specification. The patent reads: "Proportionality between glucose concentrations and Cottrell currents (recorded at t = 30 seconds after the application of potential) is shown in FIG. 7." Id. col. 8, ll. 18-20 (showing a straight line).

However, other claims suggest that the relationship between Cottrell current and concentration is not "proportional to" but "correlates with." Claims 12, 30 and 37 require "correlating the measured Cottrell current to the amount of analyte in the blood sample." Id. col. 15, ll. 1-2; id. col. 16, ll. 13-14. Similarly, Claim 33 requires "correlating the measured Cottrell current to the amount of cholesterol in the blood sample." Id. col. 16, ll. 41-42. This difference may have significance in light of the parties' argument about whether all of the conditions of the Cottrell equation must be satisfied for the current described by the 268 patent's method to be "Cottrell current." The Cottrell equation predicts that the current would be proportional to the concentration of the biologically significant compound at any point in time after the potential is applied. See Pl.'s Reply App. Exh. 2, ALLEN T. BARD & LARRY R. FAULKNER, ELECTROCHEMICAL METHODS: FUNDAMENTALS & APPLICATIONS 144 (John Wiley & Sons, Inc., 1980) ("BARD & FAULKNER").

The specification teaches several things about "Cottrell current." The 268 patent "utilizes Cottrell current micro-chronoamperometry" to quantify the amount of biologically significant compound in the sample. 268 Patent, col. 3, ll. 43-47. The patent states that

> in this method of quantification, the measurement of a diffusion controlled current at an accurately specified time (e.g. 20, 30, or 50 seconds, for example) after the instant of application of a potential has the applicable equation for amperometry at a controlled potential (E=constant) of:
>
> i(t) = nFAC[metabolite](D)<0.5>([pi] t)<-0.5>
>
> where i denotes current, nF is the number of coulombs per mole, A[] is the area of the electrode, D is the diffusion coefficient of the reduced form of the reagent, t is the preset time at which the current is measured, and C is the concentration of metabolite. Measurements by the method according to the present invention of the current due to the reoxidation of the acceptors were found to be proportional to the glucose concentration in the sample.

Id. col. 3, ll. 51-67. The equation set out in this portion of the patent is the Cottrell equation for measuring the current in a diffusion solution using a single planar electrode. See KISSINGER & HEINEMAN, at 58; BARD & FAULKNER, at 143.

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This part of the specification supports a definition for "Cottrell current" that requires the current to follow the Cottrell equation because it specifically identifies the Cottrell equation as the "method of quantification" required by the invention. Moreover, this description identifies one of the parameters for the Cottrell equation: a diffusion controlled reaction. This requirement is likely well known to one skilled in the art because a basic electrochemistry text teaches that "the important concept in [chronoamperometry] is diffusion-controlled oxidation or reduction." KISSINGER & HEINEMAN, at 52.

Furthermore, according to the specification, Figure 8 of the 268 patent "is a graphical representation of Cottrell current as a function of glucose concentration." Id. col. 5, ll. 28-29. On that graph, under the words "Cottrell Current" the equation i[t]=nFAD[HQ]<1/2> [pi] <-1/2[t]<-1/2> appears. Id. at 6, Fig. 8. Again, the label of the graph suggests that "Cottrell current" is current that varies in accordance with the Cottrell equation. However, the graph also shows that for a sample containing zero millimoles of glucose, there is a measurable current. Id. Roche argues that this suggests that the invention method is less than an "ideal" one because for zero millimoles of glucose, the Cottrell equation produces a result of zero microamperes of current. According to KISSINGER & HEINEMAN there is a "background response to the excitation signal for a solution containing supporting electrolyte only. This current decays rapidly when the electrode has been charged to the applied potential." KISSINGER & HEINEMAN, at 57. See also 268 Patent, col. 12, ll. 3-9 (discussing the occurrence of a background signal in some circumstances that must be accounted for); Bard Dep. at 173, 268 (discussing how to account for background currents); Defs.' Joint App. at 76, Protest Under 37 C.F.R. § 1.291 on Behalf of Tall Oak Ventures ("Protest"), Weber Aff. P 8.13 (describing background processes that occur during chronoamperometry and that produce measurable current). This phenomenon, then, is apparently known to one skilled in the art of chronoamperometry. Therefore, Figure 8 in the specification suggests that there is some predictable variation from the Cottrell equation based on practical or experimental error in the method practiced by the 268 patent. See Bard Dep. at 173 (discussing the results predicted by the Cottrell equation and accounting for experimental error); id. at 268 (discussing subtracting out the background current and determining experimental error around the Cottrell equation"); see also Defs.' Joint App. at 76, Protest, Weber Aff. P 8.13 (discussing deviations from the Cottrell equation in practice).

Roche also argues that the lines representing Cottrell current in Figure 8 deviate from the Cottrell equation because they show the current reaching a plateau short of zero for each glucose concentration. Roche Br. at 30; Roche Reply, at 25. Apparently it is well known to those skilled in the art of electrochemistry that the Cottrell equation, applied strictly, would not generate the plateaus in current that are represented on the "Cottrell current" graph of Figure 8; both of the defendants' experts testified as such. See Lowe Dep. at 171-73; Bard Dep. at 185, 190. Dr. Bard testified that such plateaus could be consistent with results obtained because of convection (movement of the sample fluid by external means rather than diffusion) or because of a non-planar electrode. Bard Dep. at 185. The KISSINGER & HEINEMAN basic electrochemistry textbook teaches that variations from the Cottrell equation could happen for these reasons as well. It states, in relevant part:

The Cottrell equation states that the product it<1/2> should be a constant K for a diffusion-controlled reaction at a planar electrode. Deviation from this constancy can be caused by a number of situations, including nonplanar diffusion, convection in the cell, slow charging of the electrode during the potential step, and coupled chemical reactions.

KISSINGER & HEINEMAN, at 58. See also BARD & FAULKNER, at 143-44 (discussing experimental limitations of "Cottrell conditions"). But, again, it seems these responses are predictable and do not change the fundamental decay of the current with respect to time. See KISSINGER & HEINEMAN, at 58-60; BARD & FAULKNER, at 143-46 Bard Dep. at 186 (discussing the relevant region of the lines in Figure 8 of the 268 patent); Defs.' Joint App., at 76, Protest, Weber Aff. P 8.13 (discussing practical considerations and variations of the current measurement therefrom). Therefore, the patent specification does teach, to one skilled in the art, some predictable variation from the Cottrell equation parameters. The Court must use the clues in the 268 patent claims, specification and prosecution history to clarify which Cottrell equation parameters are necessary for "Cottrell current."

The patent specification teaches that the system measures the "diffusion controlled" current and uses a "controlled potential." 268 Patent, col. 3, ll. 51-55. See also id. col. 8, ll. 21-23 (stating that "Cottrell chronoamperometry of metabolites needs the dual safeguards of enzymatic catalysis and controlled potential electrolysis" (emphasis added)). These factors are described by the ENCYCLOPEDIA OF CHEMISTRY, and would be well known to those skilled in the art:

[The potentiostatic chronoamperometry] technique consists of maintaining a constant potential without convection. When a reducing potential is imposed instantaneously on a stationary working electrode in quiescent solution, current will rise sharply and then decay as the electroactive species in the electrode vicinity is depleted by electrolysis. The magnitude of the

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current is proportional to the bulk concentration of electroactive species and is related to the electrode potential through the Nernst equation, Eq. (2). If the potential is sufficiently beyond E [degree]' [the formal standard potential], the Nernst equation demands complete conversion to the reduced form. Thus, under these conditions the current is diffusion-controlled and decays with 1/t<1/2>. This is shown by Eq. (3) [the Cottrell equation] where F is the faraday, A is the I=nFAC *[D<1/2> [pi] <-1/2>t<-1/2>] (3)

electrode area, D is the diffusion coefficient for the electroactive species, and C* is the bulk concentration of electroactive species.

Pl.'s Exh. 11, SYBIL P. PARKER, MCGRAW-HILL ENCYCLOPEDIA OF CHEMISTRY 312 (2d ed.) ("ENCYCLOPEDIA OF CHEMISTRY"). See also KISSINGER & HEINEMAN, at 52-58 ("The important concept in [chronoamperometry] is diffusion-controlled oxidation or reduction. . . . The Cottrell equation states that the product it<1/2> should be a constant K for a diffusion-controlled reaction at a planar electrode."). The 268 patent specification also teaches a planar electrode, although the claims do not require that the electrode be of a specific shape. See, e.g., id. col. 3, ll. 5-9 (teaching "laminated" electrodes); id. col. 5, ll. 45-67 to col. 6, ll. 1-57 (teaching "laminated" electrodes, electrode strips or ribbons of electrodes all with known area); but see, e.g., col. 13, ll. 60-61 ("providing a measuring cell having at least a first and second electrode"); id. col. 14, ll. 54-63 (referring to an "electrochemical cell" and "applying a sufficient potential difference between the electrodes of an electrochemical cell").

The ENCYCLOPEDIA OF CHEMISTRY describes the importance of a solution that is quiescent, or "marked by a state of inactivity or repose." WEBSTER'S UNABRIDGED, at 1865. See also 268 Patent, col. 8, ll. 25-28 (describing experiments used to verify the method as taking place in "quiescent solutions"). Apparently, a solution approaching such a condition is also necessary to generate "Cottrell current." The claims of the 268 patent teach that "Cottrell current" is the result that occurs after a potential is applied to a solution in which an oxidation reaction has proceeded "substantially to completion." See, e. g., 268 Patent, col. 13, ll. 66-67. As discussed above, this is clearly supported by the specification describing the preferred embodiments that require the oxidation reaction to proceed to completion or substantially to completion before the potential is applied and describing experiments run on "quiescent solutions." 6 See, e.g., id. col. 3, ll. 29-33; id. col. 4, ll. 55-58; id. col. 8, ll. 13-17; see id. col. 8, ll. 25-28. In other words, to practice the method of the 268 patent the concentrations of the reactants in the solution are nearly unchanging or are at equilibrium before the potential is applied. Therefore, the 268 patent teaches the importance of this Cottrell equation parameter.

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6 The Court notes that the specification also describes an embodiment in which a vibrator is used to agitate the reagents performing the oxidation of the metabolite "to enhance dissolution." 268 Patent, col. 6, ll. 64-67 to col. 7, ll. 1-2. In the context of the 268 patent, this embodiment appears to focus on making the oxidation reaction occur more quickly. This construction makes sense in light of the patent's teaching that the oxidation reaction must go to completion or substantially to completion before the potential is applied for the method of the invention to work. 268 Patent, col. 13, ll. 66-67 to col. 14, ll. 1-5; id. col. 14, ll. 60-67; id. col. 16, ll. 5-12; id. col. 16, ll. 64-67 to col. 17, ll. 1-4; id. col. 18, ll. 9-12; id. col. 18, ll. 44-47. The Court cannot construe the reference to vibration in this embodiment to mean that the inventors thought vibration or agitation of the solution after oxidation is desired or necessary.

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The prosecution history also reveals the importance of this Cottrell equation parameter, and a few others. When BMC sought to broaden the claims of the '564 patent with an application for reissue, the PTO examiner rejected the claims, in part, because the measurement of "Cottrell current" was anticipated or made obvious by the teachings in "Nankai et al. (EPO 0230472)" and Kawaguri et al. See Defs.' Joint App., at D108, D114-15, Office Action, PTO, Mailed Apr. 27, 1995 ("Apr. 27, 1995, Office Action"). The inventors filed a protest with the PTO on behalf of the reissue application, which matured into the 268 patent. In their protest the inventors specifically addressed the requirements for "Cottrell current." Id. at 48-58; 67; 73; 76, Protest. Most importantly for claim construction purposes, the PTO "dropped the [prior] art rejection in view of the original inventors explanation in their protest as to how Cottrell current is measured, and agreed with their assessment of the prior art references." 7 Id. at D183, Office Action, PTO, Mailed Jan. 22, 1996 ("Jan. 22, 1996, Office Action"). Therefore, the explanation for "Cottrell current" provided by the inventors to the PTO is important for determining the correct construction for the term in the 268 patent.

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7 The Court notes that the inventors' protest does not appear in the official file history of the 268 patent. However, it is clear that the PTO relied upon the protest with respect to the inventors' argument about "Cottrell current" because the first PTO office action in the file dated after the protest specifically refers to it as the reason for dropping the objection to "Cottrell current." Defs.' Joint App., at D183, Office Action, PTO, Mailed Jan. 22, 1996 ("Jan. 22, 1996, Office Action"). The defendants assert that the protest is a legitimate part of the prosecution history, see Inverness Br. at 50 n.33, Roche does not contest this. Based on circumstances here, where it is clear that the PTO was persuaded to allow "Cottrell current" as used in the 268 patent over its own prior art objection because of the inventors' protest, the Court finds that the protest is "intrinsic" evidence and properly considered as part of the prosecution history of the 268 patent.

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Specifically, the protest states in pertinent part:

. . . By measuring the Cottrell current, and not being required to measure a peak current, as in Kawaguri et al., the measurement of the present invention may take place at any number of points along the Cottrell current v.s. time curve, depicted in Figure 8 of the '564 Patent. The result is far greater range (up to 1000 mg/dl glucose concentration) and far greater precision (much lower coefficients of variation), as set forth in the table, Column 9, Lines 35-55 of the '564 Patent.

* * *

Nankai et al. can likewise not be practicing the measurement of a Cottrell current, as Nankai et al. deals with measuring a variation in concentration of a substance during the reaction. Nankai et al. at Page 5, Lines 3-4. Weber at Paragraphs 9.6-9.9. As noted in the attached Affidavit, "One of the requirements for obtaining a Cottrell current is that the concentration of the species being oxidized be a constant in the solution before potential is changed to the value that causes the current to flow. If the concentration of the species sought is varying, as is in Nankai et al., then the Cottrell equation will not be obeyed, and the current is not a Cottrell current." Weber at Paragraph 9.9. See also [sic], Weber at Paragraph 8.5:

8.5 Cottrell Current. Cottrell current refers to the first case mentioned and diagrammed [sic] approximately in Fig. 1. Cottrell current is proportional to:

. t<-1/2> (t=0 is when the step occurs in the applied potential),

. n, the number of electrons transferred in a single electrode reaction in which one molecule of reagent is converted to one molecule of product. E.g.[sic], n=2 when benzoquinone is reduced to hydroquinone,

F, the Faraday constant, about 96,485 coulombs/mole of electrons,

. A, the electrode area,

. D<1/2>, where D is the specie's diffusion coefficient,

. C*, the concentration of the species of interest as it was, unchanging in space and time, before the potential step.

In all of the above cases it is assumed that, except for the changes wrought by the electrode reaction discussed, there is no variation in the concentration of the species of interest. If there is variation of the specie's [sic] concentration, then the current does not fall into any of the common categories of expected electrochemical results, and is certainly not Cottrell current.

Weber, supra, emphasis added.

Id. at 52-54, Protest (quoting id. at 73, Weber Aff. P 8.5) (emphasis in original). Furthermore, the affidavit of Dr. Weber, filed contemporaneously with the inventors' protest states, in relevant part:

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9.9 One of the requirements for obtaining a Cottrell current is that the concentration of the species being oxidized be a constant in the solution before the potential is changed to the value that causes the current to flow. If the concentration of the species sought is varying as it is in Nankai, then the Cottrell equation will not be obeyed, and the current is not a Cottrell current.

* * *

10.1 At issue is whether the earlier published literature anticipates parts of the patent of Szuminsky et al. ('56[4]).

'56[4] teaches how to make a reliable, useful, reproducible measurement of a Cottrell current. The later arises in an electrochemical cell which is initially at equilibrium or open circuit, or held at a potential where no more than a negligible current is drawn, and which is subsequently perturbed by changing the potential on the working electrode to a second, constant value sufficient to oxidize (reduce) each molecule of the desired species that reaches, by diffusion only, the working electrode. In this cell, the working electrode must be planar and large . . . . Under these conditions the measured current is proportional to: t<-1/2> (t=0 is when the potential is changed from the first to the second value), the number of electrons being transferred in each overall electrochemical reaction on a single molecule, the Faraday constant, the electrode area (it's macroscopic area if it is a composite mimicking a solid electrode), the square root of the diffusion coefficient of the species undergoing reaction, the concentration of that species in solution before the potential step, and a numerical constant. Neither Kawaguri nor Nankai teach all of the requirements for generating the Cottrell response; '56[4] does so teach these requirements as indicated above.

* * *

10.3 The intrinsic value of the chronoamerometry (as opposed to the voltammetry of Kawaguri) of a reaction that has gone to completion (as opposed to measuring a variation in concentration caused by an enzyme reaction, as in Nankai) is that the Cottrell current is dependent on fewer, and more easily controlled, parameter[s]. None of the rates of chemical reactions influence the signal magnitude in '56[4]. Both Nankai and Kawaguri are making measurements during the enzyme reaction. Further, Kawaguri is using voltammetry, in which the native electron transfer rate constants of the electron transfer agent, and the physical and chemical state of the surface are important. The most reproducible and trustworthy method is chronoamperometry in a solution with unchanging concentration.

Id. at 82-84, Protest, Weber Aff. PP 9.9, 10.1 & 10.3.

The inventors and their expert teach that the parameter of paramount importance to obtaining a "Cottrell current" is that the concentration of the solution is unchanging or the solution is at "equilibrium" before the potential is applied. Id. at 83, Protest, Weber Aff. P 10.1. See also id. at 54, Protest ("It is clear that it is the measuring of Cottrell current after the reaction has proceeded to completion which yields the improved results of the subject invention."); id. at 58, Protest ("Nankai et al. does not clearly teach taking a reaction to completion i.e. a point at which the concentration of analyte would be constant, and therefore, subject to the possibility of taking Cottrell current measurements . . . ."). They teach that this is important because if the concentration is varying the current will not obey the Cottrell equation. Id. at 82, Protest, Weber Aff. P 9.9. Specifically, Dr. Weber teaches: "If the concentration of the species sought is varying . . ., then the Cottrell equation will not be obeyed, and the current is not a Cottrell current." Id. Moreover, the inventors used this factor to distinguish the Nankai et al. prior art reference. See id. at 58, Protest. They stated, in part:

Nankai et al. does not clearly teach taking a reaction to completion, i.e. a point at which the concentration of analyte would be constant, and therefore, subject to the possibility of taking Cottrell current measurement, and does not clearly specify what is meant by the 'pulse voltage' being applied; Nankai et al. therefore does not inherently teach measuring Cottrell current.

Id. (citing id. at 83, Protest, Weber Aff. P 10.1).

In addition to the Cottrell equation parameter that the concentration of the analyte be nearly unchanging before the potential is applied, the inventors also discussed other Cottrell equation parameters relevant to their invention. Specifically, Dr. Weber teaches that

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when the electrode is macroscopically planar and large with respect to the time-dependent parameter (Dt)<1/2> (D is the diffusion coefficient of the species undergoing oxidation or reduction) then the current is generally proportional to t<-1/2> following a dramatic and rapid rise in current at the actual time of the change in potential (t=0 is the time of the step change in potential).

Id. at 72, Protest, Weber Aff. P 8.3. Therefore, it is important that the electrode be planar and large. Moreover, "Cottrell current" is proportional to t<-1/2>, but "in a practical cell, where one expects a certain current that is predicted by theory, it is often not exactly what one obtains due to [background processes including capacitance, corrosion of the electrode, or electrolysis of components of the sample that result in other currents]." Id. at 76, Protest, Weber Aff. P 8.13. Dr. Weber states that

the background processes are a minor component of the total signal in the cells (biosensors) under consideration. No background process would cause the current response . . . to be misidentified. For example, current from an experiment that should produce a Cottrell current may be found to be proportional to t<-0.45> or t<-0.55> rather than exactly t<-1/2>.

Id. In other words, the current will decay with t<-1/2> to within experimental error.

In summary, the claim language, the specification and the prosecution history of the 268 patent evidence that the method produces "Cottrell current" when: (1) the reaction is diffusion controlled; (2) the electrode is planar; (3) the concentrations of the reactants in the solution are nearly unchanging before the potential is applied; (4) the potential is controlled; and (5) the measured current varies with time according to t<-1/2> within experimental error. Therefore, "Cottrell current" in the context of the 268 patent means the rate of charge flow of a diffusion controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to t<-1/2> within experimental error.

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1. Construction of the term "coupled transcription and translation"

Plaintiff contends that "coupled transcription and translation" means that "DNA is transcribed to RNA and that RNA is translated to protein during the same reaction, i.e. simultaneously." Defendant agrees that "coupled" signifies simultaneous transcription and translation, but suggests that the court must specify whether "coupled transcription and translation" covers reactions in which there is any simultaneous transcription and translation or pertains only to reactions in which all of the transcription and translation occur simultaneously. According to defendant, if the term encompasses reactions in which "any" simultaneous transcription and translation occurs, plaintiff's patents are covered by the prior art two-step reactions; if the term means that "all" simultaneous transcription and translation must take place in the same reaction, defendant's products do not infringe.

Plaintiff's patents provide little guidance to the precise meaning of the term coupled transcription and translation. The patent claims do not define the term. The specifications of both the '637 and '817 patents signify only that coupled transcription and translation refers to reactions that take place "during the [same] time," or "simultaneously." The prosecution history renders much the same vague insight: plaintiff's reply brief on its appeal of the patent examiner's final rejection of its patent application explains that "'coupling' means the simultaneous transcription of RNA from a template DNA and the translation of that RNA into a protein." It is apparent that plaintiff intended the term coupled to signify simultaneous transcription and translation. But plaintiff did not spell out clearly in the patent specifications whether coupled transcription and translation should apply to reactions with "any" simultaneous transcription and translation or only to processes in which "all" transcription and translation for the entire experiment take place at the same time. Plaintiff's failure to do so means that it did not act as its own lexicographer on that question and that the term must be accorded its ordinary and accustomed meaning to those skilled in the art.

The definitions of the term "coupled" offered by plaintiff's and defendant's experts do not resolve the dispute. Instead, they tend to suggest that plaintiff's choice of the word "simultaneous" as a synonym for coupled is accurate. Defendant protests that defining coupled transcription and translation merely as simultaneous transcription and translation does not adequately

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distinguish the reactions in plaintiff's patents from the linked or two-step reactions available in the prior art. According to defendant, claims should be construed to maintain their validity if possible, see Whittaker Corp. by Technibilt Div. v. UNR Industries, Inc., 911 F.2d 709, 711 (Fed. Cir. 1990), and if the court does not construe the term "coupled" to mean that all transcription and translation takes place simultaneously, plaintiff's claims are invalid because they are anticipated by several two-step reaction references, Roberts et al., Perara and Lingappa, Stueber et al. and Coen et al. I will address defendant's arguments about the invalidity of plaintiff's patents in another section of this opinion and say here only that those arguments do not lead me to construe plaintiff's claims simply to avoid a defense of anticipation. See Corning Glass Works v. Sumitomo Elec. U.S.A., 868 F.2d 1251, 1256 (Fed. Cir. 1989) (court should not redraft claim to avoid defense of anticipation).

There is nothing in plaintiff's patents indicating that plaintiff intended to limit its use of the term "coupled transcription and translation" to reactions in which all transcription and translation takes place together, i.e., reactions that were not preceded by a separate translation step. If any coupling takes place as a result of the processes that plaintiff describes in its patent claims, then plaintiff's patent claims cover that reaction. As defendant points out, this may pose plaintiff some problems in dealing with the defense of anticipation. But anticipation is not a reason to limit the breadth of plaintiff's claims when the claims themselves appear broad. Thus, to the extent it is necessary to elaborate on the scope of plaintiff's use of the term "coupled transcription and translation," I find the term covers reactions in which there is any simultaneous transcription and translation.
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3. covalently attached is construed to mean directly secured or joined to the solid surface such that every chemical bond between the oligonucleotide and the surface is a covalent bond. Affymetrix contends that "covalently attached" means secured to the solid surface through a covalent bond, either directly or indirectly. Affymetrix's definition requires that only the bond at the point of attachment to the surface, whether to the oligonucleotide or to the linker, be a covalent bond. (Markman hearing transcript at 413:9-415:26).

Incyte contends that "covalently attached" means the oligonucleotide is covalently bonded to the surface by the 3' end of the oligonucleotide. Incyte's definition requires that, if a linker molecule is used to covalently attach the oligonucleotide to the surface, every bond between the surface and the oligonucleotide must be a covalent bond. (Id. at 416:14-18).

The Court adopts the plain and ordinary meaning of the words, "covalently attached" to determine that the oligonucleotide is secured or joined to the solid surface by covalent bonding. The Court rejects Affymetrix's suggestion that the oligonucleotide may be "indirectly" covalently attached to the surface via a non-covalent bond between the oligonucleotide and a linker molecule, as long as a covalent bond exists between the linker and the surface. Such an interpretation contradicts the plain language of the claim, which requires covalent attachment between the oligonucleotide and the surface, not merely between a linker and the surface. Affymetrix has failed to point to any intrinsic evidence to suggest that it intended "covalent attachment" to have any meaning other than this conventional meaning.
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B. COVALENTLY BONDING

The parties dispute the construction of the method step of "covalently bonding different labels to different nucleic acids of said multi-nucleic mixture to form labeled nucleic acids." "Covalently bonding" commonly means joining together two chemical entities by a covalent bond. This term construction largely turns on whether DNA sequencing produces a labeled nucleic acid in a mixture of nucleic acids.

Amersham argues that the claim describes how different labels become covalently bonded to different nucleic acids in the "covalently bonding" step -- a process whereby a label is covalently bonded with one or more nucleotides or nucleic acids to form at least two different labeled nucleic acids. In sequencing, this occurs during the primer extension reaction whether the labels are attached initially to the primer or to the terminator nucleotides. Exs. 201, 210; TR 26:24-27:16 (Chamberlin

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testimony); TR 174:6-178:1 (Roberts testimony).

Perkin-Elmer argues that no covalent bonding of a label to a nucleic acid takes place in DNA sequencing because, in DNA sequencing, the label is attached to a single nucleotide, not a nucleic acid. See, e.g., Perkin-Elmer Illust. Exh. # 35. By employing the gerund in claim 1's phrase, "covalently bonding different labels to different nucleic acids," the claim requires that a nucleic acid (apparently, at least two nucleotides covalently bonded together) must exist before a label may be covalently bonded to it. Therefore, Perkin-Elmer argues, claim 1 must exclude DNA sequencing because a nucleic acid extension, as opposed to a single nucleotide, is not produced until the primer extension process takes place.

Perkin-Elmer's insistence that, in DNA sequencing, the labels axe bonded only to single nucleotide, and not a nucleic acid, ignores the claim as a whole, the specification, and how one skilled in the art understands the DNA sequencing process to occur. The claim language as a whole specifies "covalently bonding different labels to different nucleic acids of said multi-nucleic acid mixture to form labeled nucleic acids." See Hockerson-Halberstadt, Inc. v. Converse, Inc., 183 F.3d 1369, 1374 (Fed. Cir. 1999) ("Proper claim construction …demands interpretation of the entire claim in context, not a single element in isolation."). This language is commonly understood to describe a process resulting in labeled nucleic acids which need not necessarily occur in a single event, at one fixed moment in time. In addition, the specification discusses the formation of labeled nucleic acids by primer extension. Patent, Col.5:23-32; 9:35-10:5; Fig. 7.

Petkin-Elmer's construction ignores the process by which DNA sequencing works. Both Dr. Chamberlin (Ex.63 at 8:23-9:5; Ex.73; TR 11:12-12:24; 26:24-27:16; 34:14-23), and Professor Glazer (TR 122:12-123:18), explained how the labeled nucleic acid chains are created in a reaction that rapidly adds nucleotides to a growing extention of nucleotides (i.e., nucleic acid). By primer extension (or nucleic extension) reaction, the subject DNA is replicated as individual nucleotides are sequentially (covalently) added to the primer to produce a growing nucleic acid chain. The chain's growth is stopped when a terminator nucleotide, covalently bonded with an energy transfer dye, is incorporated into that chain. Ex. 63, at 9:21-25; Exs. 208, 209; TR 26:24-27:1. Alternatively, a primer containing energy transfer dyes, rather than a terminator, may be used. Labeled primer is covalently bonded to the series of nucleotides and the terminator to form a labeled nucleic acid, as required by the claim. Exs. 73, 203. Dr. Roberts also agreed that labeled nucleic acids are formed by covalent bonding during DNA sequencing. TR 129:13-18; 174:6-178:1. The claim's requirement that labeled nucleic acids be formed by covalently bonding the labels to the nucleic acids is entirely consistent with the primer extension process.

The covalent bonding language is a meaningful limitation in the claim. While the '648 patent method could encompass DNA sequencing processes which rely on covalent bonding of the labels, the method would not cover, for example, probing assays which use non-covalent hybridization. In most such probing assays, the labeled probe is hybridized, and not covalently bonded, to a target sequence. Ex. 63, at 4:18-27; 9:1-2 (Chamberlin); TR 183:21-185:3 (Roberts). This "covalently bonding" requirement may also exclude other methods of detection and identification of nucleic material from the scope of the '648 patent claims as well, though the parties failed to explore other contexts for the Court.

Having reviewed the claims and the specification, and considered the extrinsic evidence, the Court finds that "covalently bonding different labels to different nucleic acids of said multi-nucleic acid mixture to form labeled nucleic acids" means that the labels become covalently bonded to different nucleic acids of the multi-nucleic acid mixture, during nucleic acid extention.
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7. covalently coupled is construed to mean directly joined to the solid surface such that every chemical bond between the oligonucleotide and the surface is a covalent bond.

Affymetrix contends that "covalently coupled" means covalently joined, directly or indirectly to the surface.

Incyte contends that "covalently coupled" means covalently bonded to the surface by the 3' end of the nucleotide or nucleotide polymer.

The Court adopts the plain meaning of "covalently coupled." Coupled means joined, and "covalently" indicates joining via covalent bonding. For the reasons stated above in the construction of "covalently attached," the Court finds that every

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chemical bond which effectuates coupling of the oligonucleotide sequence and the surface must be a covalent bond.
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G. "covered"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

An immediate-release fenofibrate composition comprising:

(a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 [um] m, a hydrophilic polymer and a surfactant; and

(b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "covered" to mean "appearing on or occupying some portion of the surface of." (D.I. 238 at 10.) n11 Teva proposes that I construe "covered" to mean "to lie over; spread over; be placed on or often over the whole surface of; envelop, film, coat." (Id.)

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n11 Because this claim term appears only in the context of the asserted claims of the '670 patent, which Abbott is not asserting against Impax, Impax has not offered a proposed construction for this term and therefore all citations in Part IV.G. are to C.A. 02-1512-KAJ.

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2. The Court's Construction

This is a situation where both parties assert that they have proposed the ordinary meaning of the term as understood by a person of skill in the art. (See D.I. 237 at 16; D.I. 268 at 15-16.) Each party's proposal finds its origin in a dictionary. In fact, the same dictionary, Webster's Third New International Dictionary 524 (3d ed. 1986), contains both definitions proposed by the parties. Although both proposed constructions may seem equally applicable if viewing the claim term in isolation, it is clear when reading the claim term in the context of the claim itself that the patentees intended to impart the construction as proposed by Teva. The claim language states, "covered with at least one layer." ('670 patent, col. 9, ll. 50-51 (emphasis added).) The addition of the word "layer" makes it clear that the patentees did not intend for the hydrosoluble carrier to be covered "here and there" with micronized fenofibrate, but rather they intended it to be "enveloped" with micronized fenofibrate, to the extent that the micronized fenofibrate is discernable as a "layer." A covering "here and there" would not be discernable as a "layer," as that term is used in the '670 patent. Additionally, in the Summary of the Invention section, the specification describes that the granules can be coated "with one or several ... layer(s)." ('670 patent, col. 3, ll. 39-40.) Although in a slightly different context, this disclosure indicates that the patentees intended that the composition could have several layers on the inert hydrosoluble carrier core. If "covered" were construed to mean that the inert hydrosoluble carrier were coated "here and there," it is difficult to see how that could be described as multiple "layers," in the context of the disclosures in the specification and the claim language. Thus, I find that, in the context of being "covered with at least one layer," the ordinary and customary meaning of the term "covered" is "enveloped," as in "to be placed on or over the whole surface of."
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C. "Cream-textured matrix" (Claims 17, 25, 78 and 89)

Plaintiff argues that "cream-textured matrix" means a non-brittle, deformable or soft bound mass. Defendants argue that the phrase means a bound mass with the look and feel of cream. 2

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2 Defendants also assert that Plaintiff expressly disclaimed any composition that is thick enough to be formed into a separate extrudate for converging with the outer cereal-based extrudate to form a third, dual-component extrudate. It is unclear whether Defendants seek to incorporate this assertion into their proposed construction of the claim term.

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There is no dispute between the parties that the ordinary meaning of the term "matrix" is "bound mass." Furthermore, the ordinary meaning of "texture" is "consistency, tactile characteristic." Therefore, the ordinary meaning of the phrase "cream-textured matrix" is "a bound mass, which has the consistency of cream," and the intrinsic evidence does not appear to further elaborate or limit the ordinary meaning of the term.

In support of a more limited construction of the phrase, Defendants cite only to the prosecution history in which Plaintiff distinguishes its claim from the Prior Art. According to Defendants, Plaintiffs emphasized that the Prior Art lacked a cream-like matrix because, in order for the inner component described by the Prior Art to be operable in the co-extrusion apparatus, the inner component had to be thicker than a cream-like matrix so that it could be formed into a separate extrudate to converge with the second outer extrudate. See Defendants' Memorandum of Point and Authorities in Opposition to Kal Kan's Opening Brief (citing Jt. App. Exhibit B, pg. 136). However, while Defendants' evidence may provide instruction as to the viscosity of the inner component, it fails to have any bearing on the actual meaning or definition of the term "cream-textured matrix." Therefore, the ordinary meaning of the term is manifest, and no further elaboration is necessary.
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H. "Cross-Hybridizes to the HPV Portion of Clone pCD15 to Greater than 50%"

Plaintiff does not believe that any construction is needed for this term and the next three but it does not object to the one proposed by defendant if the court believes that it would be useful to the jury to have an explanation of the terms. The Court of Appeals for the Federal Circuit has told trial courts to "instruct the jury on the meanings to be attributed to all disputed terms used in the claims in suit so that the jury will be able to 'intelligently determine the questions presented.'" Sulzer Textil A.G. v. Picanol N.V., 358 F.3d 1356, 1366 (5th Cir. 2004) (citing Shad v. Dean Witter Reynolds, Inc., 799 F.2d 525, 532 (9th Cir. 1986)). Although the parties do not dispute the meaning of the "cross-hybridizes" and "conditions" claim terms, it will be helpful to the jury to know how persons of ordinary skill in the art understand these term. Therefore, I will adopt the construction for this term as proposed by defendant: "cross-hybridizes to the HPV portion of clone pCD 15 so as to result in the conversion of 50% of the DNAs to fully or partially-stranded DNA molecules."
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1. The '808 Patent

Ciba's case for infringement of the '808 patent turns on the meaning of "cross-linking agent," a term that is present in all of the claims of that patent. Claim 1 of the '808 patent, from which all the other claims depend, reads:

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A composition comprising cross-linked anionic or amphoteric polymeric microparticles derived solely from the polymerization of an aqueous solution of at least of [sic] one monomer, said microparticles having an unswollen number average particle size diameter of less than about 0.75 micron, a solution viscosity of at least about 1.1 mPa.s, a cross-linking agent content of about 4 molar parts to about 4000 parts per million, based on the monomeric units present in the polymer, and an ionicity of at least about 5 mole percent.

('808 patent, 9:51-60 (emphasis added).)

a. The Parties' Proposed Constructions

Hercules contends that a "cross-linking agent" is: "A chemical agent that is polyfunctional in that it has at least two double bonds, a double bond and a reactive group, or two reactive groups to link polymer chains together." (D.I. 286 at 19.) That construction is based on statements made in the '808 patent specification and prosecution history that, according to Hercules, limit the types of chemicals that may be used as cross-linking agents according to the patent.

By contrast, Ciba contends that nothing in the written description or prosecution history should be read to limit the scope of "cross-linking agent." Ciba argues that the term should mean "an agent that links the polymer chains together in use to constrain the size of the microparticle. Cross-linking agent does not dictate the specific method by which the link is established, e.g., covalently, hydrophobically, ionically etc." (D.I. 275 at 36.)

b. The Court's Construction

I conclude, based on unambiguous statements made in the '808 patent specification and prosecution history, that Hercules's construction of "cross-linking agent" is correct. Furthermore, during the patent prosecution, the patentee argued that two specific chemicals, polyoxyethylene sorbitol hexaoleate and sorbitan sesquioleate, were not cross-linking agents because they did not contain the necessary double bonds or reactive groups. Therefore, the term "cross-linking agent" will be construed as: "A chemical agent that is polyfunctional in that it has at least two double bonds, a double bond and a reactive group, or two reactive groups to link polymer chains together. Polyoxyethylene sorbitol hexaoleate and sorbitan sesquioleate, as well as compounds containing only polyethylene oxide groups or impurities with double bonds or hydroxyl groups, are not cross-linking agents."

i. Specification

In arguing for their proposed constructions, the parties both rely on the specification of the '808 patent to show the ordinary meaning of "cross-linking agent." (D.I. 275 at 15; D.I. 286 at 19.) Indeed, because "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim . . . but in the context of the entire patent," Phillips, 415 F.3d at 1313, the patent specification is "the single best guide to the meaning of a disputed term," id. at 1315 (quoting Vitronics, 90 F.3d at 1582).

According to the '808 patent, the "[p]olymerization of the monomers [to produce a polymeric microparticle] is conducted in the presence of a polyfunctional crosslinking agent to form the crosslinked composition. The polyfunctional crosslinking agent comprises molecules having either at least two double bonds, a double bond and a reactive group, or two reactive groups." ('808 patent, 4:45-50.) Hercules's proposed construction is based on that description. (D.I. 286 at 19.)

Ciba argues that the passage that Hercules relies on refers only to preferred embodiments of the invention, and that the claims should not be limited to those embodiments. (D.I. 325 at 27 (quoting Phillips, 415 F.3d at 1323).) To decide whether the patent's language should be read as a description of the invention or of a particular embodiment, the language must be read in context: "The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent." Phillips, 415 F.3d at 1323. Here, there is nothing in the specification that suggests that the above description of "cross-linking agent" refers only to specific embodiments. Rather, the language refers generally to the process of making the cross-linked compositions claimed by the patent, and is clearly separated from the "Description of the Preferred Embodiments" included elsewhere ('808 patent, 6:46-9:39). Thus, contrary to Ciba's argument, Hercules is not trying to import a limitation from a particular embodiment. n3

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n3 I note that each of the preferred embodiments uses methylenebisacrylamide ("MBA") (see '808 patent, 6:46-9:39), which is a polyfunctional cross-linking agent according to the specification (id. at 4:50-52). Thus, the description of embodiments is consistent with the general description of cross-linking agent that Hercules relies on.

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Ciba also points to another part of the specification that it contends is evidence of a broader definition for cross-linking agent. The "Background" section of the '808 patent refers to a description of cross-linking found in a published patent application from the European Patent Office, EP 0,202,780 (the "'780 application") as follows: "EP 0,202,780 describes the preparation of polymeric, crosslinked, cationic acrylamide polymer beads by conventional inverse emulsion polymerization techniques. Crosslinking is accomplished by the incorporation of a difunctional monomer, such as methylenebisacrylamide, into the polymer. This crosslinking technology is well known in the art." ('808 patent, 1:23-29.) The '780 application states that:

[C]ross linking .. . may be brought about by controlled spontaneous conditions such as heating or irradiation, provided the degree of chain branching or other cross linking is reproducible and controllable, but preferably is brought about by reaction of the monomer or monomer blend, or the final polymer, with a covalent or ionic cross linking agent.

(D.I. 316, Ex. 12 at 9:19-27.) According to Ciba, the statement that cross-linking was "well known in the art" refers to the entire collection of methods listed in the '780 application, and so the '808 patent specification does not limit itself to any particular form of cross-linking. (D.I. 275 at 15, 36-37; D.I. 325 at 27.)

I do not agree with Ciba that the reference to the '780 application imports a broad definition of "cross-linking agent" into the '808 patent. While the '780 application does indeed describe cross-linking broadly, the '808 patent specification refers to that application in language that narrows the cross-linking being referred to. According to the '808 patent, the '780 application discloses cross-linking that "is accomplished by the incorporation of a difunctional monomer, such as methylenebisacrylamide, into the polymer," and it is "[t]his crosslinking technology" that is "well known in the art." ('808 patent, 1:26-29 (emphasis added).) A difunctional monomer like methylenebisacrylamide ("MBA") is a "polyfunctional crosslinking agent" according to the '808 patent. (Id. at 4:47-52 (listing MBA as one possible cross-linking agent).) A particular method of cross-linking is singled out from the '780 application and described as being well known in the art. Thus, the reference to the '780 application, taken in context, is more narrow than Ciba contends and is consistent with Hercules's proposed construction.

ii. Prosecution History

Hercules also relies on the '808 patent prosecution history to support its proposed construction of "cross-linking agent." "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. "The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent." Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed. Cir. 2003). Here, statements were made during the '808 patent prosecution that demonstrate a narrow understanding of "cross-linking agent."

During the examination of the parent application of the '808 patent, U.S. Application 07/535,626, the patent examiner rejected several claims, including the claim that issued as claim 1, as anticipated by or obvious over U.S. Patent No. 4,681,912 (issued July 21, 1987) (the "Durand reference," D.I. 316, Ex. 7). (D.I. 316, Ex. 3 at CIBA 000515.) According to the examiner, the Durand reference discloses microparticles that are polymerized "in the presence of poly-oxyethylene sorbitol hexaoleate and sorbitan sequioleate. Since oleate contains a double bond, [the examiner argued,] it is reasonable to expect these oleates functioning to some degree as a cross-linking agent in addition to being a surfactant." (Id.) The applicants responded that the Durand reference
fail[ed] to indicate the incorporation of a cross-linking agent into the polymer produced therein. . . . [While the examiner] points out that the oleate surfactants of Durand etal [sic] contain an unsaturated group [i.e., a double bond] n4 and thus would reasonably be expected to function as a cross-linker . . . [that] assumption is erroneous in that the oleates of Durand etal [sic] are monounstaurated and if any reaction thereof with the acrylamide and/or acrylate were to occur it would occur

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linearly because a cross-linking agent must contain two functional groups to act as such, see page 7, lines 11-26 of the instant specification.

(Id. at CIBA 000526 (emphasis in original).) The reference to page seven of the specification points to the following:
The polyfunctional crosslinking agent comprises molecules having either at least two double bonds, a double bond and a reactive group, or two reactive groups. Illustrative of those containing at least two double bonds are N,N-methylenebisacrylamide, N,N-methylenebismethacrylamide, polyethyleneglycol diacrylate, polyethyleneglycol dimethacrylate, N-vinyl acrylamide, divinylbenzene, triallylammonium salts, N-methylallylacrylamide and the like. Polyfunctional branching agents containing at least one double bond and at least one reactive group include, glycidyl acrylate, acrolein, methylolacrylamide and the like. Polyfunctional branching agents containing at least two reactive groups include aldehydes such as glyoxal, diepoxy compounds, epichlorohydrin and the like.

(Id. at CIBA 000486.) That passage is in the specification of the issued '808 patent. (See '808 patent, 4:47-62.) The examiner withdrew the rejection, in apparent reliance on that argument. (D.I. 316, Ex. 3 at CIBA 000532.)

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n4 A long-standing definition of "unsaturated" is "of or relating to an organic compound, especially a fatty acid, containing one or more double or triple bonds between the carbon atoms." Am. Heritage Dictionary of the English Language (4th ed. 2000). Here, the term refers to the double bond discussed by the examiner. (See D.I. 316, Ex. 3 at CIBA 000515.)

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Ciba argues that the prosecution history does not reveal any "special definition" of "cross-linking agent" (D.I. 325 at 28) or include "words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" (id. (quoting NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1308-09 (Fed. Cir. 2005))). According to Ciba, the Durand reference is not relevant prior art because the composition disclosed there is not cross-linked by any method. (D.I. 325 at 23, 28.) Thus, according to Ciba, the argument during prosecution should be understood as simply a response to the examiner's hypothesis about the presence of cross-linking agents in the Durand composition, a response that goes no further than demonstrating that "under the examiner's theory," the Durand surfactants, poly-oxyethylene sorbitol hexaoleate and sorbitan sequioleate, could not be cross-linking agents. (Id. at 8.)

Ciba's argument fails. Whether or not it would have been sufficient to overcome the Durand reference by arguing only that the composition was not cross-linked, the argument that the applicants actually made went further. The applicants argued that the chemicals disclosed in the Durand reference were not cross-linking agents "because a cross-linking agent must contain two functional groups to act as such." (D.I. 316, Ex. 3 at CIBA 000526 (emphasis in original).) That statement was followed by a reference to the portion of the specification that forms the basis for Hercules's proposed construction. Contrary to Ciba's assertion, there is nothing hypothetical about that response. In the face of a rejection, the applicants described what they view as a "cross-linking agent," and they stated that the Durand reference did not disclose one. That must be read as a disclaimer of claim scope.

The '808 patent prosecution history does two things. First, the statement that a cross-linking agent must contain two functional groups is consistent with the portion of the '808 patent specification already cited. (Supra Section IV.A.1.b.ii.) Indeed, the prosecution history explicitly refers to that portion of the specification. Second, the prosecution history states that the surfactants disclosed by the Durand reference do not have the necessary double bonds or reactive groups. Polyoxyethylene sorbitol hexaoleate contains polyethylene oxide ("PEO") groups (D.I. 291, Ex. D at 90:1-18), and both Durand surfactants contain impurities with double bonds and hydroxyl groups (id. at 97:13-100:1). Thus, those surfactants, as well as compounds that contain only PEO groups and/or impurities with double bonds or hydroxyl groups, are not cross-linking agents under the '808 patent. Therefore, the term "cross-linking agent" will be construed as: "A chemical agent that is polyfunctional in that it has at least two double bonds, a double bond and a reactive group, or two reactive groups to link polymer chains together. Polyoxyethylene sorbitol hexaoleate and sorbitan sesquioleate, as well as compounds containing only polyethylene oxide groups and/or impurities with double bonds or hydroxyl groups, are not cross-linking agents."
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1. Crude Reaction Mixture

Although the parties initially disputed the meaning of the term "crude reaction mixture," found in claim 1 of the '481 patent, this dispute eventually evaporated in the course of the Markman hearing, with the parties ultimately reaching essential agreement as to this disputed term. Initially, Synthon proposed that the phrase "crude reaction mixture" should be defined as

all components of a chemical reaction, including, but not limited to, product, impurities, unreacted starting materials, catalyst(s), and solvent.

Pfizer, in turn, originally proposed the following definition for "crude reaction mixture":

a mixture of at least the compound of formula (3), any unreacted starting materials, and any side products.

Pfizer later expanded on this proposed definition in the course of the briefing schedule, acknowledging that the "crude reaction mixture...contains at least any unreacted starting materials (i.e., the aldehyde and the ester), any solvent, catalyst and any potential side products that have been formed." The primary difference between the parties' proposed definitions was the level of detail to be used in describing the nature and relative quantities of the mixture's components.

In the end, the parties sensibly agreed that the phrase "crude reaction mixture," found in claim 1 of the '481 patent, is appropriately defined as:

"a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent."

Synthon Ip v. Pfizer, 437 F. Supp. 2d 565, 2006 U.S. Dist. LEXIS 45814, 1:05cv1267 (E.D. Va. Mar. 17, 2006) (Transcript, pp. 20-21). n8 Significantly, this definition is consistent with the teachings of the specification, as the detailed description of the invention, as well as the various examples set forth in the specification, make clear that the "crude reaction mixture" contains not only the compound of formula (3), but also unreacted starting materials and side products, as well as a catalyst and a solvent. n9

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n8 While no mention is made of impurities in this agreed-upon definition, there seems to be little doubt that the parties also agree that the crude reaction mixture includes stray impurities imported into the mixture by its components.

n9 See., e.g., '481 Patent, col. 6, ll. 18-20 ("Typically the reaction is carried out in a reaction solvent, preferably an organic solvent such as an alcohol, especially isopropanol ... in the presence of an organic base [or catalyst] such as piperidine or piperidine acetate.") (emphasis added); id., col. 6, ll. 22-25 ("The solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be separated from the rest of the unreacted starting materials and also from any potential side products") (emphasis added).

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As the '481 patent teaches, the compound of formula (3) may be produced by reacting two starting materials -- one an ester or ketoester, and the other an aldehyde -- in a solvent, such as isopropanol, in the presence of a catalyst, such as piperidine. This chemical reaction creates a "crude reaction mixture" containing the compound of formula (3). The next step in the process is to "isolate" from the crude reaction mixture the compound of formula (3). The '481 patent then requires that "the isolated compound of formula (3)" be reacted with another organic compound -- an aminocrotonate -- to form the

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compound of formula (2), otherwise referred to as the phthalimidoamlodipine. The compound of formula (2) is a protected amlodipine compound that is essentially identical to the amlodipine compound itself, except that it also contains a phthalimide protecting group. The '481 patent further teaches that the phthalimide protecting group is ultimately removed from the compound of formula (2) by using a deprotecting agent, thereby resulting in the formation of the final amlodipine compound.

Particularly pertinent here is the '481 patent's disclosure in claim 1, the sole independent claim, of "[a] process, which comprises isolating from a crude reaction mixture compound of formula (3)," and then "reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B." '481 Patent, col. 25, ll. 50-51; col. 26, ll. 1-2. This specific claim language is the source of the parties' claim term definition disputes. Specifically, the parties initially disputed the meaning of (i) "crude reaction mixture;" (ii) "isolating;" (iii) "isolating from a crude reaction mixture compound of formula (3);" and (iv) "isolated compound of formula (3)." n2 As Synthon I reflects, application of the legal principles taught in Markman and its progeny to the intrinsic evidence resulted in the adoption of preliminary definitions for each of the disputed terms and phrases. These preliminary definitions, discussed in detail in Synthon I, were as follows:

(i) "crude reaction mixture" means "a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent;"

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3. "cryopreservation," "cryopreserving," and "cryopreserved"

"cryopreservation," "cryopreserving," and "cryopreserved" are construed to mean "preserving at very low temperatures that may also include an additional agent capable of preserving the cells, blood components, or compositions."

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2. "cryopreservative"

"cryopreservative" is construed to mean "an agent capable of preserving at very low temperatures."

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A. "Crystalline"
1. The Claim Language

The term "crystalline" is used in all five claims in the '507 patent. The parties are in general agreement that "crystalline" ordinarily means "of or made up of crystals." (Claim Construction Br. of Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Br.") at 7.) "Crystals" are distinctive because their molecules or atoms are uniformly arranged. (Abbott Laboratories's Mem. in Supp. of Their Proposed Claim Construction ("Abbott and Astellas Br.") at 12.) Therefore, the parties agree that, under the ordinary meaning of "crystalline," a compound in its crystalline form exhibits uniformly arranged molecules or atoms.

That, however, is not the end of the matter because Claim 1 is naturally read to claim a form of crystalline cefdinir which displays certain characteristics. Specifically, the text claims "[c]rystalline cefdinir which shows the peaks" at certain powder X-ray diffraction (PXRD) angles. '507 Patent col.l l. 12-15. The peaks at those PXRD angles are what distinguish the '507 patent's invention from other crystalline forms of cefdinir. Similarly, Claims 2-5 claim crystalline cefdinir which is obtainable by certain process steps, and those steps serve further to define the '507 patent's invention.

Lupin argues that "crystalline," in the context of that patent's claims, must be read to mean "Crystal A as explained in the specification." 6 First, Lupin argues that the specification implicitly defined "crystalline" to mean "Crystal A" and explicitly

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described Crystal A as "the present invention." Second, Lupin argues that the '507 patent's prosecution history confirms that Crystal A constitutes the full extent of that patent's invention. Abbott and Astellas argue, on the other hand, that the specification and prosecution history disclose nothing that requires the Court to limit the ordinary meaning of "crystalline," and that Crystal A is merely the preferred embodiment of the '507 patent's invention.

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6 Although the parties dispute the meaning of "crystalline" within the claims, the purpose of defining "crystalline" is to establish scope of "crystalline cefdinir" as described in the claims.

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2. The Specification

Abbott and Astellas urge the Court not to give any effect to the specification in the '507 patent and to confine the inquiry to the accepted meaning of the term "crystalline." (See Abbott and Astellas Br. at 5.) As noted above, however, the Federal Circuit has warned against divorcing the claims language from the specification, and instructs courts to refer to the specification in seeking to define disputed claim terms. Indeed, it is appropriate to consider the specification even where the disputed claim term has an agreed-upon general meaning, as is the case here. For example, in Astrazeneca AB v. Mutual Pharmaceutical Co., the Federal Circuit relied on the specification to narrow the construction of the term, "solubilizer," a term with a generally-accepted meaning, to "surfactant," one particular type of solubilizer. 384 F.3d 1333, 1341 (Fed. Cir. 2004). The Federal Circuit reached that conclusion because, in the specification, the patentee had stated that "solubilizer" meant, in the context of that patent, "surfactant," and because the patentee had "clearly disavow[ed]" non-surfactant solubilizers in the language of the specification. Id. at 1339-40. Given the Federal Circuit's reasoning in Astrazeneca, the Court risks misconstruing the term "crystalline cefdinir" if it turns a blind eye to the '507 patent's specification and focuses only on the word "crystalline" as it appears in text of the claims.

Moreover, the Federal Circuit has construed patents in such a way that "the embodiments of the invention set forth in the specification constituted the invention itself, in spite of claim language that could, in the abstract, be interpreted more broadly." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 907 (Fed. Cir. 2004) (citing Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1139-40 (Fed. Cir. 2003); Watts v. XL Sys., Inc., 232 F.3d 877, 882-83 (Fed. Cir. 2000); Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301-02 (Fed. Cir. 1999); Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed. Cir. 1996); Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550-51 (Fed. Cir. 1996)). Of course, those decisions do not require a patent's scope to be limited in all cases to the particular embodiments disclosed in the specification, but there certainly are instances in which the specification makes "clear that the invention was limited to a particular structure" disclosed in the specification. Id. at 908. Here, the Court has a duty to decide whether the specification plays such a role in the '507 patent.

There are no talismanic words to indicate whether an embodiment in a specification constitutes the extent of the invention or is merely an example. Sometimes, the specification operates to circumscribe broadly written claims because it contains express limiting definitions and language disclaiming other embodiments. See id. at 907. But, neither explicit definitions nor explicit disclaimers are necessary, and claims also may be coextensive with a particular embodiment simply because the inventor affirmatively, and clearly, described the invention to be a particular embodiment disclosed in the specification. See Toro, 199 F.3d at 1300-02. Accordingly, the Federal Circuit states the basic guiding principle as follows: although the claims are not necessarily limited to the preferred embodiment of the invention, "neither do the claims enlarge what is patented beyond what the inventor has described as the invention." Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001).

Here, Astellas described its invention as "Crystal A." At the outset of the '507 patent's specification, Astellas represented that "[t]he present invention relates to novel crystalline" cefdinir. '507 Patent col.1 ll. 6-8. Astellas went on to explain the invention by stating that "[a]fter an intensive study, the inventors of the present invention succeeded in obtaining the compound (I) as a special crystalline form, i.e. Crystal A and completed the present invention, which is explained in detail as follows." 7 Id. col.1 ll.34-39. The term "i.e.," of course, means "that is," and Astellas specified the special form of crystalline cefdinir that it had invented by defining it with the phrase "i.e. [that is] Crystal A." Thus, in plain language, Astellas explained that its "present invention" was a "special crystalline form" of cefdinir which Astellas called "Crystal A." 8 Astellas then went on to explain "the present invention . . . in detail." Id. col.1 ll.37-38. The ensuing explanation occupies

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the next fifteen and one-half columns of the sixteen-column patent, and references only Crystal A.

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7 According to the '507 patent's specification, "the compound (I)" is "cefdinir." '507 Patent col.1 ll.9-10.8 Abbott and Astellas offer a slightly different, but very strained, reading of this sentence, which is discussed briefly below.

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Astellas and Abbott argue that the references to Crystal A in the specification merely articulate the preferred embodiment of an invention that might encompass multiple forms of crystalline cefdinir. The linchpin of their argument is that Crystal A is only a subset of the "present invention." Abbott and Astellas contend that Crystal A is so described in the patent by the phrase "Crystal A of the compound (I) of the present invention," which appears several places in the specification. 9 (See Abbott Laboratories's Response Memorandum to Lupin's Proposed Claim Construction ("Abbott and Astellas Response Br.") at 4.)

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9 It first appears in column 2, lines 15-17, and reappears several times thereafter in the specification.

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If read in the way Abbott and Astellas propose, that somewhat awkward language is inconsistent with the antecedent language in the specification which, as explained above, describes the '507 patent's invention as Crystal A. Moreover, when the patent explains "the present invention . . . in detail," and then describes only Crystal A, the patent offers no indication that the invention is not also explained in its entirety. Indeed, the descriptions of Crystal A in the specification, when compared with the claims, confirm that Crystal A is, in fact, coextensive with "the present invention."

First, in column 1 of the specification, Astellas explains that "Crystal A of the compound (I) shows its distinguishing peaks" at the very same seven PXRD angles which define the '507 patent's invention in Claim 1. '507 Patent col.1 ll.51-62, col.16 ll.19-27. Logically, therefore, if Crystal A is "distinguished" by those seven peaks, any form of crystalline cefdinir which displays peaks at the seven diffraction angles listed in Claim 1 is "distinguished" as Crystal A. 10 Had Astellas intended, in the chart found in column 1, to distinguish Crystal A from other forms of crystalline cefdinir that also fall within the scope of Claim 1, it would have listed, at a minimum, an eighth peak associated only with Crystal A. However, by listing in column 1 only the same seven "distinguishing" peaks featured in Claim 1, Astellas confirmed that Crystal A was synonymous with the invention listed in Claim 1.

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10 "Distinguishing" is defined as: "serving to separate or set apart from others in nature, character, or quality." Webster's Third New International Dictionary 659 (2002).

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Second, and importantly, that interpretation of "crystalline cefdinir" is also appropriate in the context of Claims 2-5. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001) "a claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent"). As is discussed in greater detail below, Claims 2-5 define the '507 patent's invention according to the processes that may be used to obtain it. See '507 Patent col. 16 ll.29-50. The process steps detailed in those claims correspond with the processes for making Crystal A disclosed in the specification under the heading "The Process For Preparing Crystal A of The Compound (I)." See id. col.2 ll.13-42; Laird Decl. P 43. Moreover, those same process steps were used in the Japanese priority application to distinguish between preparations of Crystal A and Crystal B. See '199 Application col.6 ll.1-25; Laird Decl. P 45; see also Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333, 1337 (Fed. Cir. 2001) (citing foreign priority application in claim construction analysis where priority application was part of patent's file wrapper). Therefore, Claims 2-5, like Claim 1, define "Crystal A," and, accordingly, one is justified in reading "crystalline cefdinir" to mean "Crystal A" throughout the claims. 11

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11 This is true even though "crystalline" is used somewhat differently in Claims 3 and 4 than in Claims 1, 2, and 5. In Claims 1, 2, and 5, "crystalline" is followed by the chemical name for cefdinir. '507 Patent col.16 ll.13, 29, 43. In Claims 3 and 4, "crystalline" is followed by the word "substance." Id. at col.16 ll.35, 40. However, Claims 3 and 4 are dependant on Claim 2, so if Crystal A is described in Claim 2, it must be described in Claims 3 and 4. See 3 Donald Chisum, Chisum on Patents § 8.06[5], at 8-254 (2002). Moreover, in light of the specification, the only crystalline product which is described by the claims is Crystal A, so whether it is "crystalline cefdinir" or a "crystalline substance," the crystalline product described in the claims can only be Crystal A.

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However, by defining "crystalline," as used in Claims 1-5, to mean "Crystal A," the Court is not affirmatively defining Crystal A to be anything other than what the claims say it is. 12 Abbott and Astellas seem to be particularly concerned that, by defining "crystalline" to mean "Crystal A" within the context of the claims, the Court will substitute the descriptions of "Crystal A" found in the specification (or elsewhere) for the descriptions found in the claims. There, of course, is no reason or justification for so construing "Crystal A," which is amply defined by the claims language itself.

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12 The claims explicitly define what Crystal A is, but only implicitly define what it is not. At this juncture, it is neither necessary nor appropriate to decide whether any known forms of cefdinir are necessarily excluded from the scope of the '507 patent's claims as a consequence of defining the '507 patent's invention to be Crystal A. The Court notes that, as argued by Lupin, the '507 patent's specification quite clearly distinguishes the '507 patent's invention (Crystal A) from the forms of cefdinir disclosed in the '334 patent. '507 Patent col. 1 ll.24-34. However, determining the consequences of that difference is not necessary to the task of construing the claims at issue.

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Abbott and Astellas also contend that "crystalline" cannot be "Crystal A" because they have discovered, experimentally, a non-Crystal A form of crystalline cefdinir which displays peaks at "about" (this term will be discussed below) the seven PXRD angles listed in Claim 1. (See Abbott and Astellas Br. at 8.) This argument rests on the assumption that Crystal A is not actually defined by the claims in the '507 patent. As explained above, the '507 patent defines Crystal A by certain processes (Claims 2-5) and according to the seven peaks listed in Claim 1. Therefore, any subsequently discovered crystalline form of cefdinir that features the seven peaks in Claim 1 is, by definition, Crystal A, and not something else. 13

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13 The specification itself makes a similar point when it explains that "any crystal of the compound (I) which shows substantially the same diffraction pattern . . . is identified as Crystal A of the compound (I)." '507 Patent col.1 ll.68-col.2 l.2 (emphasis added).

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In sum, a close reading of the '507 patent's specification discloses Crystal A to be the patent's invention. Moreover, the specification defines "crystalline" as used in the context of the claims, to mean "Crystal A." 14

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14 Again, however, Crystal A is affirmatively defined only according to the language of Claims 1-5. The construction of "crystalline" herein does not carry with it any affirmative descriptions of "Crystal A" which do not appear in the claims themselves.

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3. The Prosecution History

The Japanese priority application already has been referenced once above and, indeed, that document, along with the rest of the '507 patent's prosecution history, confirms that "crystalline," as used in the claims, means "Crystal A." Not only does the prosecution history focus exclusively on Crystal A, but it also assists in interpreting some of the awkward language contained in the '507 patent's specification.

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First, much of the language in the Japanese priority application closely resembles, and therefore helps to clarify, the language of the '507 patent. For example, as explained in multiple places above above, the following sentence appears in the '507 patent: "After an intensive study, the inventors of the present invention succeeded in obtaining the compound (I) as a special crystalline form, i.e. Crystal A and completed the present invention, which is explained in detail as follows." '507 Patent col.1 ll.34-38. In the Japanese priority application, that sentence reads: "After an intensive study, the inventors of the present invention succeeded in obtaining the novel Crystal A and Crystal B of [cefdinir] as disclosed hereinafter and completed the present invention." '199 Application col.3 ll.22-27. According to Abbott and Astellas, that sentence, as written in the '507 patent, cannot be read, based on its plain language, to announce Crystal A as "the present invention." See Markman Hearing Tr. 38-40, Mar. 8, 2007 (arguing that the word "special" prevents one from concluding that "Crystal A" is synonymous with "the present invention"). However that sentence, as it appears in the Japanese priority application, can be read clearly to define Crystals A and B as "the present invention." Such a reading is permitted because Astellas explicitly claimed only Crystals A and B in the Japanese priority application. Therefore, in that context, "the present invention" in the Japanese priority application could be nothing more than Crystals A and B. Where that sentence is repeated, nearly verbatim, in the '507 patent, a person of ordinary skill in the art is justified in reading it to announce Crystal A as "the present invention" (rather than a subset of the invention), even if, as Abbott and Astellas contend, such a reading is not compelled by the plain language of the sentence alone. (See Laird Decl. P 28.)

Similarly, the following, rather awkward, language appears in several places in the '507 patent's specification: "Crystal A of the compound (I) of the present invention." See, e.g., '507 Patent col.2 l.16, col.3 ll.15-16. As noted above, Astellas and Abbott argue that, in the context of the '507 patent alone, that sentence may be read to indicate that Crystal A is a subset of "the present invention." However, where that same term is used in the Japanese priority application -- "Crystal A and Crystal B of [cefdinir] of the present invention" -- it is clear that the products which precede "the present invention" cannot be a subset of "the present invention" but are, in fact, the extent of "the present invention." '199 Application col.3 ll.30-32. Because that term is repeated in the '507 patent, it is logical to read it, too, as announcing Crystal A to be the extent of "the present invention." (See Laird Decl. P 29.)

The significance of the clause "of the present invention" is further clarified by reading a letter written by Astellas to the patent examiner. '507 Patent File History, 10/27/89 Response (Paper No. 6). In that letter, Astellas touted the benefits of "the crystalline product of the present invention." Id. at 4 (emphasis added). In the context of that letter, "the crystalline product" is written in the singular form, and is quite clearly the extent of "the present invention;" therefore, it is permissible to infer that the word "of," when preceding "the present invention," was not necessarily an indicator of subset to Astellas. That being the case, a person of ordinary skill in the art would be justified in reading "Crystal A of the compound (I) of the present invention" to mean that Crystal A is the invention of the '507 patent, and not merely a preferred embodiment (or subset).

Finally, the rest of the prosecution history, like the '507 patent itself, mentions only Crystal A when touting the benefits of the invention claimed in the '507 patent. While there is no explicit declaration that Crystal A "is the present invention," there is language, referenced above, indicating that "the present invention" is comprised of only one "crystalline product," and not multiple crystalline products, as Abbott and Astellas now urge. Id. at 4, 7 (using phrases such as "the crystalline product of the present invention" and "a novel crystalline form," indicating that the invention constitutes a single form or product). Given that language, the prosecution history's exclusive focus on Crystal A bolsters the conclusion that Crystal A is "the crystalline product of the present invention" and that, therefore, "crystalline," as used in the '507 patent's claims, means "Crystal A."

In sum, the '507 patent's specification and prosecution history, read carefully together with the claims, announce "Crystal A" as the '507 patent's invention. Considering that evidence, a person of ordinary skill in the art would read the word "crystalline," as used in the claims, to mean "Crystal A as outlined in the specification."
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1. "crystalline"

The Eastern District of Virginia's construction of "crystalline" in claims 1-5 as "Crystal A" included the important caveat "as outlined in the specification." Lupin CC Order, 484 F. Supp. 2d at 459. Although the Eastern District noted the parties

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agreed that "crystalline" ordinarily means exhibiting "uniformly arranged molecules or atoms," id. at 454, the court relied on the language of the claims themselves, the specification, and the prosecution history to arrive at the more specific meaning recited in the specification.

The '507 specification states that "Crystal A of the compound (I) [cefdinir] shows its distinguishing peaks" at the seven particular PXRD angles enumerated in claim 1. '507 patent col.1 ll.51-62. Indeed, the phrase "Crystal A of the compound (I)" appears throughout the written description, and the patent offers the following definition: "any crystal of the compound (I) which shows substantially the same diffraction pattern [as in the table in col.1/claim 1] is identified as Crystal A of the compound (I)." Id. at col.1 l.67-col.2 l.2. As the Eastern District correctly concluded:

Had Astellas intended, in the chart found in column 1, to distinguish Crystal A from other forms of crystalline cefdinir that also fall within the scope of claim 1, it would have listed, at a minimum, an eighth peak associated only with Crystal A. However, by listing in column 1 only the same seven 'distinguishing' peaks featured in Claim 1, Astellas confirmed that Crystal A was synonymous with the invention listed in Claim 1.

Lupin CC Order, 484 F. Supp. 2d at 456-57. The problem, within the confines of claim 1, is that defining "crystalline" as "Crystal A," where "Crystal A" incorporates the seven PXRD peak limitations, arguably renders the remainder of that claim redundant. To distinguish the invention, however, the specification refers several times to "Crystal A of the compound (I) of the present invention," see, e.g., '507 patent, col.2 ll.15-17, and offers no suggestion that the recited processes could produce non-Crystal A compounds, even though other types of cefdinir crystals, namely Crystal B, were known in the art. As noted earlier, the Crystal B formulation actually appears in the parent JP '199 application. Thus, Abbott knew exactly how to describe and claim Crystal B compounds. Knowing of Crystal B, however, Abbott chose to claim only the A form in the '507 patent. Thus, the trial court properly limited the term "crystalline" to "Crystal A." The trial court's definition correctly identifies claim 1's literal scope.

Unlike claim 1, claims 2-5 do not recite the seven PXRD peaks expressly associated with Crystal A in the '507 specification. Nonetheless, the Eastern District of Virginia limited "crystalline" to "Crystal A" in these claims as well, The trial court gave two reasons for this limitation. First, "[t]he process steps detailed in those claims [claims 2-5] correspond with the processes for making Crystal A disclosed in the specification under the heading 'The Process For Preparing Crystal A of The Compound (I).'" Id. at 457 (quoting '507 patent, col.2 ll.13-14). Second, the parent JP '199 application recited these steps "to distinguish between preparations of Crystal A and Crystal B." Id. (citing JP '199 application, col.6 ll.1-25).

In limiting "crystalline" to "Crystal A" in claims 1-5, the Eastern District of Virginia did not improperly import the preferred embodiment into the claims. Initially, Crystal A is the only embodiment described in the specification. As discussed above, the specification's recitation of Crystal A as its sole embodiment does not alone justify the trial court's limitation of claim scope to that single disclosed embodiment. See Liebel-Flarsheim, 358 F.3d at 906 ("[T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). In this case, however, the rest of the intrinsic evidence, including the prosecution history and the priority JP '199 application, evince a clear intention to limit the '507 patent to Crystal A as defined by the seven PXRD peaks in the specification and in claim 1.

Initially, the Eastern District of Virginia properly considered the JP '199 application as relevant objective evidence of the inventor's knowledge at the filing of the '507 patent. While statements made during prosecution of a foreign counterpart to a U.S. patent application have a narrow application to U.S. claim construction, Pfizer Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006), in this case the JP '199 application is part of the prosecution history of the '507 patent itself. Indeed the '507 patent claims priority from the JP '199 application. Furthermore, the trial court did not rely on attorney argument or amendments during a foreign prosecution as in Pfizer, but consulted only the contents of the foreign priority application. The JP '199 application strongly suggests that the '507 patent intentionally excluded Crystal B compounds. As discussed above, the JP '199 application establishes unequivocally that Abbott knew and could describe both Crystal A and Crystal B. Abbott could have retained the disclosure of Crystal B to support the broader claims of the '507 patent, but instead disclosed and claimed A alone.

Furthermore, the prosecution history of the '507 patent shows a clear and intentional disavowal of claim scope beyond Crystal A. Co-inventor Takao Takaya, who prepared samples according to Examples 14 and 16 of the prior art '334 patent and a sample of "Crystal A of the present application," offered a declaration that Crystal A was more stable than the prior art

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samples from the '334 patent. An analytical chemist, Yoshihiko Okamato, corroborated this evidence. J. A. 501-04. Beyond these declarations, the applicant specifically limited the invention to Crystal A: "the method of preparation of the crystalline form of the presently claimed compounds is not considered the heart of the present invention. The crystalline form of the compound represents the inventive concept hereof, and it is clear that [the '334 patent] does not anticipate or suggest said crystalline form." J. A. 511 (Response to Office Action of May 11, 1989, received October 27, 1989, at 6).

Given the exclusive focus on Crystal A in the specification as well as the prosecution history of the '507 patent, the Eastern District of Virginia properly limited "crystalline" in claims 1-5 to "Crystal A."
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Crystalline Content

The '777 claims require that the crystalline content in the thermoplastically processable starch is less that 5%. The district court construed this term as measuring "the amount of crystalline lattice structure associated with the native starch compared with the resulting mixture. A resulting mixture has a 'crystalline content of less than 5% of starch' if it has 5% or less of the crystalline content of native starch." The court so instructed the jury.

The dispute at trial centered on the measurement of the crystalline content, the defendants arguing that on correct measurement the Novamont product is excluded. The '777 patent used powder x-ray diffraction to measure crystalline content. However, the parties disagreed as to which peaks in the x-ray diffraction plots of the Novamont product should be counted as representing crystalline content. Biotec stated that some of the peaks shown in the diffraction plots for the Novamont product represent lipid-amylose complexes (referred to as V-complexes) and do not represent "true crystallinity" of starch, and thus should not be counted in determining crystalline content.

The defendants' expert stated that the '777 patent teaches that all of the peaks on the diffraction plot are counted in measuring crystallinity. Biotec's expert stated that the '777 patent's diffraction plots were for potato starch, which does not contain V-complexes, and that this explains why all of the peaks were counted to measure starch crystallinity. Biotec stated that Novamont uses corn starch, whose V-complexes give rise to additional x-ray diffraction peaks that are not due to starch crystallinity and that should not be counted. Biotec's expert testified that those skilled in this art do not consider V-complexes to be "crystalline content" of starch. The defendants stressed that the '777 patent does not draw this distinction, and argued that the patent requires determining the overall crystallinity of the resultant product, whether the crystalline-measuring diffraction peaks are due to starch or to V-complexes.

There was evidence and argument on both sides of the question of whether all of the diffraction peaks in the Novamont product should be counted in deciding crystallinity. The district court resolved this aspect, as a matter of claim construction, by describing the crystalline structure as that "associated with the native starch." The defendants argue that the district court should have gone further, and decided which peaks in the diffraction plots of the Novamont products represent crystalline starch and which represent V-complexes. The defendants argue that the jury should have been specifically instructed which peaks of the accused products, if any, should be ignored in calculating their crystalline content, and that the jury was improperly permitted to decide whether the accused products had a crystalline content in the infringing range.

We conclude that the district court reasonably satisfied its obligations of claim construction. The court was not required to remove the expert testimony from the hearing of the jury; the court's obligation was to assure that evidence was reliable and relevant to the issue of infringement. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993). Daubert, as elaborated by General Electric Co. v. Joiner, 522 U.S. 136, 139 L. Ed. 2d 508, 118 S. Ct. 512 (1997) and Kumho Tire Co. v. Carmichael, 526 U.S. 137, 143 L. Ed. 2d 238, 119 S. Ct. 1167 (1999), requires that the court assure that the scientific or technologic evidence be relevant and of appropriate scientific validity, according to the standards of the discipline. When competing views of qualified experts satisfy these criteria, the trier of fact may consider them in reaching its decision. Indeed, it would contravene fundamental principles of due and fair process to withhold evidence of disparate scientific opinion relevant to the findings -- in this case of infringement vel non -- required of the jury.
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2. "in crystalline form"

This term is found in claims 3, 6, 9 and 12. Plaintiff offers the following proposed construction: "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species." DRL on the other hand, argues that this phrase means "a solid in which the constituent molecules are arranged in an orderly, repeating pattern or lattice in all three spatial dimensions." DRL Brf. at 18. The primary difference between the two proffered constructions is the degree of crystallinity required by each. While Plaintiff's construction would require the magnesium salt of esomeprazole to exhibit only "some" degree of crystallinity, DRL's construction requires the compound to be entirely crystalline.

While Astra argues that nothing in the claim language suggests a 100% crystalline requirement, DRL similarly argues that nothing in the claim language suggests a limitation of "some." Indeed, the plain language of the claims do not require a specific degree of crystallinity. The Court therefore, first looks to the intrinsic evidence to discern the meaning of a claim as understood by a person of ordinary skill in the art.

In support of its construction, Astra points to Example 6 in the specification, which describes the preparation of an optically pure magnesium salt of the (-)-enantiomer of omeprazole, '872 patent, col. 8, lines 17-52, and is noted to be the preferred embodiment of this invention, id., col. 9, lines 28-29. It is clear that the material described in Example 6 is crystalline, as it states that "the optical purity (e.e.) has been enhanced from 80% to 98.4% simply by crystallizing the Mg-salt from a mixture of acetone and methanol. The product was crystalline as shown by powder X-ray diffraction…". '872 patent, col. 8, lines 46-49. While the specification does not state the degree of crystallinity the material, contemporaneous notes from the inventor show the product of Example 6 to have a crystallinity of 49%. Pl. Exs. '872-5 and '505-11. The product of Example 6, therefore, supports Astra's construction, which does not require the material to be entirely crystalline.

Extrinsic evidence supports Astra's construction as well. For example, Plaintiff's expert, Dr. Davies, explained that it is rare for a material be have a degree of crystallinity of 100% and that a person of ordinary skill in the art generally understands that a reference to "crystalline" material does not require that the material be completely or even mostly crystalline. Davies Decl. PP 72, 73. Consequently, the Court shall construe the phrase "in crystalline form" to mean "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species."

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As stated earlier, claim 1 of the '723 patent reads: "Crystalline paroxe tine hydrochloride hemihydrate." This language is not ambiguous but rather describes a very specific compound. The record repeatedly shows that artisans in this area of technology at the time of invention would have understood that the claim embraces PHC hemihydrate without further limitation.

The inquiry proceeds to the remainder of the intrinsic record to determine if the patent applicant gave these unambiguous words some unexpected definition. The district court limited claim 1 to commercially significant amounts of PHC hemihydrate. The trial court found support for this limitation in portions of the '723 patent that discus s the pharmaceutical and commercial properties of PHC hemihydrate. SmithKline Beecham Corp., 247 F. Supp. 2d at 1029-30. For ex ample, the specification discusses the superior handling properties of the hemihydrate form that improve the manufacture of PHC. Those references, however, do not redefine the compound in terms of its commercial properties, but emphasize that the new compound exhibits favorable characteristics. A description of characteristics does not redefine a compound with an established and unambiguous structural definition.

Moreover, nothing in the '723 patent limits that structural compound to its commercial embodiments. Rather, the '723 specification discloses PHC hemihydrate as a compound without reference to its commercial applications. For example, the specification states that the "present invention provides crystalline paroxetin e hydrochloride hemihydrate as a novel

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compound." '723 patent, col. 1, ll. 57-58. Furthermore, nothing in the prosecution history of the '723 patent defines the invention in terms of commercially significant quantities. Thus, reading claim 1 in the context of the intrinsic evidence, the conclusion is inescapable that the claim encompasses, without limitation, PHC hemihydrate -a crystal form of paroxetine hydrochloride that contains one molecule of bound water for every two molecules of paroxetine hydrochloride in the crystal structure.

The district court openly discussed the policies that led to its insertion of commercially significant quantities as a limitation on the meaning of the claimed compound. SmithKline Beecham Corp., 247 F. Supp. 2d at 1028-30. The district court observed that a claim construction that covers trace amounts of PHC hemihydrate would likely preclude attempts to make the prior art PHC anhydrate compound. Id. After explaining the "in terrorem effect" of such a "broad" claim construction, the district court rejected the literal scope of claim 1 because it would produce "absurd results" and would "not serve any policy of patent law." Id. Claim construction, however, is not a policy-driven inquiry. As stated earlier, it is a contextual interpretation of language. The scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning. See Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584 (Fed. Cir. 1995) ("It is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims."). For this precise reason, this court has repeatedly stated that a court must construe claims without considering the implications of covering a particular product or process. See Neomagic Corp. v. Trident Microsys. Inc., 287 F.3d 1062, 1074 (Fed. Cir. 2002); SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed. Cir. 1985).

The district court also justified its commercial-significance limitation to preserve the claim's validity in the face of a challenge to its definiteness under § 112, secon d paragraph. In essence, the district court considered the claim indefinite if construed to cover undetectable trace amounts of PHC hemihydrate. In other words, the trial court feared that potential infringers would not be able to determine (and avoid) infringement if they cannot detect the claimed compound. See Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1469-70 (Fed. Cir. 1993). This reasoning misses the proper purpose of the definiteness requirement.

The second paragraph of § 112 requires the specification of a patent to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P2 (2000). To satisfy this requirement, the claim, read in light of the specification, must apprise those skilled in the art of the scope of the claim. See Miles Lab. v. Shandon, Inc., 997 F.2d 870, 875 (Fed. Cir. 1993). Moreover, claims need not "be plain on their face in order to avoid condemnation for indefiniteness; rather, what [this court has] asked is that the claims be amenable to construction, however difficult that task may be." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). In this case, the claim covers a definite chemical structure. To a chemist in this field, this claim is plain on its face. Thus, claim 1 of the '723 paten t cannot be invalid for indefiniteness under § 112.

In Morton, this court affirmed a district court' s judgment of indefiniteness because "one skilled in the art could not determine whether a given compound was within the scope of the claims." 5 F.3d at 1470. Thus, the claims at issue were "not sufficiently precise to permit a potential competitor to determine whether or not he is infringing." Id. The Morton case, therefore, does not hold that the inability to detect the claimed compound in the infringing device renders a compound claim indefinite. Rather, Morton stands for the unremarkable proposition that a compound claim, to be definite, must apprise a skilled artisan of the bounds of the claim. The record in Morton contained "considerable evidence showing that those skilled in the art could not make the claimed compounds using the procedures of the specification, and no evidence that such compounds even exist." Id. at 1469-70.

This case bears little similarity to Morton. Here, claim 1 unambiguously identifies the bounds of the claim. It states: "Crystalline paroxetine hydrochloride hemihydrate." Thus, this claim recites in clear terms a discernible chemical structure. It would be difficult to imagine a more clear and definite claim.

The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention. In this case, the problem for Apotex is that it cannot accurately ascertain the nature of its own product. The scope of this claim is clear; the infringement of the Apotex product is not. Even if a claim is broad enough to embrace undetectable trace amounts of the claimed invention, "breadth is not indefiniteness." In re Gardner, 57 C.C.P.A. 1207, 427 F.2d 786, 788 (CCPA 1970). Stated more precisely, this claim is neither broad nor narrow, but definitive of this particular chemical structure. For inventing and disclosing this structure, the inventor enjoys the exclusive right to practice that

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invention for the patent's limited term. Accordingly, claim 1, as construed above, is not indefinite under 35 U.S.C. § 112, second paragraph.
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C. The Court maintains its earlier interpretation that the limitation "a daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day.

This Court now addresses, for purposes of claim construction, the meaning of "a daily dose" as that limitation applies in Claims 1 and 19. Claim 1 covers "a method of treating . . . hypertension . . . , consisting of administering a daily dose of (a) benazepril . . . and (b) amlodipine." ('802 patent, col. 5, Il. 6-21 (emphasis added).) Similarly, Claim 19 covers "[a] pharmaceutical composition consisting essentially of a daily dose of (a) benazepril . . . and (b) amlodipine." (Id., col. 6, Il. 8-19 (emphasis added).) The essential dispute over the term "a daily dose" is whether that term means the total amount of amlodipine and benazepril given in a 24-hour period, or the number of times amlodipine and benazepril are each given in a 24-hour period. In Teva, this Court concluded that "'a daily dose' means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day." 565 F. Supp. 2d at 619.

Lupin argues that Novartis limited the scope of the '802 patent to once-per-day administration during prosecution of the patent. Specifically, Lupin contends that evidence in the prosecution history not before the Court in Teva provides clear evidence that "a daily dose" means "once-daily." In other words, Lupin argues that Novartis unequivocally disavowed that "a daily dose" means anything other than "once-daily."

Lupin's argument concerning the prosecution history of the '802 patent extends from the Court's discussion of a nearly-identical issue in Teva: the Maclean reference. In that case, Teva argued that Novartis received an "obviousness" rejection from the patent examiner for the '802 patent. The patent examiner stated that the Maclean reference disclosed administering captopril (which is an ACE inhibitor of the same class as benazepril) and amlodipine and, therefore, the '802 patent proposal was "obvious" based upon the Maclean reference. Teva, 565 F. Supp. 2d at 618. In responding to the patent examiner's rejection, Novartis attempted to distinguish the '802 patent from the Maclean reference with the following argument:

> In this case, there is neither teaching, suggestion or motivation in Maclean to produce Applicants' method of treating hypertension and other conditions consisting of administering a daily dose of benazepril and amlodipine as claimed nor Applicants' pharmaceutical composition comprising benazepril and amlodipine as claimed. Maclean teaches the therapeutic usefulness of a once-daily dose of amlodipine (10 mg) given with twice-daily doses (25 mg each) of captopril. This reference does not teach a once-daily dose of an ACE inhibitor to treat hypertension.

(Carlan Decl., Ex. 11 (emphases added).) Teva argued before this Court that Novartis could not "stand on the dictionary definition of 'daily dose' because Novartis provided its own definition of the term in its attempt to distinguish the '802 patent from prior art." Teva, 565 F. Supp. 2d at 618. Teva insisted, rather, that "Novartis should be bound by the equation of 'once daily' with 'a daily dose,' regardless of the dictionary definition of the latter term." Id.

This Court rejected Teva's argument. First, Novartis explained that it "did not argue that the '802 patent taught 'once-daily' administration of benazepril, but only that benazepril's chemical structure was sufficiently different from that of captopril such that once-daily administration was possible and, therefore, the invention embodied in the '802 patent was not obvious." Id. (quoting Novartis Br. at 23.) Ultimately, Novartis successfully argued to the patent examiner that, in the Court's words, "its invention was not an obvious extension of Maclean because the '802 patent has possible applications that were impossible in Maclean." Id. at 618. Second, this Court examined Purdue Pharma v. Endo Pharmaceuticals, 438 F.3d 1123, 1136 (Fed. Cir. 2006), where the Federal Circuit found no "clear disavowal" based on facts similar to those in Teva. Thus, this Court concluded that "[w]hile Teva has raised a reasonable argument that the prosecution history amounts to a disavowal, . . . Teva has not demonstrated . . . that disavowal to a clear and unmistakable degree." Teva, 565 F. Supp. 2d at 619.

Here, Lupin attempts a double dose of the Maclean reference, but still will not enjoy the desired cure. Citing the same Maclean reference, Lupin quotes the next portion of Novartis's statement before the patent examiner to distinguish the '802

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patent from the Maclean reference:

Thus, since Maclean does not disclose a once-daily dosage of captopril or other ACE inhibitor in combination with amlodipine, Applicants respectfully submit that this reference does not teach, suggest or motivate one to produce Applicants' claimed invention. In fact, Maclean teaches away from an antihypertensive therapy consisting of a single daily dose of ACE inhibitor in combination with amlodipine and as such does not render Applicants' invention obvious.

(Amundson Decl. Ex. 33 (emphases added).) Lupin argues that this later passage demonstrates that Novartis unequivocally disavowed its interpretation of "a daily dose" to include anything but a once-daily dosage. Yet, this second statement by Novartis is difficult to distinguish from its first. In both, Novartis seems to offer that the Maclean reference is distinguishable from the '802 patent because the prior art did not cover a single-daily dosage. Further, this Court has already reviewed this second statement in Teva's papers (see Teva Br. at 38), and cited to it in finding no unequivocal disavowal, see Teva, 565 F. Supp. 2d at 618. Thus, this second statement does not truly present a new issue for the Court.

Lupin cites a compelling case from the Federal Circuit, Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978 (Fed. Cir. 1999), but the Court believes the more recent decision of Purdue Pharma, referenced by this Court in Teva, is more resonant. In Purdue Pharma, the Federal Circuit reversed the district court's finding of unequivocal disavowal. 438 F.3d at 1136. There, the plaintiff sought to patent a controlled release oxycodone formulation intended to control pain in humans. A surprising byproduct of this formulation was that the invention controlled pain over a "four-fold dosage range." Id. at 1135. During the prosecution of its patent, the plaintiff distinguished its formulation from similar prior art that employed an "eight-fold range." Id. at 1127 (internal quotation omitted). Rejecting the district court's finding of disavowal, the Federal Circuit found: "Rather than presenting the four-fold dosage range as a necessary feature of the claimed oxycodone formulation, [the plaintiff] described it as a property of, or a result of administering" its formulation. Id. (emphasis added). As plaintiff even stated during the prosecution, "by choosing th[ese] parameters in the controlled-released formulation, it is possible to acceptably control pain over a substantially narrower dosage range [i.e., four-fold] than through the use of other" formulations. Id. (emphasis added). Thus, the court held that the plaintiff's prosecution history did not satisfy the defendant's heavy burden to show clear disavowal. Id.

This Court found Purdue Pharma convincing in Teva, and the Court remains persuaded here. In this case, the prosecution history shows that Novartis differentiated the '802 patent from the Maclean reference because the Maclean reference "teaches away" from "a single daily dose." In neither statement concerning the Maclean reference, though, does Novartis clearly describe a single daily dose as a necessary feature of the entire '802 patent. As it argued in Teva, Novartis contends that its "exchange with the patent examiner was not a disclaimer of the ordinary meaning of 'daily dose,' but mere advocacy as to why Maclean's disclosure of captopril in the combination does not render obvious the use of benazepril in the claimed invention." (Novartis Reply Br. at 3.) Similar to the plaintiff's statement in Purdue Pharma that its patent was distinguishable from prior art because the four-fold dosage range was "possible," here, "Novartis successfully demonstrated that its invention was not an obvious extension of Maclean because the '802 patent has possible applications that were impossible in Maclean." Teva, 565 F. Supp. 2d at 618-19.

Lupin makes a reasonable argument that Novartis disclaimed a broad interpretation of "a daily dose," but Novartis's statements are "amenable to multiple reasonable interpretations." Omega, 334 F.3d at 1324; see also Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1375 (Fed. Cir. 2008) ("Prosecution disclaimer does not apply to an ambiguous disavowal."). It is reasonable to read Novartis's statements during prosecution as permitting, but not mandating, a single daily dose under the '802 patent. Thus, Lupin has not met its heavy burden to show an unequivocal disavowal, and the Court rejects its construction of "a daily dose" to the extent that it relies upon a purported disavowal in the prosecution history. See Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1211 (Fed. Cir. 2008) (refuting clear disavowal where the "prosecution clearly distinguish[ed] the claim[ ]" from prior art, but nevertheless did "not constrain" the claim on that distinction); Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Com'n, 383 F.3d 1352, 1375 (Fed. Cir. 2004) (rejecting theory of claim disavowal or disclaimer where "[patentee] stated only that the . . . reference was incapable of performing a certain type of search, not that the scope of the claimed invention was limited to that particular type of search."). Instead, this Court maintains its construction of the term in accordance with the dictionary definition and its decision in Teva: "A daily dose" means the total amount of amlodipine and benazepril that is to be taken within a 24-hour period, regardless of the number of administrations in that single day.

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Claim Construction

"To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." Markman, 52 F.3d at 979 (Fed. Cir. 1995) (citations omitted). "The court may, in its discretion, receive extrinsic evidence in order to aid the court in coming to a correct conclusion as to the true meaning of the language employed in the patent." Id. at 980 (quotations omitted). "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id.

The "claim construction inquiry . . . begins and ends in all cases with the actual words of the claim." Renishaw PLC v. Marposs Societa per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). There is a "heavy presumption" that the terms used in the claims "mean what they say, and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." Texas Digital Sys.,. Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). Claims are to be construed from the perspective of one skilled in the field of the patent. Brookhill-Wilk I, LLC. v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003).

At the time of this patent prosecution, the antidiuretic qualities of desmopressin were already well known, but the means of administration (usually intranasally by use of a rhinyle) were considered awkward or undesirable. It had "been traditionally accepted that proteins and peptides, such as DDAVP, are decomposed in the stomach and intestines without substantial, or any absorption taking place." 398 Patent. The stated objects of the 398 patent invention included "to avoid or substantially alleviate the . . . problems of the prior art" and "to provide DDAVP compositions which dissolve in the gastrointestinal tract in order to allow for the gastrointestinal absorption of DDAVP." Id. The invention of the 398 patent was to achieve an antidiuretic effect in a diabetic patient merely by swallowing a pill containing DDAVP for gastrointestinal absorption. The DDAVP disclosed in the patent is 1-deamino-8-D-arginine vasopressin.

Claims 1-5 cover the patented compositions and claims 6-11 cover specific methods of administration. The dispositive term "1-deamino-8-D-arginine vasopressin" is first recited in Claim one, which discloses:

An anitdiuretic composition for humans comprising a gastrointestinally absorbable, antidiuretically effective, amount of 1-deamino-8-D-arginine vasopressin and a pharmaceutically acceptable carrier in solid oral dosage form for absorption in the gastrointestinal tract of said humans.

'398 Patent, col. 4, II. 24-29. Defendant contends, and this Court agrees, that the term "1-deamino-8-D-arginine vasopressin" ("DDAVP" or "desmopressin") means exactly that, and the claims must be construed to instruct one practicing the art of the patent to use the active compound (or free base) desmopressin, and not as extending to its salts.

The Merck Index defines "desmopressin" as an "analog of vasopressin possessing high antidiuretic activity" and provides "1-desamino-8-D-arginine vasopressin" 9 as a construct of "desmopressin." The Merck Index 10th Ed. (1983) at 422. See Karen Robinson. Decl., Ex. P.

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9 "Desamino" is deemed a variation of the word "deamino." See Webster's Third New International Dictionary defining "desamination" as a different spelling of "deamination."

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Plaintiffs assert that Defendant's desmopressin acetate product infringes the patent because the term "1-deamino-8-D-arginine vasopressin" would be understood by one of ordinary skill in the art as "the active compound desmopressin and any of its salts." See Pl.'s Memo. at 12. Plaintiffs admit that in their own products, as presently made and sold, they do not practice their own invention covered by the 398 patent. See Hearing Tr. at 31. They in fact also use "desmopressin acetate," a different chemical compound and exactly what Defendant seeks to use in its ANDA. The claims of the patent cannot be construed in light of the accused product nor in light of Plaintiffs own currently marketed products. They must be construed

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in light of the public record.

At the outset, the Court considers recent Federal Circuit cases, which have addressed related issues. In Merck & Co. v. Teva Pharmaceuticals USA, Inc., 347 F.3d 1367 (Fed. Cir. 2003), the Court concluded that a sodium salt form of a claimed acid used to treat osteoporosis and Paget's disease literally infringed a patent although the sodium salt form was not explicitly specified in the claim itself. The patent claims specifically used the term "acid" in disclosing the method of treatment. In holding that the patent should be read to extend to the acid's salt forms, the Circuit Court relied on the following three factors: 1) the specification contained numerous references to the salt forms of the claimed acid in describing its application; 2) the testimony from all qualified witnesses indicated that persons skilled in the field would understand that the acid was administered in the form of the salt; and 3) extensive evidence that the persons in the field used the same lexicography as the inventors by referring to the active ingredient in the form of a salt. See Id. at 1370-71.

Merck is readily distinguished from the case at bar in that Ferring's 398 patent specification does not define DDAVP or. "1-deamino-8-D-arginine vasopressin" to include the salt form. Nor did the inventors disclose numerous (or any) usages of salt forms in the patent specification. The Circuit Court in Merck placed substantial reliance on the specification's "numerous references" to the salt form of the claimed acid in reaching its conclusion that salt forms were covered by the patent. The '398 patent specification provides no comparable basis for imputing the salt forms of DDAVP into the 398 patent. Nor does all of the expert testimony in this case convincingly indicate that a person skilled in the field would understand "1-deamino-8-D-arginine vasopressin" to be the same; as any of its salts:

Plaintiff's expert, Dr. Verbalis, an endocrinologist, stated in his expert report that the"composition claimed in claim 1 is a solid oral dosage form comprising the active ingredientdesmopressin acetate." See Steinhauer Decl., Ex. 4 at 8. He also testified that anyone in his "fieldat the time would . . . understand that it had to mean desmopressin acetate because if you look further down in Column 1 . . . not only did they define DDAVP, or 1-deamino-8-D-argininevasopressin, as the product of the Zaoral patent, they further described it in terms of its currentuse, at the time that this patent was filed." See Steinhauer Decl., Ex. 2 at 217. When asked if he reads 1-deamino-8-D-arginine vasopressin to refer to desmopressin acetate and not desmopressin in its free base, he responded: "When I read the name of a peptide like that, I allow that it could be any of the salts that are commonly used to manufacture those peptides." Id. at 21.

A second expert for Plaintiffs, Dr. Coy, when asked if there is a difference between the salt form and the free base form used in a compound, conceded that there is "a difference in the formulation, because one is - contains a counterion and one does not contain a counterion . . . this may affect things like solubility and physical chemical properties, basically nothing else." See Gioconda Decl., Ex. N at 389. He also stated that "once they're injected they're identical," see Id.), but admitted that his own peptide patents recite "the pharmaceutically acceptable salts" to ensure that the salts are covered by the claims of his patents. See Id. at 367, 398.

A third expert for Plaintiffs, Lewis Kinter, Ph.D., a medical physiologist, stated in his expert report: "Whether salt or free base, it makes no difference at all with respect to the pharmacological activities of a drug, once in a solution." See Steinhauer Decl., Ex. 5 at 18. He also stated that the "terms '1 deamino-8-D-arginine vasopressin.' DDAVP, or desmopressinwould be construed by a pharmacologist, physician or other scientist of ordinary skill involved with DDAVP to include all of the salt forms mentioned[.]" See Id.

Defendant's expert; Dr. Amidon, a professor of pharmacy, stated the following in an expert report:

The claim term "1-deamino-8-D-arginine vasopresin" is a relatively simple chemical name for desmopressin of known chemical formula C [ILLEGIBLE TEXT] The salt desmopressin acetate designates a different chemical formula [ILLEGIBLE TEXT] consistentwith the fact that it is a different compound. By using the chemical formula in defining the claimed invention, the 398 patent leaves no ambiguity that it is referring to desmopressin specifically, rather than to any of the other possible modified chemical compounds that can be prepared from the specific desmopressin compound. Because a person formulating drug products should assume the drafters of the claim meant to use the term "1-deamino-8-D-arginine vasopressin" in a scientifically accurate manner, I do not believe that the claims cover a composition using desmopressin acetate instead of desmopressin.

See Steinhauer Decl. Ex. 12 (emphasis added). This Court agrees. Dr. Amidon correctly notes that despite the [ILLEGIBLE SENTENCES] desmopression "omission is significant because the difference between desmopressin and desmopressin

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acetate is highly significant to a person investigating potential formulations for oral delivery." Id.

Incredibly, Dr. Verbalis' expert report defines Claim one of the patent as describing "the active ingredient desmopressin acetate," without even a tip of the hat to the fact that no salt is actually named in the claim. See Steinhauer Decl., Ex. 4 at 8 (emphasis added). Indeed, on the next page of his report, he contradicted that definition, stating: "the active ingredient, in this case, desmopressin, is gastointestinally absorbable . . ." Id. at 9 (emphasis added). Dr. Coy's testimony confirmed that the chemical formulas for the free base and salt forms were distinct, and from his testimony, it can be inferred that it is proper patent practice to claim the salt forms of a patented peptide. The Court is not persuaded by Plaintiffs' expert testimony, that the patent should be extended to cover salt forms of desmopressin.

In Stephens et al. v. Tech International, Inc., 393 F.3d 1269, 2004 U.S. App. LEXIS 27064 (December 29, 2004), the Federal Circuit recently considered whether an accused salt form of a patented product was covered by the patent, in the context of determining whether an infringement suit was frivolous. 10 The patent disclosed a means of removing unwanted substances from human urine samples. After conducting an infringement analysis, the Court held that the plaintiff had adequate grounds to believe that there was direct infringement, and that the suit was therefore not frivolous. The Court held:

While the 647 patent does not use the word "salt," the compelling evidence in this case that persons of skill in the field of urinalysis know of chromic acid and sodium dichromate's interchangeable use for removal of unwanted substances in urine samples outweighs that fact.

Stephens, 393 F.3d 1269, 2004 U.S. App. LEXIS 27064, at * 13. The Court then held: "Because the use of chromic acid encompasses the use of sodium dichromate in the field of urinalysis, Spectrum had adequate grounds to believe that Tech directly infringed the 647 patent." Id. Importantly, the Circuit Court limited the scope of its holding by declaring: "We do not announce that all claims of an acid inherently claim the acid's salt form; it must still be determined whether or not persons having skill in the applicable art deem the acid and salt to be interchangeable." Id. at * 13.

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10 Plaintiffs appealed the District Court's grant of attorney's fees to defendant after finding the case to be exceptional, based in part on its finding that the infringement suit was frivolous.

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The Court does not interpret the Stephens decision to materially alter the standards of claim construction and infringement analysis when the accused product is a salt form of a claimed compound. The Stephens decision is silent as to the weight that should be given to the presence or absence in a patent specification of references to salt forms, and should not be read as limiting or disapproving the rule in Merck.

Despite the lack of any reference to salts in the specification in this case, Plaintiffs argue that the specification's reference to the Zaoral patent (491), which does include salt forms, indicates that their invention should also be construed as to include salt forms of the active ingredient. The Court disagrees. The 398 patent specification defines "1-deamino-8-D-arginine vasopressin" as "DDAVP" and states: "this invention relates to the antidiuretic compound 1-deamino-8-D-arginine vasopressin, which is commonly known as DDAVP. DDAVP exhibits a high and specific antidiuretic activity and is useful in treating diabetes insipidus as disclosed in U.S. Pat. No. 3,497,491 [Zaoral]." See U.S. Pat. No. 398. "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference . . ." See Manual of Patent Examining Procedure § 608.01(p), Ex. G. It does not follow that Plaintiffs or the Court can enlarge the right to exclude others by the reference to the 491 patent. The Federal Circuit in Markman instructed that the "written, description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." Markman, 52 F.3d at 979-980. "When a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public." Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002). Ferring had the opportunity to claim the salt forms and in failing to do so, failed to cover Barr's desmopressin acetate product.

Plaintiffs also argue that "1-deamino-8-D-arginine vasopressin" should include salts under Pfizer Inc. v. Dr. Reddy's Labs., Ltd.,, 359 F.3d 1361 (Fed. Cir. 2004) and Federal Food and Drug Administration ("FDA") definitions. That case is readily

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distinguished on its facts. In it, Pfizer owned a patent which covered the administration of the drug amlodipine in both its besylate and maleate salt forms. Pfizer obtained an extension of that patent under the Patent Term Restoration Act of 1984 (codified at 35 U.S.C. § 156), but in its application had identified the drug in only the besylate salt form. The Federal Circuit held that the patent term extension applied to the drug's active ingredient, amlodipine and to its salts and esters. The Court looked to the codification of the patent extension, which specifically defined a "drug product" for purposes of the extension to mean to include "the active ingredient . . . and any salt or ester of the active ingredient." See 35 U.S.C. § 156(f)(1)(A); (f)(2).

The Federal Circuit also considered 21 C.F.R. § 60.3(b)(10), which is specifically referenced in 35 U.S.C. § 156, and defines a "human drug product" to be "the active ingredient of a new drug or human biologic product (as those terms are used in the Act and the Act and the Public Health Service Act), including any salt or ester of the active ingredient." See 21 C.F.R. § 60.3(b)(10). "Pharmaceutical equivalents" is defined to be "drug products in identical dosage forms that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety . . ." See 21 C.F.R. § 320.1(c). In Pfizer, the Federal Circuit specifically construed and applied the patent term extension statute, which is not the task before this Court. Similarly, the FDA definitions cited by Plaintiffs relate to patent term extensions and bioequivalence for purposes of new drug approval processes, which are not implicated in this analysis. Neither Pfizer nor the FDA definitions appreciably alter the Court's task of claim construction in this case, nor do they relieve Ferring of the traditional obligation to specify accurately the invention claimed.

Finally, Plaintiffs refer to the Physicians' Desk Reference, which lists pharmaceuticals and discloses their contents for physicians. "DDAVP[R]" is a trade name for Ferring's intranasal and injection products, each of which contains desmopressin acetate. See Tr. at 12. Accordingly, the desk reference indicates that Ferring's DDAVP[R] products contain desmopressin acetate. See Steinhauer Decl., Ex. 8. This reference book, which defines accurately Plaintiffs' products as sold on the market, which undisputedly contain desmopressin acetate, does not define, amend or amplify the claims in Plaintiffs' 398 patent.

Barr submitted a supplemental memorandum on June 9, 2004, arguing that Ferring contradicted its infringement argument in this case by submission of a "Citizen Petition" to the FDA for consideration by that body in connection with Barr's ANDA application. In the petition submitted on or around February 2, 2004, Ferring requested that the FDA establish unique evidentiary requirements of bioequivalence limited to ANDAs of oral products containing desmopressin. Ferring argued that as the first and only approved oral peptide, it presents "complex and novel bioavailability issues." See Donovan Decl., Ex. A. It argued that because the product is "primarily indicated for use in children, enhancing the requirements is especially appropriate. See Id. Barr now argues that Ferring's Citizen Petition is a factual admission that Barr's ANDA tablet is not bioequivalent, as Ferring asserts in this litigation. Ferring denies any contradiction between Ferring's arguments in this litigation and in the Citizen Petition.

Ferring requested in its Citizen Petition that the FDA require ANDAs for products containing desmoprressin to address the unusual properties of desmopressin (including a very low absorption rate and high potency). Ferring asked the FDA to require such ANDAs to include more stringent evidentiary proofs, including comparative clinical studies as to variability of absorption and duration of action, and separate evidence of bioequivalence for each dose level.

The Citizen Petition does appear to this Court to invoke the traditional estoppel against taking inconsistent positions in companion proceedings, and suggests by implication that the testing proffered in support of the initial NDA filed by Aventis and approved by the FDA in 1995 11 is now considered inadequate. On the other hand, the filing of such a Citizen Petition may be nothing more than a hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent and raise the transactional costs for Barr. Such antics are privileged under the First Amendment right to petition and are part of the rough and tumble which characterizes the free market. The Citizen Petition casts serious doubt on the genuineness of Ferring's insistent contention that Barr's ANDA is bioequivalent and its product would infringe. On balance, the Court is constrained to determine that the Citizen Petition does not rise to the level of an admission of fact precluding Ferring's claims of infringement.

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11 See U.S. FDA Center for Drug Evaluation and Research, www.accessdata.fda.gov.

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1. De-icing and Anti-Icing Composition

The first disputed claim term to be construed is "de-icing and anti-icing composition." In Cargill the chief battleground with respect to this term concerned whether the composition specified was limited to direct application to roadways, as Cargill argued, or instead was susceptible to indirect application by means of spraying the specified composition onto rock salt, which could then be applied to roadways. The more narrow approach advocated by Cargill was rejected, in favor of the more expansive reading advocated by Sears, resulting in the phrase being construed to mean "a composition whose intended purpose, through direct or indirect application, is to keep roadways free or rid of ice, or to prevent its formation on such surfaces." 6 Cargill, 334 F. Supp. 2d at 217.

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6 It should be noted that in Cargill Sears offered a more expansive interpretation of the term "de-icing and anti-icing composition", suggesting that the use of the patent invention should not be limited to roadways but instead was susceptible to use in other settings where icing occurs.

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The defendants urge the court not to construe the term de-icing and anti-icing composition at all, arguing that the phrase is purely preambulatory and thus does not serve to limit the scope of the patent's claims. In support of their argument, defendants offer the Federal Circuit's observation that

> [i]n general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.

Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quotations and citations omitted). This statement is consistent with the principle that it is the body of a claim, rather than the intended use specified in such introductory language, that controls and provides the critical attributes of a patented device. 7 See id.; see also Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1310 (Fed. Cir. 2002).

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7 Defendants also quarrel with the court's reference to the specification in order to limit the construed term more narrowly than under its generally understood meaning. While it is true that reference only to a single or preferred embodiment to circumscribe a patent claim term would be improper, see, e.g, Phillips, 415 F.3d at 1323 (noting that "[w]e have expressly rejected a contention that if a patent describes only a single embodiment, the claims of the patent must be construed as to being limited to that embodiment"), the specification nonetheless remains a critical element of the patent, and resorting to it in order to shed light on the intended meaning of the claim terms is a means of interpretation explicitly approved by the Federal Circuit in its en banc decision in Phillips.

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There is no particular bright line test to be followed in every case when determining whether preambulatory language is limiting; there are, however, guideposts which can inform a court's analysis. Catalina Mktg., 289 F.3d at 808. Among them is the principle that "when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope." Id. (citing Pitney Bowes, 182 F.3d at 1306). Critically, in Catalina Mktg. the Federal Circuit noted that "preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure. Id. at 809 (citing In re: Gardiner, 36 C.C.P.A. 748, 171 F.2d 313-16, 80 UPSQ 99, 101 (1948)). As an illustration of the point being made, the Federal Circuit in that case hypothesized an invention of "a composition for polishing shoes", noting that a subsequent inventor determining that the very same composition could be used to grow hair "cannot invoke this use limitation to limit

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[the patent holder's] composition claim because that preamble phrase states a use or purpose of the composition and does not impose a limit on [the patent holder's] claim." Id. at 809-10.

In support of its argument that I should define the phrase "de-icing and anti-icing composition" as I did in Cargill, Sears relies principally upon cases which are inapposite, involving preambulatory language that is both clearly limiting and gives life to particular claim terms. In Loctite Corp. v. Altraseal Ltd., for example, the Federal Circuit noted that the phrase "[a]naerobic curing sealant composition" was not merely preambulatory, but instead should be construed as interposing a limitation, providing life and meaning to the patent claims, in the face of infringement claims against the defendant which had developed a similar composition and process which was not anaerobic. 781 F.2d 861, 867 (Fed. Cir. 1985), overruled on other grounds, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998). Similarly, in Poly-America, L.P. v. GSE Lining Tech., Inc., which involved method claims for manufacturing a texture landfill liner, the court determined that the introductory phrase "blown-film" was a critical limitation of the claims of the patent in suit, thereby providing a basis to distinguish the accused device, which was not a "blown-film" liner, finding that the preambulatory term "represented an important characteristic of the claimed invention." 383 F.3d 1303, 1310 (Fed. Cir. 2004)

In this case the phrase in dispute is more closely akin to that involved in Catalina Mktg., as well as the shoe polish example cited by the Federal Circuit in that instance. The claims of both the '793 and '622 patents describe a complete composition structure, with the disputed phrase only being offered to specify the intended use of the composition.

It is true that at the outset I noted the importance of being faithful to the doctrine of stare decisis. That precept, however, does not constrict the court when considering new arguments not raised in the prior relevant proceeding. See Collegenet, 2004 U.S. Dist. LEXIS 22370, [WL] at *6. In the prior action involving the '793 patent, both Cargill and Sears sought a construction of the phrase "de-icing and anti-icing composition", urging competing definitions, without arguing over whether in fact it provided a limitation to the '793 patent claims. Under the circumstances currently presented, I find a sufficient basis to reconsider my early ruling, and will consider the phrase in issue as constituting mere preambulatory language not requiring construction by the court. 8

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8 The defendants' challenge of my construction of the term de-icing and anti-icing composition in Cargill appears to have legal significance only in the context of a separate re-examination proceeding brought in the United States Patent and Trademark Office ("PTO"), based upon the contention that an earlier radiator antifreeze patent anticipated both the '793 and '622 patents.

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i) De-icing and Anti-icing Composition

The first disputed claim term to be construed is "de-icing and anti-icing composition." While the parties' positions regarding this term do not differ markedly, Cargill attempts to restrict the term to direct pavement and roadway usage, citing the genesis for the invention and its description within the patent as a basis for its argument. Sears opposes such a restrictive interpretation, countering that there is nothing in the claims themselves to limit the utility of the invention to roadways, and that it can and should be construed to extend to other areas where icing occurs.

Notwithstanding the parties' quarrel over this term, at first blush the phrase consists of simple, understandable and unambiguous words. The use of the prefix "de" before a word is commonly accepted to mean "remove or remove from[.]" American Heritage Dictionary of the English Language 465 (4th ed. 2000). Similarly, use of the term "anti" to precede a word is defined to mean "destroying[.]" Id. at 76. Consistent with these elementary definitions, the term "de-ice" is defined in one generally accepted dictionary as meaning "to keep free or rid of ice." Marks Claim Construction Aff. Exh. 6 (Websters Third New International Dictionary, (1993 ed.) 595).

Despite this more expansive reach of the words themselves, the phrase "de-icing and anti-icing composition" cannot be

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interpreted in a vacuum; instead, one must look to the patent as a whole, including the circumstances under which it was developed and the prior art described. Plainly, each of these sources is strongly suggestive of an intended use of the '793 invention to control ice on roads and other similar surfaces. Indeed, as Cargill argues when advocating a more restrictive definition than that propounded by Sears, the '793 patent describes the background of the invention in conjunction of snow and ice removal from roadways, and begins with the observation that "the current state of the art for coping with snow and ice on roads usually involves applying a deicer material such as a salt to the road surface." '793 patent, col. 1, Ins. 10-12. Similarly, as Cargill notes one of Sears' own experts, L. David Minsk, defines the terms de-icing and anti-icing in the context of pavement maintenance. Indeed, even Sears' own promotional material for its products and those of SEACO describes anti-icing as a "preventive/proactive strategy designed to prevent packed snow or ice from bonding to pavement surfaces." Marks Claim Construction Aff. Exh. 9, at SP 03826.

Arguing in favor of a definition which restricts the de-icing and anti-icing composition to controlling ice on roadways, Cargill goes one step further, suggesting an additional circumscription which would require that the material be directly applied to the road or other pavement surface. I reject this additional limitation as unsupported by the patent claims and specification. Indeed, this position overlooks the language within the '793 patent itself which describes the inclusion of

thickeners which are used . . . to increase the viscosity of the compositions so that the liquid remains in contact with the road surface or with the solid particles in piles of rock salt/sand, or rock salt/aggregates, or rock salt alone, or sand or aggregate.

'793 patent, cols. 7, Ins. 10-15. Cargill's description also ignores the following clarifying language:

While the present invention has been particularly shown and described herein with reference to various preferred modes it will be understood by one skilled in the art that various changes in detail may be effected therein without departing from the spirit and scope of the invention as defined by the claims.

Id. col. 9, Ins. 42-47. Clearly, the '793 patent itself contemplates a composition whose utility is not necessarily limited to direct application on road pavement surfaces. See Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("the patentees were not required to include within each of their claims all of these advantages or features described as significant or important in the written description").

Based upon the foregoing, I construe the term "de-icing and anti-icing composition" as a composition whose intended purpose, through direct or indirect application, is to keep roadways free or rid of ice, or to prevent its formation on such surfaces.

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5. "decreased CYP1A induction"

This term appears in claims 4 and 16. Astra contends that this term should be construed as "a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole." DRL argues that construction of the phrase "decreased CYP1A induction" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: "the observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5- dimethyl-2 pyridinyl)methyl]sulfinyl]-1Hbenzimidazole that the average CYP1A induction in slow metabolizers treated with that compound is less than that in slow metabolizers treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature." For reasons discussed above, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of this phrase is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

Astra asserts that both the claim language and the '192 specification support its proposed construction. The Court agrees that

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a person skilled in the art reading the plain language of the claim would understand that the term "decreased" referred to a comparison to omeprazole. This is further supported by the specification, which explains that "[t]he use of the (-)-enantiomer of omeprazole would decrease the potential for CYP1A2 induction in slow metabolisers as a result of the lower plasma levels (AUC) of this compound obtained in these individuals. Since the gastrin levels obtained simply are a result of a natural feedback mechanism determined by the degree of inhibition of gastric acid secretion, the use of the (-)-enantiomer of omeprazole may also potentially result in a less pronounced increase in gastrin in slow metabolisers." '192 patent, col. 3, lines 53-61). Therefore, the Court shall construe the term "decreased CYP1A induction" to mean "a reduced production of the drug metabolizing enzyme, CYP1A, in the liver, compared to omeprazole."
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2. "so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases"

This phrase appears in claim 1 and claim 13 (absent "so as to effect"). Plaintiff and DRL differ in their approach to construction of the above terms/phrase and five others like it. 4 Plaintiff proposes separate constructions for certain discreet terms within the overall phrase. DRL, on the other hand, asserts that construction of this phrase (and the five others) is not required because it is not a limitation but rather the observed inherent result of the claimed method. However, to the extent construction would be required, DRL proposes a construction for the entirety of the phrase rather for each of the separate terms comprising the phrase.

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4 There are six similar groups of claim terms at issue: "decreased interindividual variation in plasma levels (AUC)" (claims 1 and 13), "an increased average plasma level (AUC)" (claims 2 and 14), "less pronounced increase in gastrin levels in slow metabolisers during treatment of gastric acid related diseases" (claims 3 and 15), "a decreased CYP1A induction in slow metabolisers during treatment of gastric acid related diseases" (claims 4 and 16), "an improved antisecretory effect during the treatment of gastric acid related diseases" (claims 5 and 17), and "an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during the treatment of gastric related diseases" (claims 6 and 18).

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The disputed phrase appears in its entirety in claim 1 as follows:

A method for treatment of gastric acid related diseases by inhibition of gastric acid secretion comprising administering to a mammalian need of treatment a therapeutically effective amount of a proton pump inhibitor consisting essentially of the consisting essentially of the (-)-enantiomer of 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl]sulfinyl]-1H-benzimidazole or a pharmaceutically acceptable salt thereof, so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases.

'192 patent, claim 1 (emphasis supplied).

Astra first proposes a construction with respect to the phrase "so as to effect," which Astra argues should be defined as "to bring about." Next, Astra proposes the following construction for "decreased interindividual variation in plasma levels (AUC)": "a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve." Last, Astra proposes that "treatment of gastric related diseases" be construed as "mitigating a symptom or effect of a condition associated with stomach acid."

DRL, on the other hand, contends that the phrase "so as to effect decreased interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases" is not a limitation but rather the observed inherent result of the claimed method. As such, DRL contends no construction is necessary. To the extent that construction is necessary, however, DRL asserts that this phrase means "an observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl]-1Hbenzimidazole that the average AUC

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differences among individuals treated with that compound are less than those differences among individuals treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature."

The threshold issue for the Court is whether the disputed claim term, and the five other similar claim terms (discussed below) requires construction at all. Citing Minton v. Nat'l Ass'n of Sec. Dealers, Inc., 336 F.3d 1373, 1381 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."), DRL argues that the "so as to" and "wherein" clauses in the disputed phrase should be treated as the "whereby" clause in Minton, and be considered nonlimiting.

Astra, on the other hand, points out that "when the whereby clause states a condition that is material to patentability, it cannot be ignored to change the substance of the invention." Hoffer v. Microsoft Corp., 405 F.3d 1326 (Fed. Cir. 2005); see also Fantasy Sports Properties, Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1111-16 (Fed. Cir. 2002); Griffin v. Bertina, 285 F.3d 1029, 1034, 62 U.S.P.Q.2d 1431 (Fed. Cir. 2002). In Griffin, for example, the court found that "wherein" clauses were claim limitations "because they relate back to and clarify what is required by the count. Each 'wherein' clause … expresses the inventive discovery [and] … elaborates the meaning of the preamble." Griffin, 285 F. 3d at 1033-34. Further, "the allegedly inherent properties of the 'wherein clauses' provide the necessary purpose to the steps. Id. Similarly, in the instant case, the disputed claim terms express the invention of the claimed compound at the high optical purity levels claimed. These are, for example, the unexpected and improved effects of administration of the claimed compound on individuals and the correlation between plasma levels (AUC), gastrin levels or CYP1A induction and individuals referred to in the '192 patent as "slow metabolizers".

The Court agrees with Astra that, under the above standards, construction of these disputed terms is appropriate. Because DRL's proposed construction merely embodies its argument that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow …," the Court rejects DRL's proposed construction.

Turning then to Astra's proposed construction for the phrase "so as to effect," which Astra alleges should be construed to mean "to bring about," the Court notes that Astra bases its proposed construction only the dictionary definition of the term "effect." See Pl. Ex. '192-2 at 4. Because there is no ambiguity as to the meaning of the phrase "so as to effect" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.

Next, Astra proposes that "decreased interindividual variation in plasma levels (AUC)" should be construed to mean "a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve." Ample intrinsic evidence supports this construction and Astra's position that one of ordinary skill would understand the term "decreased" referred to a comparison with omeprazole. For example, the specification explains that omeprazole exhibits polymorphic metabolism, meaning some individuals metabolize omeprazole slowly compared to the rest of the population, and these "slow metabolizers" will obtain higher than average plasma concentrations of the drug. '192 patent, col. 2, lines 16-21. Because "the inhibition of gastric acid secretion is correlated to the area under the plasma concentration versus time curve (AUC), a more pronounced effect from omeprazole is expected" in the slow metabolizers. Id., col. 2, lines 22-25. The (-)-enantiomer of omeprazole is claimed in the '192 patent "as an improved alternative to omeprazole in the treatment gastric acid related diseases" because of "higher does efficiency" and "less interindividual variation in plasma levels (AUC)" between both slow and rapid metabolizers and within rapid metabolizers. Id., col. 2, lines 28-36.

Additionally, the specification of the '192 patent states that

the use of the (-)-enantiomer of omeprazole, or a pharmaceutically acceptable salt thereof, in the treatment of gastric acid related diseases as a mean to decrease interindividual variation in plasma levels compared to omeprazole is claimed. The use of the (-)-enantiomer of omeprazole to receive increased plasma levels (AUC) of the substance compared to those of racemic omeprazole and thereby a higher dose is also claimed.

'192 patent, col. 2, lines 38-46. See also, id., col. 6, lines 27-34; col. 7, line 3-16. Consistent with the intrinsic evidence is

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certain extrinsic evidence pointed to by Astra, namely testimony of Dr. Tommy Andersson, who explained clinical studies showing decreased interindividual variation for esomeprazole as compared to omeprazole. Pl. Ex. '192-7 at 61-64.

The Court, therefore, construes the term "decreased interindividual variation in plasma levels (AUC)" should be construed to mean "a reduced difference or deviation in blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the blood levels of omeprazole, as measured by the area under the concentration-time curve."

Last, Astra proposes that "treatment of gastric related diseases" be construed as "mitigating a symptom or effect of a condition associated with stomach acid." Because Astra identifies and the Court finds no ambiguity as to the meaning of the phrase "treatment of gastric related diseases" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.
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c. "degradation by the copper ions" and "copper ion-mediated degradation"

Genentech argues that the phrases "degradation by the copper ions" of the '403-S patent (Claims 1 and 16) 11 and "copper ion-mediated degradation" of the '838 patent (Claim 1) require a rate of copper-induced degradation relative to peak C that is higher than the background degradation rate at the conditions tested. "Peak C" is a peak of degradation formed by the major degradation product of an antibody which has a molecular weight of approximately 50k. In the specification, the inventors use peak C as a scale against which other rates of degradation are measured. "Background degradation" is the degradation that naturally occurs absent the introduction of copper ions. In support of its construction, Genentech points to patent examples, Glaxo documents and testimony of the Smith inventors as evidence that the Smith patent claims require a higher degradation rate.

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11 Claim 16 of the '403-S patent claims:

A stabilized immunoglobulin composition comprising an IgG 1 and copper ions, wherein the copper is present in an amount sufficient to degrade the immunoglobulin, together with an amount of a chelator of copper ions sufficient to bind the copper ions present in the composition and protect the immunoglobulin from degradation by the copper ions

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Glaxo argues in response that the term "degradation" conveys its plain and ordinary meaning to one of skill in the art. That is, "degradation" is any copper ion-mediated degradation of an IgG 1 antibody in storage. The essence of the dispute over these phrases, therefore, is whether the invention requires that the pre-chelator immunoglobulin composition exhibit a minimum rate of degradation greater than the rate of background degradation.

In support of its position, Genentech first argues that Example 1 of the '838 patent reveals that the degradation rate in the pre-chelator immunoglobulin composition must be more than the background rate. In the example, the inventors show that the composition with no additives degrades at 12% of peak C when stored at +37 degrees C. This is the background degradation rate. With the addition of copper ions, the composition degrades at 28% of peak C. When EDTA, a chelator of copper ions, is added to the composition, it degrades at less than 1% of peak C. The example demonstrates that the introduction of a chelator can reduce degradation to negligible levels, but it does not expressly or implicitly require that the pre-chelator composition degrade at a rate higher than the background rate.

Genentech next argues that testimony of Dr. Smith reveals that the rate of copper ion-mediated degradation required by the Smith patents is greater than that of background degradation. In a deposition, Dr. Smith was asked, "so it was your understanding that copper-induced degradation caused a uniquely high level of degradation . . . ?" Dr. Smith responded, "yes our experiments indicated that copper gave vast amounts of this - of degradation." Dr. Smith's testimony reveals that copper degrades the immunoglobulin composition at greater rate, but it does not establish a patent requirement that the pre-

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chelator composition degrade at a rate higher than the background rate.

Finally, Genentech argues that recorded data from experiments done by the inventors while working on the Page patents reveal a required minimum degradation rate. Genentech specifically contends that "in experiments designed to look at the effect of EDTA in inhibiting copper induced cleavage, baseline peak C in the control sample held at +37 degrees C was approximately 12% . . . ." Genentech points out that the copper mediated degradation of the '403-S example was 12%. For reasons previously stated with regard to Example 1, the court finds that the data do not expressly or implicitly require that the pre-chelator composition degrade at a rate higher than the background rate.

After reviewing the specification, the testimony of Dr. Smith and the results of the Page experiments, the court finds that the evidence set forth by Genentech demonstrates that copper often degrades the immunoglobulin composition at a high rate relative to peak C, but it does not confirm that the Smith patents require a degradation rate above the background degradation rate. In short, the specification examples do not create implicit claim limitations. Thus, the court concludes that the phrases should be construed according to their plain meaning, and therefore interprets the phrases "degradation by the copper ions" of the '403-S patent and "copper ion-mediated degradation" of the '838 patent to require degradation of the immunoglobulin composition by copper ions.
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To reach the gist of the present dispute, this Court is able to make some initial, and what it considers obvious, determinations. Potassium polyacrylate as used in the Red-Z Zafety Pac meets an element of independent Claims 1,6,11 & 15 of the '266 Patent (and of all claims dependent therefrom, with the exception of Claims 2,8,13,14 & 17, which call specifically for sodium polyacrylate) in that it is a "first material" as described therein. Further, this Court concludes that potassium polyacrylate is the equivalent (as defined infra) of sodium polyacrylate, which is an element of Claims 2,8,13,14 & 17. Further, the biocide sodium disocyanurate as used in the Red-Z Zafety Pac meets an element of independent Claims 1,6,11 & 15 (and all claims dependent therefrom) of the '266 Patent in that it is a "second material" as described therein. To the extent that the Red-Z Zafety Pac was shown to be used and is usable in the environment claimed in Claims 6 & 15 (and claims dependent therefrom) of the '266 Patent, it meets such element. Additionally, the envelope used for the Red-Z Zafety Pac and that described in the '266 Patent each has its "physical properties impaired" in that a closed envelope which opens can be said to have its physical property impaired. Whether this means that the Red-Z Zafety Pac degrades or is degradable is another question -- the central question that remains regarding infringement.

This question is one of claim construction, a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976-979 (Fed. Cir.) (noting and resolving inconsistencies in this standard and rejecting prior case law that stated that claim construction was a mixed question of law and fact), cert. granted, U.S. , 116 S. Ct. 40 (1995); Read Corp. v. Portec, Inc., 970 F.2d 816, 822 (Fed. Cir. 1992). The claims identify what the patentee regards and what has been allowed as his invention. 35 U.S.C. § 112. To ascertain the meaning of a claim, a court may consider the claim, the specification and the prosecution history. Read Corp., 970 F.2d at 823. Expert testimony, or other extrinsic evidence, may be used to assist the court in determining the meaning of a claim by describing how those skilled in the art would interpret the claims, to define the terms therein or to demonstrate the state of the prior art. Markman, 52 F.3d at 979-981. Max Daetwyler Corp. v. Input Graphics, Inc., 583 F. Supp. 446 (E.D. Pa. 1984). A patentee may act as his own lexicographer, assigning a chosen meaning to a term he uses, regardless of the term's technical or common meaning. But when an inventor does so, his intended meaning must be found within the patent's disclosure. "The Alice-in-Wonderland view that something means whatever one chooses it to mean makes for enjoyable reading, but bad law." Autogiro Company of America v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 397 (Ct. Claims 1967). "So long as the meaning of an expression is made reasonably clear and its use is consistent within a patent disclosure, an inventor is permitted to define the terms of his claims." Intellicall, Inc. v. Phonometrics Inc., 952 F.2d 1384, 1388 (Fed. Cir. 1992).

It is clear and undisputed that the '266 Patent teaches a combination of already-existing elements used in a new invention -- consisting of a first material that absorbs and immobilizes and a second material that treats the absorbed and immobilized liquid to nullify an undesirable quality thereof, both of which materials are contained in a degradable envelope that degrades upon contact with liquid, permitting the first and second materials to come into contact with the liquid and absorb, immobilize and treat said liquid. The essence of the dispute lies in the meaning of the terms "degrade" and "degradability" in Claims 1 & 6 and the absence of these terms in Claims 11 & 15.

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When adding Claims 11-18, Multiform remarked as follows to the PTO:

"The word 'degrade' includes the definitions of 'to deprive of standing or true function' and 'to impair in respect to some physical property.' Thus when the envelope is dry and not degraded, its true function is to contain its contents. However, once it is exposed to liquid, it is deprived of its standing or true function and it has its physical property of containing its contents impaired."

Such statement was made, however and admittedly, after Multiform had become aware of the Red-Z Zafety Pac. 13 It is also noted that such statement of intended meaning is not disclosed by the patent itself. In light of the timing of such statement, this Court is inclined to accept that the Red-Z Zafety Pac prompted such. Indeed, Multiform continued: "the term 'degradable' may be subject to argument as to its meaning because others, in the event of an infringement, may tend to interpret this term as synonymous with 'disintegrate,' which is not necessary for the packet to function properly." Nonetheless and as was pointed out at trial, one does not degrade a door to enter a room. While "degrade" and "degradable" might not be synonymous with "disintegrate" or "dissolve" and their variant forms, the meanings with which Multiform attempts to imbue these former terms goes too far.

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13 "There is nothing improper about an applicant amending claims in a pending application to cover a competitor's product, so long as the claims are supported in the original application disclosure." A.O. Smith, 221 U.S.P.Q. at 974; Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988), cert. denied, 490 U.S. 1067, 104 L. Ed. 2d 633, 109 S. Ct. 2068 (1989); Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F. Supp. 948, 954-955 (S.D. Fla. 1972) (nothing inherently wrong or dishonest in amending claims in pending application to insure that such claims will cover commercial activities of third parties as long as amended claims are supported by original application), aff'd, 479 F.2d 1328 (5th Cir.), cert. denied, 414 U.S. 874, 38 L. Ed. 2d 115, 94 S. Ct. 66 (1973).

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Such is shown by the specification of the '266 Patent, wherein the properties of the envelope are described:

"The dot-matrix pattern, or any other suitable discontinuous pattern, permits liquid, which may not otherwise be able to dissolve the material of the coating * * *, to completely degrade envelope * * * because there are uncoated spaces * * * between the dots of the coating * * * through which the liquid can pass. However, the special advantage of the dot-matrix pattern is that the dots are extremely small so that even if they do not dissolve, the degraded envelope will be practically entirely disintegrated, whereas if the discontinuous pattern consisted of large areas of coating, complete disintegration might not be obtained even though the envelope itself was degraded."

This language is identical to portions of the specification of the earlier '069 Patent. The '069 Patent, a copy of which is included in the file wrapper to the '266 Patent (Deft's Exh. 100), introduced the element of a discontinuous (e.g., dot-matrix) pattern (as essentially an improvement to the '600 Patent) to facilitate the degradability of the envelope. The Background of the Invention for the '069 Patent refers to the co-pending application for the '600 Patent and notes a shortcoming of that application as justifying the application for the '069 Patent:

"In copending application Ser. No. 863,722, filed May 16, 1986, a packet is disclosed which contains sodium polyacrylate in a starch paper envelope which is coated with polyvinyl acetate for heat-sealing the envelope. However, in one embodiment the polyvinyl acetate was coated uniformly on the starch paper, and thus the envelope would not disintegrate in solutions in which the polyvinyl acetate was not soluble."

The Summary of the Invention states that the purpose of the '069 Patent was to provide an improved packet of soluble paper, "which has a discontinuous coating thereon which is used to retain portions of the envelope in sealed relationship while permitting the remainder of the soluble paper to dissolve even if the discontinuous coating is insoluble in the liquid in which the soluble paper is immersed." This discontinuous pattern is retained in the '266 Patent. The purpose of such, as the above screams out, is to increase the extent to which the starch paper envelope will dissolve (or disintegrate). In no other manner is the impairment of the envelope's physical properties -- e.g., its tearing, opening, bursting, rupturing, unsealing or peeling -- discussed. The language of the '069 Patent and of the '266 Patent specifications suggests that the term "degrade" clearly

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encompasses "dissolve" and "disintegration" (which are themselves treated more or less as synonyms). To this effect it is noted that the '266 Patent lists "DISSOLVO" as a trade-name for the "degradable" starch paper envelope. Further, the term "degradable," while proffered by Multiform as the mere adjective form of its expansively-construed "degrade," is actually more closely associated with the terms "decomposable," "disintegratable" and "biodegradable." ROGET'S INTERNATIONAL THESAURUS, at 903 (4th ed. 1977) (Deft's Exh. 106); WEBSTER'S NEW COLLEGIATE DICTIONARY at 298 (1976) (Deft's Exh. 105). Additionally, Medzam points out that the same dictionary used by Multiform to define "degrade" for the PTO -- viz., "to deprive of standing or true function" and "to impair in respect to some physical property" -- also defines "degradable" as "capable of being chemically degraded * * * < << detergents> - compare BIODEGRADABLE." Ibid. Likewise and to the extent that it might bear upon giving life to the term degradable, the prior art does not support Multiform's proffered and broad meaning of that term. The Lastovich Patent notes that Multiform's starch paper envelope is slow to dissolve completely and that its invention improves upon this characteristic. The McCabe Patent discloses a packet partially comprised of dissolvable paper. Multiform distinguished this invention to the PTO, not by asserting a distinction between degrade and dissolve, but by noting that the '266 Patent included a second material for treating the absorbed liquid. Finally, this Court discounts Multiform's expert testimony offered to show what those skilled in the art would consider degrade to mean. Common usage, dictionaries, the file wrapper of the '266 Patent and certain other patents and prior art sufficiently support this Court's rejection of Multiform's overly-expansive meanings of degrade and degradable. Degrade need not, however and as Medzam asserts, be considered synonymous with, e.g., the total disintegration, dissolution or disappearance of the envelope. The '266 Patent's specification states that an envelope can be "degraded" although "complete disintegration might not be obtained" because the portions of the starch paper coated with polyvinyl acetate may not have "dissolved." This Court concludes that "degrade" and "degradability" are most synonymous with "partially disintegrate" or "partially dissolve," and their adjective forms, but also encompass, e.g., dissolve and disintegrate. They cannot be taken to mean what was demonstrated to this Court to be the bursting of a closed envelope via the eruption of inner forces.

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Claims 1 and 6

In the '266 patent the packet is claimed as a combination of the degradable envelope, the absorbing material, and the treating material. A second group of claims describes the envelope in terms of its function, in the form authorized by 35 U.S.C. § 112 P6; these claims are discussed post. Claims 1 and 6 are representative of the first group of claims:

1. A packet for absorbing and immobilizing a liquid comprising an envelope which is degradable in said liquid, a first material in said envelope for absorbing and immobilizing said liquid, and a second material confined in said envelope for additionally treating said liquid which is absorbed and immobilized to nullify a specific undesirable quality thereof.

6. In an outer container having an inner container with liquid from which said liquid can leak, an absorbent packet located between said inner and outer containers for absorbing and immobilizing said liquid within said outer container in the event of leakage of said liquid from said inner container comprising an envelope which is degradable in said liquid, a first material in said envelope for absorbing and immobilizing said liquid, and a second material confined in said envelope for additionally treating said liquid which is absorbed and immobilized to nullify a specific undesirable quality thereof.

(Emphases added.) Medzam conceded that its packet contains all of the elements of claims 1 and 6 except the "degradable" envelope. Medzam argued that its envelope is not degradable, when that term is correctly construed, and thus that the claims are not infringed.

The disputed issue is the meaning of the term "degradable" in characterizing the claimed envelope. The district court defined this term with an eye to the accused envelope. The court held that the terms "degrade" and "degradable," as used in the '266 patent, mean that the envelope at least partially dissolves and thereby disintegrates in the liquid. The court held that this meaning of "degradable" does not include the mode of operation of the Medzam packet, wherein the envelope bursts open by expansion of the contents but the envelope itself does not dissolve and disintegrate by direct action of the liquid.

Multiform states that this claim construction is incorrect, and that upon correct construction a finding of infringement is inevitable. Multiform argues that "degradable" must first be construed based on the '266 patent documents, without

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reference to the accused device, see Jurgens v. McKasy, 927 F.2d 1552, 1560, 18 U.S.P.Q.2D (BNA) 1031, 1037 (Fed. Cir. 1991) ("claim is construed without regard to the accused product"); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1580, 18 U.S.P.Q.2D (BNA) 1001, 1013 (Fed. Cir. 1991) (the words of the claims are independently construed, focussing on the disputed elements), and that as used in the '266 patent "degradable" is not limited to dissolution and disintegration, but means any loss in the containment function of the envelope. Multiform cites dictionaries showing this broader meaning, and states that a person of ordinary skill would construe "degradable," as applied to these envelopes, as meaning a loss in their containment function.

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention -- the inventor's lexicography -- must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history. These documents have legal as well as technological content, for they show not only the framework of the invention as viewed by the inventor, but also the issues of patentability as viewed by the patent examiner.

During patent prosecution Multiform submitted dictionary definitions of "degradable" from Webster's New Collegiate Dictionary (1976), explaining the submission as follows:

The word "degrade" includes the definitions of "to deprive of standing or true function" and "to impair in respect of some physical property." Thus when the envelope is dry and not degraded, its true function is to contain its contents. However, once it is exposed to liquid, it is deprived of its standing or true function and it has its physical property of containing its contents impaired.

Multiform states that this definition is comprehensive of the degradation of the Medzam envelope that bursts apart and thus loses its true function, and is not limited to an envelope that degrades by dissolving. Multiform states that it is not necessary for the packet to disintegrate in order to degrade. Medzam responds that Multiform offered these definitions only after Multiform became aware of the Medzam packet, and that the definitions are at odds with the plain reading of the specification.

Multiform argues that, in keeping with the rule that an inventor may be his own lexicographer, its definition of "degradable" must prevail. When the meaning of a term is sufficiently clear in the patent specification, that meaning shall apply. See Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388, 21 U.S.P.Q.2D (BNA) 1383, 1387 (Fed. Cir. 1992); Lear Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 889, 221 U.S.P.Q. (BNA) 1025, 1031 (Fed. Cir. 1988). This rule of construction recognizes that the inventor may have imparted a special meaning to a term in order to convey a character or property or nuance relevant to the particular invention. Such special meaning, however, must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention.

Thus we review, de novo, the meaning of "degradable" in claims 1 and 6. We start with the specification. See Slimfold Mfg. Co. v. Kinkead Industries, Inc., 810 F.2d 1113, 1116, 1 U.S.P.Q.2D (BNA) 1563, 1566 (Fed. Cir. 1987) ("Claims are not interpreted in a vacuum, but are part of and are read in light of the specification.") The '266 specification describes the Multiform envelope as made of soluble starch, such that "when the aqueous solution comes into contact with the envelope, it degrades it . . . ." '266 patent, col. 1, lines 21-23. The specification explains that degradation of the envelope results from dissolution of the soluble envelope material. The specification illustrates an envelope whose inner layer contains a dot matrix pattern of insoluble material that permits heat-sealing, and in discussing this pattern the specification explains that it is the soluble portion that results in degradation of the envelope: "The dot matrix pattern, or any other suitable discontinuous pattern, permits liquid, which may not otherwise be able to dissolve the material of coating 17, to completely degrade envelope 11 because there are uncoated spaces 18 between the dots of the coating 17 through which liquid can pass." '266 patent, col. 3, lines 5-10. The district court discussed the specification in reaching its conclusion, and also reviewed the prosecution history. The court referred to United States Patent No. 4,124,116 to McCabe, which describes a water-soluble envelope that releases its contents upon contact with spilled aqueous liquid. The McCabe envelope is made of two sheets, one of which is made of soluble starch. The district court observed that "Multiform distinguished this invention to the PTO, not by asserting a distinction between degrade and dissolve, but by noting that the '266 Patent included a second material for treating the absorbed liquid." 1995 WL 737929 at *11. We agree that this analysis is correct.

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The district court concluded that the specification and the prosecution history do not support a meaning of "degradable" that would include an envelope that bursts open from inner pressure without any dissolution. The district court defined "degradable" in light of the mode of action of the accused device, a pragmatic expedient relevant to the issue in litigation. Thus the court held that Multiform's dictionary definitions added during patent prosecution, although stating a broad definition of "degradable," could not serve to enlarge the scope of the claims in order to cover the Medzam device. The district court did not accept Multiform's position that the dictionary definitions provided during the prosecution simply clarified the inventor's original usage of "degradable." We agree with this analysis.

Courts must exercise caution lest dictionary definitions, usually the least controversial source of extrinsic evidence, be converted into technical terms of art having legal, not linguistic, significance. The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history. The evolution of restrictions in the claims, in the course of examination in the PTO, reveals how those closest to the patenting process -- the inventor and the patent examiner -- viewed the subject matter. See Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1578, 38 U.S.P.Q.2D (BNA) 1126, 1129 (Fed. Cir. 1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning.") When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term.

We conclude that the meaning of "degradable" in claims 1 and 6 (and the claims dependent thereon) is limited to the dissolution/degradation of the envelope as described in the specification. The court correctly excluded the meaning whereby the envelope "degrades" by bursting instead of dissolving, and correctly held that "degradable" means that there must be at least partial dissolution of the envelope. Upon this claim interpretation, the district court concluded that there could not be literal infringement of claims 1 and 6. We agree, for this claim interpretation eliminated the Medzam envelope, which bursts but does not dissolve, from the literal meaning and scope of the claims.
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C. Dehydration/Dehydrated

For the reasons set forth below, this court interprets the claim terms "dehydration/dehydrated" in the '328 patent to mean:

the removal of water, but not necessarily all water.

Ansell argues that the terms "dehydration/dehydrated" require the removal of all water. It supports this argument by first referring to testimony of an Ansell employee who testified that dehydration means the "removal of water as much as possible." (Def.'s S.J. Mem. at 7.) Ansell then quotes the '328 specification:

> Aloe Vera is attached to the surface of the glove through a controlled dehydration process. The water in the Aloe Vera solution is caused to evaporate through heating.

(Def.'s 56.1(a) Stmt. P17.) By focusing on the phrase "the water . . . is caused to evaporate" Ansell argues that dehydration, as it is used in the '328 patent, should be defined as "removal of the water." Ansell apparently then assumes that the presence of "the" in the phrase, "removal of the water," requires removal of all water. Shen Wei, for its part, disputes the proposed limitation requiring the removal of all water.

Thus, it is clear that the parties agree that the terms should be construed to mean at least the removal of some water, but disagree about whether removal of all the water is required. 7 The claims do not recite Ansell's proposed limitation that the claim terms "dehydration/dehydrated" must be construed to require the removal of all water. The portion of the specification Ansell references is not an explicit or implicit definition set forth by the patentee to that effect. 8 This reference cannot be interpreted in a manner that requires the removal of all water, and even if such a clear limitation were stated, it would not necessarily act to limit a claim that contains no such limitation. See Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1368 (Fed. Cir. 2004) (quoting Tex. Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002) ("While . . . claims

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are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."). None of the intrinsic evidence set forth by Ansell justifies its proposed limitation on the claim terms "dehydration/dehydrated."

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7 Ansell has not proposed a limitation less than removal of all water. Therefore, this court will not consider whether the terms should be construed to mean the removal of a specific quantity of water less than one hundred percent.

8 This court rejects Ansell's argument that the doctrine of prosecution disclaimer requires construing the term to mean all water is removed. First, the argument suffers from a fatal procedural flaws. It was first raised in reply, thereby depriving Shen Wei of the opportunity to respond. Wright v. United States, 139 F.3d 551, 553 (7th Cir. 1998) (explaining that an argument cannot be first raised in reply). Second, this court cannot find an express disclaimer in the materials submitted by Ansell. This court can only assume that Ansell was similarly unable to find an express disclaimer which would explain why Ansell never specified a disclaimer in its memorandum except to say that it (whatever it may be) is inconsistent with defining dehydration to allow the presence of some water. (Def.'s Mem. at 7.)

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Both parties have provided extrinsic evidence, in the form of expert testimony, in support of their respective positions. This court does not believe that this is a "rare circumstance [where] the court is unable to determine the meaning of the asserted claims [therefore justifying a resort] to extrinsic evidence to help resolve any lack of clarity." Dow Chemical Co. v. Sumitomo Chemical Co., 257 F.3d 1364, 1373 (Fed. Cir. 2001). Nevertheless, even if this court felt compelled to rely upon expert testimony, the testimony does not justify Ansell's proposed limitation. Ansell has not provided any testimony that directly supports its limitation. Ansell has also made no attempt to contradict the expert testimony Shen Wei advances contradicting Ansell's proposed limitation. (Pl.'s Resp., at 11-12.) Instead Ansell relies upon what it considers to be the clear import of the claims. (Def.'s S.J. Mem. at 7.) This reliance is misplaced though, because the language of the claims provides no justification for limiting the terms "dehydration/dehydrated" to instances where all water is removed. Therefore, this court refuses to adopt Ansell's limitation of dehydration.
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"Delay condensation of watervapor on the other oxides while native oxides are being etched"

Here, the dispute is whether the condensation is merely postponed, but ultimately does occur during the process of etching the native oxides, or whether "delay condensation" can also mean "avoid or prevent condensation" during the process of etching the native oxides. ASM argues that this language should be construed as "initially no liquid film of water forms on non-native oxide surfaces, and in a later stage of the process, a liquid film of water does form on the non-native oxide surface, timed so that the time period in which only native oxides are being etched ends at the moment that a liquid film of water forms on the non-native oxide surface." Genus argues that there is no requirement that condensation occur during the process.

The '568 patent explains that:

While we do not wish to be bound by any particular theory of operation, we believe that native oxide etching is initiated and performed by HF/H[2]O in vapor phase, perhaps in conjunction with a different chemical make up and/or with H[2]O adsorbed in the native oxide, whereas the thermal oxide etching is typically not initiated until vapor condenses on the thermal oxide surface. The time offset after native oxide etching begins and before the thermal oxide begins to be etched permits the removal of the native oxide. Other deposited oxides operate similar to the thermal oxide although some begin etching more quickly than the thermal oxides.

('568 patent 4:39-50.) Thus, according to the theory of the invention, as long as the vapors do not condense on the thermal oxide surface, only native oxides will be etched.

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The summary of the invention provides:

In accordance with another aspect of the present invention, the substrate is exposed to the hydrogen halide vapor and water vapor until vapor begins to condense on the substrate.

In accordance with still another aspect of the present invention, the treating conditions are maintained to prevent water vapor from condensing on the substrate until sufficient

native oxide is etched so that substantially all of the native oxide will be etched before appreciable other oxides are etched. The temperature of the substrate and/or vapor and/or the pressure of the vapor are controlled to prevent vapor from condensing on the substrate until the native oxide is removed.

('568 patent 2:67-3:11.) Both of these aspects of the invention contemplate that condensation eventually will occur during the process of etching the native oxide. In addition, the abstract of the invention provides:

"Treating conditions are maintained to prevent water vapor from condensing on the substrate until sufficient native oxide is etched so that substantially all the native oxide will be etched before appreciable other oxides are etched." By stating that condensation will be prevented until substantially all the native oxide will be etched, the abstract contemplates that condensation will occur before all of the native oxide has been etched. Figure ID also shows the thermal oxide starting to etch before the native oxide is completely etched, and thus, under the theory of the invention, shows that condensation has begun before the native oxide is completely etched.

In one of the preferred embodiments, however, the inventors contemplate a process in which condensation will not occur at all:

It has been discovered that in the HF/H[2]O vapor process of the present invention, the liquid HF/H[2]O does not condense if the wafer temperature is above about 27 [degrees] -28 [degrees] C. Accordingly, applicants' process includes provision for heating the wafer above about 27 [degrees] -28 [degrees] C. such as up to 30 [degrees] C. via the semiconductor substrate heater described in U.S. Pat. No. 4,778,559 or with infrared or ultraviolet energy.

('568 patent 7:28-35.) According to this language, if the wafer is heated above 27 [degrees] -28 [degrees] C throughout the entire process, condensation will never occur. As the patent specification discloses a method in which condensation will never occur during etching of the native oxide, the Court almost certainly must construe the phrase "delay condensation" to mean "postpone or prevent condensation." "[A] claim construction that excludes a preferred embodiment is rarely, if ever, correct." Dow Chemical Co., Ltd. v. Sumitomo Chemical Co. Ltd., 257 F.3d 1364, 1378 (Fed. Cir. 2001) (citing Vitronics, 90 F.3d at 1583). "This is because 'it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.'" Id. (citing Hoechst Celanese, 78 F.3d at 1581).

The prosecution history also supports this construction. As Genus notes, the claim language about delaying condensation was added to the claims in the final amendment that was submitted to the patent office before the claims were allowed. (Brown Decl., Ex. H (prosecution history) at 112 (Dec. 17, 1992 amendment) and 118 (Notice of Allowance dated March 3, 1993). Those amendments were intended, in part, to distinguish a prior patent issued to Faith Jr. The applicants explained that the diagram in Figure 13 of the '568 patent "discloses, as is not taught by Faith Jr., that there are many combinations of partial pressure of constituents of the vapor mixture at specific temperatures which will result in no apparent condensate on the substrate surface." (Id. at 116 (emphasis added).) The applicants also noted that "There is no suggestion in Faith Jr. to control the partial pressures as a mechanism for delaying or preventing condensation." (Id.) This is the only discussion in the prosecution history about delaying condensation, and this language supports Genus' contention that the claim language was intended to include processes in which no condensation occurred during the etching of native oxide.

As Oldham notes in his rebuttal expert report, a requirement that condensation occur at some point during the process "is wholly inconsistent with the purpose of the invention described and claimed in the '568 patent." (Brown Decl., Ex. E, Oldham Rebuttal Expert Report at 2.)

One of ordinary skill in the art would understand that the '568 patent is directed at a method for selectively etching of

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native oxides, which means as Dr. Hammond explains, "removing native oxide without removing any significant amount of other oxides." The '568 patent teaches a particular method of selectively etching native oxides which exploits the fact that etching of the "other oxides," is "typically not initiated until vapor condenses on the [other] oxide surface," while etching of native oxides can occur "before condensation of vapor on the [other] oxide surface." … One of ordinary skill in the art would have recognized that the method described in the '568 patent generally seeks to avoid condensation of water vapor on the other oxides while the native oxides are being etched in order to achieve "selective" etching of the native oxides ….

In sum, one of ordinary skill in the art would understand that the goal of the method described in the '568 patent is avoiding condensation on the other oxides to the extent practical. This is wholly inconsistent with Dr. Hammond's opinion that the claim somehow requires ensuring that condensation occur on the other oxides at some point "within the frame of the process."

(Id. at 2-3 (citing inter alia, '568 patent 4:40-45, 7:21-26).)

ASM argues, however, that during the prosecution of the '568 patent the inventors disclaimed a process in which condensation does not occur during the process of etching the native oxide. ASM points to page 67 of the prosecution history, where the inventors attempted to distinguish the Miki prior art from their invention:

In the Miki reference it is not a matter of etching native oxide before etching thermal oxide with a particular vapor. Rather, Miki maintains that only native oxide (and not thermal oxide) will be etched by an HF and nitrogen gas as long as the HF concentration is in the range of 0.6 to 4.7 percent.

(Brown Decl., Ex. H. (Prosecution History) at 67.) ASM misinterprets this statement as explicitly disclaiming processes that did not etch thermal oxide at all, i.e., processes in which condensation on thermal oxide is avoided. First, nothing in either Miki or this part of the '568 prosecution history even mentions condensation. Indeed, at the time these statements were made to the patent examiner, the "delay condensation" language had not yet been added to the claim language of the '568 patent. For this reason alone, these statements in the prosecution history cannot limit the "delay condensation" language that was later added to the '568 patent.

Second, Miki did not realize that by postponing or avoiding condensation, it was possible to etch only the native oxides. Instead, Miki was directed at using low concentrations of HF to etch native oxides without etching thermal oxides, as the '568 inventors pointed out. (Id.) To be sure, the inventors' statements do suggest that the inventors contemplated that the invention of the '568 patent used only processes, unlike Miki, that could result, if they were permitted to run long enough, in etching of the thermal oxide. Nothing in this discussion, however, requires that the processes always run long enough to etch thermal oxide, or that condensation must occur before the process stops. Moreover, as already noted, the patent specification specifically contains language identifying a process in which condensation will never occur during the process of etching the native oxide. The Court rejects ASM's contention that, in distinguishing the Miki reference, the '568 inventors disclaimed a process in which condensation never occurs.

The Court also rejects ASM's suggestion that claim 8 would necessarily be invalid in light of Miki if the Court were to construe "delay condensation" to include processes in which condensation never occurs. Even if Miki and the claim 8 process both describe processes in which condensation never occurs, there are still a significant difference between Miki and the '568 patent. Unlike the '568 patent, Miki does not teach the use of a mixture of hydrogen halide vapor and water vapor to etch native oxide, but teaches away from it.

ASM cites Bruce Deal's deposition testimony as further evidence that condensation must occur during the etching process for the process to be covered by the '568 patent. Deal was one of the inventors of the process patented in the '568 patent. Deal's testimony is inconclusive. For example, Deal's answers to a series of questions suggested that the invention covered processes in which condensation did not occur on the thermal oxide before the native oxides were completely etched:

Q: You'd select the parameters that allowed for a sufficient delay period -- that in between the time when the native oxide starts to etch and when condensation actually occurs on the thermal oxide, correct?

A: Yeah, but you keep bringing in condensation. Even though condensation is occurring, that's not what you select. You select etch conditions, characteristics, for the thermal oxide that you might or might not want later, but you want to have

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sufficient time before that starts to occur to etch the native oxide that might be present.

(Brown Supp. Decl., Ex. D (Deal Dep.) 121:4-23.)

Q: What if you set the process parameters in terms of the partial pressures so that the thermal oxide never etched; would that be the type of method that's taught by the '568 patent, in your view?

A: It certainly would fall under the patent. There's nothing in the patent, I believe, that says you have to go ahead and etch the thermal oxide.

(Id. 133:14-20.)

Q: And you're saying that you interpret your patent, which says that you're -- to delay condensation while native oxide is being etched so that it includes a situation where you never etch the thermal oxide; did I understand you correctly?

A: Well, you can include that. Is there anything in the patent that says you can't?

(Id. 139:18-24.) Later, though, Deal's testimony changed somewhat:

Q: … You set your process parameter so that no matter how long you run it, your pressures and temperatures and partial pressures are such that you will not have condensation on the thermal oxides. Is that the kind of method that you intended to teach by the '568 patent?

A: I don't think we considered that.

Q: So the answer is, no, it is not the type of method that you intended to teach?

A: No.

(Id. 148:17-149:1.) Then Deal narrowed this testimony:

Q: So it is -- the type of method that you were intended was one where the process parameters were set up so that if they continued, at least at some point, you would etch the thermal oxide, correct?

A: That's probably correct, right.

(Id. 150:3-7.) Thus, by the end of his deposition, Deal had testified that his patent covered a process in which parameters were set so that condensation could occur, but that the process did not need to run until condensation actually did occur. The one thing that is clear from Deal's testimony is that the precise issue that is currently being debated by the parties was not an issue to which he had given a great deal of thought. Especially in light of the lack of clear evidence of intent," the subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim (except as documented in the prosecution history)." Markman, 52 F.3d at 979. Cf. Voice Technologies, 164 F.3d at 615 (inventor is competent to explain the invention and what was intended to be covered by the claims, but cannot change the invention and the claims from their meaning at the time the patent was drafted and granted).

The specification and the prosecution history both suggest that the '568 patent is not limited to processes in which condensation ultimately occurs during the process of etching the native oxide. Accordingly, the Court construes "delay condensation" to mean "postpone, prevent, or avoid condensation."
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A. "Delayed Release Tablet"/"Delayed Release"

The parties' most significant disagreement, to which they have devoted the bulk of their briefing and argument, is on the

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proper construction of the term "delayed release tablet" in claims 1 and 30 of the '341 patent. The central disputes between the parties over this term are: (1) whether I should construe the entire term "delayed release tablet" (Impax's position) or only "delayed release" (Biovail's position), (2) whether this claim term serves as a limitation on the scope of the claims, and (3) what its meaning is and how it limits the claimed invention.

1. "Delayed Release Tablet" vs. "Delayed Release"

As a threshold matter, I must decide whether the first claim term at issue is "delayed release tablet" or only "delayed release" -- a point about which there is some disagreement between the parties. Biovail identifies "delayed release" as the relevant claim term in its opening brief and throughout its papers. n4 Impax, on the other hand, maintains that the Court must construe the entire phrase "delayed release tablet." I agree with Impax that it is necessary to construe "delayed release tablet."

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n4 Curiously, however, Biovail's only suggested construction of the term "delayed release" involves reference to a "tablet": "[I]f the term is construed to be a limitation, the term refers to a tablet that exhibits a dissolution profile such that after 1 hour, from 0 up to 30 of the bupropion hydrochloride is released, after 4 hours, from 10 to 60 of the bupropion hydrochloride is released . . . ." (Biovail Opening Br. at 3.)

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First of all, I am required to construe the terms in controversy "to the extent necessary to resolve the controversy," Vivid, 200 F.3d at 803, and Biovail and Impax clearly cannot agree on a definition of "delayed release tablet." By proposing that I construe only "delayed release," Biovail seems to assume that the definition of "delayed release tablet" would flow inexorably from my construction of "delayed release." However, this is not necessarily so; it is possible that the entire phrase "delayed release tablet," as used in the '341 patent, has a meaning distinct from the sum of its component parts. The Federal Circuit has explicitly warned courts against "focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." Phillips, 415 F.3d at 1321. In the context of the '341 patent, to construe "delayed release" apart from "tablet" would be to construe that phrase in the abstract rather than in its proper context. Moreover, it makes sense to keep "delayed release tablet" together for claim construction purposes because the term "delayed release tablet" is used repeatedly throughout the '341 patent, while the words "delayed release" appear only once without the word "tablet": ". . . a more delayed release is generally obtained with a higher amount of water-insoluble, water-permeable film-forming polymer . . ." (Col. 3, lns. 14-16 (emphasis added).) Indeed, as noted above, Biovail has not proposed any definition of "delayed release" that does not make reference to a tablet.

2. Whether to Construe "Delayed Release Tablet" as a Limitation on the Claims

As another threshold issue, I must decide whether the term "delayed release tablet" in claims 1 and 30 of the '341 patent is in fact a limitation on the claims -- i.e., whether it needs to be construed at all.

Biovail asserts that because the term "delayed release tablet" resides in the "preamble" of the claims, it does not serve as a limitation on the claims and so does not require construction. In general, patent claims are drafted with a preamble, a transitional phrase, and a body. 1 R. Carl Moy, Moy's Walker on Patents § 4:60 (4th ed. 2005) ("Walker on Patents"). The essential part of a patent claim is the body, which describes each of the invention's components, usually in the form of a list in which the various parts of the invention are set out in some sort of conceptual order. Id. § 4:58. The preamble of a patent claim consists of the words at the beginning of the claim. Id. § 4:60. It typically names the invention as falling within a generic class of objects or practices and provides a context in which to understand the specific statements of included components set out in the body. Id. The transitional phrase appears immediately after the preamble and before the body, and serves to connect the generic language of the preamble to the specific invention components set forth in the body. Id. § 4:59. Examples of transitional phrases include "consisting of" and "comprising." n5

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n5 Each transitional phrase is its own term of art with specialized meanings that are not directly relevant to the patent claims

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at issue here. See 1 Walker on Patents § 4:58.

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While it is generally the body of a patent claim that sets forth what is and is not claimed in the patented invention, language in the preamble of a claim will also be considered a limitation on the claim "if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (citations omitted). However, "if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention, the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." Intirtool, Ltd. v. Texar Corp., 369 F.3d 1289, 1295 (Fed. Cir. 2004) (citations omitted). Put differently, unless there has been reliance on preamble language during prosecution, the preamble does not serve to limit the claim where the patentee "uses the preamble only to state a purpose or intended use for the invention." Catalina, 289 F.3d at 808.

Biovail asserts that because "delayed release tablet" is found in the preamble of claims 1 and 30, it is not limiting and should not be construed. However, as Impax points out and Biovail does not refute, "delayed release tablet" is actually found in the body of claim 30. In fact, as can be seen from the following chart, claim 30 does not have a preamble or a transitional phrase, but rather consists only of a body:

Claim 1
Preamble A delayed release tablet
Transitional comprising
Phrase
Body (i) a core comprising bupropion hydrochloride and conventional excipients, free of stabilizer; and
(ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, where the proportion of water-insoluble, water-permeable film-forming polymer varies between 25 and 90% of the coating dry weight, and the proportion of water-soluble polymer varies between 10 and 75% of the coating dry weight, exhibiting a dissolution profile such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

Claim 30
Preamble [none]
Transitional [none]
Phrase
Body A bupropion hydrochloride delayed release tablet free of stabilizer and free of pore-forming agent, exhibiting a dissolution profile such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from

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20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

Thus, even if I were to agree with Biovail that "delayed release tablet" is a non-limiting part of the preamble in claim 1, I would still need to construe it in claim 30. See Catalina, 289 F.3d at 810-11 (where term was found in the preamble of one claim and in both the preamble and body of another, it would be construed as a limitation on the claim of which it formed part of the body).

While recognizing that "delayed release tablet" appears in the preamble and not the body of claim 1, Impax argues that it should nonetheless be considered a limitation on the claim language because: (1) the term recites structure that is essential to the claimed invention, (2) the Federal Circuit indicated that similar language in a related patent could be construed as a claim limitation, and (3) the patentee relied on this term during the prosecution history to define the claimed invention. I find all of Impax's arguments to have merit.

First, Impax is correct that the term "delayed release tablet" in the preamble of claim 1 recites essential structure and "is necessary to give life, meaning, and vitality to the claim." Catalina, 289 F.3d at 808 (citations omitted). Courts have found preamble language to be limiting where it "states a necessary and defining aspect of the invention," rather than merely providing "an introduction to the general field of the claim." On Demand Machine Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1343 (Fed. Cir. 2006). As Impax observes, "delayed release tablet" provides the essential structure for claim 1 because it is the only term that limits the invention described in claim 1 to a tablet and not, for instance, a "capsule filled with microspheres that met the other structural limitations of claim 1." n6 (Impax Opening Br. at 29.) Thus, this is not a case where "deletion of the preamble phrase does not affect the structure or steps of the claimed invention." Intirtool, 369 F.3d at 1295. Deleting "delayed release tablet" from claim 1 would not only eliminate the invention's tablet structure, it would deprive the tablet of its fundamental characteristic, which is its delayed release. See Poly-America, L.P. v. GSE Lining Tech., Inc. 383 F.3d 1303, 1310 (Fed. Cir. 2004) (preamble language that states "fundamental characteristic of claimed invention" is "properly construed as a limitation of the claim itself").

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n6 I recognize that "delayed release" could possibly be deleted from claim 1 without rendering the claim meaningless. However, as noted above, I find it necessary to construe the term "delayed release tablet" and not just "delayed release."

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In addition, Impax points out that in two infringement cases involving U.S. Patent No. 5,427,798 ("the '798 patent"), which involves a "controlled sustained release" formulation of bupropion hydrochloride, the Federal Circuit indicated that the term "sustained release tablet" in the preamble of one of the claims could be read as a claim limitation. Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348, 1353 (Fed. Cir. 2004) ("The 'sustained release tablet' phrase recited in the preamble gives life and meaning to the claims, because sustained release is an essential feature of the invention."); see also SmithKline Beecham Corp. v. Excel Pharms., Inc., 356 F.3d 1357, 1362-63 (Fed. Cir. 2004). Because the Federal Circuit did not explicitly construe the term "sustained release tablet" in the '798 patent in these cases, they are not controlling here. However, I cannot ignore the fact that the Federal Circuit, in considered dicta, stated that a term very similar to "delayed release" in a patent very similar to the '341 patent was a limitation on the claimed invention, despite being in a claim's preamble. These highly persuasive decisions of the Federal Circuit further confirm that "delayed release" in the preamble of claim 1 should be construed as a limitation on the claim.

Finally, Impax observes that the patentee specifically relied on the phrase "delayed release" in the preamble of claim 1 during the prosecution history of the '341 patent. In Application 09/184,091 ("the '091 application"), the patent application that led to the '341 patent, claim 1 originally read "[a] controlled release tablet comprising . . . " and claim 30 read "[a] bupropion hydrochloride controlled release tablet . . . ." n7 (Prosecution History at BV 76746, 76749 (emphasis added) (hereinafter "Prosec. Hist.").) In April 1999, the United States Patent and Trademark Office (USPTO) examiner issued an Office Action that rejected all of the patentee's claims. (Id. at BV 76756-64.) Among the rejections was one for "obviousness-type double patenting." n8 (Id. at BV 76758-59.) In the April 1999 Office Action, the USPTO examiner stated:

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Claims 1-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of copending Application No. 09/184096. Although the claims are not identical, they are not patentably distinct from each other because the dissolution rates are essentially the same, the only difference being in the wording.

(Prosec. Hist. at BV 76758-59.) Application 09/184096 ("the '096 application"), which ultimately issued as U.S. Patent No. 6,033,686 ("the '686 patent"), was another patent application by the inventor of the '341 patent, Pawan Seth. The '091 and '096 applications were filed simultaneously, and the '096 application also claimed a "controlled release" formulation of a bupropion hydrochloride tablet. (Prosec. Hist. at BV 76811.)

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n7 Citations to the prosecution history of the '341 patent are to Bates-numbered pages in the certified copy that Biovail submitted to the Court.

n8 Under the doctrine of obviousness-type double patenting, "a patent is invalid when it is merely an obvious variation of an invention disclosed and claimed in an earlier patent by the same inventor." Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999). The doctrine is "designed to achieve two purposes: (i) to prevent the second patent from extending the length of the patent term, and (ii) to shield competitors from the risk of multiple, inconsistent suits for infringement." 1 Walker on Patents § 3:67.

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In August 1999, in direct response to this Office Action, the patentee filed an Amendment to his application in which, inter alia, the words "controlled release" in claims 1 and 30 were changed to "delayed release." (Prosec. Hist. at BV 76808-10.) In a section entitled "Double Patenting Rejection," the patentee explained the reason for this particular amendment:

This application [the application that led to the '341 patent] and commonly assigned U.S. Serial No. 09/184,096 filed October 30, 1998 are distinct from each other, because they are directed to two distinct release profiles.

U.S. Serial No. 09/184,096 deals with a bupropion tablet having a controlled release profile as set forth in independent Claims 1, 26, 28 and 30. The tablet exhibits a dissolution profile such that after 1 hour, from 30 to 60% of the bupropion hydrochloride is released, after 2 hours, from 55 to 80% of the bupropion hydrochloride is released, after 3 hours, from 75 to 95% of the bupropion hydrochloride is released, after 4 hours, from 80 to 100% of the bupropion hydrochloride is released.

This application, U.S. Serial No. 09/184,091, deals with a bupropion tablet having a delayed release profile as set forth in independent Claims 1, 26, 28 and 30. The tablet exhibits a dissolution profile such that after 1 hour, up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(Id. at BV 76811-12 (emphasis in original).) Thus, the patentee specifically relied on a distinction between "delayed" and "controlled" release in the preamble of claim 1 and the body of claim 30 to attempt to avoid the examiner's double patenting rejection over the '096 application.

"[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Catalina, 289 F.3d at 808; see also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1362 (Fed. Cir. 2004), cert. granted in part on other grounds, ___ U.S. ___, 126 S. Ct. 601, 163 L. Ed. 2d 501 (2005) ("A preamble may provide context for claim construction, particularly, where as here, that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history."). Here, by specifically changing "controlled release" to "delayed release" in the preamble of claim 1 in response to the PTO's action, the patentee engaged in "use of the preamble to define, in part, the claimed invention." Catalina, 289 F.3d at 808.

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Biovail counters by noting that the patent examiner did not ultimately accept the patentee's basis for distinguishing the '096 application, but instead required the patentee to file a "terminal disclaimer" of the '096 application in order to obtain the '341 patent. n9 In this terminal disclaimer, the patentee disclaimed "the terminal part of [the '341 patent] which would extend beyond the expiration date of the full statutory term of any United States Patent that may issue based upon [the '096 application]." (Prosec. Hist. at BV 76818.) The patentee further agreed that the '341 patent would be enforceable "only for and during such period that the legal title to said patent shall be the same as the legal title to any U.S. patent which may issue based upon [the '096 application]." (Id.) However, the fact that the examiner did not ultimately go along with the patentee does not change the fact that the patentee relied on the phrase "delayed release tablet" in the preamble "to define, in part, the claimed invention." Catalina, 289 F.3d at 808. Clearly, the patentee saw this preamble language as a limitation on the claims, or he would not have altered it an attempt to clarify the scope of the claims. Thus, it can properly "provide context for claim construction." Metabolite, 370 F.3d at 1362.

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n9 A terminal disclaimer is a document by which a patentee "disclaim[s] or dedicate[s] to the public the entire term, or any terminal part of the term, of a patent to be granted," 37 C.F.R. § 1.321(b), and is a common way of avoiding an obviousness-type double patenting rejection, 1 Walker on Patents § 3:67.

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3. The Meaning of "Delayed Release Tablet," as Used in the '341 Patent, to a Person of Ordinary Skill in the Art

In addition to disputing whether "delayed release tablet" must be construed at all, the parties disagree on the proper construction of the term in claims 1 and 30 of the '341 patent. Biovail asserts that "delayed release tablet" is defined solely with respect to the particular dissolution profile exhibited by the tablet:

a tablet that exhibits a dissolution profile such that after 1 hour, up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released. n10

(Biovail Opening Br. at 3.) Impax, on the other hand, claims that "delayed release tablet" means
a tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer.

(Impax Opening Br. at 9-10.) The crux of the dispute over this term is thus whether "delayed release tablet" means any tablet with the dissolution profile described in claims 1 and 30 or, more narrowly, "a tablet with specific components and a coating that controls the release of the active ingredient." (Impax Opening Br. at 9.) I ultimately conclude that Impax prevails on this issue.

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n10 I note that because both claim 1 and claim 30 explicitly limit the claimed invention to a tablet having this dissolution profile, Biovail's proposed construction of "delayed release tablet" would not seem to add any additional limitations to the claims.

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When a court construes a patent claim, the presumption is that each claim term has its "ordinary and customary meaning," in other words, "the meaning that the term would have to a person of ordinary skill in the art . . . as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313 (citations omitted). Here, there does not appear to be much dispute between the parties as to the "ordinary and accustomed meaning" of "delayed release." The experts retained by the parties agree that in general, one skilled in the art would understand a "delayed release tablet" to be any tablet that does not release its active ingredient immediately. (Biovail Supplemental Br. Ex. 1, Dep. of Arthur H. Kibbe, Ph.D. at 106; Ex. 2., Dep. of

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Robert O. Williams, III, Ph.D. at 58.) However, the fact that "delayed release" has a generally accepted meaning in the art does not necessarily mean that the patentee intended "delayed release tablet" as used in the '341 patent to incorporate this definition. "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics, 90 F.3d at 1582. Moreover, "a claim term may be clearly redefined without an explicit statement of redefinition." Bell Atlantic Network Serv., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). In this case, both parties agree that the patentee acted as his own lexicographer to give the term "delayed release tablet" a meaning different from its ordinary and accustomed one; however, they disagree on what that meaning is.

As already mentioned, Impax asserts that the patentee defines "delayed release tablet" in the specification of the '341 patent to mean a tablet comprising a core and a coating with specific ingredients, in which the coating controls the release of the drug. Biovail, on the other hand, claims that the patentee defined the term more broadly in the course of the '341 patent's prosecution history, and that it encompasses any tablet that achieves the dissolution profile stated in claims 1 and 30. The parties' different definitions of "delayed release tablet" are ultimately immaterial in claim 1, because that claim already recites a tablet having a core and a coating. However, Impax's proposed construction would also limit claim 30 to a tablet in which a coating controls the release of the active ingredient, while Biovail's construction would allow claim 30 to cover any bupropion hydrochloride tablet with the specified dissolution profile, with or without a coating, provided that the tablet was free of stabilizer and pore-forming agent. Thus, the parties' ultimate dispute over the definition of "delayed release tablet" is whether, as Biovail contends, the term "delayed release tablet" in claim 30 can be construed to cover bupropion hydrochloride tablets in which the release is controlled other than by a special coating. Resolving this dispute requires an inquiry into the essence of the invention disclosed in the '341 patent.

The proper construction of "delayed release tablet" is a close question, and both parties' positions were ably presented in their briefs and at oral argument. However, Impax's proposed construction is ultimately the correct one because the Federal Circuit has made it clear that "the claims cannot be of broader scope than the invention that is set forth in the specification." On Demand, 442 F.3d at 1340. As discussed further below, because the '341 patent, as set forth in the specification, does not teach any means of controlling the release of bupropion hydrochloride other than by a special coating, I cannot construe the patent to cover tablets in which the release is not controlled by a coating, as Biovail requests. Because Impax's proposed construction of "delayed release tablet" is "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention," Phillips, 415 F.3d at 1316 (citations omitted), it is the construction that I adopt.

a) Impax's Proposed Construction

Because "claim construction analysis must begin and remain centered on the claim language itself," Innova, 381 F.3d at 1116, I look first to the claims of the '341 patent. The claim language supports Impax's proposed construction of "delayed release tablet," which would limit the claimed invention to a tablet having both a core and a coating. See Phillips, 415 F.3d at 1314 ("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms . . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive."). Claim 30 states that the delayed release tablet of the invention is to be free of "pore-forming agent." (Col. 12, line 4.) While the parties disagree as to the exact definition of pore-forming agent, both parties agree that it is a substance "capable of being eluted from a coating." (Biovail Opening Br. at 3; Impax Opening Br. at 35.) As Impax points out, there would be little reason to mention a substance that can be "eluted from a coating" in claim 30 unless that claim was understood to require a coating. Thus, the claim language itself indicates that "delayed release tablet" should be construed to limit claim 30 to a tablet in which the coating controls the release of the drug.

Standing alone, the claim language might not compel Impax's construction; however, as explained fully below, when read in light of the specification, the claim language necessarily limits the claimed invention to a tablet in which a special coating controls the release of the active ingredient. This is dispositive of the construction of "delayed release tablet," because in addition to being "the single best guide to the meaning of a disputed term," Phillips, 415 F.3d at 1315 (citing Vitronics, 90 F.3d at 1582), the specification also serves as the "the scope and outer boundary of claims," On Demand, 442 F.3d at 1338.

In its en banc decision in Phillips, the Federal Circuit considered "the extent to which [courts] should resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims." 415 F.3d at 1312. Observing that it had "long

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emphasized the importance of the specification in claim construction," the court reaffirmed this importance, noting that it "derives from . . . the statutory requirement that the specification describe the claimed invention in 'full, clear, concise, and exact terms.'" Id. at 1315-16; see also Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 397-98 (Ct. Cl. 1967) (specification acts as a "concordance for the claims"); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) (specification is "the primary basis for construing the claims"); Markman, 52 F.3d at 979 (claims "must be read in view of the specification, of which they are a part"); Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose."). Thus, the Federal Circuit concluded that it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Phillips, 415 F.3d at 1317.

Subsequently, the Federal Circuit gave further content to this principle in On Demand. That case involved a patent for a system of printing and binding a single copy of a book, generally at the point of sale, after providing the customer with computerized information about the book. 442 F.3d at 1334. The defendants accused of infringing this process included printing companies that printed single copies of books for wholesalers and retailers, but did not sell to retail consumers directly. Id. at 1335. The defendants disputed, inter alia, the district court's construction of claim 8 of the patent, which claimed "[a] method of high speed manufacture of a single copy of a book" comprising certain steps, including "storing sales information relating to . . . books in a computer" and "providing means for a customer to visually review said sales information." Id. at 1336. The district court construed the term "customer" to include not only retail customers but anyone who buys goods and services, and construed "sales information" to include any data stored in a computer involved in the promoting and selling of a book, including price, title, and ISBN number. Id. at 1338-39. So construed, the patent was found infringed. Id. at 1336.

On appeal, the Federal Circuit found the district court's claim construction to have been erroneous and reversed. At the outset, the On Demand court noted that Phillips had "stressed the dominance of the specification in understanding the scope and defining the limits of the terms used in the claim." Id. at 1337-38. The court went on to state that "the role of the specification is to describe and enable the invention. In turn, the claims cannot be of broader scope than the invention that is set forth in the specification." Id. at 1340. Turning to the claim terms at issue, the court found that the patent's specification indicated that "customer" was meant to include only end retail consumers, not retailers and wholesalers of books, and that the district court had erred in construing the term otherwise. Id. at 1340. Similarly, the court found that "[t]he specification makes clear that sales information is that which would help the consumer to choose a book," such as the book's synopsis and critical reviews, and thus the district court's construction, insofar as it also encompassed basic information such as title and ISBN number, was broader than the specification allowed. Id. at 1338.

In the present case, as in On Demand, the specification of the patent at issue serves as the "outer boundary" of the claims. To the extent that Biovail's proposed construction of "delayed release tablet" would encompass tablets in which something other than a special coating controls the release of the active ingredient, Biovail's construction is broader than the specification of the '341 patent allows and must be rejected in favor of Impax's.

Impax cites numerous sections of the '341 patent's specification indicating that a coating is an integral part of the invention. Looking at the specification as a whole, it becomes evident that the essence of the invention disclosed in the '341 patent is, as Impax claims, a tablet with both a core and a coating in which the coating controls the release of the active ingredient. On the very first page of the '341 patent, the abstract n11 provides:

The invention provides a controlled release tablet, free of stabilizer and free of pore-forming agent comprising: (i)a core consisting essentially of bupropion hydrochloride, a binder and a lubricant; and (ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer.

('341 patent, abstract (emphasis added).) On the next page, the Summary of the Invention n12 repeats the abstract verbatim (col. 1, lns. 46-52) and goes on to state that "the controlled release is obtained thanks to a semi-permeable release coating" (id. lns. 56-58). Thereafter, the Detailed Description of the Invention n13 provides that "[t]he invention consists in a tablet comprising a core and a coating" (id. lns. 66-67) and that "[t]hese tablet cores are then coated with the semi-permeable coating designed to achieve a controlled release of bupropion hydrochloride" (col. 2, lns. 50-53) (emphasis added). Finally, Impax points out that in each of the Best Modes of Practicing the Invention, n14 it is the coating of the tablet that controls the release of bupropion hydrochloride. n15 "[W]hile it is of course improper to limit the claims to the particular preferred

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embodiments described in the specification, the patentee's choice of preferred embodiments can shed light on the intended scope of the claims." Astrazeneca AB v. Mut. Pharm. Co., 384 F.3d 1333, 1340 (Fed. Cir. 2004). In short, the specification of the '341 patent establishes that the essence of the invention disclosed is a tablet in which release of the active ingredient is controlled by a coating. n16

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n11 "The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." USPTO, Manual of Patent Examining Procedure 608.01(b) (8th ed. 2005) (hereinafter "MPEP") (quoting 37 C.F.R. § 1.72).

n12 "A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, be commensurate with the invention as claimed and any object recited should be that of the invention as claimed. Since the purpose of the brief summary of invention is to apprise the public, and more especially those interested in the particular art to which the invention relates, of the nature of the invention, the summary should be directed to the specific invention being claimed . . . ." MPEP § 608.01(d) (quoting 37 C.F.R. § 1.73) (emphasis added).

n13 "The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old." 37 C.F.R. § 1.71(b) (emphasis added).

n14 "The best mode contemplated by the inventor of carrying out his or her invention must be set forth in the description." MPEP § 608.01(h) (citing 35 U.S.C. § 112). Compliance with the best mode requirement requires disclosing the inventor's "preferred embodiment" of the claimed invention. Bayer AG & Bayer Corp. v. Schein Pharms., Inc., 301 F.3d 1306, 1316 (Fed. Cir. 2002).

n15 Biovail claims that in Examples 6-9, ingredients in the core may contribute to the rate of release of the active ingredient. However, Biovail does not contend that in any of these embodiments it is the core that is controlling the release of the drug.

n16 In its briefs and at oral argument, Impax also pointed to certain extrinsic evidence (such as the deposition testimony of Biovail's expert and the inventor, and Biovail's statements in related patent litigation) that, according to Impax, reflect a general consensus that the '341 patent discloses a tablet with a core and a coating in which the coating controls the release of the drug. While not entitled to as much weight as the intrinsic evidence, this extrinsic evidence confirms the conclusion I have reached by looking at the claim language and the specification.

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"Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc., 450 F.3d 1350, 2006 U.S. App. LEXIS 11675, 2006 WL 1277815, at *3 (Fed. Cir. 2006) (quoting SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001)); see also Boss Control, Inc. v. Bombardier Inc., 410 F.3d 1372, 1379 (Fed. Cir. 2005) ("Because the specification makes clear that the invention involves a two-stage interrupt mode, the intrinsic evidence binds Boss to a narrower definition of 'interrupt' than the extrinsic evidence might support."). Here, the specification of the '341 patent makes clear that the tablet of the invention does not include any means for controlling the release of the drug other than a specialized coating. Thus, I cannot adopt a construction of "delayed release tablet" that would encompass such technology, even though the term "delayed release tablet" might admit of such a definition if construed in the abstract.

In opposition to Impax's proposed construction, Biovail argues that: (1) it impermissibly imports limitations from the specification into the claims, one of the "cardinal sins" of claim construction, Phillips, 415 F.3d at 1320, and (2) it would give claims 1 and 30 essentially the same scope, thus violating the doctrine of "claim differentiation" under which different claims of a patent are presumed to have different scope, see Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006). Both of these arguments fail.

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First of all, there is a difference between reading a limitation from the specification into the claims, which is improper, and reading the claims "in view of the specification, of which they are a part," Markman, 52 F.3d at 979, which is not only proper but required. The Federal Circuit has observed that while "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice . . . the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms." Phillips, 415 F.3d at 1323.

Here, when read in light of the specification, it is clear that "delayed release tablet" must be construed to require a core and a coating that controls the release of the drug. This is not importing a limitation from the specification into the claims, but rather viewing the claims in the way that a person of ordinary skill would, mindful that the specification constitutes "the scope and outer boundary" of the claims. On Demand, 442 F.3d at 1338. To see how this analysis falls on the proper side of the line between interpretation and importation, it is instructive to compare this case with SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337 (Fed. Cir. 2001).

SciMed involved a patent for a balloon dilation catheter used in coronary angioplasty. Id. at 1338. Catheters contain tubular passageways called "lumens," and two configurations of lumens are known in the art: dual (or adjacent), in which lumens are positioned side by side within the catheter, and coaxial, in which one lumen is placed inside the other. Id. at 1339. Just as in this case I conclude that the specification limits the '341 patent to a tablet in which the coating controls release of the drug, in SciMed, the Federal Circuit held that the specification of a patent for a catheter limited the claimed invention to a "coaxial" type of catheter. Id. at 1339. In SciMed, the abstract and summary of the invention sections of the patent contained language indicating that the catheter's tubes were placed inside one another in a coaxial configuration. Id. at 1342-43. Similarly, in present case, the abstract of the '341 patent refers to a tablet comprising both a core and a coating and the written description repeatedly attributes control of the release of the drug to the tablet's semi-permeable coating. In SciMed, the patent's specification contained a discussion of the disadvantages of dual lumen catheters, which was considered evidence that the patentee disclaimed that technology in favor of a coaxial configuration. Id. at 1342-43. Likewise, the specification of the '341 patent discusses the disadvantages of "matrix technology," which is a method for controlling the release of the active ingredient that involves the core rather than the coating. (Impax Opening Br. Ex. C at 9, Expert Report of Arthur H. Kibbe, Ph.D.) The specification ultimately concludes that "[m]atrix technology is however not suited for the manufacture of a tablet, since it implies the use of a stabilizer" (col. 1, lns. 24-26), further indicating that it is the coating and not the core of the tablet that controls release of the drug in the '341 patent. The plaintiff in SciMed argued, much as Biovail argues here, that limitations from the written description or preferred embodiments of the invention must not be read into the claims. However, the Federal Circuit found that this was "not an accurate characterization of what the district court did. Instead, the district court properly followed the invocation that claims must be read in view of the specification, of which they are a part." Id. at 1340 (citations omitted). Similarly, I reject Biovail's argument.

As stated earlier, Biovail also argues that Impax's proposed construction would violate the doctrine of claim differentiation, which is the "presumption that each claim in a patent has a different scope." Curtiss-Wright, 438 F.3d at 1380. Biovail claims that Impax's proposed construction gives claims 1 and 30 essentially the same scope because it limits them both to a tablet comprising a core and a coating with specific components that exhibits a certain dissolution profile. First of all, the Federal Circuit has recognized that claim differentiation is most relevant when a party tries to give the same meaning to a dependent claim and the independent claim on which it depends. Id. That is not the case here, because claims 1 and 30 are both independent claims in that they do not depend on any other claim for their meaning. n17 Moreover, as Impax notes and Biovail does not refute, claims 1 and 30 would still have a different scope even with Impax's proposed construction of "delayed release tablet": claim 1 would recite a tablet with a core and a coating containing specific proportions of certain ingredients, while claim 30 would recite a tablet wherein the components of the core need not be in any particular proportions. Where there is any difference in scope between two claims, claim differentiation loses its force as an analytical tool. See, e.g., Creo Prods. v. Presstek, Inc., 305 F.3d 1337, 1349-50 (Fed. Cir. 2002); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1325-26 (Fed. Cir. 2001). Thus, Biovail's claim differentiation argument is rejected.

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n17 "One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application." MPEP § 608.01(n). For example, in the '341 patent, claims 2-25 are dependent claims depending

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on claim 1. Claim 2 claims "[t]he tablet of claim 1, where the water-insoluble, water-permeable film-forming polymer is ethylcellulose." (Col. 10, lns. 1-2.)

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b) Biovail's proposed construction

Biovail essentially relies on the prosecution history of the '341 patent to support its proposed construction. Biovail argues that in the prosecution history (specifically the August 1999 Amendment), the patentee defined "delayed release" in contrast to "controlled release" by reference to the specific dissolution profile set forth in claims 1 and 30. As noted above, in August 1999, the inventor of the '341 patent attempted to overcome a double-patenting rejection over the '096 application by amending claims 1 and 30 of the '341 patent to recite a "delayed release" tablet as opposed to a "controlled release" tablet. Biovail argues that in doing so, the patentee tied "delayed release" to the dissolution profile in claims 1 and 30 of the '341 patent and "controlled release" to the dissolution profile in the claims of the '096 application. Biovail thus asserts that the only limitation the term "delayed release tablet" imposes on the tablets described in claims 1 and 30 is that they have a particular dissolution profile. n18

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n18 As noted earlier, because both claim 1 and claim 30 already require this dissolution profile, Biovail's proposed limitation on the claims is not really a limitation at all.

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It is true that the patentee may act as his or her own lexicographer to define a claim term during the prosecution history, as well as in the specification. See Schoenhaus v. Genesco, Inc., 440 F.3d 1354, 1358 (Fed. Cir. 2006) (patentee may set forth special definitions of claim terms in either the patent specification or the file history). However, the Federal Circuit has consistently afforded more weight to the specification than to the prosecution history in the context of claim construction. See Phillips, 415 F.3d at 1317 ("[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."); id. at 1315 (quoting Multiform Desiccants v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)) ("T]he best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history."). Here, the construction that Biovail would draw from the prosecution history is broader than the "outer boundary" set forth in the specification, in that it would encompass tablets in which something other than a coating controls the release of the drug. Thus, even assuming arguendo that the prosecution history does support Biovail's proposed construction, I cannot rely on the prosecution history to assign "delayed release tablet" a meaning that is broader than the specification allows. Accordingly, Biovail's construction of "delayed release tablet" must be rejected in favor of Impax's:
A tablet comprising a core which includes bupropion hydrochloride and conventional excipients and a coating designed to achieve a controlled release of bupropion hydrochloride, said coating comprising a water-insoluble, water-permeable film-forming polymer, together with a plasticizer and a water-soluble polymer.
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3. at a density exceeding 400 different oligonucleotides per square centimeter is clear and does not require interpretation.

Affymetrix contends that "exceeding 400 different oligonucleotides per square centimeter" does not require interpretation.

Hyseq contends that "exceeding 400 different oligonucleotides per square centimeter" means that oligonucleotides must be attached to the solid support at more than 400 different predefined regions per square centimeter.

Incyte offered no proposed construction in the Joint Claims Construction Statement, but agreed with Hyseq's definition during the hearing.

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The customary and ordinary meaning of this claim term does not require an absolute minimum number of nucleotides. To read it as such would ignore the meaning of the term "density," which denotes a concentration of nucleotides per unit area. Hyseq's definition would impose the unfounded limitation of an absolute minimum of 400 oligonucleotides and consequently would impose the limitation of a minimum surface area of one centimeter. 8 There is no basis for such limitation, and the Court therefore rejects Hyseq's and Incyte's interpretation.

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8 In arguing that this claim term must require a minimum of 400 different predefined regions per square centimeter, Incyte proposed a hypothetical situation where any array having as few as two different polymers would infringe if the polymers were placed closely enough together. (Markman hearing transcript at 227:6-18; 242:8-243:5). However, as Incyte itself recognized ultimately, even this extreme hypothetical example is not necessarily precluded by the prior art when this term is read in the context of the entire claim. (See id. at 247:15-248:4).

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A. "Derivative of General Formula: [X]"

Although the parties never specifically agree to the meaning of these terms, it is clear from the extensive briefings that there no longer exists a dispute as to the meanings of these terms as used in the claims of the '277 Patent. 1 Accordingly, I recommend the following definition:

"Derivative of General Formula: [X] means the precise chemical reactant shown in the claim, permitting variations only to the R group."

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1 Also, as far as I can discern from the briefs of the parties, there is no longer a need to define the terms "replaced by hydrogen" and, accordingly, I have not discussed these terms in this report.

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6. "derived"

"derived" is a commonly understood word and requires no additional construction.
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3. "gene derived from"

Claims 1, 2, 7, 8, 13, 14, 19, and 20 of the '600 patent contain the phrase "gene derived from a Bacillus thuringiensis." Monsanto claims that this phrase is limited to covering those genes that encode an amino acid sequence that is identical to that of the native Bt gene. Mycogen claims that this gene need only encode an amino acid sequence that results in a pesticidal protein.

The term "derived from" is defined in the specification:
Derived from is used to mean taken, obtained, received, traced, replicated or descended from a source (chemical and/or

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biological). A derivative may be produced by chemical or biological manipulation (including but not limited to substitution, addition, insertion, deletion, extraction, isolation, mutation, and replication) of the original source.

Col. 7, lines 44-49.

Monsanto claims that representations made by Mycogen to the PTO in the prosecution of the '831 patent narrows the scope of the phrase. In that prosecution, Mycogen repeatedly described their invention as being limited to those genes having "an amino acid sequence essentially identical to that of a native Bt insecticidal protein," Exh. 4 at 130. Monsanto points to the declaration of Dr. Michael Murray, in which he describes the patented method as involving the encoding of "a protein homologous to the native protein. " Exh. 4 at 685. In finding the claims of the '831 patent to be allowable, the patent examiner noted that his finding was "particularly [based upon] the Murray Declaration." Exh. 4 at 736. The '600 patent's specification defines homology as the "identity or near identity of nucleotide or amino acid sequences." Col. 6, lines 24-25. The specification also states that "minor nucleotide modifications (e.g., substitutions, insertions or deletions) in certain regions of the gene sequence can be tolerated and considered insignificant whenever such modifications result in changes in amino acid sequence that do not alter functionality of the final product."

Mycogen argues that the relevant portion of the prosecution history appears in the application process for the '600 patent. In an Office Action dated November 9, 1995, the patent examiner rejected claims containing the phrase "derived from a native Bt gene" because it failed to require that the gene produce a pesticidal protein. D.I. 142, Tab 3. Mycogen amended the phrase to include the phrase "encoding a pesticidal protein toxin." D.I. 142, Tab 4. This is the phrase that is included in the final patent. Mycogen thus argues that the patent does not require homology, but only that the resulting protein be pesticidal.

The difference between the portions of the prosecution history that Monsanto cites, and the portions that Mycogen cites, is that Monsanto points to language describing the resulting synthetic gene, while Mycogen points to the language describing the initial gene that is analyzed and modified by its patented process. The '600 patent claims a method for modifying a gene. Specifically, it is a method for modifying a gene "derived from a [Bt] gene which encodes a pesticidal toxin." The portions of the prosecution history cited by Monsanto merely relate to the issue of how the synthetic gene created by the modification may differ from that initial gene.

Since the "derived from" language is only used when describing the initial gene, the court finds that the definition in the patent specification for "derived from" adequately explains the meaning of this phrase. "Derived from a Bt" means taken, obtained, received, traced, replicated, or descended from Bt. Such derivation may include chemical or biological manipulation of the native Bt gene. Since such manipulation may include such techniques as extraction or mutation, a gene derived from a Bt need not encode a protein that is identical to the protein encoded by the native Bt gene.
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5. Derived from a feedstock

Plaintiff contends that the phrase "derived from a feedstock" is unambiguous. Therefore, "derived from a feedstock" means "derived from a feedstock," and no additional limitations should be imported into the claim.

Defendants contend that the phrase should be construed as "derived from a condensate of the vapor of a fast pyrolysis after removing flavor causing components." Defendants argue that throughout the specification, the patentees emphasized that the invention was a product derived from a vapor from which all remaining flavor-causing components are removed. 102

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102 Docket Entry 56 at 10.

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Defendants' argument is not persuasive. The abstract language and the field of invention language cited by Defendants explain that the impregnated casing does not add undesirable characteristics or a strong flavor to the food encased with the treated casing. Neither refers to the removal of all flavor causing components from the liquid composition. Likewise the

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specification passages cited by Defendants in their brief, while describing the invention's purpose and an apparatus useful for fast pyrolysis of the feedstock, do not require the removal of all the flavor-causing components from the liquid composition. 103

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103 Docket Entry 56 at 10-11, 067 patent, Col. 6, lines 32-35, 44-46, 59-69, Col.7, lines 1-69, Col. 8, lines 1-20.

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The critical feature of the invention is the low-flavor liquid composition, which has low acid content, high levels of browning carbonyls, and low levels of phenols. Each of these characteristics is described as a ratio to the browning index and in the context of the specification, is relative to the prior art liquid smoke solutions applied to casings. These characteristics make the invention, a casing impregnated with the low-flavor liquid composition, superior to prior art casings treated with liquid smoke solutions.

The specification states that "a fast pyrolysis process which uses hot participate solids and/or inert gases to rapidly transfer heat to the wood feedstock in a reactor system is preferred" to make the liquid composition. 104 However, the specification does not expressly or implicitly disavow any other method for producing the low-flavor liquid composition. Accordingly, as pertains to the 067 patent, the critical features of the invention are the characteristics of the liquid composition applied to the casings, and not the method of producing the liquid composition.

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104 067 patent Col. 6, lines 43-46

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The District Court should determine that the phrase "derived from a feedstock" as used in the claims at issue in the 067 patent is unambiguous and means "derived from a feedstock."
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5. Derived from vapor of a pyrolyzed material

The parties also disagree on the construction of the phrase "derived from a pyrolyzed material." Plaintiff maintains that the quoted language is unambiguous and needs no further construction. Defendants contend that phrase should be construed as "derived from a vapor of pyrolyzed sugar, starch and/or mixtures thereof by removing all remaining flavor-causing components from a liquid condensate of the vapor.

Plaintiff's construction of the phrase at issue is better supported by the intrinsic evidence. First the language of the claim is plain. The browning liquid is derived or produced from pyrolyzed material. Each of the claims specify that the pyrolyzed material is "selected from the group consisting of sugar, starch, and mixtures thereof." Accordingly, defendants' proposal, which replaces "material" with "sugar, starch, and/or mixtures thereof," adds nothing to the construction and is redundant.

Further, defendants' limitation "by removing all remaining flavor-causing components from a liquid condensate of the vapor" is redundant in light of the construction that flavorless refers to the browning liquid composition. The specification sets forth the process for pyrolyzing the sugars and starches. After the pyrolysis vapor is condensed, the resulting water soluble pyrolysis liquid can be further processed to remove flavoring materials. This additional processing yields the high browning flavorless aqueous liquid described in the claims. Nothing in the specification requires the removal of all the remaining flavor-causing components from the liquid. The construction that all remaining flavoring materials are removed is also inaccurate because the parties preface their claims as being "virtually" flavorless whether speaking terms of the browning liquid or the foodstuffs to which it is applied. Based on the foregoing, the District Court should determine that the phrase "derived from a pyrolyzed material" is unambiguous and requires no further construction.
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E. "derived from said filaggrin by replacing at least one arginine residue in the amino acid sequence with a citrulline residue"

Claim 1 states that the claimed fragment comprises an amino acid sequence derived from filaggrin by replacing at least one arginine with a citrulline. '724 Patent col.15 l.25-28. Plaintiff's construction provides for an amino acid sequence obtained from filaggrin and "changed by substituting at least one arginine residue in the filaggrin sequence with a citrulline residue." (Doc. No. 105 at 5.) Defendant's construction states that the amino acid sequence "includes an amino acid sequence of filaggrin (SEQ ID NO: 19) with changes including at least one arginine residue substituted by a citrulline residue." (Id.) Defendant's construction is more open-ended, while Plaintiff's implies that the only permissible change is the arginine-citrulline substitution. The Court agrees with Defendant on this issue.

The Court first notes that the use of the word "comprises" indicates that the fragment's composition is open-ended -- including but not limited to an amino acid sequence derived from filaggrin. CIAS, 504 F.3d at 1360. In addition to the language of the claim itself, the patent's specification is "the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. Here, the Patent's specification confirms Defendant's interpretation:

To a person skilled in the art it will be apparent that there are a number of possible variations to the present invention as specified by the apended claims. For instance, the peptides mentioned on the formula sheet may also be part of other oligopeptides. They may be provided at one or both ends with one or more amino acids while also, two or more peptides according to the invention may be part of one oligopeptide. It is also possible to shorten the peptides by one or more amino acids, provided this does not have a significantly adverse effect on the reactivity.

'724 Patent col.3 l.37-46. Thus, the specification expressly provides for modification of the amino acid sequence beyond citrullination.

Plaintiff argues that the claim is limited by statement that the sequence is "derived from filaggrin." Plaintiff contends that "an amino acid sequence cannot be considered to be 'derived' from the parent sequence if it has been changed beyond recognition to something that cannot be recognized as having been originally obtained, actually or theoretically, from the parent sequence." (Pl.'s Br. at 20.) Plaintiff objects to the fact that Defendant's proposed construction places no limit on the extent of changes that may be made to filaggrin sequence. However, Defendant's construction is consistent with the patent language itself. Neither proposed construction specifies the scope of allowable changes. This is appropriate, as the extent to which a fragment may deviate from filaggrin and still fall within the claim is a question of fact for the jury. See PPG Indus., 156 F.3d at 1354-55 (holding that whether a substance had a composition "consisting essentially of" listed ingredients was not a matter of claim construction but an infringement issue for the jury).
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The Court has construed the limitations of Claim 1, in relevant part, as follows:

"Active" means producing an intended action or effect: active ingredients.
"Pharmacologically effective" means an amount that is medically effective.
"Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate 1, dermatan sulfate, keratan sulfate and acemannan, for example.
"Amount effective" means a quantity that produces a result.
"Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
"Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.
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The parties also dispute the meaning of the term "designed to allow" as it is used in claim 6 of the '841 patent. Claim 6 reads:

The method of claim 1 wherein the labeled nucleic acid comprises fragments which are designed to allow detection of extra or missing chromosomes, extra or missing portions of a chromosome, or chromosomal rearrangements.

'841 patent, col 18, lines 1-5 (emphasis added). Oncor argues that this phrase should be interpreted as "capable of." The University contends that "designed to allow" means "intentionally selected to achieve the detection goals set forth in the claim."

The ordinary English meaning of the word "design" is "to plan or have in mind as a purpose; intend." Webster's Third New International Dictionary, at 611. "Allow" means "to make a possibility; provide opportunity or basis." Id at 58. Since there is nothing in the patent history or specification that contradicts these ordinary English definitions, the court interprets the phrase "designed to allow" as "intentionally selected to make possible the detection goals set forth in the claim."
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H. "Said Computer is Programmed to Detect and/or Quantitate Said Target Target Compounds"

* * *

Claim30 describes the invention's apparatus as follows: "wherein said computer is programmed to detect and/or quantitate said target compounds." '829 Patent, col. 14, II. 18-20. The parties agree that "detect and/or quantitate" means to detect and determine the amount of target compounds; however, Eppendorf also seeks to add that language specifying that the computer apparatus "perform[s] mathematical comparison(s) of the quantity of precipitate associated with the discrete region(s) to one or more references or standards." As explained above, the Court will not construe claim terms by referring generally to "references and standards," which provides no guidance to the jury as to how the patent functions. As for the language concerning mathematical comparisons, Eppendorf only relies upon extrinsic evidence, namely Eppendorf expert Dr. Steven M. Blair's declaration, for support. Neither Eppendorf nor Dr. Blair provides any intrinsic evidence indicating that the computer apparatus in fact performs mathematical comparisons in order to detect and/or quantitate the target compounds, and instead make state in conclusory fashion that the patent's claim language, specification, and prosecutionhistory support Eppendorf's proposed definition. Accordingly, the Court has construed "wherein said computer is programmed to detect and/or quantitate said target compounds," to be "detect and/or determine the specific amount of the target compounds."
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D. "Presence of detectable HIV-encoding nucleic acid" and "absence of detectable HIV- encoding nucleic acid"

Roche argues that these terms be construed as a "qualitative result indicating greater than or less than 40 copies of HIV RNA per 200 ul of sample." Stanford argues that no construction in necessary because the plain meaning is sufficient to guide the jury's fact finding.

Roche seeks to construe this term as a qualitative yes or no test based upon the lowest detection level taught by the patent, 40 copies per 200 micro-liters of sample, because these terms are in direct contrast to the claims that include a specific measuring step. Roche again attempts to interject a specific copy number limitation into the construction. This attempt fails for the same reasons as above, where a construction including a temporal limitation or particular assay limitation was rejected. The plain and ordinary meaning of "detectable" has to be an amount of substance that is higher than the lowest level of sensitivity of whatever assay is actually used in practicing the claimed methods. Furthermore, the patent

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demonstrates that the patentee inserted specific numerical limitations when desired. See '730 patent, Claim 9. The court refuses to integrate numerical limitations into the construction where none was contemplated by the patentee.

Roche argues that different terms in different claims must have different meaning and that Stanford's construction reduces "presence" and "absence" to "measuring." Roche is correct in its contention that a difference in meaning is presumed. Nystrom v. Trex Co., 424 F.3d 1136, 1143 (Fed. Cir. 2005). The presumption, however, may be overcome, as in the case here. Even though the presence or absence of a substance is indeed a yes or no test, determining whether a compound is present or not is not fundamentally different from measuring the amount of compound. Presence or absence is merely a specific manifestation of measuring for the compound where the actual amount of the compound present is not of any import if the compound is indeed present.

In addition, there is no basis for Roche's claim that the detection process be a qualitative process. In fact, there is evidence to the contrary--that a quantitative process was envisioned. See, e.g., '730 patent at 5:53-57, 10:34-40, 12:58-60. This is further buttressed by Stanford's statements made while prosecuting the patents, which distinguish an article by Ottoman based on the fact that the article described using non-quantitative PCR assays. See Rhyu Dec., Exh. 25 at STAN 1435, 1458. This evidence may be relied upon in spite of Honeywell Int'l v. ITT Indus., Inc., 452 F.3d 1312 (Fed. Cir. 2006). Honeywell only disallows the patentee's own statements if they are "broad and vague statement[s]" that "contradict the clear statements in the specification describing the invention more narrowly." Id. at 1318-19. That is not the case here.

A quantitative process is necessary because a minimum amount of the compound must be present for any detection method to test for the presence or absence of the compound. Thus testing for the "presence" or "absence" is really the same as "measuring," except that if the measurement reveals any amount greater than zero (or the minimum amount necessary to be detectable), the actual amount of the compound is irrelevant.

Stanford's neglect in failing to define the terms is of no import and consequently the terms will not be construed against Stanford. Though the patentee may choose to be his own lexicographer, he does not have to be. In general, the claim terms will carry their ordinary and customary meaning and this court will not import limitations from the specifications into the claims unless it is clear from the specifications that the same was intended.

Finally, for reasons described above, Roche's enablement arguments are just as misplaced here as they were with respect to the other claim terms.

In sum, the court holds that no construction is necessary for "presence of detectable HIV-encoding nucleic acid" and "absence of detectable HIV-encoding nucleic acid."
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a. "Detecting a complex as formed"

Plaintiff contends that this phrase should be construed to mean "any process by which one can determine that a hybridization complex has been formed between the probe and nucleic acids of HCV." Defendant disputes this construction vigorously, arguing that the court should adopt the construction: "Detecting a complex that is formed with said probe and said nucleic acids of HCV." The essential difference between the parties is that defendant believes that the phrase "as formed" requires that detection take place while the complex is present, or, in other words, while the reporter molecule is still attached to the hybridization complex when it signals the formation of a complex. Under defendant's construction, the phrase would not apply to a process in which the destruction of a previously formed complex liberates the "reporter" end of a probe and causes it to glow, as happens when the Taq polymerase destroys a complex during realtime PCR.

Defendant defends its proposed construction with a plethora of arguments. It relies first on the claim language, which in its view requires detection of a complex, not just a remnant of the complex after it is destroyed. Defendant adds that any possibility of ambiguity on this point is eliminated by the words "as formed," which define "complex." According to defendant, the use of "as" implies "in the present; at the same time." Next, defendant argues that the claim specifies the composition of the complex as being a complex "formed with said probe and said nucleic acids of HCV."

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Defendant offers no persuasive reason why detection cannot be accomplished by the observation of fluorescence from the probe, rather than by the observation of the amplification of the target nucleic acid by the probe. It is inherent in the nature of realtime PCR that the reporter end of the probe does not emit light unless the taq polymerase has destroyed the hybridization complex. If the complex does not exist, the taq polymerase will have nothing to destroy and no light will be emitted. The fluorescence demonstrates the existence of the complex, albeit a past existence.

The claim language does not require detection of a presently existing complex, much as defendant would like to read it that way. Defendant relies on the argument that "as" in the phrase "as formed" is a conjunction that "can only mean 'at the time that' and reflects the present tense." Dft.'s Br., dkt. # 51, at 19. That argument would have more force if the patent read "while it is formed." It does not. "As" is a protean word with myriad definitions and uses in the English language, but it seems most likely that in claim 1 it is serving as a substitute for "that" or "which," or, in other words, as a pronoun that does not provide temporal information. The two-word phrase "as formed" could be written as "that is formed," "that has been formed" or "that was formed" and retain the same meaning. Equally, "as" could be omitted without changing the meaning of the phrase. The word is not serving the usual function of a conjunction, which is to join together sentences, clauses, phrases or words, as in this example: "She joined me at the bus stop as the rain began to fall."

I can leave it to grammar mavens to make the conclusive characterization of the role, of "as" in claim 1. The court's task is to determine whether "as formed" must be construed as meaning "still existing." I see no reason why it must be. Whether a hybridization complex is detected while existing or immediately upon destruction, what is detected is still a complex "formed with said probe and said nucleic acids of HCV," as the patent prescribes.

Defendant maintains that plaintiff restricted its claim language during the course of prosecution, beginning with "detecting the complexes possibly formed between said probe and the nucleotide sequence of the HCV isolate to be identified," moving on to "detecting any complex as formed with said probe and nucleotide sequence of the HCV isolate to be identified," and ending up with "detecting a complex as formed with said probe and nucleic acid of HCV." Defendant reads this progression as increasingly focusing the claim choice to specify detecting an actual [existing] complex, that is, one "as formed." I agree with defendant that the second and third versions are more restrictive than the first, which seems to require nothing more than the possibility of a complex. The changes seem directed to clarifying the object of the detection as a formed complex. They imply nothing about whether the formed complex must still be in existence when detection occurs.

Defendant argues that "detecting" a complex that has been destroyed is akin to "detecting" the existence of a wine bottle by finding a cork. The analogy is inapt. A cork can exist independently of a wine bottle; the fluorescence that realtime PCR assays detect cannot exist independently. At the risk of redundancy, I repeat that if the complex has not been created, the reporter end of the probe will not emit light because the taq polymerase will have nothing to destroy.

Finally, defendant points out that some of the preferred embodiments described in the specification utilize existing complexes, but it is settled law that the reach of a patent is determined by its claims and not its specifications. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001). "[A]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." Id. (citing SRI Int'l v. Matsushita Electric Corp. of America, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). Moreover, the inventors specified in the '704 patent that the detection of hybrids "may be determined by means of colorimetric, fluorescent, radiometric detection or any other method comprised in the state of the art."

Realtime PCR is an investigative tool that allows researchers to determine the existence of certain structures in target strands of DNA or RNA. That determination cannot be made if the structures have never been formed. Therefore, whether the structure is still existing or has ceased to exist, if a researcher can determine that it was formed during the hybridization phase of the process, the researcher has "detected" it in the target strand. It is irrelevant that using the process to find those structures results in the destruction of the structures. I will construe the claim term as requiring detection of a complex that is or has been formed.

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A. Infringement

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Defendant bases its motion for a new trial on infringement on its contention that the court's construction of the term "detecting a complex as formed" was erroneous. Prior to trial, when I construed the disputed terms of the patent, I held that "detecting a complex as formed" meant "detecting a complex that is or has been formed." Op. & Order, dkt. # 218, at 18, 31. Under this construction, the patent claim extends to Realtime PCR technology, which employs the Taq polymerase to destroy a complex that has been formed between the probe and the nucleic acids of HCV, thereby liberating the "reporter" end of a probe and causing it to glow. Although the complex is destroyed, the probe will not emit light unless the Taq polymerase has found the specific complex to which it is directed. Realtime is as reliable a means of detecting a formed complex as the older methods in which the reporter signaled the formation of the complex while still attached to the hybridization complex. Nothing in defendant's arguments persuades me that it was error to construe the claim as I did or to find as a matter of law that defendant's use of Realtime PCR in its assays to not make the products noninfringing.

Defendant raises a new argument in its post-trial brief to the effect that the court's construction of "detecting a complex as formed" reads out of existence crucial limitations of claim 1. Apparently, defendant believes that it was error not to consider or construe the phrase "with said probe and said nucleic acids of HCV," which modifies "formed." I do not agree that failing to consider the phase "read [it] out of existence," as defendant contends. There was no need to consider the phrase because neither party contested its meaning or denied that it described the formed complex. Even now, defendant does not contend that the complex identified by the Realtime PCR technology was not formed "with said probe and said nucleic acids of HCV."

Defendant has another variant of its attack on the court's claims construction. It contends that it was error to construe the meaning of a claim term without limiting the construction to what would have been known by a person of ordinary skill at the time the patent application was filed. In other words, if Realtime PCR was not in routine use at that time, it was error to construe the patent to include it as part of the patented method.

Defendant did not raise this issue before trial when it could have been given thorough consideration. Instead, it raised the issue for the first time at 9:30 p.m. on the night before the start of trial and did so simply by submitting a proposed jury instruction, rather than by bringing the matter directly to the attention of the court and opposing counsel. According to the new proposal, the jury would be instructed that it could find that defendant's products did not infringe if it found that the products used new technology that had not been available at the time the patent application was filed. Oddly enough, defendant did not raise this new theory of non-infringement when plaintiff moved at the outset of trial for judgment as a matter of law on infringement. This would have been the time to bring it up, if defendant believed that the court had erred in deciding the motion for summary judgment by not acknowledging that the claims of a patent were limited to technology known in the art at the time of the patent application. Rather than doing so, however, defendant's counsel told the court that defendant had no evidence of non-infringement beyond what it had submitted in support of its motion for summary judgment on the issue of infringement. Trial Transcript, dkt. # 310, at 73-74.

Defendant argues incorrectly that it had no obligation to move for reconsideration of the court's claim construction or come forward with an offer of proof to support new arguments it did not raise during the briefing on claim construction. In support of this position, it cites Wilson v. Williams, 182 F.3d 562, 567 (7th Cir. 1999), in which the court held that

> once the ruling is definitive, the function of the objection requirement has been served, and both parties are entitled to formulate trial strategies that make the best use of the evidence that the judge has decided to admit or exclude. We overrule [United States v.] York, [933 F.2d 1343, 1360 (7th Cir. 1991)] to the extent it holds that an objection at trial is invariably required to preserve for appeal arguments that were fully presented to the district court before trial.

In citing Wilson, defendant seems to overlook the significant difference between it and this case. As the quotation makes clear, the objecting party in Wilson had fully presented its arguments before the court issued its "definitive" ruling. By contrast, in this case, defendant kept the court in the dark about many of its arguments. That kind of conduct constitutes forfeiture. E.g., Backwater, Inc. v. Penn-American Insurance Co., 448 F.3d 962, 965 (7th Cir. 2006) (parties' argument is "not a bad argument, but unfortunately for the [plaintiffs] it's also not an argument they made during the trial; instead of responding to [defendant's] objection with an offer of proof or by asking that the testimony be admitted subject to a limiting instruction, they simply moved on, forfeiting any charge of error."). I conclude that defendant forfeited its argument that the court's claim construction was flawed because that construction did not limit the reach of the claim to technology known at the time of the invention.

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This ruling has no effect of the outcome of the case. Even if defendant had not forfeited its challenge, its argument would fail on its merits. First, it is likely that plaintiff could have shown that Realtime PCR was known to persons of ordinary skill in the art in 1992, when the inventors applied for their European patent, or in 1994, when they applied for the '704 patent. In the proposed findings of fact, submitted in support of its motion for summary judgment on infringement, defendant proposed the fact that "Realtime PCR was developed in the early 90's," Dft.'s PFOF, dkt. # 52, at No. 28, and its expert stated in his report that "Realtime PCR using 5' to 3' exonuclease activity was pioneered around 1991," Patterson Non-infringement Opin., dkt. # 39, at 6. In addition, the Resnik '708 patent that defendant asserted as prior art to the '704 patent disclosed Realtime PCR as "another suitable assay system" for "detecting hybrids formed" between probes and target nucleic acids. Resnick '718 pat. at col. 18, Ins. 47-57, Exh. 5 to Anstaett Decl. dkt. # 390.

Second, it is immaterial whether defendant had evidence that persons of ordinary skill would not have known about Realtime PCR before the application for the '704 patent was filed. Plaintiff made it plain in the '704 specifications that the detection of hybrids formed between the specific target region and the probes was not confined to any one method. Rather, it said, the detection depends on the nature of the reporter molecule used "and may be determined by means of colorimetric, fluorescent, radiometric detection or any other method comprised in the state of the art." '704 pat., col. 6, lns. 36-42. Defendant never identified or produced any evidence to suggest that the language in claim I would not include Realtime PCR. Moreover, it has never produced any evidence that when researchers use defendant's products, hybrids do not form between the specific target regions and the probes or that the products do not utilize reporter molecules attached initially to probes.

Defendant cites a numbers of cases for the proposition that the literal scope of a claim term is limited to what it was understood to mean at the time of filing. That proposition is unremarkable. It is also inapplicable. Although a court must consider what was known to one of ordinary skill in the art at the time of filing, Bayer AG v. Biovail Corp., 279 F.3d 1340, 1348 (Fed. Cir. 2002), the claims of the patent are not necessarily limited to technologies known at the time of filing. SuperGuide Corp. v. DirecTV Enterprise, Inc., 358 F.3d 870, 879 (Fed. Cir. 2004) ("The law 'does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention.'") (quoting SRI International v. Matsushita Electric Corp. of America, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). "[I]t is not necessary to embrace in the claims or describe in the specifications all possible forms in which the claimed principle may be reduced to practice." See also CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (no requirement that patentee describe in patent every possible future embodiment of his invention).

Finally, defendant devotes considerable space in its post-trial briefs to arguing that the doctrine of equivalents would not apply to support a finding of infringement. It is not necessary to address these arguments in light of my conclusion that defendant's products infringe the patent claims literally.

I conclude that defendant has not shown that it was error to grant judgment as a matter of law on plaintiff's claim of literal infringement.

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1. A method for detecting nucleic acid sequences is construed to mean a method for determining the presence or absence of two or more nucleic acid molecules.

Affymetrix and Hyseq contend that this term means determining the presence or absence of two or more nucleic acid molecules.

Incyte contends that this term means a method for determining the sequence of nucleic acids as opposed to fingerprinting and mapping applications.

The parties agree that the preamble is a limitation of the claim. Incyte argues that the preamble limits claims 1 and 3 to applications involving determining the nucleotide sequence of nucleic acids. The Court agrees with Affymetrix and Hyseq that the ordinary meaning of the term does not restrict the term to sequencing applications. "Detecting nucleic acid sequences" may be plainly interpreted to mean "detecting the presence or absence of nucleic acid sequences." This meaning is fully supported by the specification, which is entitled "Method of Detecting Nucleic Acids" and expressly characterizes

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the invention as encompassing more than sequencing:

The present invention provides improved methods useful for de novo sequencing of an unknown polymer sequence, for verification f known sequences, for fingerprinting polymers, and for mapping homologous segments within a sequence.

('992 patent, col. 2:26-29). Incyte fails to provide persuasive evidence that Affymetrix intended to use the term "detecting nucleic acid sequences" in a manner that excludes all applications other than sequencing. Finally, for the reasons previously discussed, the Court rejects Incyte's attempt to limit the claims to only those embodiments which Incyte asserts are enabled by the specification.
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D. '824 Patent, Claim 1(b): "Detecting Said Compound or Compounds so as to Detect Said Nucleic Acid"

Claim 1 of the '824 Patent discloses two steps to the claimed method for detecting the compound that includes the signaling moiety: (a) hybridizing the nucleic acid sample to the specified compounds; (b) "detecting said compound or compounds so as to detect said nucleic acid." '824 Pat. 31:42-43. Plaintiffs argue that this terminology means that the compounds which are detected do not necessarily have to remain hybridized to the nucleic acid in order to permit detection of the nucleic acid. They base their argument on the fact that dependent claim 24 claims a "method of claim 1 wherein said detecting step (b) is carried out when the compound is hybridized to the nucleic acid, '824 Pat. 32:51-53. Where a dependent claim contains this kind of limitation, it is "presum[ed] that the limitation in question is not present in the independent claim," see Phillips, 415 F.3d at 1315 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)), because if it were present in the independent claim, the dependent claim would be redundant, see id. at 1324-25.

Defendants construe the claim language at issue to mean "detecting said compound or compounds hybridized to said nucleic acid sample" so as to detect said nucleic acid. In other words, they argue the patent does not cover detection of the probe after it has been separated from the sample.

The specification, however, is not limited to methods of detection only while the DNA duplex is hybridized. The specification states that its "general scheme illustrates only procedures used for gene mapping (cytogenetics), and recombinant DNA-technologies," i.e., for purposes of "detecting and/or localizing specific polynucleotide sequences. . . ." '824 Pat. 19:22-23, 61-63. The specification states that the invention may also be useful for diagnosing infections ("bacterial, fungus, virus, yeast, or mammal" or drug resistant organisms), i.e. where the scientist does not need to know the sequence of the polynucleotides, merely that polynucleotides from an infectious organism are present. For the latter purpose, the specification states,

. . . a polynucleotide is prepared which is complementary to the nucleic acid sequence which characterizes the organism or its antibiotic resistance and which additionally includes one or more modified nucleotides according to this invention. This polynucleotide is hybridized with nucleic acid obtained from the organism under scrutiny. Failure to hybridize indicates absence of the organism or of the resistance characteristic. Hybridized nucleic acid duplexes are then identified by forming a complex between the duplex and a suitable polypeptide which carries a detectable moiety, and detecting the presence of the complex using an appropriate detection technique. Positive detection indicates that the complex, the duplex and therefore the nucleic acid sequence of interest are present.

'824 Pat. 20:24-38 (emphases added). Contrary to defendants' argument, it does not appear that this aspect of the specification was intended to describe the method's application to "gene mapping" and "recombinant DNA technologies," which were the primary intended use. Rather, the description quoted above, including its reference to "hybridized nucleic acid duplexes" being detected, are limited to the diagnostic examples.

Further, as plaintiffs argue, Claim 24 claims a method where the "detecting step . . . is carried out when the compound is hybridized to the nucleic acid." Again, drawing on the dependent-independent claim logic in Phillips, supra at 14, because the dependent claim contains this limitation, the independent claim is presumed not to include it. Phillips, 415 F.3d at 1315.

For these reasons, the Court adopts plaintiffs' construction of "detecting said compound or compounds so as to detect said

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nucleic acid" to mean that the compounds which are detected do not necessarily have to remain hybridized to the nucleic acid in order to permit detection of the nucleic acid.
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V. "detecting the labeled nucleic acid fragments which are hybridized to the interphase chromosomal DNA to determine"

The phrase "detecting the labeled nucleic acid fragments which are hybridized to the interphase chromosomal DNA to determine" appears in claim 1 of the '479 patent:

(c) detecting the labeled nucleic acid fragments which are hybridized to the interphase chromosomal DNA to determine whether an extra or missing portion or portions of a chromosome, or a translocation or an inversion of a portion or portions of a chromosome is present in the target interphase chromosomal DNA.

'479 patent at 16:24-29 (emphasis added).

Abbott argues that the phrase should be construed to mean "ascertaining in a single cell nucleus the presence of labeled nucleic acid hybridized to the target unique sequence in the interphase DNA to determine . . ." Dako argues that the phrase should be construed to mean "detecting the labeled nucleic acid containing only unique segments hybridized to target interphase chromosomal DNA in a morphologically identifiable cell nucleus to decide or settle conclusively and authoritatively . . ." The parties' constructions differ in three respects. First, Dako's construction expressly requires that the labeled nucleic acid contain only unique segments. Second, Dako's construction requires that the hybridization take place in a morphologically identifiable cell nucleus. Third, Dako's construction requires that the determination be "conclusive" and "authoritative."

The "labeled nucleic acid fragments" recited in element (c) of claim 1 constitute a subset of the heterogeneous mixture of fragments recited in element (a); the fragments in element (c) have been "hybridized to the interphase chromosomal DNA." '479 patent at 16:25. The parties do not dispute that for detection to be possible, the vast majority of hybridized fragments must be unique sequence fragments. This requirement is implicit in Abbott's proposed construction, which requires that the hybridization be to "the target unique sequence in the interphase DNA." Dako further concedes, both in its papers and at argument, that the binding of a very small number of fragments to repetitive sections of the chromosomal DNA will not prevent detection. Given the undisputed understanding that the vast majority of fragments bonded to the chromosomal DNA must be unique sequence fragments, Dako's "containing only unique segments" limitation, which is too narrow in any case, is not needed.

Nor do the parties dispute that the hybridization-and subsequent detection-must occur in a morphologically identifiable cell nucleus. The construction of that phrase, which the parties continue to vigorously dispute, is currently at issue in the appeal of the court's ruling on Abbott's motion for a preliminary injunction.

The remaining dispute centers on the meaning of the word "determine." Abbott argues that claim 1 does not require that one using the claimed process determine anything conclusively by examining a single cell, but rather permits the determination to involve review of multiple cells. Abbott cites Oncor in support of its contention. The defendant in Oncor argued that researchers using the accused method "do not use its technology to 'look at' a single chromosome or cell nucleus when identifying the location of a stain," and thus did not infringe claim 1 of the '841 patent. Oncor, 1997 U.S. Dist. LEXIS 15068, 44 U.S.P.Q.2d at 1334. The court rejected this argument, noting that the claim "focuses on the objective results of the chromosome-staining process, not the activities of researchers who monitor those results." Id. Instead, the claimed process "mandates that the target DNA be present and detectable on a single chromosome or cell nucleus." Id. In other words, the claimed process must permit accurate determination for each cell examined, but a researcher may aggregate the results from examining multiple cells in order to make a more global diagnosis.

The reasoning of the Oncor court does not help Abbott for two reasons. First, the Oncor court expressly held that the process claimed in the '841 patent must yield "objective" results for each cell to which it is applied. Second, claim 1 of the '479 patent requires more than claim 1 of the '841 patent. In addition to requiring "detect[ion]," the '479 patent requires "determin[ing] whether an extra or missing portion or portions of a chromosome, or a translocation or an inversion of a

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portion or portions of a chromosome is present in the target interphase chromosomal DNA." Abbott does not dispute that this determination must take place in a morphologically identifiable cell nucleus, which per the parties' stipulated construction (and the construction of the Oncor court) is a single cell nucleus. Claim 1 of the '479 patent thus requires, based on its plain language, a determination through the examination of a single cell.

Adding the words "conclusive" and "authoritative" to the definition does not add clarity, and lacks support in the intrinsic record. Indeed, neither party's construction adds clarity to the existing claim language. Other than the clarification that "determine" means "determine," for each cell on which the claimed method is performed, no further construction is necessary.
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5. determinable sequence is construed to mean a polymer of known sequence or of sequence that can be determined using conventional methods.

Affymetrix contends that "determinable sequence" means a nucleic acid polymer "of known sequence or of sequence that can be determined using conventional methods.

Incyte contends that "determinable sequence" means a polymer synthesized monomer by monomer and whose sequence is determined by the monomer by monomer synthesis process used to generate it.

Hyseq contends that "determinable sequence" means a spatially addressable polymer synthesized monomer-by-monomer whose sequence is determined by the process of monomer-by-monomer synthesis used to generate it.

The Court adopts the plain and ordinary meaning of the term "determinable sequence," that is, a sequence that can be determined. Incyte and Hyseq attempt to limit this definition to the VLSIPS technology which they allege is the only enabled type of determinable sequence. For the reasons previously discussed, the Court will not limit the claim term based solely on putative non-enablement. Moreover, Incyte and Hyseq have failed to produce, any intrinsic evidence to establish that Affymetrix intended the term to have any meaning other than its conventional meaning. "Determinable sequence" thus is not susceptible to the definitions proffered by Incyte and Hyseq. The Court cannot import extraneous limitations into a claim, even to avoid invalidity. The Court therefore rejects Incyte's and Hyseq's constructions.
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5. "To Determine"

GTG proposes the construction "to conclude or ascertain," while Applera proposes "to fix conclusively or authoritatively." The main dispute is whether the analysis of the DNA strand must be absolutely correct to fall within the scope of the claims.

Nothing in the dictionary definition of the term "to determine" implies that the determination must be 100% accurate, and nothing in the claims, specification, or prosecution history indicates any intent to limit the patent in that fashion. The term "to determine" is construed as: to conclude or ascertain.
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"Determining the glucose concentration in the sample" was construed to mean "ascertaining the amount of glucose contained per unit volume in the sample." (Id. at 6). The Court rejected LifeScan's proffered construction, which would have encompassed "premature" and "intermediate" measurements which do not reflect the actual glucose concentration. (Id. at 7).
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C. "Determining the Possible Presence and Quantification of Precipitate(s) in Said Discrete Region(s)"

Claim Term	Eppendorf's Construction	Nanosphere's Construction
"determining the possible presence and quantification of precipitate(s) in said discrete region(s)"	acquiring one or more special representation(s) of the array comprising one or more sets of pixel data, and processing and/or filtering the pixel data (i) to determine the location(s)of the discrete region(s) having precipitate(s), and (ii) to determine one or more values related to the amount of precipitate(s) in the discrete region(s)	determining the possible presence of the metallic precipitate(s) and determining, by comparison to reference standards, the specific amount of the volume of metallic precipitate(s)
"detecting and quantifying said precipitate in said discrete region(s)"		detecting and determining, by comparison to reference standards, the specific amount of the volume of metallic precipitate in said discrete region

Claims1 and 16 specify that the method described in the '829 Patent comprises "determining," and "detecting and quantifying" the "precipitate in said discrete region(s)." '829 Patent, col. 11, II. 58-59; col. 13, II. 1-2. Eppendorf's proposed construction describes the precipitate determination process as "comprising one or more sets of pixel data," and Nanosphere's proposed constructions largely recite the words in the disputed claim terms in question, but specify that the method described in the '829 Patent determines the "volume" of precipitate, "by comparison to reference standards."

Turning first to the appropriate measure of precipitate, Eppendorf has conceded that "obtaining the three-dimensional volume of the precipitate is undeniably an embodiment disclosed and claimed in the '829 Patent," but insists that the invention, as presently used by the parties, comprises "obtaining a two dimensional scan of the array and assigning pixel values based on the intensity readings." (Pls.' Resp. 8.) Both parties rely upon numerous extrinsic sources such as expert declarations to support their proposed constructions (Pls.' Resp. 7-15; Def.'s Resp. 3-12), but have not provided the Court with reasonscompelling the inclusion of the appropriate measure for determining precipitate in the construction of the disputed terms. Not only is this Court reluctant to adopt a construction that imports "additional precision or specificity" not present in the patent itself, PPG Indus., 156 F.3d at 1355, but also, the Federal Circuit does not require "mathematical precision" in a patentee's definition of his invention. Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1340-41 (Fed. Cir. 2003).

As for Nanosphere's recommendation that the construction include "by comparison to reference standards," the Court finds such language imprecise and unhelpful, given that Nanosphere's proposed construction does not explain what the appropriate reference standards are, and how the quantification of the precipitate can be compared to any such standard. The Court, therefore, will not construe the precipitate quantification process as involving either pixel data or comparisons to reference standards.

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With the exception of the reference to "pixel data," Eppendorf's proposed construction, unlike Nanosphere's, does not largely recite the words in the disputed claim terms, and instead explains that the process ofdetecting and quantifying precipitate involves acquiring "spatial representation(s)" and determining "values related to the amount of precipitate(s)." Accordingly, the Court has construed the disputed terms regarding quantifying the precipitate to mean "acquiring one or more spatial representation(s) of the array (i) to determine the location(s) of the discrete region(s) having precipitate(s), and (ii) to determine one or more values related to the amount of precipitate(s) in the discrete region(s)."
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c. "developed"

DuPont asserts that the term "developed" should be construed to mean "[t]reated to form a flexographic printing plate." (DuPont Responsive Br. at 18.) But MacDermid defines the term as the "[r]emoval of unexposed, uncured portions of the photosensitive elastomer layer." (MacDermid Opening Br. at 32.)

DuPont argues that its proposed construction is supported by (1) the word's commonly accepted definition, and (2) the intrinsic evidence and context of the '758 patent, which is directed to a photosensitive element that can be thermally developed to form a flexographic printing plate. (DuPont Responsive Br. at 18-19; Tr. at 89-92.) It also attacks MacDermid's proposed construction as too narrow because it does not cover the removal of other layers such as the in situ mask. (Tr. at 89-92.) MacDermid contends that its approach is supported by language contained in the patent's specification. (MacDermid Opening Br. at 32; Tr. at 154-56.) MacDermid further attacks DuPont's alternative construction as too broad and unduly ambiguous. (Tr. at 154-56.)

The Court agrees with MacDermid. The specification for the '758 patent defines "developed" by stating: (1) "In a thermal development process, the photosensitive layer, which has been image-wise exposed to actinic radiation, is contacted with an absorbent layer at a temperature sufficient to cause the composition in the unexposed portions of the photosensitive layer to soften or melt and flow intothe absorbent material" ('758 Patent at col. 1, lines 41-46); and (2) "'Developing temperature' is the temperature to which the imagewise exposed photosensitive layer is heated to remove the uncured portions of the layer" (id. at col. 2, lines 5-7). The Court therefore construes "developed" as meaning the "removal of unexposed, uncured portions of the photosensitive elastomer layer."
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Dihydrofolate Reductase (DHFR)	A proteinaceous material which acts as an enzyme and when present in increased concentrations allows eucaryotic cells to survive in the presence of increased concentrations of methotrexate

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1. Dihydroxyphenylpropionic Acid

The term "dihydroxyphenylpropionic acid" ("DHPPA") appears in Claim 1, Step 2, and Claim 4(h) of the '311 patent. The patent also refers to this acid in its abbreviated form "DHPPA." (Col. 14, line 23). The patent also refers to "DHPPA analog" (Col. 15). The only specific reference to a variation of DHPPA is reference to 3,4-dihydroxyphenylpropionic acid (3,4-DHPPA) in example 2 (Col. 14, line 34). Defendant Metametrix argues that DHPPA is undefined anywhere in the patent claim, specification, or prosecution history except for these brief references. Metametrix argues through its expert Dr. Jeffrey Winkler that DHPPA includes 49 potential and distinct compounds and simply referring to DHPPA creates

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ambiguity. Specifically, Dr. Winkler argues that Fig. 1 of the '311 patent identifies peak U as DHPPA, but with Gas Chromatography/Mass Spectrometry ("GC/MS") it would be impossible to determine which of the 49 potential compounds is meant to correspond with peak U. In response, Great Plains and Dr. Shaw argue that the term DHPPA may be construed by the patent itself. Plaintiffs argue that DHPPA refers to the genus term and includes the isomers of this compound as well as the conjugate base.

A brief introduction to organic chemistry is helpful in determining the scope of the claim term. An organic acid is the form of a molecule in which the acid portion of the molecule retains a proton, usually as part of the carboxylic acid portion of the molecule. Such molecules are denoted with the suffix "ic" and the word acid. When the proton attached to the carboxylic acid, a portion of the molecule is lost. The name of the organic acid is changed by converting the word through the use of the suffix "ate." The "ate" form denotes the conjugate base, which is the form of the acid when a proton has been lost. The ionized form of the acid may also be referred to as anions. In an aqueous solution, both the organic acid and the conjugate base is present. When using a GC/MS or Liquid Chromatography-Mass Spectrometry-Mass Spectrometry (LC/MS/MS), a particular compound will be converted into one form (e.g. the acid form), and the instrument will measure the quantity of the compound.

In reviewing the claim and specification, the court finds that DHPPA should be construed broadly to include its isomers and conjugate bases. In every instance the patent refers to the broader term "DHPPA." The patent appears to acknowledge that this compound may exist in other forms in referring to DHPPA analog, which in chemistry refers to a substance that is similar but not identical to another. This reference thus indicates that the inventor understood variations of the compound existed and should be considered. In both Claims 1 and Claim 4(h), the patent refers to DHPPA rather than a specific isomer or conjugate base. Thus, the court finds that this term should be construed broadly to include its isomers and conjugate bases.

There was much discussion at the Markman hearing as to whether Fig. 1, peak U was properly identified. Based on the patent language itself, peak U was only referred to as DHPPA and the specific isomer was not identified. Subsequent research revealed the name of the particular isomer. However, this information is not relevant to the court's claim construction. At present, the court is satisfied that the patent identifies the compound as DHPPA.

Additionally, in Example 2, the patent refers to the general term "DHPPA" but refers to 3,4-DHPPA as the analytical standard. Now, Dr. Shaw identifies 3-hydroxyphenyl-3-hydroxypropionic acid ("HPHPA") as the analytical standard. Since the inventor consistently refers to DHPPA in the patent and 3,4-DHPPA is only referenced as an analytical standard in the embodiment, the court finds no reason to import a limitation to the claim term "DHPPA."

Therefore, "DHPPA" means any form of DHPPA, including any or all of the 49 possible isomer of DHPPA.
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di-allyl di-methyl ammonium chloride (DADMAC)

The parties and the Court agree that the term should be construed as "a polymer of quaternized ammonium moiety formed by the reaction of any allyl with an amine, wherein an allyl is a substance containing the allyl group [CH[2]=CH-CH[2]]+, and wherein an amine is a derivative of ammonia [NH[3]] in which one or more hydrogen atoms have been replaced by an alkyl or aryl group. For example, DADMAC, DMDAAC, DAMEAC, DAEEAC, and DAMPAC are all examples of the DADMAC variety. Polymers of this variety comprise the quaternized nitrogen moiety in a branch from the polymer backbone."
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7. detecting differential expression is construed to mean the assessment of relative levels of gene activity.

Affymetrix contends that this term means the assessment of the relative levels of gene activity, where the concept of relative

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levels includes assessment of gene expression above and below the level of detection.

Incyte contends that this term means the assessment of the relative levels of gene activity, where differential gene expression analysis requires the simultaneous and competitive hybridization of samples derived from different cells to an appropriate array and the subsequent quantitation of the resulting relative levels of hybridization.

The Court adopts the plain and ordinary meaning of "differential expression." The Court declines to import further limitations on this preamble term. "A claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615 at 615-20 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999). In this case, the Court finds that the preamble merely states a description of the method that is more fully set forth in the body of claim 4. See IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434 (Fed. Cir. 2000). For example, steps [1] and [2] describe the sequence of steps that comprise the method. Because the body of the claim fully and intrinsically sets forth the complete invention, and the preamble merely states the purpose of the invention, the Court finds that "detecting differential expression" in the preamble cannot be construed as a limitation of the claim.
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4. Disputed claim term "diameter" means: value represented by the diameter of a sphere having the same volume as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis.
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C. "Diminished incidences of nausea and emesis"

The phrase "diminished incidences of nausea and emesis" is found in asserted claims 20, 22, and 23 of the '171 patent, 1 of the '120 patent, and 1, 3, and 4 of the '958 patent. For example, claim 20 of the '171 patent states:

A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

Wyeth asks the Court to construe the phrase as:

The degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily doses of an immediate release formulation that is administered at least twice a day.

Mylan again argues that the phrase is an unnecessary preamble to the claim; to the extent that the Court determines otherwise, however, it provides the following alternate construction:

A decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day.

Thus, the parties' dispute centers on the meaning of the term "incidence," and whether it refers solely to the number of occurrences of the side effects, or also encompasses the severity of those occurrences.

1. Unnecessary Preamble

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Despite Mylan's contention that the term "diminished incidence of nausea and emesis" is merely an unnecessary preamble to the claims in which it is found, the Court concludes that this phrase is necessary to give "life, meaning and vitality" to those claims. The specification reveals that reducing the negative side effects associated with the immediate release version of the drug is an important use aspect of the invention. The "Background of the Invention" explains that the most common side effect associated with the plural daily dosing regime is nausea, and that many patients also experienced vomiting, or emesis. '171, Col. 2:7-11. The "Brief Description of the Invention" then states "in accordance with this use aspect of the invention, there is a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride . . . ." Id. at Col. 2:55-58.

Consequently, because the specification reveals that "reducing the incidence of nausea and emesis" is a stated and intended objective of the invention, see Cruciferous Sprout, 301 F.3d at 1347, the phrase is not an unnecessary preamble but instead constitutes a claim limitation that must be construed.

2. Meaning of "Incidence"

Both parties agree that "incidence" refers to the frequency, or number of occurrences, of the nausea and emesis. Wyeth, however, contends that the term also encompasses the severity or degree of those side-effects, arguing that, because the specification uses the terms "incidence" and "level" interchangeably, the inventors intended the term "incidence" to encompass both meanings. Wyeth additionally contends that the use of "diminished" to modify "incidences" further indicates that the reduction refers not only to the number of patients experiencing side effects, but also the severity or degree of those effects.

The claims themselves refer only to "diminished incidences" of nausea and emesis. Wyeth relies on Webster's Third New International Dictionary (1993) for the proposition that "diminish" means "to make less or cause to appear less: reduce in size, number or degree." Wyeth Ex. 33. Thus, as Wyeth contends, the term is not necessarily limited to a numerical focus. Nevertheless, just because the term may be used to reference degree, as well as number, does not mean it is used in that capacity in every case. Unfortunately, taken alone, the claim language does not indicate the intended meaning of the term, and thus the Court must turn to the specification for guidance.

The "Abstract" states that the invention provides a "lower incidence of nausea and vomiting than conventional tablets." In the "Background of the Invention," the inventors describe the side effects commonly associated with immediate release Effexor(R), stating that the most common side effect is nausea, "experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride." '171, Col. 2:7-10. They then state that vomiting occurs in approximately seventeen percent of patients using the immediate release version. Id. at Col. 2:10-11. Thus, the inventors describe the problem in terms of the number of patients experiencing the side effects, rather then in the context of the severity of those side effects.

The inventors then describe the positive effect of the extended release version of the drug in the "Brief Description of the Invention," explaining that, during clinical trials of extended release venlafaxine hydrochloride, "the probability of developing nausea" greatly reduced after the first week. Id. at Col. 2:49:52. Again, the inventor's description of the benefit achieved by the extended release formulation is given in the context of the number of people affected, rather than the severity of the nausea.

Beginning in the "Brief Description of the Invention," the inventors use an additional term that is not used anywhere else in the patent. Specifically, they twice refer to "the level of nausea and incidence of emesis." See '171, Col. 2:47-48 and 56-57. Wyeth asserts, and the Court agrees, that the term "level" implies "degree" or "severity" rather then "number." Thus, in the "Brief Description," the inventors appear to describe a reduction in both the degree of nausea experienced and the number of patients experiencing vomiting, or emesis. Wyeth therefore argues that the inventors intended to associate both types of reductions with the new invention. It further asserts that, because the terms "level" and "incidence" are both used to modify "nausea," the inventors clearly intended the words to be used interchangeably.

To the Court, however, the inventors' use of the term "level" indicates that they understood a difference between "level" and "incidence." Specifically, they use "level" in reference to "degree" or "severity," and "incidence" in reference to the number of occurrences. This interpretation is supported by the fact that the inventors never refer to the "level of emesis," but instead

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only discuss the "incidence of emesis." Thus, they appear to have understood a difference between level and incidence, and used the terms accordingly. Consequently, the Court must find meaning in their decision to use only the term "incidence" in the body of the claims.

Moreover, because claim terms are presumed to be used consistently throughout a patent, see Phillips, 415 F.3d at 1314, the Court is unpersuaded that the inventors would have distinguished between "level" and "incidence" in the "Brief Description of the Invention," but then intended to incorporate both meanings into the term "incidence" within the body of the patent claims.

Finally, as Mylan points out, the fact that the specification indicates the "level" of nausea may be reduced by the extended release formulation does not require the Court to read that limitation into the claims. In Phillips, the Federal Circuit noted that "'[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives.'" Id. at 1327 (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908 (Fed. Cir. 2004)).

For these reasons, the Court construes the term "diminished incidences of nausea and emesis" to mean "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."
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B. "Diminished Incidences of Nausea and Emesis"

Wyeth contends that the term "incidences" as related to the phrase "diminished incidences of nausea and emesis" should be construed to mean a reduced degree and/or frequency of nausea and emesis. Specifically, Wyeth contends that "diminished incidences of nausea and emesis" means "the degree and/or frequency of nausea and emesis from the extended release formulation administered once a day is less than what would be experienced by patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

In contrast, Impax contends that the term "incidences" refers to the number of patients with nausea and emesis. Thus, Impax contends that the "diminished incidences of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

The parties agree that the prosecution history is not instructive regarding the meaning of this phrase. Accordingly, the Court must turn to the claim language and the specification for instruction regarding the meaning of the phrase "diminished incidences of nausea and emesis." The term "diminished" is used only in the claim language and not elsewhere in the specification. However, the specification discusses the effect of the invention on nausea and emesis in three specific areas. First, the Abstract of the invention discloses that the invention "provides a lower incidence of nausea and vomiting than conventional tablets." (emphasis added). The Background of the Invention discusses nausea and emesis in the context of the immediate release tablets using a numerical focus. Specifically, the Background of the Invention explains that "[w]ith the plural daily dosing regimen, the most common side effect is nausea, experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride. Vomiting also occurs in about seventeen percent of the patients." Ex. 1, col. 1, l. 63 - col. 2, l. 11 (emphasis added). The Brief Description of the Invention contrasts the clinical advantages of the invention with the disadvantages of multiple daily dosing and discusses nausea and emesis in more general terms, as follows:

The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation

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of venlafaxine hydrochloride once a day in a therapeutically effective amount.

Ex. 1, col. 2, ll. 45-62 (emphasis added).

Reviewing the specification as a whole and in context, the Court concludes that the inventors did not intend to limit the term "diminished incidences of nausea and vomiting" to a numerical or percentage based definition. Interestingly, that portion of the specification that refers to specific percentages does not even use the term "incidences," which suggests to the Court that the inventors did not necessarily intend to equate the term "incidences" with percentages or numbers. Further, instructive to the Court is the specification's reference to nausea, which embraces terminology pertaining to both degree and/or frequency. For example, the Abstract discusses the "lower incidence of nausea and vomiting" while the Brief Description of the Invention refers to "reducing the level of nausea and incidence of emesis." The interchangeable use of the terms "level" and "incidence" in the specification with respect to nausea, along with the inventors' failure to specifically equate the term "incidences" with either percentages or numbers in the specification, leads the Court to believe that Wyeth's broader definition of the term "diminished incidences of nausea and emesis" is correct. Indeed, the Court agrees with Wyeth that if the inventors intended to maintain a strictly numerical focus with respect to the "diminished incidences of nausea and emesis" the claim language would have used a term more commonly connected to numerical values such as "fewer incidences of nausea and emesis" or would have alternatively linked the claim language more specifically to a decreased percentage or number of patients suffering from nausea and emesis. Instead, the inventors used the term "diminished incidences." Unlike the term "fewer," the term "diminished" is not limited to a numerical focus. Instead, the term "diminished" suggests the broader concept of a reduction in size, number and degree. Accordingly, the Court concludes that Wyeth's proposed construction of the term diminished is consistent with the choice of wording in the claim, as well as with the descriptions provided for in the specification, and therefore, the Court construes the phrase "diminished "incidences of nausea and emesis" to mean "the degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."
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In this case, the first issue is whether the district court erred in construing "discoloration" to mean "oxidative discoloration" instead of just "change in color." We do not think that it did. As the court noted in its summary judgment ruling, the only type of discoloration referred to in the '450 patent is oxidative discoloration. Summary Judgment, 289 F. Supp. 2d at 524. The Background section of the patent, for example, lists cyclization, hydrolysis, and "oxidation to form products having often unwanted coloration," as the three types of degradation exhibited by ACE inhibitors. '450 patent, col. 1, ll. 9-12. The specification then goes on to disclose one embodiment that withstands "oxidative, hydrolytic, and cyclization degradation." Id. col. 1, ll. 20-22; see also id. col. 1, ll. 29-35 (touting one advantage of the invention as being "no detectable oxidative discoloration"). Additionally, the parties previously stipulated that "discoloration" referred to oxidative discoloration. Warner-Lambert Co. v. Teva Pharm. USA, Inc., No. 99-922 (D.N.J. May 7, 2002) ("Stipulation and Order") ("The phrase 'a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration' in Claim 1 of the '450 patent means 'an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor is sufficient to treat hypertension or congestive heart failure.'" (emphasis added)). Therefore, we conclude that embodiments of claims 1, 4-10, and 12, must include an ACE inhibitor that is susceptible to oxidative discoloration, and must also include an alkali or alkaline earth metal carbonate (or bicarbonate) 14 that inhibits oxidative discoloration.

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14 Our prior decision in Schwarz Pharma, Inc. v. Warner-Lambert Co., 95 Fed. Appx. 994, 997-99 (Fed. Cir. 2004), construed "alkali or alkaline earth metal carbonates," as used in the claims of the '450 patent, to include both carbonate and bicarbonate ions.

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4. discrete known regions are construed to mean identified localized areas on a surface which are, were, or are intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface.

Affymetrix originally argued that "discrete known regions" are physically distinguishable and known regions. However, during its rebuttal argument, Affymetrix embraced the definition, provided in the specification, that "region" is a localized area on a surface which is, was, or is intended to be activated for formation of a polymer. (Markman hearing transcript at 374:22-23). Affymetrix then asserted that "formation" is not limited to synthesis of the polymer on the surface. Affymetrix argued that formation encompasses both synthesis on the surface and immobilization of preexisting polymers on a surface.

Incyte contends that a "discrete known region" is a localized area on a surface which is, was, or is intended to be activated for synthesis of a polymer, and which is also spatially addressable for activation of monomer by monomer synthesis.

Both parties accept the definition of "regions" that the patentee explicitly offers in the specification. In defining "predefined region," the '934 specification states:

A predefined region is a localized area on a surface which is, was, or is intended to be activated for formation of a polymer. The predefined region may have any convenient shape, e.g., circular, rectangular, elliptical, wedge-shaped, etc. For the sake of brevity herein, "predefined regions" are sometimes referred to simply as "regions."

('934 patent, col. 8:5-10). The remaining dispute thus concerns the meaning of "activated for formation of a polymer" within this definition.

After accepting the '934 patent's definition of "regions" and acknowledging that the parties' real dispute now is as to the meaning of the definition (Markman hearing transcript at 375:9-18), Affymetrix did not present any definition of "activated." Affymetrix noted simply that the disclosed embodiment which uses caged binding members ('934 patent at col. 30:6-col. 31:3), is a "clear example" of activation. (Markman hearing transcript at 376:12-18).

The '934 patent likewise does not provide an explicit definition of "activated." However, it does describe "radiation, electric fields, electric currents" as examples of "activators" which expose a functional group which has been provided with a protective group. ('934 patent at col. 8:65-col. 9:2). Based on this description in the specification, the Court interprets "activated" to mean exposed to an energy source adapted to render a group active for formation of the polymer. This definition is consistent with Affymetrix's observation that the caged binding member embodiment demonstrates an example of activation. In that case, the caged binding members (which are not active) are attached to the surface of a solid support. (Id. at col. 30:35-39). "Upon application of a suitable energy source, the caging groups labilize, thereby presenting the activated binding member." (Id. at col. 30:43-46). Neither party has provided any evidence to contradict this meaning of "activated."

The Court now turns to the meaning of "formation of a polymer." The plain and ordinary meaning of this term would appear to define formation as equivalent to synthesis of a polymer, in contrast to attachment of a preformed polymer onto the surface. However, Affymetrix argues persuasively that, if "predefined region" is limited to the localized area on a surface which is, was, or is intended to be activated for synthesis of a polymer only, the caged binding member embodiment and the discussion thereof is made nonsensical. The '934 patent states:

According to this alternative embodiment, the invention provides methods for forming predefined regions on a surface of a solid support, wherein the predefined regions are capable of immobilizing receptors. The methods make use of caged binding members attached to the surface to enable selective activation of the predefined regions. . . . The activated binding members are then used to immobilize specific molecules such as receptors on the predefined region of the surface.

(col.30:14-26). The specification therefore uses the term "predefined regions" to encompass a localized area on a surface which is, was, or is intended to be activated for attachment of a preformed polymer to the surface. In the caged binding

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member example, the polymer is a polypeptide receptor. In light of this disclosure, the Court finds that the specification uses "formation of a polymer" to mean both synthesis and immobilization of preformed polymers. However, the inquiry does not end with the specification. The Court must consider the prosecution history to determine whether the patentee relinquished any part of this definition to obtain allowance of the patent.

Incyte points to one statement in the prosecution history of the '934 patent to argue that "formation of polymer" should be limited to synthesis of the polymer on the surface, monomer by monomer, to the exclusion of attachment of a preformed polymer. In response to a rejection for obviousness based on prior art, Affymetrix stated:

Lowe et al. teaches directly away from the invention claimed herein. As recited herein, the present invention provides for the fabrication of many sites wherein different oligonucleotides are formed. Lowe et al. suggests the formation of a biochemical MOSFET, a commonplace device in the semiconductor industry. However, when those of skill in the art fabricate semiconductor devices such as those of Lowe et al., thousands or millions of the same thing are fabricated on a single substrate. Diversity is abhorred. Hence, the teachings of Lowe et al. would lead one directly away from combination with the admittedly non-enabling teachings of Southern et al.

(Livornese Decl., Exh. 57 (10/26/94 Amendment/Response) at 10). The Court does not agree that this statement limits the meaning of "formation of a polymer" or "predefined regions" in the manner Incyte suggests. The Amendment/Response characterizes the '934 invention as providing for "fabrication of many sites wherein different oligonucleotides are formed," but does not specify that formation is limited to synthesis of the oligonucleotide on the surface. Instead, the emphasis is on formation of different oligonucleotides by way of the invention. As explained in the specification, "formation" by immobilization of polymers also allows creation of many sites wherein different polymers are formed. ('934 patent, col. 30:26-34). Therefore, Affymetrix's characterization of the invention does not exclude formation of different polymers by immobilization.

Furthermore, the Court concludes that the '305 prosecution history does not limit "formation of a polymer" to synthesis, to the exclusion of immobilization of polymers. 7 Incyte cites an Amendment/Response during the prosecution of the '305 patent, in which Affymetrix stated:

Applicants respectfully point out that it is not the density of individual polymer sequences within a particular predefined region that is recited within the claim, but the density of "different polymer sequences" on the surface of the substrate, i.e. the number of different polymers that one can synthesize in a given area.

(Livornese Decl., Exh. 24 (9/23/96 Amendment/Response) at 6). The Court does not agree that this statement disclaims a definition of "predefined region" that encompasses a localized area on a surface which is, was, or is intended to be activated for immobilization of a polymer. Although Affymetrix mentions synthesis of polymers in this Response, it does so in the context of emphasizing the density of "different polymer sequences" on the surface, as distinguished from the density of individual polymer sequences. The question of immobilized polymer sequences is not at all at issue in this exchange with the PTO, and the Court declines to use this excerpt as a basis for narrowing the meaning of "formation of a polymer" which is clearly discernable from the specification, as discussed above.

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7 Because the Court finds that the statements in the '305 prosecution history do not limit the meaning of "discrete known regions," the Court need not reach the question of whether statements made during prosecution of the '305 patent, which was filed after the issuance of the '934 patent, serve to limit the terms in the '934 patent.

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Lastly, for the reasons previously discussed, the Court rejects Incyte's argument that the construction of "discrete known regions" should be limited to only those embodiments which Incyte asserts are enabled by the specification.

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1. Claim Construction

The court construes the words of a claim according to "their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). A claim term's "ordinary and customary meaning" "is the meaning that the term would have to a person of ordinary skill in the art in the question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. Where "the meaning of a claim term as understood by persons of skill in the art is . . . not immediately apparent," the court turns to publicly-available sources to ascertain the meaning, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. at 1314 (quotation marks omitted).

Upon application of these principles, the court concludes that the limitation "wherein said mixture of excipients comprises a disintegrating agent and swelling agent" means a combination or blend of non-effervescent inert substances or vehicles which includes at least one substance that causes disintegration and at least one substance that, when contacted with liquid, absorbs the liquid and expands in volume.

The above construction is consistent with the language of the claim, the specification and the prosecution history. Claim 1 provides that the "mixture of excipients comprises a disintegrating agent and swelling agent which are responsible for the disintegration of the tablet . . . ." The use of the plural "are" refers to multiple agents, as opposed to the singular mixture of excipients, signifying that there must be at least one disintegrating agent and at least one swelling agent which are responsible for the disintegration of the ODT. 14 The specification likewise refers to both a disintegrating agent and a swelling agent: "The disintegration rate is obtained due to a mixture of excipients or vehicles which comprises generally a disintegrating agent . . . and a swelling agent . . . ." (PTX 1 at col. 1:13-16) (emphasis added); "the mixture of excipients comprises one or several disintegrating agents . . ., one or several swelling agents . . ., and possibly a direct compression sugar . . . ." (Id. at col 1:47-55) (emphasis added).

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14 The use of the word "comprises" means that, while the mixture of excipients must include at least one disintegrating agent and at least one swelling agent, it may permissibly include other types of excipients, as well as more than one disintegrating agent and more than one swelling agent. See Cias, Inc. v. Alliance Gaming Corp., 504 F.3d 1356, 1360-61 (Fed. Cir. 2007).

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Finally, the prosecution history of the '632 patent is consistent with the requirement that there be both a disintegrating agent and a swelling agent. The original application required neither a disintegrating agent nor a swelling agent in claim 1; this limitation was initially contained only in the dependent claims of the application, which required either a disintegrating agent or a swelling agent. (D.I. 115, ex. 2 at TVLODT072683) An examiner's rejection prompted an amendment to claim 1, which read upon allowance:

A rapidly disintegratable tablet . . . wherein said tablet comprises an active substance and a mixture of non-effervescent excipients . . . and wherein said mixture of excipients . . . are selected from the group consisting [of] at least one disintegrating agent and at least one swelling agent.

(PTX 1 at col. 7:51-62) (emphasis added) During reexamination, the patentee cancelled the Markush group and further limited claim 1 to require both a disintegrating agent and a swelling agent. (PTX 1, Reexamination Certificate at col. 1:23 - col 2:17)

With respect to the proper construction of the disintegrating agent and the swelling agent, it is noteworthy that the most explicit evidence within the four corners of the specification as to the characteristics of these agents consists of a single passage which provides that, in a preferred embodiment, "the mixture of excipients comprises one or several disintegrating agents of the carboxymethylcellulose type or insoluble reticulated PVP type, one or several swelling agents which may consist of a carboxymethylcellulose, a starch, a modified starch, for instance a carboxymethylated starch, or a

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microcrystalline cellulose . . . ." (PTX 1 at col 1:47-50) The examples given of swelling agents are consistent with the ordinary meaning of such, that is, a substance which, when contacted with liquid, absorbs the liquid and expands in volume. The parties do not dispute this construction.

The parties do take issue as to whether a disintegrating agent, as contemplated by claim 1, must "cause" disintegration or merely "facilitate" disintegration. The extrinsic references identified by the parties define "disintegrating agent" as a substance that both "facilitates" and "causes" the breakup or disintegration of a tablet. (D.I. 115, ex. 5 at 1606; PTX 61 at 218) Looking to the specification, the examples identified as disintegrating agents are known in the art as "super-disintegrants," i.e., excipients whose disintegrating characteristics bear a strong causal relationship to the breakup of a tablet. (D.I. 115, ex. 16 at 109-10) Super-disintegrants are classified as such due to the comparatively low amount of excipient required to achieve the disintegration of a formulation. 15 (PTX 56)

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15 Super disintegrants can cause effective disintegration at concentrations of 2-4 wt%. (PTX 56)

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Like the specification, the prosecution history 16 is more consistent with a construction requiring an agent that "causes" disintegration. During prosecution, the examiner rejected the claims of the application leading to the '632 patent ("the application") as unpatentable over U.S. Patent No. 5,073,374 granted to McCarty ("McCarty"). (D.I. 115 at TVLODT072765) McCarty teaches a quickly dissolving tablet comprising a soluble API, a lubricant and "a soluble, directly compressible tablet excipient." (PTX 85 at col. 2:8-12) The soluble excipient disclosed in McCarty "is typically a sugar, such as sucrose or lactose." (Id. at col 2:14-15) Although claim 1 of McCarty describes a buccal tablet where ". . . disintegration occurs from 0.5 to 5 minutes after administration" (emphasis added), in traversing the rejection, the patentee nevertheless alleged that McCarty "clear[ly] . . . does not teach disintegrating agents." (D.I. 115 at TVLODT072765)

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16 The Federal Circuit endorses use of the prosecution history to assist the person of ordinary skill in the art to assess the scope of an issued patent. See Hockerson-Halberstadt, Inc. v. Avia Group Int'l, 222 F.3d 951, 957 (Fed. Cir. 2000) (noting that "[t]he prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention."). The Federal Circuit has further explained that this "use of the prosecution history ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." See Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005).

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In light of the descriptions of "disintegrating agent" given in the specification and the prosecution history, the court concludes that a causal relationship must exist between the disintegrating agent and the act of disintegration. Put another way, excipients that facilitate disintegration, but are not known in the art to cause disintegration as "disintegrating agents," will not fall within this limitation.

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World Health alleges that Chelation is infringing patent number 5,602,180 (the "'180 patent"), which is held by World Health. The '180 patent claims: "A suppository for chelation therapy, said suppository comprising an inert meltable carrier containing dissolved or suspended disodium EDTA and a controlled-release matrix for releasing the complexes into the body over a period of three to four hours after anal administration of the suppository." (United States Patent Number 5,602,180, Feb. 11, 1997, attached as Ex. A to Memo. in Supp. of Defs.' Mot. for Part. Summ. J. & in Opp'n to Plf.'s Mot. for Prelim. Injunc. (dkt. # 32-1)[hereinafter Memo. in Opp'n]).

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the

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right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks and quotation omitted). Words used in a patent claim "are generally given their ordinary and customary meaning." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The Federal Circuit has frequently stressed that claim construction should not occur in a vacuum and that courts should consider the language of the claims in light of the patent's specification and prosecution history. See Phillips, 415 F.3d at 1317. Indeed, in Phillips, the Federal Circuit highlighted the value of examining a patent's prosecution history when interpreting the patent's claims:

The prosecution history, which we have designated as part of the 'intrinsic evidence,' consists of the complete record of the proceedings before the [Patent and Trademark Office] . . . . [T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

Id.

In this case, the claim language, when viewed in light of the patent's prosecution history, indicates that World Health is unlikely to successfully argue that Chelation's Kelatox product infringes the '180 patent. World Health alleges that Kelatox is identical to World Health's Detoxamin product. Further, and more importantly, World Health asserts that the '180 patent covers the Detoxamin formula and, by extension the Kelatox formula as well. The evidence does indicate that the two products are virtually identical. Both are anal suppositories designed to provide chelation therapy. Both utilize an inert carrier that contains calcium disodium ethylene diamine tetraacetic acid. Both use a controlled-release matrix. And, although Chelation claims that Kelatox is distributed through the body at a slightly quicker rate than Detoxamin, the treatment times associated with the products are similar.

While World Health may be correct that Kelatox is virtually indistinguishable from Detoxamin, its claim of patent infringement is not likely to succeed because the products sold by both World Health and Chelation differ from the suppository claimed in the '180 patent. Specifically, both the Detoxamin and Kelatox suppositories deliver calcium disodium EDTA, while the '180 patent claims only delivery of disodium EDTA. While this distinction can be seen on the face of the patent itself, the prosecution history shows that the distinction between calcium disodium EDTA and disodium EDTA was recognized by the inventor of the '180 patent and that the inventor expressly disclaimed the use of calcium disodium EDTA in pursuing the patent.

For example, after the patent application was initially rejected, the applicant responded with an amendment to the application, hoping to allay the concerns that prompted the initial rejection. The applicant took great pains to stress that the presence of calcium in the EDTA preparation would severely hamper the purpose of the suppository, rendering it ineffective for its intended purpose. For example, the applicant stated that "[i]n the lower bowel, the disodium 10 EDTA would be a highly effective chelating agent for a suppository, whereas Calcium EDTA would not be." (Amendment 2, attached as Ex. C. to Memo. in Opp'n.) The applicant also stated that "[t]he use of Calcium EDTA, as in the Rosenberg patent, would be completely ineffective in an anal suppository." (Id. at 3.) Most tellingly, the applicant stressed the ineffectiveness of calcium disodium EDTA considering the purpose the suppository was designed to serve. "The disease target of the present invention is atherosclerosis. The disease . . . is a chronic metabolic disorder in which calcium ion plays a role in the formation of arterial plaque . . . . EDTA administration relieves the disorder by removing calcium from the blood stream." (Id. at 3-4.) The parties' filings with the court indicate that calcium disodium EDTA would not effectively remove calcium from the blood stream because calcium is already present in the compound, which would prevent the compound from attaching itself to additional calcium found in the bloodstream.

In short, the plain language of the patent, combined with the prosecution history, support the conclusion that the claims of the '180 patent are expressly limited to disodium EDTA and that the use of calcium disodium EDTA is not covered. Accordingly, it is not likely that World Health can exclude Chelation's production of Kelatox by relying on the '180 patent.
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(L) Disperse

Distribute throughout the composition.

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4. "an organic dispersing agent"

This disputed term appears in Claims 1 and 22 of the '529 patent and in claims 1 and 26 of the '660 patent. The parties dispute the meaning of this term for the same basic reasons in each patent. According to Plaintiff, this term should be construed to mean "any agent that assists or promotes the dispersion of solid particles in oil." Chart at 3, 19. In support of its position, Plaintiff points to the specifications of the patent and notes that the specifications do not limit the organic dispersing agents to any particular compound or class of compounds. Indeed, the specifications support a broad construction of the term, stating that "[m]any types of organic dispersing agents have been developed and are available for use in promoting the dispersion of particles in oily media." '660 patent, col. 3, lines 45-48; '529 patent, col. 4, lines 34-37. Furthermore, the specification describes"organic dispersing agent" in functional terms as "promot[ing] the dispersion of the particulate zinc oxide [or titanium dioxide] in the chosen oil." '660 patent, col. 3, lines 44-45; '529 patent, col. 4, lines 33-34.

Defendant, on the other hand, argues for an alternate construction. According to Kobo, when properly construed, the term "organic dispersing agent" means

an organic surface active reagent which, when added to a mixture of a particular grade and size of zinc oxide [or titanium dioxide] in a dispersion mill, and a particular oil in said dispersion mill with said particular zinc oxide [or titanium dioxide] has the effect of significantly increasing the amount of zinc oxide [or titanium dioxide] in the dispersion and causes particles to disperse. This is done by promoting the dispersion of the zinc oxide [or titanium dioxide] in the oil. "Organic dispersing agent for said particles" does not broadly include all materials which could be milled with particles in the desired media, whether, for example, exerting mechanical, molecular, or other forces on the particles to be dispersed or stabilizing a dispersion or affecting its viscosity.

It does not include any emulsifier, or surfactant which may be active [as a dispersing agent, as defined above, but only] 6 in another system.

Chart at 3-4, 19-20. In its briefing, Kobo argues that the phrase, because it contains the word "organic," should be limited to materials having a carbon-carbon bond and which in a particular system have an appreciable effect as dispersing agents when added to other ingredients. See Abrutyn Affidavit, PP 40, 41. It appears, therefore, that an essential dispute between the two parties' constructions is whether the term encompasses silicone-based fluids. Kobo has provided an affidavit from its expert stating that the term "organic" in the late 1980's and early 1990's "was generally limited to carbon based molecules." Abrutyn Affidavit P 40. However, Plaintiff points to several texts, both pre- and post the referenced time period, which show that silicone-based materials could be considered "organic" compounds. See Calve Cert. Ex. 43, 44 and 45. Indeed, Plaintiff notes that Kobo's own patent application with respect to "Organosilicon Treated Cosmetic Powders" discloses examples of such compounds. The Court, therefore, finds that because a broader construction is more consistent with the intrinsic evidence, the proper construction of the disputed term does not exclude silicone-based fluids.

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6 The bracketed language appears only in Kobo's proposed construction of the term in the '660 patent, but not the '529 patent.

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Accordingly, the Court shall construe the term "an organic dispersing agent" to mean "any agent that assists or promotes the dispersion of solid particles in oil."

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Claims 10, 11,14, and 15 describe the Form A preparation process as involving "displacing" of the solvent, '759 Patent, col. 18, ll. 13, 30, 39, & 41, Claims 10 and 11 provide that the process uses a "displacing agent," id. col. 18, ll. 13, 31, and Claims 10 and 11 describe the process as "displacing the solvent with a displacing agent," id. col. 18, ll. 13, 30-31. Apotex urges the Court to construe "displacing agent" and "displacing," while GSK proposes a construction for "displacing the solvent with a displacing agent." (GSK Opening Br. 17-21; Apotex Opening Br. 20-31.)

1. The Parties' Contentions

According to GSK, Claim 10 involves a two-step procedure--"first, crystallizing paroxetine hydrochloride that has solvent not removable by drying; and second, displacing the solvent with a displacing agent"--and the disputed claim terms relate to the second step. (GSK Opening 18.) GSK contends that the specification repeatedly describes the displacing process as "contacting" the paroxetine hydrochloride with the displacing agent, and teaches that the crystallization product has been conventionally dried before such contact takes place, and that after the contact, the use of additional drying displacesthe solvent. (GSK Opening 18.) GSK argues that the specification thereby shows that the displacing agent alone does not remove the solvent, but that removal is accomplished through a combination of contact and drying. (GSK Resp. 33-35.) GSK continues that Apotex ignores this and reads out of the specification the conventional drying aspects, by proposing a construction whereby the displacing agent actively "removes" the bound solvent. (GSK Resp. 35.)

GSK also takes issue with Apotex's construction that "displacing agent" is limited to water, supercritical carbon dioxide, and hydrochloric acid. (GSK Opening 18-19; GSK Resp. 33-35.) GSK avers that the specification expressly leaves open the possibility that other displacing agents may be selected by way of routine experimentation, that the intrinsic evidence did not suggest that the applicants only contemplated the three listed displacing agents, and that it is contrary to Federal Circuit precedent to limit the specification to the listed embodiments. (GSK Opening 19.) To the extent that Apotex's construction suggests that organic solvents cannot be displacing agents, GSK contends that "the specification contains no teaching" to thiseffect. (GSK Opening 19 (emphasis removed).)

Apotex responds that the intrinsic evidence demonstrates that drying cannot be a part of the "displacing" step, because the applicants represented that conventional drying alone did not remove the solvent bound inside the crystal, but that "the 'displacing agent' is the actor solely responsible for 'displacing' the bound solvent." (Apotex Resp. 14.) Apotex therefore contends that "removes" rather than "contacts" is the proper verb to use in construing "displacing" for purposes of the '759 Patent. (Apotex Resp. 14-15.)

Apotex also contends that it is necessary to limit the construction of "displacing agent" to the three listed in the specification, because there is no ordinary meaning of the claim term, and the three listed agents have no common properties that would permit the discovery of additional displacing agents through routine experimentation. (Apotex Resp. 6-8.) Apotex continues that notwithstanding the specification's language indicating that other displacing agents might exist, the specification also indicates that using a different "displacing agent" could lead to an undesired result, and that in prosecuting the patent, the inventorsindicated that they did not contemplate additional displacing agents. (Apotex Opening 20-23.) Apotex further avers that as an English Court of Appeals found under a counterpart to the '759 Patent, an "organic solvent not removable by drying" is not a "displacing agent," and thus, the organic solvent acetone cannot itself be a displacing agent. (Apotex Opening 24-28.) Apotex then contends that adopting GSK's broad construction would run afoul of Section 112's specificity and enablement provisions by not explaining to those skilled in the art how to identify additional displacing agents. (Apotex Opening 28-31.) Apotex concludes that its proposed constructions are supported by the record and thus should be adopted.

2. Analysis

The parties' proposed constructions present two primary disputes: (1) whether "displacing agent" should be limited to the three listed in the patent; and (2) whether the displacing agent actively removes the organic solvent from the paroxetine hydrochloride or merely facilities this removal.

For the first question, the parties do not dispute, and the Court finds, that there are only three "displacing agents" identified in the patent specification: water, see '759 Patent,col. 5, ll. 21-22, 25-34; id. col. 9, l. 35 (Example 4), supercritical carbon dioxide, see id. col. 5, ll. 21-22, 48-54, and hydrochloric acid, see id. col. 9, l. 33 (Example 4); id. col. 10, l. 4 (Example 5).

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The specification, however, also expressly states, "It is possible to use other displacing agents which may be selected by means of routine experimentation." Id. col. 5, ll. 22-24. The Phillips court made clear that the construction of a claim term should not be restricted to the patent's preferred embodiments, thereby reading in unnecessary and unintended limitations. 415 F.3d at 1323. Here, the Court does not view the prosecution history as showing that the inventors conceded that they could not conceive of additional "displacing agents."

Apotex points to several declarations filed with the Patent and Trademark Office (PTO) that purportedly demonstrate that the inventors do not conceive of other possible "displacing agents" for purposes of the '759 Patent. In particular, Dr. Victor Jacewicz, one of the inventors, stated that he could not reproduce prior art methods for making paroxetine hydrochloride anhydrate and that using water, "[u]nexpectedly," he "found a procedure by whichit was possible to displace . . . as described in the present application despite the fact that vigorous vacuum drying was ineffective." (Apotex Opening Ex. 19, at 4.) Jacewicz's boss, Dr. Wellman, then remarked that "the fact that this solvent could be displaced by water, without causing conversion to . . . hemi-hydrate was particularly unexpected," and that he was "very surprised" that tightly bound propan-2-ol could be removed "using an agent such as water or supercritical carbon dioxide." (Apotex Opening Ex. 20, at P 7.) Professor Joel Bernstein, a crystallography and polymorphism expert, expressed similar "surprise," and further stated, "I cannot think of another way over and above what is described in the present application, which could reasonably expect to be successful, of preparing paroxetine hydrochloride anhydrate substantially free of bound solvent." (Apotex Opening Ex. 21, at P 9.) Apotex essentially asks this Court to find that GSK disclaimed coverage of "displacing agents" not listed in the specification.

"The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specificmeanings disclaimed during prosecution." Omega Eng'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003). "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Id. at 1325. The Federal Circuit, however, requires statements to be "both so clear as to show reasonable and deliberateness" and "so unmistakable as to be unambiguous evidence of disclaimer" before applying the doctrine. Id. at 1325; see also id. at 1324-25 (describing and comparing cases involving an ambiguous claim disavowal with those involving a clear disavowal). Such a requirement aims "[t]o balance the importance of public notice with the right of patentees to seek broad patent coverage." Id. at 1325.

Jacewicz, Wellman, and Bernstein's comments fall short of constituting unequivocal disavowal: The statements only indicate that the invention was novel and surprising given prior art methods for making paroxetine hydrochloride anhydrate. While Bernstein's comments come the closest to suggesting that he does not contemplate other "displacing agents,"he never expressly states this, remarking only that he cannot think of "another way over and above what is described in the present application" (Apotex Opening Ex. 21, at P 9), an application that expressly left open the possibility that other "displacing agents" could be discovered through routine experimentation. Dr. Bernstein never stated that routine experimentation could not lead to the discovery of additional "displacing agents." '759 Patent, col. 5, ll. 22-24. Prosecution disclaimer, therefore, does not apply, and the Court will not limit the definition of "displacing agent" to those identified in the patent specification. 5

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5 The Court declines to come to a contrary result based on foreign court decisions regarding foreign counterparts to American patents, because the Federal Circuit has cautioned against doing so, and because the intrinsic record supports GSK's construction. See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072 n.2 (Fed Cir. 1994) ("We take notice of the fact that the theories and laws of patentability vary from country to country, as do examination practices. Caution is required when applying the action of a foreign patentexaminer to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved.")

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Turning next to the question of the role displacing agents play in removing organic solvent, the patent specification repeatedly uses the word "contact" to describe the interaction the displacing agents have with the paroxetine hydrochloride during displacement. 6 The patent specification then teaches that after such "contact," drying takes place to remove the

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organic solvent. 7 At oral argument, Apotex, with the help of a computer animation video purportedly illustrating the displacement process, asserted that the displacing agent removes organic solvent from the paroxetine hydrochloride's crystal structure, and that subsequent drying then removed that solvent from the overall structure.

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6 See '759 Patent, col. 5, ll. 26-27 ("It is important that the paroxetine hydrochloride solvate is contacted with enough water . . . .") (emphasis added); id. col. 5, ll. 30-33 ("The amount of water, the form of the water, . . . and the length of time which the paroxetine hydrochloride solvate is contacted with the water differsfrom solvate to solvate.") (emphasis added); id. col. 5, ll. 44-46 ("After contact with water to displace the bound solvent, the product is suitably dried." (emphasis added).

7 See '759 Patent, col. 5, ll. 44-46 ("After contact with water to displace the bound solvent the product is suitably dried, for example, in vacuo at elevated temperature."). Several Examples in the specification involved drying following contact with the displacing agent. See id. col. 8, ll. 4-8 (Example 1); id. col. 9, ll. 31-35 (Example 4); id. col. 10, ll. 3-7 (Example 5); id. col. 10, ll. 36-40 (Example 5); id. col. 12, ll. 23-25 (Example 9); id. col. 12, ll. 59-62 (Example 10); id. col. 13, ll. 27-29 (Example 11); id. col. 14, ll. 14-16 (Example 13); id. col. 15, ll. 9-11 (Example 15).

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The Court declines to determine at this stage whether Apotex and its intrinsic evidence correctly characterize the exact removal process, or whether "contacting" and "drying" are two separate steps, as GSK contends (GSK Resp. 34-40), because the intrinsic record does not support Apotex's construction. The Court has not found language in the patent or subsequent prosecution history indicating that the displacing agents activelyremove organic solvent from the paroxetine hydrochloride's crystal structure, nor has Apotex identified any such language. Instead, as already detailed, the intrinsic evidence shows that the displacing agent's contact with the paroxetine hydrochloride is followed by drying, which results in removal of organic solvent. The Court declines to add "precision or specificity" to the claim terms respecting the displacing process that the patent itself lacks. PPG Indus., 156 F.3d at 1355. The Court notes that its construction of displacing as permitting the removal of bound organic solvent does not preclude Apotex from presenting evidence on how active of a role the displacing agent plays in removing organic solvent at trial.

Consistent with the determinations described above, the Court will construe "displacing" to be "contacting to permit reduction of," "displaced" to be "contacted to permit reduction of," and "displacing agent" to be "agent permitting reduction of solvent to obtain paroxetine hydrochloride anhydrate that cannot be obtained by drying alone," and "displacing the solvent with a displacing agent" to be "contacting the paroxetine hydrochloride with a displacing agent to permitreduction of the solvent to obtain paroxetine hydrochloride anhydrate that cannot be obtained by drying alone."
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4. The Term "Disposed on" Does Not Require a Separate Processing Step

Andrx argues that the phrase "disposed on" requires that the subcoating be "physically applied to" the core, as opposed to forming spontaneously. Andrx's definition attempts to import process limitations into a product claim. It is improper to limit product claims to a particular process. Vanguard Prods. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372-73 (Fed. Cir. 2000) (holding scope of claim for electromagnetic shielding gasket not limited to method of manufacture set forth in specification). A novel product that meets the criteria for patentability is not limited by the process by which it is made, Vanguard Prods., 234 F.3d at 1372-73, and the specification need not describe every possible way of making the product, SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121-22 (Fed. Cir. 1985). Andrx's claim construction position ignores this basic principle and attempts to narrow the product claims of the '505 and '230 patents to cover only those formulations made by applying the subcoating in a particular way. However, the product claims are not limited in the manner in which the product is made and so would include products in which the subcoating was formed in situ. See Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1581 (Fed. Cir. 1984) (upholding the district court's rejection of defendant's argument that because its product is formed in situ it is different from the claimed product) ("It is the claimed product, . . . not the process of forming it, that is involved.").

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The intrinsic evidence is crystal clear. The '505 patent contains 8 asserted product claims and 1 asserted process claim. It is not surprising, therefore, that the specification contains disclosure about the process. Even if the patent contained only product claims, the law would require the patent to enable the making of the invention. See 35 U.S.C. § 112. For this reason, Defendants are wrong when they refer to the different methods disclosed in the specification as evidence that the product claims are limited. 29 The phrase "disposed on" only appears in the product claims, which provide a composition and structure for the claimed formulation. As such, the phrase "disposed on" as used is used in its conventional patent law sense--that is, to refer to the position or location of an element in a structure. See generally Moeller v. Ionetics, Inc., 794 F.2d 653, 655 (Fed. Cir. 1986); Lawler Mfg. Co. v. Bradley Corp., 2000 U.S. Dist. LEXIS 20511, No. IP98-1660, 2000 WL 33281119, at *21 (S.D. Ind. Nov. 30, 2000). Contrary to Andrx's arguments, the court finds that the patentees did not act as their own lexicographers to define this commonly understood phrase with any special meaning. The ordinary meaning of the phrase "disposed on" in the context of these product claims refers to the position of the subcoating relative to the core and, as mentioned above, means that the subcoating is in contact with the core region. The court finds that the term "disposed on" does not require that the subcoating be applied using any particular process and that the subcoating need not necessarily be "physically applied to" the core in a separate processing step. 30

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29 None of the portions of the '230 file history that Andrx relies on in support of this argument actually addresses a process step.

30 Astra's construction is further supported by the '281 patent prosecution history. In particular, the examiner of the '281 patent interpreted the product claims of the '230 patent to cover products where the subcoating forms in situ, without a separating subcoating step, and rejected the then-pending product claims over the '230 patent. (P9A at 2, '281 File History Office Action of 11/5/98.) The patent examiner recognized that the product claims in the '230 patent covered the formulation regardless of the process used to manufacture the product. (Id.) In response, Astra canceled the product claims and the '281 patent eventually issued with process claims, but not product claims. (P9A, '281 File History, Amendment under 37 C.F.R. § 1.115, at 7.)

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The district court correctly construed "disposed on" because nothing in the context or meaning of the term provides limitations beyond a reference to the layer's location. "Disposed on" does not specify any method or structure involved in application of the subcoating.
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A. Supplemental Claim Construction

Ivax and Depomed dispute the meaning of the term "dissolution and diffusion." The parties did not ask the Court to construe this term in the Claim Construction Order. But Ivax now moves for supplemental claim construction of the term and both parties agree that the Court should clarify its meaning. The term is found in claim 1 of the '475 patent and claim 1 of the '280 patent and refers to the release mechanism of the drug from the matrix. Claim 1 of the '475 patent is reproduced here for reference:

Claim 1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20, said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode, that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said

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gastric fluid, that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug within about eight hours after such immersion, and that remains substantially intact until all of said drug is released.

(Emphasis supplied). The term "dissolution and diffusion" appears in an identical context in claim 1 of the '280 patent.

Ivax argues that "dissolution and diffusion" should be construed according to its plain language to mean "dissolution of the drug in the matrix by the gastric fluid and diffusion of the drug out of the matrix." Ivax contends that the plain meaning of "dissolution and diffusion" does not connote a rate-controlling step. Dissolution-controlled release, diffusion-controlled release and swelling-controlled release may all involve the acts of dissolution of the drug from the matrix and diffusion of the drug out of the matrix. Therefore, Ivax urges that the claim encompasses all three of these release mechanisms. 4

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4 Ivax does not argue that "dissolution and diffusion" should be construed to include erosion-controlled release mechanisms. The claims explicitly state that the dosage form remains substantially intact (i.e., does not substantially erode) until the drug is released.

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Depomed counters that the term is limited to diffusion-controlled release mechanisms. It argues that "diffusion and dissolution" should be construed within the broader context of the claim, "by the dissolution and diffusion of said drug out of said matrix by said gastric fluid," to mean "rapid dissolution of the drug by the gastric fluid, followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate primarily controlled by the rate of diffusion." Depomed asserts that one skilled in the art would read the term to require diffusion-controlled release because the claim recites high solubility drugs. These drugs rapidly dissolve in solution so that a dissolution-controlled system would not exhibit the claimed controlled-release profile. Depomed finds further support for its construction in the patent specification. The "Summary of the Invention" section states that the dosage form "releases the drug primarily by diffusion," '475 patent at col. 5, 11. 60-62, that "[t]he rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix," id. at col. 6, 11. 14-16, and that "[f]or highly soluble drugs, the swelling of the polymeric matrix . . . retards the rate of diffusion of the highly soluble drug long enough to provide multi-hour, controlled delivery of the drug into the stomach," id. at col. 6, 11. 18-23.

The Federal Circuit recently cautioned against "plac[ing] too much emphasis on the ordinary meaning of [a term] without adequate grounding of that term within the context of the specification of the [] patent." Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed. Cir. 2006). In Curtiss-Wright, the Federal Circuit overturned the district court's construction of the term "adjustable" for placing too much emphasis on the ordinary meaning. Id. The court explained that the specification consistently used the term within a given context and it thus limited the term to that context. Id. at 1379. The court further explained that a broader reading of the term "renders that limitation nearly meaningless." Id.

Similarly, in Nystrom v. Trex Company, Inc., 424 F.3d 1136 (Fed. Cir. 2005), the Federal Circuit affirmed construction of the term "board" to mean a board cut from a log even though the claim language did not limit the board's composition to any given material, and the specification did not explicitly disavow other materials. The court noted that "Nystrom consistently used the term 'board' to refer to wood cut by a log. Although there was no clear disavowal of claim scope, there was nothing in the intrinsic record to support the conclusion that a skill artisan would have construed the term 'board' more broadly…." Id. at 1145.

Ivax is correct that the ordinary meaning of "diffusion and dissolution," standing alone, does not specify a rate-limiting release mechanism. However, the claim must be read in light of the specification. See Phillips, 415 F.3d at 1315. The patent specification explicitly states that the "beneficial effects" of the invention are "achieved by using a formulation in which the drug is dispersed in a polymeric matrix that . . . releases the drug primarily by diffusion." '475 patent at col. 5, 11. 60-62. The specification further states that "[t]he rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix." Id. at col 6., 11. 14-16. The specification consistently refers to the dominant release mechanism as controlled-diffusion. See Curtiss-Wright, 438 F.3d at 1379 (limiting a term to a context consistently used throughout the specification); Nystrom, 424 F.3d at 1145 (same).

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In addition, Ivax's reading of the term would "render[] that limitation nearly meaningless." See Curtiss-Wright, 438 F.3d at 1379. Ivax argues that "dissolution and diffusion" encompasses any release mechanism that exhibits dissolution of the drug within the matrix and diffusion of the drug out of the matrix. But any drug release mechanism may exhibit some amount of dissolution and diffusion, however negligible.

Ivax nevertheless maintains that the specification never specifies a rate-limiting release mechanism. First, Ivax points to statements in the specification that discuss dissolution and diffusion without denoting a rate-limiting step. See, e.g., '475 patent at col. 6, 11. 6-10 ("dissolution of the drug in the penetrating fluid and diffusion of the drug back out of the matrix"); id. at col. 9, 11. 7-13 ("[t]he release rate of a drug from the matrix is primarily dependent upon the rate of water imbibition and the rate at which the drug dissolves and diffuses from the swollen polymer…"). However, such statements simply note that the drug is released by dissolution and diffusion. Diffusion-controlled release mechanisms require dissolution. Thus, the statements Ivax quotes in no way contradict other statements in the specification that explicitly define diffusion as the primary release mechanism. See, e.g., id. at col. 5, 11. 60-62.

Second, Ivax contends that, read in the broader context, statements referring to release as primarily diffusion-controlled only serve to contrast "dissolution and diffusion" against erosion-controlled release mechanisms. Ivax first points to the statement that "[t]he rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix rather than erosion, dissolving or chemical decomposition of the matrix." Id. at col 6., ll. 14-18 (emphasis supplied). It argues that this statement only compares the rate of diffusion versus erosion, and not that of diffusion to dissolution. This argument is unpersuasive. Although the statement only mentions diffusion- and erosion-controlled release mechanisms, it does not thereby equate the term "diffusion" with any release mechanism other than erosion, such as "diffusion," "dissolution," or "swelling." The quoted text explicitly states that "controlled diffusion" is rate-limiting.

Similarly, Ivax points to the full context of the statement that "the drug is dispersed in a polymeric matrix that . . . releases the drug primarily by diffusion":

Each of the beneficial effects enumerated above is achieved by using a formulation in which the drug is dispersed in a polymeric matrix that is water-swellable rather than merely hydrophilic, that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion. It has further been found that the rate of diffusion of the drug out of the matrix can be slowed by . . .

'475 patent at col. 5, ll. 57-64. Ivax argues that this passage does not specify diffusion-controlled release but is simply saying that the release of the drug out of the matrix is by dissolution and diffusion and not by erosion. As above, Ivax's argument is unpersuasive. Nothing in the broader context of the statement suggests that the patentee intended "releases the drug primarily by diffusion" to be read as "releases the drug primarily by dissolution and diffusion" without distinguishing the two. Indeed, the following sentence goes on to discuss the rate of diffusion specifically, as shown in the quoted text above.

Finally, Ivax contends that Depomed's construction is inconsistent with the release of insoluble drugs. Ivax notes that both the specification and unasserted method claims specify the release of insoluble drugs by "dissolution and diffusion." Because it is not feasible to release low solubility drugs via diffusion-controlled release, see Hopfenberg Decl. P 31, "dissolution and diffusion" must be construed more broadly. For example, Ivax points to claim 27 of the '475 patent, which describes the release of cyclosporin, a low solubility drug. The claim recites "dissolving of said drug by said gastric fluid and either erosion of said matrix or diffusion of said dissolved drug out of said matrix." '475 patent at col. 19, ll. 36-40. Ivax argues that the diffusion element is impermissibly superfluous if, as Depomed argues, low solubility drugs must be released by erosion-controlled systems. Ivax's arguments do not follow from the claim language or Depomed's expert testimony. Depomed's expert Dr. Hopfenberg claims that erosion, rather than "dissolution and diffusion," would be the dominant release mechanism for low solubility drugs. See Declaration of Dr. Harold B. Hopfenberg in Opposition to Defendants' Motions for Supplemental Claim Construction and for Summary Judgment on the Bases of Invalidity and Inequitable Conduct (Hopfenberg Supp. Claim Const. Decl.) P 31. But he does not state that erosion-controlled mechanisms cannot release at least some amount of the drug by diffusion. Moreover, the claims reciting low solubility drugs specify release by dissolution and either erosion or diffusion. Because "erosion" and "diffusion" are used in the disjunctive, the claim is operable as written for an erosion-controlled release mechanism with little to no diffusion, or vice versa.

In this case, the intrinsic record limits the meaning of "dissolution and diffusion" to a diffusion-controlled dominate release

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mechanism. Ivax's arguments to the contrary "place[] too much emphasis on the ordinary meaning of [the term] without adequate grounding of that term within the context of the specification of the [] patent." Curtiss-Wright, 438 F.3d at 1378. The Court concludes that "by the dissolution and diffusion of said drug out of said matrix by said gastric fluid" means "rapid dissolution of the drug by the gastric fluid, followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate primarily controlled by the rate of diffusion."
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H. "dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate"

Claim 1 of the '881 patent, which is representative of the use of this term in the Stamm patents, is as follows:

A composition comprising micronized fenofibrate, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

('881 patent, col. 10 ll. 44-65 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M [i.e. molar] sodium lauryl sulfate" to mean "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate." (D.I. 270 at 13.) Teva proposes that I find that this phrase "is indefinite and incapable of construction." (D.I. 223 at 38.) n12

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n12 Although this term appears in several claims asserted against Impax, Impax has not disputed Abbott's proposed construction of this term in their briefs on claim construction, and as such, all citations in Part IV.H. are to C.A. 02-1512-KAJ. (See D.I. 169, 205.)

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Teva asserts that this claim term is indefinite because it means that "an unknown amount of 0.025M sodium lauryl sulfate solution is added to an unknown amount of water." (D.I. 223 at 37.) In support, Teva cites to two disclosures in the specification, one where the dissolution medium is defined as consisting "of 1000 ml of water to which 0.025M sodium lauryl sulfate sodium is added..." ('881 patent, col. 2 II. 28-30) and one which describes "a dissolution medium constituted by water with 0.025M sodium lauryl sulfate" ('881 patent, col. 3 II. 56-57). Teva asserts that in each of these disclosures, an unknown amount of 0.025M sodium lauryl sulfate solution is combined with, in the first instance 1000 ml of water, and in the second instance, an unknown amount of water. (D.I. 223 at 28.)

In response, Abbott asserts that a person of skill in the art, would understand the claim language and the disclosures in the specification as designating a particular concentration of sodium lauryl sulfate, specifically 0.025M sodium lauryl sulfate. (D.I. 270 at 14.) Further, Abbott asserts that Teva's own expert, Ms. Gray, interpreted this claim term to require a specific concentration, and that she dissolved a sufficient amount of sodium lauryl sulfate in water to obtain 1 liter of a 0.025 molar solution. (Id. at 14-15.)

Teva counters that "Plaintiff's proposed construction ... is legally untenable because it eliminates the term "with" from the claim element... ." (D.I. 268 at 9 (emphasis omitted).) Thus, Teva asserts that the claim term is "fatally ambiguous." (Id.)

2. The Court's Construction

Although Teva's "grammatical savvy" is noted, I believe that any ambiguity created by the word "with" was likely an

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inadvertent error. See Merck, 395 F.3d at 1371 n.8 (finding that the omission of the word "about" was likely an inadvertent error, rather than an intentional product of claim drafting). In the context of the Stamm patents, the claim term is understood by persons of ordinary skill in the art as expressing a concentration, rather than a specific volume. (See D.I. 267, Ex. K at 4, 5, Expert Report of Vivian Gray (noting that Ms. Gray used 1200 ml of dissolution medium at a concentration of "0.025 M Sodium Lauyrl Sulfate" to test samples provided by Fournier).) Although Ms. Gray also stated that "the wording describing the 0.025 M Sodium Lauryl Sulfate medium was not clear," she was able to test the samples according the methodology disclosed in the Stamm patents. (Id. at 5.) Furthermore, Abbott's expert, Dr. Amidon, stated that it is inconceivable that anyone of skill in the art would interpret the claim term in the manner suggested by Teva. n13 (See D.I. 236, Ex. 11 at 339:4-5, Dep. of Dr. Amidon, Nov. 19, 2004.) Thus, the claim term is not indefinite because one of ordinary skill in the art would read the term as requiring a concentration of 0.025 molar sodium lauryl sulfate. Therefore, I construe "dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate" to mean "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate."

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n13 Although at the Markman hearing, counsel for Teva argued that Ms. Gray used 0.025 molar sodium lauryl sulfate because the prosecution history discussed testing under those conditions (D.I. 297 at 81:21-82:3, C.A. 02-1512-KAJ), her methodology is persuasive evidence that a person of ordinary skill in the art practicing the invention claimed in the patents would do the same thing, and look to the prosecution history to clarify any perceived ambiguity. Although I do not find that the claim term is ambiguous. I merely note that Ms. Gray and Dr. Amidon's opinions are instructive as to how one of ordinary skill in the art would view the claim term.

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D. "DISSOLUTION PROFILE"

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Dissolution profile	A quality control assay conducted according to instructions found in the United States Pharmacopoeia. The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.	No need to construe.	A quality control assay conducted according to instructions found in the United States Parmacopoeia. The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.

A dissolution test is a type of 'in vitro' (i.e., test tube test) quality control test commonly used in the pharmaceutical industry to characterize the performance of a drug product, specifically to measure drug release over time. (Williams Decl., P 19.)

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Biovail explains that in this context dissolution testing involves adding a quantity of a bupropion hydrochloride tablet, the drug product, to a water-based fluid or dissolution medium. (Id., P 19.) Further, after the bupropion hydrochloride is added to the fluid or dissolution medium, samples of the fluid are removed and tested at various times to determine how much of the bupropion hydrochloride is in the fluid. (Id.) A dissolution profile is obtained by determining the amount of bupropion hydrochloride that is released from the drug product at various times. (Id.)

Anchen asserts that the "dissolution profile" limitation of claims 1 and 30 is indefinite because it does not specify the conditions under which it should be measured. (Anchen's Opening Claim Construction Brief, p. 8.) Anchen avers that dissolution testing can be conducted by using a number of different testing apparatuses, under a number of different agitation conditions, and using a number of different dissolution media with different pH vales. (Id.) Anchen contends that "[c]hanges in the variable aspects of a dissolution method will often change the resulting dissolution profile measure for the same drug product." (Id.)

Anchen avers that Biovail is attempting to brief the invalidity issue in connection with the Markman hearing, and asks the Court to defer resolution of this dispute until after Anchen has conducted additional discovery. (Id.)

According to Biovail, the '341 patent does not specify any specific dissolution conditions because the dissolution conditions will depend on the particular performance characteristics of the bupropion hydrochloride product at issue. (Williams Decl., P 20.) Biovail avers that a person of ordinary skill in the art would know that. Biovail explains that some drug formulations are designed to release in the stomach, and others are designed to release the active ingredient in the small intestine. (Id., P 22-25.) Biovail contends that one skilled in the art would look to the USP to determine which parameters should be used in conducting a dissolution test. (Id., P 22.)

The Court agrees with Biovail, and that the term "dissolution profile" is not indefinite. In addition, the Court finds that Biovail's reliance on the USP is proper and adopts Biovail's construction of the term "dissolution profile."
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D. "Dissolution Profile"

Finally, the parties disagree on whether "dissolution profile" in claims 1 and 30 is capable of being construed at all. Biovail asserts that "dissolution profile" means "a quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, i.e., the ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to guidance and instructions found in the United States Pharmacopoeia." (Biovail Opening Br. at 4.)

Impax, on the other hand, claims that "dissolution profile" is fatally indefinite and that I should delay construing it until after both sides have briefed invalidity. Impax argues that no part of the '341 patent directs the reader to the United States Pharmacopoeia (USP). In the alternative, Impax claims that even if one skilled in the art would know to look to the USP for guidance, the USP itself provides more than one potential method for determining the dissolution profile of a bupropion hydrochloride tablet, each of which leads to different results.

As Impax recognizes, at this early stage of the litigation, it would be premature for me to conclude that the term "dissolution profile" renders the '341 patent invalid for indefiniteness under 35 U.S.C. § 112 P2 . "[W]hen a claim is not insolubly ambiguous, it is not invalid for indefiniteness." Energizer Holdings v. ITC, 435 F.3d 1366, 1370 (Fed. Cir. 2006) (citations omitted); see also Bancorp Servs., L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1371 (Fed. Cir. 2004) ("We have held that a claim is not indefinite merely because it poses a difficult issue of claim construction; if the claim is subject to construction, i.e., it is not insolubly ambiguous, it is not invalid for indefiniteness."). The parties have not yet briefed any issues pertaining to invalidity, and the Federal Circuit has "certainly not endorsed a regime in which validity analysis is a regular component of claim construction." Phillips, 415 F.3d at 1327. However, I do not find it necessary or appropriate to delay construing "dissolution profile" until after briefing on invalidity. The parties are entitled to my construction of this term as they brief invalidity and infringement issues. In any event, my construction of the term "dissolution profile" is without prejudice for the parties to request reconsideration at a later stage of the litigation. "[D]istrict courts may engage in rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of

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the technology evolves." Energizer Holdings v. ITC, 429 F.3d 1364, 1377 (Fed. Cir. 2005) (citations omitted).

Because Impax has not proposed an alternative construction, I adopt Biovail's proposed construction of "dissolution profile," a nearly identical version of which was approved by the Anchen court: "A quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, i.e., the ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to guidance and instructions found in the United States Pharmacopoeia." In adopting Biovail's proposed construction in that case, the court noted that "one skilled in the art would look to the USP to determine the parameters to be used in conducting a dissolution test." I agree with this assessment of how one skilled in the art would understand "dissolution profile" in the '341 patent, and save for another day the question of whether the USP resolves the ambiguity in the claim term sufficiently to satisfy the claim definiteness requirement of 35 U.S.C. § 112 P2 .
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10. The parties agree that Claim 1 of the '199 patent covers a cleavable fusion expression process. However, Novo raised two issues regarding claim interpretation: (1) whether the term "DNA" and the reference to Figures 1 and 3 in the claim exclude the of genomic DNA from the claim, and (2) whether the claim is a "means plus function" claim, therefore covering only the use of trypsin and the amino acid extensions recognized by trypsin and their "equivalents." For the reasons set forth below, the court finds that (1) the claim does not exclude genomic DNA and (2) enzymatic action is a generic term not limited to trypsin and its "equivalents" and the amino add sequence is simply one which is specifically cleavable by the enzyme of choice.

1. Claim 1 Of The '199 Patent Contains No Limitation For The Source Of DNA Coding For Human Growth Hormone

11. The court rejects Novo's argument that Claim 1 of the '199 patent should be construed to contain a limitation on the source of the DNA utilized in the claimed process. No such limitation appears in the language of the claim (96 Tr. 396-397, Peet). Moreover, it is clear from the '199 patent prosecution history that both the Examiner and Genentech stated that the source of the DNA coding for human growth hormone was irrelevant and could include chemically synthesized DNA, cDNA or genomic DNA (GNE 201, pp. 83, 91). Indeed, this issue arose during prosecution of the '199 patent. The Examiner stated specifically his understanding that the DNA was generic and would include genomic DNA (GNE 201, p. 83). In response to a specific inquiry from the Examiner, Genentech stated that the source of the DNA was not critical and "need not be recited in the claims." (GNE 201, p. 91). Thus, the file history explicitly states that the claim of the '199 patent contained no limitation as to the source of the DNA, and can include genomic DNA (96 Tr. 396, Peet).

12. Novo also argues that the claim language "which conjugate protein consists essentially of amino acids 1-191 of human growth hormone as set forth in combined FIGS. 1 and 3" requires the use of semi-synthetic DNA, i.e., a combination of synthetic DNA and cDNA, because the Figures show the preferred semi-synthetic DNA. Novo's argument, however, fails as a matter of simple grammatical construction. First, the phrase is set off by a comma from the DNA portion of the claim, indicating that the phrase modifies the conjugate protein, not the DNA. Second, Figures 1 and 3 show both a DNA sequence and an amino acid sequence. The claim language requires only that the hGH component of the conjugate protein be the amino acid sequence 1-191 disclosed in the referenced Figures. It does not require the particular example of the DNA for amino acids 1-191. Thus, the reference to the Figures has no bearing on the source of the DNA. The phrase relates only to the amino acid sequence.

13. Novo also argues that because the specification does not explicitly mention it, genomic DNA cannot be within the claim's scope (96 Tr. 1139, Villa-Komaroff). This argument is without merit. First, the claim language clearly does not require a particular source of DNA, as compared, for example, to the '832 patent, which does require a particular source, namely a combination of synthetic DNA and cDNA (NN 200). Second, although the specification refers to synthetic DNA and cDNA, Novo has conceded previously that everything in the specification is not necessarily in a claim (95 Tr. 1561, 1667-1668 Rzucidlo). The restriction requirement early in the prosecution of the parent '832 patent case distinguished as classes of inventions the use of semi-synthetic DNA to code for a protein (i.e., the '832 patent) and the methods of making hGH (Pl. Ex. 56; 95 Tr. 1322-1324, 1667-1668, Rzucidlo)). Third, the prosecution history is clear that the claim is generic as to the source of DNA (GNE 201; pp. 83, 91; 96 Tr. 394-96, Peet).

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14. Finally, the court has considered Novo's argument that because it was not known whether the genomic DNA coding for amino acids 1-23 was without introns and, therefore, useful, n4 the claim cannot include genomic DNA. The court finds this argument irrelevant. Methods to determine whether a genomic DNA sequence contained introns were known by 1979 (96 Tr. 1308-1311, Villa-Komaroff). Moreover, generic language in a claim can cover future improvements. Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1559 (Fed. Cir. 1996).

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n4 Introns are interrupting sequences in genomic DNA (96 Tr. 77-78, Falkinham).

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15. Therefore, the term "DNA coding for human growth hormone" in Claim 1 may include chemically synthesized DNA, cDNA, genomic DNA or any combination thereof. Furthermore, the claim's reference to "FIGS. 1 and 3" describes the amino acid sequence of the hGH component of the conjugate protein and, therefore, does not limit the source of the DNA.
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F. DNA Encoding Human Erythropoietin

The phrase "DNA encoding human erythropoietin" is contained in Claim 1 and related to dependent Claims 3 and 7 of the '349 patent. Amgen, on the one hand, contended that the claim terms are so straightforward that interpretation of any of the terms was unnecessary. TKT, on the other hand, argued that the phrase means "human EPO DNA that is exogenous to the cell in which the EPO is produced, i.e., the human EPO DNA did not originate in the genome of the cell into which it is inserted," Defs.' Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. 19 -- more succinctly, "exogenous DNA encoding human erythropoietin." TKT argued that because the patent specification only taught using DNA that encoded for human erythropoietin that did not originate in the genome of the host cell (exogenous DNA), the claim term should not be interpreted to include both exogenous and endogenous human EPO DNA. Because TKT activates the human erythropoietin gene in the human host cell (the endogenous EPO gene), one can understand TKT's motivation in proffering its construction.

Yet, as the Court pointed out, TKT's construction is merely "a variant of the argument that's already been made here." Tr. of Markman Hr'g, Vol. III at 23:2-3. TKT was once again employing invalidity contentions in an attempt to add limitations into claim terms that by their plain meaning were not amenable to such limitations. The plain meaning of the claim terms simply do not call for any such limitation. This portion of the claim language claims any and all DNAs that encode human erythropoietin regardless of such DNA's relationship to the host cell in which it is expressed. Thus, the Court held that "DNA encoding human erythropoietin" means "DNA which encodes human erythropoietin, not including the word exogenous DNA which encodes human erythropoietin." Id. at 35:1-3. 14

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14 While such a construction, in light of its tautology, probably would neither satisfy a third grade English teacher nor be a sufficient dictionary definition, it was nonetheless more than sufficient to aid the parties and the Court in organizing the presentation of evidence.

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VI. "Signaling domain" and "capturing domain"

A. Parties' Contentions

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Enzo contends that I should construe the claim language "signaling domain" and "capturing domain" according to their ordinary meaning. Enzo contends that one of ordinary skill in the art would recognize these terms as having their ordinary meaning. Further, Enzo contends that I should not construe these terms to be means plus function elements because it did not use the term "means."

Digene contends that if I do not construe these terms as means plus function elements, I should limit the definition of these terms to a binding between a specific discrete and identifiable portion of the "complex" and the "capturing entity" because, during prosecution of the '581 patent, Enzo overcame a prior art reference with this definition of the claim terms.
B. Interpretation

I conclude that the terms "signaling domain" and "capturing domain" are not properly construed as means plus function elements. The claim language of the '581 patent does not use the term "means," and therefore, a presumption arises that 35 U.S.C. § 112, P 6 does not apply. See Mas-Hamilton Group v. Lagard, Inc., 156 F.3d 1206, 1213 (Fed. Cir. 1998). Moreover, I agree with Enzo that the claims recite sufficient structure, material, and acts necessary to perform the functions described by the terms, and therefore, do not invoke Section 112 P 6. See Sage Prods. v. Devon Indus., Inc., 126 F.3d 1420, 1427-28 (Fed. Cir. 1997).

I find that the term "domain" has an ordinary and customary definition to one of ordinary skill in the art. The ordinary meaning of "domain" is "[a] structurally and/or functionally discrete portion of a protein, nucleic acid, or membrane." The Encyclopedia of Molecular Biology 296 (Sir John Kendrew ed. 1994). Further, I am persuaded that one of ordinary skill in the art would be able to determine sufficient structure of. "capturing domain" and "signaling domain" by observing the "discrete portion" of the first complex or complexes that complexes with the second entity, i.e. the domain in the first complex where the second entity binds (capturing domain), or with a complex forming moiety (signaling domain), as described in the claims of the '581 patent.

Additionally, I conclude that Digene has not demonstrated that Enzo's distinguishing U.S. Patent No. 4,724,202 (the "Dattagupta et al. reference") to overcome the Examiner's rejection narrowed the scope of "capturing domain" and "signaling domain" to a binding between a specific discrete and identifiable portion of the "complex" and "capturing entity." In reaching this conclusion, I have found the Declaration of Enzo's consultant, Dr. James G. Wetmur persuasive in setting forth the distinctions between the capturing or collection described in the '581 claims and those of Dattagupta's direct and non-specific immobilization. (D.I. 231, Ex. X at 5, 6, 7, and 8.) In sum, I accept Enzo's proposed construction of the terms "capturing domain" and "signaling domain."
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A. "DOSAGE FORM" (BOTH PATENTS).

The term "dosage form" is ubiquitous in both the '088 and '939 patents. It appears in every claim of the '088 patent and in seventeen of the claims in the '939 patent. King argues that the definition of "dosage form" is "a pharmaceutical product having active ingredients (an opioid agonist and an opioid antagonist) that are present in a structural arrangement in which agonist particles and antagonist particles are interspersed in the product and are not isolated from each other in two distinct layers." (Pls.' '088 Opening Markman Br. 16; Pls.' '939 Opening Markman Br. 21.) In contrast, Purdue believes "dosage form" should be construed using its ordinary meaning, "the physical form of a drug product." (Def.'s '088 Rebuttal Cl. Constr. Br. 2-3; Def.'s '939 Opening Cl. Constr. Br. 21.)

I find that Purdue's definition is indeed the customary and ordinary meaning of "dosage form" ascribed by one skilled in the art of pharmaceutical manufacturing. For example, the Federal Drug Administration (the "FDA") defines "dosage form" as "the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable." Drugs@FDAGlossary of Terms, http://www.fda.gov/ Drugs/InformationOnDrugs/ucm079436.htm (last visited June 1, 2010). And, nowhere in its briefs does King argue that "the physical form of a drug product" is not the typical meaning of "dosage form." The more pertinent issue is whether the inventors of the patents-in-suit deviated from the ordinary meaning by adding the structural restrictions King cites. I find that they did not.

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The first place to look for the definition of a term is within the claims themselves, and this is where King's definition immediately fails. See Phillips, 415 F.3d at 1314 ("[T]he use of a term within the claim provides a firm basis for construing the term"). As King conceded at oral argument, "dosage form" must be defined the same for both patents because the '939 patent is a continuation of the '088 patent. Additionally, a term "cannot be interpreted differently in different claims because claim terms must be interpreted consistently." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995); see also Phillips, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can oftenilluminate the meaning of the same term in other claims.").

In contradiction to King's definition of "dosage form," claim 4 of the '939 patent states:

An oral dosage form comprising an opioid agonist and the opioid antagonist composition of claim 1, wherein the hydrophobic material separates the opioid antagonist from the opioid agonist.

'939 patent, col. 52, ll. 61-64 (emphasis added). In this claim, the opioid antagonist and agonist are not "interspersed" and in fact are isolated from each other in some manner. Thus, to define "dosage form" as including the limitation that "agonist particles and antagonist particles are interspersed in the product and are not isolated from each other in two distinct layers" would mean to limit claim 4 in a way that it is not supported by the language of the claim itself. Because claim terms should be construed consistently throughout both patents, the rest of the claims cannot use that definition of "dosage form" either.

King nonetheless argues that the structural limitations in its definition of "dosage form" are required because throughout the specification of the '088 patent, the inventors repeatedly describe their invention as dosage forms "whereinthe agonist and antagonist are interdispersed 1 and are not isolated from each other in two distinct layers." See, e.g., '088 patent, col. 4, ll.18-30, col. 5, ll. 5-19. However, courts must be careful not to read a limitation into a claim simply because the embodiments contain such a limitation. Phillips, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments").

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1 Based on the definition of "interdispersed" given by the parties at oral argument, I find the word as used here is indistinguishable from "interspersed."

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Moreover, while several of the embodiments of the invention in the '088 patent do explicitly require that "the agonist and antagonist are interdispersed and are not isolated from each other in two distinct layers," this is not a characteristic of all the embodiments. Compare, e.g., '088 patent, col. 4, ll. 18-30, with '088 patent, col. 4, ll. 31-45. For example, several embodiments of the dosage forms are said to contain an opioid agonist and an opioid antagonists "wherein the antagonist is in the form of multiparticulates individually coated withsequestering material," but these embodiments mention nothing about whether or not the agonist and antagonist are "interdispersed." '088 patent, col. 4, ll. 31-45; see also id., col. 5, ll. 54-59.

Moreover, the section that most comprehensively addresses the meaning of "dosage form" states:

The oral dosage form containing an opioid agonist in combination with a substantially non-releasable form of an opioid antagonist includes, but are not limited to, tablets or capsules. The dosage forms of the present invention may include any desired pharmaceutical excipients known to those skilled in the art. The oral dosage forms may further provide an immediate release of the opioid agonist. In certain embodiments, the oral dosage forms of the present invention provide a sustained release of the opioid agonist contained therein. Oral dosage forms providing sustained release of the opioid agonist may be prepared in accordance with formulations/methods of manufacture known to those skilled in the art of pharmaceutical formulation, e.g., via the incorporation of a sustained release carrier into a matrix containing the substantially non-releasable form of an opioid antagonist; or via a sustained releasecoating of a matrix containing the opioid agonist and the substantially non-releasable form of the opioid antagonist.

'088 patent, col. 10, ll. 40-57; '939 patent, col. 10, ll. 30-46. None of this section contradicts the ordinary meaning of "dosage form" derived from the claims.

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However, King cites the '088 patent's abstract, which states, "Disclosed is an oral dosage form . . . wherein said agonist and antagonist are interdispersed and are not isolated from each other in two distinct layers." '088 patent, Abstract. This is the strongest argument for altering the ordinary definition of "dosage form" because "the location [of a statement] can signal the likelihood that the statement will support a limiting definition of a claim term. Statements that describe the invention as a whole [such as the abstract], rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 864 (Fed. Cir. 2004). Yet, the abstract alone is not enough to show that the ordinary meaning, which is supported by the claims and the remainder of the specification, should be abandoned. See id. ("[C]ertainsections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although what import to give language from the specification must, of course, be determined on a case-by-case basis"). Importantly, the abstract for the '939 patent mentions "dosage form" but does not say the agonist and antagonist are interspersed. The prosecution histories of the patents-in-suit also offer nothing to suggest a meaning of "dosage form" different from the ordinary and customary meaning. Therefore, I do not find that the definition of "dosage form" requires the antagonist and agonist be interspersed.

Beyond the structural limitations King proposes, it also asserts that "dosage form" must be defined as "having active ingredients (an opioid agonist and an opioid antagonist)" because throughout both patents, the oral dosage forms invented are described as comprising an opioid agonist and antagonist. However, the court concluded in Phillips that when a claim refers to "steel baffles," rather than simply "baffles," it "strongly implies that the term 'baffles' does not inherently mean objects made of steel." 415 F.3d at 1314. Similarly,the fact that the claims of the patents-in-suit continually recite that dosage forms contain agonists and antagonists, strongly implies that these ingredients are not inherently included in the meaning of "dosage form."

Consequently, I find the proper definition of "dosage form" is its ordinary and customary meaning: "the physical form of a drug product."
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1. Written Description

As stated in the Court's December 7, 2004 "Order Construing Claims and Denying Summary Judgment," the parties have stipulated that a "dosage form" is "a pharmaceutical preparation in which doses of medicine are included" and a "solid dosage form" is "a dosage form that is neither liquid nor gaseous."

As used in the '355 Patent . . .the term "dosage form" comports with its broad stipulated definition. In the section entitled "Objects of the Invention," the patent qualifies the term in numerous ways: "sustained-release dosage form," "solid-oral dosage pharmaceutical form," "drug delivery dosage form," "controlled-release dosage form," and, most notably, "an osmotic dosage form." '355 Patent, cols. 2-3. The examples in the written description also indicate that the invention encompasses more than one dosage form. Moreover, the patent refers to both osmotic and non-osmotic dosage forms. Thus, in the examples cited by Mylan, the osmotic dosage form is merely a preferred embodiment . . .

Alza Corp. v. Mylan Labs., 349 F. Supp. 2d 1002, 1010 (N.D. W. Va. 2004).

The '355 patent only refers to "dosage form" or "dosage forms"; unlike the '895 patent, it makes limited use of the term "osmotic." (JX 1). It also claims "a method for treating incontinence" instead of claiming "a delivery device." (Id. at 12). Moreover, Dr. Amidon testified that skilled artisans would be aware of the different types of dosage forms encompassed by the genus of sustained-release dosage forms claimed by the '355 patent. (Amidon Tr. at 1051-52). Thus, while the words "non-osmotic" dosage form and "polymer matrix" are not expressly written in the patent, one of skill in the art reading the '355 patent would realize that the term "dosage form" includes a variety of known pharmaceutical preparations, including a non-osmotic polymer matrix delivery device.
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"Dose"

Neither party addressed this term in its briefs. However, in the Joint Claim Construction Chart, Nutrition 21 identified "dose" as a distinct term in certain claims of the '156 Patent and suggested the term means "a quantity of CP or CR" (CR presumably stands for chromium). Nevertheless, GNC does not ask the Court to construe this term. "Dose" is used according to its ordinary meaning, which the jury will be familiar with. Accordingly, the term does not require construction.
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2. "the downstream side of the resin bed"

The next disputed term is "the downstream side of the resin bed." (Joint Stmt. p. 2). Defendants submit the following definition:

"…the side of the resin bed from which the flow of material exists after it passes through the resin bed recited in step (b). If the column of resin is standing vertically (that is, up and down), the downstream side is the bottom of the column of resin." (Joint Stmt. p. 2).

Plaintiff interprets the phrase to simply mean "the side of the resin bed from which the flow of material exits after it passes through the resin bed." (Joint Stmt. p.2). The court agrees with Plaintiff that the additional definition that "the downstream side is the bottom of the column of resin" is not required by the claim language. (Joint Stmt. p. 2). The plain construction of the phrase simply means "the side of the resin bed from which the flow of material exits after it passes through the resin bed." (Joint Stmt. p. 2; Penney Decl. P 29). This interpretation is consistent with the ordinary and customary meaning of the term "downstream." (Penney Decl. P 29). Furthermore, this interpretation does not compromise Defendants' proposed construction because so long as the flow of material exits at the "bottom" of the column, then that side is properly referred to as the "downstream side;" there is no need to additionally define the "downstream side" as the "bottom" of the column.
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A. Ocean Spray's Process Does Not Treat A Dried Fruit

Ocean Spray asserts that its manufacturing process does not infringe Claim 1 of the Mazin patent, because it does not treat "dried fruit" as that term is used in Claim 1. Ocean Spray contends that one of ordinary skill in the relevant art would understand "dried fruit" to mean "fruit with a moisture content between about 10% to 18%." In support of this interpretation, Ocean Spray contends that the court should rely on the intrinsic record, the patent's written description, and prosecution history. It argues that the court should disregard extrinsic evidence offered by Amazin' Raisins.

In contrast, Amazin' Raisins contends that one of ordinary skill in the relevant art would understand "dried fruit" to mean a "fruit or fruit piece that has had a portion of its naturally occurring moisture content removed." In support of this construction, Amazin' Raisins urges the court to look beyond the intrinsic record to extrinsic testimony offered by its two experts.

The court concludes that neither party's construction is correct, although Ocean Spray's is quite close to correct. The court concludes that a person of ordinary skill in the art of food processing, reading Claim 1 in light of the written description and the prosecution history, would understand "dried fruit" to mean "fruit from which natural moisture has been removed which has approximately 10 to 18% moisture remaining."

In construing the term "dried fruit," the court has considered the purposes of the patent law and patents, as well as the principles of claim construction articulated by the Court of Appeals for the Federal Circuit. "A patent is a government grant

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of rights to the patentee." Markman v. Westview Instruments, Inc., 52 F.3d 967, 968 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). Among other things, it gives the patentee rights, for a limited period of time, to exclude others from using the invention claimed. Id. A patent serves as a species of "deed which sets out the metes and bounds of the property the inventor owns for the term and puts the world on notice." Id. at 997. This notice informs the public, and in particular, a patentee's competitors, of the scope of the patentee's claimed invention. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). At the same time, such notice informs a competitor, who may be contemplating an expensive investment, of what is permissible. "Competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." Id. at 1583. The notice function also provides a competitor assurance that "if infringement litigation occurs, [] a judge, trained in the law, will similarly analyze the test of the patent and its associated public record and apply the established rules of construction, and in that way arrive at the true and consistent scope of the patent owner's rights to be given legal effect." Markman, 52 F.3d at 979.

It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). "[T]he claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim." Renishaw PLC v. Marposs Societa' per Aziona, 158 F.3d 1243, 1248 (Fed. Cir. 1998). Those words are generally given their ordinary and customary meaning, as construed by a person of ordinary skill in the art in question at the time of invention. See Phillips, 415 F.3d at 1312-13.

In some cases, the ordinary meaning of claim language as understood by persons of skill in the art may be readily apparent even to lay judges, and claim construction in those cases involve little more than the application of the widely accepted meaning of commonly understood words. Id. at 1314. "In such circumstances, general purpose dictionaries may be helpful." Id. at 1314. Here, the term "dried" in Claim 1 modifies fruit, indicating that "dried fruit" is a fruit that has had some amount of its usual moisture removed. The Princeton WordNet dictionary defines "dried fruit" as "fruit preserved by drying," and defines "dried" both as a verb ("remove the moisture from and make dry") and an adjective ("preserved by removing natural moisture"). See Princeton WordNet, http://wordnet.princeton.edu/perl/webwn. Merriam Webster's dictionary defines "dried" as "to make dry," and defines "dry" as, among other things, "free or relatively free from a liquid and especially water" and "devoid of natural moisture." See Merriam-Webster Online, http://m-w.com/cgi-bin/dictionary. However, neither of these definitions makes the meaning of "dried fruit" to one of ordinary skill in the art readily apparent. Rather, these definitions are ambiguous concerning how much moisture must be removed to say that a fruit has been dried and concerning how "dry" the fruit must be to be considered "dried fruit."

The person of ordinary skill in the art would properly read a claim term not only in the context of the particular claim in which it appears, but in the context of the entire patent, including the specification. See Phillips, 415 F.3d at 1313. The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Id. at 1315 (citing Vitronics, 90 F.3d at 1582).

Two interpretive principles guide reliance on the specification. The court generally may not read a limitation into a claim from the written description, but the court can generally look to the written description to interpret a term already in a claim limitation which requires definition. See Renishaw, 158 F.3d at 1248. In this case, the term "dried fruit" is in Claim 1 and requires definition.

Where a patentee acts as lexicographer, the patentee's definition of term governs. See Phillips, 415 F.3d at 1316. In this case, however, Amazin' Raisins has not expressly defined "dried fruit" in the specification. Therefore, the court must decide whether the specification indicates what, if any, moisture content "dried fruit" as used in Claim 1 must have. The court may rely in part on dictionary definitions when construing the meaning of the term "dried fruit" as it is used in Claim 1, but only so long as such reliance accords with the intrinsic record. See Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 996 (Fed. Cir. 2006) (citing Phillips, 415 F.3d at 1322-24 and Free Motion Fitness, Inc. v. Cybex Int'l, Inc., 423 F.3d 1343, 1348-49 (Fed. Cir. 2005)).

The court understands that "[i]t is usually incorrect to read numerical precision into a claim from which it is absent, particularly when other claim contain the numerical limitation." Modine Mfg. Co. v. United States Int'l Grade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996). However, there are circumstances in which it is necessary and appropriate to construe a claim to include a numerical range found only in the specification. Id. at 1552. Indeed, as discussed below, Modine was such a case. Id.

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Generally, when, as here, there is a term in a claim that requires further definition, the written description may provide that definition. See Renishaw, 158 F.3d at 1248; Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) ("there must be a textual reference in the actual language of the claim with which to associate the proffered claim construction.").

The written description "can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed even if the guidance is not provided in explicit definitional format." Thus, when a patentee uses a claim term throughout the entire patent specification in a manner consistent with only a single meaning, he has defined that term "by implication."

Bell Atlantic Network Servs., Inc. v. Covad Communs. Group, Inc., 262 F.3d 1258, 1271 (Fed. Cir. 2001) (quoting Advanced Cardiovascular Sys. Inc. v. Scimed Life Sys. Inc., 261 F.3d 1329, 1344 (Fed. Cir. 2001) and Vitronics, 90 F.3d at 1582) (emphasis in original).

This is a case in which the term "dried fruit" is defined by implication in the specification. As indicated earlier, that term in Claim 1 requires further definition. The term is not expressly defined in the written description. However, the written description repeatedly and consistently refers to the dried fruit to be treated at the outset of the patented process to remove flavor as having "between about 10 to 18% moisture." See Mazin patent, 3:60-62. 3:64-4:4, 4:14-17; 6:65-9:67. Therefore, a person ordinarily skilled in the art would understand that the patent claimed and covered a process that removed flavor from fruit with moisture in that range. Thus, Claim 1 must be construed as a process that begins with fruit having between about 10 to 18% moisture.

More specifically, in the "Detailed Description of the Invention," the first paragraph states:

The dried fruit which may be flavored employing the processes of the invention include peach, apple, pear, raisins, prunes, apricots, and cherries. Any dried fruit which contains between about 10% to 18% moisture may be employed. The process can be employed on whole or sectioned pieces of dried fruit.

Id. at 3:58-63. This precedes any discussion of the patent's preferred embodiment, which is discussed in the immediately following paragraphs, see id. at 3:64-6:60, or other embodiments, listed after the preferred embodiment, id. at 6:65-9:67. Of the seven fruits included in the quoted paragraph, only two--raisins and prunes--are themselves inherently dried fruit. The Princeton Wordnet Dictionary defines a raisin a "dried grape" and a prune as a "dried plum." See Princeton WordNet, http://wordnet.princeton.edu/perl/webwn. The others fruits--peaches, apples, pears, apricots, and cherries--are not inherently dried fruit. Something must be done to make them dried fruit. The sentence immediately following the list of fruits indicates that the five other fruits become dried fruit for purposes of the patent when water is removed so that they have about 10 to 18% moisture. See Mazin patent at 3:60-63.

This is consistent with the patent's preferred and other embodiments, all of which teach one ordinarily skilled in the art how to apply Amazin' Raisins's process to raisins. Id. at 3:64-9:67. Each embodiment is consistent with the requirement that the fruit have a moisture range of about 10 to 18%. Example 1 states that "the treated raisins were then dehydrated . . . to 12% moisture remaining in the product." Id. at 7:2-7. Examples 2 to B rely expressly on Example 1. Id. at 7:11-8:9. Examples 9 and 10, on which Examples 11 to 14 rely, use an "Australian sultana raisin." Id. at 8:11-9:67. The patent does not expressly indicate what moisture range of the sultana raisin. However, the United States Department of Agriculture regulations, which both Ocean Spray and Amazin' Raisins accept as they apply to raisins, indicate that all raisins, except the Monukka variety, can contain no more than 18% moisture, by weight. See 7 C.F.R. § 52.1846 (1990). The Monukka variety, which is not mentioned in the Mazin patent, may not contain more than 19% moisture content. Id. Therefore, each of the embodiments in the Mazin patent is consistent with a construction that "dried fruit" is fruit that has about a 10 to 18% moisture range.

The Detailed Description of the Invention, which precedes the Examples, states:

The processing of many of the different dried fruits will require conditions specifically adapted to the dried fruit. The following description will be restricted to the conditions which are particularly suitable for preparing raisin products but it will be understood that persons skilled in the art, given the particular process conditions and steps set forth in this general description as well as in the Examples, could readily adapt the processes of the invention to other dried fruits.

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Id. at 4:5-13. This language indicates that the patentee did not intend that Claim 1, which covers dried fruits generally, be limited by the patent's preferred embodiments, all of which involve raisins and are specifically covered by Claims 2 to 6. Id. at 10:26-12:17. The court understands that generally a patentee's claim cannot be limited to the patent's embodiments, even if only one embodiment exists, unless the embodiment is the "invention itself." See Modine, 75 F.3d at 1551; Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2004).

However, as indicated earlier, the language referring to the about 10 to 18% moisture range appears before this statement, and before any of the embodiments. This language would communicate to one skilled in the art what moisture level a fruit like a "peach, apple, pear, . . . apricot[], and cherr[y]" must have in order to be employed in the process described in Claim 1. The statement that "persons skilled in the art, given the particular process conditions and steps set forth in this general description as well as in the Examples, could readily adapt the processes of the invention to other dried fruits," Mazin patent at 4:9-13 (emphasis added), would instruct one ordinarily skilled in the art who wishes to apply the process covered by Claim 1 to a non-dried fruit to look both to the general description, which teaches that fruits other than raisins should be reduced to roughly 10 to 18% moisture levels prior to exposure to the Mazin process, and to the embodiments, all of which involve raisins consistent with a moisture range of "about 10 to 18%." See Mazin patent at 3:64-4:4, 4:14-17; 6:65-9:67.

Therefore, because the specification assigns significance to the numerical range and because the specification, including the embodiments, repeatedly use a consistent moisture range, it is appropriate to construe Claim 1 as covering dried fruit as fruit which has a moisture content of about 10 to 18%. See Advanced Cardiovascular, 261 F.3d at 1339 (stating exception to general proscription again importing limitations from specification into general claim language where the "specification assigns significance" to the limitation); Bell Atlantic, 262 F.3d at 1271 (finding a claim term defined by "implication" where the specification used the term consistently throughout).

In essence, the court finds that this case is closely comparable to Bell Atlantic. In Bell Atlantic, the Federal Circuit addressed whether the district court had correctly construed the claim term "mode." 262 F.3d at 1271. In affirming the district court's construction, the Federal Circuit rejected the contention that its construction of the term "mode" improperly imported a limitation found in the specification's embodiments into a claim term. Id. at 1270. It reached this conclusion after describing how the Summary of the Invention, the Detailed Description of the Preferred Embodiments, and every other reference to the term "mode" in the written description was consistent and supported the district court's construction. Id. at 1270-73. Therefore, the Federal Circuit concluded that:

We acknowledge that it is generally impermissible to limit claim terms by a preferred embodiment or inferences drawn from the description of a preferred embodiment. Johnson Worldwide, 175 F.3d at 992. However, that is not the case here. We note that "the usage 'preferred' does not of itself broaden the claims beyond their support in the specification." Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed. Cir. 1999). Moreover, unlike Johnson Worldwide, this case does not involve the "varied use of a disputed term." Id. at 991. Instead, the patentees defined the term "mode" by implication, through the term's consistent use throughout the '786 patent specification. Vitronics, 90 F.3d at 1582. Given this definition; the three modes described in the Detailed Description of the Preferred Embodiments describe the three possible modes of the invention, and the claims are not entitled to any broader scope. Wang, 197 F.3d at 1383.

Id. at 1273.

As the instant case too involves a claim term, dried fruit, that requires further definition and the written description repeatedly and consistently describes dried fruit as fruit with a range of moisture of about 10 to 18%, the term has been defined by implication. Id.

This conclusion is not qualified by the decisions on which Amazin' Raisins primarily relies. Rather, each of those cases is distinguishable from Bell Atlantic and the instant case in material respects.

In contrast to RF Delaware, Inc. v. Pacific Keystone Technologies, Inc., 326 F.3d 1255, 1263 (Fed. Cir. 2003), and like Bell Atlantic, the instant case does not involve claim language that is "clear on its face." Id. at 1263. Therefore, reference to the Specification is proper here. See Bell Atlantic, 262 F.3d at 1270. Moreover, unlike RF Delaware, this case does not involve importing a limitation from a dependent claim into an independent claim, violating the principle of claim differentiation. See RF Delaware, 326 F.3d at 1263.

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Edwards Systems Technologies, Inc. v. Digital Control Systems, Inc., 99 Fed. Appx. 911 (Fed. Cir. 2004), also implicated the doctrine of claim differentiation. More specifically, Edwards involved the impermissible importation of a numerical range from a narrower dependent claim into an independent claim. Id. at 917-18. However, there is no comparable dependent claim in the instant case.

In contrast to Bell and the instant case, in Modine the term at issue was not used consistently throughout the specification. See 75 F.3d at 1552-54. However, despite the general proscription against importing numerical ranges from the specification into general claim terms, in Modine the Federal Circuit found that the embodiment in which the numerical range was found was the "invention itself" and, therefore, was properly imported into the general claim language. Id. at 1551-52.

Finally, Edwards Systems and Specialty Composites v. Cabot Corp., 845 F.2d 981 (Fed. Cir. 1988) were cases in which no significance was attached to the disputed reference in the specification. See Edwards, 99 Fed. Appx. at 917-18; Specialty Composites, 845 F.2d at 987. They were, therefore, analogous to cases in which the Federal Circuit declined to use drawings in the specification to limit claim language because "nothing in the specification assign[ed] significance to the drawings." Advanced Cardiovascular, 261 F.3d at 1339. In the instant case, however, the specification's discussion of non-dried fruits suitable for use with the Mazin process, if dried to a range of about 10 to 18%, assigns significance to the numerical range. This case, therefore, is comparable to cases in which limitations were properly found in the specification. See e.g., Kraft Foods, 203 F.3d at 1367-69 (indicating that the claim term "protecting back panel" was limited to a "relatively stiff" panel because, in addition to other intrinsic evidence, the specification's text described the back panel in the patent's drawings as being "constructed of a relatively stiff material"); Toro Co. v. White Consol. Indus., 199 F.3d 1295, 1300-02 (Fed. Cir. 1999) (construing the claim term "including" to mean "part of" and "permanently attached" because, in addition to the patent's drawings, the specification's text stressed that the claimed vacuum/blower's flow restriction ring was part of and attached to the invention's air inlet cover); Wang Lab., 197 F.3d at 1382-83 (noting that the claims were limited to a character-based protocol because of the express teachings of such a protocol in both the patent's specification and the drawings)

Therefore, as stated earlier, the court concludes that one reasonably skilled in the relevant art would construe "dried fruit" as used in Claim 1 of Mazin patent to include fruit with a moisture range of "about 10 to 18%" before the flavor is removed. Generally, the use of "about" is intended to avoid a "strict numerical boundary to the specified parameter." Pall Corp. v. Micron Separations, 66 F.3d 1211, 1217 (Fed. Cir. 1995). However, unless the patentee serves as his own lexicographer and defines the term differently, it should be given its ordinary and accustomed meaning of "approximately." See Conopco, Inc. v. May Dep't Stores Co., 46 F.3d 1556, 1561 n.2 (Fed. Cir. 1994). Construed in light of the claim language and the specification, "about" in this case means "approximately."

The Mazin patent generally teaches a process for raisins which have about 10 to 18% moisture content. Claim 1 is broader, encompassing any "dried fruit." The remainder of the claims, which cover only raisins, the written description, and the embodiments, also all raisins, would teach one ordinarily skilled in the art who wished to apply the process to a fruit other than a raisin that it is necessary to dry that fruit to a moisture content of approximately 10 to 18% before removing the flavor.

The prosecution history is consistent with this construction of "dried fruit." As a general rule, the court looks to prosecution history, the final piece of the intrinsic record, after reviewing the claim language and the specification. See Phillips, 415 F.3d at 1317. Because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and is, therefore, less useful for claim construction purposes. Id. Nevertheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. Id.

In this case the prosecution history shows that the PTO originally rejected the Mazin patent as obvious in light of the prior art. In order to overcome this objection, Amazin' Raisins made statements distinguishing the prior art. Particularly relevant is the argument that was made to distinguish the Mazin process from the Agarwala patent. As described earlier, the Agarwala patent teaches a process for treating fresh fruit, including frozen or canned fruits. Woodford Decl., Ex. 4, at 7. Amazin' Raisins emphasized to the PTO that Agarwala disclosed treating fresh fruit, while the Mazin process involved dried fruit. Id. This indicates that Amazin' Raisins understood that the prior art encompassed fruits with sufficient moisture to be deemed "fresh" and supports a construction of dried fruit that has an upper moisture range limit.

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The court recognizes that it has the discretion to consider the extrinsic record, although such evidence is less significant than anything in the intrinsic record. See Phillips, 415 F.3d at 1317-18. However, "a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, the written record of the patent." Id. at 1318 (quoting Key Pharma. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998)).

Amazin' Raisins has proffered the expert testimony of one of the Mazin patent's inventors, Amir Lalji, and of Dr. Keith Cadwallader, a professor of food sciences at the University of Illinois. Both opine, in identical words, that "dried fruit" for the purposes of Claim 1 means a "fruit or fruit piece that has had a portion of its naturally occurring moisture removed." See Cadwallader Decl., P 5; Lalji Decl., P 6.

The court finds that this proffered expert evidence deserves little, if any weight. Cadwallader testified that Lalji and he had never spoken. See Second Supp. Woodford Decl., Ex. 10, at 141. The fact that they provide the identical definition of dried fruit suggests that the definition was contrived by counsel solely for the purposes of this litigation and, therefore, "suffer[s] from a bias that is not present in [the] intrinsic evidence." See Phillips, 415 F.3d at 1318.

Moreover, as an inventor, Lalji's testimony is "entitled to little or no consideration." Bell & Howell Document Mgmt. Prods. C. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997). This is because "[t]he testimony of an inventor often is a self-serving after-the-fact attempt to state what should have been part of his or her patent application." Id.

Moreover, the expert opinions of both Lalji and Cadwallader are clearly at odds with the intrinsic evidence. See Phillips, 415 F.3d at 1318. Their definition of dried fruit would effectively eliminate the repeated, consistent references to a moisture range of "about 10 to 18%" in the written description. This would be inappropriate. See Curtiss-Wright Flow Control Group v. Velan, Inc., 438 F.3d 1374, 1381 (Fed. Cir. 2006); Asyst Techs. v. Emtrak, Inc., 402 F.3d 1188, 1195 (Fed. Cir. 2005); Phillips, 415 F.3d at 1318-19. Adopting their definition of dried fruit would also be inconsistent with the distinction the patentee made between fresh and dried fruit to overcome the initial rejection for obviousness. See Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1364 (Fed. Cir. 2006).

In essence, the court finds that this is the quintessential case contemplated by the Federal Circuit when it wrote:

Once a dispute over claim construction arises, "experts" should also not be heard to inject a new meaning into terms that is inconsistent with what the inventor set forth in his or her patent and communicated, first to the patent examiner and ultimately to the public. Patents should be interpreted on the basis of their intrinsic record, not on the testimony of such after-the-fact "experts" that played no part in the creation and prosecution of the patent. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995) ("Evidence extrinsic to the patent and prosecution history, such as expert testimony, cannot be relied on to change the meaning of the claims when that meaning is made clear by those documents."). Use of expert testimony to explain an invention may be useful. But reliance on extrinsic evidence to interpret claims is proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence, Vitronics, 90 F.3d at 1584, i.e., when the intrinsic evidence is "insufficient to enable the court to construe disputed claim terms." Id. at 1585. Accordingly, any expert testimony that is inconsistent with unambiguous intrinsic evidence should be accorded no weight. Id. at 1584 (citing Southwall, 54 F.3d at 1578; Markman, 52 F.3d at 983.

Bell & Howell, 132 F.3d at 706. Therefore, the court has given little, if any, weight to the opinions of Amazin' Raisins' experts. These opinions do not alter the court's construction of the term "dried fruit" as it is used in Claim 1.

Accordingly, the court construes "dried fruit" to mean "fruit from which natural moisture has been removed which has about 10 to 18% moisture remaining." The term "about" means "approximately." See Conopco, 46 F.3d at 1561, n.2.

The court must, therefore, decide if the evidence would permit a reasonable factfinder to conclude that the Ocean Spray process involves removing flavor from fruit with a moisture content of approximately 10 to 18%. See Kraft, 203 F.3d at 1366. As explained earlier, in deciding this motion for summary judgment, the court must determine whether the admissible evidence puts any material fact genuinely in dispute. See Feliciano, 160 F.3d at 787. "When a party fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party bears the burden of proof at trial, there can be no longer be a genuine issue as to any material fact . . . and the moving party is entitled to

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judgment as a matter of law." See Smith, 40 F.3d at 12; see also Techsearch, 286 F.3d at 1369.

Amazin' Raisins has the burden of proving infringement. See Techsearch, 286 F.3d at 1371. It is undisputed that prior to being subject to the CCE process which removes its flavor, the defrosted cranberries used by Ocean Spray have a moisture content of approximately 87%. On behalf of Ocean Spray, its Senior Operations Manager, Michael Scott, has provided an affidavit, based on personal knowledge, asserting that at the end of the CCE process, the moisture content of the cranberries remained about 90%. See Scott Decl., P6. Consistent with this, Mantius, the inventor of the Ocean Spray process, testified that the CCE process essentially replaced sugars and acids with water. See Supp. Woodford Decl., Ex. 9, at 101. Therefore, the moisture content at the end of the CCE process remains roughly the same and the emerging product is "very, very moist," indeed "wet." Id.

While Amazin' Raisins argues that Ocean Spray has not actually measured the moisture content of its product at the end of the CCE process, it is undisputed that Amazin' Raisins has not measured it either. Nor has it submitted any other evidence of the moisture content after the CCE process is complete. Therefore, there is no evidence that would permit a reasonable factfinder to conclude that Ocean Spray's decharacterized fruit has a moisture content in approximately the 10 to 18% range.

In Conopco, the Federal Circuit found that there was "simply no basis for interpreting the phrase 'about 40:1' to encompass [a] 162.9:1 ratio. That would imply an expansion of the term 'about' to encompass over a fourfold increase in the specified numerical ratio and thus would ignore the ordinary meaning of that term." 46 F.3d at 1561. The approximately 87% moisture content of the fruit from which Ocean Spray removes flavor, which is also about the moisture content after the flavor is removed, is more than four times greater than the 10 to 18% range the Mazin patent uses to define dried fruit. 87% is not about 18%, the upper end of that range. Therefore, a reasonable factfinder could not conclude that Ocean Spray's process removes flavor from dried fruit. Thus, Ocean Spray has "shown that, on the correct claim construction, no reasonable jury could [find literal] infringement on the undisputed facts or when all reasonable inferences are drawn in favor of the patentee." Techsearch, 286 F.3d at 1371. Accordingly, Ocean Spray is entitled, for this reason alone, to summary judgment on the contention that it literally infringes Claim 1.

In addition, the evidence compels the conclusion that Ocean Spray does not infringe Claim 1 under the doctrine of equivalents. Ocean Spray cannot recover claim scope that it surrendered during prosecution to obtain the patent. See Conoco, Inc., 460 F.3d at 1363-64. In this case, Amazin' Raisins, in its amendment letter responding to the patent examiner's initial rejection of its patent, distinguished its patent on several grounds. With regard to the term "dried fruit," it asserted that its process is (1) directed at dried fruit, unlike the Barlow process, and (2) does not treat fresh fruit, unlike the Agarwala process. See Woodford Decl. Ex. 4, at 4, 7. This evinces a "clear and unmistakable" surrender of subject matter--fresh fruit and fruit that is not dry. See Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., 347 F.3d 1314, 1326 (Fed. Cir. 2003); Conoco, 460 F.3d at 1363-64. That is, after reading the patent and the prosecution history, "'a competitor would reasonably believe that [Amazin' Raisins] had surrendered'" any claim to fresh fruit and non-dry fruit in Claim 1. Conoco, 460 F.3d at 1363-64 (quoting Cybor, 138 F.3d at 1457).

Moreover, even assuming that Amazin' Raisins did not evince a "clear and unmistakable" surrender, it still would not prevail under the doctrine of equivalents because that doctrine may not operate to vitiate an entire claim limitation. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997); Asyst, 402 F.3d at 1195. In essence, Amazin' Raisins cannot reclaim by equivalents what the language of the patent disclaims--fresh and non-dry fruit. See Asyst, 402 F.3d at 1195.

Accordingly, as the court finds that the evidence, even when viewed in the light more favorable to the plaintiff, is not sufficient to prove that the Ocean Spray process removes flavor from "dried fruit," Ocean Spray is entitled to summary judgment on the contentions that it infringes Claim 1 of the Mazin patent literally or under the doctrine of equivalents.
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II. Construction Of The Disputed Phrases

The parties dispute the construction of four phrases: "substantially powdered form," "mixing the drug and the carbohydrate material," "solid integral mass," and "drug-containing matrix." The four disputed phrases appear in independent Claims 1, 6,

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18, and 37 of the '737 patent. Claims 1 and 18 are method claims and Claims 6 and 37 are article of manufacture claims. The language of Claims 1 and 6 are representative of the disputed phrases. In full, Claim 1 provides (emphasis added):

1. A method for producing a drug-containing lollipop for use in transmucosal delivery of the drug to a patient, the method comprising the steps of:

(a) obtaining a pharmacologically effective dose of the drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus;

(b) obtaining a soluble carbohydrate material capable of forming a compressible confectionary matrix and capable of dissolving in the mouth of the patient;

(c) mixing the drug and the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material to form a drug-containing matrix such that the drug is dispersed substantially throughout the matrix, the drug-containing matrix being capable of releasing the drug for absorption through the mucosal tissues upon dissolution of the matrix in the mouth of the patient;

(d) compressing the drug-containing matrix in a mold to form an integral mass such that, when the integral mass dissolves in the mouth of the patient, the drug is released for absorption through the mucosal tissues; and

(e) incorporating a holder as part of the integral mass in order to form the drug-containing lollipop.

('737 patent, col. 26, 11. 35-60).

In full, Claim 6 provides (emphasis added):

6. A drug-containing lollipop for use in transmucosal delivery of the drug to a patient comprising:

a soluble, compressible carbohydrate material;

a pharmacologically effective dose of a drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus and being dispersed substantially uniformly throughout the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material and compressed with the carbohydrate material into a solid integral mass which is capable of dissolving in the mouth of the patient so that the drug is released for absorption through mucosal tissues of the mouth, pharynx, and esophagus upon dissolution of the integral mass in the mouth of the patient;

holder means secured to the integral mass so as to form a drug-containing lollipop, the holder means being configured so as to permit convenient insertion and removal of the drug-containing integral mass into and out of the mouth of a patient.

('737 patent, col. 27, 11. 12-33).

The essence of the dispute with regard to all four disputed phrases is whether they should be construed to require the absence of "free liquid." "Free liquid" is defined by Barr as "any liquid that not incorporated chemically into the fine particles, beyond that which may be sorbed naturally." (D.I. 41 at 15 n.8.) Cephalon takes no position with regard to whether Barr's definition of "free liquid" is correct. (D.I. 50 at 7 n.17.) The Court construes "free liquid" in accordance with Barr's definition.

Cephalon contends that the disputed claim phrases should not be limited by requiring the absence of free liquid, first, because the plain and ordinary meaning of the phrases does not require it, and second, because neither the specification nor the prosecution history shows any clear disclaimer of the use or presence of free liquid. In response, Barr contends that statements in the specification that describe the "present invention" limit the scope of the claims to preclude free liquid. Barr further contends that the prosecution history shows an effective disclaimer of the use of free liquid in the methods and articles of manufacture claimed by the '737 patent.

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The Federal Circuit's recent decision in Phillips v. AWH Corp. clarified the approach that a court should take in construing disputed terms of a patent claim. 415 F.3d 1303 (Fed. Cir. 2005) . Rather than beginning with a broad, dictionary definition and then limiting it in accordance with the specification and the prosecution history, the preferred approach is to focus "at the outset on how the patentee used the claim term in the claims, specification, and prosecution history . . . ." Id. at 1321. Here, both the specification and the prosecution history demonstrate that the inventions actually described and claimed by the '737 patent are a method of producing drug-containing lollipops using the compression of dry, powdered ingredients, and the products resulting from the use of that method. Nowhere in the claims, the specification, or the prosecution history do the inventors ever discuss the possibility of using a liquid as part of their invention. In addition, and more significant, many of their statements indicate that the inventors viewed their invention as enveloping only the dry mixing and compression of powders to form the drug-containing lollipops.

The following are illustrative examples. In the Summary of the Invention section, the '737 patent states that "the present invention teaches the combination of dry powdered ingredients by geometric dilution," ('737 patent, col. 5, 11. 43-45); and "flavorings, drugs, and other components (which may be insoluble in liquid form) are easily mixed when they exist as a dry powder," (Id. at col. 6, 11. 6-8). In the General Discussion of the Preferred Embodiments section, the '737 patent states that "the present invention teaches the mixing of solid powders at room temperature, as opposed to liquid components at elevated temperatures," (Id. at col. 7, 11. 62-65); and "because solid powders are combined together, constituents which may be chemically incompatible when in a heated solution or suspension can be mixed," (Id. at col. 8, 11. 3-6). In the Methods of Manufacture of the Preferred Embodiments section, the '737 patent states that "each of the components is mixed with the other components in dry form to produce the compositions of the present invention." (Id. at col. 11, 11. 47-49).

Cephalon argues that these examples do not amount to a clear disclaimer of the use of liquid in the claimed manufacturing method (D.I. 50 at 12-13), but that argument is misplaced. Whether or not there was an explicit disclaimer, the consistent use of a claim term by the inventor in the specification may serve to limit the scope of a claim. Nystrom v. Trex Co., 424 F.3d 1136, 2005 U.S. App. LEXIS 19748, 2005 WL 2218632, 6-7 (Fed. Cir. 2005).

"What Phillips now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to . . . those of ordinary skill in the art . . . that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."

Id. 2005 U.S. App. LEXIS 19748, at 7 (citing Phillips, 415 F.3d at 1321). Here, the inventors consistently referred to the "present invention" as teaching the formation of drug-containing lollipops through the compression of "dry" or "solid" powders. There is nothing in the written description or the prosecution history to suggest that they intended the disputed phrases to cover methods or articles using free liquid. Therefore, it would be improper for this Court to broaden the inventors' use of the disputed phrases and construe them to encompass the use of free liquid.

This result is not, as Cephalon argues (D.I. 50 at 12-13), the improper importation of limitations from the specification into a claim. This is a case where "the specification read as a whole suggests that the very character of the invention requires the limitations to be a part of every embodiment." Alloc, Inc. v. ITC, 342 F.3d 1361, 1369 (Fed. Cir. 2003).

For the reasons discussed above, the Court construes the disputed claim phrases as follows:

A. "Substantially powdered form" means "largely in the form of fine particles absent the presence of free liquid."

B. "Mixing the drug and the carbohydrate material" means "combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids."

C. "Solid integral mass" means "a drug, largely in the form of fine particles absent the presence of free liquid, pressed or squeezed together with the carbohydrate material, without the use of free liquids, into a unitary mass that is not liquid or gaseous."

D. "Drug-containing matrix " means "drug-containing powder matrix."

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Claim 18 recites a "drug delivery system constituted by at least 24 separate daily dosage units." The system comprises four to five "initial dosage units" each containing unopposed estrogen, "followed by twenty-one follow-up dosage units" each containing progestin. Seizing on language from the patent's written description stating that a "drug delivery system embodying the present invention contains a pharmaceutical package having at least 24 active dosage units arranged sequentially therein," '724 patent, col. 5, ll. 33-35, the district court construed claim 18 to refer to a single package of at least 24 pills in which the first pills contain unopposed estrogen and the remainder contain progestin. The court rejected the argument that the terms "initial" and "follow-up" in claim 18 refer to different portions of the menstrual cycle rather than to the placement of the pills in the package. The court also rejected BTG's argument that claim 18 should be construed to include multiple packages of pills used in sequence, so that the claim would read on any group of pills from successive packages in which 4 to 5 estrogen pills were to be taken before 21 progestin pills.

The district court's construction of claim 18 was unduly restrictive. While it is true that the written description of the '724 patent described the "drug delivery system embodying the present invention" as containing a single package having at least 24 dosage units in it, characterizing a particular drug delivery system as "embodying" the invention is not the same as stating that the term "drug delivery system" is limited to that embodiment. We find no other evidence that the patentee intended the drug delivery system claims (claim 18 and its dependent claims) to be limited in scope to a single one-month pill package, a construction that would allow any potential infringer to avoid liability through any of a number of elementary expedients, such as cutting each of its monthly packages in two.

Instead, we interpret the term "drug delivery system" in claim 18 to refer more generally to a system consisting of at least 24 separate dosage units of the types specified, to be taken in the specified order. The particular form that the drug delivery system takes is not critical. Thus, the drug delivery system could consist of a blister pack, a set of blister packs, a device that dispenses one pill each day over a lengthy period, or any other system that provides for the delivery of the appropriate drug at the specified point in time.

This is not to say that claim 18 reads on any drug delivery system that contains the recited groups of estrogen and progestin pills, regardless of the stage of the woman's menstrual cycle at which pills from each group are to be taken. Instead, we construe the references in claim 18 to "initial" and "follow-up" dosages of estrogen and progestin, respectively, to refer to the respective stages of the woman's menstrual cycle at which those drugs are taken. As discussed above, the patent explains that "throughout the present specification and claims," the menstrual cycle is characterized as commencing on the first day on which the onset of menses is noted. '724 patent, col. 3, ll. 8-9. Moreover, the patent repeatedly characterizes the contraceptive system in terms of the timing of the administration of the dosages of estrogen and progestin vis-a-vis the respective stages of the woman's menstrual cycle. For example, the Summary of the Invention specifically ties the delivery system of the invention to the stage of the menstrual cycle in which each of the two drugs is delivered:

> The present invention relates to a two-stage oral contraceptive system in which an unopposed estrogen compound is administered during a terminal portion of the first 7-day segment of the menstrual cycle, counting as Day 1 the onset of menses. . . . Following this initial administration of a relatively small dosage of an unopposed estrogenic compound, the second stage of the contemplated contraceptive system is commenced. In the second stage, a daily administration of a follow-up composition containing a progestin, alone or in combination with an estrogenic compound, is continued to about Day 28 of the menstrual cycle.

'724 patent, col. 2, ll. 26-45.

The scientific explanation of why the invention is effective, set forth in some detail in the patent, also ties the particular drugs administered to particular stages of the menstrual cycle:

> The present invention utilizes the fact that estrogen suppresses FSH [follicle stimulating hormone] levels. Thus, by administration of estrogen during the first seven days of the menstrual cycle, the follicular period, escape ovulation is less likely to occur if a dosage unit is missed.

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Estrogen administration at this early stage of the menstrual cycle also prevents recruitment of the dominant follicle and thus allows a reduction in the dose of the estrogen and progestin in the combination oral contraceptive needed between Days 7 and 28 of the menstrual cycle to prevent conception. . . .

Following the period of unopposed estrogen administration during the follicular period of the menstrual cycle, a second stage of administration comprising a 21-day regime of daily dosages of a standard oral contraceptive composition is followed. The second stage period comprises the administration of successive daily dosages of a progestin-containing compound.

'724 patent, col. 3, l. 63 to col. 4, l. 13.

Moreover, the portion of the written description that is specifically directed at describing the drug delivery system makes it clear that the claimed drug delivery system employs the method of contraception described earlier in the patent, which ties the types of drugs administered to particular stages in the woman's menstrual cycle. The patent explains: "This drug delivery system has at least four dosage units for the first stage of the method of the present invention and 21 dosage units for the second stage thereof." '724 patent, col. 5, ll. 37-39 (emphasis added).

The prosecution history is to the same effect. It makes clear that the inventor intended the system recited in claim 18, the independent "drug delivery system" claim, to mirror the method recited in claim 1, the independent method claim. In a 1995 amendment submitted to the PTO in connection with the reissue proceeding, the inventor explained that "the claims are drawn to a method of contraception by suppressing recruitment of the dominant follicle and to a drug delivery system for carrying out this method."

Accordingly, we construe claim 18 as requiring that the recited drug delivery system be designed to deliver the four or five "initial dosage units" of unopposed estrogen at an early stage of the woman's menstrual cycle, i.e., during the last four or five days of the first week after the onset of menses, and the "follow-up dosage units" of progestin during the remaining 21 days of the 28- day cycle. Construed in that fashion, claim 18 reads on the accused Duramed product only if the product is designed to deliver the estrogen pills near the beginning of the menstrual cycle and the progestin pills during the remaining period of the cycle.

To prove infringement of claim 18, BTG therefore must establish that a menstrual shift occurs after a woman begins using the Duramed product, such that the use of that product after an initial period of time results in the delivery of estrogen pills near the beginning of the menstrual cycle and progestin pills during the last three weeks of the cycle. As in the case of claim 1, the menstrual shift evidence that BTG introduced in the summary judgment proceedings is sufficient to overcome Duramed's motion for summary judgment. We therefore reverse the summary judgment on claim 18 and its asserted dependent claims, and remand for further proceedings on those claims.

We do not address the district court's ruling regarding the doctrine of equivalents, both because the issue of literal infringement of claims 1 and 18 is yet to be resolved and because the district court's ruling on the doctrine of equivalents was affected by the court's construction of the claims in suit. We therefore leave that issue for the district court to address, if necessary, in light of the claim construction we have adopted and in light of any further arguments the parties may wish to make in view of our decision regarding the scope of the asserted claims.

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A. Claim 15

Claim 15 of the patent reads "A drug delivery system comprising a spherical microporous polymeric network of interconnecting channels containing a drug wherein said drug is distributed essentially within the channels of said microporous polymeric network."

The parties first argue over whether "a drug delivery system" is a preamble that has no legal effect. "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one

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the patent protects." Bell Communications Research, Inc. v. Vitalink, 55 F.3d 615, 620 (Fed. Cir. 1995) (citations omitted). "In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Mktg. Int'l. Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1784, (Fed. Cir. 2002). Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." Rowe v. Dror, 112 F.3d 473, 478 (Fed.Cir.1997). Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed.Cir.2001). In this case, the preamble states the intended use for the invention, i.e. a drug delivery system. The preamble was not relied upon to distinguish the claimed invention from the prior art. Thus, it does not impose a claim limitation. Nonetheless, the Court construes the phrase "drug delivery system" to mean "a system for administration of drugs."
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A. "dry"

1. The Parties' Proposed Constructions

Rhodia contends that the word "dry" needs no construction, as it is a common English word. (D.I. 167 at 1.) If I do construe the word, Rhodia proposes that I construe it to mean "dry to touch; not wet. This term does not require that the particulates be completely dry." (Id.)

PPG proposes that I construe the word to "mean[] that the silica particulates, as a result of spray drying, hav[][e] little or no residual moisture content." (Id.) In support of its proposed construction, PPG offers an excerpt from the '234 patent specification stating that the patented silica "'particulates … [are] prepared by atomizing to dryness a pulverulent aqueous suspension of silica'" (id. (quoting '234 Patent at col. 5 ll. 10-30), and PPG directs me to some statements made during patent prosecution describing how the silica particulates are formed. (Id.)

2. The Court's Construction

I construe the word "dry" to mean that the silica particulates of the patented invention are dry to the touch, not wet. That is, they have little or no residual moisture content.

The parties could have and should have agreed with respect to the word "dry," as the word carries a common English meaning that is not contradicted by the intrinsic record. I adopt both parties' proposed constructions because they are not inconsistent and are both applicable and supported by standard dictionary definitions. See, e.g., MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 355 (10 ed. 2002).
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I. Dry Mix Composition

Dyno advocates that the meaning of a "dry mix explosive composition" as defined in the '950 Patent and in the industry means an explosive composition that is made by mixing an initially "dry" component, such as ammonium nitrate in prill form, with another component that may be a liquid, such as fuel oil, other oils, a water-in-oil emulsion, or water to produce an explosive composition that, once mixed, cannot be described as "dry" as that term is usually used outside the industry. In contrast, LDE contends that the term "dry mix explosive composition" means an explosive mixture of an oxidizer, fuel, and bulking agent such that the resulting composition has substantially no separate or free liquid that can be absorbable by some external material (such as paper) - i.e., the composition is substantially "dry to the touch." The Court adopts LDE's construction because it comports with the term's ordinary meaning in the industry and it is supported by the specification.

A. Ordinary and Customary Meaning

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The Court adopts LDE's proposed construction because it is in accordance with the plain and customary meaning of the word, both in the explosives art and in the customary meaning. There is a "heavy presumption" that a claim term carries its ordinary and customary meaning as viewed by one of ordinary skill in the art. Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1369 (Fed. Cir. 2003). The Court may review extrinsic evidence to assist it in comprehending the technology in accordance with the understanding of skilled artisans and as necessary for actual claim construction. Id. A court may look to extrinsic evidence to determine the customary meaning in the art. Vitronics Corp., 90 F.3d at 1584 & n.6 (noting that the Court may consult technical treatises and dictionaries at any time to better understand the underlying technology and may rely on dictionary definitions that do not contradict express definitions found in the patent documents). Due to the fact that the '950 patent does not expressly set forth any special definition for these terms, they should be given their ordinary and customary meaning.

The Court finds that the term "dry mix explosives composition" has an understood meaning in the explosives art. In the explosives industry, ANFO-based compositions come in essentially two different types: "dry mixes" or "slurries." Melvin Cook, The Science of Industrial Explosives 1 (1974); (O'Dette Patent, col. 1, Il. 10-16, Def.'s Ex. I.) Even in "dry mix" compositions, liquids are added to the dry material. See Surface Mining 543 (2d ed. 1990). 1 Several treatises discuss the composition of dry blasting agents. See, e.g., SME Mining Engineering Handbook 11-88 (1973). This reference defines a dry blasting agent as "a material or mixture that (1) consists of a fuel and an oxidizer, (2) is intended for blasting, (3) is not otherwise classified, and (4) provided that the finished product, as mixed and packaged for use or shipment, cannot be detonated by means of a No. 8 blasting cap. Id. at 11-88. This reference does not specifically discuss the consistency of a dry blasting agent; however it offers some guidance. The Handbook states that dry blasting agents can be purchased in several forms including: "in paper, polyethylene or burlap packages." Id. at 11-89. A blasting agent that contains a substantial amount of separable liquid could not be packaged in paper. In contrast, the same reference indicates that another form of blasting agent, a "slurry" is required to "satisfy the definition in the 'Dry Blasting Agent' section," but may have the consistency "anywhere from a liquid to a cohesive gel." Id. at 11-90. 2

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1 The Court recognizes that ANFO is a combination of ammonium nitrate and fuel. See Surface Mining 543 (2d ed. 1990) (stating that "a variety of fuels could be used with the ammonium nitrate" to form an ammonium nitrate dry mix and that "for maximum energy output, the oxygen balanced mix of approximately 94.4% AN to 5.6% FO gives the optimum mix").

2 Moreover, the reference states that "dry slurries" which "are essentially dry blasting agents that have been coated with a water barrier or a material that forms a seal when exposed to water, are under study. They show promise of being useful in moderately wet conditions. Experimental products that have increased density due to a larger proportion of liquid ingredients also have been studied." Id. at 11-90.

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The Science of Industrial Explosives indicates that there are two classes of high explosives called blasting agents: dry and slurry. The dry blasting agent ANFO is a simple mixture of prilled ammonium nitrate (AN) and fuel oil (FO) at the nearly oxygen balanced ratio of 94/6 AN/FO." Melvin Cook, The Science of Industrial Explosives 1 (1974). Although the reference does not discuss the texture or consistency of the dry blasting agent, the reference refers to slurries being "an aqueous solution." 3

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3 Aqueous is defined as "pertaining to, similar to, containing, or dissolved in water; watery." The American Heritage Dictionary 123 (2d ed. 1982).

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The Court draws from these references' failure to provide a consistency description for "dry blasting agents" but providing a consistency description for "slurry" blasting agents is that the consistency of a dry blasting agent is obvious; it is self-defined by using the word "dry." Moreover, the consistency is defined by implication. Both references, when describing a

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"slurry," created a contrast to a dry mix by stating that a "slurry" is required "to satisfy the definition in the 'Dry Blasting Agent' section," but may have the consistency "anywhere from a liquid to a cohesive gel," or noting that slurries are "an aqueous solution." SME Mining Engineering Handbook 11-90; Melvin Cook, The Science of Industrial Explosives 1. Based on these references, the Court determines that a "dry mix composition" may not have the consistency of "anywhere from a liquid to a cohesive gel" and it may not be "an aqueous solution."

Furthermore, several patents issued near the time the '950 Patent was issued are instructive on this issue. These patents do describe the consistency of this type of blasting agent; they describe "dry mix" as being an explosive composition having substantially no separate or free liquid within the composition. For example, in a patent issued in the United States, the patentee stated:

A "blasting agent" is an explosive material, generally comprising a mixture of at least two essential components: a fuel and an oxidizer. The agent can be either a dry powder or a slurry; slurries are generally aqueous systems. The choice of dry or slurry depends to some extent on the conditions in which the blasting agent is to be used. In modern blasting practice, dynamite and other systems related to nitro-glycerin have now almost completely been replaced by systems in which ammonium nitrate is the oxydiser, and a carbonaceous compound e.g. a hydrocarbon oil, is the fuel. These systems, if blended properly, are both effective blasting agents, and are comparatively safe to handle, in either dry or water-wet slurry form. They are generally described as AN-FO systems, or blasting agents.

In general, dry AN-FO systems have two disadvantages: low density, and low water resistance. In an attempt to overcome these main disadvantages, the water slurry systems were developed. These slurries generally contain about 15% water. But, in their turn, although the slurries do to some extent overcome the density and water resistance problems, in that a water-wet system will still explode the slurries also have the disadvantage that they are much less sensitive to detonation than the dry systems.

(O'Dette Patent at col. 1, Il. 10-34, Def.'s Ex. I.)

This concept is described in another patent that issued in Canada. The patentee stated:

This invention relates to explosives and more particularly is concerned with a novel "dry" explosive composition exhibiting high energy which gives reliable, uniform energy releases from batch to batch. The terms "dry mix," "dry explosive", "dry composition" and "dry explosive composition" as used herein are to be taken in their generally accepted meaning in the explosive art and refer to explosives which are granular or thick, paste-like in nature and have substantially no free liquid phase thereby differentiating from the slurry type blasting compositions. These dry mixes are further characterized as being non-pumpable.

Dry, granular explosives based on ammonium nitrate, e.g. the common ANFO compositions containing generally about 94 weight per cent prilled ammonium nitrate and about 6 weight percent fuel oil, have been commercially used for a number of years.

(Canadian Patent No. 888,102 at 1, Def.'s Ex. J.)

This patent also explains that liquids are added to the composition, however, the liquids are added in a way that does not create separate and solid phases in the composition; thus the product remains substantially a dry mix. It states:

Small amounts of liquids such as petrolic liquids, including natural mineral oils and fractionated products from oil refining, as well as other liquid organics having a favorable carbon-oxygen ratio such that there is no detrimental completion of the carbon with the metal for available oxygen in the systems, can be used to promote component packing and also act as additional fuel. Also, a small amount of naturally occurring water may be present such as that naturally absorbed by the nitrates present in the compositions. The quantities of such materials at a maximum to be employed within the ranges disclosed herein are such that formation of separate liquid and solid phases is not realized and the product is a dry composition; i.e. granular or pasty.

(Canadian Patent No. 888,102 at 5, Def.'s Ex. J.)

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The Court's construction of the term is further supported by another patent in which the patentee stated:

Due to the large percentage of solid ammonium nitrate [in the composition], the product is relatively dry to the touch and water is not easily absorbed from the formulation. The product can thus be packed in paper in the customary manner, and the product stored for at least six months without any substantial deterioration of properties.

(South African Reference at 3, 4-5, Def.'s Ex. K.)

The above references indicate that "a dry mix explosive composition" can contain certain amounts of liquid substances, however the composition remains a "dry mix" explosive because such liquids are added in an amount in which the composition remains relatively "dry to the touch," no free liquid forms in the composition, and liquid cannot be easily absorbed from the composition by paper or other materials. This construction of the term "dry mix explosive" is similarly consistent with the ordinary definition of the word as established in dictionaries. Under the ordinary meaning, dry is commonly understood to mean "free from liquid or moisture; not wet, damp, or moistened." Webster's Dictionary at 401 (Def.'s Ex. E.)

Dyno contends that the '950 patent defines what it means by "dry mix explosive compositions" by the examples and compositions taught and claimed. The Court finds Dyno's assertion unpersuasive. "[T]he claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). In the Background section of the patent, the inventors stated that "dry mix explosive compositions are all essentially different mixes of oxidizers and fuel." '950 Patent, col. 1, ll. 10-11. Plaintiff asserts that its conclusion is supported by the plain claim language because many of the claims in the '950 Patent include various liquids in the "dry mix explosive composition." 4 However, the Court finds that Dyno's proposed construction as set forth by way of example is not specific and definite enough to overcome the ordinary and customary meaning of the phrase that one of skill in the art would have understood. Moreover, the claims offered in support of Dyno's proposed construction actually fit within LDE's definition. As discussed above, the Court recognizes that the term "dry mix" covers explosives compositions "that include liquids." The Court notes that all ANFO-based explosive compositions "include liquids" since ANFO by definition, means ammonium nitrate (AN) and some type of fuel oil (FO). However, the Court finds that in an ANFO composition, fuel is added in such a manner as to be absorbed by the dry substance. Thus, the Court's interpretation does not ignore the specification and claim language that indicates that liquids are added to the composition.

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4 Many of the claims in the '950 Patent include various liquids in the "dry mix explosive composition" such as:

Claim 2: "a dry mix composition . . . further including a binding or holding agent in the form of a water-in-oil emulsion." '950 Patent, col. 4, ll. 52-55.

Claim 5: "a dry mix explosive composition . . . wherein said bulking agent includes from .5-10% (by weight) lipids." '950 Patent, col. 4, ll. 62-65.

Claim 6: "a dry mix explosive composition . . . further comprising dry oxidizer salts and carbonaceous liquid fuel." '950 Patent, col. 4, ll. 65-68.

Claim 10: "a dry mix explosive composition . . . further comprising dry oxidizer salts and carbonaceous fuel in the form of fuel oil." '950 Patent, col. 5, ll. 12-14.

Claim 12: "a dry mix explosive composition . . . wherein . . . said expolsive composition further includes a fuel in the form of fuel oil." '950 Patent, col. 5, ll. 19-22.

Claim 13: "a dry mix explosive composition . . . comprising . . . from 3%-6% (by weight) fuel oil." '950 Patent, col. 5, ll. 22 to col. 6, 1.5.

Claim 14: "a dry mix explosive composition . . . wherein said bulking agent contains from 0.5% - 10% (by weight) lipids.

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'950 Patent, col. 6, Il. 6-11.

Claim 15: "a dry mix explosive composition . . . further including a binding or holding agent in the form of a water-in-oil emulsion consisting of a water-based solution of one or more oxidizer salts held in disperse phase of oil and/or wax." '950 Patent, col. 6, Il. 12-16.

Claim 16: "a dry mix explosive composition . . . comprising . . . up to 60% (by weight) of a water-in-oil emulsion." '950 Patent, col. 6, Il. 17-21.

Claim 17: "a dry mix explosive composition . . . wherein said fibrous vegetable protein additive contains less than 20% (by weight) water." '950 Patent, col. 6, Il. 22-24.

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Moreover, the Court notes that both sides provide expert testimony regarding this issue. The parties' experts provide contradictory opinions of what the term "dry mix composition" meant to one of skill in the art when the patent application was filed. The Court will not rely on either of those experts. The Court finds the extrinsic evidence of treatises and patents issued around the time that the patent application was filed are more reliable than experts opining as to what was known to one of skill in the art more than ten years ago.

B. Specification

The Court finds further support for its construction in the patent specification. The specification repeatedly discusses the purpose of the invention. Specifically, the specification describes the problems associated with dry mix explosive compositions. Namely, they can be blown away during mixing or when loading the composition in the blast hole. '950 Patent, col. 2, Il. 30-32 to col. 3, Il. 41-33. Moreover, the specification indicates that the use of a "fibrous vegetable protein additive" is a critical aspect of the invention because it "assists in holding together the component parts of the composition and contributes towards resisting segregation, such as may be caused by wind, external forces, or during loading of blast holes and the like." '950 Patent, col. 2, Il. 26-32, col. 3, Il. 41-44.

The Court finds that the contrary construction offered by plaintiff would render the intended purpose of the invention unnecessary. Dyno's interpretation would cover both dry mix and slurry compositions. Such a construction would nullify the need and purpose of the invention; of having a fibrous additive. If a slurry mix is not susceptible to the problems discussed in the specification, such as needing a fibrous vegetable matter to prevent segregation due to external causes such as wind, then the composition described cannot be a slurry. The Court cannot provide an interpretation that would be contrary to the proposed purpose of the invention. Due to the discussion regarding the need for the "fibrous additive," this Court finds that the '950 Patent is not inclusive of slurry compositions.
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A. The Invention

The '806 patent, inventor Dr. Charles B. Hilton, is directed to a method of reducing iodide contamination in organic medium, particularly acetic acid. When the acetic acid is catalytically converted to vinyl acetate, the presence of iodide in more than about one part per billion poisons the catalyst. Such iodide contamination was known to be removable by contacting the acetic acid with silver-charged gel ion exchange resins, but the process was slow and impractical in large commercial volume. In seeking to improve the Celanese commercial process, Dr. Hilton discovered that by using a macroreticulated (sometimes described as macroporous) silver-charged cation exchange resin having specified characteristics, he obtained effective, rapid, large-volume removal of minute traces of iodine, to a degree of effectiveness, practicality, and utility not previously available.

When BP encountered iodide contamination in the commercial production of acetic acid BP sought other methods of removal before adopting the method, using a macroreticulated silver-charged cation exchange resin, that is charged with infringement. Celanese brought suit, asserting that the BP method infringed claims 2 and 6 of the '806 patent. Claim 2 is

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shown, with claim 1 from which it depends:

1. A method for removing iodide compounds from a non-aqueous organic medium comprising contacting the medium containing said iodide compounds with an ion exchange resin characterized in that the resin is a macroreticulated strong-acid cation exchange resin which is stable in the organic medium and has at least one percent of its active sites converted to the silver or mercury form.

2. The method of claim 1 wherein the non-aqueous organic medium is acetic acid and from about 25 to about 75 percent of the active sites are in the silver form.

The question of infringement turns on the meaning of the word "stable" in the claims. It is no longer disputed that all of the other claim elements and limitations are present in the BP method.

B. Review Procedure

Trial was to a jury, lasting for seven days. The jury found that the '806 patent was infringed and that the infringement was willful. The district court, denying duly made motions for a new trial and for judgment as a matter of law, entered judgment on the jury verdict. In its opinion the court identified the evidence in support of the jury verdict, identified the evidence supporting each party's theory of the meaning of certain disputed terms in the patent, and stated its own view of the meaning of these terms. In following this procedure the court relied on Read Corp. v. Portec, Inc., 970 F.2d 816, 822 n.3, 23 U.S.P.Q.2D (BNA) 1426, 1432 n.3 (Fed. Cir. 1992), as requiring or advising that a judicial statement be made of the meaning of disputed claim terms.

BP points out that Read v. Portec has been superseded by the decision in Markman v. Westview Instruments, Inc., 52 F.3d 967, 34 U.S.P.Q.2D (BNA) 1321 (Fed. Cir.) (en banc), cert. granted, 116 S. Ct. 40 (1995), and that Markman requires the Federal Circuit to decide de novo disputed questions of claim interpretation without deference to the trier of fact. BP points out that the disputed question of the meaning of the claim term "stable" is dispositive of the issue of infringement, and therefore that no deference need be given to the jury's finding of infringement. We agree that Markman so requires, and that the issue of infringement is decided by the meaning of "stable" as used in the claims. See Markman, 52 F.3d at 999, 34 U.S.P.Q.2D (BNA) at 1346 (Newman, J., dissenting) (pointing out that the disputed meaning of technical terms often decides the fact of infringement).

"Stable" is defined in the body of the specification as turning on the meaning of "dimension." Although "dimension" appears in the specification, not in the claims, implementation of the Markman decision appears to require that the meaning of "dimension" be given the same de novo determination by the Federal Circuit as the meaning of "stable" in the claims, lest we add further complexities to the trial of patent cases.

C. Construction of the Terms "Stable" and "Dimension"

A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning. ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579, 6 U.S.P.Q.2D (BNA) 1557, 1560 (Fed. Cir. 1988); Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387, 21 U.S.P.Q.2D (BNA) 1383, 1386 (Fed. Cir. 1992).

The meaning of "stable" as used in the claims is defined in the specification, col. 4, lines 31-35, as follows:

By the term "stable," it is meant that the resin will not chemically decompose, or change more than about 50 percent of its dry physical dimension upon being exposed to the organic medium containing the iodide compounds.

Thus the meaning of "stable" depends on the meaning of "dry physical dimension." On the BP position that "dry physical dimension" refers to volume, the BP process does not infringe; but on the Celanese position that "dimension" is a linear measure, there is literal infringement. Celanese states that linear dimension is the plain meaning of "dimension" as understood by persons of skill in this field and as used by the inventor. The BP position is that the term "stable" refers to volume as the physical dimension being measured, pointing out that the resin is in the shape of spherical beads and that the

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inventor in his research measured volume change. BP states that since its resin changes by more than 50% in volume when exposed to acetic acid, there can not be infringement.

The parties have provided us with photographs and experimental data, the testimony of the scientists who produced the data and interpreted it, and the testimony of experts in the field. Markman limits appellate reliance on extrinsic evidence to evidence in explanation of the technology and technical terms:

> Through this process of construing claims by, among other things, using certain extrinsic evidence that the court finds helpful and rejecting other evidence as unhelpful, and resolving disputes en route to pronouncing the meaning of claim language as a matter of law based on the patent documents themselves, the court is not crediting certain evidence over other evidence or making factual evidentiary findings. Rather, the court is looking to the extrinsic evidence to assist in its construction of the written document, a task it is required to perform.

52 F.3d at 981, 34 U.S.P.Q.2D (BNA) at 1331. However, we have found it necessary to rely on the evidence presented at the trial and credit certain evidence over other evidence, for we are not personally qualified to know the scientific meanings of "stable" and "dimension" as applied to macroreticulated cation-exchange resins in organic medium.

The evidence was sharply in conflict. The technical expert presented by Celanese testified as follows:

> Q. The second part of this has to do with its dimension. What does that mean?
>
> A. For the case of a spherical resin, it typically means its diameter.
>
> Q. The word "dimension," does it mean volume dimension?
>
> A. There is no such thing as volume dimension.

In turn, the BP expert testified that "dimension" meant volume dimension, stating that volume is what one skilled in the art would understand the term to mean:

> Q. Okay. Is that all the reasons [why you believe the term "stable" refers to volume]?
>
> A. There are at least two, perhaps three, additional very important reasons. One is that really it is the common practice of measuring changes that a resin experiences as it swells in a solvent in terms of volume percentage swelling. That is very amply documented in the literature. It is the easiest thing to do. Conversely, it is rather difficult to pick a single bead, measure the change in diameter of that bead, for example, because not every one bead in a sample of resin is identical to the rest of the beads. . . .
>
> . . . .
>
> The other rather important reason is that it is clearly the objective of this patent to distinguish between a resin that works because it has a porosity independent of swelling, such as Amberlyst 15, and another type of resin which has a porosity that depends upon swelling. That would be the gel type resin in the language used by the patent.

Both sides cite dictionary definitions that support their respective positions. Webster's Ninth New Collegiate Dictionary at 355 (1988) defines "dimension" as:

> measure in one direction; specif. one of three coordinates determining a position in space or four coordinates determining a position in space and time.

In partial contrast, the Concise Oxford Dictionary of Current English at 327 (8th ed. 1990) defines "dimension" as:

> a measurable extent of any kind, as length, breadth, depth, area, and volume.

This court has occasionally relied on general and technical dictionaries to determine the meaning of technical and other

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terms. In this case the dictionaries do not distinguish in a dispositive manner between the contested technical meanings. Further, a general dictionary definition is secondary to the specific meaning of a technical term as it is used and understood in a particular technical field. See Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563, 15 U.S.P.Q.2D (BNA) 1039, 1043-44 (Fed. Cir. 1990), cert. dismissed, 499 U.S. 955 (1991). Thus we return to the testimony at trial.

Dr. Hilton, the inventor, testified under direct examination as follows:

Q. What is meant by that sentence? In other words, how much swelling does that definition of stable accommodate?

A. A 50 percent change in dimension. The dimension is a distance. A dimension is not volume. Okay? It's the distance between my hands, or it's the distance across my chest. It's the radius of a sphere. A dimensional change in a spherical particle of 50 percent would lead to a swelling or a volume increase of 337 percent.

Dr. Hilton was challenged as to his assertion that "dimension" means distance or linear dimension, for he had measured the swelling volume of these resins during his research. The following exchange occurred on cross-examination:

Q. When did you first form a view that dimension means something other than volume dimension, dimension in this definition of stable?

A. I have never thought of volume as being a dimension. Dimension is not -- volume is not a dimension. Volume of a sphere formula, four thirds pi, distance cubed, radius cubed, distance times distance times distance. Dimension is a distance.

Q. You've never heard the term "volume" used as a dimension?

A. No.

Q. Yet you consider the volume expansion in order to design a guard bed, do you not?

A. Yes, you do.

Q. How many dimensions does volume have?

A. Volume has three dimensions.

The district court called Dr. Hilton's testimony "highly credible." Although we are at a disadvantage in attempting to make credibility determinations, the inventor's testimony reads as that of an expert in the field. See Palumbo v. Don-Joy Co., 762 F.2d 969, 976, 226 U.S.P.Q. (BNA) 5, 9 (Fed. Cir. 1985) (concluding that particular inventor's declaration as to claim meaning was by a "knowledgeable declarant"), overruled on other grounds, Markman, 52 F.3d at 979, 34 U.S.P.Q.2D (BNA) at 1329. Markman requires us to give no deference to the testimony of the inventor about the meaning of the claims. Id. at 983, 34 U.S.P.Q.2D (BNA) at 1332. However, we have treated Dr. Hilton's testimony as cumulative to the other evidence, and as enlarging our understanding of the technology and the usage of the disputed terms.

In addition, the specification of the '806 patent shows the resin characteristic of mesh size of the dry resin, a linear measure based on diameter. The specification also contains swelling data stated to be from the Technical Bulletin for Amberlyst (R) 15 and which, according to the inventor's testimony, is the percentage of swelling by volume. A videotaped "swelling test" that was presented to the jury is stated to have shown that Celanese's preferred Amberlyst (R) 15 resin expanded slightly more than 50% by volume in acetic acid, while BP's Purolite (R) resin of the same chemical composition (polystyrene cross-linked with divinylbenzene) expanded 103% by volume but less than 50% in linear dimension upon exposure to acetic acid.

The district court observed that BP's interpretation of "stable" as meaning dimension by volume would exclude from the claims the Celanese preferred embodiment that is described in the specification. However, if stable is measured by linear dimension, the claims include the resin that Celanese specifies in its invention. We share the district court's view that it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way. See Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75

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F.3d 1545, 1550, 37 U.S.P.Q.2D (BNA) 1609, 1612 (Fed. Cir. 1996) (claim interpretation that would exclude the inventor's device is rarely the correct interpretation).

We find that the more reasonable explanation is that volume has three dimensions, and we give weight to the argument that on the BP definition the Celanese preferred embodiment would not be within the claims of the Celanese patent. Thus we conclude that "dry physical dimension" as used in the specification means linear dimension. On this definition of dimension, and defining "stable" accordingly, the claims read literally on the BP process.
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With regard to literal infringement, the only ground we detect for disturbing the judgment is the claim clause "replacing said rinsing fluid with said drying vapor," which appears in each of the asserted claims. After holding a Markman hearing prior to trial, the district court construed the claim term "drying vapor" as "a vapor that facilitates the removal of liquid from a surface," wherein a "vapor" is "the gaseous state of a substance that, under ordinary circumstances, is usually a liquid or solid." CFMT, Inc. v. Steag Microtech, Inc., No. 95-442-RRM, slip op. at 11 (D. Del. Nov. 25, 1997) (unpublished memorandum opinion). Additionally, the court construed the claim term "replacing" as "taking the place of." Id. at 12. We have considered Steag's arguments that the district court's construction of "drying vapor" is wrong; however, we are not persuaded. Rather, we agree with these aspects of the district court's claim construction.
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1. "during the same cycle of a chromatographic simulated moving bed system"

The first dispute involves the phrase "during the same cycle of a chromatographic simulated moving bed system." (Joint Stmt. p. 5). Plaintiff asserts that no definition is needed here, but alternatively, Plaintiff would accept an interpretation that the phrase means "that the three product fractions are recovered during the cycle defined in the claim." (Joint Stmt. p. 5). Defendants, however, are concerned that this construction would cover a system where the fractions are recovered using two stages of columns (as opposed to single-state separation, i.e. a single series of columns). (Markman Hearing Tpt. p. 228). Thus, Defendants advocate an interpretation that the phrase means that "the three product fractions are recovered simultaneously from the same series of columns of the system…" (Emphasis added) (Joint Stmt. p. 7). For support, Defendants refer to Figure 1 of the '957 patent which diagrams the recovery of all three product fractions from the same series of columns. (DTX 2, Fig. 1). Additionally, Defendants point to the prosecution history of the '957 patent wherein the applicants represented to the PTO that "Applicants' process simultaneously recovers three fractions from molasses: rest molasses, sucrose and betaine." (DTX 13 at 2) (original underline emphasis).

The court finds that the claim language plainly states that the patent teaches "a method for the recovery of betaine and sucrose from beet molasses as substantially separate product fractions during the same cycle of a chromatographic simulated moving bed system…" (DTX 2, Col. 10) (emphasis added). In the Examiner's Statement of Reasons for Allowance, the Examiner explained that "none of the prior art of record teaches . . . a method for recovering betaine and sucrose as substantially separate product fractions during the same cycle of a chromatographic simulated moving bed system . . ." (DTX 15 at 2) (emphasis original). The plain language of the claim clearly explains that the three product fractions are recovered during the same cycle of a SMB system, which is what the Examiner found to be novel. Furthermore, the specification (Figure 1) illustrates the recovery of the three product fractions from the same series of columns of a SMB system. Thus, the court construes the disputed phrase to mean "the three product fractions are recovered from the same series of columns during the same cycle defined in the claim." So long as the three product fractions are recovered during the same cycle of the SMB process from the same series of columns, the construction is consistent with the claim language and the specification. Adding the word "simultaneously" to the construction, as suggested by Defendants, is thus extraneous.
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B. "dust-free and non-dusting"

1. The Parties' Proposed Constructions

Rhodia argues that I should construe "dust-free and non-dusting" to mean that "the level of dust present in the particulates, as well as the level of dust formed by the particulates during handling, is very low when compared to other silica forms." (D.I. 108 at 14.) Rhodia asserts that "'dust-free' should be viewed as related to the size component of the silica particulates' morphology …", and asserts that "the 'non-dusting' property is connected to the shape component of that morphology." (Id.) Therefore, maintains Rhodia, the "dust-free and non-dusting" morphology distinguish the patented silica particulates over prior art and give them the characteristic of producing less dust than other known forms of silica. (Id. at 14-15.)

Furthermore, contends Rhodia, it is illogical to treat the terms as requiring the patented silicas to be "completely free of dust and exhibit[] no dusting." (Id. at 16.) This is so, argues Rhodia, because "such a condition would likely never exist, and excluding all dust and dusting would be a completely unacceptable 'definition' of the terms since it would mean that the claims have no scope." (Id.) Rhodia asserts, moreover, that those skilled in the art, including those skilled in the art at PPG, used the words consistently with Rhodia's proposed construction. (Id. at 16-17.)

PPG proposes that I construe "dust-free and non-dusting" to mean that the "product produces no dust cloud whatsoever when poured under the test conditions in the specification relating to Figures 3-6, as in the example on the right hand side of those Figures." (D.I. 106 at 11.) In support of its proposed construction, PPG directs my attention to the '234 patent prosecution history, noting that the inventors added the phrase "dust-free and non-dusting" to the asserted claims to overcome prior art cited by the examiner. (Id. at 6-11.) Additionally, PPG references the inventors' arguments during patent prosecution made in relation to the phrase "dust-free and non-dusting", emphasizing that the inventors made no qualifying remarks, did not provide a definition for the language in the specification, and, in fact, used specific language indicating that the patented invention would not form dust. (Id.)

2. The Court's Construction

I construe "dust-free and non-dusting" to mean a level of dust formation associated with the silica particulates of the '234 patent, as measured in percentage weight according to DIN 53 583 3, that has a fines content value less than or equal to 13 and weight loss by abrasion value less than or equal to 0.5.

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3 "DIN 53 583" is an industrial standard provided by the Deutsches Institut fur Normung e.V., a self-governing institution of trade and industry responsible for the preparation of National Standards in Germany, for measuring the fines content and weight loss by abrasion of pelletized carbon black used as fillers in the rubber processing industry. The inventors of the '234 patented silica made specific reference to that standard as a means of measuring the dust qualities of their silica. I am referring specifically to DIN 53 583 dated November 1969. (D.I. 179 Ex. B.)

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Admittedly, this construction of "dust-free and non-dusting" is narrow and incorporates specifics from the written description of the '234 patent. However, the phrase "dust-free and non-dusting" cannot be viewed as meaning literally that the invention creates no silica dust at all. As Rhodia notes, that is neither possible nor what one skilled in the art would have expected the phrase to mean. It is, instead, a relative phrase, including within its ambit a desirable characteristic of the invention. Relative language in patent claims, though, can run afoul of the requirement that the claims must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P 2. Unless taken literally, the terms "dust-free" and "non-dusting" are no more particular or distinct than the words "hot" and "cold". Rhodia's proposed construction is similarly non-particular and non-distinct, as it employs the relative modifying phrase "very low".

Therefore, faced with ambiguity in the language, I adopt a construction based upon the only meaningful guidance provided in the patent. The inventors state in the written description of the '234 patent that "dust formation and abrasion were … measured" (D.I. 1, '234 Patent at col. 6 I. 66) according to the procedure detailed in DIN 53 583. A comparison of dust

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formation is then provided in Tables I and II in the '234 patent written description. Since Examples Five and Ten appear within the scope of the '234 patent claims and since the greatest DIN 53 583 values specified in those Tables is a fines content value of 13 and an abrasion loss value of 0.5, I adopt those DIN 53 583 values to give meaning to the phrase "dust-free and non-dusting". I note, in this regard, that Rhodia made specific reference to Table I and similar disclosures in the patent when arguing its proposed construction in this case. (D.I. 115 at 52-55.)
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B. Claim Construction of "dust-free and non-dusting"

Courts construe claim terms in order to assign a fixed, unambiguous, legally operative meaning to the claim. Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1367 (Fed. Cir. 2004). Claim construction begins with the intrinsic evidence of record, looking first to the claim language itself to define the scope of the patented invention. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "When the claim language itself lacks sufficient clarity to ascertain the scope of the claims," we look to the written description for guidance. Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1324 (Fed. Cir. 2003). We consult the written description "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582. Finally, we refer to the prosecution history, when it is of record, to discern the applicant's express acquiescence with or distinction of the prior art as further indication of the scope of the claims. Liquid Dynamics, 355 F.3d at 1368.

Here the district court determined that the disputed term "dust-free and non-dusting" could not be read literally to mean that the invention creates no silica dust at all. Claim Construction Opinion, 2003 U.S. Dist. LEXIS 18695, slip op. at 10. It reached this conclusion recognizing that the test results detailed in the written description indicate that the invention itself produces some dust, but less dust than the prior art. '234 patent, Figs. 3-6 & Tables I & II. Because a literal construction of the term "dust-free and non-dusting," which PPG advocates to mean "no dust cloud whatsoever," would not read on the preferred embodiment, we agree with the district court that a person of ordinary skill in the art would not interpret this term in that manner. As we have frequently stated, a construction that "would not read on the preferred embodiment … would 'rarely if ever [be] correct and would require highly persuasive evidentiary support.'" Interactive Gift Express, Inc. v. Compuserve Inc., 231 F.3d 859, 876 (Fed. Cir. 2000) (quoting Vitronics, 90 F.3d at 1583); Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996); see also Modine Mfg. Co. v. United States Int'l Trade Comm 'n ,75 F.3d 1545, 1550 (Fed. Cir. 1996) ("a claim interpretation that would exclude the inventor's device is rarely the correct interpretation"). The specification, prosecution history and prior art contain no "highly persuasive evidentiary support" that would require reaching such an unlikely construction. Modine Mfg., 75 F.3d at 1550.

Relying on the use of the term in the written description, Rhodia proposes that the term "dust-free and non-dusting" should be construed to mean that the level of dust "is very low when compared to other silica forms." As the district court recognized, this definition is "a relative phrase, including within its ambit a desirable characteristic of the invention," which can only be understood in comparison to the prior art. Claim Construction Opinion, 2003 U.S. Dist. LEXIS 18695, slip op. at 10. Accordingly, we look to the written description to determine the scope afforded to the comparative phrase very low levels of dust.

The written description includes ten examples of different forms of silica selected to illustrate the advantages of the invention. '234 patent, col. 3, l. 40 -- col. 8, l. 48. Varying combinations of the examples were subjected to testing designed to quantify certain physical properties in order to document and reveal the patentable characteristics of the claimed invention. The resultant physical properties of the ten examples are accumulated in Tables I and II of the '234 patent "such that the physiochemical properties of the various final products can be compared." '234 patent, col. 7, ll. 23-24. It is worth noting that, with the exception of particle size, all the physical properties for which numerical ranges are specifically provided in Claim 1, namely fill density, BET surface area and CTAB surface area, are outlined in Tables I and II. "Dust formation and abrasion as in DIN 53 583, in % by weight" appears in the last row of each of each table.

Although ten examples of silica products are referenced in the written description, the parties agree that only two of the examples constitute a product of the issued claims: Examples 5 and 10. Example 5 is twice referred to as the product of the invention: "As additional illustrations of the product according to the invention, Fig. 1 is an enlarged photograph of a pellet

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according to the invention (Example 5)," Id., col. 8, ll. 50-51, and "the product according to the invention (Example 5)," Id., col. 9, ll. 2-3. Example 10 is a refined version of Example 5. Id., col. 8, l. 45. Thus, although ten examples are addressed in the description, the preferred embodiment of Example 5 is repeatedly described as the invention itself. See id., col. 8, ll. 50-51 & col. 9, ll. 2-3.

The written description identifies two tests that were conducted to assess the tendency of the different examples to form dust. The first test was conducted on Examples 1, 2, and 4, whereas the second test was conducted on Examples 4, 5, 9 and 10. The first test used stable, fluidized beds of Examples 1, 2 and 4 and applied a vector gas to them to assess "the quality of the resulting product … expressed in terms of the formation of dust therefrom and its resistance to attrition." Id., col. 6, ll. 47-49. The description of this test concluded with the statement: "dust formation and abrasion were also measured in accordance with the standard DIN 583 [sic]." Id., col. 6, ll. 66-67.

Results according to the DIN 53 583 standard were provided for Examples 4, 5, 9 and 10. Id., Tables I and II. Because the only measurement of the dust produced by Examples 5 and 10 was articulated in terms of the DIN 53 583 standard, the district court properly incorporated that articulation into its construction of the term "dust-free and non-dusting." The results of the DIN testing showed that Example 5 produced more dust than Example 10. Accordingly, the court defined the outer limit for the level of dust created by the invention by reference to the DIN test results for Example 5.

We agree with the district court that the reference to the DIN test results for Example 5, as provided in the written description, reconciles the ambiguous claim language with the inventor's disclosure. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (indicating that interpreting claim language in light of the specification is proper when a term is "so amorphous that one of skill in the art can only reconcile the claim language with the inventor's disclosure by recourse to the specification"). As such, the court's construction of the term "dust-free and non-dusting" does not contravene the basic teaching that limitations from the specification should not be imported to the claims. Id. at 1186-87; see also E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 19 88) (counseling that it is improper to read a limitation "into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim"). Furthermore, this construction is consistent with the proposition that "when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment." Modine Mfg., 75 F.3d at 1551.

Rhodia challenges the court's construction on the grounds that the DIN 53 583 standard is not the only means by which to assess the amount of dust produced by the invention in comparison to the prior art. It asserts that the pour test, which was applied to Example 5, could also be used to determine the level of dustiness identified in the claim. The written description provides the following summary of the pour test:

The test comprises placing one liter of the product to be studied in an Erlenmeyer flask having a neck 4.4 cm in diameter. The flask is rocked and the flowability of the product visually observed. The height from which the product is spilled is 63 cm. The experiment is shown in Fig. 3 at the very instance that the product begins to flow/spill, and then, in the subsequent photographs, every two seconds thereafter.

It will be seen from the first photograph that the product according to the invention has a fluid appearance and was more freely flowing from the very outset. It can then clearly be seen that the product according to the invention not only flows better than a product in powder form (that prepared as in Example 2), but also flows better than a granulated product as prepared in Example 4. The granulated product is in the center of the photographs while the product according to the invention (Example 5) is at the right hand side thereof.

'234 patent, col. 8, l. 54 -- col. 9, l. 3. According to Rhodia, the results of the pour test, which appear in the patent only as a series of pictures, can serve as an alternative means of distinguishing the level of dust produced by the invention from the prior art and therefore it is inappropriate to limit the term "dust-free and non-dusting" to the DIN specifications. In support of this interpretation, Rhodia relies heavily on statements made during the prosecution of the patent showing that the pictures of the pour test were cited as evidence of the "non-dusting and free-flowing properties."

Rhodia's argument ignores the written description of the patent and the fundamental purpose of the claims, which is to define the scope of the patented invention. Liquid Dynamics, 355 F.3d at 1368. Although the pour test may also provide evidence of the dust produced by the various forms of silica, the results presented in the patent were only identified as

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evidence of the products' flowability. See '234 patent, col. 8, ll. 56-57. There is no language in either the claims or the written description that teaches application of the pour test to determine the level of dust production claimed by the invention and Rhodia's statements made during the prosecution of the patent cannot serve to fill that gap. "Although the prosecution history can and should be used to understand the language used in the claims, it … cannot 'enlarge, diminish, or vary' the limitations in the claims." Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995). Although the pour test and the stabilized fluid bed test may provide alternative means for assessing dust production, it remains that the only articulation of the dustiness of the claimed invention is made with reference to the DIN 53 583 standard.

Rhodia chose to define the term "dust-free and non-dusting" solely by reference to characteristics of the prior art and the only comparison of those characteristics was explained according to the DIN 53 583 standard. It was not improper for the district court to limit the scope of this relative term to the only disclosure on the subject made in the patent. We affirm the claim construction of the district court.

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C. "EPSP Synthase"

The Court must next construe the term EPSP Synthase. Claim 1 of the patent states: "A fertile transgenic Zea mays plant containing an isolated heterologous DNA construct encoding EPSP synthase wherein said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate . . . . " EPSP synthase is an abbreviation for an enzyme with the technical name of 5-enolpyruvylshikimate-3-phosphate synthase.

The legal arguments made by the Parties are similar to those made in relation to the term "promoter." DeKalb argues that there is no restriction on the term EPSP synthase and that the heterologous DNA can encode for any type of EPSP synthase, not just bacterial EPSP synthase. Syngenta argues that the specification limits the claim to bacterial EPSP synthase. The Court will not repeat the legal standard for claim interpretation as it relates to the interpretation of claim terms in light of the specification. See § III.B.2 above.

The plain language of the claim supports DeKalb's interpretation. There is no limiting language in the claim, rather, the claim asserts that the corn plant contains "an isolated DNA construct encoding EPSP synthase . . .. " United States Patent 5,554,798, claim 1. Furthermore, the Court does not find any limitation in the specification. Syngenta is correct that the specification does not specifically recognize the use of non-bacterial EPSP synthase, however, the specification does list a number proteins for which the DNA can encode. The passage in the specification states: "For example, the DNA can encode a bacterial dad A for increased lysine production; Bacilius thuringiensis (BT) t-endotoxin or protease inhibitor for insect resistance; bacterial EPSP synthase for resistance to glyphosate herbicide; and chitinase or glucen endo-1,3-B-glucosidase for fungicidal properties." United States Patent 5,554,798, column 8, lines 6-9, 62-63.

The Court is cognizant that Syngenta's argument is slightly more sophisticated, in that the items listed in the specification are examples for which the DNA can encode, and it lists bacterial EPSP synthase, not specifically as an example of a type of EPSP synthase, but in reference to the beneficial trait of glyphosate resistance. Syngenta argues that one of ordinary skill in the art would read this to mean that in order to provide glyphosate resistance, one should use a bacterial EPSP synthase. However, the Court is not convinced that this distinction is significant. It is still clear, from the specification language, that the invention can be used to encode for any number of beneficial traits, and that the use of bacterial EPSP synthase to encode for glyphosate resistance is just an example.

In Microsoft Corporation, the Federal Circuit did limit the meaning of a claim term based on the patent specification. 357 F.3d at 1347. The Court stated that "one purpose for examining the specification is to determine the patentee has limited the scope of the claims." Id. (internal citation omitted).

When the specification "makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question."

Id. at 1347 (quoting SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1341 (Fed.Cir.

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2001)). However, Microsoft Company, is distinguishable, as that case contains a number of specific references throughout the specification, that the invention is intended to run over or through a telephone line. 357 F.3d at 1347-1348. In that case, despite finding that the claim language was broad enough to include the infringing device, the Federal Circuit recognized that "[n]onetheless, the claims must be interpreted in light of the specification, which . . . repeatedly and consistently describes the local and remote systems of the claimed inventions as communicating directly over a telephone line." Id. Therefore, the court concluded that the invention was limited by the specification. Id. The present case does not have such specific language in the specification. In column 8, as quoted above, the patent does state "bacterial EPSP synthase," however, as correctly stated by DeKalb, these are merely examples of how heterologous DNA can be used to enhance beneficial features of a transgenic corn plant. United States Patent No. 5,554,798, column 8, lines 1-10. The patent specification is of little use in interpreting the term EPSP synthase, and certainly does not clearly limit the use of that term to bacterial EPSP synthase.

The Court agrees with Syngenta, that the only mention in the specification is to bacterial EPSP synthase, however, this is not conclusive. 15 The term of the claim itself is clearly without limitation. While, the Court recognizes Syngenta's argument that the interpretation of the claims is intended to provide the scope of the invention, and that in describing the invention, DeKalb at no point referenced any type of synthase outside of bacterial EPSP synthase. However, the Court cannot use this to place a limitation on the clear language of the claims. At no point in the specification did DeKalb make statements which suggest that the term EPSP synthase is limited to bacterial EPSP synthase. Rather, DeKalb stated that this was an example of what could be used to create glyphosate resistance. Therefore, the Court concludes that DeKalb's interpretation of the terms EPSP synthase is correct, and is not limited to bacterial EPSP synthase.

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15 The Court also notes that the prosecution history is equally silent on the definition of the term. Syngenta asserts that the prior version of a claim in the related '045 patent, DeKalb specifically stated bacterial EPSP synthase. Syngenta's Opening Claim Construction Brief, 10. However, this wording did not remain in the final claim. This language does not assist the Court as it could be read to mean that the final version of the claim was intended to be broader, than the first.

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Claim Construction

Central to the disposition of this appeal is the construction of the term "edetate," which is a limitation in each of the asserted claims. Claim 1 of the '520 patent is a representative claim. It reads, in pertinent part, as follows:

1. A sterile pharmaceutical composition for parenteral administration which comprises an oil-in-water emulsion in which propofol dissolved in a water-immiscible solvent, is emulsified with water and stabilized by means of a surfactant, and which further comprises an amount of edetate sufficient to prevent a no more than 10-fold increase in growth of each of Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027 and Candida albicans ATCC 10231 for at least 24 hours as measured by a test . . . .

'520 patent, col.11 ll.33-41 (emphasis added).

The district court construed "edetate" as "EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized." AstraZeneca, 352 F. Supp. 2d at 417. In construing "edetate," the court noted that the patentees defined "edetate" in the specification as "EDTA and derivatives thereof." '520 patent, col.4 ll.51- 52. The court proceeded to define the term "derivatives" by adopting a broad definition, specifically one that encompasses structural analogs of EDTA as well as synthetic derivatives. n4 The district court found that that broad definition of "derivatives," and thus "edetate," was most consistent with the use of the term in the specification.

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n4 Relying on the declaration of Michele M. Winneker, the court stated that a structural analog is "a compound that has the

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same structural components as the lead compound," even if it cannot practically be prepared from that lead compound. AstraZeneca, 352 F. Supp. 2d at 414 n.6. The court further stated that a synthetic derivative, in contrast, is a compound that "is synthesized from that lead compound" by one or more chemical reactions. Id.

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Mayne argues that the district court erred by adopting an overly broad definition of "edetate," particularly by including structural analogs as "derivatives." Mayne contends that that definition is unsupported by the intrinsic evidence. Mayne asserts that based on the intrinsic evidence, the correct construction of "edetate" is "the salts or anions of EDTA."

Abraxis responds that the district court correctly construed "edetate" to include structural analogs of EDTA. In defining the term "derivatives," Abraxis asserts that the district court properly adopted the broader definition, particularly in light of certain statements in the specification.

"Words of a claim 'are generally given their ordinary and customary meaning.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). A patentee, however, can "act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning." Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) (citation omitted). To a person of ordinary skill in the art, the term "edetate" can refer to the common name of an EDTA salt, namely, a salt of ethylenediaminetetraacetic acid. n5 J.A. at A6624. That term could also refer more generally to "[a]ll anions derived from [EDTA]." Id. at A6796. As the district court properly concluded, however, the patentees acted as their own lexicographers by defining "edetate" in the specification. In particular, the patentees stated that: "By the term 'edetate' we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof . . . ." '520 patent, col.4 ll.51-52. The district court correctly noted that a plain reading of that statement indicates that "edetate" includes "EDTA and derivatives of EDTA." AstraZeneca, 352 F. Supp. 2d at 413 (citing Webster's Third New International Dictionary 2372 (1993) for the definition of "thereof"). We disagree, however, with the district court's definition of "derivatives." Under the district court's construction, structural analogs of EDTA fall within the literal scope of the claim. The intrinsic evidence, however, fails to support that conclusion.

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n5 As noted in the specification, EDTA stands for ethylenediaminetetraacetic acid. '520 patent, col. 4 ll. 51-52.

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As this court recognized in Phillips, "claims 'must be read in view of the specification, of which they are a part.'" 415 F.3d at 1315 (quoting Markman, 52 F.3d at 979). We further stated that "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Id. (internal citations omitted). Here, the specification leads us to the conclusion that the patentees intended a more narrow meaning for the term "derivatives" than the definition adopted by the district court.

We first note that the part of the specification describing "edetate" reads:

By the term "edetate" we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof, for example the disodium derivative is known as disodium edetate. In general suitable edetates of this invention are those salts having lower affinity for EDTA than calcium. Particular derivatives of use in the present invention include trisodium edetate, tetrasodium edetate and disodium calcium edetate.

'520 patent, col.4 ll.51-57 (emphases added). Thus, the inventors listed several derivatives of EDTA that are suitable for the invention. Notably, all of these derivatives are salts of EDTA, none are structural analogs.

Abraxis argues, and the district court agreed, that the EDTA salts merely serve as examples of "derivatives" and thus "may not be used to limit a claim term." AstraZeneca, 352 F. Supp. 2d at 413. We disagree. When reading these statements in the context of the entire specification, it is evident that the listing of various EDTA salts defines the term "derivatives." At the very least, "derivatives" does not include structural analogs.

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Earlier in the specification, the patent discloses that considerable effort had been spent experimenting with a number of known preservatives including, among others, benzyl alcohol, sodium methyl hydroxybenzoate, sodium metabisulphite, and sodium sulphite. '520 patent, col.4 ll.22-28. The patentees noted that none of those preservatives met their requirements. Instead, after extensive experimentation, the universe of potential antimicrobial agents was narrowed down to one particular agent, i.e., edetate. The patentees explained:
We then investigated the possible use of other agents which might have the action that we sought. We unexpectedly found that edetate, which is not regarded as a broad spectrum antimicrobial agent was the only agent that would meet our requirements.

Id., col.4 ll.28-33 (emphasis added). That statement indicates that edetate possessed particular chemical properties that allowed it to work as an effective antimicrobial agent and that the term "derivatives" was not intended to extend broadly.

The patentees further proceeded to describe their experimentation. They noted:
As can be seen from the experimental section, sodium calcium edetate has some advantages over other additives but disodium edetate is exceptional. Accordingly, most preferably the edetate is disodium edetate.

Id., col.4 ll.64-67 (emphases added). That statement again emphasizes the significance of the patentees' discovery that edetate, or more particularly EDTA salts, worked as successful antimicrobial agents. Notably, in the experimental section which that statement references, the patent lists five different agents including sodium metabisulphite, sodium sulphite, hydroxybenzoates, sodium calcium edetate, and disodium edetate dehydrate. As noted above, three of those agents had already been rejected by the patentees as suitable agents. Significantly, the two remaining agents, sodium calcium edetate and disodium edetate dehydrate, which the patentees described as advantageous, preferable and "exceptional," are EDTA salts.

We thus conclude that the listing of EDTA salts as "[p]articular derivatives of use in the present invention," coupled with the statements regarding the uniqueness of edetate as the only successful antimicrobial agent, and the patentees' description of EDTA salts as advantageous, preferable, and "exceptional," limit the term "derivatives" to EDTA salts or compounds that maintain the EDTA free acid structure. Those statements are inconsistent with a definition of "derivatives" that includes structural analogs that can encompass a large number of non-derivative compounds. That definition fails to recognize that the patentees' discovery focused on the unexpected effectiveness of edetate and its salts as antimicrobial agents.

Abraxis argues that a narrow definition is unsupported by the specification, particularly in light of the patentees' statement that "[t]he nature of the edetate is not critical, provided that it fulfils the function of preventing significant growth of microorganisms for at least 24 hours in the event of adventitious extrinsic contamination." Id., col.4 ll.57-61. But, when read in context, that statement does support a narrow construction. It appears in the specification directly after the listing of the various EDTA salts that the patentees identified as suitable edetates. Thus, the statement that the "nature of the edetate is not critical" only connotes that the choice of which particular agent to use, i.e., EDTA or any EDTA salt, itself is not of critical importance, as long as the agent chosen can adequately prevent microbial growth. Contrary to Abraxis' suggestion, that sentence does not support a broad construction for "derivatives."

Abraxis also relies on another statement in the specification in support of its definition for "derivatives." Abraxis points to the patentees' use of the term "derivatives" in the context of silicone. The patent identifies" dimethicone" and "simethicone" as "silicone derivative[s]." Id., col.3 ll.40-41. Those compounds are not synthetic derivatives of silicone, but are structural analogs. Abraxis contends that using the term in that manner to broadly describe a class of antifoaming agents supports a broader definition for "derivatives" in the context of "edetate." We disagree. That term was used to describe a general class of antifoaming agents as disclosed in another patent. That is far removed from the pointed discussion in the specification identifying the "derivatives" of "edetate." Thus, the passing reference to silicone derivatives fails to overcome our conclusion that the patentees narrowly defined edetate "derivatives" to mean EDTA and its salts.

In light of the foregoing analysis, despite the district court's thorough analysis and review of the patent, we conclude that the district court erred by adopting a broad definition of the term "derivatives." Based on the specification, "derivatives" does not include structural analogs. Accordingly, the proper construction of "edetate" is EDTA and derivatives of EDTA, such as salts, but not including structural analogs.
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A. Edetate

The first disputed term of the '520 patent is "edetate." Claim 1 recites a pharmaceutical composition that comprises an oil-in-water emulsion having propofol solvent, which further comprises edetate. Plaintiffs suggest that the edetate ought to be defined as ethylenediamine tetraacetic acid ("EDTA") and "derivatives that are structurally related to EDTA regardless of how they are synthesized." (Pl. Mem. at 25; see also Tr. at 8; Declaration of Jules E. Goldberg, dated Aug. 17, 2004 ("Goldberg Decl.") Ex. P: Joint Claim Construction Statement.) Defendant urges this Court to adopt one of three definitions it proposes: (i) the salts of EDTA; (ii) EDTA and salts thereof; or (iii) EDTA and compounds synthesized from EDTA. (Def. Mem. at 2.)

"The first step in claim construction is to determine the ordinary and customary meaning, if any, that would be attributed to the term by those skilled in the art." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1346 (Fed. Cir. 2003); Astrazeneca AB, 384 F.3d at 1337 ("The goal of claim construction is to determine what an ordinary artisan would deem the invention claimed by the patent, taking the claims together with the rest of the specification."). AstraZeneca contends that "one of ordinary skill in the art here would have a Ph.D. in pharmaceutics or pharmaceutical microbiology, or a B.S. or M.S. with three to five years of experience and training in one or more of the following disciplines: pharmaceutics, industrial parenteral formulation, or pharmaceutical microbiology, or an M.D. with two or three years clinical experience administering parenteral products." (Pl. Mem. at 12-13; Declaration of Michele M. Winneker, dated Aug. 25, 2004 ("Michelle Decl.") Ex. 26: Expert Report of James Boylan, dated May 12, 2004, IT 43-44.) While Mayne disputes what one of one of ordinary skill in the art would know, it does not dispute AstraZeneca's characterization of the qualifications and experience such a person would have. (Defendant's Reply Memorandum, dated Aug. 31, 2004 ("Def. Reply Mem.") at 1-2; Goldberg Decl. Ex. K: Rebuttal Expert Report of Jeffrey Winkler, dated June 14, 2004.) Accordingly, this Court adopts AstraZeneca's description of one of ordinary skill in the art.

When construing a claim, a court starts by looking at the "words of the claims themselves, both asserted and nonasserted." Vitronics, 90 F.3d at 1582. "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics, 90 F.3d at 1582. The parties do not dispute that the patentees manifested their intent to act as their own lexicographers in defining edetate. (Def. Mem. at 8.) Indeed, the '520 patent includes the patentees' express desire to impart a specific definition to edetate: "By the term 'edetate' we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof." (Col. 4, lines 51-52.) See Astrazeneca AB, 384 F.3d at 1339 (finding that inventors "deliberately acted as their own lexicographers" where they provided express definitions to the relevant claim elements); Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001) (a patentee's redefinition away from the ordinary meaning of claim terms may occur expressly, when a patentee has "chosen to be his or her own lexicographer").

1. Defendant's First Proposed Definition

Defendant argues that even though patentees attempted to be their own lexicographers, they failed in their attempt, and therefore this Court must give edetate its "ordinary and customary meaning." (Def. Mem. at 9.) In particular, Mayne argues that the patentees failed in their attempts to define edetate clearly and that their attempted definition is ambiguous. (Mem. Def. 8-9.) This Court disagrees.

"It is black letter law that a patentee can 'choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning.'" Jack Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1360 (Fed. Cir. 2002) (quoting Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001)); accord Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed. Cir. 1999). "[A] definition of a claim term in the specification will prevail over a term's ordinary meaning if the patentee has acted as his own lexicographer and clearly set forth a different definition." 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1371 (Fed. Cir. 2003). This is because "the specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582. Further, the patentee may define a claim element more broadly than its ordinary meaning. See Jack Guttman, 302 F.3d at 1360.

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Here, the patentees explicitly defined "edetate":
By the term "edetate" we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof, for example the disodium derivative is known as disodium edetate.

(Col. 4, lines 51-53.) Mayne, however, argues that the patentees' use of "EDTA and derivatives thereof" is ambiguous and unclear. Therefore, Mayne's continues that the Court must give edetate its ordinary and customary meaning, which it posits is "salts of EDTA." (Def. Mem. at 10-11.) Mayne excludes EDTA itself from this first proposed definition. n5

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n5 Mayne's first proposed definition for edetate excludes EDTA, but its second proposed definition includes EDTA. (Def. Mem. at 2, 9, 11.)

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In ordinary English usage, "EDTA and derivatives thereof" means "EDTA and derivatives of EDTA." See Webster's Third New International Dictionary 2372 (1993) (definition of "thereof"). Indeed, the patentees expressly listed EDTA as an edetate and provide examples of EDTA derivatives that fit their definition, which conclusively establishes that the patentees intended to define edetate as "EDTA and derivatives of EDTA." (Col. 4, lines 52-57.) Further, when advancing its second proposed meaning for edetate, Defendant admits:

The passage from Column 4 of the '520 patent provides a clear and unambiguous interpretation of "edetate." In construing claim terminology, the court should look first to the intrinsic evidence and employ extrinsic evidence only when ambiguity arises. Based upon this reading of the Patents in Suit, no extrinsic evidence, i.e. dictionaries or expert evidence, is required to interpret the term "edetate."

(Def. Mem. at 13.) In light of Mayne's admission, its contention that patentees failed in their efforts to be their own lexicographers is absurd. Thus, this Court finds that the '520 patent clearly defines edetate and rejects Mayne's proposed definition of the term as "salts of EDTA."

2. Defendant's Second Proposed Definition

Next, Mayne argues that if this Court were to consider the intrinsic evidence, edetate must be defined as "EDTA and salts thereof." (Def. Mem. at 11-14.) This Court disagrees.

Mayne acknowledges that the specification defines edetate as EDTA and derivatives of EDTA. (Col. 4, lines 51-52; Def. Mem. at 12.) However, it argues that because the patentees only listed salts of EDTA as examples of EDTA derivatives, this Court must limit its construction of the word "derivatives" to mean salts. (Def. Mem. as 11-12.) The '520 patent teaches, for example, that "the disodium derivative is known as disodium edetate." (Col. 4, lines 52-53.) The '520 patent further explains that "in general suitable edetates of this invention are those salts having lower affinity for EDTA than calcium." (Col. 4, lines 53-55.) Finally, it states that "particular derivatives of use in the present invention include trisodium edetate, tetrasodium edetate and disodium calcium edetate." (Col. 4, lines 55-57.) Because all these enumerated examples are salts of EDTA, Defendant argues that the word "derivatives" must be construed to mean salts. (Def. Mem. at 12.)

It is well established that examples enumerated in a specification may not be used to limit a claim term. Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1151 (Fed. Cir. 2003) ("The general rule . . . is that claims of a patent are not limited to the preferred embodiment, unless by their own language."); Teleflex, Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1328 (Fed. Cir. 2002) (noting that the claimed invention may not be limited to preferred embodiments or specific examples in the specification); Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998) (noting that limitations from the specification are not to be read into the claims). The portions of the '520 patents that Defendant points to for support of its proposed definition include phrases such as "for example," "in general" and "particular derivatives of use." These phrases make it clear that patentees were merely providing illustrations. No portion of the specification expressly limits the definition of derivatives to the enumerated examples or disclaims EDTA derivatives not specified. Further, the '520 patent explains that "the nature of the edetate is not critical, provided that it fulfils the function of

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preventing significant growth of microorganisms for at least 24 hours in the event of adventitious extrinsic contamination." (Col. 4, lines 57-61.) Therefore, this Court disagrees with Defendant that the cited examples in the specification restrict the definition of edetate to EDTA and salts of EDTA.

Mayne argues that the prosecution history of the '520 patent also supports its contention that "edetate" must be defined as EDTA and salts of EDTA. (Def. Mem. 13-14.) They cite to the October 15, 1996 Office Action and the patentees' June 18, 1997 Amendment and Response ("Response"). (Def. Mem. at 13-14; Goldberg Decl. Ex. H.) However, a review of the patentees' Response clearly shows that the patentees and the Patent Office were not defining "edetate," but instead were discussing the proper amount of edetate in the claimed pharmaceutical composition and the microbiological tests. Thus, the prosecution history does not restrict the definition of "derivatives" to salts.

3. Defendant's Third Proposed Definition

Lastly, Defendant argues that the definition of "derivatives" must be limited to synthetic derivatives only. (Tr. at 47-48.) In contrast, Plaintiffs contend that "derivatives" must be defined as "compounds that have a similar structure to a parent compound" (Tr. at 9-10) and the definition includes both synthetic derivatives and structural analogs. n6 (Pl. Mem. at 12.)

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n6 A synthetic derivative of a lead compound is one that is synthesized from that lead compound. (Winneker Decl. Ex. 30 at 260.) In contrast, a structural analog is a compound that has the same structural components as the lead compound, but may not be synthesizable from that lead compound. (Winneker Decl. Ex. 30 at 20-21.) Said differently, it may be possible to prepare the structural analog from the lead compound theoretically, but not practically. (Winneker Decl. Ex. 30 at 20-21.)

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Where "the patentee has clearly defined a claim term, that definition 'usually . . . is dispositive; it is the single best guide to the meaning of a disputed term.'" Jack Guttman, 302 F.3d at 1360 (quoting Vitronics, 90 F.3d at 1582). However, the written description must unambiguously set forth a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term." Process Control, 190 F.3d at 1357; accord Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998) ("The patentee's lexicography must . . . appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994))). Accordingly, as already stated, because there is no dispute that the patentees intended to define edetate, the sole question before this Court is whether they succeeded in defining edetate with "with reasonable clarity, deliberateness, and precision" for one of ordinary skill in the art.

The '520 patent teaches that edetate is to be construed as EDTA "and derivatives thereof." (Col. 4, lines 51-52.) The key disagreement between Plaintiffs and Defendant is with respect to the definition of "derivatives." (Col. 4, lines 51-52; compare Tr. at 9-10, with Tr. at 45-47.)

The specification does not expressly define the term. (Tr. at 9, 12.) The parties have cited to a plethora of dictionaries, treatises, scholarly articles and issued patents for support of their proffered definitions. (See, e.g., Tr. at 14-16, 45; Pl. Mem. at 16; Winneker Decl. Exs. 28, 41, 43; Def. Mem. at 10, 12, 15, 17-19; Goldberg Decl. Exs. D-G, J, N-O, R-S.) While some of these sources express Mayne's limited definition, others define "derivatives" more expansively. (Compare Goldberg Decl. Ex. J: The American Heritage Dictionary 489 (4th ed. 2000) ("American Heritage"), with Winneker Decl. Ex. 41: Webster's Third New International Dictionary 608 (1971) ("Webster's")).

The Federal Circuit has explained that dictionaries, encyclopedias and treatises are reliable sources for determining the established meanings for the claim terms:

Dictionaries, encyclopedias and treatises, publicly available at the time the patent is issued, are objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art. Such references are unbiased reflections of common understanding not influenced by expert testimony or events subsequent to the fixing of the intrinsic record by the grant of the patent, not colored by the motives of the parties, and not inspired by litigation. Indeed, these materials may be the most meaningful sources of

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information to aid judges in better understanding both the technology and the terminology used by those skilled in the art to describe the technology.

Texas Digital, 308 F.3d at 1202-03.

This Court begins its analysis by trying to establish the ordinary meaning of the disputed term with an examination of general purpose dictionary definitions. See Novartis Pharm. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306, 1308 (Fed. Cir. 2004); Texas Digital, 308 F.3d at 1203-04; see also Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378 (Fed. Cir. 2002).

American Heritage defines a derivative as "[a] compound derived or obtained from another and containing essential elements of the parent substance." American Heritage 489. Webster's defines a derivative more broadly: "a chemical substance that is so related structurally to another substance as to be theoretically derivable from it even when not so obtainable in practice (the methoxy of naphthalene)." Webster's Int'l 608. Thus, while some of the general purpose dictionaries provide support for Defendant's suggested definition for derivative, others define the term as proposed by Plaintiffs.

Technical dictionaries can also assist claim construction by showing how those skilled in the art define "derivatives." Moba v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed. Cir. 2003) ("As this court has repeatedly counseled, the best indicator of claim meaning is its usage in context as understood by one of skill in the art at the time of invention."); Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1373 (Fed. Cir. 2001) (holding that courts may consult scientific dictionaries and technical treatises to determine the ordinary meaning of a technical term to persons skilled in the art). Here, again, the cited sources provide divergent definitions. Defendant cites to treatises that support its limited definitions. For example, Mayne's cited treatises support its first proposition that "derivatives" ought to be defined as "salts of EDTA" (Def. Mem. at 10), as well as its third proposed definition of "EDTA and compounds synthesized from EDTA" (Def. Mem. at 15-16, 18). In contrast, Plaintiffs' cited references suggest that derivatives ought to include both synthetic derivatives and structural analogs. (Pl. Mem. at 13, 16.) The cacophony of dictionary definitions cited by the parties does not aid this Court's analysis of whether either definition is conclusively established. n7

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n7 This Court notes that the Federal Circuit is currently examining the role of dictionaries in claim interpretation. Phillips v. AWH Corp., 376 F.3d 1382 (Fed. Cir. 2004).

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Where terms have multiple dictionary definitions "the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor." Texas Digital, 308 F.3d at 1203 (citing cases). "If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital, 308 F.3d at 1203. Therefore, this Court must examine the specification and the prosecution history to determine which definition or definitions are consistent with the spirit of the claimed invention. See Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc., 112 F.3d 1137, 1143 (Fed. Cir. 1997) ("Although limitations may not be read into the claims from the specification, claims are to be read in view of the specification of which they are a part."); see also Dunhall Pharms., Inc. v. Discus Dental, Inc., 243 F.3d 564, (Fed. Cir. 2000) ("Whether or not a specific definition of a term is present in the specification, 'the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.'" (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985))); Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1372 (Fed. Cir. 2002).

The '520 patent teaches that disodium edetate, trisodium edetate, tetrasodium edetate and disodium calcium edetate are appropriate EDTA derivative. (Col. 4, lines 51-57.) However, the '520 patent notes that the exact type of edetate is not important, as long as the chosen edetate can prevent significant growth of microorganisms for at least twenty-four hours if there is adventitious extrinsic contamination. (Col. 4, lines 57-64.) Thus, the specification supports a broad definition of edetate: EDTA or an EDTA derivative that can prevent significant growth of microorganisms for at least twenty-four hours.

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In support of their proffered definition, Plaintiffs, pointing to the background of the '520 patent, argue that patentees used "derivatives" broadly to describe both synthetic derivatives and structural analogs. (Pl. Mem. at 14.) For example, they note that the '520 patent lists the antifoaming agents dimethicone and simethicone as silicone derivatives, even though these agents are not synthetically derived from silicone. (Col. 3, lines 40-41; Winneker Decl. Ex. 32 at 48:15-51:21.) Defendant does not dispute that dimethicone and simethicone are structural analogs of silicone, but instead argues that the patentees did not use the word "structural analog" in their patent. (Tr. at 55-56.) Therefore, Mayne argues that patentees definition of derivatives in the context of EDTA does not incorporate structural analogs. (Tr. at 55-56.) However, it is unnecessary for patentees to expressly use the words "structural analog" to describe all the derivatives contemplated by their invention. See Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification"). Patentees may provide a broader definition by implication, such as by incorporating examples that go beyond the literal meaning. Vitronics, 90 F.3d at 1582 (noting that the specification may define claim terms by implication); see also Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-80 (Fed. Cir. 1995).

Mayne cites Astrazeneca AB for the proposition that this Court ought to limit edetate's definition to "the particular compounds the Plaintiffs tested." (Correspondence from Jules Goldberg, dated Sep. 30, 2004.) The holding of Astrazeneca AB is inapposite to this case. There, the patentee disavowed the very features that it was attempting to incorporate into the claim definition: "Where the general summary or description of the invention describes a feature of the invention (here, micelles formed by the solubilizer) and criticizes other products (here, other solubilizers, including co-solvents) that lack that same feature, this operates as a clear disavowal of these other products (and processes using these products)." Astrazeneca AB, 384 F.3d at 1340. Here, by contrast, the patentees did not disavow structural analogs from their definition of derivatives or criticize their usage. Instead, as already discussed, the patentees use of the word derivatives suggests that they intend their definition to incorporate compounds that are similar in structure to the parent compound.

It bears noting that this Court evaluates what the specification teaches one of ordinary skill in the art. As noted earlier, there is no dispute here that one of ordinary skill is fairly sophisticated in the art of the claimed invention. See supra at III.A. In light of the broader use of the term derivatives in the '520 patent and the teaching that the exact nature of edetate is not important as long as it fulfills the primary function of slowing significant microbiological growth, this Court finds that one skilled in the art would understand that the patentees intended to use the broader dictionary definition of derivatives. In particular, this court finds that one of ordinary skill in the art would understand that the patentees intended to define derivatives as "a chemical substance that is so related structurally to another substance as to be theoretically derivable from it even when not so obtainable in practice." Therefore, the proper definition of edetate includes EDTA as well as synthetic derivatives and structural analogs of EDTA, so long as they prevent significant growth of microorganisms for twenty-four or more hours.

Accordingly, this Court defines edetate as "EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized, and which can prevent a no more than 10-fold increase in growth of each of Staphylococcus aureus ATCC 6538, Escherichia coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027 and Candida albicans ATCC 10231 for at least 24 hours."
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A. "Edible Mass"

At issue is whether the term "edible mass," as used in Claims 30, 32-34, 38-40, 42, and 44, can include a lipid. The claim language suggests that it cannot. First, several of the asserted claims do not recite the presence of a lipid. See, e.g., Claims 32-34, 38-40, and 44.

Furthermore, according to the "edible mass" claims that do include lipids, the manufacture of the edible mass is complete prior to the addition of any lipid material. Thus, for example, Claim 41 (upon which Claim 42 is dependent) discloses a two-step process for "preparing a simulated, non-cultured food product" by

> admixing dry particulate rennet casein as the principal source of protein, water and an edible solvation agent [deleting

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specific quantities and types of solvation agent] . . . and maintaining said admixture at said temperature for a time period of about 2 minutes to about 4 minutes to solvate said rennet casein to form an edible mass . . .

admixing with said edible mass a bland, edible lipid material . . .

heating said new admixture to a temperature of about 150 [degrees] F. to about 300 [degrees] F. with agitation, and maintaining said new admixture at said temperature with agitation to produce said food product.

(Patent 728, col. 16, l. 63 - col. 17, l. 27.) The recipe for "edible mass," found in the first quoted paragraph, lists rennet casein, water and an edible solvation agent as the only ingredients. The second quoted paragraph explicitly demonstrates that the "edible mass" is formed prior to the addition of a lipid, otherwise the phrase (edible mass) could not be used as it is. Finally, the third paragraph describes the edible-mass-plus-lipid created pursuant to the second paragraph as a "new admixture" which, after additional cooking, produces "said food product." Again, if the edible mass was not complete until the addition of a lipid, the phrase "new admixture" would be inappropriate. 6

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6 Claim 41 is representative of all the "edible mass" claims that teach the presence of a lipid: Claims 25, 29, 30, and 37.

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The prosecution history supports our conclusion that "edible mass" as used in Patent 728 is complete prior to the addition of any lipid material; that it is made from rennet casein, water and solvation agents. In an amendment submitted to the patent examiner on September 20, 1995, Schreiber relied on the lack of lipid in the edible mass to distinguish prior art:

Claims 1-3, 26-28, 32-34 and 38-40 all require that an edible mass without lipid material be formed. These claims differ from the method used to make the [1976 cheese] because it was not made by first solvating the rennet casein to form an edible mass and then mixing a lipid material with the edible mass.

(Saputo Ex. G, Tab 49, Amendment of Sept. 20, 1995, at 17.) The only amendment submitted after the 1995 Amendment contains purely formalistic changes, such as adding commas and underlining material not contained in Patent 800. (See, generally, Saputo Ex. G, Tab 50, Amendment of Sept. 3, 1996.) Schreiber cannot successfully repudiate an interpretation so explicitly argued to the Patent Office, particularly when the interpretation was advanced to avoid prior art. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.").

Schreiber advances three arguments in support of its position that edible mass may include lipids. First, it points to various parts of the specification. But neither the narrative sections nor the examples cited by Schreiber ever use the phrase "edible mass"; instead, they refer to a "paste-like mass," (Patent 728, col. 2, l. 26), or a "smooth, fluid mass," (Patent 728, col. 7, l. 57). Schreiber specially defined "edible mass" to the patent examiner and may not escape that definition by resort to other terms.

Second, Schreiber argues that the removal of the phrase "without lipid material" from Claim 32 disproves our conclusion. In 1993 Schreiber proposed an amendment to Claim 32: "A substantially homogenous, aqueous, [non-lipid containing] edible mass without lipid material." (Saputo Ex. G, Tab 33, Amendment of January 14, 1993, at 5 (brackets, underline, and double underline in the original).) Schreiber maintains that the deletion of this language shows that the Patent Office did not rely on a lipidless edible mass to distinguish the 1976 cheese. But both "[non-lipid containing] and "without lipid material" were deleted by September 1994, long before the 1995 Amendment, in which Schreiber persisted in distinguishing the "edible mass" claims from the 1976 cheese on this basis. (See Saputo Ex. G, Tab 44, Amendment of Sept. 26, 1994, at 9 ("32. (Four times amended) A substantially homogenous, aqueous, edible mass which comprises . . .").) This earlier change, therefore, does not undermine our reliance on Schreiber's 1995 representations.

Finally, Schreiber insists that the transitional term "comprises" used in many of the "edible mass" claims leaves the ingredient list open-ended. However, as Schreiber argued to the Patent Office Board of Appeals, "while it is true that the claims use the phrase 'comprising,' other portions of the claim require the exclusion of the lipid material found in the May,

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1976 product." (Saputo Ex. G, Tab 22, Schreiber Reply Br. to the Bd. at 8; see also Tab 44, Amendment of Sept. 26, 1994, at 16-17 (In the context of "comprises/consisting of" transition, Schreiber states, "as noted during the interview, col. 5 line 65 to col. 6 line 11 of the patent specification provides support for an edible mass that includes solvated rennet casein and other ingredients but excludes lipids.").)

At base, Schreiber spent twenty years trying to convince the Patent Office that its edible mass claims were not barred by the 1976 cheese because the "edible mass" step, unlike the first step in manufacturing the 1976 cheese, does not include a lipid; rather, an edible mass is made from rennet casein, water, and a solvation agent. It cannot, at this late date, shift gears for the sole purpose of alleging a cause of action against Saputo. The phrase "edible mass" excludes the presence of lipid material.
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F. "EFFECT" ('939 PATENT).

Finally, King contends the term "effect" as used in claims 14-17 in the '939 patent is "impermissibly vague." (Pls.' '939 Opening Markman Br. 27.) "Effect" appears in claims 14 and 16 in the phrase "[an amount of the opioid antagonist] released . . . insufficient to produce an antagonistic effect" and in claims 15 and 17 in the phrase "[an amount of the opioid antagonist] released . . . will substantially block an effect of the opioid agonist." ('939 patent, col. 54, ll. 1-32.) King's general argument is that for "effect" to have a definite meaning, these claims must give the specific amounts of particular opioid antagonists that are "insufficient to produce an antagonistic effect" and "will substantially block aneffect of" a specified opioid agonist. King adds that such a task is virtually impossible because the amount changes from patient to patient and from antagonist to antagonist.

Purdue, in turn, offers "does not rise to a level which significantly impacts or changes the analgesic efficacy of the dose of opioid agonist included in the dosage form" as the definition of "insufficient to produce an antagonistic effect" and asserts that "effect" should be given its plain and ordinary meaning in claims 15 and 17. (Def.'s '939 Opening Cl. Constr. Br. 30.)

I find that "effect" does not need to be defined. It is a term that is relative by nature and widely used in pharmaceutical patents. For example, "'effective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003).

King argues that "effect" must be precisely defined so as to better analyze the infringement claims, but certain ambiguities are permissible.

Claims are often drafted using terminologythat is not as precise or specific as it might be. As long as the result complies with the statutory requirement to particularly point out and distinctly claim the subject matter which the applicant regards as his invention, that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product.

PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998) (internal citation, quotation marks, and alterations omitted). The PPG court held it was proper for the district judge to let the jury decide whether amounts of iron sulfide in the patented glass have a "material effect" on the glass, rather than resolve the issue in claim construction, because the patent was silent about what constituted a material effect on the properties of glass. Id. at 1354-55. "[A] sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems . . . is properly left to the trier of fact." Acumed LLC v. Stryker Corp., 483 F.3d 800, 806 (Fed. Cir. 2007).

King's contentionthat the amount will differ from patient to patient, while true, is not a basis for finding a pharmaceutical patent indefinite because setting out the amounts of active ingredient necessary for an "effect" in every person is an impossible task. The '939 patent will require experimentation such as clinical trials to determine "effective amounts," but clinical trials are not considered "undue" experimentation. See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365-66 (Fed. Cir. 2008). One skilled in the art in pharmaceutical manufacturing is certainly accustomed to testing dosages and performing clinical trials to determine the amounts of active ingredients necessary for effect in different

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population groups, but at the same time, testing will never achieve a precise "effective amount" for every conceivable patient. Thus, the fact that there is no one-size-fits-all "effective amount" dictated in the '939 patent certainly cannot be a reason to find the patent indefinite. Accordingly, I find, as the court in PPG, "effect" is definite enough for a jury to determine whether another pharmaceutical product infringes on the '939 patent, and therefore, does not need to be anyfurther defined.
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C. "EFFECT"

Plaintiffs in support of their construction of "effect" point to the description in the written language of the '963 patent of what occurs when the product called for by the claim comes into contact with the urushiol ". . . the solution . . . bond[s] with the urushiol . . ." and "a secondary effect . . . is that [the solution] interacts with the C filters of the nervous system . . ." (col.3, ll 62-67).

Defendants' construction of "effect" is more restrictive and goes beyond the "effect" of the composition on the skin to describe what occurs as the urushiol penetrates the skin.

Again, the Court is in the dark of the consequences of the differences between the competing constructions.

"Effect" is not a technical term. There is no indication that the inventor intended to give any special meaning to the word. The American Heritage Dictionary of the English Language defines "effect" as "the way in which something acts upon or influences an object."

"Effect" simply means the consequences described in the specification which follow on the application of the composition to the affected area.
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The Court has construed the word "effective" to mean safe and efficacious finding that "[s]afety was a paramount concern of the inventors" of the '741 patent. Daiichi Pharm. Co., 380 F. Supp. 2d at 488.
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3. The Term "Effective Amount"

Subpart (a) of claim 1 of the '505 patent requires an "effective amount of a material selected from the group consisting of omeprazole plus an alkaline reacting compound," (P1, col. 16:43-45), and the parties dispute the meaning of the phrase "effective amount." 24 The dispute between Astra and the four Defendants before the court boils down to a disagreement over whether the phrase "effective amount" applies to the omeprazole alone or to both the omeprazole and the alkaline reacting compound in the core. Astra argues for the former, while Defendants prefer the latter construction. The Second Wave Defendants also weigh in to argue that the claimed oral structure cannot be construed to encompass a capsule containing multiple "core regions," each one of which does not have an "effective amount" of omeprazole because claim 1 of the '505 patent requires a single core region that contains the entire "effective amount." The court agrees with the Second Wave Defendants in so far as the court finds that each core or core region must contain an "effective amount." 25 The plain language of subpart (a) of claim 1 dictates that finding. The question remains--an effective amount of what? 26

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24 The phrase "effective amount" also appears in claim 14 of the '505 patent, but it does not appear in the claims of the '230 patent. Even though the claim limitation of an "effective amount" is not present in '230 patent, the court notes that its

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construction of the term "alkaline reacting compound" requires the stabilization of the acid labile compound. Even though no explicit ratio or quantity relationship is present in the claims of the '230 patent, that requirement is implicit in the characteristics of the ARC as defined by the patentees. According to the disclosures in the specification of the '230 patent, unless there is sufficient ARC in the core to create a micro-pH around the particles of the active ingredient of not less than pH 7, the formulation simply will not work. The '230 patent, however, must be enabling, and therefore, "effective amount" is found implicitly in the ARC claim limitation.

25 As will become apparent in the portion of this court's opinion devoted to infringement analysis, there is no prejudice to Astra in this court's decision to consider the claim construction arguments proffered by the Second Wave Defendants with respect to the phrase "effective amount." Under the construction adopted by the court, the ANDA products of Defendants Genpharm, Cheminor, and Andrx contain an "effective amount" of omeprazole and an alkaline reacting compound in each individual core.

26 Adopting Astra's construction for "effective amount," which requires a therapeutically effective amount of omeprazole, the Second Wave Defendants argue that an "effective amount" cannot be construed to cover an oral pharmaceutical preparation with multiple pellets in which no single pellet has a core region with sufficient omeprazole to equal an entire therapeutically effective amount of omeprazole. This theory would restrict findings of literal infringement such that claim 1 of the '505 patent would cover only a tablet with a single coated core with a therapeutic amount of omeprazole or a capsule containing pellets where each pellet has a coated core with a therapeutic amount of omeprazole. Of course, the First Wave Defendants are precluded from relying on that argument in support of noninfringement. It has never been raised by a First Wave Defendant and no notice was provided to Astra of that position prior to this trial. Astra has had no opportunity for discovery of evidence that would support claims of infringement under the doctrine of equivalents. It seems likely that any Defendant whose formulation infringed literally when made in the form of one large core would also infringe under the doctrine of equivalents by using numerous small cores or beads filled into a capsule.

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Astra's proposed construction of the claim term "effective amount" is a therapeutically effective amount of omeprazole sufficient to reduce gastric acid secretion. Under Astra's proposed construction, such an effective amount is a daily dose that can range from 1 to 400 mg of omeprazole, depending on the individual. This range is the only therapeutically effective amount of omeprazole disclosed in the '505 patent specification. (See P1, col. 6:12-20, and '505 Certificate of Correction.) The court declines to adopt Astra's proposed construction. The term "effective amount" in claims 1 and 14 of the '505 patent does not have the word "therapeutically" associated with it, and therefore, contrary to Astra's proposed construction, a person of ordinary skill in the art understands the term "effective amount" in claims 1 and 14 to have a different meaning than the phrase "therapeutically effective amount," which appears in claim 10. (P1, col. 16:43, 17:25, 18:15; Auslander Tr. 2538:7-2540:15; Langer Tr. 735:8-740:5.) On its face, claim 1 cannot be construed so that the "effective amount" requirement only refers to the amount of the omeprazole. First, the term "effective amount" modifies the phrase "a material selected from the group consisting of." Simple grammar rules indicate that the "effective amount" requirement applies to whatever, alone or in combination, constitutes the "material." Claim 1 also makes clear that the "material" is the group consisting of (1) omeprazole plus an ARC; (2) an alkaline omeprazole salt plus an ARC; and (3) an alkaline omeprazole salt alone. (P1, col. 16:43-47.) If the court were to define "effective amount" solely by the active ingredient, then in any given formulation the effective amount of "an alkaline omeprazole salt plus an alkaline reacting compound" would always be the same as the effective amount of "an alkaline omeprazole salt alone," because in those formulations the alkaline omeprazole salt is the active ingredient. Such a construction would thus effectively write out part of claim 1--option 2--as redundant, and is inconsistent with the specification's teaching that the alkaline salt can be mixed beneficially with an ARC, as stated in option 2. (See P1, Exs. 7 & 8, Col. 10:66-Col. 11:41, Comparative Ex. V, Col. 13:41-65.) The claim requires "an effective amount of material," not just an effective amount of active ingredient.

Having determined that the term "effective amount" applies to all substances required as part of the "material" required in claim 1(a), the court now concerns itself with the combination of omeprazole plus an ARC, which is the only option in claim 1(a) asserted by Plaintiffs against Defendants. The court finds that the term "effective amount" applies to both omeprazole and the ARC and requires an amount of each substance such that the combination of omeprazole plus the ARC meets the stated goal of the invention of stabilizing the omeprazole. (Accord Auslander Tr. 2539:8-2540:15.) That is, the term "effective amount" is a relative term. It requires that the ARC and omeprazole be present in the "material" in an appropriate ratio such that the ARC stabilizes the omeprazole. The ARC is used in the claimed formulation to improve

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storage stability. (Langer Tr. 740:6-741:2, see also Langer Tr. 735:8-740:5.) Therefore, an "effective amount" of an ARC in relation to a chosen amount of omeprazole in a given formulation is an amount sufficient to stabilize the omeprazole in the formulation's core. (Langer Tr. 740:23-741:15; see generally Langer Tr. 735:8-741:15.) As the specification discloses, that stabilization is achieved by using an ARC in the core to create a micro-pH around the omeprazole particles of not less than pH 7.
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As to "effective amount," this court rejects Astra's argument that the ARC is a simple excipient and thus "effective amount" only applies to omeprazole. "Excipient" is defined as a "pharmacologically inert, adhesive substance, as honey, syrup, or gum arabic, used to bind the contents of a pill or tablet." Random House Webster's Unabridged Electronic Dictionary (1996). The ARC is not an inert adhesive, and thus does not fit within that definition. Instead, the ARC is alkaline and reacts to stabilize the active drug. The district court thus correctly construed "effective amount" as limiting both the drug component and the ARC.
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F. "Effective Amount"

Novartis proposes the following construction of the term "effective amount" as used in Claim 1:

An amount effective for the treatment of PHN in the mammal in need of such treatment.

(Id., at 4.) Roxane, on the other hand, defines "effective amount" as used in Claim 1 to mean:

50 mg to 1 g of the active ingredient, administered in doses one to four times daily.

(Id.) Novartis argues that Roxane's proposed constructionincludes a dosage range identified in the patent as but one possible range. Thus, Novartis argues that Roxane's construction would include ineffective amounts and exclude effective amounts. The specification states:

An amount effective to treat the virus infection depends on the nature and severity of the infection and the weight of the mammal. A suitable dosage unit might contain from 50 mg to 1 g of active ingredient, for example 100 to 500 mg. Such doses may be administered 1 to 4 times a day or more usually 2 or 3 times a day. The effective dose of a compound will, in general, be in the range of from .2 to 40 mg per kilogram of body weight per day or, more usually, 10 to 20 mg/kg per day in the case of famciclovir, the dosage unit would be 250 mg, 500 mg or 750 mg, preferably 250 mg or 500 mg.

(581 Patent, Col. 3:33-44 (emphasis added).) The Court agrees that the specification does not limit the dosage range to the one proposed by Roxane. However, the Court also finds that Novartis's mere switching of the words "effective amount" by itself is insufficient as a construction of the term. Therefore, the Court construes the term "effective amount" in Claim 1 to mean: An amount effectivefor the treatment of PHN in the mammal in need of such treatment, depending on the severity of the infection and the weight of the mammal and which usually will be in the range of from .2 to 40 mg per kilogram of body weight per day.
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I. "Effective amount"

I agree with Plaintiffs that "effective amount" should be construed as "an amount shown to cause improvement, in comparison to placebo." This is the plain and ordinary meaning of the term to one having ordinary skill in the art, as is evident both from the intrinsic evidence 11 and the extrinsic evidence. 12 Defendants' proposed construction -- "an amount

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that is therapeutically effective" -- is insufficiently precise to be helpful. Therefore, I recommend that "effective amount" be construed as "an amount shown to cause improvement, in comparison to placebo."

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11 See, e.g., JA767 (patentees' reexamination filing distinguishing prior art as showing "no statistically calculable proof for the superiority of Memantine over placebo") (internal quotation marks omitted); JA970 (reexamination declaration explaining: "Physicians would have considered the results of Marcea's non-placebo-controlled study to be scientifically unreliable, both in 1989 and today. It is well established that a placebo group is a necessity in any valid drug assessment study because it enables the investigators to distinguish the effects of an experimental treatment from the effects of having no treatment at all. It was, and continues to be, an accepted standard that the experimental treatment must produce better results than the placebo in order to be considered effective."); JA981 (declaration in support of patentee during reexamination noting declarant "personally worked on a study of this drug in Alzheimer's disease patients and found that hydergine was no more effective than placebo").

12 See, e.g., JA Exs. B26-B30 (secondary sources available in 1989 explaining required process of comparing results of "experimental group" to those of placebo "control group" to determine effectiveness of proposed treatment).

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"Effective Amount"

The term "effective amount" should be construed to mean "a sufficient amount of treating composition to facilitate healing." First, the language of the claim supports this conclusion. It is a common and accepted practice to claim an invention in terms of an "effective amount" of an ingredient or substance where the amount is not critical and those skilled in the art could determine specific values for the amount based on the patent disclosure. See Manual of Patent Examining Procedure § 2173.05[c]; In re Mattison, 509 F.2d 563, 565 (C.C.P.A. 1975); In re Halleck, 57 C.C.P.A. 954, 422 F.2d 911, 914 (C.C.P.A. 1970). The ordinary meaning of "effective" is "producing a . . . desired effect." Webster's Ninth New Collegiate Dictionary 397 (1990). The Federal Circuit has expressly recognized that the term "effective amount" has a customary usage of a sufficient amount to provide the claimed result. See 3M v. Chemque, Inc., 303 F.3d 1294, 1299, 1304 (Fed. Cir. 2002), cert. den., 538 U.S. 972, 155 L. Ed. 2d 533, 123 S. Ct. 1779 (2003) (affirming construction of "effective amount" to mean "a sufficient amount of the specified component to form [claimed] encapsulant having the specified properties under the specified conditions, if any"); see also Abbott Labs. v. Baxter Pharm. Prods., 334 F.3d 1274, 1277-78 (Fed. Cir. 2003) (customary meaning required construing "effective amount" to mean the amount of claim Lewis acid inhibitor needed to provide claimed result of preventing degradation of sevoflurane).

The patent specification also supports the conclusion that "effective amount" refers to "a sufficient amount of treating composition to facilitate healing." One skilled in the art would understand from the specification that an effective amount of a treating composition will vary depending on many considerations. The specification describes the complex process of tissue healing, and explains the many platelet derived factors involved in the healing process. It discloses that the treatment compositions of the invention are effective for many different types of wounds, including external wounds and internal wounds. The specification also suggests that the treating compositions of the invention may be placed over the entire wound at a relative uniform thickness. Alternatively, sutures may be impregnated with the composition to speed internal healing, or the compositions may be coated over implantable devices or surgical instruments. Disclosed examples of wounds successfully treated according to the invention include an open foot wound, a large amputation stump, and nonhealing ulcers in diabetic patients. In each case, the treatment therapy occurred over extended periods of time. The specification does not suggest that the amount of treating composition used is critical. Rather it is apparent from the disclosed wide-ranging applicability of the invention that the effective amount of treating composition will depend on the nature and severity of the particular wound, the application method, the patient's overall health, the desired rate of healing, and other factors assessed by the treating professional. Moreover, the disclosed methods for preparing the treating compositions of the invention involve isolating platelets from blood. The blood may be taken from the injured animal or from another animal of the same species. The resulting platelet-rich plasma may be further concentrated, diluted in a buffer, and/or mixed with a

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carrier to form a paste. Several different activators may be used to release the various healing factors from the platelets. Thus, the '938 patent teaches that the make-up of treating compositions made according to the invention may vary considerably. Persons in the art would also understand that the specific formulation of the composition may impact the preferred amount to be applied. This provides additional evidence that the patentee did not deviate from the accustomed meaning of "effective amount" by requiring that a particular amount of treating composition be applied during the treatment protocol.

Finally, the prosecution history also supports the conclusion that "effective amount" refers to an amount sufficient to facilitate healing. Application claims 20-65 were pending at one stage of the prosecution. Those claims included several method claims directed to applying a treating composition "in an amount sufficient to cause" certain claimed results relating to tissue healing. The PTO Examiner rejected these claims over the prior art and also under 35 U.S.C. § 112 as non-enabled "since the dosage of active ingredients to be used in the treatment is not set forth." Claims 20-65 were then cancelled and replaced by claims 66-90. Several of the substituted claims also used the "amount sufficient to cause" terminology. The patentee responded to the Examiner's previous objection to that phrase under § 112 as follows:

Applicant's invention includes the broad concept, for example, that compositions containing substances which are chemotactic for capillary endothelial cells, particularly the materials released from platelets, can be applied topically to induce the formation of capillaries for cosmetics and wound healing. This concept encompasses all dosages of such compositions that will produce the result that applicant has discovered is achievable by such means. Therefore, the specific dosage of such compositions is not critical to the invention as defined by [the] claims . . . From the disclosure, including the examples, those in the art will be able to determine, without undue experimentation, what dosage of such compositions is necessary to achieve the result recited by the claims.

This response also drew the Examiner's attention to the case In re Halleck, which condoned use of the phrase "effective amount" in a growth stimulating composition for animals. 422 F.2d 911, 57 C.C.P.A. 954. The response equated the phrase to the phrase "amount sufficient to cause" present in the then-pending claims in asserting that those claims were also properly enabled without reciting a specific dosage. The Examiner thereafter withdrew the non-enablement rejection premised on the phrase "amount sufficient to cause." That phrase was eventually replaced by the term "effective amount" in the issued claims. Thus, the prosecution history confirms that the term "effective amount" was used in its ordinary sense to mean a sufficient amount to achieve the claimed result of facilitating healing.

Defendants argue that the term "effective amount" should be construed to mean "8-10 ml of supernatant per gram of carrier." As an initial matter, Defendants' proposed construction would have the phrase specify the make-up of the treating composition and the relative proportions of its components, which is not an "amount." Construing "effective amount" as such would also arguably add new limitations which are not present in the claims, a practice prohibited in claim construction. See, e.g., Storage Tech. Corp. v. Cisco Sys., 329 F.3d 823, 831 (Fed. Cir. 2003); International Visual Corp., 991 F.2d at 771-72.

However, Defendants' main argument for construing the term "effective amount" as "8-10 ml of supernatant per gram of carrier" is the prosecution history, namely that the application expressly defined the phrase "an effective amount" by making reference to a portion of the specification during prosecution. But even if the applicant had made reference to the specification for purpose of defining the phrase "an effective amount," the passage referenced does not support Defendants' argument. It reads:

The resultant composition is thicker and will tend to remain in position in contact with the wound. Debrisan brand wound dressing which contains Sepharose brand beads, trademarks of Pharmacia Fine Chemicals, Inc. of Pitscataway, New Jersey, may be utilized as an alternative carrier. Preferably, about 8-10 ml of supernatant per gram of carrier is used to produce a paste. Application of the wound treating composition is by physically applying the material over an [sic] into the wound as in applying a medicated salve. Treatments should be repeated on a daily basis as long as the wound remains open. A preferred treatment is to apply an approximately one mm thick dressing of the platelet factor/carrier complex to the wound in the morning.

Most apparent is that the disclosure of using a paste containing about 8-10 ml of supernatant per gram of carrier is only a preferred composition of the paste, not the amount of its application. See Transmatic, 53 F.3d at 1277 ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."). There is nothing indicating

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that this particular preferred paste composition is required by the claims. Moreover, the portion of the passage more pertinent to the claim phrase "an effective amount" of the treating composition is the disclosure of applying "an approximately one mm thick dressing" of the composition to the wound in the morning. But this too is expressly described as a "preferred treatment," not a required treatment.

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The '156 Patent

With respect to the' 156 Patent, Nutrition 21 argues that "effective amount" means "at least about 10 mcg. of chromium as chromic tripicolinate in a day." GNC argues that the term means "amount of chromic tripicolinate determined to increase the blood serum levels of HDL-cholesterol in the individual." n6 In supporting these respective constructions, the parties rest on their arguments with respect to the '623 Patent. n7 Those arguments -- to the extent they apply to "effective amount" as the term appears in Claim 17 of the ' 156 Patent -- are equally unconvincing here. Accordingly, for the same general reasons already stated, the Court construes "effective amount" as it appears in the '156 Patent to mean "amount to increase the blood serum levels of HDL-cholesterol in the individual."

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N6 GNC also argues that the Court should construe "effective dose" as found in the '156 Patent to mean "effective amount" because "the normal meaning of 'dose' is 'an amount.'" GNC's Resp. Br. at 26 (Docket No. 65-1 at 32). The Court rejects this argument because the term "effective dose" does not appear in the '156 Patent.

n7 Though both parties' constructions of "effective amount" as found in the '156 Patent differ from their proposed constructions for the term as found in the '623 Patent, the parties do not address these variances. Therefore, the Court presumes the parties intend their articulated arguments with respect to the '623 Patent to apply generally to all their proposed constructions of "effective amount."

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"Effective amount" and "effective dose"

1. The '623 Patent

With respect to the '623 Patent, Nutrition 21 asks the Court to construe "effective amount" and "effective dose" to mean "at least about 50 mcg. of chromium in a day." n3 GNC argues the terms should be construed to mean "amount determined to reduce hyperglycemia and stabilize serum glucose" or "200 micrograms of chromium."

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n3 On the Joint Claim Construction Chart, Nutrition 21's proposed constructions for "effective amount" and "effective dose" differ slightly: only the proposed construction for "effective amount" includes the word "about." Regardless, Nutrition 21's brief argues that both terms should be construed to mean "at least about 50 mcg. of chromium in a day."

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Claim 1 uses "effective amount," but does not mention any dosage amount. Claim 3, which is dependent on Claim 1, specifies a method employing a dosage of "at least about 50 mcg. of chromium." See '623 Patent, cols. 15:21-16:2. Nutrition 21's apparent importation of that dosage amount in its proposed construction is questionable because the doctrine of claim differentiation presumes that limitations stated in a dependent claim are not part of the independent claim. Curtiss-Wright

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Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006). Nutrition 21 argues that the specification refers to "about 50 micrograms" as the floor for the range of chromium dosages that the inventors anticipated would be effective in reducing hyperglycemia and stabilizing glucose levels. See '623 Patent, col. 13:24-31. Nutrition 21 also cites language from the specification that notes CP "may typically be administered on a daily basis." Id. at col. 13:22-23. However, the inventors' inclusion of the 50 microgram dosage in dependent Claim 3 indicates that the inventors envisioned independent Claim 1's "effective amount" to encompass something more general than a dosage of "at least about 50 micrograms of chromium," daily or otherwise. Because Nutrition 21 points to no other evidence that convincingly rebuts the claim differentiation doctrine's presumption, the Court does not adopt Nutrition 21's proposed construction of "effective amount."

The Court also rejects applying Nutrition 21's proposed construction to the term "effective dose." The term is found only in Claim 7, which reads in relevant part: "a method . . . comprising administering chromic picolinate . . . in an effective dose having at least 50 micrograms of chromium per day to an individual in need thereof." Id. at col. 16:13-18. Thus, adopting Nutrition 21's proposed construction of "effective dose" would render the term redundant. While not an absolute rule, all claim terms are presumed to have meaning in a claim. Innova/Pure Water, 381 F.3d at 1119. Nutrition 21 cites no evidence to rebut this presumption.

GNC's proposes the terms be construed as "amount determined to reduce hyperglycemia and stabilize serum glucose." However, during oral argument GNC acknowledged that potential confusion could arise from its proposed use of "determined" -- specifically, it raises the question of who does the "determining." GNC offered to forego its "amount determined . . ." construction in favor of the construction "200 micrograms of chromium." According to GNC, because 200 micrograms is the only dosage that was actually administered in the studies described in the '623 Patent's specification, this was the only amount demonstrated to be effective. As such, interpreting the asserted claims to cover amounts other than 200 micrograms of chromium "would give Nutrition 21 claim coverage for quantities of chromium that the inventors did not test and for which there is no evidence or reason to believe that those amounts are effective in achieving the claimed results." n4 Additionally, GNC argues the specification itself notes that the National Academy of Sciences determined 200 micrograms of chromium to be the maximum "safe" intake amount of chromium per day. See '623 Patent, col. 5:36-39. GNC argues that "effective amount," and "effective dose" logically cannot exceed this maximum "safe" amount.

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n4 GNC's Resp. Br. at 16-17 (Docket No. 65-1 at 22-23).

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GNC's central argument in opposing Nutrition 21's proposed construction is that an amount or dosage stated in the construction must actually be effective and not just presumed or anticipated to be effective. n5 However, neither GNC nor Nutrition 21 support their mutual premise that "effectiveness" hinges on administration of a particular dosage in the first place. There is no evidence that the inventors envisioned the actually-administered dosage to be the only "effective amount" or "effective dose" to reduce hyperglycemia and stabilize serum glucose, or that one of ordinary skill in the art would interpret the terms to encompass only the actually-administered dosage.

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n5 GNC repeats this central argument in opposing Nutrition 21's proposed constructions of "effective lean-body[-] mass increasing amount," "effective body-fat-reducing amount," "effective[,] blood serum lipid[-]reducing amount [dose]," and "effective HDL-cholesterol increasing dose," all of which are terms in the '624 or '156 Patents. See GNC's Resp. Br. at 20-22, 25-26 (Docket No. 65-1 at 26-28, 32-33).

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Accordingly, the Court construes "effective amount," and "effective dose" to mean "amount to reduce hyperglycemia and stabilize serum glucose." This construction retains the simplistic appeal of GNC's first proposed construction without requiring a "determination." Likewise, it avoids infusing specific amounts or dosages into the construction, which neither party has justified and the patent does not require.

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E. "Administering an Effective Amount of" (Claim 2 of the '823 patent)

Claim Term	Amgen's Construction	Teva's Construction
"administering an effective amount of"	administering an amount adequate and suitable for therapeutic use	to give an amount sufficient to cause desired effect

Teva proposes that "administering" be given its plain and ordinary meaning: "to give." Teva Br. at 29. Teva argues that this construction is supported by the intrinsic record of the specification and the prosecution history because "administering" is used to describe"giving" hpG-CSF to cell cultures and mammals. Id. Amgen responds that this definition is too broad, that "administering" actually implies a remedial use for a mammal and not just "to give," and that "administering," read together with the preamble in the context of therapeutically treating a mammal, does not simply mean giving to cells in a petri dish. Amgen Resp. at 26-27. We find that Amgen's construction is correct because "administration," as used in the context of providing therapy, requires more than merely "giving" a dose of a substances to a cell culture. Decl. of J. Wolfson in Support of Teva's Opening Brief on Claim Construction, Ex. 23 (Webster's 1986).

With regard to "an effective amount," Teva argues that "effective" generally means "capable of bringing about an effect." Teva Br. at 31. Teva argues "effective amount" should mean an amount of hpG-CSF sufficient to cause a desired effect of hpG-CSF increasing the number of granulocytes. Id. Teva contends that a person of ordinary skill in the art would understand that an "effective amount" is an amount of hpG-CSF that can elicit the desired effects named in the specification. Id. at 31-32.

Amgen argues that reading the "effectiveamount" limitation in conjunction with the preamble indicates that the term refers to the amount effective to treat a mammal therapeutically by stimulating the production of granulocytes. Id. That is, the '823 patent claim 2 requires that hpG-CSF be present in a quantity and quality sufficient to prevent, cure, or alleviate life-threatening and debilitating conditions in a mammal by stimulating the production of granulocytes. Id. Amgen argues that an "effective amount" is an amount that is both adequate and suitable for therapeutic use. Amgen Br. at 33. Amgen claims that this construction is supported by the specification, which states that pharmaceutical compositions "useful in hpG-CSF therapy" must comprise "effective amounts" of hpG-CSF. Id. at 34; '755 Patent at 4:24-27.

Amgen contends that Teva's construction should be rejected because it does not reference the required therapeutic objective and further ignores the full implication of "effective," which requires an hpG-CSF product that is both suitable and adequate for therapeutic use. Amgen Resp. at 27. According to Amgen, Teva's construction does not use "effective amount" in terms of an amount effective for therapy -- administeringa minuscule amount to cause inconsequential increases in the number of granulocytes, as well as administering an overdose of hpG-CSF to cause death, would both fall within the scope of the claims as Teva defines them. Id.

"Effective amount" has a customary usage. Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1277 (Fed. Cir. 2003). Here, the term would mean the amount of a hpG-CSF polypeptide that will provide "granulocytopoietic therapy to a mammal." '823 Patent, Claim 2.

We must take the preamble into account in determining the proper construction for the meaning of "an effective amount." Again, a claim preamble is limiting if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. Intirtool, 369 F.3d at 1295. 5 An "effective amount" should be an effective amount for "providing granulocytopoietic therapy to a mammal," as the full claim states. "Effective amount" must be an amount effective for therapy.

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5 A preamble may also provide context for claim construction, particularly where that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history. Metabolite Labs., Inc. v. Lab. Corp. Of

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America Holdings, 370 F.3d 1354, 1362 (Fed. Cir. 2004).

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Tevacites Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293 (Fed. Cir. 2006), to support its position that "effective amount" should mean "to give an amount sufficient to cause a desired effect," claiming that "a desired effect" is an amount that will cause any one or all of the effects listed in the specification. Teva Br. at 31. But, in Amgen v. Hoechst Marion Roussel, the claim in question specified only "[a] pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture." Id. at 1300. In that case, Amgen argued that a "therapeutically effective amount" meant that there would be an increase in hematocrit as well as any or all of the biological effects previously attributed to the natural version of the patented product. Id. at 1301. This case is different. Amgen argues only that "effective amount" must be an amount effective to provide therapy to a mammal. That language is written into the claim itself and must be given effect. We therefore agree with Amgen that Teva's construction must be rejected becauseit does not reference the required therapeutic objective. Amgen Resp. at 27. We will adopt Amgen's construction.
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4. "antirestenosis effective amount" and "antiproliferative effective amount"

The term "antirestenosiseffective amount" is found in claims 1 and 2 of the '781 patent and claim 1 of the '146 patent. The term "antiproliferative effective amount" is found in claim 2 of the '728 patent. The center of the dispute regarding this claim term is on the phrase "effective amount." Plaintiff contend that this term means "an amount that is capable of reducing the incidence or degree of [restenosis or cell proliferation]." Defendants, on the other hand, first argue that this term is indefinite. Alternatively, Defendants assert that the term should be construed as "an amount sufficient to stop or significantly reduce [restenosis or cell proliferation]."

Under § 112 of the Patent Act, to be sufficiently definite, a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, P 2. The boundaries of the claim must be discernible to one skilled in the art based on the language of the claim, the specification, and the prosecution history, as well as that person's knowledge of the relevant field of art. See Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-51 (Fed. Cir. 2008).Claims that are "not amenable to construction" or "insolubly ambiguous" are indefinite. Datamize LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir.2005).

As recently noted by the Federal Circuit, "because claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet an exacting standard." Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776, 783 (Fed. Cir. 2010) (quotations omitted). Consequently, to show indefiniteness, an accused infringer is required to "demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art." Id.

The Court finds Defendants have not met this burden. "'[E]ffective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003). Defendantsargue that the claim term "effective amount" is indefinite because the patents fail to provide any benchmark for what amount of rapamycin provides an effective reduction in restenosis or proliferation. But Defendants simply have not shown by clear and convincing evidence that a person of ordinary skill in the art would be unable to determine the specific amounts without undue experimentation. Plaintiffs, on the other hand, have presented a declaration from Dr. Nigel Buller, a cardiologist experienced in the field of stents and restenosis, who notes that the specification of the Morris patents explains how an effective amount of rapamycin can be determined: by starting "with small dosages," and increasing the dose "until the optimum effect under the circumstances is reached." '781 patent at 12:14-17. Dr. Buller explains that by using the teachings in the specification, a person of ordinary skill could determine an effective amount by employing different amounts of rapamycin and measuring the results using standard angiographic and sonographic techniques. Buller Decl. P 18.

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Finding that the disputed term is not ambiguous and is amenable to construction, the Court must next determine theappropriate construction. The Court finds Defendants' proposed construction -- which require that an "effective amount" be "sufficient to stop or significantly reduce" restenosis or cell proliferation -- is flawed in that it improperly reads into the claim an "effect" that goes beyond merely a measurable effect. There simply is not support for such a requirement. The Court, therefore, shall adopt Plaintiff's proposed construction, and shall construe "antiproliferative effective amount" to mean "an amount that is capable of reducing the incidence or degree of cell proliferation." "Antirestenosis effective amount" shall be construed to mean "an amount that is capable of reducing the incidence or degree of restenosis."
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B. Claim Construction: The '259 and '933 Patents

Citing concerns of efficiency and judicial economy, plaintiffs do not move for summary judgment on the '259 and '933 patents because they assert that they are entitled to judgment on the '789 patent alone. See Pl. Mem. at 2. Defendant, however, has moved for summary judgment on non-infringement under the '259 and '933 patents as well as the '789 patent, arguing that the "specific medium" requirement of the '789 patent is also a limitation of the '933 and '259 patents. 3 According to defendant, because the specifications of the '933 and '259 patents define the claimed invention as "a 'specific medium' in that it will support growth in log phase of only the target microbes, rather than a general medium which will also support growth in log phase of microbes other than the target microbes" and states that "the medium will only support reproductive growth of the target microbes," Def. Br. at 17, all three patents contain the claim limitation that the medium must support log-phase, reproductive growth of only the target microbes, even though the term "specific medium" is not used in the claims in either the '933 patent or the '259 patent.

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3 The parties agree that the '933 and '259 patent are identical for purposes of the claims at issue here.

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Plaintiffs assert without citation that "the subsequently issued claims in the '933 and '259 Patents foreclose the very non-infringing arguments CPI is making here" and argue that "CPI is asking the Court to sweep all of this history under the rug without even giving plaintiffs a full and fair opportunity to be heard on matters raised in the subsequent prosecution." Pl. Opp. at 29. However, interpretation of the '933 and '259 patents is a matter of law for the Court to determine, and plaintiffs's opposition to defendant's motion for summary judgment has provided them with ample opportunity to be heard. 4 Therefore, the Court will proceed to interpret the '933 and '259 patents in the context of defendant's motion for summary judgment on non-infringement.

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4 Although plaintiffs claim that they would be "severely prejudiced if the claims of the '933 and '259 patents are construed on this incomplete record and/or in the context of briefing on the pending motions for summary judgment of infringement and non-infringement," there is no explanation as to the nature of any such prejudice, nor why they could not complete the record in their opposition submission. Pl. Opp. at 5.

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According to plaintiffs, the '933 and '259 specifications differ from the '789 patent specification by permitting the growth of some non-target microbes. Defendant does not dispute that there are some differences between the '789 and '933 and '259 patents, but claims that these differences are not different in any material respect with regard to the construction of the "specific medium" requirement. The Court agrees.

When construing a patent claim, the Court must first analyze "the intrinsic evidence of record -- the claims and written description of the patent itself, and, if in evidence, the prosecution history." Biovail Corp. Int'l v. Andrx Pharmaceuticals,

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Inc., 239 F.3d 1297, 1300 (Fed. Cir. 2001). As discussed above, a patentee may limit the scope of its claims through statements made in the specification. See Scimed, 242 F.3d at 1341; Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed."). As with the '789 patent, the specification of the '259 patent expressly states that the medium of the invention is a specific medium in which non-target microbes will not experience log-phase reproductive growth. Accordingly, such a limitation is properly construed as part of the claims.

The '259 patent specification states that:

This invention relates to the detection of a target microbe through the use of a testing medium which medium contains a nutrient which can be significantly metabolized only by the target microbe during log phase of growth in the medium . . . . The medium is thus a 'specific medium' in that it will support growth in log phase of only the target microbes, rather than a general medium which will also support growth in log phase of microbes other than the target microbes. . . . The nutrient-indicator actively participates in the growth of the target microbes by serving as the preferred or primary nutrient source. The target microbes can grow, metabolize and multiply into log phase because they, and substantially only they, can use the indicator as their primary nutrient. . . . Because microbes other than the target microbes are prevented from growing, metabolizing or multiplying substantially into log phase, the medium is so specific that it does not have to be sterilized before use.

* * *

The testing medium also includes a minor amount of a growth accelerant which will boost the target microbes and all of the other viable microbes in the sample through lag phase and toward log phase growth in the testing procedure. . . . The accelerant is present in a small amount so as to be dissipated by the time the microbes enter log phase of growth.

* * *

As previously noted, using the invention, there is very little or no competition for food or nutrients among the microbes in the medium because the only nutrient present in the medium which can be metabolized to any significant extent can be metabolized solely by the target microbes . . . The nutrient used will be one that the target microbes greatly prefer over any other nutrients, and also, one for which other microbes in the sample have little or no preference, and cannot significantly assimilate.

'259 Patent, Column 1, 11. 20-29; Column 2, 11. 39-42, 62-64; Column 3, 11. 20-25, 28-31.

The patent specification further states:

In general, with respect to this invention, after the specific medium has been added to the sample, during the lag phase while the microbes are adjusting to the presence of the medium no substantial microbial metabolism will occur with either the target or non-target microbes. At the beginning of the log phase, all of the microbes will begin to metabolite [sic] the vitamin and mineral components of the medium, but only the target microbes will also metabolize the specific nutrient component of the medium. This specific nutrient is the only ingredient in the medium which will allow substantial growth, i.e., growth which will allow microbial reproduction at logarithmic rates (log phase), of any microbes in the sample. Thus, the medium will only support reproductive growth of the target microbes. For this reason the population of non-target microbes in the sample will not substantially increase, and will actually begin to decline during the log phase.

Column 7, 11. 13-29.

Claim 1 of the '259 patent claims "a target microbe-specific medium . . . comprising . . . b) an effective amount of a nutrient-indicator which is provided in an amount sufficient to support log phase growth of said target microbe . . . said nutrient-indicator being incapable of supporting continued logarithmic growth of any viable non-target microbes in the medium/sample mixture to produce a detectable characteristic signal . . . ."

In light of this Claim language and the specification, the Court concludes that the invention claimed by the '259 and '933 patents is limited to those media in which only the target microbes can metabolize and experience log phase, reproductive

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growth. This construction does not differ markedly from the Court's prior construction of the '789 patent ("the claim limitation which discloses a 'specific medium' means a medium that will support reproductive growth of only the target microbes").

This interpretation of the '259 and '933 patent language is further supported by claims made during the prosecution history of these patents. "Prosecution history serves as a limit on the scope of claims by excluding any interpretation for the claim language that would permit the patentee to assert a meaning of the claim that was disclaimed or disavowed during prosecution in order to obtain claim allowance." Zenith Lab., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1421 (Fed. Cir. 1994).

Rejections based upon prior art, including Feng et al. and Trepeta et al., were withdrawn following an amendment, because:

Applicants appear to claim an invention whereby in a balance of growth rates and media constituents target organisms and non-target organisms are initially boosted from lag to log phase with a limited amount of an 'accelerant.' Subsequently, the selective and differential nature of the other constituents allows target organisms to thrive while other organisms do not. Such a concept is not taught by the prior art of record.

Examiner's Office Action, dated May 31, 1991, in application No. 07/349,653 (emphasis added); see also Amendment and Request for Reconsideration dated May 21, 1991, in application No. 07/349,653. Plaintiffs thus expressly represented, and the patent examiner expressly relied on the fact that the claimed invention would permit log-phase reproductive growth of only the target microbe. Accordingly, plaintiffs cannot now "obtain, through litigation, coverage of subject matter relinquished during prosecution." Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1577 (Fed. Cir. 1993).

Having construed the claims, the Court now turns to plaintiffs' claims of infringement. Infringement, unlike claim construction, is a question of fact. See Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054 (Fed. Cir. 1988).
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a. "Thermoplastic" and "Effective Amount of the Processing Additive Composition"

These two terms are used in asserted Claim 20, and "thermoplastic" is used in asserted Claim 17. Dupont Dow and Dyneon agree on the proposed constructions for both terms. (Dyneon's Opp'n Br. at 16). The proposed construction for "thermoplastic" is "capable of softening or fusing when heated and of hardening again when cooled." The proposed construction for "effective amount of the processing additive composition" is "that which either (a) reduces the occurrence of melt defects occurring during extrusion of the host polymer below the level of melt defects occurring during the extrusion of a host polymer that does not employ the multimodal fluoropolymer-based processing additive composition of the invention, or (b) delays the onset of the occurrence of such defects to a higher extrusion rate (that is a higher shear rate)."

The proposed constructions for these claim terms are consistent with the ordinary meaning of the term to one of skill in the art ("thermoplastic"), or comport with the intrinsic evidence. See '919 Patent, c. 4, 11. 22-30 (defining "effective amount" as used in the specification and claims). Both terms are used in asserted claims, but may not be readily understood by a jury. The Court therefore adopts the proposed constructions for the claim terms "thermoplastic" and "effective amount of the processing additive composition" that are set out above.
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F. Effective Amount

The mostly hotly disputed claim term is the last one -- "effective amount of 1 [alpha]-OH-vitamin D[2] to lower and maintain lowered serum parathyroid hormone levels." Defendants contend that this phrase needs no construction because its ordinary meaning applies. 3 Plaintiffs propose the following construction: "an amount of 1 [alpha]-OH-vitamin D[2] (also known as doxercalciferol, 1 [alpha]-hydroxyergocalciferol, or 1 [alpha]-vitamin D[2]), which, when chronically

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administered, reduces blood concentrations of PTH in a clinically significant manner and maintains these clinically significant reductions with a low incidence of hypercalcemia." Defendants object to three elements of Plaintiffs' proposed construction: (1) the description of the "effective amount" as one that is "chronically administered"; (2) the requirement that PTH levels be reduced in a "clinically significantmanner"; and (3) the description of the "effective amount" as one that causes "a low incidence of hypercalcemia." Defendants argue that, in each instance, Plaintiffs are improperly importing limitations from the specification into the claim.

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3 In their claim construction briefs, Defendants took the position -- based on the doctrine of claim differentiation -- that "effective amount" should be construed as "a range that is broader than the range set forth in claim 3." However, during the claim construction hearing, Defendants' counsel explained that the "effective amount" "could be any amount." Therefore, it appears that the parties agree -- consistent with the patent specification -- that the "effective amount" is a dose that will vary patient-to-patient based "on a wide variety of factors," including "the efficacy of the specific compound employed, * * * the age, body weight, general state of health, [and] sex [of the patient], * * * the timing and mode of administration, * * * the rate of excretion, and * * * the medicaments used in combination and the severity of the particular disorder to which the therapy is applied." '116 patent, col. 7, lines 7-14.

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1. Chronically Administered

Plaintiffscontend that in order to maintain lowered serum PTH levels, as the claim language requires, medication must be administered regularly over an extended period of time. In other words, lowered PTH levels can only be maintained if the drug is administered regularly, or "chronically." Defendants counter that the addition of the words "chronically administered" is inconsistent with Example 3, which discusses short-term treatment (6 weeks), and with Example 5, which discusses both short term treatment (12 weeks) and allows for the possibility that treatment be suspended in the event that a patient develops marked hypercalcemia or hyperphosphatemia. '116 patent, col. 12, ll. 43-48. According to Defendants, such short-term and periodic treatment cannot be considered "chronic."

Defendants' argument regarding the short term nature of the treatment described in Examples 3 and 5 is not persuasive. Both examples discuss clinical trials, which, by necessity, are short term. However, Defendants' point regarding the suspension of treatment is more compelling.

In response, Plaintiffs concede that, occasionally, when a patient develops hypercalcemia, treatment with doxercalciferol must be suspended untilthe patient's calcium levels fall. However, according to Plaintiffs, treatment with doxercalciferol results in few incidents of hypercalcemia, such that treatment must be suspended only infrequently. Thus, Plaintiffs' proposed inclusion of the phrase "chronically administered" is related to their proposed inclusion of the phrase "a low incidence of hypercalcemia." In particular, according to Plaintiffs, doxercalciferol causes fewer incidents of hypercalcemia than prior vitamin D therapies for secondary hyperparathyroidism, which used analogs of vitamin D[3] as opposed to vitamin D[2]. Consequently, treatment with doxercalciferol will need to be suspended much less frequently than treatment with conventional therapies, making it possible to maintain lowered serum PTH levels.

The word "chronic" means "continuing indefinitely; perpetual; constant." WEBSTER'S NEW WORLD COLLEGE DICTIONARY 262 (4th ed. 2007). Plaintiffs' concession that the claimed invention at times requires the suspension of treatment with doxercalciferol -- regardless of how frequently (or infrequently) those incidents may occur -- undermines Plaintiffs' contention that claim 7 calls for chronic, or constant, administration.Therefore, the Court declines to construe claim 7 as requiring chronic administration.

2. Clinically Significant Manner

Plaintiffs maintain that a POSA would understand an "effective" treatment to be one that reduces PTH levels in a clinically significant manner (i.e., a manner that benefits the patient). According to Plaintiffs, an amount that reduces PTH levels only nominally cannot be considered "effective," and therefore Defendants' construction -- which would encompass amounts that lead to any reduction no matter how insignificant -- reads the term "effective" out of the claim. But Plaintiffs provide no

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guidance as to what "clinically significant" means in this context, or what amount of reduction in PTH levels would be beneficial to a patient. Without such guidance, Plaintiffs' proposal does not clarify the scope of the claim. Rather, by adding a phrase that is vague on its face, it invites confusion. Moreover, the Court finds that the claim term "effective" is not ambiguous in the context of claim 7. Therefore, the Court declines to limit the scope of claim 7 to amounts of 1 [alpha]-OH-vitamin D[2] that produce "clinically significant" reductions in PTH levels.

3. Low Incidenceof Hypercalcemia

Finally, Plaintiffs contend that the scope of claim 7 should be limited to methods that result in a "low incidence of hypercalcemia." It is axiomatic that, because "the claims define the scope of the right to exclude[,] the claim construction inquiry * * * begins and ends in all cases with the actual words of the claim." Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002) (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998)). And there is a "heavy presumption" that a claim term carries its ordinary and customary meaning. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). Here, claim 7 does not explicitly recite a "low incidence of hypercalcemia" limitation, nor is that phrase included in the "ordinary and customary meaning" of the claim term "effective."

However, because claims must be read in light of the specification of which they are a part, the Federal Circuit has recognized that in some instances the ordinary meaning of a claim term may be narrowed by the specification. See Teleflex, Inc., 299 F.3d at 1325 ("The specification may limit the scope of the claims"); Watts v. XL Sys., Inc., 232 F.3d 877, 882, 56 USPQ2d 1836, 1839 (Fed. Cir. 2000)("One purpose for examining the specification is to determine if the patentee has limited the scope of the claims."). In particular, the specification will be found to restrict the scope of the claims if "the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by * * * characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, 299 F.3d at 1327 (emphasis added).

For example, "where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims." Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1370 (Fed. Cir. 2003). See also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enoughto encompass the feature in question."). However, courts must be mindful not to impermissibly import limitations from the specification. Id. In Alloc, the Federal Circuit offered guidance to district courts seeking to achieve the proper balance between interpreting claims in light of the specification, and avoiding incorporating limitations only found in the specification. According to the Alloc court, that balance "turns on how the specification characterizes the claimed invention." Id. The court further explained that courts should "look[] to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment." Id.

Applying that standard, the Alloc court concluded that the "specification read as a whole [led] to the inescapable conclusion that the claimed invention must include play in every embodiment," and held that the disputed claims included a "play" limitation, despite the fact that the claims did not recite a "play" limitation. Id. In reaching that conclusion, the court was persuaded by the following:(i) the "specification criticize[d] prior art floor systems without play," (ii) "all the figures and embodiments disclosed in the asserted patents impl[ied] * * * [or] expressly disclose[d] play," and (iii) "the patents d[id] not show or suggest any systems without play." 342 F.3d at 1369-70. While the court found that "the specification alone [was] sufficiently clear," it noted that "the prosecution history of [the] patent family confirm[ed] the description in the specification of each patent, namely, that play is a key feature of the claimed invention." Id. at 1371.

Similarly, in SciMed, the court found that the specification limited the scope of the asserted claims to catheters with coaxial lumens, and disclaimed catheters with dual lumen configuration, despite the absence of such limiting claim language. For that conclusion, the court relied on statements in the specification identifying the inflation lumen as coaxial rather than dual in structure, including numerous statements characterizing "the coaxial configuration as part of the 'present invention.'" 242 F.3d at 1342-43. The court also was persuaded by statements in the specification "distinguish[ing] the prior art on the basisof the use of dual lumens and point[ing] out the advantages of the coaxial lumens used in the catheters that [were] the subjects of the SciMed patents." Id. at 1343. Finally, the court noted that the specification expressly identified the coaxial

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lumen configuration as "the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." Id. (emphasis in original).

The specification, in conjunction with the patent prosecution history, also was found to limit claim terms in Ormco Corp. v. Align Technology, Inc., 498 F.3d 1307 (Fed. Cir. 2007), on which Plaintiffs rely. In Ormco, the Federal Circuit concluded that the asserted claims required automatic computer control of the finish tooth positioning, despite the fact that the claim language did not expressly recite such a limitation. The court was persuaded, in part, by statements in the specification distinguishing the invention based on "its high level of automation in the design of custom orthodontic appliances as compared to the prior art," and "specifically stat[ing] that the prior art had encountered difficulties in 'the task of developing an automated system that includes reliable and efficientdecision making algorithms and techniques for automatically determining an ideal finish position of the teeth.'" 498 F.3d at 1313 (emphasis in original). The court also relied on the fact that the specification did not "suggest or even allow for human adjustment of the computer-calculated tooth finish positions." Id. The court noted that "all those statements by the inventors in the specification of the Ormco patents, standing alone, may not be conclusive in showing that the claims require completely automatic determination of final tooth positions," but found that "statements made during prosecution in order to overcome a rejection over prior art" confirmed the conclusion. Id. at 1316.

In light of the foregoing discussion, the question presented to this Court in the parties' briefs is whether the specification compels the conclusion that claim 7 includes a hypercalcemia limitation. Plaintiffs contend that the specification indicates that the patentee intended to limit the scope of claim 7 to amounts of doxercalciferol that result in a "low incidence of hypercalcemia." In support of that contention, Plaintiffs note that the specification describes "the present invention" as having lowertoxicity (i.e., less resultant hypercalcemia and hyperphosphatemia) than conventional therapies using vitamin D[3] compounds. See '116 patent, col. 4, ll. 11-17 ("SUMMARY OF THE INVENTION" section stating that "[t]he treatment method of the present invention is * * * characterized by providing an active vitamin D compound having equivalent bioactivity [to conventional therapy with vitamin D[3] compounds] but much lower toxicity than these conventional therapies."); id., col. 4, ll. 60-62 ("The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia"); id., col. 13, ll. 57-59 ("The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia."). Statements in the specification describing a particular feature as part of the "present invention" can be "strong evidence" that the claims should be read to require that feature. SciMed, 242 F.3d at 1343. See also Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (construing claim term to be limited to a fuel filter where "[o]n at least four occasions, the written description refer[red] to the fuelfilter as 'this invention' or 'the present invention'").

Statements in the '116 patent specification criticizing the prior art (i.e., conventional therapies using vitamin D[3] compounds) for causing toxicity in the form of hypercalcemia and hyperphosphatemia, and touting the claimed invention as a solution to those toxicity problems, provide additional support for a narrowing construction along the lines suggested by Plaintiffs. See '116 patent, col. 2, ll. 6-9 ("at the dosage ranges required for [vitamin D[3] compounds] to be truly effective, toxicity in the form of hypercalcemia and hypercalciuria becomes a major problem"); id., col. 2, ll. 26-29 ("the prior art teaches that due to their toxicity, 1-hydroxylated vitamin D compounds can only be administered at dosages that are, at best, modestly beneficial in preventing or treating loss of bone or bone mineral content"); id., col. 3, ll. 5-7, 14-15 (1 [alpha], 25-(OH)[2]D[3] and 1 [alpha]-OH-D[3] often cause "toxic side effects (hypercalcemia and hyperphosphatemia)" at certain dosages); id., col. 3, ll. 35-41 (despite the "known problems with use of the hormonally active vitamin D[3] for secondary hyperparathyroidism, the art has notadequately responded to date with the introduction of other vitamin compounds, derivatives or analogs that possess less inherent toxicity"); id., col. 5, ll. 1-9 ("In accordance with the invention, it has been found that when the analogs of formula (I) are administered * * *, PTH concentration is lowered with significantly less hypercalcemia and hyperphosphatemia than is observed after the same amount of activated vitamin D administered in previously known formulations"); id., col. 5, ll. 30-31 ("The analogs of formula (I) are substantially less toxic than their vitamin D[3] counterparts.").

As a general matter, the Federal Circuit has stated that where "[t]he specification * * * teaches about the problems solved by the claimed invention, the way the claimed invention solves those problems, and the prior art that relates to the invention[,] * * * [t]hese teachings provide valuable context for the meaning of the claim language." Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1554 (Fed. Cir. 1997), overruled in part on other grounds by Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998). More specifically, the Federal Circuit repeatedly has foundthat statements criticizing the prior art and distinguishing the invention as a solution to the identified problem may serve to

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narrow the scope of a claim. See Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharmaceutical Co., 384 F.3d 1333, 1340 (Fed. Cir. 2004) ("Where the general summary or description of the invention describes a feature of the invention * * * and criticizes other products * * * that lack that same feature, this operates as a clear disavowal of these other products"); Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (finding that specification's "detailed discussion of the prior art problem addressed by the patented invention * * * further supports the conclusion that * * * the patentee has limited the scope of the '879 patent claims").

Here, a number of statements in the '116 patent specification -- describing the invention in terms of lower incidences of hypercalcemia, criticizing the prior art, and distinguishing the claimed invention from the prior art on the basis of lower toxicity -- "make[] clear * * * that the claimed invention is narrower than the claim language might imply." Alloc, 342 F.3d at 1370. The questionis how much narrower. Based on its examination of the language used in the specification, the Court concludes that Plaintiffs' proposed construction -- which allows for only a "low incidence of hypercalcemia" -- is too narrow.

As noted above, the specification repeatedly refers to the method of the invention as causing "lower toxicity" and "less resultant hypercalcemia" than conventional extant therapies that used Vitamin D[3] compounds. And in its discussion of the prior art, the specification similarly emphasizes that the invention would lead to "significantly less hypercalcemia" and would be "substantially less toxic" than its Vitamin D[3]-based predecessors. These references have as their common focus not a "low" incidence of hypercalcemia in some absolute sense, but rather an incidence of hypercalcemia that is "less" or "lower" than the incidence reported from the prior therapies which used analogs of Vitamin D[3], as opposed to Vitamin D[2]. The phrase "low incidence of hypercalcemia" appears nowhere in the specification.

The upshot of this analysis is that while the specification does narrow the claim scope, it does not narrow it as much as Plaintiffs contend. In particular, thespecification contains a "clear disavowal" of amounts of doxercalciferol resulting in an incidence of hypercalcemia that is equal to or greater than the incidence of hypercalcemia associated with the then-conventional Vitamin D[3] treatments. See Teleflex, 299 F.3d at 1327. But the specification does not clearly disavow all amounts of doxercalciferol that cause more than a low incidence of hypercalcemia. Thus, claim 7 encompasses amounts of doxercalciferol that result in a lower incidence of hypercalcemia relative to previously available therapies, even if a POSA would not consider that relatively lower incidence to be "low" in absolute terms. Or, put slightly differently, the specification leads to the "inescapable conclusion" that claim 7 is limited to amounts of doxercalciferol that result in a lower incidence of hypercalcemia than was associated with the conventional Vitamin D[3] treatments in existence at the time of the invention. See Alloc, 342 F.3d at 1370.

Defendants maintain that certain portions of the intrinsic evidence -- specifically Examples 3 and 5 and the Tan manuscript -- do not support the narrow construction Plaintiffs propose. The Court finds all three examplescited by Defendants to be entirely consistent with the construction set forth above. With respect to Example 5, Defendants point to the fact that the protocol for the clinical trial discussed in the example allows for a dosage reduction for patients who develop persistent mild hypercalcemia or mild hyperphosphatemia during treatment with 1 [alpha]-OH-vitamin D[2], and calls for patients who develop marked hypercalcemia or hyperphosphatemia to immediately suspend treatment. '116 patent, col. 12, ll. 43-48. Plainly the fact that the protocol for Example 5 allows for the possibility of incidents of hypercalcemia is not inconsistent with the Court's construction, which merely requires a lower incidence of hypercalcemia than that observed with traditional Vitamin D[3] therapies, not a complete prevention of hypercalcemia.

The Tan manuscript describes a clinical trial involving the administration of 1 [alpha]-OH-vitamin D[2] to ESRD patients, and reports 13 instances of hypercalcemia in 24 treated patients. PH001420, PH001423. The Tan manuscript also reports just 4.7 episodes of hypercalcemia per 100 weeks of treatment, and concludes that "[t]he results demonstrate that this vitamin D analog[1 [alpha]-OH-vitamin D[2]] is highly effective in lowering serum [PTH] levels with a very low incidence of hypercalcemia and hyperphosphatemia." Defendants' own expert concedes that a POSA would consider "4.7 episodes of hypercalcemia per 100 weeks of treatment * * * [to] be an acceptable low occurrence of hypercalcemia." Chesnut Dep. at 29. Thus, the Tan manuscript is consistent with the Court's construction, and, in fact, lends support to Plaintiffs' even narrower construction.

Finally, Example 3, which discusses a clinical trial in which five ESRD patients were administered 1 [alpha]-OH-vitamin D[2] at a dosage of 4 [mu] g/day for six weeks, also is consistent with the Court's construction. In Example 3, three of the five patients "developed mild hypercalcemia (serum calcium, 10.3-11.4) that reversed after stopping 1 [alpha]-OH-vitamin

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D[2]." Id., col. 11, ll. 20-23. Defendants argue that 60% of patients developing hypercalcemia cannot be considered a low incidence, and that Example 3 therefore refutes Plaintiffs' claim that the specification supports a low incidence of hypercalcemia limitation. Presumably, Defendants also would take the position that three of the five patientsdeveloping hypercalcemia cannot be considered a "lower" incidence as compared to the prior art. The problem with Defendants' analysis is that it focuses on the absolute number of incidents of hypercalcemia, as opposed to the frequency of those incidents over time. In other words, Defendants fail to put the raw data (i.e., how many patients experience an episode of hypercalcemia) into the proper context (i.e., how often patients experienced hypercalcemia during treatment). But when it comes to the "incidence of hypercalcemia," the pertinent inquiry is the frequency with which patients develop hypercalcemia during extended periods of treatment. As a result of its brevity, Example 3 provides no information regarding how many times the patients described in the example developed hypercalcemia over time. Therefore, Example 3 does not undermine the Court's hypercalcemia limitation, which speaks to the frequency with which patients experience hypercalcemia.

Defendants also argue that the inclusion of a limitation addressing the incidence of hypercalcemia but not the incidence of hyperphosphatemia would be improper. Plaintiffs respond that a limitation regarding hyperphosphatemia is not properbecause a low incidence of hyperphosphatemia is not central to the functioning of the claimed invention. See Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1351-52 (Fed. Cir. 2004) (concluding that claim term included a limitation that the specification made clear was "central to the functioning of the claimed inventions," but did not include a second limitation that "the specification [did not] indicate [was] necessary for the multiplexing function" of the inventions). As Plaintiffs note, other drugs -- namely phosphate binders -- existed to control that side effect. The specification indicates repeatedly that the inventors intended for the claimed method to be used in conjunction with phosphate binders to control hyperphosphatemia. See '116 patent, ex. 3, col. 11, ll. 3-8 ("Throughout the * * * treatment period, patients * * * ingested significant amounts of calcium phosphate binders (1-10 g elemental Ca) to keep serum phosphorus levels below 6.9 mg/dL"); id., ex. 4, col. 11, ll. 53-55 ("Oral calcium phosphate binders are used as necessary to maintain serum levels of phosphorus below 7.0 mg/dL"); id., ex. 5, col. 12, ll. 39-43 ("patients * * * ingest calcium phosphatebinders (such as calcium carbonate or calcium acetate) in an amount sufficient to keep serum phosphate controlled"); id., col. 4, ll. 60-64 ("The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia, especially in patients who use oral calcium phosphate binders to control serum phosphorus levels."). The specification therefore indicates that controlling hyperphosphatemia is not an essential function of the claimed method of treatment. Consequently, the Court's construction -- which includes a hypercalcemia-related limitation but not a hyperphosphatemia-related limitation -- is appropriate.

Finally, the Court considers the prosecution history, which both sides contend supports their respective positions regarding the proposed low incidence of hypercalcemia limitation. U.S. Patent Nos. 5,104,864 (the "'864 patent") and 5,403,831 (the "'831 patent"), which are part of the '116 patent prosecution history, contain claims that are structurally similar to claim 7 in the '116 patent. In that regard, the '864 and '831 patent claims refer only to an "amount" -- not an "effective amount" -- and expressly require that the "amount"not cause hypercalcemia at all. For example, Claim 1 of the '864 patent states:

A method for reversing loss of bone mass or bone mineral content in a human being displaying or predisposed to developing osteoporosis, comprising the step of: administering to said human being an amount of 1 [alpha]-hydroxyergocalciferol (l [alpha] OHD[2]) sufficient to reverse loss of bone mass or bone mineral content without causing hypercalciuria or hypercalcemia, said amount being at least 2.0 [mu] g/day."

'864 patent, col. 7, ll. 39-46. 4

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4 Similarly, claim 1 of the '831 patent states:

A method for preventing loss of bone mass or bone mineral content post menopausal women, comprising: administering to said human an amount of 1 [alpha]-hydroxyl vitamin D[2] [l [alpha]-OH-vitamin D[2]) sufficient to prevent loss of bone mass or bone mineral content without causing hypercalcemia or hypercalciuria."

'831 patent, col. 8, ll. 5-10.

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Defendants contend that if the inventors of the '116 patent had intended to require a specific incidence of hypercalcemia in claim 7 -- e.g., a "low incidence" or "without causing hypercalcemia [at all]" -- they would have said so explicitly, as they did in the earlier related patents.Plaintiffs counter that the similarity between the claims illustrates that the term "effective," as it is used in claim 7 of the '116 patent, is a short-hand reference to the prevalence of side effects such as hypercalcemia.

While the Court finds Plaintiffs' contention to be unconvincing, the import of the omission of an express reference to hypercalcemia is not so clear as to provide useful guidance for purposes of construing claim 7 one way or the other. 5 The Federal Circuit has advised that "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Phillips, 415 F.3d at 1317. Here, the Court is looking at the final product, but the substance of the negotiations that led to the omission -- and thus the reasons behind the omission -- are not clear. Therefore, the prosecution history does not undercut the Court's conclusion that claim 7 includes a hypercalcemia-related limitation. Here -- as is often the case -- the specification is "dispositive." Vitronics, 90 F.3d at 1582.

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5 Parenthetically,the Court observes that even if the Court were to accept Plaintiffs' claim that "effective" is shorthand for "without causing hypercalcemia or hypercalciuria," Plaintiffs' proposed construction does not comport with that argument. In particular, Plaintiffs argue for a "low incidence of hypercalcemia" limitation, not a complete lack of hypercalcemia limitation (which they concede would be inconsistent with the examples in the specification) like the one in the '864 and '831 patents.

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In sum, the "specification read as a whole leads to the inescapable conclusion that" claim 7 is limited to amounts of doxercalciferol that result in a lower incidence of hypercalcemia than was associated with the conventional Vitamin D[3] treatments in existence at the time of the invention. See Alloc, 342 F.3d at 1370. As described above, "the specification makes clear that the invention does not include" amounts of doxercalciferol resulting in an incidence of hypercalcemia that is equal to or greater than the incidence of hypercalcemia associated with the then-conventional Vitamin D[3] treatments. SciMed, 242 F.3d at 1341. In light of that "clear disavowal of claim scope" (Teleflex, 299 F.3d at 1327), theCourt construes the final disputed claim term as follows: "an effective amount of 1 [alpha]-OH-vitamin D[2] to lower and maintain lowered blood concentrations of PTH with a lower incidence of hypercalcemia than is associated with the extant conventional Vitamin D[3] treatments."

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C. The Court's Revised Claim Construction

Although the Court is not persuaded by the arguments addressed above, the apparent confusion that has arisen in regard to the Court's construction persuades the Court that some clarification of its prior construction is advisable. The Court's inclusion of a hypercalcemia limitation in its construction of claim 7 followed from numerous statements in the specification which, in the Court's view, limited the scope of the claim. As noted above, those statements repeatedly compared the "present invention" to the prior art and stressed that, vis-à-vis the prior art, the present invention had equivalentbioactivity and lower toxicity. In the interest of clarity, the Court revisits the critical portions of the specification and places a finer point on its construction of claim 7.

• "These studies also indicate that at the dosage ranges required for [1 α,25-(OH)2 vitamin D3 and 1α-OH vitamin D3] to be truly effective, toxicity in the form of hypercalcemia and hypercalciuria becomes a major problem." '116 patent, col. 2, ll. 6-9.

• "Thus, the prior art teaches that due to their toxicity, 1-hydroxylated vitamin D compounds can only be administered at dosages that are, at best, modestly beneficial in preventing or treating loss of bone or bone mineral content." '116 patent, col.

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2, ll. 26-29.

• "The treatment method of the present invention is an alternative to conventional therapy with 1 α,25-(OH)2 vitamin D3 or 1α-OH vitamin D3; the method is characterized by providing an active vitamin D compound having equivalent bioactivity but much lower toxicity than these conventional therapies."'116 patent, col. 4, ll. 11-17

• "1α-OH vitamin D2 is equally active as 1α-OH vitamin D3 in the healing of rickets, in the stimulation of intestinal calcium absorption and in the elevation of serum inorganicphosphorous of rachitic rats." '116 patent, col. 4, ll. 22-25.

• "In accordance with the invention, it has been found that when the analogs of formula (I) are administered to end stage renal disease patients with elevated serum parathyroid hormone, PTH concentration is lowered with significantly less hypercalcemia and hyperphosphatemia than is observed after the same amount of activated vitamin D administered in previously known formulations. Thus, the compounds of formula (I) have an improved therapeutic index relative to vitamin D3 analogs."'116 patent, col. 5, ll. 1-9.

• "In parent application, Ser. No. 08/119,895 and its parent application, now U.S. Pat. No. 5,104,864, it has been shown that 1α-OH vitamin D2 has the same biopotency as 1α-OH vitamin D3 and 1 α,25-(OH)2 vitamin D3 but is much less toxic."'116 patent, col. 5, ll. 58-62.

On the basis of its reexamination of the language of the specification and the parties' commentary on the prior construction, the Court believes that certain modifications are in order. To begin with, the Court construes "effective amount" to be "an amount sufficient to" — a construction that finds support in several Federal Circuit cases. See, e.g., Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 334 F.3d 1274, 1277-78 (Fed. Cir. 2003)(noting that "the term 'effective amount' has a customary usage * * * mean[ing] 'the amount of Lewis acid inhibitor that will prevent the degradation of sevoflurane by a Lewis acid."); Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1299, 1304 (Fed. Cir. 2002) (affirming the district court's construction of the claim term "effective amount" to mean "a sufficient amount of the specified component to form an encapsulant having the specified properties under the specified conditions, if any"). In addition, the Court alters the back end of its construction to make clear that (1) the comparison made throughout the specification is between 1α-OH-vitamin D2 and two specific vitamin D3 compounds — namely, 1 α,25-(OH)2 vitamin D3 and 1α-OH vitamin D3; and (2) the present invention claims to lower PTH with a lower incidence of hypercalcemia than would be observed using the prior art to achieve the same level of PTH suppression.4 The Court's revised construction of claim 7 thus reads:

A method for lowering elevated blood concentrations of parathyroid hormone ("PTH") or maintaining lowered blood concentrations of PTH in human patients having increased (i.e., above normal) secretion ofPTH by the parathyroid gland as a result of a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation, comprising: administering an amount of 1α-OH-vitamin D2 sufficient to lower and maintain lowered blood concentrations of PTH with a lower incidence of hypercalcemia than would result from using 1α,25-(OH)2 vitamin D3 or 1α-OH vitamin D3 to achieve the same level of PTH suppression.

Within those parameters — equivalent effectiveness with respect to PTH suppression and lower toxicity — a person of ordinary skill in the art (1) would understand that the particular effective dosage of the various vitamin D2 and vitamin D3 compounds (i.e., 1α-OH-vitamin D2 or 1 α,25-(OH)2 vitamin D3 or 1α-OH vitamin D3) varies from patient to patient and (2) would be able to determine the appropriate dosage regime to treat a given patient. Indeed, both parties acknowledge that "[d]etermination of the 'effective amount' for a given patient is within the skill of the POSA." Def.'s Claim Construction Brief [229] at 16; Pl.'s Response [433] at 8 n.8; see also Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003)("'effective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation").

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4 Defendants complain that the Court's claim construction resolves disputed issues of fact. Not so. The claim construction rests on what has been claimed, not what has been proven. In other words, the claim construction makes no assumptions concerning the actual superiority (or inferiority) of 1α-OH-vitamin D2 as compared to 1α,25-(OH)2 vitamin D3 or 1α-OH vitamin D3. Rather, the construction rests on an assertion of superiority. To the extent that there may be a gap between what

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has been claimed in the '116 patent and what can be proved by the evidence, that is not a claim construction issue. Nothing in the Court's claim construction forecloses Defendants from arguing (and presenting evidence) that treatment with 1α,25-(OH)2 vitamin D3 or 1α-OH vitamin D3 is not associated with high (or higher) incidence of hypercalcemia or that Plaintiffs have no evidence that treatment with 1α-OH-vitamin D2 results in less hypercalcemia that treatment withthe vitamin D3 compounds. If Defendants are correct as to Plaintiffs' failure of evidence, then the likely result would be that claim 7 is inoperable, not indefinite. See Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1382 (Fed.Cir.2001) (stating that inoperable embodiments present "an issue of enablement, and not indefiniteness"); Miles Labs., Inc. v. Shandon Inc., 997 F.2d 870, 875 (Fed. Cir. 1993) ("The invention's operability may say nothing about a skilled artisan's understanding of the bounds of the claim.").

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"Effective body fat reducing amount," "effective, lean-body-mass increasing amount," "effective[,] blood serum lipid[-] reducing amount [dose]," and "effective HDL-cholesterol increasing dose"

The Court construes these terms based on the reasoning supporting its construction of "effective amount" and "effective dose." See supra, n.5. Accordingly, the term "effective body-fat-reducing amount," which appears Claim 13 of the '624 Patent, means an "amount to reduce the percentage of body fat in the mammal." The term "effective, lean-body-mass increasing amount," which appears in claims from the '624 Patent, means an "amount to increase lean body mass in the mammal." The term "effective[, blood serum lipid[-] reducing amount [dose]," which appears in claims from the' 156 Patent, means an "amount to reduce blood serum lipid levels in the individual." Finally, the term "effective HDL-cholesterol increasing dose," which appears in Claim 18 of the '156 Patent, means an "amount to increase the blood serum levels of HDL-cholesterol in the individual."

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D. "Amount of Triclosan Effective To Kill Microorganisms Present On The Skin"

Plaintiffs' Construction	Defendants' Construction
An amount of triclosan that has the desired effect of killing microorganisms on the skin.	From 0.001% - 5% by weight of triclosan.

The dispute among the parties is whether this term should be limited to a specific numerical range mentioned in the specification. Defendants contend that the claims should be so limited because the specification explains that "[t]he antimicrobial chemical agent is normally present in an amount of from 0.001-5% by weight, preferably from 0.05-2% by weight, and more preferably from 0.1-1% by weight." ('516 patent at 4:42-45.) Plaintiffs respond that this passage only refers to the percentage by weight of "antibacterial agent in general" and does not specifically set forth particular ranges of triclosan concentrations. (D.I. 144 at 16; D.I. 175 at 13.) Defendants, however, note that no other antimicrobial component other than triclosan is mentioned in the specification, so this passage must be referring to triclosan. (See D.I. 192 at 63:4-7 (Defendants argue at the Markman hearing that "[i]f that [paragraph] doesn't apply to triclosan, then what on earth does it apply to?").)

Helpful in this case is the Federal Circuit's guidance in Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-1384 (Fed. Cir. 2003). In Geneva, the claim term at issue was "synergistically effective amount of clavulanic acid," which the district court found to be ambiguous. Relying on a passage in the specification stating that "[e]ach unit dose will usually contain from 50 to 500 mg," the district court construed the term to be limited to the 50 to 500 mg range. 3 Geneva Pharms., Inc. v. Glaxosmithkline PLC, 213 F. Supp. 2d 597, 606 (E.D. Va. 2002). Concluding that the district court erred in adopting this construction, the Federal Circuit explained that "'effective amount' is a common and generally acceptable term

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for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." Geneva, 349 F.3d at 1383-1384 (citing In re Halleck, 422 F.2d 911, 914, 57 C.C.P.A. 954 (C.C.P.A. 1970)). The Federal Circuit further explained that "synergistically effective amount" is a "functional limitation" that should cover all embodiments capable of achieving "therapeutic synergy," not just those in the disclosed 50 to 500 mg range. Id.

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3 The district court endeavored to construe this term in the context of an obviousness-type double patenting analysis, not the typical context of a Markman hearing. Nevertheless, the Court still finds the Federal Circuit's guidance in this case to be instructive.

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Here, as in Geneva, the disputed claim term is a "functional limitation" that uses the "common and generally acceptable" "effective amount" language. Furthermore, just as the specification in Geneva stated that the relevant amount was "usually" in a particular range, the specification of the '516 patent states only that the antimicrobial agent is "normally" within 0.001-5% by weight. The Court sees nothing further in the intrinsic evidence to more strongly suggest that the claims should be limited to a particular numerical range. Accordingly, following Geneva, the Court will not limit the claim term to 0.001 to 5% triclosan.

Indeed, the Federal Circuit has explained that "[w]hen a claim term is expressed in general descriptive words, [courts] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998). This is a principle that the Federal Circuit has repeatedly applied, 4 and, the Court sees no reason why it should not apply here as well, particularly in light of the fact that the specification (1) does not refer to a particular antimicrobial agent and (2) merely explains that the concentration of antimicrobial agent is "normally" within a certain range.

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4 See, e.g., Conoco, Inc. v. Energy & Envtl. Int'l. L.C., 460 F.3d 1349, 1358 (Fed. Cir. 2006) (declining to limit the term "water-alcohol mixture" to a composition that was at least 30 percent water when the specification stated that "the amount of alcohol employed in the suspending material may vary widely but it usually forms between 0 and 70 weight percent of the suspending material, and more usually between about 30 and 50 weight percent") (emphasis in original); Innovad, Inc. v. Microsoft Corp., 260 F.3d 1326, 1332-33 (Fed. Cir. 2001) (holding that the term "small volume" was not limited to being smaller than 4.4 cubic inches when the specification related the term to a function and provided no specialized meaning for the term); Brassica Protection Products LLC v. Sunrise Farms (In re Cruciferous Sprout Litig.), 301 F.3d 1343, 1348 (Fed. Cir. 2002) (declining to construe a claim term in terms of a specific numerical limit when, among other reasons, the patent included no indication that the claim term should be so limited).

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Having decided not to adopt Defendants' proposed construction, the Court must now decide whether it should adopt Plaintiffs' proposed construction. The Court concludes that Plaintiffs' proposed construction merely paraphrases the common term "effective," offering nothing to enhance the understanding of the claims to one of skill in the art. Accordingly, the Court will not adopt Plaintiffs' proposed construction either. Having resolved the essential dispute over whether this claim term should be limited to a particular range of antimicrobial agent concentrations, the Court concludes that the term requires no additional construction.

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2. "effective to treat"

Daiichi argues that the phrase "effective to treat" otopathy means "safe and efficacious to treat." (Daiichi Br., at 21.) Apotex

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disagrees, and argues that the term "safe" should not be read into the patent claim. The Court agrees with Daiichi.

It is proper to interpret terms and phrases appearing in the claim in light of the fundamental purpose and significance of the invention. Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559 (Fed. Cir. 1992);In re Research Corp. Techs., Inc., No. 97-2836, 1998 U.S. Dist. LEXIS 23150 at *12 (D.N.J. Oct. 16, 1998). Doing so in this case amply supports Daiichi's argument that "safety was a paramount concern of the inventors" of the '741 patent. (Daiichi Br., at 22.)

In describing the background to the invention, the patent specification recites the following:
Conventionally employed topical preparations for treating otopathy . . . have ototoxicity as side effects or therapeutic effects thereof tend to be decreased due to emergence of resistant microorganisms.

* * *

In order to overcome the above-described problems, the inventors have conducted extensive investigations and, as a result, have reached the present invention.

* * *

Ofloxacin is of high safety. Acute toxicity (LD[50]) of ofloxacin was found to be 5450 mg/kg (p.o.) in mice, 200 mg/kg or more (p.o.) in dogs, and from 500 to 1,000 mg/kg (p.o.) in monkeys.

* * *

The preparation according to the present invention exhibits marked improvements over the conventional drugs in terms of not only otoxicity but also tissue distribution and excellent therapeutic effects on otopathy . . .

(Krol Decl., Exh. A.) In addition, the specification describes a number of animal studies involving the ototoxic effects of topically applied ofloxacin and data concerning the drug's safety.

In light of the extensive discussion of side-effects and safety in the patent specification, the Court concludes that it is proper to construe the disputed term "effective to treat" as "efficacious and safe." n10

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n10 In addition, at least one district court has construed the term "effective' so as to implicitly include minimization of side effects. Purdue Pharma. L.P. v. F.H. Faulding & Co., 48 F.Supp.2d 420. 437 (D.Del. 1999), aff'd, 230 F.3d 1320 (Fed. Cir. 2000) (construing "effective to treat pain" to mean "an individual patient is provided with adequate pain reief . . . without unacceptable side effects").

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After holding a Markman hearing on July 22, 2005, the Court held that a person ordinarily skilled in the art would have a medical degree, experience treating patients with ear infections, and knowledge of the pharmacology and use of antibiotics. Daiichi Pharm. Co., 380 F. Supp. 2d at 485. Additionally, that person would be a pediatrician or general practitioner-those doctors who are often the first line of defense in treating ear infections. Id. Furthermore, the Court construed the term "otopathy" to mean "bacterial ear infection," the words "effective to treat" to be interpreted as "safe and efficacious," and the phrase "intratympanically injected through a puncture of the tympanic membrane" to mean "introduced into the middle ear with an instrument such as a syringe." Id. at 485-89.
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2. The meaning of the phrase "effective treatment of pain"

Based on the testimony of its medical expert, Dr. Gelmann, Faulding contends that the phrase "effective treatment of pain" in clinical practice means "control of pain that is acceptable to the patient in the context of an acceptable level of side effects." (Tr. 1091). According to Faulding, the effective treatment of pain does not require complete alleviation of pain, but patient satisfaction. In Dr. Gelmann's words, "If the patient is satisfied, then that is sufficient." (Tr. 1091-92). Faulding also contends that an effective pain regimen includes the use of "rescue medication," meaning additional doses of immediate release morphine in addition to the sustained release morphine, as well as the use of nonopioid analgesics such as aspirin, acetaminophen or ibuprofen, and adjuvant drugs that enhance the effectiveness of opioid therapy or control side effects such as laxatives. (Tr. 1086, 1134). Faulding points out that an inventor of the '360 Patent, Dr. Goldenheim, testified that the '360 Patent contemplates the use of rescue medication and "other medicines" in combination with morphine sulfate. (Tr. 199-200). Thus, according to Faulding, the plain meaning of the claims encompasses a treatment regimen which includes the appropriate use of rescue medication, nonopioid analgesics and adjuvants.

In their Answering Brief To Defendants' Opening Post-Trial, Purdue contends that there is "no real dispute" concerning the proper meaning of the phrase "effective treatment of pain" as used in the asserted claims. (D.I. 320 at 11). Further, Purdue agrees with Faulding that the claimed methods of the '360 Patent include the appropriate use of rescue and other medication in combination with the sustained release opioid dosage form. Thus, according to Purdue, "both Purdue and Faulding agree that the language 'effective treatment of pain' means that the individual patient is provided with adequate pain relief from the sustained release opioid dosage form without unacceptable side effects." (D.I. 320 at 11).

In its Post-Trial Reply Brief, Faulding seemingly agrees with Purdue that there is no "real dispute" concerning this language, because it does not revisit its claim construction argument about the effective treatment of pain as it does with its previous claim construction argument concerning patients "on average." However, in its Response to Plaintiffs' Additional Findings Of Fact, Faulding states that it "does not agree" (D.I. 330 at 7, emphasis in original) with Purdue's statement that "both Purdue and Faulding agree that the language 'effective treatment of pain' means that the individual patient is provided with adequate relief from the sustained release opioid dosage form without unacceptable side effects," because (1) Purdue has not defined "adequate relief," and (2) Purdue uses the "redundant requirement that "'the sustained release opioid dosage form' provide the 'adequate' pain relief." (D.I. 330 at 8).

The Court finds that Faulding's disagreement with Purdue's characterization is a disagreement of form over substance. The Court finds that there is no "real dispute" between the parties over what is meant by the phrase "effective treatment of pain." Both parties agree that rescue medication and other drugs are contemplated by the claims of the '360 Patent, and both parties discuss effective pain treatment in relation to the individual--Purdue using the word "adequate" to the individual and Faulding using the word "acceptable" to the individual.

In its definition, Purdue seeks to emphasize that the "adequate" or "acceptable" balance of pain relief and side effects for the patient primarily comes from the sustained release opioid dosage form, rather than from a combination of the drugs that the patient received. Although the construction Faulding urges does not expressly state what provides the "control of pain that is acceptable to the patient in the context of an acceptable level of side effects," Faulding does not dispute Purdue's contention, and in fact, acknowledges that "the morphine contributes the majority of pain relief." (D.I. 330, at 8; Tr. 1092, 1177).

The construction urged by Purdue includes the connection between the sustained release opioid dosage form and the control of pain, which both parties agree is part of the claim's requirement, as well as the individual frame of reference for pain relief, which again both parties agree is part of the claim's requirement. Thus, the Court finds that the construction urged by Purdue comprehensively embodies what is essentially the parties' substantive agreement over the meaning of the phrase "effective treatment of pain." Accordingly, for purposes of claim construction, the Court finds that the "effective treatment of pain" means that an individual patient is provided with adequate pain relief from the sustained release opioid dosage form without unacceptable side effects.

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1. Claim Construction

As discussed above, the '343 and the '481 patents both claim a silver catalyst containing "an efficiency-enhancing amount . . . of a mixture of [salts]." '343 patent, col. 32, l. 63-col. 33, l. 9; '481 patent, col. 27, ll. 48-56. On appeal, Union Carbide argues that the district court erred when it construed "efficiency-enhancing amount . . . of a mixture of [salts]" to mean that the salts themselves must be efficiency enhancing. According to Union Carbide, the efficiency enhancing limitation requires only that the catalyst containing the salt mixture increase the efficiency of the ethylene oxide reaction, not that the salts be the agents responsible for that increase in efficiency. In support of this argument, Union Carbide relies extensively upon the salt patents' specifications, asserting that they teach that one measures the efficiency of the catalyst overall rather than the efficiency of the salts on the catalyst. In a related vein, Union Carbide argues that due to the uncertain nature of the chemical reactions involved, the only way to measure efficiency enhancement is to measure overall catalyst efficiency.

Finally, Union Carbide asserts that Shell agreed to this construction before trial when it filed its response to Union Carbide's statement of issues on claim construction. In this response, Shell stated that it "agreed with [Union Carbide's] interpretation that 'one must compare the efficiency of the catalyst with a base value efficiency of a comparable silver-only catalyst,' . . . so long as the testing of the catalyst efficiencies is conducted under the same conditions." Union Carbide argues that this statement clearly reveals that both parties were in accord that a catalyst contains "an efficiency enhancing amount . . . of a mixture of [salts]" if the catalyst's efficiency is greater than that of a comparable silver-only catalyst, and that Shell was therefore bound by that construction at trial.

Shell responds that the court's claim interpretation was correct as supported by the plain language of the claims and the specification. Shell argues that Union Carbide's proposed claim construction effectively reads a limitation out of the claims by failing to require that the salts themselves enhance the efficiency of the catalyst. Shell also argues against Union Carbide's assertion that Shell violated the parties' pre-trial agreement on the correct construction of the claims. At oral argument, Shell did not dispute the fact that it had agreed that the asserted claims require one to compare the efficiencies of a catalyst containing the salt mixture with those of a silver-only catalyst. Shell maintained, however, that this agreement is not tantamount to a concession that only the catalyst, and not the salts themselves, need be efficiency enhancing to fall within the scope of the claims. Shell agrees that one must compare the relevant salt-containing and silver-only catalysts, but it also argues that, as required by the efficiency enhancing limitation, the salt mixture itself must cause the increase in efficiency observed during the comparison.

We conclude that the district court properly construed the claim term "an efficiency-enhancing amount . . . of a mixture of [salts]" to mean that the salts themselves must enhance the efficiency of the catalyst. As Union Carbide conceded at oral argument, the claim language itself is unambiguous. The term "efficiency-enhancing" modifies the phrase "amount . . . of a mixture of [salts]," clearly indicating that the asserted claims of the '343 and the '481 patents are not directed to all catalysts that both contain salts and are more efficient but rather to those catalysts that are more efficient because they contain a particular mixture of salts. While Union Carbide is correct when it asserts that the claims must be construed in light of the specification, Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352, 58 U.S.P.Q.2D (BNA) 1076, 1079 (Fed. Cir. 2001), where the claim language is unambiguous on its face, as it is here, "our consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of the claims is specified," Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331, 59 U.S.P.Q.2D (BNA) 1401, 1407 (Fed. Cir. 2001); see also Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1371, 61 U.S.P.Q.2D (BNA) 1647, 1657 (Fed. Cir. 2001) ("Limitations from elsewhere in the specification will not be read in where, as here, the claim terms are clear.").

In the instant case, the intrinsic evidence does not support such a deviation. On the contrary, the salt patents' specifications indicate that the asserted claims are directed to those catalysts that are rendered more efficient by the presence of a particular mixture of salts. The '343 patent's Detailed Description of the Invention, for example, specifies that "the optimum cesium salt and other alkali metal and/or alkaline earth metal salt concentration for a particular catalyst will be dependent upon performance characteristics, such as, catalyst efficiency, rate of catalyst aging and reaction temperature." '343 patent, col. 14, ll. 20-24 (emphases added). Elsewhere, the '343 specification states that the preferred embodiment of the invention is characterized by a combination of metal salts "so as to achieve a synergistic result," which the specification defines as an

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efficiency greater than that demonstrated by a catalyst containing either one of the salts on its own. Id. at col. 12, ll. 58-68. Similarly, the '481 specification states that "by the use of mixtures of cesium salts, enhanced performance of the catalyst in terms of one or more of activity, efficiency, stability, and sensitivity to changes in process conditions can be obtained." '481 patent, col. 9, ll. 34-39 (emphases added). The '481 specification also discusses "the ratio of cesium salt to any other alkali metal and alkaline earth metal salt(s), if used, to achieve desired performance." Id. at col. 10, ll. 66-68. In other words, both the '343 and the '481 specifications describe a catalyst that contains a particular amount of a certain combination of salts in order to increase efficiency. Even if, as Union Carbide argues, the specification teaches that one measures the general efficiency of the catalyst rather than the efficiency of the specific salt mixture, this does not change the fact that the specification clearly indicates that it must be a catalyst's salts that enhance that efficiency.

Union Carbide's argument concerning the uncertain nature of the chemical reactions involved is similarly without merit. In effect, Union Carbide argues that because no one is certain exactly how the salts affect the ethylene oxide reaction, one cannot measure the efficiencies of the salts themselves, and the disputed claim term must therefore be construed to encompass any catalyst that both contains a mixture of salts and is more efficient. This argument is undermined, however, by the fact that Union Carbide introduced evidence at trial that the salts themselves enhanced catalyst efficiency. Furthermore, we note that the inventor of the '343 and the '481 inventions chose to claim them by use of the efficiency enhancing limitation. As the patent assignee, Union Carbide must live with the legal consequences of that choice.

Finally, we reject Union Carbide's argument concerning Shell's statement of issues on claim construction. Before the trial court and on appeal, Union Carbide relied heavily on the section of Shell's statement where Shell "agreed with [Union Carbide's] interpretation that 'one must compare the efficiency of the catalyst with a base value efficiency of a comparable silver-only catalyst,' . . . so long as the testing of the catalyst efficiencies is conducted under the same conditions." In Union Carbide's view, this statement reveals that both parties accepted that only the catalyst containing the salts, and not the salts themselves, must be efficiency enhancing. We disagree. Shell's statement does not demonstrate that Shell agreed to Union's Carbide's construction of the efficiency enhancing limitation. As the district court found, Shell did not accept Union Carbide's construction in its statement but instead protested that this construction constituted "a completely rewritten construction of the [claim] language." Union Carbide, 163 F. Supp. 2d at 443. Moreover, Shell asserted that Union Carbide's proposed construction was "unnecessary" because the limitation included no disputed terms. While Shell did consent that the efficiencies of the salt-containing and the silver-only catalysts must be compared, this agreement is not inconsistent with Shell's view that any increase in the salt-containing catalyst's efficiency must be the result of the salts themselves. Like the district court, we conclude that Shell did not assent to Union Carbide's proposed claim construction prior to trial. See id. Shell was not, therefore, bound by that construction or precluded from arguing a different construction at trial. Cf. Interactive Gift Express, 256 F.3d at 1347, 59 U.S.P.Q.2D at 1419-20 ("Applying the doctrine of waiver . . ., [the patentee] is precluded from proffering a claim construction on appeal that changes the scope of any of the claim construction positions that it advanced in its binding [claim construction] report."); Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 715, 48 U.S.P.Q.2D (BNA) 1911, 1915-16 (Fed. Cir. 1998) ("Ordinarily, doctrines of estoppel, waiver, invited error, or the like would prohibit a party from asserting as 'error' a position that it had advocated at the trial.").

Because the district court did not err when it construed "an efficiency-enhancing amount . . . of a mixture of [salts]" to mean that the salts themselves must increase the catalyst's efficiency, we affirm its construction of the disputed terms of the '343 and the '481 patents.

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D. "An Electroactive Reaction Product"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"electroactive reaction product"	A chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode under	The product resulting from the reaction of the glucose and the reagent [an enzyme and a mediator] during the open circuit or delay

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	appropriate conditions.	period.

For two reasons, the Court will not adopt Defendants' proposed construction. First, for the reasons set forth above, the Court will not construe the claims to require a "delay period." Second, to the extent Defendants' proposed construction requires that the "electroactive reaction product" arise from the "reaction of the glucose and the reagent," the Court concludes that this language is superfluous in light of the explicit claim language calling for "the reagent reacting with glucose to produce an electroactive reaction product." See, e.g., '146 patent at Claim 1. Likewise, with regard to Plaintiffs' proposed construction, the Court sees no evidence that the phrase "under appropriate conditions" would illuminate the meaning of this claim term to one of skill in the art. Accordingly, the Court will construe the term "electroactive reaction product" to mean "a chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode."
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K. "Electrooxidize"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"electrooxidize"	To cause a molecule or atom to donate at least one electron at an electrode.	No construction necessary.

Plaintiffs note that the specifications of the patents-in-suit explain that "oxidized" means "donates at least one electron." (D.I. 357 at 29 (citing '147 patent at 7:28-38).) Thus, according to Plaintiffs, "electro-oxidized" is "merely an oxidation reaction that occurs at an electrode." (Id.) Defendants agree that "oxidize" means "to donate at least one electron," but object to Plaintiffs' proposed construction as being too broad for its failure to mention the use of a "delay period." Defendants further object to Plaintiffs' proposed construction because "[t]he claims do not recite electrooxidizing 'a molecule or atom'; the claims recite electro-oxidation of the electroactive reaction product."

The Court will not adopt either parties' proposed construction. To the extent Plaintiffs propose that electrooxidize be limited to "a molecule or atom," the Court will not adopt Plaintiffs' proposed construction. Indeed, the Court sees no reason why a cluster of loosely bound atoms or molecules could not be the subject of an electrooxidation. However, the Court will adopt the remainder of Plaintiffs' proposed construction. As noted, the parties agree that "oxidize" refers to the donation of an electron. Furthermore, the specification indicates that "electrooxidation" does indeed take place at an electrode. See, e.g., '146 patent at 7:35-36 ("electrooxidation of the mediator at the working electrode"); id. at 8:7 ("Mediator electroxidized at the working electrode . . . ."); id. at 8:10-12 ("oxidized mediator reduced at the counter electrode can migrate to the working electrode for electrooxidation"). Finally, although Defendants object that Plaintiffs' proposed construction fails to refer to a "delay period," the Court has, as explained above, concluded that the claims do not require a "delay period." Accordingly, the Court will construe the term "electrooxidize" to mean "to donate at least one electron at an electrode."
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4. "Emulsifying agent"; An ingredient added to stabilize an emulsion (an emulsion is, e.g., a dispersion of oil in water).

('062 patent, col. 2, ll. 68 to col. 3, ll.1; col. 4, ll. 19-25)
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E. "Encapsulated"

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Wyeth asks the Court to construe the term "encapsulated," as found in asserted Claims 20 through 25 of the '171 patent and Claims 2 and 14 of the '120 patent, to mean "filled into a pharmaceutically acceptable capsule." Mylan asserts that the correct construction is "enclosed by a protective coating or membrane." Both parties contend that their definition constitutes the ordinary meaning of the term to someone skilled in the pharmaceutical arts.

In the opinion of Wyeth's expert, McGinity, Wyeth's construction comports with his understanding of the ordinary meaning of the term "encapsulated." Wyeth Ex. 19, PP 48-51. McGinity relies on a pharmaceutical textbook, Remington: The Science and Practice of Pharmacy 1642 (19th Ed. 1995), for the proposition that "capsules" are "solid dosage forms in which the drug substance is enclosed in either a hard or soft, soluble container or shell of a suitable form of gelatin." Id. That definition is followed by a note that "encapsulation of medicinal agents remains a popular method for administering drugs." Id. From this, McGinity concludes that the definition found in Remington confirms that Wyeth's proposed construction is the ordinary meaning of the term. Id.

Mylan, on the other hand, relies on the opinion of its expert, Van Buskirk, that the American Heritage Dictionary, available at www.Dictionary.com, supports Mylan's contention that the ordinary meaning of the term "encapsulated," is "enclosed by a protective coating or membrane." Mylan, Barry Dec., Ex. C, PP 25-27. Van Buskirk acknowledges that a person of ordinary skill in the art would recognize that "materials that are 'encapsulated' can include drug product formulations that are placed into either hard or soft gelatin capsules." Id. at P 26. He contends, however, that the term "encapsulated" is not limited to gelatin capsules and that the broader definition suggested by Mylan is more accurate. Id.

Claims 20-25 of the '171 patent use the term "encapsulated" identically: "A method . . . which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides . . . ." (Emphasis added). Claim 2 of the '120 patent simply states: "A method of claim 1 wherein the extended release formulation is encapsulated." Similarly, Claim 14 of the '120 patent provides: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." Thus, the plain language of the claims provides no indication as to which construction is intended.

The specification, however, does provide guidance. In the "Background of the Invention," the inventors describe the conventional process in the pharmaceutical industry for preparing encapsulated drug formulations that provide extended or sustained release properties. '171, Col. 1:35-40. They explain that, after the spheroids are created, they are "film-coated to retard dissolution." Id. at Col. 1:45-47. "The film coated spheroids may then be placed into pharmaceutically acceptable capsules, such as starch or gelatin capsules, in the quantity needed to obtain the desired therapeutic effect." Id. at Col. 1:46-50.

While the information provided in the Background is a review of the conventions of the industry, rather than an explanation of the specific invention in this case, it clearly indicates that the inventors understood the process of filling spheroids into "pharmaceutically acceptable capsules" as a step separate from coating the spheroids with a film. This distinction is reenforced in the "Brief Description of the Invention," in which the inventors describe various preferred formulations of the invention. Each formulation provides a specific formula for the "film coating" that is applied to the spheroids. Following a list of several "lower dose formulations," the Brief Description section concludes with the following sentence: "Each of these formulations is also preferably contained in a gelatin capsule, preferably a hard gelatin capsule." Id. at Col. 3:60-63. The term "encapsulated" does not appear anywhere in the "Brief Description."

Finally, Example No. 1, found in the "Detailed Description of the Invention," clearly distinguishes between coating the spheroids with a film and putting them into capsules. Id. at Col. 5:38-56. Specifically, the inventors state that, after separating out coated spheroids of a specific size, "[t]hese selected film coated spheroids are filled into pharmaceutically acceptable capsules conventionally, such as starch or gelatin capsules." Id. at Col. 5:53-56. Thus, they again distinguish between the process of coating the spheroids with a film and filling them into capsules, which they specify must be "pharmaceutically acceptable."

Because a patent's specification is considered the best source for understanding technical terms, Phillips, 415 F.3d at 1315, the Court has no trouble concluding that the ordinary meaning of "encapsulated" to one of ordinary skill in the art would be "filled into pharmaceutically acceptable capsules." Contrary to Mylan's assertions, Wyeth's construction does not limit the types of capsules that may be used, other then to require that they be "pharmaceutically acceptable." Rather, the inventors repeatedly describe the process of filling drug formulations into pharmaceutically acceptable capsules, which, as they

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indicate, may (not must) be starch or gelatin capsules.

Moreover, Mylan's definition, "enclosed by a protective coating or membrane," would create confusion, given that the inventors repeatedly refer to "coating" the spheroids with a film that aids in the extended-release process. Although Mylan insists that it is not trying to imply that the extended-release coating placed on the spheroids is the "encapsulation" of those spheroids, adopting Mylan's definition would certainly raise that inference.

In addition, to the extent that extrinsic evidence is helpful to determine what a person of ordinary skill in the art would have understood at the time of the invention, the Court concludes that Wyeth's source is more reliable. Wyeth's proposed construction comports with the definition of encapsulated provided by Remington, a pharmaceutical textbook, while Mylan's definition is drawn from the online American Heritage Dictionary. Because Remington is a guide used by those skilled in the pharmaceutical arts, while the American Heritage Dictionary is not specific to that field, the Remington definition is more persuasive.

Accordingly, the Court concludes that a person of ordinary skill in the pharmaceutical arts would have understood the term "encapsulated" to mean "filled into a pharmaceutically acceptable capsule," and therefore adopts Wyeth's construction of this term.
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4. "encapsulated"

Wyeth asserts that "encapsulated" means "[a] formulation that is present in a capsule, i.e., one that is filled into a pharmaceutically acceptable capsule." (Chart). Teva essentially proposes two different constructions depending on how the Court construes the term "extended release formulation." If the Court construes "extended release formulation" broadly to not include any particular ingredients, Teva contends that "encapsulated" means "[a] formulation that is present in a capsule." (Id.). On the other hand, if the Court construes "extended release formulation" to include particular ingredients, Teva agrees with Wyeth's narrower construction. (See, e.g., Teva's Br. at 29 ("If the Court adopts Teva's construction of the term 'extended release formulation,' there is no dispute concerning the term "encapsulated.")).

Although the Court disagrees with Teva's argument that the construction of the term "encapsulated" is contingent on the construction of "extended release formulation," there appears to be no need for this Court to perform an exhaustive analysis of how this term should be construed because the Court has adopted the narrower construction of "extended release formulation." That being the case, the parties do not dispute the meaning of the term "encapsulated." Accordingly, the Court finds that "encapsulated" means "a formulation that is filled into a pharmaceutically acceptable capsule."
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E. End Stage Renal Disease

Plaintiffs contend that "endstage renal disease" should be construed as "a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation." Defendants counter that the appropriate construction of "end stage renal disease" is "renal impairment which is irreversible and permanent and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life." The parties' constructions present two disputes: (1) whether the dialysis required by patients with ESRD should be described as "chronic"; and (2) whether the dialysis or kidney transplantation required by patients with ESRD should be described as necessary to "ameliorate uremic symptoms."

1. Chronic Dialysis

Plaintiffs' proposed description of the required dialysis as "chronic" is consistent with the patent specification. See '116 patent, col. 11, ll. 43-44 (referring to "men and women with renal disease who are undergoing chronic hemodialysis"); id.,

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col. 12, ll. 13-14 (describing patients as "undergoing chronic hemodialysis"). A U.S. Department of Health and Human Services report relied on by Defendants also supports Plaintiffs' position that ESRD patientsrequire "chronic" dialysis. See Health Care Financing Research Report, End Stage Renal Disease 1992, HCFA Pub. No. 03359 (Exh. N to [229]) (defining "ESRD patient" as "[a] person with irreversible and permanent kidney failure," and states that they are eligible for Medicare benefits once a "physician certif[ies] that the individual requires chronic dialysis or kidney transplant to maintain life"). Moreover, Defendants' own proposed construction states that ESRD patients require dialysis (or a transplant) to maintain life, thereby implying that the required dialysis is chronic.

Nevertheless, Defendants object to Plaintiffs' proposed inclusion of the term "chronic." Defendants do not take the position that describing the dialysis required by patients with ESRD as "chronic" would be erroneous. Indeed, Defendants agree that patients with ESRD require regular dialysis (or a kidney transplant) in order to survive. Rather, Defendants contend that the inclusion of the adjective "chronic" is superfluous. The Court disagrees. The inclusion of the term "chronic" results in a fuller, more robust definition that is consistent with the claim language and the specification.

2. Uremic Symptoms

The parties'second dispute regarding the construction of "end stage renal disease" centers on Defendants' proposed inclusion of the phrase "to ameliorate uremic symptoms." Defendants' proposed construction is not based on any intrinsic evidence, but is drawn directly from the U.S. Department of Health and Human Services report referenced above. That report defines "end stage renal disease" as "that stage of renal impairment which is irreversible and permanent and requires dialysis or kidney transplantation to ameliorate uremic symptoms and maintain life." Plaintiffs object to the inclusion of any reference to "uremic symptoms" on the grounds any such reference would improperly exclude patients with hyperparathyroidism secondary to ESRD from the scope of the claim if: (1) they never exhibit such symptoms, or (2) they did exhibit such symptoms, but as a result of treatment, including treatment according to the claimed method, they stopped exhibiting such symptoms.

The Court finds that the inclusion of a reference to "uremic symptoms" does nothing to clarify the scope of the claim, but risks inviting confusion, as the added terms -- "uremic symptoms" -- would themselves likely require additional construction.Therefore, the Court declines to include such a reference in the construction of claim 7.

In sum, the Court construes "end stage renal disease" as "a disease wherein the patients' kidneys no longer function at a level necessary to sustain life and thus require chronic dialysis or kidney transplantation."
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M. Enhance non-specific defenses

The terms "enhance the non-specific defenses of mononuclear cells or macrophages or both" and "enhancing the non-specific defenses of mononuclear cells or macrophages or both" appear in claim 8 of the '720 Patent. Claim 8 is:

A method of treating an immunocompromised human or animal comprising administering to said human or animal an amount of an underivatized, aqueous soluble yeast [beta] (1-3) glucan sufficient to enhance the non-specific defenses of mononuclear cells or macrophages or both in said animal or human, thereby treating said immunocompromised human or animal by enhancing the non-specific defenses of mononuclear cells or macrophages or both.

Plaintiffs assert that the terms do not need construction. Immunocorp and Biotec offer this construction: "Administration of the soluble glucan enhances the non-specific defenses of mononuclear cells or macrophages or both, but does not result in increased body temperature." Immunocorp and Biotec rely on the following passage from the '720 Patent's specification to support their inclusion of the language regarding body temperature:

Glucan produced by the present method enhances the non-specific defenses of mammalian mononuclear cells and significantly increases their ability to respond to an infectious challenge. The unique property of glucan- macrophage activation is that it does not result in increased body temperatures (i.e., fever) as has been reported with many non-specific stimulants of host defenses. This critical advantage of glucan may lie in the natural profile of responses it mediates in white

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blood cells.

'720 Patent, col. 5, ll. 33-41. The Court declines to import "but does not result in increased body temperature" into the construction of the disputed terms and concludes that further construction is not necessary.
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B. "Enhancer element at a site within an active region of said vector sufficiently close to said transcription unit to enhance production of mRNA independent of its orientation and position within said active region."

Plaintiffs propose that this term be construed according to its plain meaning as "an enhancer element that is inserted into an active region of the vector at a site close enough to the transcription unit to enhance production of mRNA, and is operative in either position (upstream or downstream) and in either orientation with respect to the transcription unit." ImClone argues that the characteristics of orientation independence and proximity to the transcription unit were well known in the prior art. That may be true, but prior art is not at issue for present purposes. Accordingly, the claim will be construed in terms consistent with those proffered by plaintiffs.
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5. "wherein product fractions are eluated"

In addition, the parties dispute the phrase "wherein product fractions are eluated." Defendants interpret the phrase to mean that "the product fractions are recovered from the columns connected in series." (Emphasis added) (Joint Stmt. p. 8). In contrast, Plaintiff's defines the phrase to mean that "the product fractions are removable." (Emphasis added) (Joint Stmt. p. 8). The court agrees with Plaintiff that the claim language does not necessarily require that the product fractions be recovered. The claim states "…wherein product fractions are eluated during the molasses feeding step, [the] eluent water feeding step, or both… wherein each of said product fractions are recoverable during said cycle." (Emphasis added) (DTX 2, Col. 10). The claim language describes that the product fractions, which consist of a rest molasses fraction, a betaine fraction, and a sucrose fraction, are separated from the molasses feed solution as it flows through the columns during both the molasses feeding step and the eluent water step such that these product fractions are "recoverable." Performing a process that allows something to be recoverable does not necessarily mean that it must be recovered. Thus, that the specification and the prosecution history describe actual recovery of the product fractions does not necessarily require that they must be recovered. The Federal Circuit has stated that "where a specification does not require a limitation, that limitation should not be read from the specification into the claims." (Emphasis original) Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988). Because the claim explicitly uses the word "recoverable," the court will adopt this language.

Accordingly, "wherein product fractions are eluated "means "that the product fractions are separated from the molasses feed solution such that they can be recovered." In the same vein, "wherein each of said product fractions are recoverable during said cycle" means that "at least one each of the three product fractions is recoverable during the same cycle."
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III. Disputed terms in claim 2 of Patents '127 and '717: "a product of enzymic conversion of said analyte by said second enzyme"

Claim 2 of both patents reads: "The method as claimed in claim 1 wherein said sample is contacted with a second enzyme serving to convert said analyte and assessment of said analyte is effected indirectly by assessment either of a substrate of said second enzyme other than said analyte or of a product of enzymic conversion of said analyte by said second enzyme." (emphasis added).

General Atomics argues that construction of this term is unnecessary because "the Court has determined the meaning of

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'homocysteine conversion products.'" Responsive Br. 24-25. General Atomics' logic is unclear. The "product" at issue in this claim results from the conversion of the analyte, not from conversion of homocysteine. Neither party has ever alleged that homocysteine is an analyte. The Court's construction of "homocysteine conversion products" is therefore irrelevant to construction of this phrase, which is easily accomplished using the plain text of the claim. The proper construction of "a product of enzymic conversion of said analyte by said second enzyme" is "a product of the reaction in which the said analyte is a substrate of the second enzyme."

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epichlorohydrin di-methyl amine (Epi-DMA)

The parties and the Court agree that the term should be construed as "a polymer of quaternized ammonium moiety formed by the reaction of epichlorohydrin with an amine, wherein epichlorohydrin comprises a carbon [C] compound containing at least one chlorine [Cl] atom and at least three carbon [C] atoms, wherein two of said carbon atoms, which do not have a site filled with said chlorine [Cl] atom, fill a site for each other and share an oxygen [O] atom, wherein said oxygen [O] atom fills a site on each of two said carbon [C] atoms, thereby forming a triangle of said carbon [C], carbon [C], and oxygen [O] atoms. For example: Epi-DMA, Epi-MEA, Epi-EEA, Epi-MPA, etc. are all examples known in the art as being of the Epi-DMA variety. Polymers of this variety comprise the quaternized nitrogen moiety in the polymer backbone, as compared to those of DADMAC variety which comprise the quaternized nitrogen moiety in a branch from the polymer backbone."

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I. Equivalent

The parties dispute the meaning of the term "equivalent" in claim 24, from which asserted claims 26, 33, 34, and 39 depend. Claim 24 recites:

24. A modified release product having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release formwhich becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a Cmax in a human subject equivalent to the Cmax obtained when the first of three doses of a standard immediate release formulation having one third the amount of guaifenesin is dosed every four hours over a 12 hour period and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.

'252 patent, claim 24 (emphasis added).

The district court construed "equivalent" as "within 80% to 125% of the value with which it is being compared, at a 90% confidence interval." Adams, Civ. No. 1:07-CV-993, 2010 U.S. Dist. LEXIS 12008, *6 (W.D. Mich. Feb. 11, 2010) (Claim Construction Order). The court based its construction on Adams' statements during reexamination, concluding that "Adams explicitly stated during reexamination that 'equivalent' meant 'the FDA bioequivalence guidelines.'" Id.

On appeal, Adams challenges the requirement of a 90% confidence interval. It notes that the specificationdoes not require or even mention any confidence interval. Adams argues that during reexamination, it expressly, consistently, and repeatedly defined equivalent to mean within the 80 to 125% range, but it never included in that definition a 90% confidence interval. It asserts that the 90% requirement makes sense in the context of drug approval, where the FDA is concerned with safety and consistency. But in the context of proving infringement, Adams argues that it must simply show that it is more likely than not that Perrigo's ANDA, if approved, would permit Perrigo to market a product that infringes the '252 patent. Adams asserts that by requiring the 90% confidence interval, the court required Adams to prove that Perrigo's product would infringe 90% of the time.

Perrigo argues that the inventors "expressly defined 'equivalent' as FDA's bioequivalence guidelines, i.e., 'within 80% to

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125% of the value with which it is being compared, at a 90% confidence interval." Perrigo Br. 20. Perrigo asserts that the 80 to 125% range "means absolutely nothing in terms of establishing bioequivalence under FDA's guidelines without the 90% confidence interval, as, among other things, it is the confidenceinterval itself that must fall within the 80-125% range." Id. at 23.

We construe "equivalent" to require a Cmax that is 80% to 125% of the value to which it is being compared. Contrary to Perrigo's assertion, Adams did not define equivalent as meeting all of the requirements of the FDA's bioequivalence guidelines. When Adams referred to the FDA guidelines in the context of defining the term equivalent, it referred specifically to the 80 to 125% range. J.A. 545 ("the FDA bioequivalence guidelines of 80 to 125%"); id. 626 ("FDA bioequivalent range of -80% /+125%"); id. 635 ("FDA bioequivalent range of -80% /+125%"). Adams never adopted or even mentioned the 90% confidence interval. The range and the confidence interval are independent concepts. The range reflects "a medical decision that, for most drugs, a -20%/+25% difference in the concentration of the active ingredient in blood will not be clinically significant." FDA Guidelines at ix. On the other hand, the 90% confidence interval reflects the FDA's concern that a generic drug consistently match the performance of the branded drug. See id. at x. Patent infringement does not require bioequivalence, and Adams did not import the 90%confidence interval into its claim. Requiring a 90% confidence interval would inappropriately raise the bar for establishing infringement. Adams must show that it is more likely than not that Perrigo's ANDA product will have a Cmax within the 80 to 125% range. Adams is not required to show that Perrigo's product will meet this requirement 9 times out of 10.
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10. "essentially devoid of its (+)-enantiomeric contaminant"

This term appears in claim 23 which reads: "The method according to claim 1 or 2 wherein the (-)-enantiomer of the proton pump inhibitor is essentially devoid of its (+)-enantiomeric contaminant." '192 patent, col. 8, lines 52-54 (emphasis supplied). Astra asserts that the proper construction of this phrase is "nearly completely lacking an impurity of (+)-omeprazole." Astra further contends that a compound "essentially devoid of its (+)-enantiomeric contaminant" has a "very high optical purity," meaning at least 99.8% e.e., and a higher optical purity than the compound of claim 1. DRL argues that the proper construction of this phrase is "having almost no R-omeprazole [(+)-omeprazole]."

Given the Court's construction of claim 1 and the reasons therefor, the Court shall construe the phrase "essentially devoid of its (+)-enantiomeric contaminant" consistent with Plaintiff's proposed construction.
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In review of Glaxo's likelihood of success, this court examines the construction of claim 1 and its application to Ranbaxy's proposed product. Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 704, 45 U.S.P.Q.2D (BNA) 1033, 1036 (Fed. Cir. 1997). Claim language defines claim scope. York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1572, 40 U.S.P.Q.2D (BNA) 1619, 1622 (Fed. Cir. 1996). To determine the meaning of disputed claim terms, however, a construing court may consider the patent specification and the administrative record leading to patent issuance. Whittaker Corp. v. UNR Indus., Inc., 911 F.2d 709, 711, 15 U.S.P.Q.2D (BNA) 1742, 1744 (Fed. Cir. 1990).

As found by the district court, "essentially" means "fundamentally." Webster's Third New Int'l Dictionary 777 (1986). "Free from" means "without." Thus, in other words, "essentially free from crystalline material" means "fundamentally without crystalline material." See In re Marosi, 710 F.2d 799, 803, 218 U.S.P.Q. (BNA) 289, 291-292 (Fed. Cir. 1983) (interpreting "essentially free" to mean that a material is present only as an unavoidable impurity). The claims do not further enlighten the amount of crystalline material permitted within the scope of claim 1.

The written description of the '181 patent discloses in several places that cefuroxime axetil should be "substantially amorphous." E.g., Col. 2, ll. 24-25. The written description further discloses: "The cefuroxime axetil ester in accordance with the invention is preferably essentially free from crystalline material." Col. 2, ll. 38-40. The examples in the written description also shed little further quantitative light on the meaning of "essentially free from crystalline material."

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According to Example 1, an analysis of the prepared product by the Debye- Scherrer x-ray method "gave a plain halo (absence of crystals, confirming the amorphous nature of the product)." Col. 8, ll. 8-9. The same analysis of the Example 18 product "showed a few faint lines which may suggest the presence of a few crystals." Example 21 states: "Microscopic examination suggested <1% crystalline material." Col. 10, ll. 4-5. Tests of several other examples by x-ray crystallography, microscopic examination, and infrared analyses showed a "substantially amorphous" product. No example specifically quantifies "substantially amorphous" or "essentially free from crystalline material."

The prosecution history of the '181 patent, however, is more illuminating. As originally filed on June 29, 1983, claims 1 and 4 of the application which led to the '181 patent recited:

1. Cefuroxime axetil in highly pure, substantially amorphous form.

. . . .

4. The product of claim 1 essentially free from crystalline material.

Dependent claims are generally narrower in scope than the claims from which they depend. Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1376, 56 U.S.P.Q.2D (BNA) 1445, 1453 (Fed. Cir. 2000). Accordingly, "essentially free from crystalline material," as recited in original dependent claim 4, would apparently carry a narrower meaning than "substantially amorphous." Example 22 of the written description states: "X-ray crystallography revealed the product was substantially amorphous with a small content of crystalline material." Col. 10, ll. 26-28. Thus, cefuroxime axetil that is "essentially free from crystalline material" must have less than "a small content of crystalline material."

During the prosecution of Glaxo's United States Patents Nos. 4,994,567 and 5,013,833, both related to the '181 patent and containing the same Example 22, Glaxo explained: "Example 22 of the specification has shown that the product contains approximately 10% crystalline material." Further, during trial, Glaxo conceded that Example 22 does indeed contain 10% crystalline material. As noted above, the written description characterizes Example 22 as "substantially amorphous." In the original application, the independent claim 4 used the term "substantially amorphous," while a dependent claim used the narrower term "essentially free from crystalline material." This chain of reasoning suggests that "essentially free from crystalline material" means a maximum crystalline cefuroxime axetil content of less than 10%.

Other prosecution history bolsters this reading of "essentially free from crystalline material." The '181 patent claims priority to United Kingdom Patent Application No. 8222019. During prosecution of the '181 patent, Glaxo submitted a copy of the UK application to show its claim of priority. The UK application states:

The cefuroxime 1-acetoxyethyl ester in accordance with the invention is preferably essentially free from crystalline material, by which we mean that any amount of crystalline material which may be present is low as to be undetectable by X-ray crystallography, i.e., that an X-ray photograph of a sample of the compound shows no rings. The crystalline content of such a sample may be assumed to be zero for all practical purposes.

Col. 3, ll. 25-33 (emphasis added).

To explain this language during trial, Glaxo submitted a 1983 internal Glaxo report of methods for detecting low levels of crystalline material in amorphous cefuroxime ester. Glaxo further submitted the declaration of its expert, Dr. Lancaster, explaining the 1983 report. In his declaration, Dr. Lancaster opined that "it is difficult to distinguish between 5%, 10%, and 15% mixtures" of crystalline material. He further opined: "the detection level is about 10 to 15% crystalline material." Based on this declaration and reference to various x-ray photographs, the district court determined that "a level between 10% to 15% is, 'for all practical purposes,' essentially free of crystalline material." Glaxo Group Ltd., slip op. at 33.

The 1983 report itself, however, explains more fully the value of x-ray photographs. In the presence of cefuroxime axetil with a crystalline content over 10%, X-ray photographs, according to the 1983 report, identify the particular isomers and polymorphs of the crystalline material--not the presence of crystalline material in the first place. The report specifically explains that "Isomer A (I) did not show up in the 5% mixture but was visible in the 10 and 15% mixtures. Isomer A (II) was visible at the 5% level." A summary table in the report concludes that an appropriate X-ray photograph detection limit for

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crystalline material is 10%. In other words, a crystalline content above 10% would show up as rings in X-ray photographs. Therefore, because the UK priority application says that the X-ray photograph should show no rings, "essentially free from crystalline material" means a maximum crystalline content of less than 10%.
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F. "essentially spheroidal in geometrical configuration"

1. The Parties' Proposed Constructions

Rhodia asserts that I should construe "essentially spheroidal in geometrical configuration" to mean that "the particulates are generally sphere shaped. In this regard, the term 'essentially' indicates that less than perfect spheres are embraced." (D.I. 108 at 10.) Rhodia argues that the phrase "essentially spheroidal" relates to the shape of the particulates. (Id.) Additionally, Rhodia maintains that the phrase "essentially spheroidal in geometrical configuration" distinguishes the patented invention from other forms of prior art silica such as granules and powders because the silica particulates of the patented invention are regularly shaped, thus, increasing flow properties. (Id. at 11.) Moreover, Rhodia contends that those skilled in the art would recognize that since the silica particulates of the patented invention are formed by atomization, their spheric shape would, at times, be less than perfect. (Id. at 11-12.)

PPG proposes that I construe "essentially spheroidal in geometrical configuration" "to mean that the precipitated silica particulates have a smooth outer appearance and have a round geometrical shape resembling a sphere." (D.I. 106 at 18.) PPG contends that its proposed construction is consistent with the inventors' disclosure in the '234 patent. (Id. at 17-18.)

2. The Court's Construction

I construed the phrase "essentially spheroidal in geometrical configuration" to mean that the geometric shape of the silica particulates essentially resembles a sphere. Less than perfect spheres are embodied by this definition.

The inventors delimited their patented invention by claiming silica particulates that are "essentially spheroidal in geometrical configuration". "Essentially" is a common English adjective, meaning that something is an inherent or important characteristic. See MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 396 (10 ed. 2002). Like the word "generally," the word "essentially" allows for less than perfect conformity with the described characteristic. "Spheroidal" is also a common English adjective, meaning that something is shaped like a sphere. Id. at 1128. And the prepositional phrase "in geometrical configuration" directly signifies that the "essentially spheroidal" character refers to the shape of the silica particulates claimed. The phrase in dispute is broad enough to encompass less than perfect spheres.
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B. "Esterified" and "Esterifying"

These disputed terms are used in the independent process claims 1 and 16 of the '277 Patent. BMS suggests that these terms mean: "the specific reactants identified in the claims, i.e., the linear phenylisoserine and C-13-OH taxane, are esterified." (BMS Post Hearing Response, p. 3.) RPR offers the following definition: "the 'esterification' step of claims 1 and 16 therefore require only that protected side chain precursor and protected taxol core starting materials ultimately form an ester group at the C-13 position of the protected taxol core" (RPR, Post Hearing Memorandum, p. 14.)

BMS' requested interpretation relies on testimony elicited from RPR's expert, Dr. Martin at the Markman hearing:

> "RPR's Dr. Martin testified at the hearing (Martin Hrg. Tr. 96-97, Tab 1):
>
> Q. As a matter of the claim language, is esterified with refers to this reactant is esterified with the second reactant, right?

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MR. ROUX: Objection. No foundation for the word reactant.

THE SPECIAL MASTER: Can you answer that question?

[Dr. Martin]: I think so.

A. That is simply what it says, yes.

THE SPECIAL MASTER: They are not talking about in this claim any other chemical compounds other than the two that are shown there, are they, in the claim?

THE WITNESS: In the claim those are the only two shown, yes.

THE SPECIAL MASTER: It is not that complicated.

THE WITNESS: As a chemist, one understands that more has to be involved.

THE SPECIAL MASTER: I understand that to esterify you have to have other things going. But in this specific claim it is talking about these two products being esterified, right?

THE WITNESS: Right.

Q. That is the way a chemist would understand those terms, right, sir?

A. In a general sense.

Q. In a specific sense, right, sir? Those reactants are esterified.

A. OK, yes."

(BMS Post-Hearing Br., pp. 3, 4, 9).

Thus, there is strong and uncontradicted evidence in the record for referring to the compounds involved in the reaction, (2 R, 3S) 3-phenylisoserine derivative of the general formula shown in claim 1, and the taxane derivative of general formula also shown in claim I as "reactants" rather than "starting materials." Dr. Martin clearly agreed with the identification of these chemicals as "reactants." Also, at the Markman hearing, in response to one of my questions, Dr. Martin again referred to the chemicals in the reaction as "reactants" (See Markman hearing transcript, pp. 58-60). Nothing in the intrinsic or extrinsic evidence, including the description of the reaction in the JACS article, supports RPR's position that these derivatives should be referred to as "starting materials."

The next issue related to the construction of these terms relates to whether or not it is correct, as BMS proposes, to state that these specific reactants are merely "esterified" or to construe the words, as RPR suggests, to mean that "the reactants both ultimately form an ester group at the C-13 position of the protected taxol core."

Dr. Martin of course agreed with BMS's counsel that the "reactants are esterfied," but he more fully explained the process earlier in his testimony at the Markman hearing:

"Q. Can you tell the Court what ["esterified with"] means?

A. "Well, esterify is a word which is describing a certain kind of chemical reaction, but really what it refers to is simply hooking up or linking this side chain precursor to the taxane core to provide this ester functional group here that's on C-13. It's the essential link between the taxane core and the side chain itself, and so we are forming an ester in this particular reaction and by coupling or hooking these two pieces together, we are referring to esterification because that describes the kind of reaction it is generally.

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Q: What kind of reaction again is that sir?

A: Esterification.

Q: What is the results of that?

A: An ester. An ester functional group. As an ester is being formed by that bond forming step and that ester is, as I mentioned, this ester group right here. [referring to the ester of the general formula shown and identified as (V) (Column 3, lines 29-41) in the '277 Patent.

(Hearing Tr., p. 41. To the same effect, pp. 58, 59.)

BMS offered no testimony from its expert, Dr. Corey on the issue, but relies completely on Dr. Martin's testimony cited above: "Those reactants are esterified." However, the Court must take into consideration the further testimony of Dr. Martin quoted above, which provides a more complete explanation of the process. This additional testimony stands uncontradicted and explains the reaction as a POSA would understand it.

Accordingly, I recommend the following definition:

Esterified and esterifying: means "a chemical reaction in which the reactants (2R, 3S) 3-phenylisoserine derivative and the C-13 OH, taxane derivative (shown in claims 1 and 16) are linked or coupled to form the ester of the general formula designated as (V) in the '277 Patent (Column 3, lines 29-41)."

One additional point in connection with these disputed term requires review by the Court. BMS, in connection with the esterification step, also takes the position that:

"Claim 1 does not specify any esterification conditions, and so Bristol contends that claim 1 includes any esterification conditions. RPR's reliance on claim differentiation with respect to this limitation (RPR Br. 23-25) merely confirms that claim 1 includes esterification methods whether any activating and condensing agents are used or whether none are." (BMS Post Hearing Response Memo p. 3, fn. omitted.)

The section of the RPR Brief referred to above that relates to whether the esterification step in claim 1 is in anyway limited, states as follows:

"Likewise, to preserve the distinction between claim 1 and claims 3, 4, 5, 6, 7 (not asserted against Bristol but relevant to claim interpretation), and claim 8, claim 1 cannot be limited to processes in which the 'esterification' reaction is performed: (a) using activating and condensing agents (claims 3, 4, and 5); (b) embenzene, poluene, xylenes, ethylenes, ethylbezene, isopropylbenzene or chlorobenzene (claim 6); (c) at a temperature between 60 and 90 degrees C (claim 7); or (d) whether removal of the hydroxy-protecting groups is performed in an acid medium (claim 8).

The doctrine of claim differentiation supports RPR's position that the claim terms in independent claim 1 of the '277 must not be construed to include limitations already found in other narrow claims, or the patent example." (RPR Br. pp. 25).

I agree with BMS's position that in light of the foregoing unambiguous statements by RPR, claim I does not specify any esterification conditions and therefore includes esterification methods whether any activating and condensing agents are used or whether none are.

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D. Esterifying the Salt . . . to a Degree of Esterification Ranging from 9.5% to 14%

Aventis and Amphastar request construction of the phrase, "Estenfying the salt to a degree of estenfication ranging from 9 5% to 14%." This phrase is used in subpart (b) part of claim 7 which claims a three-step process. Specifically, claim 7 is a "process for the preparation of the heterogeneous polysacchande admixture as defined by claim 1, comprising (a) salifying a

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hepann with a long-chain quaternary ammonium salt in an aqueous medium, (b) estenfymg the salt thus produced to a degree of estenfication ranging from 9 5% to 14%, and then (c) depolymenzing such ester having a degree of estenfication ranging from 9 5% to 14%."

Amphastar contends that claim 7 requires a fourth step which measures the degree of estenfication before depolymenzmg Amphastar's support for this measunng step is through one example included in the specification of the 618 patent. In example 5, Aventis illustrated "the preparation of a mixture not in accordance with the invention" because the degree of estenfication fell outside the limits of the claim 618 patent, 8 55 -- 9 31. Amphastar claims that this constitutes a disclaimer of example 5's admixture and establishes the requirement of the fourth measuring step. Even assuming Aventis disclaimed the particular admixture not made in accordance with the claims process, an issue that is beyond the scope of this inquiry, there is simply no basis for reading a fourth measuring step into the claim language. The plain language of the claim does not contain a fourth step. The summary of the invention and preferred embodiments do not require the fourth step. Example 5 of the 618 patent does not require the fourth step. Finally, the prosecution history does not suggest a measuring step.

Thus, the court construes "Esterifying the salt to a degree of esterification ranging from 9 5% to 14%" as not requiring a measuring step.
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E. "At Least One Ethylene Interpolymer"

Dow's Construction	NOVA's Construction
A polymer made from ethylene and at least one other comonomer.	At least one substantially linear ethylene polymer prepared from a catalyst with constrained geometry about the metal atom as described in U.S. Patent No. 5,272,236

This claim term appears only in the '023 patent and is used to refer to the "(A)" component of the claimed polymer blends. The dispute between the parties is essentially whether this claim term should be limited to "substantially linear" ethylene polymers (NOVA's position) or not (Dow's position). 3 NOVA contends that the prosecution history of the '023 patent confirms that this claim term should be so limited. However, "[i]n order to disavow claim scope during prosecution a patent applicant must clearly and unambiguously express surrender of subject matter." See Voda v. Cordis Corp., 536 F.3d 1311, 1321 (Fed. Cir. 2008)(citations omitted). Furthermore, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Phillips, 415 F.3d at 1317. Accordingly, this Court is cautious in narrowing the scope of claims based on the prosecution history. As set forth below, in the Court's view, NOVA has not identified anything in the prosecution history justifying its proposed construction.

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -

3 NOVA's construction also includes the requirement that this term refer to a polymer prepared from a "catalyst with constrained geometry about the metal atom." However, NOVA's briefing includes little, if any, discussion of this "catalyst" requirement. In fact, NOVA appears to equate this "catalyst" requirement with the limitation that the polymer be "substantially linear." (See D.I. 141 at 19 ("NOVA proposes that the claim term 'at least one ethylene interpolymer' be construed to be limited to a 'substantially linear ethylene polymer,' i.e., a 'polymer prepared from a catalyst with constrained geometry about the metal atom as described in U.S. Patent No. 5,272,236.'").) Accordingly, the Court understands NOVA as taking the position that the "substantially linear" requirement is interchangeable with the "catalyst" requirement.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

First, NOVA notes that during prosecution of the '023 patent, Dow stated that an amendment to the specification was made "to more distinctly set forth that the present invention [was] directed to substantially linear ethylene polymers," a limitation

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that was expressly present in all the original claims. (D.I. 141 at 18 (emphasis added) (citing D.I. 128, Exh. F at F-053).) However, after making this statement, Dow canceled the original claims in favor of new claims that did not include the "substantially linear" limitation. (See D.I. 128, Exh. F at F-074 to F-077.) The examiner thereafter acknowledged that the new claims, which are at issue in this case, were not limited to "substantially linear" ethylene polymers but were instead "generic in scope." (Id. at F-091.) In these circumstances, the Court cannot conclude that Dow's early statement during prosecution regarding the scope of the invention is effective to limit the scope of the issued claims.

Second, NOVA points to a declaration that Dow submitted in support of patentability (the "Markovich Declaration") in which Dow allegedly referred to two polymer blends made from substantially linear ethylene polymers as "Inventive Examples" and another polymer blend made from something other than substantially linear ethylene polymers as a mere "Comparative Example." (Id. at 18-19.) Having characterized the polymer blends with substantially linear ethylene polymers as "inventive," NOVA contends that Dow demonstrated an intent to limit claim scope. However, the Court has reviewed the Markovich declaration, and, in the Court's view, Dow was distinguishing the "Inventive Examples" largely on the basis of performance properties, such as slope of strain hardening coefficient, and not on the basis of the presence of a "substantially linear" polymer. (See D.I. 129, Exh. F at F-079.) Furthermore, it appears that the so-called "Comparative Example" referred to in the Markovich declaration was 38.14% "substantially linear" polymer, a percentage nearly identical to the two so-called "Inventive Examples." (Id. at F-081 to F-082.) Thus, the Court cannot conclude that Dow was using the Markovich Declaration to describe "inventive" blends as including a "substantially linear" polymer.

Finally, NOVA contends that "[i]n his statement of his Reasons for Allowance, the Examiner indicated his understanding that the claims were directed to blends made from 'substantially linear' ethylene polymers," and that Dow failed to respond to this statement. (Id. at 19.) However, although such statements by the examiner are perhaps relevant to claim construction, "an applicant's silence regarding statements made by the examiner during prosecution, without more, cannot amount to a 'clear and unmistakable disavowal' of claim scope." Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1345 (Fed. Cir. 2005). Furthermore, on reviewing the examiner's Reasons For Allowance, which the Court finds somewhat unclear, the Court concludes that the examiner was, as Dow contends, simply withdrawing an incorrect inherency rejection. In particular, the examiner's rejection appears to have been based on a misunderstanding that a particular prior art reference disclosed polymer blends made using the same processes used to prepare the polymer blends disclosed in the patent. To the extent the examiner unilaterally distinguished the claimed polymer blends from the prior art, it appears to have been on the basis of an exemplary catalyst used to prepare one component of the polymer blends, which yielded "polyolfeins[sic] with different properties" from those in prior art polymer blends. (See D.I. 129, Exh. F at F-163.) However, the Court sees no evidence that either the examiner - or patentee - understood the claims as being limited to polymer blends prepared using only a single particular catalyst. The Court is thus unpersuaded that the Examiner's Reasons for Allowance establish a clear and unmistakable disavowal of claim scope.

Having concluded that the prosecution history does not support NOVA's proposed construction, the Court turns to Dow's proposed construction. Dow notes that the '023 patent expressly defines the term "interpolymer" as follows:

The term 'interpolymer' is used herein to indicate a copolymer, or a terpolymer, or the like. That is, at least one other comonomer is polymerized with ethylene to make the interpolymer. Ethylene copolymerized with two or more comonomers can also be used to make the homogeneously branched substantially linear interpolymers useful in this invention. Preferred comonomers include the C 3 -C 20 a-olefins, especially propene, isobutylene, 1-butene, 1-hexene, 4-methyl-1-pentene, 1-heptene, 1-octene, 1-nonene, and 1-decene, more preferably 1-butene, 1-hexene, 4-methyl-1-pentene and 1-octene.

'023 patent at 4:1-12 (emphasis added). The Court concludes that this intrinsic evidence adequately supports Dow's proposed construction. Accordingly, the Court will construe the term "at least one ethylene interpolymer" to mean, as Dow contends, "at least one polymer made from ethylene and at least one other comonomer."

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Eucaryotic Cell	A cell of an organism classified under the Superkingdom Eucaryotes including organisms of the Plant and Animal

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kingdoms, characterized by true nuclei formed by nuclear envelopes and by meiosis, including both a wild-type and a mutant cell

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(1) The term "eugenol" is not defined in the claims or the specification. Plaintiffs argue that construction is unnecessary because (a) the meaning of the term is apparent, and (b) defendants have admitted that their products utilize "100% clove oil, a eugenol which is acceptable in foodstuffs." The second argument implies that "clove oil" is the same thing as "eugenol," a construction that is not supported by the claim language or the specification. Claim 1 mentions eugenol, isoeugenol, and their salts and specifically requires that the fogging mist be comprised of "80 to 100% by weight" of these principles: there is no reference to cloves or clove oil. The specification discusses a number of alternative active principles, but again makes no mention of cloves or their oil. While prosecuting the patent before the Patent and Trademark Office, the inventor compared the size, duration, and coating qualities of mist solutions containing different percentages of eugenol. The composition with the highest eugenol content was described as "a non-aqueous natural clove oil based formulation, containing 80% eugenol, and related clove oil ingredients." Decl. of Edgar R. Cataxinos, Ex. 4 at 2 and 4. The inventor thereby acknowledged that eugenol is a component of clove oil: they are not the same thing for purposes of the invention.

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1 Plaintiffs' motion to strike Dr. Hyde's revised expert report (Dkt. # 39) is GRANTED. Dr. Hyde's original report was timely submitted and his proposed constructions were considered by the Court. The amended report was filed long after expert reports regarding Markman issues were due and for the first time disclosed Dr. Hyde's analysis of the disputed terms and his explanation for why defendants' proposed constructions are proper. The explanations contained in the revised report (Dkt. # 38-2) were not, therefore, considered.

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In light of the claims, the specification, and the prosecution history, the Court finds that one skilled in the art would understand that "eugenol" is not the same thing as "clove oil." 2 That does not, however, mean that "eugenol" needs to be construed or that defendants' proposed definition is appropriate. Eugenol has meaning to those familiar with the art: the inventor did not think it necessary to explain the term or to provide a definition. Defendants' proposed definition of eugenol as "a colorless or pale-yellow liquid which is present in clove oil in a range between approximately 30% and 95%" is not supported by the patent. Defendants do not explain why they chose a definition based on color and potential source (as opposed to chemical structure, smell, viscosity, etc.) or how it would be helpful to the jury. The Court finds that "eugenol" need not be construed: plaintiffs will be required to show that the accused products exhibit eugenol in the range recited in the claims.

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2 Despite their attempt to convert defendants' statement regarding the use of clove oil into an admission that the eugenol limitation of claim 1 is satisfied, plaintiffs recognize that they have the burden of showing that the accused products use eugenol, not just clove oil, in the range recited in the claims. Plaintiffs' Responsive Brief (Dkt. # 57) at 6.

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"Evaluating," "evaluation," "re[-]evaluating," and "re[-]evaluation"

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Nutrition 21 argues that the Court should give these terms from the '156 Patent their "plain and ordinary meaning." In other words, Nutrition 21 argues that the Court should construe "evaluating" and "evaluation" to mean "assessing [assessment of] the condition of something" and "reevaluating" and "reevaluation" to mean "reassessing [reassessment of] the condition of something."

GNC argues that "evaluating" and "evaluation" mean "performing [performance of] medical testing to determine" the level of HDL-cholesterol, LDL-cholesterol, or blood serum lipids in either a "subject" or an "individual" and "evaluating the results thereof." GNC contends "reevaluating" and "reevaluation" in Claims 13 and 14 mean "re-performing of medical testing previously performed, evaluating the results thereof, and comparing the results of the evaluation with the re-evaluation." For Claim 19, GNC says "reevaluating" means "re-performing medical testing to determine the HDL-cholesterol level in an individual and evaluating the results thereof and comparing the results of the evaluation with the re-evaluation." For Claims 21 and 22, GNC says "reevaluating" and "reevaluation" mean "re-performing medical testing to determine the LDL-cholesterol level in an individual and evaluating the results thereof and comparing the results of the evaluation with the results of the re-evaluation."

GNC's constructions all require "medical testing." GNC argues that medical testing is essential to determine whether one suffers from a medical condition treatable by one of the claimed methods. However, GNC cites no intrinsic or extrinsic evidence to support its contention that one of ordinary skill in the art would understand these terms to connote medical testing or that the inventors limited the scope of the term to require medical testing. Whether blood serum lipid levels may be evaluated without supervised medical tests is a fact issue and not a claim construction issue. The specification uses the root word "evaluate" only once -- when specifying that the study depicted in Example 5 was performed "to evaluate the anabolic effect of chromic tripicolinate in male subjects." ' 156 Patent, col. 11:23-24. Although the experiment was a supervised activity that seems to have involved measurement of the subjects' body fat, this does not suggest that the inventors intended (or that skilled artisans would deem) a real-world subject's ordinary regime of CP usage to entail the same methods of laboratory measurement. n8 Moreover, the Federal Circuit cautions against limiting the claimed invention to preferred embodiments or specific examples in the specification. Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986).

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n8 The Court will not speculate as to whether the laboratory measurement methods described in the specification constitute "medical testing."

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Nutrition 21 argues that its constructions, which are based on the "ordinary dictionary meaning" of the root word "evaluate" simply reflect what skilled artisans would find such ordinary meaning to be. But Nutrition 21 offers no evidence to support its contention that skilled artisans would view its chosen dictionary definition -- which Nutrition 21 admits was selected from several available definitions -- as a reflection of the ordinary meaning of the root word "evaluate." Therefore, Nutrition 21 does not adequately support its proposed constructions.

Although the Court does not adopt Nutrition 21's proposed constructions, the Court agrees that the '156 Patent uses the derivatives of "evaluate" in accordance with their ordinary, everyday meaning, with which the jury will be familiar. Accordingly, "evaluating," "evaluation," "reevaluating," and "reevaluation" do not require construction.
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"Exercise regimen"

Nutrition 21 contends that this term, which appears in Claim 10 of the '624 Patent, means "to regularly perform physical exertion related to achieving a fitness benefit." GNC contends the term means "a regular course of strenuous bodily exertion for the sake of developing and maintaining physical fitness." The parties' proposals are relatively close except for GNC's inclusion of the adjective "strenuous." GNC argues that without including the adjective, "Nutrition 21's requested construction is so broad it could be argued that walking from one's office to the break room or even the daily removal of the

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cap from a bottle of chromium picolinate pills is an 'exercise regimen.'" However, Nutrition 21's construction does require that the exertion be "related to achieving a fitness benefit."

GNC provides no intrinsic support for including "strenuous" in the construction. The specification does not reference exercise at all except to note that during the experiment depicted in Example 3 the volunteers were requested not to alter their daily exercise habits and to note that the volunteers for the experiment depicted in Example 5 followed a prescribed weight lifting protocol for a total of three hours each week during the experimental period. See '624 Patent, cols. 6:66-68, 11:34-36. Although weight training may well be strenuous bodily exertion, GNC makes no argument, and there is no reason to believe, that the Example 5 volunteers' exertion is the type of exertion that the inventors envisioned when they adopted the claim term "exercise regimen" or that skilled artisans would limit the term to that type of exertion.

Nutrition 21's proposal expresses the term's ordinary meaning, as used in the specification. Accordingly, the Court construes "exercise regimen" to mean "to regularly perform physical exertion related to achieving a fitness benefit."
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Wherein the excipient is chosen from [a list of excipients] n3, and mixture thereof

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n3 "[A] list of excipients" substitutes for the controlled-release excipients listed in claim 1: "microcrystalline cellulose, hydroxypropylmethyl cellulose, ethylcellulose, cellulose acetate butyrate, cellulose acetate phthalate, polyvinyl acetate phthalate, hydroxypropylmethyl cellulose phthalate, polyethylene oxide, polyvinylpyrrolidone, polyethylene glycol, zein, poly-DL-lactide-co-glycolide, dicalcium phosphate, [and] calcium sulfate." '707 Patent col.19:40-47.

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The Court agrees with MRI, modifies BSN's proposed construction, and construes the term as "wherein the excipient is chosen from [a list of excipients], and mixtures of two or more of the above listed excipients and may include excipients not listed." BSN argues that the formulation only includes excipients listed because the list is a closed Markush group. See Abbott Labs v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1280 (Fed. Cir. 2003). BSN argues that the list is a closed Markush group because the Patent Examiner suggested an amendment to claim 1 to incorporate a Markush group of specific controlled release excipients.

BSN's argument is unconvincing. First, a Markush group must be "characterized with the transitional phrase 'consisting of,' rather than 'comprising' or 'including.'" Id. at 1280-81. MPEP section 2173.05(h) states that "it is improper to use the term 'comprising' instead of 'consisting of,' when drafting a Markush group." While the Patent Examiner did suggest incorporation of a controlled-release excipient Markush group, the patentee's claim 1 amendment lacked the language necessary to create a closed group. See Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005) (holding that "group of" did not create a Markush group because "consisting" did not appear in the disputed claim).

Second, it is useful to clarify that patentee broadly defined excipient in the patent as any compound that is "intended to act merely as a carrier, i.e., not intended to have any biological activity itself." '707 Patent col.4:66-5:2. Claim 1 as originally submitted did not identify controlled- release excipients and the Patent Examiner suggested the addition of a controlled-release excipient Markush group. The patentee's amendment--rather than add a Markush group--states that the excipient is chosen from a specified list of controlled-release excipients and "mixture thereof." The Court agrees with MRI that the formulation includes at least one listed controlled-release excipient, but does not exclude unlisted excipients because "mixture" refers to a combination of ingredients that includes at least one listed ingredient. See Mars, Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1374-75 (Fed. Cir. 2004) (holding that "mixture" is an open-ended term).

Finally, BSN's construction is unduly restrictive because it excludes at least twenty of the twenty-seven preferred embodiments. See, e.g., Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1347 (Fed Cir. 2004) ("[C]laims should rarely, if ever, be construed to exclude a preferred embodiment."). MRI's interpretation encompasses the preferred embodiments, some of which use generic terms that would include species that became part of the claim language. n4

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n4 BSN alleges in its brief that MRI's interpretation excludes five of the preferred embodiments--embodiments 1-3 and 17-18. The Court is not persuaded that this is technically correct since some of the examples use generic terms--e.g. "organic polymer"--that would be understood to encompass claimed materials such as microcrystalline cellulose.

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Excipient material

The parties and the Court agree that the term should be construed according to the patent definition as "any compound forming a part of the formulation which is intended to act merely as a carrier, i.e., not intended to have biological activity itself." '707 Patent co1.4:66-67; 5:1-2.

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An excipient material comprising the remainder of the formulation

The Court modifies BSN's proposed construction and construes the term as "the formulation includes only AAKG and excipient materials."

MRI argues that "comprising" is an open patent term and therefore "the formulation-in-question must include at least one excipient material from the list but does not exclude additional, unrecited elements." See U.S. PTO, Manual of Patent Examination Procedure ("MPEP") § 2111.03. MRI further contends that the use of "comprising" in both the preamble and in the term-at-issue shows the patentee's intent to leave the claim open to additional elements. MRI argues that the term is open because the Patent Examiner never outright rejected the original, open claim. However, MRI's construction improperly reads out the term limitations because there is no difference between its construction of "an excipient material comprising the remainder of the formulation" and the pre-amendment "an excipient material." The patentee added a limitation that must be given effect. See Schoenhaus v. Genesco, Inc., 440 F.3d 1354, 1359 (Fed. Cir. 2006) (stating there must be a "substantial reason relating to patentability for including the limiting element added by amendment").

BSN argues that the term is closed to additional elements for two reasons. First, while "comprising" is always construed as an open term when used in a claim preamble, it has no such automatic meaning when used within the body of a claim. See Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 n.8 (Fed. Cir. 1986) (construing "comprising" according to normal rules of claim interpretation where the term was not used as part of a transitional phrase). The Court agrees with BSN that "comprising" in the body of the term should be construed according to normal claim construction rules.

Second, BSN argues that MRI acquiesced to a closed claim term during patent prosecution. See Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978-79 (Fed. Cir. 1999) ("Acquiescence may be found where the patentee narrows his or her claims by amendment ....") (citation omitted). The term "comprising" in the preamble of claim 1 is an open term, and as originally submitted the claim was open to additional elements. However, the Patent Examiner suggested that the patentee specify the amounts of AAKG and excipient in claim 1, and the patentee amended claim 1 to include "about 50-70% [AAKG]" and "an excipient material comprising the remainder of the formulation." The Court construes "remainder" according to its ordinary and customary meaning as "a quantity that remains after subtraction." See WEBSTER'S ENCYCLOPEDIA UNABRIDGED DICTIONARY OF THE ENGLISH LANGUAGE 1213 (1st ed. 1989); Phillips, 415 F.3d at 1312-13. The Court agrees with BSN that the patentee's amendment indicates that the excipient amount is defined as 100% of the formulation minus the AAKG. Therefore, because the patentee added the term-in-issue, claim 1 is an exception to the general rule that a claim using "comprising" in the preamble is open. This construction is consistent with all twenty-seven preferred embodiments, which contain only excipient and AAKG. See '707 Patent co1.8:18-10:50; Phillips, 415 F.3d at

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1314-15.
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The parties dispute the construction of the term "fusion protein comprised of human IGF-I fused at the N-terminus to amino acid sequence exogenous to human IGF-I." Plaintiffs contend that the terms means a non-natural protein encompassing an amino acid sequence that corresponds to the mature human IGF-I sequence linked at its N-terminus to an amino acid sequence from any other source other than the human IGF-I sequence. Defendants contend that the term means " 'a fusion protein' composed of an amino acid sequence taken from a prokaryotic cell attached to the N-terminus of a domain with the amino acid sequence of 'Human IGF-I.'" Defendants separately construe the term "a fusion protein." According to Defendants, "a fusion protein" means "a final translation product that is a single polypeptide chain composed of amino acid sequences from two or more distinct proteins." At the hearing, however, the parties agreed that the Court need not construe the term "fusion protein," nor any other term except "exogenous to human IGF-I."

Plaintiffs point out that Defendants' experts conceded that the ordinary meaning of the term "exogenous" does not convey a specific source for the amino acids, and encompasses anything outside of that which is endogenous. See, e.g., Gaede Dec., Ex. 9 at 195-97. Defendants do not, however, show a clear disclaimer of the ordinary meaning through "redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002).

As Plaintiffs note, the claim language defines the fusion protein in reference to only one source, the human IGF-I amino acid sequence, and requires only that the fusion partner be an amino acid sequence not derived from that source. Unlike in claim 5, no other source limitations are recited, and the language encompasses any amino acid sequences, not just portions from proteins. Claim 5 expressly restricts the fusion partner source by reciting that it comes from a bacterial protein, a limitation not present in claim 9. During prosecution, the Examiner required Plaintiff Genentech to limit claim 5 to "bacterial protein" fusions, but did not impose such a requirement on claim 9, leaving its scope undisturbed.

The Court construes the term "exogenous to human IGF-I" to mean any other source other than the human IGF-I sequence.
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C. "Exposure to the Smoke Cooled to Between 0 [degree] and 5 [degrees] C."

Additionally, TPI and HISI disagree about the meaning of the Yamaoka Patent's claim to the process of "smoking the tuna meat at extra-low temperatures by exposure to the smoke cooled to between 0 [degree] and 5 [degrees]." HISI argues that this phrase should be construed so as to limit the Yamaoka Patent to processes in which the smoke is first cooled, and then the tuna is exposed to the already-cooled smoke. It argues that the Yamaoka Patent does not extend to cover a process by which the tuna is exposed to smoke, and then both the tuna and the smoke are simultaneously cooled to between 0 [degree] and 5 [degrees] C. TPI argues, however, that its claim should not be so limited and that the Yamaoka process does not require that the smoke be cooled prior to its exposure to the tuna.

TPI's position is contradicted by the plain language of the claim itself. First, the use of the definite article "the" in "the smoke cooled to between 0 [degree] and 5 [degrees] C" indicates that it is some particular smoke, not smoke in general, which is being referred to in this step. The only plausible referent for "the smoke cooled to between 0 [degree] and 5 [degrees] C" is the smoke discussed in the preceding step of the claim, which describes "cooling the smoke passed through the filter in a cooling unit to between 0 [degree] and 5 [degrees] C." Claims can require that their steps be performed in a certain order where "the sequential nature of the claim steps is apparent from the plain meaning of the claim language and nothing in the written description suggests otherwise." Interactive Gift Exp., Inc. v. Compuserve Inc., 256 F.3d 1323, 1342 (Fed. Cir. 2001). That is the case here. Smoke is cooled to between 0 [degree] and 5 [degrees] in one step; the subsequent step then describes how "the smoke cooled to between 0 [degree] and 5 [degrees]" is exposed to the fish.

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Moreover, even disregarding the presence of the definite article "the," the use of "cooled" to modify "smoke" indicates that the smoke has already been cooled before the fish is exposed to the smoke. In other words, even if the claim had been written as "exposure to a smoke cooled to between 0 [degree] and 5 [degrees] C," it would still describe only a process in which the smoke has already been cooled prior to exposure. "Cooled" is a participial adjective that modifies the word "smoke." It is formed from the past participle of cool, which is "cooled," and then used as an adjective rather than a verb. Because it is derived from the past participle, rather than the present participle, the use of "cooled" as an adjective indicates that the action has already taken place or already been completed. Here, that means that the smoke has already been cooled to a specific temperature, namely, to between 0 [degree] and 5 [degrees] C.
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a. Expression

The parties dispute whether this claim covers both fusion and direct expression of a human IGF-I-encoding DNA sequence. Their differing constructions of terms in this claim arises out of this dispute. Plaintiffs contend that claim 1 covers both. Defendants, however, claim that claim 1 covers only direct expression, not fusion.

Defendants' expert conceded that a person of ordinary skill in the art understands the term expression to encompass both fusion and direct expression. See Gaede Dec., Ex. 5 at 79:25-80:3. The Federal Circuit instructs that the ordinary meaning of a term governs absent an express disclaimer in the patent. See, e.g., NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1308-9 (Fed. Cir. 2005). As Plaintiffs note, here, there is no express disclaimer. Instead, the patent itself, the specification and the prosecution history demonstrate that the inventors used the ordinary meaning of the term "expression."

Although claim 1 uses the term "expression" without the adjectives direct or fusion, claims 5 and 9 expressly refer to fusion expression. n1 The term "direct expression" is used in the specification, demonstrating that the inventors were aware of the two different types of expression and, when appropriate, specified which form of expression they were discussing.

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n1 Claim 5 provides, "A method for producing human IGF-I comprising preparing a replicable expression vector capable of expressing in prokaryotic cells a DNA sequence encoding a fusion protein comprising the amino acid sequence of mature human IGF-I and a bacterial protein, transforming prokaryotic cells with said vector, culturing said transformed cells under conditions permitting expression of said DNA sequence to produce the fusion protein, recovering the fusion protein from the culture, and cleaving the fusion protein to obtain mature human IGF-I, wherein the prokaryotic cells are capable of such expression and of processing the IGF-I."

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In the prosecution history, the Examiner raised an enablement issue as to claim 1, which was then claim 5: "In addition, claims 5 and 21 encompass direct expression of IGF-I and IGF-II in prokaryotes in the absence of a fusion partner." Stipulated File History of the '414 patent, Tab 4 at 7-9. Plaintiffs note the word "encompass," used by the Examiner, shows that the. claims's scope includes but is not limited to direct expression. Defendants' argument, that the Examiner's objection was based on the difficulty of producing IGF-I or IGF-II without regard to whether the protein was expressed directly or as a fusion protein, is irrelevant in determining whether claim 1 includes both direct and fusion expression. During the prosecution, Plaintiff Genentech confirmed its belief that expression was not limited to direct expression when it wrote: "The Examiner also urges that claims 5 and 21 encompass direct expression of human IGF-I and IGF-II in prokaryotes, as well as fusion proteins and secreted proteins, with no guidance model." Id, Tab 8 at 15.

In light of the claims, the specification and the patent history, Defendants' arguments that claim 1 entails only direct expression are not convincing. Accordingly, the Court construes the term "expression" used in claim 1 as covering both fusion and direct expression.
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C. Shelf Life

Several claims refer to the term "shelf life." Michael Foods defines shelf life as "the period of time during which the product is not obviously spoiled per the criteria set forth in the patent under refrigerated (4 [degrees] C) conditions." (Michael Foods' Initial Markman Br. at 19-20.) Sunny Fresh defines the term to mean the USDA approved shelf life, for an approved process, under storage at about 40 [degrees] F (4 [degrees] C) based on the validation and verification procedures set forth in the USDA criteria for use of an expiration date for extended shelf life liquid egg products dated April 26, 1991 and February 3, 1992. (Kempf Aff., Ex. 26, App. at 2.)

The claim language does not define "shelf life." However, the specification offers a clear definition and explanation of the term. It provides: "Shelf Life. The times of spoilage of egg…," meaning the time the product can be stored before spoilage. (Kempf Aff., Ex. 1, Col. 15, l. 26.) Under the section titled "Refrigerated Storage Effect," the inventors explain what criteria should be used to judge whether or not the product is spoiled. It states that spoilage means "obviously spoiled, as indicated by organoleptic evaluations." (Id., Col. 13, ll. 57-61.) The patent gives the criteria for organoleptic evaluation:

The criteria for judgment were: (1) that the color was normal, i.e., within the expected range of color observed for eggs immediately post-processing, and (2) that there was no objectionable aromas or flavors…. Bright yellow colors, off-aromas, and pH values below seven were typical of samples judged to be spoiled.

(Id., Col. 13, ll. 63-67; Col. 14, ll. 1-6.) The specification therefore acts as a dictionary, Markman, 52 F.3d at 979, defining the term "shelf life" to mean the period of time during which the product is not obviously spoiled using the organoleptic tests set forth in the patent under refrigerated (4 [degrees] C) conditions. The court therefore construes the term as such.

Sunny Fresh's argument that "shelf life" refers to the USDA criteria of 1991 and 1992 fails because one of ordinary skill in the art at the relevant time - 1986 - could not have understood the term "shelf life" to be referring to criteria that did not exist yet. Moreover, the Papetti's litigation did not define "shelf life" as the "USDA approved minimum shelf life" as Sunny Fresh asserts. 8 (Sunny Fresh's Opening Markman Br. at 22.) In Papetti's, the parties disputed whether Papetti's "pre-selected" an actual shelf life. Papetti's argued that it was entitled to summary judgment because Michael Foods did not prove predetermination of actual shelf life. (Kempf Second Aff., Ex. 50 at 42-43.) In considering that argument, Judge Barry did not decide whether "shelf life" means "actual shelf life" or "the minimum shelf life necessary for U.S.D.A. approval." She found this distinction "unimportant." (Id.) Instead, she held that the U.S.D.A. shelf life applies regardless of how shelf life is defined, meaning under either definition of shelf life. 9

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8 Because both parties rely on Papetti's in their memoranda, and because the court refers to Papetti's throughout its opinion, the court discusses its precedential value. Decisions are mixed as to whether one district court should follow another co-equal district court's interpretation of a patent claim under the doctrine of collateral estoppel. See, e.g., Graco v. Children's Prods. Inc. v. Regalo Intern., LLC, 77 F. Supp. 2d 660, 664-665 (E.D. Pa. 1999)(finding that patent owner was not bound by previous construction of claim in subsequent lawsuit against third party); TM Patents, L.P. v. Int'l Bus. Mach. Corp., 72 F. Supp. 2d 370, 375 (S.D.N.Y. 1999)(holding that construction given to claims in another district with another infringer has collateral estoppel effect in the present litigation). Here, Papetti's carries weight as part of the prosecution history and thus the intrinsic record. The court therefore does not reach the question of whether the Papetti's decision has collateral estoppel effect in the present action because the court instead relies on Papetti's as part of the intrinsic evidence.

9 Judge Barry stated:

Papetti's distinction between "actual shelf life" and the minimum shelf life necessary for U.S.D.A. approval is unimportant. Although the U.S.D.A. is unconcerned with the actual shelf life of a product so long as it lasts until the "pull date" Papetti's preselects a desired shelf life, albeit a minimum one, when it seeks to receive approval for that minimum duration. (Def. Opp. to Infr., at 34-38) Although there is a dispute over the meaning of [the] term "shelf life," it is clear that it is used and understood by those of "ordinary skill" in the art of commercial production as applying to a U.S.D.A. shelf

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life.

(Kempf Aff., Ex. 8 at 19 n. 18 (first emphasis added).)

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Moreover, contrary to Sunny Fresh's assertion, Michael Foods' reversal of their position from Papetti's is not barred by the doctrine of judicial estoppel. Judicial estoppel does not hinge on whether the party previously argued a position, but instead hinges on whether that party was successful in having the court adopt that position. As the Supreme Court stated in New Hampshire v. Maine, 532 U.S. 742, 750-752, 149 L. Ed. 2d 968, 121 S. Ct. 1808 (2001):

… courts regularly inquire whether the party has succeeded in persuading a court to accept that party's earlier position, so that judicial acceptance of an inconsistent position in a later proceeding would create "the perception that either the first or second court was mislead."… Absent success in a prior proceeding, a party's later inconsistent position introduces no "risk of inconsistent court determinations"… Id. (citations omitted).

In Papetti's, Michael Foods was not successful in arguing its position because Judge Barry did not chose between the parties' competing definitions of "shelf life." Thus, based upon clear intrinsic evidence, the court construes the term "shelf life" to mean the period of time during which the product is not obviously spoiled using the organoleptic tests set forth in the patent under refrigerated (4 [degrees] C) conditions.

Sunny Fresh also requested that the court construe the term "extended refrigerated shelf life." Based upon a review of the file, record and proceedings, and relying upon the court's construction of the term "shelf life," the court construes the term "extended refrigerated shelf life" to mean a longer shelf life than the 7 to 14 day shelf life of refrigerated liquid whole egg products which have been conventionally pasteurized. (See Kempf Aff., Ex. 1, Col. 1, ll. 38-40 (describing the conventional shelf life of liquid egg product as between 7 to 14 days.)
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B. Extended Release

As recited above, claim 1 of the '081 patent provides: "A solid preparation providing extended release of an active compound with very low solubility in water copmrising [sic] a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer. . . ." (Emphasis added). The term "extended release" is also recited in dependent claims 8, 12, 14 and 15. In addition, claim 17 provides: "A process for making a solid preparation that provides extended release of an active compound with very low solubility in water. . . ." (Emphasis added).

Mutual argues that extended release is a relative term and that an examination of the specification is therefore needed for additional guidance. Astra argues that the term should be construed based on its ordinary meaning. Astra contends that extended release is generally understood in the art to mean releasing the active ingredient from the dosage form over time in a manner that reduces the dosage frequency as compared to immediate release dosage forms. As defined in the dictionary, extended means "drawn out in length especially of time," while release means: "to set free from restraint." Merriam Webster's Third New International Dictionary (1993).

Astra also points to various places in the record where Mutual has defined its own drug as having an extended release component without defining the term. Mutual represented to the FDA in its original ANDA application that one function of the component Hydroxypropyl Methylcellulose is to be an "extended release agent." (Pl.'s Ex. 15 at M024966.) In describing its drug in a Product Development Report, Mutual explained that, "the matrix-forming and controlled-release agent (Methocel K100LV) . . . would provide for the extended drug release properties of the finished felodipine tablets." (Pl.'s Ex. 14 at M036592) (emphasis added). In a Mutual Report on its drug, Mutual concluded that, ". . .the Mutual and Astra Merck (Plendil) 10 mg felodpine extended-release tablets are bioequivalent under fasting conditions." (Pl.'s Ex. 38 at M040290).

Mutual, after quoting extensively from the specification, concludes that "the intrinsic record appears to suggest that an

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extended release dosage form is a composition including one or more components that provide for prolonged release of a pre-solubilized drug." (Def. Mem. at 23-24) (emphasis added). As observed by plaintiff, the claim language does not include the term "extended release dosage form," rather, it is limited to extended release. Moreover, it is unclear where in the patent Mutual incorporated the term "pre-solubilized drug." Mutual recites portions of the specification without offering any substantive argument as to why the cited written description should narrow the term extended release.

This Court concludes that those skilled in the art would understand extended release to mean releasing the active ingredient from the dosage form over time in a manner that reduces the dosage frequency as compared to immediate release dosage forms. Further concluding that Mutual has not directed this Court in any persuasive way to any portion of the intrinsic record which would indicate that a varied construction should apply.
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A. "Extended release formulation"

Both parties focus primarily on the proper construction of the phrase "extended release formulation," as that term is used in asserted claims 20-25 of the '171 patent, claims 1, 2, 13, and 14 of the '120 patent, and claims 1-6 of the '958 patent.

Wyeth proposes the following construction:

A drug formulation (other than a hydrogel tablet) that releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation.

Mylan, on the other hand, argues that the Court should construe the term as:

An extended release formulation consisting of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropyl methylcellulose coated with a mixture of ethyl cellulose and hydropropyl methylcellulose.

Both parties agree that Wyeth's construction is the "ordinary and customary" meaning in the art given to the term "extended release formulation." Moreover, both parties urge the Court to consider the patent in its entirety, including the claims, specification and prosecution history, in construing the term in accordance with "what the inventors actually invented and intended to envelop with the claim." Phillips, 415 F.3d at 1316 (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

Mylan, however, contends that the specification reveals that Wyeth has acted as its own lexicographer in defining the term "extended release formulation," by limiting the term, as used in these patents, to include venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropyl methylcellulose coated with a mixture of ethyl cellulose and hydropropyl methylcellulose ("the specific ingredients"). It asserts that, by consistently limiting the formulation to the specific ingredients throughout the specification, the inventors implicitly redefined the term. See Bell Atlantic Network Serv., Inc. v. Covad Comm. Group, 262 F.3d 1258, 1271 (Fed. Cir. 2001) ("when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication.'")(quoting Vitronics, 90 F.3d at 1582).

Initially, the Court must apply a "'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). This presumption is overcome, however, where an inventor has chosen to be his own lexicographer, thereby defining a term differently from the meaning it would otherwise possess. Phillips, 415 F.3d at 1316. Such special meaning may be bestowed explicitly or implicitly, Bell Atlantic, 262 F.3d at 1268, but the new definition must be reasonably clear and have been done deliberately. In re Paulsen, 30 F.3d at 1480. Indeed, "the intrinsic evidence must 'clearly set forth' or 'clearly redefine' a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term." Bell Atlantic, 262 F.3d at 1268.

In determining whether a new definition has been implicitly bestowed, courts consider how the term is used in the claims, the specification and, if provided, the prosecution history. See id.

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1. The Claims

The term "extended release formulation" appears in each of the asserted claims in this case. A typical example of its use appears in Claim 1 of the '958 patent:

A method of providing a therapeutic blood plasma concentration of venlafaxine . . . which comprises administering orally to a patient in need thereof, an extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient.

(Emphasis added.)

To refute Mylan's assertion that the inventors acted as their own lexicographer with regard to the term "extended release formulation," Wyeth relies heavily on the ways in which the term is used in the claims. It contends that adopting Mylan's proposed construction for that term would render certain aspects of the claims redundant, and that such construction would violate the doctrine of claim differentiation.

a. Redundancy

Within the asserted claims, each use of the term "extended release formulation" is followed by the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient." Wyeth argues that such limitation strongly implies that the term is not defined by its specific ingredients.

In Phillips, the Federal Circuit explained that the term "steel baffles" "strongly implies that the term 'baffles' does not inherently mean objects made of steel." 415 F.3d at 1314. The court then reiterated its longstanding principle that "the use of the term within a claim provides a firm basis for construing the term." Id. Thus, where, as here, a term used in a claim is followed by a limitation, a strong implication exists that the term does not already include that limitation. To find otherwise would render the limitation redundant or superfluous. See Oak Tech., Inc. v. Int'l Trade Com'n, 248 F.3d 1316, 1330 (Fed. Cir. 2001) (finding that the language of a claim itself can impose significant restrictions on a term within the claim).

As used in the asserted claims, the term "extended release formulation" is consistently followed by the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient;" a strong presumption thus exists against construing the term as suggested by Mylan, whose proposed construction begins "consisting of venlafaxine hydrochloride." Indeed, Mylan's construction of "extended release formulation" would render the limiting phrase found in the asserted claims redundant.

b. Claim Differentiation

Wyeth next argues that the doctrine of claim differentiation further indicates that the inventors did not act as their own lexicographer in narrowly defining the term "extended release formulation." Under the doctrine of claim differentiation, "dependent claims are presumed to be of narrower scope than the independent claims from which they depend." Regents of Univ. of Cal. v. Dakocytomation Cal., Inc., 517 F.3d 1364, 1375 (Fed. Cir. 2008), (quoting AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234, 1242 (Fed. Cir. 2003)). Thus, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. This doctrine originates with 35 U.S.C. § 112, which states that "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed."

The presumption created by this doctrine is rebuttable, however; thus, if a patent's specification clearly sets forth the scope of the claim language, claim differentiation cannot be used to broaden the claim's scope. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed. Cir. 1998). The presumption may therefore be overcome if, after looking to the specification, the court determines that the inventor bestowed a special definition on a claim term, even though such definition renders aspects of the dependent claim superfluous.

Claim One of the '120 patent, an independent method claim asserted in this case, includes the term "extended release formulation" but does not recite the specific ingredients. Dependant Claim Three, however, states "[t]he method of claim 1

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wherein the extended release formulation comprises venlafaxine hydrochloride in a spheroid comprised of [the specific ingredients]." Under the doctrine of claim differentiation, the Court must presume that the specific ingredients listed in Claim Three narrows the scope of Claim One. Thus, the Court further presumes that those ingredients are not included in the definition of "extended release formulation." Because claim terms are generally used consistently throughout a patent, the differentiation established in this example is applicable throughout. See Phillips, 415 F.3d at 1314.

2. The Specification

In this case, Mylan contends that the presumption of differentiation is overcome by looking at the specification. It argues that the inventors bestowed a special meaning on the term "extended release formulation" by limiting the term to a formulation containing the specific ingredients.

Specifically, Mylan asserts that the inventors repeatedly apply a narrow definition, including the specific ingredients to the term in the specification. As examples, it points to the Abstract, which, after indicating that the invention relates to "a 24 hour extended release dosage formulation," states:

> More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethlycellulose.

'171, Abstract. Similarly, the "Brief Description of the Invention" describes the invention as

> an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171, Col. 2:63-67, 3:1-2. Finally, the "Detailed Description of the Invention" states:

> The extended release formulations of this invention are comprised of 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexano hydrochloride in admixture with micro-crystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose to provide the desired level of coating . . . .

Id. at Col. 4:9-16. Mylan contends that these passages, as well as others not cited here, indicate that the term is limited to the specific ingredients.

Although acknowledging that the specification repeatedly references the specific ingredients, Wyeth argues that nothing in the specification reveals that the inventors clearly intended to apply a special meaning to the term "extended release formulation." Instead, it contends that the specification describes the invention broadly and the specific ingredients are merely included as a preferred embodiment of the invention, not the sole embodiment. Wyeth further points out that the "Brief Description of the Invention" describes a broad "use aspect" of the invention, which describes an extended release formulation of venlafaxine hydrochloride, but does not suggest that any specific inactive ingredients are required. See '171, Col. 2:55-62. It contends that the specification reveals that term is limited by its pharmacologic properties rather than any specific set of ingredients.

Wyeth further points out that the inventors understood how to limit a claim by its specific ingredients, and did so in the product claims. Thus, the fact that the inventors did not include the specific ingredients in any of the method claims would appear to be intentional. As the court in Impax concluded:

> That [a] list of ingredients was not provided with respect to the method claims and the portions of the specification corresponding to the method claims leads the Court to believe that the inventors knew how to limit the term when they so desired, and chose not to do so with respect to the method claims.

526 F. Supp. 2d at 480.

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After closely considering the specification, the Court concludes that the inventors did not set forth a new definition for "extended release formulation" with the reasonable clarity, deliberateness and precision required when an inventor applies his own lexicography to a claim term. See In re Paulsen, 30 F.3d at 1480. Rather, it agrees with Wyeth that the term, as used in the specification, is defined by its pharmacologic properties, such as creating "twenty-four hour therapeutic blood levels," rather then the specific ingredients.

Moreover, because the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment," Phillips, 415 F.3d at 1323, the Court declines to limit the meaning of "extended release formulation" merely because Wyeth has disclosed only one set of specific ingredients.

3. The Prosecution History

The prosecution history further supports a conclusion that "extended release formulation" is not limited to the specific ingredients. During the prosecution of a related patent application, an examiner with the Patent and Trademark Office ("PTO") apparently understood that the term "extended release formulation" was being used in the patents according to its ordinary meaning. That application, like the subsequent applications that became the patents-in-suit, included product claims that recited the specific ingredients, as well as method claims that recited the term "extended release formulation" but did not recite any of the specific ingredients. Wyeth Ex. 23. During a telephone conference, the examiner informed the inventors that they had to amend the method claims to make them dependent on a product claim that recited the specific ingredients, because the method claims would otherwise be too broad. Wyeth Ex. 24, 002-000850 to 582.

After considering this recommendation, Wyeth abandoned that application rather than make the method claims dependant on the product claims, which recited the specific ingredients. Wyeth Ex. 25. Shortly thereafter, it filed a continuation-in-part application that included the same independent method claims, set forth in the same manner. Wyeth Ex. 26. In other words, the inventors specifically chose not to limit the method claims by including the specific ingredients or by making them dependant on a product claim that included those ingredients. During the prosecution of this second application, a new examiner allowed the patents to issue without requiring that the method claims include the limitation. Wyeth Ex. 27, 002-000719. Moreover, the second examiner explicitly noted that the method claims "[do] not recite any limitations describing the formulation." Id. at 002-000718.

This history clearly indicates that the inventors as well as both PTO examiners understood the term "extended release formulation" to hold its common and ordinary meaning. Moreover, Wyeth explicitly declined to limit its method claims by including the specific ingredients or making the claims dependant on a product claim that recited those ingredients. Thus, the prosecution history clearly supports Wyeth's proposed construction of this term.

Although Mylan argues that "a rejection by a first examiner followed by the allowance of the same claims in a continuation application by a new examiner raises serious questions about the reliability of the new examiner's conclusion," Mylan Opening Brief, p. 17 (citing Syntex (USA) LLC v. Apotex, Inc., 407 F.3d 1371, 1382-83 (Fed. Cir. 2005)), this argument challenges the validity of the patent, and thus is not appropriate at this time.

In conclusion, the Court finds that the inventors did not clearly and deliberately set forth a new definition for "extended release formulation" in the specification. Mylan therefore has failed to overcome the strong presumption against its proposed construction because, among other things, adopting that construction would render certain dependent claims in the patents redundant, thus violating the doctrine of claim differentiation. Finally, the prosecution history further supports the conclusion that the inventors intended the common and ordinary meaning of the term to apply. For these reasons, the Court adopts Wyeth's proposed construction of this term.

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A. "Extended Release Formulation"

With respect to the term "extended release formulation," Impax contends that the term requires specific ingredients referred to in the specification. Specifically, Impax contends that "extended release formulation" means "a formulation comprising

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venlafaxine, microcrystalline cellulose, and optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24 hour period of administration." Impax contends that other extended release technologies exist and were known to those skilled in the art, including such technologies as drug-coated sugar beads, diffusion systems, reservoir systems, enteric coatings and waxing coatings. However, Impax contends that these other technologies are not embraced by the specifications for the patents-in-suit, because the inventors specifically referenced certain ingredients necessary for the extended release formulation they claimed. Impax also directs the Court to the Markman ruling issued by the New Jersey district court in the Teva Litigation, which adopted this approach.

In response, Wyeth contends that the term "extended release formulation" should be construed consistent with its ordinary and customary meaning, and therefore, no specific ingredients are required to define the term. In support of its argument, Wyeth relies on the doctrine of claim differentiation, pointing out to the Court that the asserted method claims recite "extended release formulation" without specifying ingredients, whereas other unasserted claims recite an "extended release formulation" with specific ingredients. Because the unasserted claims would become redundant if "extended release formulation" is construed to require specific ingredients, Wyeth contends that the term "extended release formulation" must be construed more generally to mean "a formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation."

Reviewing the plain language of the asserted claims in light of the patents' specifications and prosecution histories, the Court agrees with Wyeth's position that the term "extended release formulation" should not be limited to specific ingredients. As Wyeth points out, the asserted claims do not define the claimed "extended release formulation" by reference to any specific ingredients except for the active ingredient venlafaxine hydrochloride. Several unasserted claims, however, including certain claims dependent on those asserted here, recite specific inactive ingredients. As the Court of Appeals for the Federal Circuit recently reiterated in Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., "'the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. (quoting Phillips v. AWH Corp., 415 F.3d at 1315; see also Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1333 (Fed. Cir. 2007) (noting that some passages of patent specification described device as comprising at least one pressure activated seal, but noting that those passages do not expressly state that the pressure activated seal is an essential component of the invention and declining to limit the claims "where the language of the claims so clearly distinguishes between those claims that require the presence of a pressure activated seal and those that do not . . .").

Impax directs the Court to portions of the specification which it contends override this presumption and demonstrate that the inventors intended to limit the term "extended release formulation" to specific active ingredients. Reading the specification as a whole and in context, the Court is not persuaded that it supports the claim limitations sought by Impax. Throughout the specification, the claimed invention is described first in broad terms and later in more narrow terms. These broad terms describe a "use aspect" of the invention which correspond to the method claims Wyeth asserts here. The portions of the specification relating to this "use aspect" do not limit the "extended release formulation" to a specific list of inactive ingredients, and instead, describe the methods of achieving certain results that represent the claimed invention in terms of an "extended release formulation of venlafaxine hydrochloride." For example, the specification provides:

[I]n accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and valleys attending the pharmocokinetic utilization of multiple daily tablet dosing with venlafaxine hydrochloride which comprises administering to a patient in need of treatment with venlafaxine hydrochlcride, a one-a-day, extended release formulation of venlafaxine hydrochloride.

Ex. 1, col. 2:38-45 (emphasis added).

Similarly, the specification goes on to describe another "use aspect" of the invention in similar terms:

Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in needs of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

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Ex. 1, col. 2:55-62 (emphasis added). With respect to the more narrow descriptions provided for in the specification, the Court concludes that those descriptions either relate to the "formulation aspect" of the invention contained in the unasserted claims and/or suggest preferred embodiments for practicing the invention. The Federal Circuit has cautioned against importing limitations from the specification into the claim language 1, and the Court declines to do so, particularly, where as here, it is not clear to the Court from the portions of the specification cited by Impax that the inventors intended to depart from the ordinary and customary meaning of the term "extended release formulation." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (recognizing that a patentee may choose to be his own lexicographer and depart from the ordinary and plain meaning words, "as long as the special definition of the term is clearly stated in the patent specification or file history".) Indeed, when a departure from the ordinary meaning of the term "extended release formulation" was required, as in the unasserted formulation claims, the claim language and the corresponding portions of the specification specifically go on to list the ingredients required for the "extended release formulation." That this list of ingredients was not provided with respect to the method claims and the portions of the specification corresponding to the method claims leads the Court to believe that the inventors knew how to limit the term when they so desired, and chose not to do so with respect to the method claims.

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1 See e.g., Pfizer Inc. v. Ranbaxy Labs., Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006) ("while the examples do describe reaction sequences that produce racemates, restricting claim 1 on this basis would improperly import limitations from the specification into the claims . . ."); Phillips, 415 F.3d at 1323.

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The Court's conclusion in this regard is also consistent with the prosecution histories of the patents. Initially, the patent examiner concluded that the method claims would only be patentable if Wyeth agreed to make these claims dependent upon the product claims recited in the patent. The first examiner's approach to the patents reflected his view that "extended release formulation" was broadly interpreted and not limited to specific ingredients. Although Wyeth initially agreed to this amendment and the examiner issued a Notice of Allowance, Wyeth later abandoned the application and refiled a continuation-in-part application which left the method claims in the broader form, without making them dependent on the narrower product claims. The second examiner allowed the refiled method claims to issue without rejection or amendment.

Impax also contends that the Court should not adopt Wyeth's proposed construction of the term "extended release formulation," because it excludes hydrogel tablets, and therefore, it is not consistent with the ordinary and plain meaning of the term "extended release formulation" as that term is used by one skilled in the art. As Wyeth points out, however, hydrogel tablets do not produce the desired dissolution rates called for in the patents. In this regard, the specification explains:

Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies.

* * *

Thus, the desired dissolution rates of sustained release dosage forms of venlafaxine hydrochloride, impossible to achieve with hydrogel tablet technology, has been achieved with the film-coated spheroid compositions of this invention.

Ex. 1, col. 4, ll. 60-64, col. 10, ll. 53-57 (emphasis added). In the Court's view, the emphasized language makes it clear that hydrogel tablets are not within the scope of the invention, and therefore, the Court concludes that hydrogel tablets are properly excluded from the construction of the term "extended release formulation." Accordingly, the Court construes the term "extended release formulation" to mean "a formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation."

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1. "extended release formulation"

Wyeth contends that "extended release formulation" should be given its ordinary meaning and construed as "[a] formulation which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." (Chart). Teva asserts that the patentees acted as their own lexicographers by identifying certain ingredients that must be present in the formulation. Teva asserts that "extended release formulation" means "[a] formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration." (Id., emphasis added). Because the Court agrees with Teva that the patentees acted as their own lexicographers, the Court will adopt Teva's proposed claim construction.

The Court begins by looking at the context in which the term "extended release formulation" is used in the claims of the patents-in-suit. Wyeth argues that the asserted claims demonstrate that the patentees did not intend to limit "extended release formulation" to any specific set of ingredients. Every asserted claim recites: "A method . . . which comprises administering orally to a patient in need thereof, an . . . extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient." (See, e.g., '171 patent, claim 20, emphasis added). Wyeth argues that if in fact "extended release formulation" encompassed particular ingredients, including venlafaxine hydrochloride, then the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient" would be superfluous. (Wyeth's Br. at 11). According to Wyeth, if "extended release formulation" already included venlafaxine hydrochloride, then there is no need for the claims to specify the active ingredient. Thus, argues Wyeth, "extended release formulation" does not include any particular ingredients.

Wyeth also contends that the doctrine of claim differentiation supports its broad construction of "extended release formulation." The doctrine of claim differentiation gives rise to a presumption that a limitation added in a dependent claim is not present in the independent claim. Phillips, 415 F.3d at 1314-15. Comparing independent claim 1 of the '120 patent with dependent claim 3, Wyeth argues that the doctrine creates a presumption that "extended release formulation" does not include specific ingredients. (Wyeth's Br. at 13). Independent claim 1 recites: "A method . . . which comprises administering orally to a patient in need thereof, an extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient." '120 patent, claim 1 (emphasis added). Dependent claim 3 recites: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose." ' 120 patent, claim 3 (emphasis added). Because claim 3 includes the additional limitation of specific ingredients, the Court agrees with Wyeth that a presumption arises that claim 1 does not include that limitation. Thus, the Court agrees with Wyeth that the plain language of the claims implies that "extended release formulation" does not include specific ingredients.

Teva does not dispute that the claims, on their face, imply a broad construction for "extended release formulation." Rather, Teva argues that the presumption the broader construction applies is overcome by the narrow definition given to "extended release formulation" by the patentees in the specification. This Court agrees.

The patentees defined "extended release formulation" several times in the specification. In the abstract, they disclosed:

More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlfaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, Abstract. They reiterated this same restrictive definition in the "Brief Description of the Invention:"

The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

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'171 patent, col. 2, line 62 - col. 3, line 2. Only after setting forth this description of their invention, did the inventors then go on to address the preferred embodiments of their invention. See '171 patent, col. 3, lines 5-62. Similarly, in the "Detailed Description of the Invention," the patentees defined "extended release formulations" by their ingredients:

The extended release formulations of this invention are comprised of [venlafaxine] hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose [sic] to provide the desired level of coating . . . .

'171 patent, col. 4, lines 9-15 (emphasis added).

Wyeth asserts that these statements merely identic a preferred embodiment of the invention. The Court disagrees. Because the specification definitively states that the "extended release formulations" of the invention are limited to particular ingredients, the Court finds that the patentees acted as their own lexicographers and limited the meaning of "extended release formulation." See Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) (finding that the inventors acted as their own lexicographers and limited the term "solubilizer" to surfactants by stating in the specification that "the solubilizers suitable according to the invention are defined below", and later describing the suitable solubilizers as surfactants).

Moreover, the specification provides additional support for a narrow construction of "extended release formulation." Although it is improper to limit the claims based on the preferred embodiments, the Federal Circuit has stated that the "preferred embodiments can shed light on the intended scope of the claims." Id. at 1340. Here, the specification sets forth seven examples describing different embodiments the named inventors worked with. Each and every embodiment of an "extended release formulation" recited in these examples includes venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC n3 coated with ethyl cellulose and HPMC. See, e.g., '171 patent, col. 5, line 33 - col. 10, line 57. The fact that all of these examples use the same core set of ingredients buttresses the conclusion that "extended release formulation" should be narrowly construed. See Astrazeneca, 384 F.3d at 1340-41 (finding additional support for a limited construction of "solubilizer" in the fact that "all of the solubilizers listed in the specification and used in the working examples were surfactants").

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n3 "HPMC" is the abbreviation for "hydroxypropylmethylcellulose."

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Further, the specification distinguishes the "extended release formulations" of the invention from extended release hydrogel tablet formulations. Wyeth admits that under its proposed construction, an extended release hydrogel tablet having the claimed in vivo characteristics may fall within the asserted claims. (See Wyeth's Br. at 16 n.6). The specification, however, discloses that the inventors' attempts to develop extended release hydrogel tablets were "fruitless" and teaches one of ordinary skill that it is "impossible to achieve" the desired dissolution rates using hydrogel tablet technology. Col. 4, lines 60-64; col. 10, lines 53-57. These statements were made without qualification. Accordingly, the specification supports construing "extended release formulation" more narrowly than Wyeth proposes. See Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed.").

Wyeth responds that the specification supports its broader, ordinary meaning of the term. Wyeth asserts that Teva ignores several portions of the specification which allegedly refer only to the "extended release formulation" as including venlafaxine hydrochloride. See, e.g., '171 patent, Abstract ("This invention relates to a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant . . . .") (emphasis added); Id. at col. 2, lines 14-16 ("In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug s [sic] component . . . .") (emphasis added); Id. at col. 2, lines 37-44 ("Hence, in accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and valleys . . . which comprises administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride.") (emphasis added). Wyeth further asserts that its broad construction is supported by those portions of the specification that compare "extended release

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formulations" with immediate release formulations. See, e.g., '171 patent, col. 2, lines 24-37 (contrasting blood plasma profiles for both types of formulations without reference to specific ingredients). And Wyeth contends that Table 1 in the specification supports a broader construction because it allegedly teaches an ordinary artisan how to screen for other useful inactive ingredients that may work in combination with venlafaxine hydrochloride to develop an extended release venlafaxine formulation. But there is no merit to Wyeth's arguments because they ignore those portions of the specification set forth above that explicitly characterize and limit the invention to a formulation containing specific ingredients.

When the term "extended release formulation" is looked at in its proper context in the specification, this Court believes that one of ordinary skill in the art would construe the term to include specific ingredients. The unequivocal language the patentees used when describing their invention - "the invention comprises an extended release formulation of", "the formulations of this invention comprise" and "the extended formulations of this invention are" - rebuts the presumption established by the doctrine of claim differentiation. See, e.g., Kraft Foods, Inc. v. Int 'l Trading Co., 203 F.3d 1362, 1368-69 (Fed. Cir. 2000) (finding the presumption of claim differentiation overcome because the specification and prosecution history described the "protecting back panel" as one that must be relatively stiff). Although this may make certain dependent claims coterminous and certain claim limitations superfluous, that result is inevitable and inescapable in a case such as this where the patentees act as their own lexicographers. See Multiform Desiccants, Inc. v. Medzam. Ltd., 133 F.3d 1473, 1480 (Fed. Cir. 1998) ("The doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence."); Sule v. Kloehn Co., Ltd., 149 F.Supp. 2d 115, 128 (D.N.J. 2001) ("Claim differentiation is a guide, not a rigid rule. If a claim will bear only one interpretation, similarity will have to be tolerated.") (quoting Autogiro, 384 F.2d at 404).

The portions of the prosecution history in evidence do not alter this conclusion. Although Wyeth contends that the prosecution history supports a broader construction because the method claims were allowed without limitation to specific ingredients, given the clear and unambiguous language in the specification, the Court believes that the prosecution adds, at most, nothing more than the claims themselves reveal. That being the case, the definition provided by the specification, which is the "single best guide to the meaning of a disputed term," shall be adopted. Vitronics, 90 F.3d at 1582.

Because the meaning of the term can be ascertained from the intrinsic record, the Court will not rely on extrinsic evidence that suggests a broader construction. See Phillips, 415 F.3d at 1324 (prohibiting the use of extrinsic evidence to contradict the unambiguous meaning provided to a claim term by the intrinsic evidence). That evidence takes the term out of its all-important context in the specification and, thus, will be given no weight.

In sum, "extended release formulation" means "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration."
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Solexaargues that the district court improperly construed certain terms of claim 1 of the '597 patent. Claim 1 of the '597 patent reads:

1. A method for identifying a sequence of nucleotides in a polynucleotide, the method comprising the steps of:

(a) extending an initializing oligonucleotide along the polynucleotide by ligating an oligonucleotide probe thereto to form an extended duplex;

(b) identifying one or more nucleotides of the polynucleotide; and

(c) repeating steps (a) and (b) until the sequence of nucleotides is determined.

Solexa challenges the district court's construction of each step.

The construction of step (a) centers on whether each oligonucleotide probe must be ligated to an initializing nucleotide

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during repetition of the cycle or whether the oligonucleotide probe can be ligated to an extended duplex (an initializing probe that has already been extended by an oligonucleotide probe). Solexa argues for the former construction. The district court determined that "step (a) includes an extension process, whereby, with each repetition, an additional probe is added to what is already there, so that the chain gets longer and longer." Applera, No. 07-2845, D.I. 383, at 7 (N.D. Cal.Jan. 22, 2009) (Supplemental Claim Construction Order). The court further explained that "step (a) includes a scenario where the initializing oligonucleotide is originally attached to the polynucleotide and thereafter an ever-extending chain of probes is ligated thereto to form an ever-extending duplex, all beginning with the same initializing oligonucleotide." Id. Solexa argues that step (a) requires ligating a probe to an initializing nucleotide--not an extended duplex--and therefore during each repetition of the cycle, a new initializing nucleotide must be laid down along the polynucleotide.

The specification describes the invention as "repeated cycles of duplex extension." '597 patent col.3 l.2. It further discloses that:

> such extension starts from a duplex formed between an initializing oligonucleotide and the template. The initializing oligonucleotide is extended in an initial extension cycle by ligating an oligonucleotide probe to its end to form an extended duplex. The extended duplex is then repeatedly extended by subsequent cycles of ligation.

Id. col.3 ll.3-9 (emphasis added). Thus, once an extended duplex is formed, it "is further extended in subsequent cycles." Id. col.3ll.15-16. This description of the invention is echoed throughout the specification, which repeatedly describes regenerating an extendable end on the extended duplex to allow for successive cycles of ligation. See, e.g., id. col.8 l.55-col.9 l.55 (describing the regeneration extendable termini on extended duplexes to allow for successive cycles of ligation); id. col.10 l.33-col.11 l.11 (describing schemes for extending an initializing nucleotide or an extended duplex); id. col.16 ll.26-28 (stating that at the end of Example 1, the extendable duplexes have regenerated 3'-hydroxyls and are ready for the next cycle of ligation/extension/cleavage). We agree with the district court that step (a) includes repeated cycles of extension of extended duplexes.

The district court determined that the term "identifying one or more nucleotides" in step (b) "requires that at least one nucleotide be identified during step (b), that is, its identity as an A, G, C, or T must be determined." Supplemental Claim Construction Order at 7. The court also determined that step (c) requires that each identification step occur "within each cycle" (i.e., it is not sufficient to repeatedly add oligonucleotide probesand then perform one identification step at the end). Applera, No. 07-2845, D.I. 133, at 16 (N.D. Cal. Feb. 21, 2008) (Claim Construction Order). Solexa argues that the term comprising "permits an accused method to include additional steps beyond those expressly recited in the claims." In simple terms, claim 1 requires that one extend, identify, and repeat. Under Solexa's proposed construction, the word "comprising" indicates that one could systematically skip the identification step during each cycle, and so long as one or more nucleotides were identified at the end of the process, that would satisfy the claim limitations. "'Comprising' is not a weasel word with which to abrogate claim limitations." Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (citation omitted). Here, the claims require repeating the extend and identify steps until a sequence of nucleotides is determined. This repetition is described in the specification, which states that "[i]n one aspect, the invention calls for repeated steps of ligating and identifying of oligonucleotide probes." '597 patent col.8 ll.57-58. The specification further explains that "the ligation of multiple probes to the sameextended duplex in the same step would usually introduce identification problems." Id. at col.8 ll.59-60. The specification does not describe any way in which one could ligate multiple probes to the same extended duplex and later identify a sequence of nucleotides. Therefore, we agree with the district court that step (b) requires the identification of one or more nucleotides during each cycle. In other words, in order to repeat steps (a) and (b), one must actually perform step (b).

The district court construed step (c) as "conditional, meaning that there is no need for repetition if the sequence of the polynucleotide has been fully determined in the first cycle." Solexa argues that this construction is inconsistent with arguments made during the prosecution history. During prosecution, the applicant distinguished the invention from a prior art reference by noting that "[t]he reference does not teach 'repeating steps (a) and (b) until the sequence of nucleotides is determined, as recited in the present claim. Because the prior art method identifies only a single nucleotide, not a sequence of nucleotides, there would be no need for such repetition." Contrary to Solexa's argument, thisstatement does not require one to repeat steps (a) and (b) even when the polynucleotide has been determined in the first cycle (indeed, it states that the cycle is repeated "until the sequence of nucleotides is determined"). The distinguishing feature of the invention is that it taught a method for identifying a sequence of nucleotides, rather than a method for identifying a single nucleotide. Using the method of claim 1, a sequence of nucleotides may be identified after only one cycle using parallel reactions employing

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different initializing nucleotides, each out of register by one nucleotide. See '597 patent col.3 ll.19-36, ex. 1. Thus, we reject Solexa's argument based on the prosecution history. We construe step (c), as the district court did, to have its plain and ordinary meaning. To meet the limitations of claim 1, one must repeat steps (a) and (b) until the sequence of nucleotides is determined. There is no need for repetition once the sequence of the polynucleotide has been fully determined.
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J. Extent.

Noting that the term "extent" is not defined in either one of the patent specifications, 3-DP contends that the ordinary meaning of the word should control. See, e.g., Zelinski, 185 F.3d at 1315; Desper Prods., 157 F.3d at 1336. Because "extent" in this instance would appear to serve as synonym for "amount" or "degree," 3-DP purports to advance this interpretation. 3 While Scriptgen appears to take issue with this proposed definition, it fails to provide an alternate construction. After reviewing the language of the representative claim, which discusses "the extent to which the target protein occurs in the folded state, the unfolded state or both in the test combination and in the control combination," the court will afford the term "extent" its ordinary meaning, i.e., as meaning "amount" or "degree."

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3 In actuality, it seems that 3-DP intends the words "amount" or "degree" to have a fairly narrow meaning. As the court will explain, 3-DP appears to argue that these two terms require there to be an actual "amount" or "degree" of folding or unfolding by the target protein.

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F. "Extracellular Domain"

A number of dependent claims in the patent are directed toward monoclonal antibodies that "bind[] to the extracellular domain of the human breast cancer antigen." '561 Patent, Claims 7, 11, 15, 21, 25. The parties agree that one skilled in the art would interpret "extracellular" to mean "outside the cell." The meaning of "domain" is the focus of the parties' dispute.

"Domain" is ordinarily understood to refer to "region" or "area." Thus, Chiron posits that "extracellular domain" means "the portion of the human breast cancer antigen that is external to the cell." Genentech would have the court ignore the plain meaning of the term because the specification states: "The term 'domain,' or 'polypeptide domain' refers to that sequence of a polypeptide that folds into a single globular region in its native conformation, and that may exhibit discrete binding or functional properties." Id. at 12:38-42. Read in context, however, it is clear that the quoted text refers to antibodies, not antigens. The specification states that the invention relates to "novel polypeptides having structure and function substantially homologous to native antibody-antigen binding sites." Id. at 1:31-33. The specification further describes polypeptides as embodiments of the invention (i.e. monoclonal antibodies). See id. 4:1 ("in various related embodiments, monomeric polypeptides are provided ..."). Thus, by polypeptides, the specification is clearly referring only to antibodies. Therefore, the definition of "domain" in the specification has no bearing on what is meant by the "extracellular domain" of the human breast cancer antigen. Accordingly, the court adopts the following construction:
The term "extracellular domain" means the portion of the human breast cancer antigen that is external to the cell.
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1. "Extract of green tea" and "green tea extract"

Green tea is produced from a plant species known as Camellia sinensis of which one variety is Camellia sinensis assamica

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(hereinafter referred to as "assamica"). Iovate proposes that the terms "extract of green tea" and "green tea extract" should be construed to mean "a preparation of Camellia sinensis which has been processed to be concentrated in catechols." Allmax proposes a narrower definition: "a concentrated preparation obtained from the leaves or buds of Assamica type Camellia sinesis."

In support of its proposed construction, Allmax relies on two particular elements from the prosecution history of the '765 and '986 Patents. First, it notes that inventor Max Rombi ("Rombi") submitted a disclosure to the PTO examiner stating that "only [assamica] produced the synergistic thermogenic proportions of caffeine and catecholamines according to the present invention." Next, Allmax notes that apparently the examiner allowed the issuance of the patent only after Rombi pointed out that his disclosure taught an extraction that utilized two leaves and the bud of the green tea.

Iovate responds that prosecution history cannot be used to limit claim scope unless the applicant (and not the examiner) "took a position before the PTO that would lead a competitor to believe the applicant had disavowed" claim scope. See Schwing GmbH v. Putzmeister Aktiengesellschaft, 305 F.3d 1318, 1324 (Fed. Cir. 2002); see also Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1345 (Fed. Cir. 2005). Iovate suggests that the applicant for the '986 and '765 Patents at all times maintained a position that "green tea" covers all varieties of Camellia sinensis. Indeed, even when the examiner initially rejected his claim because the term was not limited to assamica or any other specific variety of Camellia sinensis, the applicant continued to argue that "green tea" was a generic term covering all varieties of Camellia sinensis and that the claim "should not be limited to a particular tea variety."

Moreover, Iovate asserts that Rombi's disclosure with respect to assamica was made specifically to contradict the examiner's assertion that the pending claim lacked novelty because any green tea extract using an 80% ethanol extraction would contain the claimed concentrations of catechols. Thus, Rombi sought to demonstrate that, although some varieties of green tea such as assamica produce the claimed extract, others do not.

In light of the evidence offered by Iovate, the applicant's effort to distinguish his invention from prior art did not "clearly disavow[]" the scope of the claim and, accordingly, the Court will adopt the construction proposed by Iovate rather than Allmax's more narrow construction based purely on the prosecution history. See Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1327 (Fed. Cir. 2003).
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4. Extruded

The final claim term in dispute is "extruded." According to AVI, extruded means foam created by using the well-known extruder apparatus that uses a screw-device to continuously force pressurized polymer gel through a die into a lower pressure area. Dow's definition, by contrast, is that of forcing a polymer gel through a die under a compressive force.

Essentially, the point of disagreement between the parties is whether extruded should be limit to any one type of process or to the use of any specific apparatus. As to this construction issue, I side with Dow. The language in the specifications of the perforation patents does not limit the term extruded to a specific type of process and apparatus. See Du Pont, 849 F.2d at 1433; American Standard Inc., 722 F. Supp. at 93; Hoganos 9 F.3d at 950. Rather, the specifications state, in pertinent part:

Providing the plastic foam comprises blending of various components, including a resinous melt of a foamable polymer and a blowing agent, under pressure to form a foamable plastic gel and extruding the foamable gel through a conventional die (not shown) to a region of lower pressure to form the foam. The blending of various components of the foamable gel may be accomplished according to known techniques in the art. Suitably a mixer, extruder, or other suitable blending device (not shown) may be emphasized to obtain homogeneous gel. The molten foamable gel is then be [sic] passed through conventional dies to form the foam.

'016 patent, col. 4, lines 16-27 and '058 patent, col. 4, lines 33-44 (emphasis added). Furthermore, no limitation on the term is provided anywhere in the patents or the prosecution histories. Although the example in the '016 patent utilizes an extruder apparatus that appears to be of a conventional screw-type, it is improper to read this extraneous limitation in the specification into the claims. See, e.g., Du Pont, 849 F.2d at 1432; Intervet, 887 F.2d at 1056.

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Accordingly, I find that extruded means forcing a polymer gel through a die under a compressive force.
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Because the parties do not dispute that Dr. Jacob publicly used MSM (R) to treat pain more than one year prior to the effective filing date of the '878 patent, the sole issue on appeal is one of claim construction: whether the terms "feeding" and "beneficial amount" limit the claims to the use of MSM (R) for nutritional purposes. Claim construction is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71, 34 U.S.P.Q.2D (BNA) 1321, 1322 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), that we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1172 (Fed. Cir. 1998) (en banc). In interpreting claims, a court "should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1577 (Fed. Cir. 1996). Claim terms are to be given their ordinary and accustomed meaning "unless it appears from the specification or the file history that they were used differently by the inventor." Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1577, 27 U.S.P.Q.2D (BNA) 1836, 1840 (Fed. Cir. 1993).

As always, our claim construction analysis begins with the actual words of the claim. E.g., Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1334, 54 U.S.P.Q.2D (BNA) 1289, 1295 (Fed. Cir. 2000) ("We begin the claim construction process by considering the words of the claim itself.") (citing Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619-20, 34 U.S.P.Q.2D (BNA) 1816, 1819 (Fed. Cir. 1995); Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1577 ("First, we look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention."). We agree with MSM Investments that the ordinary meaning of the term "feeding" would indicate that the method in claim 1 entails supplying or providing food or nourishment. See, e.g., Webster's II New Riverside University Dictionary 469 (1988) (defining "feed" as "1. a. To supply with nourishment . . . b. To provide as food or nourishment"). 1 Thus, the ordinary meaning of the term "feeding" provides some support for MSM Investments' argument that the method in claim 1 is limited to the use of MSM (R) for nutritional purposes.

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1 Standard dictionary definitions indicate ordinary meaning. E.g., Optical Disc, 208 F.3d at 1335, 54 U.S.P.Q.2D (BNA) at 1295 ("For such ordinary meaning, we turn to the dictionary definition of the term.") (citing Vitronics, 90 F.3d at 1584 n.6, 39 U.S.P.Q.2D (BNA) at 1578 n.6 (explaining that although dictionaries are extrinsic evidence, "judges are free to consult such resources at any time in order to better understand the underlying technology")).

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However, claim language must always be construed in light of the specification. Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1577 ("It is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning."); Markman, 52 F.3d at 979, 34 U.S.P.Q.2D (BNA) at 1330 ("Claims must be read in view of the specification, of which they are a part."). Contrary to the ordinary meaning arguably suggested by its dictionary definition, when viewed in light of the specification, we conclude that the term "feeding" does not limit claim 1 to nutritional uses, nor does it exclude the use of MSM (R) for pharmaceutical or pharmacological purposes. See Vitronics, 90 F.3d at 1584 n.6, 39 U.S.P.Q.2D (BNA) at 1578 n.6 ("Judges may . . . rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents."). While the written description does not specifically define the term "feeding," it does disclose that MSM (R) may be used "as a food and as a normalizer of biological function," '878 patent, col. 7, ll. 53-56, and although its use as a "food" suggests that MSM (R) may be used for nutritional purposes, the written description broadly defines the word "food" as meaning "a nutritive material taken into an organism for growth, work, protection, repair, restoration and maintenance of vital processes." Id. at col. 8, ll. 20-23 (emphasis added). This expansive definition of the word "food," coupled with the disclosed use of MSM (R) as a "normalizer of biological function," clearly suggests that the claimed method of "feeding" includes both nutritional and pharmacological uses. Indeed, in addition to stating that MSM (R) may be used as a "normal dietary ingredient," the specification also explicitly states that MSM (R) has "multiple functions in the body" and that "at higher levels [of ingestion] it functions as a pharmaceutically active agent." Id. at col. 3,

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l. 67 to col. 4, l. 3. The written description explains that "the major differences between the use of [MSM (R)] as a food and as a normalizer of biological function is the concentration and amount employed, dosage forms, and routes of systemic entry." Id. at col. 7, ll. 53-56.

Furthermore, the written description provides numerous examples of specific pharmacological benefits derived from the ingestion of MSM (R) . E.g., id. at col. 13, l. 53 to col. 14, l. 62 ("The following are pharmacological benefits from the ingestion of exogenous methylsulfonylmethane . . . ."). These examples range from relieving various types of pain and treating parasitic infections to improving the overall health of animals. Id. The specification states that these pharmacological benefits may be effectuated by adding MSM (R) to the "daily diet" of the patient, id. at col. 20, ll. 3-11, or by administering MSM (R) "in admixture with one or more foodstuffs ingested daily by the patient, e.g., milk, coffee, tea, cold desserts, etc.," id. at col. 22, ll. 60-68. It is also clear that animals may be administered pharmaceuticals by including them in their animal feed. E.g., id. at col. 10, l. 58 to col. 13, l. 52. Such examples erase the distinction that MSM Investments attempts to create between the use of MSM (R) as a nutritional food or dietary supplement and the use of MSM (R) for pharmacological purposes.

MSM Investments argues that the examples of pharmacological uses of MSM (R) in the specification "were actually examples of different inventions claimed in different, but related, patents," and that the district court's "improper reliance" on these examples led to an erroneous claim construction. However, that argument is unpersuasive. According to its own written description, the '878 patent discloses additional examples of pharmacological benefits that were not disclosed in parent applications. Id. at col. 2, l. 67 to col. 3, l. 5 ("In addition to the pharmacologically beneficial effects [of] methylsulfonylmethane . . . which are specifically disclosed in my parent applications, it is useful in the treatment of a surprising variety of other diseases and adverse physiological conditions, as disclosed in detail hereinafter.").

Moreover, the fact that other related patents have claims that are limited to certain pharmacological uses (e.g., treatment of gastrointestinal upset, nocturnal muscle cramps, etc.) does not compel the conclusion that the claims of the '878 patent must be limited to nutritional uses. While a patent specification may contain a description of separately patentable inventions that end up claimed in multiple patents, the specification of this patent indicates that the generic term "feeding" encompasses the administering of pharmaceuticals. The specification commingles pharmaceutical uses with nutritional uses and does not describe nutritional benefits and pharmacological benefits as mutually exclusive. Thus, when reading the claim language in light of the specification, the term "feeding" in claim 1 of the '878 patent covers both nutritional and pharmacological uses of MSM (R).
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A. "Fertile transgenic Zea mays plant," "progeny," and "seed"

Under Claim 1, the patent covers "a fertile transgenic Zea mays plant containing an isolated heterologous DNA construct encoding EPSP synthase . . . . " U.S. Patent 5,554,798, column 26. Claim 3 covers "a seed produced by the transgenic plant of Claim 1 which comprises said heterologous DNA construct[,]" and Claim 4 covers "a progeny transgenic Zea mays plant derived from the transgenic plant of claim 1 . . .. " Id. Each of these claims raise the question of whether a fertile transgenic Zea mays plant, its seed, and its progeny, cover future generations of plants, and seed, or whether these claims are limited to the R0 through R2 generations, as argued by Syngenta. DeKalb defines the term "fertile transgenic Zea mays plant" to mean a corn plant that is (1) transgenic because it includes DNA that was introduced into the plant or one of its ancestors through genetic engineering and (2) "fertile" because it can pass that introduced DNA on to its offspring. The plant is not limited to an R0 plant, because if DNA was introduced into the plant, that means that it is talking about the R0 plant, but when it goes on to say "[i]ntroduced into one of its ancestors," an R0 plant does not have ancestors, so this construction covers R0, R1, R2, R3 . . . . Rn. DeKalb argues that two other terms, "progeny," appearing in Claims 1 and 4, and "seed," appearing in Claims 3 and 5, similarly have no limits to a single generation. DeKalb's claim construction for "progeny" means all succeeding generations of progeny, and "seed" means all succeeding generations of seeds.

Syngenta's position is that the Claims of the '798 Patent do not cover unlimited generations of plants. Syngenta says that Phillips teaches that the role of the specification is to describe and enable the invention. In turn, the claims cannot be of broader scope than the invention that is set forth in the specification. You cannot teach narrowly but claim broadly. The inventors only did experimentation with hygromycin, 5 and they only went to the R1 progeny plant described in the '798

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Patent. They did not get beyond the R2 generation. Syngenta argues that they tried, but could not do it. You do not look to the intent of the invention, but what the invention actually is. Syngenta points to the Prosecution History in support of their position, specifically that DeKalb tried to claim R1 and higher generations, and it had a claim that said that, and it cancelled that claim. Syngenta says it's claim construction is consistent with what the inventors said in the Specification:

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5 Hygromycin is an antibiotic. The eventual use of the claimed invention was to show resistance to glyphosate, which is a herbicide, however, the original experiments were with hygromycin.

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Claim 1 - A fertile transgenic Zea mays plant containing an isolated heterologous DNA construct. That, says Syngenta , is the R0 plant.

Claim 2 - The transgenic plant of Claim 1 wherein the heterologous DNA construct comprises a promoter. That, says Syngenta, is the R0 plant.

Claim 3 - A seed produced by the transgenic plant of Claim 1. Syngenta says the seed gives rise to the R1 generation.

Claim 4 - A progeny transgenic Zea mays plant derived from the transgenic plant of Claim 1. Syngenta says the progeny plant is the R1 plant.

Claim 5 - A seed derived from the progeny plant of Claim 4, wherein said seed gives rise to the R2 generation.

Claim 6 - This is a product by process claim.

1. "Isolated" argument

Syngenta challenges DeKalb to define the word "isolated" in Claim 1, and argues that DeKalb wants this Court to ignore the word isolated, which Syngenta asserts limits Claim 1 to the R1 generation, which in turn limits the remaining claims which refer back to Claim 1. K-2 Corporation v. Salomon, 191 F.3d 1356 (Fed. Cir. 1999) and Ethicon Endo-Surgery, Inc. v. United states Surgical Corporation, 93 F. 3d 1572 (Fed. Cir. 1996), according to Syngenta, caution that if the term need not be included in the claim, it cannot be ignored. You must give effect to all limitations of the claim. In Bicon, Inc. v. The Straumann Company, 441 F.3d 945 (Fed. Cir. 2006), Syngenta argues that it has been decided that allowing a patentee to argue characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess at the patent's scope.

To dispel Syngenta's argument that the term "isolated" in Claim 1 "means that isolated heterologous DNA can only be heterologous DNA that's in the R0 plant, it can't be in R1 and it can't be in R2," DeKalb points out that Claim 1 also says, "said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate, . . . " talking about DNA as expressed in the plant. The term "said DNA construct," has its antecedent basis in the term "isolated heterologous DNA construct." Claim 1 says "said DNA construct." Claim 2 says, "the heterologous DNA construct," again referring back to this as the antecedent claim. Claim 3 says, "said heterologous DNA construct;" again referring back. Claim 4 says, "said heterologous DNA construct," and so on. All of these claims have "said heterologous DNA construct" in them. All refer back to isolated heterologous DNA. DeKalb argues that if Syngenta's argument were true, these claims could not be set up this way, because they would be referring back only to the R0 generation, and could not refer to any subsequent generations of patents. They could not all be saying "said heterologous DNA construct."

The Federal Circuit in Bicon held that "[a]llowing a patantee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous." 441 F.3d at 950. The Court recognizes the requirement that claim language is not to be ignored, for doing so creates ambiguity for the public trying to comply with the patent's restrictions, however, it is not clear that Plaintiff's interpretation renders the word "isolated" redundant. The Court in Bicon, held that physical characteristics described in the claim could not be ignored, 441 F.3d at 950, the case before this Court, however, does not involve clearly

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referenced physical descriptions in the claims. Phillips instructs the Court to give terms their ordinary meaning as understood by one of ordinary skill in the art. 415 F.3d at 1313. While one of ordinary skill in the art may understand isolated to refer to the first generation, as that is the generation in which the modified DNA is isolated, this term must be looked at in the context of the claims as a whole. The remaining claims repeatedly reference "said DNA construct," implying that the term isolated references the DNA, and that it is that DNA in all subsequent generations which is claimed under the invention. This reading is not unreasonable, and does not render the term "isolated" redundant, as argued by Syngenta.

2. Comprising argument

Disputed terms within the claim are to be interpreted within the context of the language of the claims as a whole. Phillips, 415 F.3d at 1312. DeKalb uses this principle to argue that the language contained in Claim 6 supports the meaning ascribed to the terms in Claims 1, 3, and 4 by DeKalb, namely that the patent covers all subsequent generations. Syngenta uses this same principle to argue that the definitions of progeny, seed, and fertile transgenic Zea mays plant, refer only to limited generations, to do otherwise would render many of the claims superfluous, contrary to the rules of claim interpretation.

DeKalb summarizes Syngenta's argument as follows: because you can make an R0 plant using three steps in Claim 6, and because this claim is defining a transgenic plant in Claim 1, the transgenic plant in Claim 1 must be limited to the R1 plant. DeKalb argues that the first problem with that argument is that these steps are not recited in Claim 1. These steps are only recited in Claim 6, and Syngenta cannot read those limitations from Claim 6 into Claim 1. Secondly, DeKalb argues that Claim 6 is not limited to the R0 plant. Claim 6 says the plant is "obtainable," you could obtain it by a process comprising these three steps. DeKalb argues that the word "comprising" has a very well-known meaning in the patent business; it means including but not limited to. Accordingly, Claim 6 covers a process that must include these three steps but may include other steps as well; it could include steps before these three steps, in between these three steps, or after these three steps. So, there is no reason why this claim should not cover progeny plants - - R3, R4 . . . Rn, which are made by crossing steps, backcrossing steps, breeding steps, that occur after the three steps that are recited in Claim 6. The key word is "comprising." Syngenta disputes that the term "comprising" allows such an open ended construction.

The Federal Circuit in Gillette Company v. Energizer Holdings Inc., held that "the word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." 405 F.3d 1367, 1371 (Fed.Cir. 2005). The Court went on to state that "[b]ecause the patentee invoked this open-ended treatment in claim 1 of the . . . patent, the scope of claim 1 encompasses all safety razors satisfying the elements set forth in claim 1. The addition of elements not recited in the claim cannot defeat infringement." Id. at 1371-1372. "The transition 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements." Id. at 1372 (citing KCJ Corp. v. Kinetic Concepts Inc., 223 F.3d 1351, 1356 (Fed.Cir. 2000)). The Court is persuaded by the reasoning in Gillette Company. The specification provides a detailed history of the field at the time of the invention. Up until the time of the invention, no one had been able to create a fertile transgenic plant, this invention changed that. The specification goes onto say that the fertile transgenic plant can be used in conventional breeding programs. The process of breeding corn was not new, and therefore the specific steps required to breed future generations need not have been included in Claim 6 of the patent. The Court agrees that Claim 6 does not serve to limit the claims of the patent to specific generations, due to the use of the all inclusive language "comprising."

The Court has considered all arguments raised by the Parties regarding the language of the claims themselves and concludes that the term "fertile transgenic Zea mays plant," "progeny," and "seed" refer to the first and all subsequent generations. 6 Furthermore, this is thoroughly supported by the intrinsic record. The ordinary meaning of the terms transgenic, progeny and seed, support a finding that the patent covers the first and subsequent generations.

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6 Syngenta contends that DeKalb's construction, contrary to Syngenta's proposed construction, results in redundant claims. If DeKalb's view is adopted, Claim 1 covers R0, R1, R2, R3, R4 . . . Rn. Claim 4 covers R1, R2, R3, R4 . . . Rn, and is therefore completely redundant over Claim 1. There is no need for Claim 4. The only difference between Claim 1 and Claim 4 is that Claim 4 does not cover R0. The same thing is true with Claims 3 and 5. DeKalb's construction, says Syngenta, is completely illogical. DeKalb disputes this position, arguing that while the claims contain overlap, they are not redundant. Neither party presents any case law in support of their respective arguments, and the Court concludes that neither argument is persuasive. While the claims do contain overlap, they are clearly not identical, and the Court considers the specification

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and prosecution history to further support its conclusion regarding the appropriate claim construction.

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The specification defines transgenic as follows:

"Transgenic " is used herein to include any cell, cell line, ceallus, tissue, plant part or plant, the genotype of which has been altered beneficially by the presence of heterologous DNA that was introduced into the genotype by a process of genetic engineering, or which was initially introduced into the genotype of a parent plant by such a process and is subsequently transferred to later generations by sexual or asexual cell crosses or cell divisions.

United States Patent 5,554,798, column 4, lines 55-62. While there is some focus in the patent on the process of producing a first generation transgenic plant through particle bombardment and selection, reading the specification, one would understand the patent to refer to all subsequent generations. United States Patent 5,554,798, p.1 ("This invention relates to fertile transgenic plants of the species Zea mays (oftentimes referred to herein as maize or corn). The invention further relates to producing transgenic plants via particle bombardment and subsequent selection techniques which have been found to produce fertile transgenic plants."). Other language found in the specification further supports this conclusion. In the "Summary of the Invention," the specification states "[t]he invention further relates to regenerated fertile mature maize plants obtained from transformed embryogenic tissue, transgenic seeds produced therefrom, and R1 and subsequent generations." Id. at column 4, line 15-20 (emphasis added). The "Description of the Preferred Embodiments" section states: "Some of the plants of this invention may be produced from the transgenic seed produced from the fertile transgenic plants using conventional crossbreeding techniques to develop transgenic elite lines and varieties, or commercial hybrid seed containing heterologous DNA." Id. column 5, lines 13-18; see also Id. at column 4, line 48-52 ("[T]he present invention is directed to the production of fertile transgenic plants and seeds of the species Zea mays and to the plants, plant tissues, and seeds derived from such transgenic plants, as well as the subsequent progeny and products derived therefrom."). Finally, the Court notes that in describing how to create fertile transgenic plants, the specification recognizes that it may take 6-8 generations before two parent corn plants are created which contain the heterologous DNA. United States Patent 5,554,798, column 13, lines 47-52 ("This backcrossing process is repeated until the original normal parent has been converted to a line containing the heterologous DNA and also possessing all other important attributes originally found in the parent. Generally, this will require about 6-8 generations.").

All of the portions of the specification, cited above, support a finding that the invention was intended to allow the production of fertile corn plants which could be crossbred to produce additional plants which contained the desired heterologous DNA. Other processes had been developed which could be used to transform the DNA of plants, however, these processes had not successfully resulted in fertile plants, which could produce seed and pass the desired mutated DNA onto future generations. This stated purpose supports DeKalb's position that the term "fertile transgenic Zea mays plant" includes all generations through Rn, and that progeny and seed have similarly broad meanings.

The interpretation of the terms at issue in this section is clearly discernable from the claims themselves and the specification. Syngenta relies heavily on the prosecution history to support its proposed construction, 7 however, the prosecution history in this case is convoluted. DeKalb also points to portions of the prosecution history in support of their position. 8 While the Court recognizes that Phillips includes the prosecution history as part of the intrinsic record, having considered the ordinary meaning of the terms within the context of the claims and the specification, the Court does not find it necessary to parse the specific language of the prosecution history. The Court adopts DeKalb's proposed construction.

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7 For example, Syngenta argues that earlier versions of the patent included broader language that was eventually deleted from the claim language. A very important fact, says Syngenta, is that the original Claim 16 of the earliest filed 1990 '983 application, said "[t]he R2 and higher generations of the plant of Claim 1." That language was dropped. It does not appear in the issued Patent. Again, Claim 16 of the 1995 Patent, '073, stated "generations derived from the plant of claim 1." That language was also dropped. In 1995, there was a very broad claim pending, "a fertile transgenic Zea mays plant containing heterologous DNA which is heritable." Syngenta says that would clearly have covered all generations. See e.g. United States Patent 5,554,798, column 1 (under BACKGROUND OF THE INVENTION, this language appears: "European patent applications . . . describe the introduction of DNA into maize pollen followed by pollination of maize ears and formation of seeds. The plants generated from these seeds are alleged to contain the introduced DNA, but there is no suggestion that the

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introduced DNA was heritable, as has been accomplished in the present invention. Only if the DNA introduced into the corn is heritable can the corn be used in breeding programs as required for successful commercialization of transgenic corn."). But, the language was narrowed. The word "isolated" was inserted, and the word heritable was removed. That word was put in, says Syngenta , because it was limited to the R0 generation. The Court disputes that this claim history is significant, and further finds that there are numerous references in the patent specification to the heritable quality of the fertile transgenic Zea mays plant. Following the definition of transgenic, the specification defines heritable to mean 'that the DNA is capable of transmission through a complete sexual cycle of a plant, i.e., it is passed from one plant through its gamates to its progeny plants in the same manner as occurs in normal corn." United States Patent 5,554,798, column 5, lines 3-6. The invention is described as relating "to transgenic Zea mays seeds stably containing heterologous DNA and progeny which have inherited the heterologous DNA." Id. at column 3, lines 65-68 (second emphasis added). The patent specification further states that "[o]nly if the DNA is heritable can the corn be used in breeding programs as required for successful commercialization of transgenic corn." Id. at column 1, lines 58-60 (emphasis added). These references support DeKalb's position that the invention covers a transgenic Zea mays plant which contains heterologous DNA which is heritable. This also supports DeKalb's position that the claim language covers all subsequent generations and is not limited as proposed by Syngenta.8 For example, DeKalb points to portions of a prior Lundquist and Walters Patent application which specifically limited the generations covered as evidence that no such limitations exist in the present patent. Claim 1 of the Lundquist and Walters' '956 Patent clearly recites the R0 generation. Claim 1 of the '798 patent does not. Claim 5 of the '956 Patent clearly recites an R1 generation plant derived from the plant of Claim 1. Claim 4 of the patent at issue does not; it recites progeny derived from the transgenic plant of Claim 1. Claim 6 of the '956 Patent does not recite any particular generation. It says progeny derived from the progeny of Claim 5.

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IV. CONCLUSION

The Court concludes that the disputed terms have the following meaning:

1. "Fertile transgenic Zea mays plant" in claim 1 means a corn plant that is transgenic, because it includes DNA that was introduced into the plant or one of its ancestors through genetic engineering and fertile because it can pass that introduced DNA on to its offspring.

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4."Fibrous Absorbent Layer"

Claim 16 of the '693 patent refers to a fibrous absorbent layer. Claim 16 provides in part, "a foldable sheet having a water-vapor-impermeable polymeric layer disposed between a printable layer and a fibrous absorbent layer. . . ." Fort James suggests that this term has plain meaning to a POSITA and need not be interpreted. 48 Coating Excellence suggests the following: "a fibrous layer having a distinct sublayer of fibers bearing foraminous hydrophobic water-vapor permeable pellicle and a sublayer having highly absorbent material comprising an ionic complex of two essential ingredients: a water-soluble anionic polyelectrolyte, and a polyvalent metal cation."

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48 Plaintiffs' Final Proposed Claim Constructions [Dkt No. 175] at pp. 3-4.

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Coating Excellence, in short, asserts that the abstract and certain other references in the specification require the finding that each reference to absorbent layer in the claims of the '693 patent is a reference to an absorbent layer containing highly absorbent material. 49 Coating Excellence also asserts that the absorbent layer must be a "sublayer." In response, Fort James takes the view that, while certain embodiments encompass highly absorbent material in the form of the sublayer, claim 16 is not so limited and claim differentiation supports the point. 50

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49 Hearing Transcript at p. 127, lines 7-23.50 Hearing Transcript at p. 123, lines 6-16, p. 123, line 6 -- p. 124, line 9.

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Beginning with the claim language, the undersigned finds that the term "fibrous absorbent layer," as it appears in claim 16, has an ordinary meaning to a POSITA and requires no construction unless intrinsic evidence requires a contrary conclusion. 51 See Biotec, 249 F.3d at 1349.

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51 Defendants' Amended Claim Construction Statement [Dkt. No. 176] at Ex. A, p. 7 contains no reference to the file history or any extrinsic evidence; therefore, none has been considered.

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Coating Excellence correctly notes that the title of the patent refers to "Highly Absorbent Wrap Material" and that the abstract indicates that the "absorbent layer will include highly absorbent material." There also is at least one specification reference linking the invention to the highly absorbent material. (E.g., '693 patent, col. 6, lines 38-58.) However, these intrinsic record references do not end the analysis.

As noted above, the Background of the invention describes the invention without any mention of highly absorbent material. The sandwich wrap of the present invention provides greatly improved moisture control while decreasing adhesive tendencies between sandwich components and the absorbent inner layer by interposing a foraminous hydrophobic water-vapor-permeable pellicle on fibers positioned between the sandwich and the moisture-vapor-impermeable polymeric layer." (Id., col. 1, lines 60-66.) The specification then goes on to describe how, "In preferred embodiments, highly absorbent materials are included in at least a portion of the absorbent layer." (Id., col. 2, lines 3-5.) Similarly, at the beginning of the section entitled "Description of the Preferred Embodiments," the inventors first describe the invention in part by stating that it has a first absorbent layer bearing the pellicle. (Id., col. 4, lines 29-32.) Then, the inventors go on to describe a certain type of highly absorbent material that may be present in preferred embodiments. (Id. at col. 4, lines 34-37; see also col. 3, lines 1-17 ("In a preferred embodiment, at least a portion of the [absorbent material] layer will also include highly absorbent material. . . .").)

In summary, the undersigned finds that the intrinsic record as a whole makes clear that the highly absorbent material is just one aspect of the invention (i.e., part of the preferred embodiments) and should not be construed to be a limitation of claim 16. See Seachange Int'l, Inc. v. C-Cor Inc., 413 F.3d 1361, 1377 (Fed. Cir. 2005) (noting that it is improper to import limitations from a preferred embodiment into a claim); Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908 (Fed. Cir. 2004) ("The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives."). 52 Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1348 (Fed. Cir. 2004), relied upon by Coating Excellence, is distinguishable. In that case, the patent specification repeatedly referred to data transmission via telephone lines and no where referred to the use of a packet switching network. Consequently, in light of the specification as a whole, the court found that the communications must be via telephone. Id. Here, in contrast, the '693 patent plainly indicates that the use of highly absorbent materials is one embodiment of the invention, but not required for all embodiments of the invention. ('693 patent, col. 4, lines 34-37; col. 3, lines 1-25.)

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52 Fort James also notes that certain other claims specifically include a limitation describing one form of highly absorbent material, supporting the notion that the inventors understood how to draft such limitation when they so desired. For instance, claim 20, which is dependent upon claim 16, contains a limitation directed to the highly absorbent material described in the specification. Reading "highly absorbent material" into claim 16 would violate the theory of claim differentiation, which requires that an independent claim not be construed to contain a limitation added by a dependent claim. Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380-81 (Fed. Cir. 2006).

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The undersigned likewise rejects Coating Excellence's attempt to read a "sublayer" limitation into claim 16. Again, as was the case with the pellicle, there is support (e.g., Fig. 4) for the existence of sublayers of highly absorbent material and pellicle bearing fibers residing in separate sublayers in certain embodiments of the invention, but claim 16 is not so limited. The word "sublayer" does not appear in claim 16 and should not be read into claim 16.

Finally, Coating Excellence suggests that "fibrous absorbent layer" be construed to be a sublayer comprised of a certain type of highly absorbent material: "a water-soluble anionic polyelectrolyte, and a polyvalent metal cation." 53 While this may describe a specific embodiment of the invention, there is no intrinsic support for limiting claim 16 to such absorbent material.

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53 Defendants' Amended Claim Construction Statement [Dkt. No. 176] at Ex. A, p. 5.

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For the above reasons, the undersigned finds that no construction of the term "fibrous absorbent layer" is necessary or appropriate. See Biotec, 249 F.3d at 1349.
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II. Fibrous Vegetable Protein Additive

The '950 Patent's only independent claim, Claim 1, reads as follows:

A dry mix explosive composition including a bulking agent, comprising from 1-20% (by weight) of a fibrous vegetable protein additive, said bulking agent having a bulk density of from 0.1-0.6 grams per cubic centimeter and said explosive composition having a bulk density of from 0.5 to 1.1 grams per cubic centimeter.

'950 Patent, col. 4, Il. 46-52 (emphasis added).

The parties dispute: (1) whether the word "additive" refers to the "bulking agent" or to "fibrous vegetable protein;" (2) the meaning of the words "fibrous" "vegetable" "protein;" and (3) the meaning of "comprising from 1-20% (by weight)."

Dyno contends that the claim only requires that the bulking agent contains between 1 and 20% fibrous vegetable protein and does not require anything else. Dyno alleges this covers (1) a bulking agent made of one substance that inherently supplies the fibrous vegetable protein; and (2) a bulking agent made of more than one substance and in which one or more of these substances supplies the fibrous vegetable protein. In contrast, LDE contends that the term "fibrous protein additive" means a substance added to the bulking agent, that (1) must be of a substantially fibrous nature made up of slender, elongated, threadlike objects or structures that assist in holding together the component parts of the explosive composition; (2) must be a vegetable substance (as opposed to animal or mineral); and (3) must have a significant or meaningful amount of protein that is not incidental.

A. Whether the Word "Additive" Refers to the "Bulking Agent or to "Fibrous Vegetable Protein"

Dyno argues that because the "bulking agent" is always added to the composition, the "bulking agent" must be the "additive." Thus, Dyno claims that the "bulking agent" itself is the "additive" to the claimed "explosive composition." In contrast, LDE contends that the plain language of Claim 1 requires that the word "additive" refers to "fibrous vegetable protein" and it is added to the "bulking agent." The Court adopts in part LDE's interpretation and rejects Dyno's interpretation because LDE's interpretation: (1) comports with the plain language of Claim 1; (2) is consistent with the prosecution history; and (3) a contrary interpretation may render patent invalid.

1. Plain Language

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The Court's interpretation is supported by the principles of normal English language usage. When two adjectives precede a noun and the adjectives are not separated by a comma, the first adjective modifies the combined idea of the second adjective plus the noun. The Gregg Reference Manual P 169. Thus, the noun in the phrase "fibrous vegetable protein additive" is "additive." "Fibrous vegetable protein" are adjectives that describe what type of additive is required. See The Gregg Reference Manual P 169. Furthermore, "additive," used as a noun, is defined as "a substance added in small amounts to something else to improve, strengthen, or otherwise alter it." The American Heritage Dictionary of the English Language 15 (Def.'s Ex. E.) Thus, according to the ordinary meaning of the words and the patentee's choice of phrasing, Claim 1 requires the use of "an additive," described as fibrous vegetable protein in nature; that is "added . . . to something else," here, the bulking agent.

Moreover, Dyno's proposed interpretation is nonsensical and violates the plain meaning of the phrase. According to Dyno, the Court should ignore the term "additive" because it is duplicative and a superflous reference to the use of a "bulking agent" in the composition. Dyno asserts that because the bulking agent is always added to the composition, the "bulking agent" must be the additive. 5 Unfortunately, Dyno ignores the grammatical phrasing of the claim. In full context, the claim language provides "a dry mix explosive composition including a bulking agent, comprising from 1-20% (by weight) of a fibrous vegetable protein additive, said bulking agent having a [specified bulk density]." The phrase "comprising from 1-20% (by weight) of a fibrous vegetable protein additive" offset by commas, directly follows the term "bulking agent." Thus, it cannot refer to the dry mix composition; it clearly refers to the bulking agent.

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5 Dyno contends that the ordinary meaning of "bulking" is "to increase in size; expand; swell." (Pl.'s Ex. E at 275.) It further argues that the ordinary meaning of "agent" is "a natural force or object producing or used for obtaining specific results." (Pl.'s Ex. E at 28.) Dyno then concludes that the bulking agent, therefore is a material added to the explosive composition to produce the effect, or obtain the result, of increasing volume of the explosive composition by expansion or by swelling, as if by increasing pore spaces. (Pl.'s Ex. E at 1922) (defining "swell" to mean "to increase gradually in volume). Dyno asserts that the ordinary meaning of "additive" is "something that is added, as one substance to another, to alter or improve the general quality or to counteract undesirable properties." (Pl.'s Ex. E at 22-23.) Dyno then concludes that in the '950 patent, since the "bulking agent" unquestionably is a material that is "added" to an explosive composition to "bulk" or increase the volume of the explosive composition, that the bulking agent is the "additive" to the explosive composition. Dyno asserts that is logically follows that the word "additive" in the claim language references the bulking agent.

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Furthermore, defining "additive" as meaning "bulking agent" would render the term "additive" superfluous because claim 1 already requires a bulking agent. Claim 1 specifically states: "A dry mix explosive composition including a bulking agent." (emphasis added). According to Dyno's interpretation, Claim 1 would be read as: "a bulking agent, comprising from 1-20% of itself." The Court will not read the term "additive" out of the claim. See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582-83 (Fed. Cir. 1996) (recognizing that a court "must give meaning to all the words in [the] claims."). Dyno argues that the term "fibrous vegetable protein additive" is not an additive at all, but instead covers any bulking agent that is a "fibrous vegetable substance" with 1-20% content. The Court's role in a claim construction hearing is to interpret and construe the claim terms, not to re-write the claims. Construing claim 1 as advocated by Dyno Nobel, would require the Court to completely re-write the claims. The drafting of the phrase simply does not support Dyno's construction. If the patentee desired that the word additive refer to the addition of the bulking agent to the explosive composition, he could have drafted the claim to reflect that preference.

2. Prosecution History

Moreover, the prosecution history provides support for the Court's construction. The claim terms must mean something that places the claims outside the scope of the cited prior art, as the applicant argued to the PTO during prosecution. See, e.g., Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). LDE contends that Dyno's construction of this phrase brings the claims of the patent back within the scope of the prior art that led to the rejections by the PTO.

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a. Australian Prosecution History

The '950 patent claims priority based on two provisional patent applications filed in Australia. These applications issued as Australian Patent No. 598,130. The Australian patent, as originally filed, was rejected by the Examiner as overly broad. He stated:

The specification does not fully describe the invention because insufficient teaching as to the nature of the "vegetable protein" has been provided. The use of vegetable protein includes the use of virtually all plant matter. The preferred embodiment refers to legumes such as nuts and nut shells however these are known in the field of art. The description does not specifically define the types of protein which characterize the present invention and as a result a skilled addressee would be unable to gleen enough information from the specification in order to carry out the invention. Clarification of these matters is required."

* * *

However, it is noted that the use of vegetable matter in explosive compositions is well known in the field of art.

(Def.'s Ex. G at 01528-01529.)

After this rejection, the claims were amended to limit the invention to a bulking agent containing from 1 to 20% of a fibrous vegetable protein additive, with examples of this additive (nuts and nut shells) described in the specification. The patentees argued:

"Referring to item 1 of the official letter, we point out to the Examiner that the claims and statement of invention have been amended so that the vegetable matter referred to in the earlier specification and claims is now referred to as a fibrous vegetable protein additive which finds ample basis within the body of the specification. It is clear from the specifications and more particularly pages 8 and 9 thereof, that the fibrous vegetable protein additive can be any additive falling within that broad definition. . . . In particular, it is pointed out that the claims are now limited to a composition which includes a bulking agent, that bulking agent comprising from 1-20% (by weight) of a fibrous vegetable protein additive. Examples of that fibrous additive are given within the body of the specification and each statement is therefore clearly based on the disclosure.

(Def.'s Ex. G at 1526.)

b. U.S. Prosecution History

Similar to the process in Australia, the USPTO rejected the claims as originally filed because prior art already disclosed the use of bulking agents made from various sorts of vegetable protein matter, including nuts and nutshells. (10/28/88 Office Action, Def.'s Ex. B at 1403.) 6 Again, as in the Australian prosecution history, the patentee amended the claims and changed the phrase fibrous vegetable protein "content" to the phrase "fibrous vegetable protein additive." 7 The patentee argued that although prior art disclosed the use of vegetable matter (including ground nuts and grain hulls) as bulking agents, none of the prior art disclosed "the use of a fibrous vegetable protein matter as a bulking agent additive." (Def.'s Ex. B at 1431.) 8 The patentee, during the prosecution, claimed that the '950 patent included a bulking agent that must contain an additive, and the additive must be "fibrous, vegetable, and protein" in nature.

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6 The USPTO stated:

Claim 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103 as obvious over Yorke et al, Bampfield (I), (II) and Ciaramitaro et al.

Each of the references discloses explosive compositions containing vegetable matter such as nut hulls or shells. It would appear that the explosive products of the references would inherently possess applicants' desired properties for their composition or render applicants' composition obvious.

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(10/28/88 Office Action, Def.'s Ex. B at 1403.)

7 Specifically, dependent claim 4, which originally read, "said bulking agent comprises up to 5% (by weight) of said fibrous vegetable protein content" was amended to read "said bulking agent comprises up to 5% (by weight) of said fibrous vegetable protein additive." (4/28/89 Amendment, Def.'s Ex. B at 1426; 4/28/89 Amendment, Def.'s Ex. B at 1428.).

8 The patentee also stated: "The specification further emphasizes that the use of the fibrous vegetable protein matter in the bulking agent serves to assist in the holding together of the component parts of the composition." (Def.'s Ex. B at 1429-30.) He also stated: "While the Yorke patent refers to the use of fillers in the form of vegetable matter, such as ground nuts or grain hulls, . . . the Yorke disclosure fails to suggest in any way a specific bulking agent comprising from 1-20% by weight of a fibrous vegetable protein additive." (Def.'s Ex. B at 1431-32.)

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The Court finds pursuant to the amendment and the arguments presented by the patentee, the PTO issued the '950 Patent over the prior art references that previously disclosed bulking agents made up of vegetable protein matter, such as ground nuts, nut shells, and grain hulls. Thus, when faced with the Patent Examiner's rejection based on prior art that taught using nut shells as the bulking agent (which have a protein content in the 1-20% range), the applicant expressly amended the claims that used the phrase "fibrous vegetable protein content" to read "fibrous vegetable protein additive." (10/28/88 Office Action, Def.'s Ex. B at 1403, 1426, 1428.) The Court will not allow the patentee or subsequent patent owner to reclaim what was disclaimed or distinguished in the prosecution history.

3. Potential Invalidity

The Court is concerned that Dyno's interpretation of the patent will render the patent invalid because it would read on prior art. "[C]laims should be read in a way that avoids ensnaring prior art if it is possible to do so." Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1153 (Fed. Cir. 1997). As the Patent Examiner noted, the prior art already disclosed the use of ground nuts, nut shells, and grain hulls for use as bulking agents in explosive compositions. (10/28/88 Office Action at Def.'s Ex. at 1403; 4/28/89 Amendment at 1431-33.) Peanut shells are fibrous vegetable substances that contain approximately 8.5% protein content. '950 Patent, col. 4, Il. 22-27; (Helms Decl. P 4, Def.'s Ex. V.) Because Dyno argues that Claim 1 covers any bulking agent that is simply a "fibrous vegetable" substance with a protein content between 1-20%, the '950 patent would claim bulking agents (such as nut shells) that were previously disclosed in the art. According to the Patent Examiner, without the amendments, the patent could not be issued because it was either obvious or anticipated under 35 U.S.C. §§ 102 or 103 pursuant to the Yorke, Bampfield, and Ciaramitaro patents. (Def.'s Ex. Y.)
B. Construction of the Words "Fibrous," Vegetable," and "Protein"

Each of the words in questions has a plain meaning. Absent evidence in the patent that the patentee meant something other than the plain meaning, the ordinary meaning governs. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2002).

1. "Fibrous"

The parties dispute the ordinary meaning of the term. LDE contends that "fibrous" should be construed as "having, consisting of, or resembling fibers, which are slender, elongated structures; a filament or stand." The American Heritage Dictionary of the English Language 487 (10th ed.) (Def.'s Ex. E.) Dyno advocates that "fibrous" should be given a food like definition. Dyno asserts that because the claim also has the term "vegetable" in it, and that vegetable is a food, a food definition must be used. Thus, Dyno concludes that the "ordinary meaning" of fibrous vegetable protein is any protein from "the structural part of edible plants or plant products." The Court adopts LDE's construction because it comports with the purpose of the invention as set forth in the specification.

The Court finds support for its construction in the specification. The specification explains that the additive can be in the form of legumes, including nuts and nut shells, and preferably in the form of peanut shells or walnut shells. '950 Patent, col. 5, Il. 22-33. 9 The Specification also explains a problem associated with dry mix explosive compositions -- they can be blown away during mixing or when loading the composition into the blast hole. Col. 2, Il. 30-32; col. 3, Il. 41-44. The

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specification further explains that the "fibrous nature" of the additive is a critical aspect of the invention because it assists in holding together the other components of the dry composition. '950 Patent, col. 2, Il. 26-32; col. 3, Il. 41-44.

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9 Peanut shells are fibrous because they contain thread-like structures.

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The Court finds Dyno's position unpersuasive. The specification and prosecution history of the '950 Patent describe a structural benefit of the fibrous nature of the additive to the bulking agent. The '950 Patent specification emphasizes that the "fibrous nature" of the additive is critical because it is the "fibrous nature" that assists in holding together the component parts of the dry composition. '950 Patent, col. 2, Il. 26-32; col. 3, Il. 41-44 (stating that "the fibrous nature of such vegetable matter assists in holding together the component parts of the composition and contributes towards resisting segregation"). Dyno's interpretation of "fibrous" gives no meaning to the word.

2. "Vegetable"

LDE contends that "vegetable" should be construed to mean "of, pertaining to, or derived from a plant or plants. The American Heritage Dictionary of the English Language 1419 (10th ed.). In contrast, Dyno contends that "vegetable" means "any plant whose . . . parts are used for food." Webster's New Universal Unabridged Dictionary 2109 (1996). The Court finds that the patent gives no indication as to which construction is appropriate and both provided definitions appear to be consistent with the claims. Thus, the Court will adopt LDE's proposed construction that "vegetable" means "of, pertaining to, or derived from a plant or plants" because it encompasses both definitions provided. In addition, Dyno provides no justification in the specification for its more restrictive definition. See Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2002) ("If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings.").

3. "Protein"

Dyno did not object to LDE's proposed construction of the term. Thus, the Court construes "protein" as "any of a group of complex nitrogenous organic compounds . . . that contain amino acids as their basic structural units." The American Heritage Dictionary of the English Language 1051 (10th ed.).

However, LDE contends that the Court should add a limitation that requires that the additive have a non-incidental amount of the above discussed qualities. LDE argues the inherent concept of the additive "altering" the bulking agent plainly excludes items that have insignificant or incidental amounts of these qualities. Finding that there is no support in the patent claims and specifications for such a limitation, the Court refuses to engage in this type of interpretation.

C. The Meaning of "comprising from 1-20%"

LDE submits that "1-20%" refers to the amount of the additive, and Dyno argues that "1-20%" refers only to the amount of protein content. Based on a plain reading of the claim language and the above constructions, the Court finds that the "fibrous vegetable protein additive" must be 1-20% (by weight) of the bulking agent. 10

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10 The Court's interpretation is supported by the prosecution history. In the amendment, the applicant stated:

It is important in order for the desired results to be achieved so that the final explosive composition satisfies the objects of the present invention, relative to a dry mix explosive composition, that the bulking agent added comprise of from 1 to 20% by weight of the fibrous vegetable protein additive.

(4/28/89 Amendment, Def.'s Ex. B at 1430.)

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b. "filler"

MacDermid argues that the term "filler" should be defined as referring to: "An inert material consisting of fine particles. The filler may be colorless and transparent or have color and be nontransparent." (MacDermid Opening Br. at 40.) DuPont does not respond to MacDermid's proposed construction in its briefing. The Court, in the Preliminary Injunction Opinion, assumed "that DuPont accept[ed] MacDermid's proposed construction of those terms or phrases that DuPont did not address in its brief." (Prelim. Inj. Op. at 22 n.5.)

DuPont contended at the Markman hearing that there is no need for the term to be construed because it (1) does not assert the specific Markush member containing this term, and (2) would be readily understood by a person of ordinaryskill in the art. (Tr. at 47-50.) It further argues that MacDermid's proposed construction improperly reads examples from the specification into the claim. (Id. at 48.) But MacDermid contends that its proposed construction is supported by: (1) Hawley's definition of the term as an inert mineral powder used in plastic products and rubber mix; (2) the specification's statement that the filler is a fine powder that may have color or be colorless; and (3) the specification's subsequent statement that a colorless particulate matter forms a transparent layer while a particulate matter having color forms a nontransparent layer. (MacDermid Opening Br. at 40-41; Tr. at 175-77.) MacDermid further contends that the term must be construed because invalidity of one member of a Markush group invalidates the entire group. (Tr. at 175-77.)

The Court finds that the term "filler" need not be construed, at least at this point. At the very least, such a term would be readily understood by a person of ordinary skill. Also, the parties evidently agree that the term encompasses inert materials, with DuPont noting that the various "filler" examples provided in the specification are all inert materials. (Tr.at 48.)
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2. Film

A film is a thin layer of material. A film may have voids, cracks, or other discontinuities.
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1. "Filtering"

HISI contends that "filtering" includes "not just the use of filters, but also settling of taste causing components by cooling and/or storage over time, or aging of the smoke so as to allow time for the taste causing components to settle or weaken in strength." (HISI Brief 19.) TPI argues, however, that the specifications of the Kowalski patent distinguish "filtering" from cooling and settling, and so "filtering," as used in Claim 67, cannot be read to encompass these other terms. TPI points to the statement in the specifications that "[c]omplete super purification of smoke can be accomplished using one method, or a combination of methods, in current practice, including filtering, separating, distilling, scrubbing, cooling, freezing, inertial impact, centrifugal force, or settling." (Kowalski Patent, Col. 12, at 13-17.) TPI argues that because "filtering," "cooling," and "settling" are each listed as distinct means of achieving "super-purification," the word "filtering" cannot be read to include cooling and settling when used in Claim 67.

In response, HISI points to other places in the specifications where cooling and settling are included within the definition of filtering. These include the Kowalski Patent's discussion of prior art techniques that include "cooling" and "settling" as types of "filtering methods," 3 (Kowalski Patent, Col. 8, at 24-26), as well as its explanation that "allowing the phenols, and any other remaining carcinogens, in the smoke to settle, or 'age' . . . is the final backup filtering step in the process," (Kowalski Patent, Col. 14, at 19-23). Moreover, the Kowalski Patent's preferred embodiment discloses a process in which the smoke is

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"partially filtered by the ice" through cooling and condensation (Kowalski Patent, Col. 18, at 33-34), and is then eventually put through a final "settling step of aging the smoke" (Kowalski Patent, Col. 19, at 43).

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3 This discussion, in its entirety, reads as follows.

The amounts of tar, soot, ash, char and other microscopic particulates have been filtered and minimized by many methods in current practice including tar settling systems, baffling systems, and washing systems in the line form the smoke generator to the smoking chamber. In addition, cooling and storage reduces the concentrations of phenolic particulate through settling. Some of these filtering methods . . . .

(Kowalski Patent, Col. 8, at 19-26 (emphasis added).)

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There is little doubt that the Kowalski Patent discloses settling and cooling processes to remove certain particles from smoke; the issue is whether the word "filtering," as used in Claim 67, encompasses these processes. The Court finds that it does. While the specifications do occasionally use "filtering" in its narrow sense, they more often use it in a broader sense that does include both cooling and settling processes. This is particularly so when the specifications are read as a whole, in context, from beginning to end. The overview of different filtering processes discussed in the "Background Art" section of the specifications recognizes cooling and settling as two types of filtering. And while filtering is initially used in its narrow sense early in the "Summary of the Invention" section, the later parts of the summary make it clear that "filtering" is a much broader term. (See Kowalski Patent, Col. 14, at 19-23.) Thus, viewed in their entirety, the Kowalski specifications demonstrate that "filtering" is a broadly-defined process including not only passing a gas or liquid through a porous material, but also the cooling and settling of the smoke.
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Theparties agree that a "fire" is "the burning of combustible material." Defendants attempt to add an additional limitation that a fire, as used in the claims, is also to be defined by a borehole temperature reading of greater than 90 degrees Fahrenheit. Defendants find their 90-degree limitation from the specification's repeated statements that a fire is considered to be extinguished when the surface temperature is reduced to 90 degrees or below. See '336 patent, 5:52-57; 6:30-35; 9:42-46; 10:53-59; 9:65-10:1; 11:1-4. While that may be true, it tells a person of ordinary skill in the art what it means to extinguish a fire, not what it means for there to be a fire. For example, if a borehole temperature read 95 degrees, but there has never been any burning of combustible material, according to Defendants' proposal, the temperature reading alone would indicate that there was a fire even in the absence of burning. Common sense tells the Court that Defendant's proposed limitation cannot be part of the correct construction. The Court construes "fire" to mean "burning of combustible material."
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Plaintiff has asserted claims 1, 17, 18, and 25 of this patent. n21 Claim 1 provides:
A method for detecting a polynucleotide sequence which comprises:

fixing said polynucleotide sequence to a solid support which comprises or is contained within a transparent or translucent, non-porous system, such that a single-strand of the polynucleotide is capable of hybridizing to complementary nucleic acid sequences;

forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, said probe having attached thereto a chemical label further comprising a signalling moiety capable of generating a soluble signal; and

generating and detecting said soluble signal.

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n21 Claims 17, 18, and 25 require no claim constructions independent of that given to claim 1.

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In brief, the technology at issue in this patent involves the determination of whether substances, described as "analytes," are present in biological or non-biological samples, such as "blood[,] urine, feces, saliva, pus, semen, serum, other tissue samples, fermentation broths, culture media, and the like." '373 patent col. 5, 11. 22-27. Detection of these substances is accomplished by "denaturing" strands of DNA or RNA found in the sample, such that these normally two-stranded molecules are separated into single-stranded form. See id. at col. 5, 11. 37-41. The single-stranded DNA or RNA of the sample is then attached to a solid surface, and a probe, which is single-stranded DNA or RNA sequence complementary to the analyte, is introduced. If the analyte is present in the sample, then the probe will bind, or hybridize, to the sample. Detection is accomplished by washing away unhybridized probes and then searching for the presence of the labeled probe using a variety of techniques. See id. at col. 5, ll. 58-68, col. 6, ll. 1-8.

All parties agree that it is possible for the test just described to be conducted by attaching unlabeled single-stranded probes to the solid surface and then introducing labeled strands of the sample. If the sample contains DNA or RNA complementary to the probe (that is, if the analyte is present in the sample), then hybridization will occur and the same steps will be taken to detect the presence of the label. See, e.g., Hr'g Tr. at 308, 520-21.

The question before the Court is whether claim 1 of the '373 patent contemplates conducting the test using the latter process described, i.e., attaching the probe to the solid surface. This Court finds that it does not.

The language of claim 1 indicates that "a polynucleotide sequence" is fixed to a "solid support" and "hybridized to a polynucleotide or oligonucleotide probe." Although plaintiff is correct that this language is theoretically broad enough to encompass conducting the test in either of the above fashions, n22 the patent specification contains definitions which necessarily limit the claim to the method whereby the sample, and not the analyte's complementary sequence, is fixed to the solid support. The patent defines "probe" as "[a] labelled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide sequence of a particular analyte and which hybridizes to said analyte sequence." '373 patent col. 1, ll. 42-45 (emphasis added). "Analyte," which is defined as "[a] substance or substances, either alone or in admixtures, whose presence is to be detected," id. at col. 1, ll. 28-30, is described as possibly being present in "any biological or non-biological sample" including blood, urine, and saliva, id. at col. 5, ll. 22-26. It is thus clear from these descriptions that the "probe" in claim 1 cannot be the sample, but, rather, is the sequence complementary to the analyte. In addition, because the patent requires that the probe be labeled, it would be impossible to conduct this test with the probe fixed to the solid support, since to do so would result in false positives. See, e.g., Hr'g Tr. at 520, 539-40. Therefore, this Court finds that claim 1 of the '373 patent requires that the sample, which is the substance within which one is looking for the presence of the analyte, must be fixed to the solid support, and that the probe, which is a labeled sequence complementary to the analyte, is not so fixed. n23

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n22 The reason for this is, quite simply, that the labeled sample could be thought of as acting as a "probe" when the sequence complementary to the analyte is fixed to the solid support. In effect, the labeled sample would look for its complementary sequence and hybridization (and later detection) would reveal the analyte's presence.

n23 Plaintiff's argument that example 5 compels a contrary construction is unpersuasive. Although that example indicates that "[t]he advantages of this invention are also obtainable when the probe is immobilized on a non-porous plastic surface," as explained above, the language of the patent places that setup for the test outside the scope of claim 1.

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Buszard argues that the Eling reference shows only a rigid polyurethane foam which when mechanically crushed loses its rigidity because it is in small particles. Buszard states that the Eling rigid foam product is chemically different from a flexible polyurethane foam that is directly produced by polymerization, without crushing, and that this difference is readily understood by a person of ordinary skill in the field of polyurethane foams. Thus Buszard states that the flexible foam mixture required by his claims is different in kind from the rigid foam mixture described by Eling, whether or not Eling's product is subsequently crushed into small particles.

The PTO states that Buszard's claims, when given their broadest interpretation, read on the Eling product and thus are anticipated by Eling. Buszard states that this interpretation is devoid of support, even when viewed in accordance with the protocols of patent examination. During examination, the patent application claims may be given their broadest interpretation consistent with the specification, in order to facilitate sharpening and clarifying the claims at the application stage. In re Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984) ("The PTO broadly interprets claims during examination of a patent application since the applicant may 'amend his claims to obtain protection commensurate with his actual contribution to the art.'") (citation omitted). Thus the patent examiner and the applicant, in the give and take of rejection and response, work toward defining the metes and bounds of the invention to be patented. See In re Zletz, 893 F.2d 319, 321-22 (Fed. Cir. 1989) (the broadest reasonable construction of claims during examination serves to target ambiguities in claims at the time when the claims are readily amended). As explained in Zletz: "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." Id. at 322. Buszard argues that the Board's construction of the claims to read on and thus be anticipated by Eling's crushed solid foam is not reasonable.

The Board interpreted the claim term "flexible polyurethane foam reaction mixture" to mean "any reaction mixture which produces, at least ultimately, a flexible polyurethane foam." Buszard states that persons experienced in the field of polyurethane foams know that a flexible polyurethane foam reaction mixture is different from a rigid polyurethane foam reaction mixture, and that this process limitation cannot be found in Eling, no matter how broadly that reference is read. The PTO Solicitor agreed, at the argument of this appeal, that the flexibility or rigidity of foamed polyurethane depends on the composition of the reaction mixture, which controls the degree of chemical cross-linking and thus the flexibility of the polymer. The Solicitor agreed that a person of ordinary skill in the field of polyurethane foams knows that a flexible foam and a rigid foam have different chemical structures and are produced from different chemical reactants. Nonetheless, the Solicitor argued that the rejection should be sustained simply because the examiner is entitled to give claims their broadest reasonable interpretation during examination. Buszard responded that the examiner's interpretation is not reasonable, as a matter of well-known chemistry, for flexible foam reaction mixtures are different from rigid foam reaction mixtures, and one does not encompass the other.

The Solicitor proposed at oral argument that when a rigid foam is mechanically crushed, the chemical bonds are broken and the product is the same as the flexible product of a flexible foam reaction mixture. There was no rejection on this ground, there is no evidence or argument to this effect in the record, this theory was not mentioned by any examiner or in the Board's opinion, and it appears to be contrary to science. This theory was proposed without support or citation, and without opportunity for Buszard to refute it. It is not sufficiently creditable to warrant further consideration.

Buszard's specification and claims specifically state the requirement of a flexible polyurethane foam reaction mixture. No matter how broadly "flexible foam reaction mixture" is construed, it is not a rigid foam reaction mixture. The Eling reference describes only a rigid foam reaction mixture that produces a rigid product. Only by mechanically crushing the rigid product into small particles is it rendered flexible, as a rock can be mechanically crushed to produce particles of sand. This description cannot reasonably be construed to describe, and thus to "anticipate," the flexible foam product of a flexible foam reaction mixture. We agree with Buszard that it is not a reasonable claim interpretation to equate "flexible" with "rigid," or to equate a crushed rigid polyurethane foam with a flexible polyurethane foam.

The decision of the Board is reversed, and the case is remanded for appropriate further proceedings.

REVERSED and REMANDED
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Because the Board is entitled to give claim language its broadest reasonable interpretation, our precedent requires that our review of the Board's interpretation be limited to determining whether it was reasonable. In re Crish, 393 F.3d 1253, 1256 (Fed. Cir. 2004); In re Bigio, 381 F.3d 1320, 1324 (Fed. Cir. 2004); In re Hyatt, 211 F.3d 1367, 1372-73 (Fed. Cir. 2000); Morris, 127 F.3d at 1055. Although the majority opinion pays lip service to this precedent, it does not apply it in this case.

II

In this case, the only disputed issue is whether the Eling reference discloses a "flexible polyurethane foam reaction mixture" as required by Buszard's pending claims. The Board construed this term to include "any reaction mixture which produces, at least ultimately, a flexible polyurethane foam." In re Buszard, No. 2006-1120, 2006 WL 1665669, at *2 (Bd. Pat. App. & Int. Apr. 20, 2006). This construction encompasses mixtures that produce polyurethane foams that are made flexible upon crushing, such as the mixture disclosed in the Eling reference. Accordingly, the Board concluded that Buszard's representative claims were anticipated by the Eling reference. Id.

Because the Board must give claim language its broadest reasonable interpretation, I would affirm the Board's construction of "flexible polyurethane foam reaction mixture." Of course, had Buszard's specification provided a definition of the term "flexible polyurethane foam reaction mixture," the Board would have been required to give that term the definition recited in the specification. See Morris, 127 F.3d at 1054. But Buszard's specification does not define this term. And the Board's interpretation, while broad, is not unreasonable. As explained by the Board, a broad construction is consistent with Buszard's specification:

For example, the specification discloses in the last full sentence on page 7 that "[t]he flexible polyurethane foam compositions . . . according to the present invention include all well known, industrial compositions" (emphasis added). Use of the term "all" supports the proposition that the aforementioned industrial compositions include the compositions of Eling. Additionally, in the sentence bridging pages 7 and 8 of the specification, [Buszard] disclose[s] that "flexible polyurethane foam compositions can be made according to the present invention by reacting an isocyanate with a polyol in the presence of a foam-forming agent and a blend of tetra-halophthalate esters and phosphorus-containing flame retardant additives." Because these enumerated ingredients correspond fully to those taught by Eling, the claim interpretation [of "flexible polyurethane foam reaction mixture"] discussed earlier is consistent with this disclosure of [Buszard's] specification.

Buszard, 2006 WL 1665669, at *2.

On appeal, Buszard alleges--and the majority appears to agree--that the term "flexible polyurethane foam reaction mixture" has a specific meaning to one of ordinary skill in the art. But neither Buszard's specification nor his briefs provide a definition. Indeed, he boldly asserts in his reply brief that he "suffer[s] no duty to define an art recognized term."

I disagree. For one thing, "[i]t is the applicant['s] burden to precisely define the invention, not the PTO's." Morris, 127 F.3d at 1056; see also 35 U.S.C. § 112 P 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."). Moreover, although Buszard asserts that the term "flexible polyurethane foam reaction mixture" has a well-defined meaning to someone skilled in the art, not only has Buszard failed to provide any evidence to back up this assertion, his briefs also fail to tell us what that meaning is. The only enlightenment Buszard provides regarding the meaning of "flexible polyurethane foam reaction mixture" is a single page from the Kirk-Othmer Encyclopedia of Chemical Technology, which generally describes the differences between "flexible foam" and "rigid foam." Nowhere in the record, however, is there any evidence regarding how a person of ordinary skill in the art would interpret the phrase "flexible polyurethane foam reaction mixture."

In oral argument, Buszard, for the first time, argued that the term "flexible polyurethane foam reaction mixture" should be interpreted to mean a mixture of ingredients that produces flexible foam upon polymerization, without a crushing step. Yet Buszard's claims do not specifically exclude a crushing step. 1 Nor are his claims limited to chemical reactants that would produce flexible foam without a crushing step.

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1 Indeed, as the Board noted, "an artisan would consider the flexible polyurethane foam disclosed by [Buszard] as resulting from certain steps (e.g., adding, mixing, heating, etc.), and [Buszard] point[s] to nothing in [his] claims which would have excluded from these steps the crushing step of Eling." Buszard, 2006 WL 1665669, at * 2.

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Buszard nevertheless urges us to engage in the same claim construction process that courts employ in an infringement suit. According to Buszard, we should interpret the disputed claim term narrowly in light of his specification, which describes mixtures of ingredients that produce flexible foam without a crushing step. Buszard also points out that the flexible foams described in his specification are consistent with the general description of "flexible foam" in the Kirk-Othmer Encyclopedia of Chemical Technology.

But whether Buszard can provide descriptions of flexible foam that he believes are consistent with his desired interpretation is beside the point. "Absent an express definition in [his] specification, the fact that [Buszard] can point to definitions or usages that conform to [his] interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation." Morris, 127 F.3d at 1056. And in this case, the Board identified passages in Buszard's specification that support a broad interpretation. I would, therefore, affirm.

III

The majority concludes that Buszard's claims are not anticipated because flexible foam made from a mixture of ingredients that produces flexible foam upon polymerization (i.e., without a crushing step) is different from flexible foam made by first producing rigid foam and then crushing it. That may be true, 2 but it is irrelevant. The relevant question is whether Buszard's claim language can reasonably be interpreted to include the mixture disclosed in the Eling reference, which is capable of producing a flexible polyurethane foam. It can.

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2 It is noteworthy that, before the Board, Buszard "[did] not even present argument, much less evidence," that his flexible foam product differed from the flexible foam product disclosed in the Eling reference. Buszard, 2006 WL 1665669, at *1.

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Because a patent has not yet issued, Buszard has the ability to correct any ambiguities in his claim language. If Buszard seeks a specific claim interpretation, he should amend his claim so it conveys his intended meaning.
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flocculated suspension

The parties and the Court agree that the term should be construed as "the agglomeration in water of a solid with a chemical coagulant and/or flocculent."
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The parties contend for different meanings of the term "stable flocculated suspension" and other terms as those terms appear in claims 19 and 41 of the 318 patent and as they appear in claim 1 of the '320 patent. In particular:

1. Roxane contends that in all claims "flocculated suspension" means "a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with scaffold-like structure, and not a solid cake."

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Par contends that a "stable flocculated suspension" means "a suspension that resists caking and is redispersable after settling, wherein individual insoluble particles form open network aggregates. Stable flocculated suspensions are not limited to suspensions that exhibit the stability of commercially viable suspensions, such as those disclosed as preferred embodiments of the '318 and '320 patents."

2. Roxane contends that in all claims the term "stable," which modifies the phrase "flocculated suspension," means "the flocculated suspension, upon sedimentation after storage at 40 [degrees] c and 75% relative humidity for a period of three months, can be shaken to reform the original, uniformly dispersed, flocculated suspension."

Par contends that the claims contain no such temperature, humidity and time limitations and relies on its definition of "stable flocculated suspension."

3. Roxane contends that in claims 19 and 41 of the '318 patent, the phrase "an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising . . .(b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) a surfactant" means: "the surfactant and component (b) must each be present in sufficient quantity to form a stable flocculated suspension."

Par asserts that claims 19 and 41 have no such function or quantity limitation.

4. Roxane contends that the comparable language in claim 1 of the '320 patent means "component (a) [the wetting agents] and the surfactant must each be present in sufficient quantity to form a stable flocculated suspension."

Par asserts that claim 1 of the '320 patent, like claims 19 and 41 of the '318 patent, does not have such function or quantity limitation.

5. Roxane contends that in claim 1 of the '320 patent, the claim limitation "forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant ... ; and combining the solution with megestrol acetate" means "components (a) and the surfactant must be added to the water before the addition of megestrol acetate."

Par contends that, properly interpreted, the plain language of claim 1 of the '320 patent contains no requirement that component (a) and the surfactant be added to the water before the addition of megestrol acetate.

II. Discussion

A. Legal Standards: In the recent case of Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit articulated at some length general principles of claim construction. Under Markman, of course, claim construction presents a question of law to be resolved by the court. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips, 415 F.3d at 1312. Further, "the words of a claim 'are generally given their ordinary and customary meaning.'" and "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. The court "'cannot look at the ordinary meaning of the term ... in a vacuum. Rather, [it] must look at the ordinary meaning in the context of the written description and the prosecution history.'" Id.

The Court noted that "[b]ecause the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.' Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" Id. at 1314 (citations omitted).

By way of further guidance, the Court suggested that "[o]ther claims of the patent in question, both asserted and unasserted,

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can also be valuable sources of enlightenment as to the meaning of a claim term. Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claims." Id. at 1314-15 (citations omitted).

Referring specifically to the specification, the Court noted that "the specification 'is always highly relevant to the claims construction analysis. Usually, it is dispositive; it is the best single guide to the meaning of a disputed term'... 'The specification is, thus, the primary basis for construing claims.' On numerous occasions since then, we have reaffirmed that point, stating that 'the best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." Id. at 1315 (citations omitted). Despite the importance of the specification the Court referred to Texas Digital Systems, Inc., v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002), which noted "'one of the cardinal sins of patent law - reading a limitation from the written description into the claims.'" Id. at 1319.

Referring to the prosecution history, the Court stated that "[i]n addition to consulting the specification, we have held that a court should also consider the patent's prosecution history, if it is in evidence.' ... Furthermore, like the specification, the prosecution history was created by the patentees in attempting to explain and obtain the patent. Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of their negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id. at 1317 (citations omitted).

The Federal Circuit has "also authorized district courts to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.' However, while extrinsic evidence 'can shed useful light on the relevant art,' we have explained that it is 'less significant than the intrinsic record in determining the legally operative meaning of claim language.' Within the class of extrinsic evidence, the court has observed that dictionaries and treaties can be useful in claim construction. We have especially noted the help that technical dictionaries may provide to a court 'to better understand the underlying technology' and the way in which one of skill in the art might use the claim terms. Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." Id. at 1317-18 (citations omitted).

As a cautionary note, the Federal Circuit stated that "[w]e have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms. ... In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of the patent claim scope unless considered in the context of the intrinsic evidence. " Id. at 1318-19.

As the Court explained, "[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Id. at 1324.

With these principles in mind the court will attempt to resolve the parties' disputes about the meaning of the claim language.

B. Stable Flocculated Suspension: Putting aside for the moment the meaning that Roxane attributes to "stable," the meaning of "flocculated suspension" will be addressed. Each of independent claims 19 and 41 of the '318 patent and independent claim 1 of the '320 patent includes that term. The parties agree, and the patent states, that a suspension is made up of a particulate matter suspended uniformly in a medium but not soluble in it ('318 patent, col 3, lines 36-37; '320 patent, col 3 lines 56-57). Suspensions are important when formulating drugs that are insoluble in conventional solvents such as water. When in suspension the drug remains dispersed in solid form in the solvent. The problem, such as that addressed in the patents in issue, is to prevent the drug particles when they settle from forming a hard cake that cannot be redispersed.

The patents at issue solve this problem with respect to megestrol in the following manner:
Individual solute molecules do not bond tightly to form a cake in a flocculated suspension due to the fact that they form an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely. Flocculated suspensions have a high sedimentation height, due to the natural tendency for

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an open network aggregate to not form a cake. The resulting sediment is loosely packed and possesses a scaffold-like structure. Particles do not bond tightly to each other and a hard, dense cake does not form. Therefore, the sediment is easy to redisperse, so as to reform the original suspension. These properties make the flocculated suspension very desirable, particularly for liquid pharmaceutical formulations.

('318 patent, col. 3, 1. 37-51; '320 patent, col 3, 1. 56 to col. 4, 1.4).

It is Roxane's contention that a flocculated suspension as used in the claims includes only a particular type of suspension of uniformly dispersed solid matter, namely, one in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network, over time, forming a loosely packed sediment with a scaffold-like structure, and not a solid cake.

Par contends that Roxane's proposal that flocculation necessarily requires that the open network aggregate over time, forms a loosely packed sediment finds no supports in the claims nor does Roxane's proposed requirement that formation of a sediment be a necessary characteristic of flocculation.

Stating the issue in practical terms, Roxane contends that flocculated suspension, as defined in the claims, does not extend to other types of pharmaceutical suspensions, in particular a structured vehicle, which avoids formation of hard cake. According to Roxane, the pertinent patent claims describe a flocculated suspension as one which results in a loosely packed sediment with a scaffold-like structure, while a structured vehicle involves a stable suspension in which the suspended particles are in a state of more or less permanent suspension, never forming a sediment that is re-flocculated by vigorous shaking.

To resolve this issue it is useful to examine the claims and specification in the context of the pharmaceutical art in which the controversy arises. Both parties refer to, and rely on, Robert A. Nash, Pharmaceutical Suspensions, in Pharmaceutical Dosage Forms: Dispense Systems Vol 1 and Vol 2 (Herman A. Lieberman, et al., eds 1996). Nash writes, "Flocculation refers to the formation of a loose aggregation of discrete particles held together in a networklike structure ... The floccule referred to as a 'stable floc' usually contains varying amounts of entrapped liquid medium or vehicle within the networklike structures." (Nash Vol 2 p. 18).

Nash cites the chief advantages of a stable floc as "1. [t]he aggregates tend to break up easily under the application of small amounts of shear stress, such as gentle agitation of a bottle or vial ... Flocculation, therefore, imparts a structure to the suspension with virtually no increase in viscosity." "2. [i]n contrast to peptized or deflocculated systems, the stable floc will settle rapidly, usually to a high sediment volume, and may be easily resuspended even after standing for prolonged periods of storage..." (Nash Vol. 2 p. 19).

Nash notes that there are several methods of producing flocculated pharmaceutical suspensions. He refers to one of these as "controlled flocculation procedures" (Nash Vol 2, p. 20-21). These all appear to contemplate the appearance of a sediment and the avoidance of caking.

Distinct from these methods is the "structured vehicle" method which Nash describes as follows:
The final approach to the preparation of a stable suspension is based on the concept of the "structured vehicle," in which the viscosity of the preparation, under static conditions of very low shear on storage, approaches infinity. The vehicle is said to behave like a "false body" which is able to maintain the suspended particle in a state of more or less permanent suspension.

Structured vehicles are not normally considered for the preparation of parenteral suspensions: because of their high viscosity, such systems lack sufficient syringeability for ease of use.

Nash, Vol 2 p. 22.

There is a discussion of both flocculation and methods of achieving flocculation in Swarbrick, J., Coarse Dispersions in Remington: The Science and Practice of Pharmacy, 19th Ed. 1995 Vol. 1. He first notes that "[t]he pharmaceutical formulator is concerned primarily with producing a smooth, uniform, easily flowing (pouring or spreading) suspension or emulsion in which dispersion of particles can be effected with minimum expenditure of energy." Id. at 278. Further, "[a] pharmaceutical suspension may be defined as a coarse dispersion containing finely divided insoluble material suspended in

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a liquid medium." Id. He added:
There are certain criteria that a well-formulated suspension should meet. The dispersed particles should be of such a size that they do not settle rapidly in the container. However, in the event that sedimentation does occur, the sediment must not form a hard cake. Rather, it should be capable of redispersion with a minimum of effort on the part of the patient. Finally, the product should be easy to pour, have a pleasant taste and be resistant to microbial attack. The three major concerns associated with suspensions are (1) ensuring adequate dispersion of the particles in the vehicle, (2) minimizing settling of the dispersed particles and (3) preventing caking of these particles should a sediment form. Much of the following discussion will deal with the factors that influence these processes and the ways in which they can be minimized.

Id. at 279

Swarbrick noted that, although some workers in the field use "flocculation" differently, in his article "the term flocculation is used for all aggregation processes irrespective of mechanism." Id. He further noted that the "formulation of a suspension possessing optimal stability depends on whether the particles in suspension are to be flocculated or to remain deflocculated." He described three methods of obtaining a suspension of optimal stability - controlled flocculation as a means of preventing cake formation upon sedimentation, structured vehicles whereby flocculated particles are supported in a structured vehicle and a combination of those two methods.

Patel, N. et al., Pharmaceutical Suspensions, in THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY, 3rd Ed., 1986 (Lachman, L. et al. Eds) at 481-484 states:

Although there have been several attempts in the literature to clarify the imprecise terminology used to describe aggregation phenomena, the problem of definition is formidable. The terms used in the colloid science and pharmaceutical science do not coincide, and to make matters worse, individual workers tend to use the terms "flocculation," "coagulation," and "aggregation" interchangeably. Regardless of the mechanism of aggregation, it is convenient to classify the end result of the aggregation of suspended particles on the basis of the morphological characteristics of the aggregate.

Note first the open network aggregate or floccule. This aggregate is characterized by a fibrous, fluffy, open network of aggregated particles. Id. at 482-483.

Thus a review of the literature suggests that "flocculation" per se had a plain and ordinary meaning at the time of Par's invention, that is, loose or open aggregations of particles regardless of the mechanism that formed the aggregation. The issue, therefore, is whether the invention claimed in the '318 and '320 patents is limited to a particular method of achieving a stable flocculated suspension and to the product of such a method.

Roxane would define "stable" separately from "flocculated suspension". Specifically, a "stable" suspension is that kind of a suspension that can be shaken to reform the original, uniformly dispersed flocculated suspension, after storage at 40 [degrees] and 75% relative humidity for a period of three months. Roxane derives this limitation from Example 4 in the common specification, entitled "Suspension Stability."
The tendency of each suspension, prepared according to Example 1-3, to flocculate was assessed as follows. Each suspension is allowed to settle in a controlled environment of 40 degree c, and 75% relative humidity for a period of 3 months. Following that, each of the sedimented suspensions was shaken and easily redispersed reforming the original suspension.

('318 patent, col. 7, lines 29-38; '320 patent, col. 8, lines 9-19).

Further, Roxane finds support for its definition of "stable" in the prosecution history of the patents. n1 During the prosecution of the '241 application, which is the grandparent of the application that issued as the '318 patent and the great grandparent of the application that issued as the '320 patent, in response to a rejection of all pending claims under 35 U.S.C. § 112, the inventors stated:

The Examiner rejected claims 1-22 under 35 § 112, second paragraph, allegedly, because the claims comprise formulas whose stability is not of a definite range.

In response, applicants have herein above amended claim 1 to indicate that a stable flocculated suspension in water is a

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suspension capable of being redispersed after being allowed to settle at 40 [degrees] c and 75% relative humidity for a period of three months. Accordingly, the Examiner is kindly requested to withdraw this rejection.

(Page 3 of September 29, 1999 Amendment in '241 application). Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004) ("[T]he prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application").

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N1 The '318 patent issued on July 15, 2003 from a patent application filed in the U.S. Patent and Trademark Office ("PTO") on January 9, 2001. The '320 patent issued on July 15, 2003 from a patent application filed in the PTO on April 30, 2002. Both patents are titled "Flocculated Suspension of Megestrol Acetate" and both patents have the same specification. The '318 patent claims stable flocculated suspensions of megestrol acetate, and the '320 patent claims a method of making such compositions.

The series of patent applications which resulted in issuance of the '318 patent is described on the first page of the patent. It shows that the '318 patent issued from patent application Serial No. ("S/N") 09/757,261 filed on January 9, 2001 ("the '261 application"), which was a "continuation" of an earlier application, S/N 09/416,841, filed April 20, 1998 ("the '241 Application"). As is evident from the first page of the '320 patent , the sequence of applications which led to issuance of the '320 patent is the same, except that it issued from S/N 10/136,823 ("the '823 Application"), filed April 30, 2002, which was a "division" of the '261 Application.

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Roxane argues that having thus defined stability, Par cannot assert a different meaning for that term in the suit patents, and that accordingly, the only way to understand the term "stable" as used in the claims of the suit patents is as described by the inventors, namely, that following sedimentation upon storage at 40 degree [degrees] c and 75% relative humidity for a period of three months, the sedimented suspension can be shaken to reform the original, uniformly dispersed suspension.

Roxane's attempt to narrow the meaning of stable flocculated suspension by attributing a special limitation to the word "stable" is not supported by the language of the claim or the intrinsic evidence. Claims 19 and 41 of the '318 patent and claim 1 of the '320 patent do not include the degree [degrees] c and 75% relative humidity limitation. Despite the fact that Example 4 (with its reference to Examples 1-3) refers to a specific controlled environment, the balance of Example 4 makes clear that the claims are not limited to the controlled environment used in the Examples: "The invention has been described in terms of preferred embodiments thereof, but is more broadly applicable as will be understood by those skilled in the art. The scope of the invention is therefore limited only by the following claims." ('318 patent, col. 7, 11 39-42; '320 patent, col. 8, 11 21-24).

The prosecution history does not support Roxane's position. Although claims in the '065 "grandfather" patent were narrowed to recite the 40 degree [degrees] c and 75% relative humidity limitations, in the ongoing negotiations between the PTO and Par's inventors the inventors broadened the claims in the '318 and '320 patents to include both stable flocculated suspensions with the 40 degree [degrees] c and 75% relative humidity limitations ('318 patent, claims 36-40 and 54-58) and stable flocculated suspensions without that limitation ('318 patent, claims 19 and 41). The examiner allowed these broader claims. "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1314-15 (citations omitted).

Neither the language of the claims, nor the specification nor the prosecution history support Roxane's contention that the use of the term "stable" in "stable flocculated suspension" incorporates into the respective claims a limitation that flocculation must occur after storage at 40 degree [degrees] c and 75% humidity for a period of three months.

Probably the most critical interpretive question is whether "stable flocculated suspension" means, as Par contends "a suspension that resists caking and is reversible after settling, wherein individual insoluble particles form open network aggregates. Stable flocculated suspensions are not limited to suspensions that exhibit the stability of commercially viable suspensions, such as those disclosed as preferred embodiments of the '318 and '320 patents;" or, on the other hand, whether

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"stable flocculated suspension" means, as Roxane contends "a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with a scaffold-like structure and not a solid cake."

Par's definition, according to Par, is broad enough to embrace a structured vehicle such as the accused formulation in this case. Roxane's definition, according to Roxane, is limited to flocculated suspensions in which the solid matter forms an open network aggregate which, over time, forms a loosely packed sediment with a scaffold - like structure and not a solid cake. A structured vehicle does not result in the formation of a loosely packed sediment; rather its solid matter remains permanently in a uniformly dispersed suspended state, held there by the nature of the substance in which it is dispersed.

The language of the claims does not specifically exclude a structured vehicle approach. In such an approach there is a pharmaceutical composition; it is referred to in the art at least occasionally as a form of stable flocculated suspension in water and it might well include (a) megestrol acetate, (b) at least two [or one] of the compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (c) a surfactant.

Applying the teaching of Phillips, the words of a claim are generally given their ordinary and customary meaning, that is, the meaning that the term would have to a person of ordinary skill in the art in question at the time of the Invention. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. Two admonitions confront the construing court: First, "the specification 'is always highly relevant to claims construction analysis. Usually, it is dispositive, it is the best single guide to the meaning of a disputed term' ...' The specification is, thus, the primary basis for construing claims...'" Id. at 1315. Second: the court must not commit "one of the cardinal sins of patent law - reading a limitation from the written description into the claims." SciMed Life Systems v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1340 (Fed. Cir. 2001).

With these admonitions in mind the court will turn to the specification of each of the two patents in issue to determine whether the term "stable flocculated suspension" as used in the claims is broad enough to encompass suspensions derived from processes other than those described in the specification examples, which involve formation of a sediment which is not subject to caking.

Although the Summary of the Invention contains no language that limits the generality of the term "stable flocculated suspension," the Detailed Description of the Invention describes throughout a product and/or a method that involves formation of a sediment that does not cake and that can be flocculated by shaking.

In the common specification shared by the '318 and '320 patents, the inventors describe their invention as follows:

In accordance with the invention, a flocculated suspension of megestrol acetate can surprisingly be formulated in the presence of any surfactant and at least one compound selected from the group consisting of polyethylene glycol, proplylene glycol, glycerol, and sorbitol. ['318 patent, col. 3, 11.31-35; '320 patent, col. 3, 11. 51-55].

...

What is surprising about the present invention is that any surfactant can effectively wet megestrol acetate and together form a stable flocculated suspension in the presence of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol. The surfactant can be anionic, cationic, or non-ionic. ['318 patent, col. 4, 11. 5-9; '320 patent, col. 4, 11.30-37].

The presence of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol is critical to the suspendability of megestrol in a flocculated composition. ['318 patent, col. 5, 11. 11-14; '320 patent, col. 5, 11. 44-48].

In the common specification of the suit patents, the inventors explain what they mean by "flocculated suspension": Individual solute molecules do not bond tightly to form a cake in a flocculated suspension due to the fact that they form an open network aggregate with many branch points in the primary structure which prevents individual floccules from

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approaching each other closely. Flocculated suspensions have a high sedimentation height, due to the natural tendency for an open network aggregate to not form a cake. The resulting sediment is loosely packed and possesses a scaffold-like structure. Particles do not bond tightly to each other and a hard, dense cake does not form. Therefore, the sediment is easy to redisperse, so as to reform the original suspension. These properties make the flocculated suspension very desirable, particularly for liquid pharmaceutical formulations.

('318 patent, col. 3, 11. 37-51; '320 patent, col. 3, 1. 56 to col. 4, 1.4).

The following paragraph of the specification describes a deflocculated suspension and formation of cakes and the consequence of caking; "When a hard cake is formed, it is difficult, if not impossible, to redisperse. ('318 patent, col. 3, 11 64-65; '320 patent col. 4, 11.21-22).

Use of a structured vehicle does not contemplate settling to form a sediment. Rather, by virtue of the nature of the liquid in which the megestrol is suspended, there is permanent suspension of the flocculated particles. Arguing that the claim term encompasses the structured vehicle form of flocculation, Par points to language in the common specification which suggests the utility of using a suspending agent: "Conventional pharmaceutical carriers can be present. Xanthan gum is preferably used as a suspending agent ... The use of a suspending agent maintains the megestrol acetate particles in a uniformly suspended state for a longer period of time during the dose administration period thereby permitting uniform dosing. Xanthan gum is a high molecular weight polysaccharide having thixotropic properties with immediate viscosity recovery." ('318 patent, Col 5, 11 23-31; '318 patent, Col 5, 11 56-64). Although use of Xanthan gum prolongs the state of suspension, it in no way is suggested as a means of creating a permanent suspension; rather its use is suggested as a means of prolonging the suspended state before sedimentation occurs.

The common specification contains three formulations (Examples 1, 2 and 3) of flocculated suspensions of megestrol acetate, each differing from the others by only one or two ingredients. The common specification also describes the method used to make the formulations of the Examples. As described in the common specification, the method used to make the suspensions of the Examples has the following sequence of steps:
. Any one or more of polyethylene glycol, propylene glycol, glycerol and/or sorbitol and a surfactant are combined in water to form a solution.

. Xanthan gum is added to this solution to uniformly hydrate the gum.

. Citrates and flavor are added to the dispersion and the slurry is passed through a screen.

. Megestrol acetate is added to the dispersion to provide a uniform suspension.

. The entire suspension is passed through a colloid mill or homogenizer to produce the final product, a stable, flocculated suspension of megestrol acetate.

('318 patent, col. 5, 1. 54 to col. 7, 1.27; '320 patent, col. 6, 1.32 to col. 8, 1.7).
Stability of the suspensions of Examples 1-3 is described in Example 4.

Suspension Stability

The tendency of each suspension, prepared according to Examples 1-3, to flocculate was assessed as follows. Each suspension is allowed to settle in a controlled environment of 40 degree [degrees] c and 75% relative humidity for a period of 3 months. Following that, each of the sedimented suspensions was shaken and easily redispersed reforming the original suspension.

('318 patent, col. 7, 11.29-38; '320 patent, col. 8, 11. 10-19).

It has previously been determined that the controlled environment of 40 degree [degrees] c and 75% relative humidity for a period of 3 months is not part of the claim term. However, all four of the examples contemplate sedimented suspensions which can be reflocculated by shaking. In view of the language following the examples to the effect that the invention is more broadly applicable than the preferred embodiments thereof, the examples alone might be insufficient to confine "stable

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flocculated suspension" as used in the claims. However, the examples serve to confirm the language of the description. That language conveys to a person skilled in the art that the claimed invention is the formation of a stable flocculated suspension in which the drug particles are allowed to settle to form a sediment, but in which the nature of the resulting sediment is controlled such that formation of a hard cake is avoided.

Par argues strenuously that this construction of "stable flocculated suspension" ignores how that phrase is used in the asserted claims and commits one of the "cardinal sins" of claim construction of importing limitations from the specification into the claims. In SciMed the Court addressed the contention that in construing the claims based on the written description, the district court committed this cardinal sin. Rejecting this argument, the court stated:

As this court has recently explained, "[o]ne purpose for examining the specification is to determine if the patentee has limited the scope of the claims." Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims read without reference to the specification, might be considered broad enough to encompass the factors in question.

242 F.3d at 1341 (citation omitted).

In the present case even though the language of the claims, read without reference to the common specification, might be considered broad enough to encompass a stable flocculated suspension of any character, a person skilled in the art upon reading the description in the specification (as illustrated in the examples) would understand that the invention is limited as recited above.

C. Effect of Surfactant and Wetting Agents: Roxane contends that in claims 19 and 41 of the '318 patent the phrase "an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising ... (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) a surfactant" means: "the surfactant and component (b) must each be present in sufficient quantity to form a stable flocculated suspension." Roxane also contends that the comparable language in claim 1 of the '320 patent means "component (a) [the wetting agents] and the surfactant must each be present in sufficient quantity to form a stable flocculated suspension.

The language of the claims themselves does not impose the requirement for which Roxane contends. There is nothing in the specification that imposes a quantity or function requirement on each of the two categories of components listed in these claims. Other claims do contain quantity limitations. For example, claim 26 depends from claim 19, and includes the limitation that the total concentration of the Markush group elements present "is up to 40% weight/volume." ('318 patent, col. 8, 11.54-57). The absence of a quantity limitation in claim 19 is significant and must have been intended. Other examples need not be recited.

Similarly, the specification calls for the presence, not specific quantities of the two categories of components. ('318 patent, col. 4, 11. 5-10; col. 5, 11. 11-15). The preferred embodiments are in this context, as in the context of construing "stable," simply examples of formulations prepared according to the invention.

There is no basis for Roxane's proposed claim construction, and it will be rejected.

D. Order of Combination: Roxane contends that in claim 1 of the '320 patent the claim limitation "forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant ...; and combining the solution with megestrol acetate" means "components (a) and the surfactant must be added to the water before the addition of megestrol acetate." Par contends that the claim language imposes no such order of preparation when formulating the final product.

Roxane notes that a wetting agent is required to assist in dispersing an insoluble substance (such as megestrol acetate) in water and that: "[t]o achieve that result, the wetting agent must be present in the water before the insoluble substance is added. If the insoluble substance were added to the water before the wetting agents, the insoluble, unwetted substance would clump and not disperse properly. It is only by first dispersing the wetting agents in the water and then adding the insoluble substance that the insoluble substance can be made to disperse throughout the water. This further supports a claim construction of claim 1 of the '320 patent that requires the wetting agents, i.e., components (a) and (b) of claim 1, to be added to the water to form a solution before the megestrol acetate is added." (Roxane's Opening Brief at pp. 17-18). In

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further support of its position Roxane points to the three Examples in the specification in which the order of mixing followed that specified in claim 1 of the '320 patent.

Par contends that Roxane's argument that "if the solution is not already formed by combining water with components (a) and (b), it would be impossible to perform the final step, 'combining the solution with megestrol acetate'" is flawed. The specification discloses that "any surfactant can effectively wet megestrol acetate and together form a stable flocculated suspension in the presence of at least one compound selected from the group polyethylene glycol, etc., '320 patent, col. 4, 11. 30-36. The wetting is accomplished because "the hydrophobic group of the surfactant is sequestering the megestrol [acetate] while the hydrophilic group of the surfactant is solubilized in the bulk water" Id. col. 5, 11 2-5. The surfactant alone is all that is required to wet the megestrol acetate. This negates Roxane's functional argument supporting its construction of claim 1. As was the case when construing "stable," the Examples are not by themselves claim limitations, and the fact that a particular order of mixing is employed in them does not preclude a different order of mixing.

Par's most difficult hurdle is the language of the claim itself. Because the claim recites steps in a particular order, the claim construction is not limited to that order unless grammar, logic or the written description itself requires the steps be performed in that order. Bell Comm. Res., Inc. v. Fore Sys. Inc., Nos. 02-1083 and 02-1084, 62 Fed. Appx. 951, 955 (Fed. Cir. March 27, 2003). Neither logic nor the written description require that the component (a) (sometimes referred to as the "Markush" group elements) and the surfactant be added before the solution is combined with megestrol acetate. However, the grammar of claim 1 clearly does require a specific order of mixing:
forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

Par engages in grammatical gymnastics in an attempt to establish that this language does not require first, the creation of the solution and then combining the solution with megestrol acetate. These efforts are not persuasive, and Par must live with the unambiguous language of its claim as written by it.

III. Conclusion

To summarize, the court resolves the various claim construction issues as follows:

A "stable" flocculated suspension as used in the patent claim is not limited to a suspension that can be shaken to reform the original, uniformly dispersed flocculation suspension, after storage at 40 degree [degrees] c and 75% relative humidity for a period of three months.

A "stable flocculated suspension" as used in the patent claims means a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with a scaffold-like structure and not a solid cake.
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4. "Flour" (Claims 5, 6-8, 10)

Dawn argues that flour is "the total flour of the accused product." Kim contends that "flour is included in the claims of the '355 patent to particularly point out and distinctly claim that the Plaintiff's potassium bromate replacers I and II are used with flour in the manufacture of yeast-leavened products but not used with fruit juice beverages, etc." (Emphasis in original).

The Court rejects Dawn's construction because it is improper to construe a claim by referencing the Accused Products. Jurgens v. McKasy, 927 F.2d 1552, 1560 (Fed. Cir. 1991) ("[A] claim is construed without regard to the accused product."). The Court rejects Kim's construction because it defines the purpose of the flour rather than the meaning of the claim.

The Court adopts the ordinary meaning of the word "flour," which is "the finely ground meal of grain, esp. wheat, separated

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by bolting." Random House Webster's College Dict. at 499.
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9. "Flowing Said Sample Solution of Substantially Constant Composition Through Said Immunosorbing Zone"

It is not clear what is in dispute between the parties as concerns this claim language. Although Dade Behring extensively sets out its construction in its brief, Biosite only suggests possible constructions and concludes the terms are too indefinite to reach a single definitive position. As previously discussed, the Court finds that Biosite's invalidity argument is more properly made after claim construction. See supra note 8. The Court will therefore interpret this Claim language according to claim construction principles.

The claim language itself requires that the solution, which flows through the "immunosorbing zone," have "substantially the same composition." However, it is unclear whether substantially the same composition refers to a solution having substantially the same concentration when it first contacts the immunosorbing zone, or has substantially the same composition after it flows through the immunosorbing zone.

The specification states: "In the subject invention, the mip containing layer in contact with the solution continuously contacts substantially the same composition as the solution diffuses through the layer." See Col. 6, lines 18-21. This relatively constant concentration is contrasted with prior art where, "the layer encounters a continuously changing solution composition as solute becomes bound to the layer or dissolves into the liquid." See Col. 6, lines 15-18. Furthering elucidating this claim's meaning, the prosecution history states: "In the subject invention, one is continually exposing the immunosorbing zone to a solution of the same composition." See D.I. 129, Ex.3 at 10; see also id., Ex. 5 at 17; id.,Ex. 11 at 28.

The intrinsic evidence of the patent indicates therefore that the inventors of the patent contemplated that the immunosorbing zone would be exposed to a solution of substantially the same solution. As a result, there is only way to interpret the claim consistent with the purpose of the invention, which is to concentrate the analyte in the immunosorbing zone: The claim must be referring to the composition of the solution when it first makes contact with the immunosorbing zone. Indeed, because the analyte in the sample solution must bind with mips in the immunosorbing zone for the invention to function properly, it would make no sense to interpret this claim language as requiring the sample solution to have substantially the same composition even after the analyte is removed from the sample by the mip layer in the immunosorbing zone. See D.I. 129, Ex. 11 at 30 ("As the sample continuously flows through the immunosorbing zone, the analyte is removed from the sample and concentrated in the immunosorbing zone.").

Accordingly, the Court construes "flowing said sample solution of substantially constant composition through said immunosorbing zone" as requiring only the sample solution to have substantially the same composition when it first comes into contact with the mips in the immunosorbing zone, not thereafter.
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b. "Fluoropolymer."

"Fluoropolymer" is used in asserted Claim 1. It also is used as part of the construction of the claim term "multimodal." The parties agree that the proper construction of "fluoropolymer" is a "polymer based on fluorine replacement of hydrogen atoms in hydrocarbon molecules." (Dyneon's Opp'n Br. at 15-16). However, in contrast to the agreed constructions for the preceding claim terms, Dyneon urges the Court not to construe "fluoropolymer" because Dupont Dow "has already admitted that the accused product is a fluoropolymer[.]" (Id. at 15). Dupont Dow responds that agreement on the presence of a claim element in the accused product does not obviate the Court's responsibility for claim construction, particularly since "fluoropolymer" is a central claim term in the infringement and invalidity cases. (Dupont Dow's Rep. Br. at 6).

Dyneon argues that agreement on the presence of a claim element precludes the need for construction of the term, citing

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Sulzer Textil A.G. v. Picanol N.V., 358 F.3d 1356 (Fed. Cir. 2004) (Dyneon's Opp'n Br. at 16). The Sulzer court's opinion offers insight into the necessity of claim construction where the meaning of claim terms is undisputed, see 358 F.3d at 1366, but it does not hold that agreement on the presence of a claim element precludes construction of the claim term. The Court recognizes that Markman does not require the trial judge to "repeat or restate every claim term in the court's jury instructions." Id. Yet the Court's fundamental duty in a patent case is to provide the jury with instructions "adequate to ensure that the jury fully understands the court's claim construction rulings and what the patentee covered by the claims." Id. In that context, the Federal Circuit has held that district courts "may -- indeed, often must -- interpret or define a term in the claims that is not in dispute in order to provide a proper context for the discussion of the terms that are in dispute." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1353 (Fed. Cir. 2003).

Here, "fluoropolymer" is a claim term. The Court does not assume that the meaning of "fluoropolymer" will be automatically obvious to the jury even with the benefit of expert or other testimony at trial, particularly since this term will crop up repeatedly in the infringement and the invalidity cases. The Court therefore adopts the proposed construction for "fluoropolymer" as a "polymer based on fluorine replacement of hydrogen atoms in hydrocarbon molecules" notwithstanding the parties' agreement that this claim element is found in the accused products. Doing so will simply facilitate the jury's understanding of the technical terms that will be used repeatedly at the trial with respect to disputed issues.
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The parties dispute whether foam concentrate can be a substance (i.e., one type of material), or must be a solution (i.e., a mixture of two or more liquids). Nothing in the claims, specification, or prosecution history suggest that a foam concentrate is limited to a solution. Substance encompasses a solution as well as any other single-substance foam concentrate, such as a powder. The Court construes "foam concentrate" to mean "foamable substance."
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This claim reads as follows:

1. A method of producing a protein consisting essentially of amino acids 1-191 of human growth hormone comprising:

(a) expressing in a transformant bacterium, DNA coding for a human growth hormone conjugate protein, which conjugate protein consists essentially of amino acids 1-191 of human growth hormone as set forth in combined FIGS. 1 and 3 unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto and an additional amino acid sequence which is specifically cleavable by enzymatic action, and

(b) cleaving extracellularly said conjugate protein by enzymatic action to produce said protein consisting essentially of amino acids 1-191 of human growth hormone.

8. A patent applicant may apply for and obtain a series of patents based on the same application (96 Tr. 392, Peet). It is common practice for the applicant to obtain a series of different claims in separate patents covering different specific embodiments until satisfied that the issued claims provide coverage for the full scope of the invention disclosed in the specification (96 Tr. 392, Peet). This is what Genentech did with the '199 patent (96 Tr. 392-93, Peet).

III. LIKELIHOOD OF SUCCESS ON THE MERITS

A. Claim Interpretation--The Scope Of Claim 1 Of The '199 Patent

9. The interpretation and construction of a patent claim, which define the scope of the patentee's rights under the patent, is a matter of law to be determined exclusively by the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-971, (Fed. Cir. 1995) (en banc), aff'd, U.S. , 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). To determine the meaning of claims, courts look to the claim language, the specification, and the prosecution history. See, e.g., Minnesota Mining and

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Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1576-77 (Fed. Cir. 1992). The prosecution history "is of primary significance in understanding the claims" because it provides an "undisputed public record" of the proceedings in the Patent and Trademark Office. Markman, 52 F.3d at 980. Additionally, claims should be interpreted as "those skilled in the art would interpret the claims." Id.

10. The parties agree that Claim 1 of the '199 patent covers a cleavable fusion expression process. However, Novo raised two issues regarding claim interpretation: (1) whether the term "DNA" and the reference to Figures 1 and 3 in the claim exclude the of genomic DNA from the claim, and (2) whether the claim is a "means plus function" claim, therefore covering only the use of trypsin and the amino acid extensions recognized by trypsin and their "equivalents." For the reasons set forth below, the court finds that (1) the claim does not exclude genomic DNA and (2) enzymatic action is a generic term not limited to trypsin and its "equivalents" and the amino add sequence is simply one which is specifically cleavable by the enzyme of choice.

1. Claim 1 Of The '199 Patent Contains No Limitation For The Source Of DNA Coding For Human Growth Hormone

11. The court rejects Novo's argument that Claim 1 of the '199 patent should be construed to contain a limitation on the source of the DNA utilized in the claimed process. No such limitation appears in the language of the claim (96 Tr. 396-397, Peet). Moreover, it is clear from the '199 patent prosecution history that both the Examiner and Genentech stated that the source of the DNA coding for human growth hormone was irrelevant and could include chemically synthesized DNA, cDNA or genomic DNA (GNE 201, pp. 83, 91). Indeed, this issue arose during prosecution of the '199 patent. The Examiner stated specifically his understanding that the DNA was generic and would include genomic DNA (GNE 201, p. 83). In response to a specific inquiry from the Examiner, Genentech stated that the source of the DNA was not critical and "need not be recited in the claims." (GNE 201, p. 91). Thus, the file history explicitly states that the claim of the '199 patent contained no limitation as to the source of the DNA, and can include genomic DNA (96 Tr. 396, Peet).

12. Novo also argues that the claim language "which conjugate protein consists essentially of amino acids 1-191 of human growth hormone as set forth in combined FIGS. 1 and 3" requires the use of semi-synthetic DNA, i.e., a combination of synthetic DNA and cDNA, because the Figures show the preferred semi-synthetic DNA. Novo's argument, however, fails as a matter of simple grammatical construction. First, the phrase is set off by a comma from the DNA portion of the claim, indicating that the phrase modifies the conjugate protein, not the DNA. Second, Figures 1 and 3 show both a DNA sequence and an amino acid sequence. The claim language requires only that the hGH component of the conjugate protein be the amino acid sequence 1-191 disclosed in the referenced Figures. It does not require the particular example of the DNA for amino acids 1-191. Thus, the reference to the Figures has no bearing on the source of the DNA. The phrase relates only to the amino acid sequence.

13. Novo also argues that because the specification does not explicitly mention it, genomic DNA cannot be within the claim's scope (96 Tr. 1139, Villa-Komaroff). This argument is without merit. First, the claim language clearly does not require a particular source of DNA, as compared, for example, to the '832 patent, which does require a particular source, namely a combination of synthetic DNA and cDNA (NN 200). Second, although the specification refers to synthetic DNA and cDNA, Novo has conceded previously that everything in the specification is not necessarily in a claim (95 Tr. 1561, 1667-1668 Rzucidlo). The restriction requirement early in the prosecution of the parent '832 patent case distinguished as classes of inventions the use of semi-synthetic DNA to code for a protein (i.e., the '832 patent) and the methods of making hGH (Pl. Ex. 56; 95 Tr. 1322-1324, 1667-1668, Rzucidlo)). Third, the prosecution history is clear that the claim is generic as to the source of DNA (GNE 201; pp. 83, 91; 96 Tr. 394-96, Peet).

14. Finally, the court has considered Novo's argument that because it was not known whether the genomic DNA coding for amino acids 1-23 was without introns and, therefore, useful, n4 the claim cannot include genomic DNA. The court finds this argument irrelevant. Methods to determine whether a genomic DNA sequence contained introns were known by 1979 (96 Tr. 1308-1311, Villa-Komaroff). Moreover, generic language in a claim can cover future improvements. Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1559 (Fed. Cir. 1996).

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n4 Introns are interrupting sequences in genomic DNA (96 Tr. 77-78, Falkinham).

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15. Therefore, the term "DNA coding for human growth hormone" in Claim 1 may include chemically synthesized DNA, cDNA, genomic DNA or any combination thereof. Furthermore, the claim's reference to "FIGS. 1 and 3" describes the amino acid sequence of the hGH component of the conjugate protein and, therefore, does not limit the source of the DNA.

2. Claim 1 Of The '199 Patent Is Not A "Means Plus Function" Claim

16. Novo next argues that because the DNA coding for the conjugate protein is described in part by what it does (encodes the conjugate), the claim is a "means plus function" claim under 35 U.S.C. § 112(6). Novo then argues that because its process uses a different (and allegedly nonequivalent) amino extension and enzyme, it does not infringe. The court finds this claim characterization to be inconsistent with the claim, the specification and the prosecution history.

17. A "means plus function" claim is one in which a critical element is drafted so generally (as a "means for" or a "step for" performing a function) that the words alone cover all the means or methods for performing that function. Jonsson v. Stanley Works, 903 F.2d 812, 819 (Fed. Cir. 1990). However, not every claim including functional language is subject to § 112(6) analysis. See, AMP, Inc. v. Fujitsu Microelectronics, Inc., 853 F. Supp. 808 (M.D.Pa. 1994) (the specific means language in the claim "'bus solder tail means' rather than just any means to accomplish the function" found not to trigger the application of § 112(6)). Even when one of the elements is recited in a claim using "means plus function" language, 35 U.S.C. § 112(6) applies only to that element, and not to the entire claim. Johnston v. IVAC Corp., 885 F.2d 1574, 1580 (Fed. Cir. 1989). Claim 1 of the '199 patent is not a "means plus function" claim (96 Tr. 428-429, Peet). First, it does not contain the language that traditionally has been used in such claims. Second, the claim does not cover all means of encoding hGH but rather recites the required material--DNA. As the file history explains, the source of the material is not critical and is not limited, just as the source of the other starting materials are not limited (GNE 201, p. 91). Third, the claim covers only one of several possible processes for expressing human growth hormone--cleavable fusion.

18. The specification generally discloses the enzymes for performing extracellular cleavage. The '199 patent (col. 7, 1. 57-59) identifies trypsin by example (GNE 200). Similarly, the file history makes clear that both Genentech and the Examiner stated that Claim 1 covered enzymes generally (GNE 201, pp. 181, 194). In an office action dated July 9, 1993, the Examiner proposed to allow a claim limiting the enzyme to trypsin (Id. at 181). In response, Genentech stated that "trypsin must be regarded as a mere example of various enzymes that would be available in order to cleave the additional amino acids in the conjugate so as to give the 191 human growth hormone product after such cleavage" (Id. at 194). Genentech provided the Examiner with evidence showing not only the existence of many such enzymes, but also that those skilled in the art knew how to use them to effect specific cleavage (Id. at 156-162). Following Genentech's submission, the Examiner allowed the claim without the proposed limitation (Id. at 210-211). Thus, the claim cannot be reasonably construed as a "means plus function" claim as Novo suggests.

19. The cases relied upon by Novo to establish that Claim 1 of the '199 patent should be construed as a "means plus function" claim are distinguishable. Ex parte Maizel, 27 U.S.P.Q.2D (BNA) 1662 (Bd.Pat. App. 1993), the Board analogized the language "biologically functional equivalent thereof" to "means plus function" language. Unlike the instant case, neither the DNA nor the protein was defined. In the '199 patent, the end product, 1-191 hGH, is a specific amino acid sequence. Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993) did not involve 35 U.S.C. § 112(6); rather, the Court held that the patent claim at issue failed to meet the written description requirement of 35 U.S.C. § 112(1). Moreover, Fiers is clearly distinguishable because the patent claimed DNA whereas in the present case, the claim is to a method of making the protein. Likewise, Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed. Cir. 1994) is inapposite. Genentech also involved 33 U.S.C. § 112(1), not 33 U.S.C. § 112(6).

20. Moreover, even if Novo is correct, the designation of Claim 1 of the '199 patent as a "means plus function" claim would be of little help to Novo. 35 U.S.C. § 112(6) provides that a "means plus function" claim "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." As shown in more detail below, Novo's process for manufacturing hGH clearly uses equivalents to the enzymes and amino acid cleavage sites disclosed in the specification.
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Claims 1 and 2 of the '355 patent read as follows:

1. A sustained-release oxybutynin formulation for oral administration to a patient comprising a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that delivers from 0 to 20% of the oxybutynin in 0 to 4 hours, from 20 to 50% of the oxybutynin in 0 to 8 hours, from 50 to 85% of the oxybutynin in 0 to 14 hours, and greater than 75% of the oxybutynin in 0 to 24 hours for treating incontinence in the patient.

2. A sustained-release oxybutynin formulation for oral administration to a patient in need of treatment for urge incontinence comprising a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that delivers from 0 to 1 mg in 0 to 4 hours, from 1 mg to 2.5 mg in 0 to 8 hours, from 2.75 to 4.75 mg in 0 to 14 hours, and 3.75 mg to 5 mg in 0 to 24 hours for treating urge incontinence in the patient.

1. The Parties' Proposed Constructions

Both claims 1 and 2 recite "a sustained-release oxybutynin formulation for oral administration to a patient comprising a therapeutic dose of oxybutynin" that delivers a specified percentage or milligram amounts of oxybutynin at the end of certain time intervals. Pursuant to the stipulations in the parties' Joint Claim Construction Report, "formulation" means "something that is prepared according to a formula." (JCCR at 2.) Mylan contends that "sustained-release oxybutynin formulation" lacks any meaningful structure, and therefore must be construed as a means-plus-function limitation. See 35 U.S.C. § 112, P 6. Mylan also maintains that, in the specification, the only described structure that administers the specified amounts of oxybutynin is the bilayer push/pull osmotic pump delivery system ("osmotic pump system" or "osmotic dosage form") disclosed in Examples 15-21. Accordingly, Mylan asserts that the "formulation" claims only cover the osmotic dosage form and its equivalents. See id. Alza, on the other hand, argues that "sustained-release oxybutynin formulation" recites sufficient structure and encompasses both osmotic and non-osmotic dosage forms.

2. The Court's Construction

According to 35 U.S.C. § 112 P 6,

An element in a claim for combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

"Through use of means-plus-function limitations, patent applicants are allowed to claim an element of a combination functionally, without reciting structures for performing those functions." Apex, Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 1371 (Fed. Cir. 2003) (citation omitted). As § 112, P 6 indicates, however, the scope of means-plus-function claims is limited "to the means specified in the written description and equivalents thereof." O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1583 (Fed. Cir. 1997).

"[A] claim term that does not use 'means' will trigger the rebuttable presumption that § 112, [paragraph] 6 does not apply. The term 'means' is central to the analysis." Apex, 325 F.3d at 1371-72 (quoting Personalized Media Comm. v. Int'l Trade Comm'n, 161 F.3d 696, 703 (Fed. Cir. 1998)) (citation omitted). The challenger "can rebut this presumption if it demonstrates [by a preponderance of the evidence] that the claim term fails to 'recite sufficiently definite structure' or else recites a 'function without reciting sufficient structure for performing that function.'" Id. at 1372 (quotation and internal quotation omitted). "'To help determine whether a claim term recites sufficient structure, [a court should] examine whether it has an understood meaning in the art.'" Id. (quoting Watts v. XL Sys., Inc., 232 F.3d 877, 880 (Fed. Cir. 2000)).

Here, claims 1 and 2 do not include the term "means." Therefore, Mylan bears the burden of showing that the disputed claim limitations, as understood by one of ordinary skill in the art, rely "on functional terms rather than structure or material to describe performance of the claimed function." Id. To determine whether the claim limitations recite sufficient structure, the Court may properly consider extrinsic evidence, including expert testimony. Personalized Media Comm., 325 F.3d at 1374.

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The disputed language, "sustained-release oxybutynin formulation," is a preamble in claims 1 and 2. "In general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Mktg. Int'l v. Coolsavings.com, 289 F.3d 801, 808 (Fed. Cir. 2002) (quotation omitted). Alza contends that the preamble serves as a limitation to the claims. Likewise, Mylan's means-plus-function argument presupposes that the preamble is a limitation. In light of this tacit agreement, the Court will construe the preamble accordingly.

Although Mylan suggests otherwise, a claim limitation does not need to "connote a precise physical structure in the minds of those of skill in the art." Personalized Media Comm., 161 F.3d at 705. Indeed, the Federal Circuit has held that a term which conveys "a variety of structures" to a skilled artisan is "sufficiently definite . . . to preclude the application of § 112, [paragraph] 6." Id. Moreover, "sustained-release oxybutynin formulation" "is not a generic structural term such as 'means,' 'element,' or 'device'; nor is it a coined term lacking a clear meaning, such as 'widget.'" Id. at 704 (footnote omitted). To the contrary, Mylan's expert, Dr. Okerholm, agreed that the term "denotes particular types of structures, a variety of structures." (Alza's Resp. to Mylan's Opening CC Br. at 10.) Mylan offers no evidence that a skilled artisan in September, 2000, would have only understood "sustained-release oxybutynin formulation" in functional terms, as opposed to structural or material terms. Thus, Mylan fails to prove that claims 1 and 2 contain means-plus-function limitations, and the Court will construe the claim language according to the parties' stipulated definitions.
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The first disputed phrase is "a composition for reducing apolipoprotein B ['apoB'] production." 13 The parties agree that this phrase is a claim limitation (KGK's Br. at 8-10; SourceOne's Br. at 19-20). SourceOne proposes construing this phrase to mean "a composition intended to reduce the production of apolipoprotein B" (SourceOne's Br. at 19). KGK proposes a different construction: "a composition having the ability to reduce the production of apolipoprotein B" (KGK's Br. at 8).

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13 ApoB is the principal protein of low-density lipoprotein ("LDL"), also known as "bad" cholesterol.

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As was the case for the previous patents, the parties dispute whether the word "for" implies an intent, as SourceOne contends, or a capability, as KGK contends. The intrinsic evidence, including the prosecution historyof the '125 patent, persuades us that SourceOne's proposed construction is correct.

The original patent application claimed methods and compositions of an effective amount of polymethoxyflavone that could reduce substances that contribute to cardiovascular diseases or disorders, such as apoB, cholesterol, low density lipoprotein, or very low density lipoprotein (J.A. at 705-06). In an office action dated September 9, 2002, the examiner rejected the original claims as obvious in view of prior art that teaches that polymethoxyflavones may be used in a composition for reducing the level of substances that contribute to cardiovascular diseases or disorders (J.A. at 747).

Subsequently, on March 4, 2003, the applicant canceled all of the original claims and replaced them with ten new claims drawn solely to methods and compositions "for reducing apolipoprotein B production comprising providing an apolipoprotein B reducing amount of a polymethoxyflavone" (J.A. at 752-54). The applicant argued that the prior art "fails to teach compositions or methods for reducing the levels of Apolipoprotein [sic] B production by providing an apolipoprotein B reducing amount"of the composition (J.A. at 757).

On May 20, 2003, the PTO examiner again rejected the applicant's claims for obviousness (J.A. at 764). The examiner explained that the prior art teaches that flavonoids, including polymethoxyflavones, inhibit LDL cholesterol and apoB synthesis, thus reducing apoB levels and lowering the risk of cardiovascular disease (J.A. 765). On August 20, 2003, the applicant canceled most of the prior claims and added six new claims drawn solely to methods and compositions "for reducing apolipoprotein B production comprising providing an apolipoprotein B reducing amount of a polymethoxyflavone" (J.A. at 772-76). The applicant argued that the prior art does not teach that the specifically claimed

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polymethoxyflavones in the application are a method for reducing levels of apoB (J.A. 779-80). On September 9, 2003, the examiner again rejected these claims (J.A. at 786), and the applicant appealed (J.A. at 789-804). On July 7, 2004, the applicant canceled the previous claims and added three new claims. These claims recited compounds making up the polymethoxyflavone that were not recited in the prior art (J.A. at 821-25). These claims were allowed and are currently thepreamble in Claims 1 through 3 in the '125 patent (J.A. at 829).

The prosecution history shows that the applicant made a "clear and unmistakable" disclaimer of the claim scope in order to achieve patentability, by giving up the reduction of substances other than apoB. KGK's proposed construction of the disputed terms as "having the ability to reduce" apoB production, however, could embrace compositions that are not directed to reduction of apoB. That is an impermissible construction because KGK cannot now recapture claim scope that was given up during prosecution: specifically, the reduction of substances other than apoB. See Edwards Lifesciences, 582 F.3d at 1334 ("[The patentee] cannot now reclaim what it disclaimed during prosecution and throughout the specification. . . ."). Various language in the specification selected by KGK to support its proposed construction -- that polymethoxyflavones are "inhibitors" of apoB production and "result in" the reduction of apoB, and that "an object of" the invention is to provide compositions and methods to reduce, prevent, and/or treat cardiovascular diseases (KGK's Br. at 8-9 and n.2) -- is not inconsistent with a construction drawn solely toreducing apoB.

By contrast, SourceOne's proposed construction of the disputed phrase gives meaning to the limitations in the claims required by the PTO examiner. The examiner ultimately approved claims that were drawn solely to methods and compositions for reducing apoB, and thus, construction of the phrase must be limited to this scope.

Accordingly, we construe the phrase to mean "a composition intended for reducing the production of apolipoprotein B."
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A. Claim Construction

Bristol argues that the district court erred by not giving effect to the preamble "for reducing hematologic toxicity" and the expression "an antineoplastically effective amount" in the '803 claims. In particular, Bristol asserts that "an antineoplastically effective amount" is limiting because it was added by amendment to distinguish over Kris, who observed no antitumor efficacy. Similarly, Bristol argues that the court improperly read out the phrase "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" from claims 5, 6, 8, and 9 of the '537 patent, asserting that this expression is the only difference between claims 1 and 5 and therefore must be given effect under the doctrine of claim differentiation. Finally, Bristol argues that these expressions are limitations because they distinguish the new use of the process over the prior art, which did not show usefulness for treating cancer in three-hour paclitaxel infusions.

The defendants respond that the expressions "reduced hematologic toxicity" and "antineoplastically effective amount" in the '803 patent claims merely state the intended result of those claims and are non-limiting. Furthermore, the defendants point out that "antineoplastically effective amount" was not required by the examiner to distinguish over the prior art because Bristol voluntarily added the phrase to the claims after the examiner had found them allowable. The defendants also assert that the preamble language of the '537 claims, "to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity," only states an intended result of that claimed method. Moreover, the defendants assert that the doctrine of claim differentiation does not apply to distinguish the scope of claim 5, which recites that expression, from claim 1, which does not, because both claims are independent. The defendants also argue that Bristol's claim construction arguments violate the rule of consistency, which requires courts to construe claims consistently for both validity and infringement. Finally, the defendants respond to Bristol's argument that the asserted claim limitations are necessary to distinguish over the prior art on the basis of the discovery of the new "usefulness" of three-hour paclitaxel infusions, arguing that the prior art was directed to that same use -- treating cancer -- and that Bristol's sole contribution was in recognizing a new result of that same use, i.e., that it worked to treat cancer.

We first address the preamble language of the claims in the '803 patent, "for reducing hematologic toxicity." We discern no error in the district court's interpretation of that language as non-limiting, and merely expressing a purpose of reducing hematologic toxicity relative to the toxicity experienced by a patient undergoing a twenty-four-hour infusion. The steps of

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the three-hour infusion method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim. See, e.g., In re Hirao, 535 F.2d 67, 70, 190 U.S.P.Q. (BNA) 15, 16-17 (CCPA 1976) (holding that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim). Furthermore, this is not a case in which a new use of a process should be considered to be a limitation because that new use distinguishes the process over the prior art, as we will discuss infra. We therefore affirm the district court's construction of this expression as non-limiting.

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2.

The second disputed phrase in Claim 1 of the '114 patent is "for treating a mammal at risk of or suffering from cancer." SourceOne proposes construing this phrase to mean "for giving medical aid to a mammal at risk of developing or suffering from cancer" (SourceOne's Br. at 16). KGK proposes construing this phrase to mean "suitable for administering to a mammal at risk of or suffering from cancer and capable of preventing or inhibiting transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis" (KGK's Br. at 22). As an initial matter, we adopt SourceOne's use of the word "developing" to clarify the meaning of the claim language, "at risk of . . . cancer." Although the word "developing" does not appear in KGK's proposed construction, KGK agrees with that meaning (see KGK's Br. at 22-23 ("[The formulations] may be used for those individuals who are 'at risk' for developing cancer.") (emphasis added)). We agree that the addition of thisword will add clarity to the claim without altering its meaning or scope.

The parties dispute the meaning of the rest of the phrase. SourceOne seeks the more narrow construction of "for treating" as "for giving medical aid," while KGK proposes the broader "capable of preventing or inhibiting." 11 In the '400 patent, however, the parties agreed that the term "treating" meant "inhibiting or preventing." As explained above, identical claims terms in the same patent family should be construed consistently, and the parties have not provided the Court with any reason to deviate from the previously agreed upon construction of "treating."

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11 SourceOne again points to extrinsic evidence -- dictionary definitions -- to support its proposed construction. Because the Court is able to construe the claim in light of the intrinsic evidence, we do not analyze the numerous dictionary definitions provided by SourceOne (SourceOne's Br. at 16).

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Likewise, we again construe the preposition, "for," as "intended for," as opposed to the far broader words "capable of." As a continuation-in-part of the application that led to the '400 patent, the claims of the '114 patent must be construed in light of the restrictionrequirement in the prosecution history of the '400 patent. Omega Eng'g., Inc., v. Raytek Corp., 334 F.3d 1314, 1333 (Fed. Cir. 2003). As explained above, the patentee made a "clear and unmistakable" disclaimer of claim scope in its prosecution of the '400 patent, giving up all claims directed to the treatment of diseases other than cancer, such as hypercholesterolemia. Id. "[W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning." Id. at 1334. Moreover, "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999). Consequently, the Court construes the word "for" to mean "intended to," as it did in construing that same word in the '400 patent.

Similarly, as we did with respect to the '400 patent, we reject KGK's complex definition of "cancer." See Terlep v. Brinkmann Corp., 418 F.3d 1379, 1382 (Fed. Cir. 2005) (holding that claim construction is "a wayof elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims"). Consistent with our construction of the same term in the '400 patent, we find that the customary meaning of "cancer" that would be understood by a person of ordinary skill in the art at the time of invention and in view of the intrinsic evidence is sufficient to cover all applicable phases of cancer development and avoids the confusion to the finder of fact that could result from

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adopting KGK's needlessly long and complex proposed construction.

We also find that it is unnecessary to insert the word "development" before "at least one form of cancer" as SourceOne has done in its proposal because it is not essential to the proper construction of the claim, and may impermissibly narrow the meaning of cancer to include less than all of its phases. 12 The words, "at least one form of cancer," need no further construction. Thus, we construe the phrase "for treating a mammal at risk of or suffering from cancer" to mean "intended to treat a mammal at risk of developing or suffering from cancer."

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12 The Court further notes that SourceOne did not deem it necessary toadd the term "development in its proposed construction of cancer in the '400 patent.

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B.

Having determined that the preamble limits the scope of Claim 1, we now construe the phrase "a pharmaceutical composition for treating breast cancer in a human subject." 5 SourceOne proposes construing this phrase as "a drug; i.e., a substance used in the treatment or prevention of a disease intended to give medical aid to prevent or inhibit breast cancer in a human subject" (see doc. # 91: SourceOne's Br. at 9 and 12). By contrast, KGK proposes the following construction: "a formulation or preparation that is (a) suitable and safe for administration to mammals and (b) capable of preventing or inhibiting transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis" (doc. # 101: KGK's Br. at 20). For the following reasons, we do not agree with eitherproposed construction.

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5 Although the parties discuss this phrase in two parts -- "a pharmaceutical composition" and "for treating breast cancer in a human subject" -- it is a basic tenet of patent law that "claims must be construed in a way that comports with the instrument as a whole," and that "preserves the patent's internal coherence." Versa Corp. v. Ag-Bag Int'l Ltd., 392 F.3d 1325, 1336 (Fed. Cir. 2004) (quoting Markman, 517 U.S. at 389-90). Construing the disputed phrase in pieces would be more likely to lead to inconsistent or erroneous constructions; accordingly, we construe the disputed phrase as a whole, and in the context of the entire patent.

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In construing the disputed terms, we look first to the '400 patent's specification. See Phillips, 415 F.3d at 1315. Initially, KGK's description of the claimed invention as a "formulation or preparation" rather than a single "substance," finds ample support in the specification. The '400 patent repeatedly refers to the invention as a formulation or preparation of various substances (see, e.g., J.A. at 9, '400 patent, Col. 8, lines 44-67). Thus, the Court adopts the terms "formulation or preparation" as part of the construction.

Contraryto KGK's arguments, however, the '400 patent does not teach that the description of the formulation as "pharmaceutical" is "merely" a synonym for "purity and safety" or "suitable" (see KGK's Br. at 17). Nor does the '400 patent teach that the formulation is suitable and safe for "administration to mammals," because that would contradict the plain language which claims an invention "for treating breast cancer in a human subject." Moreover, contrary to SourceOne's contentions, the word "drug" should not be substituted for "pharmaceutical." Where KGK's proposed construction would improperly expand the scope of Claim 1, SourceOne's proposed construction would improperly narrow its scope. The '400 patent does not state that the "pharmaceutical composition" must be a "drug" rather than some other formulation consistent with the language in Claim 1, that it is "for treating breast cancer." SourceOne cites to numerous dictionary definitions in support of its proposed construction (see SourceOne's Br. at 9-10). However, one potential shortcoming of relying on dictionary definitions in particular is that it "focuses the inquiry on the abstract meaning of words rather than on the

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meaning of claimterms within the context of the patent." Phillips, 415 F.3d at 1321. The dictionary evidence cited by SourceOne -- which is secondary to the language in the patent itself -- does not persuade us to ascribe to the term a meaning not set forth in the specification or prosecution history. 6

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6 SourceOne also argues that the claim should be limited to a "drug" because the invention is "directed at the treatment of breast cancer, a deadly disease which requires professional care and highly refined and purified drugs to treat" (doc. # 111: SourceOne's Reply at 8). This argument, however, further demonstrates how adding the term "drug" may alter or narrow the meaning of the claim -- such as by implying something "highly refined and purified."

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Rather, as explained above, the meaning of "pharmaceutical" as used in Claim 1 is evident from the words of the claim itself, as well as from the specification. The "pharmaceutical composition," or the "pharmaceutical formulation or preparation" as construed by the Court, would be understood by a person of skill in the art as simply introducing and describing the components of the invention. 7 The limitations in Claim 1 "define[] a structurally completeinvention," while the words "pharmaceutical composition" are "merely duplicative of" and "give context for" the limitations in the body of the claim. Symantec, 522 F.3d at 1288-89. The body of the claim states that the invention would be comprised of a certain formulation or preparation of citrus limonoids, citrus flavonoids, and/or tocotrienols that would be used to treat breast cancer. Thus, we find that "pharmaceutical" as used in Claim 1 of the '400 patent is merely descriptive and needs no further construction. 8

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7 The parties dispute the probative value of additional patents to the claim construction at issue. KGK attaches the prosecution history of U.S. patent application number 09/481,724 ('724 patent), and SourceOne attaches U.S. Patent No. 5,919,818 ('818 patent). The '724 patent application (abandoned before any patent issued) was a continuation-in-part application to the '400 patent, and the '818 patent was cited in the prosecution of the '400 patent. While these patents are of limited probative value, the Court notes that these patents support the Court's decision not to further construe the word, "pharmaceutical." In the '724 patent, the examiner noted that lemon juice,beet juice, and bee honey could all be "pharmaceutical compositions" (KGK's Br. at 15 n.15), while the '818 patent showed that pharmaceutical compositions may take numerous forms, such as tablets, capsules, powders, solutions, lotions, or creams (KGK's Br. at 18). This is further evidence that the words "pharmaceutical composition" merely describe a variety of potential formulations or preparations.

8 The term "pharmaceutical composition" is also used in asserted Claims 2, 4, and 5 of the '400 patent. The parties do not argue that the term should be construed differently in those claims than in Claim I. We find that the presumption that the same claim terms in the same patent carry the same construed meaning applies here. See Omega Eng'g., Inc., v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003).

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The limiting phrase, "for treating breast cancer in a human subject," further shows that "pharmaceutical composition" simply describes the subsequent limitations set forth in the claim. KGK and SourceOne agree that "treating" breast cancer should be read as "prevent[ing] or inhibit[ing]" breast cancer (SourceOne's Br. at 12; KGK's Br. at 19). 9 The parties disagree, however, on what meaningis imparted by use of the preposition "for," found in the phrase "for treating breast cancer." KGK argues that it means "capable of" (KGK's Br. at 19), while SourceOne contends that it means "intended to" (SourceOne's Br. at 12). SourceOne's construction as "intended to" is narrower, and would mean that the invention in Claim 1 would be used for the sole purpose of treating breast cancer, while KGK's construction as "capable of" is broader, and would mean that the invention covers any use within any art, so long as one of these uses could be treating breast cancer.

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9 In its entirety, SourceOne argues that the word "treating" should be construed to mean as "used in the treatment or prevention of a disease intended to give medical aid to prevent or inhibit . . ." The words before "to prevent," however, are

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redundant. The disputed phrase already indicates that the invention is for treating a disease -- breast cancer -- which inherently connotes a "medical" use. Courts eschew redundant constructions, so we decline to adopt SourceOne's excess verbiage. See Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1348 (Fed. Cir. 2009) (finding that the patent drafters could not haveintended to claim "soluble calcium sulfate anhydrite" because the word "anhydrite" would be redundant).

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The prosecution history in this case is instructive in resolving the dispute about how the word "for" should be construed. The original patent application filed on September 26, 1997, included claims directed to hypercholesterolemia (high cholesterol) and neoplastic diseases (e.g., cancer). However, as explained above, the examiner issued a restriction requirement, because he found that the claims directed to the treatment of cancer represented a distinct invention from the claims directed to the treatment of hypercholesterolemia (J.A. at 139-40). To continue prosecuting the application, the applicant elected to restrict the application to only those claims that were directed to the treatment of cancer (J.A. at 140). Then, following an interview on August 24, 1999 (J.A. 159), the examiner further limited Claim 1, issuing an amendment to the preamble which specified that the invention is for the treatment of breast cancer in particular (J.A. 162-64).

A patent applicant disclaims, or surrenders, protection of certain subject matter if during prosecution, the applicant's statements constitute"a clear and unmistakable" surrender of subject matter. Ecolab, Inc. v. FMC Corp., 569 F.3d 1335, 1342 (Fed. Cir. 2009) ("since, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."). Here, the applicant's election to pursue only those claims directed to the treatment of cancer was a "clear and unmistakable" disclaimer, or surrender, of the claims directed to the treatment of any diseases other than cancer. Further, the limitation added by the examiner's amendment and not contested by the patent applicant -- that the claims were directed to breast cancer, specifically -- was a "clear and unmistakable" disavowal of claims directed to other types of cancer. As explained above, the Court presumes that the PTO had a substantial reason related to patentability for including the limiting element added by amendment. Warner-Jenkinson, 520 U.S. at 33.

If we were to construe the disputed phrase in Claim 1 as KGK requests -- as merely a formulation capable of treating breast cancer -- the limitation of Claim 1 to cancer, and to breast cancer, in particular, would be meaningless.Under KGK's preferred construction, Claim 1 would cover not only other types of cancer, but also other diseases, such as hypercholesterolemia. We decline to construe the claim this way, because it would impermissibly allow KGK to reclaim what was disclaimed during the prosecution in order to secure the patent. See Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322, 1334 (Fed. Cir. 2009) ("[The patentee] cannot now reclaim what it disclaimed during prosecution and throughout the specification . . . ."). Therefore, in accordance with the prosecution history, the Court construes the disputed phrase of the '400 patent as "a pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject." 10

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10 Because the intrinsic evidence -- the prosecution history -- convinces the Court that the meaning of the word "for" is "intended to," we do not address SourceOne's numerous dictionary definitions of the word. See Phillips, 415 F.3d at 1319 ("[U]ndue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records' . . . ."). We note that in any event, the proffered dictionarydefinitions are of little help here. For example, New Collegiate Dictionary states that "for" may be defined not only as "used as a function word to indicate purpose" and "used as a function word to indicate an intended goal," as proposed by SourceOne, but also "used as a function word to indicate suitability or fitness," as proposed by KGK (SourceOne's Br. at Ex. 1) (emphasis added). In addition, Random House Unabridged Dictionary defines "for" as both "with the object or purpose of" and "appropriate or adapted to" (SourceOne's Br. at Ex. 6), Neither SourceOne nor KGK offers a principled basis to pick one dictionary definition over another.

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Finally, we note that KGK proposes that the phrase "breast cancer" should be construed as "transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis." However, changing the readily understood word,

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"cancer," to the more complex phrase, "transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis," would unnecessarily complicate the meaning of Claim 1. While the specification of the '400 patent states that "[p]referred compositions of the invention are thosewhich specifically or preferentially prevent transformation of preneoplastic cells to tumor cells, and prevent or inhibit tumor cell proliferation, invasion and metastasis," (J.A. at 6, '400 patent, Col. 1, lines 21-28), these "preferred compositions" are not the "exclusive" compositions. See Symantec, 522 F.3d at 1290-91 (holding that it was improper to limit the claims to cover only the preferred embodiment when the specification did not so limit the claims). Furthermore, "the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. We find that the customary meaning of "breast cancer" that would be understood by a person of ordinary skill in the art at the time of invention and in view of the intrinsic evidence is sufficient to cover all applicable phases of breast cancer development and avoids the confusion to the finder of fact that could result from adopting KGK's proposal.

Based on the foregoing analysis, the Court construes the phrase, "a pharmaceuticalcomposition for treating breast cancer in a human subject," as "a pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject." With this construction, Claim 1 of the '400 patent reads: "A pharmaceutical formulation or preparation intended to prevent or inhibit breast cancer in a human subject, said composition comprising anti-neoplastic effective amounts of: a citrus limonoid selected from the group consisting of limonin and nomilin, and a tocotrienol."
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Foreign DNA I	A polynucleotide that is inserted into the eucaryotic cell

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III. "Form Of A Dosage Unit"

GSK's Proposed Construction	Teva's Proposed Construction
Form suitable for administration to a human, e.g., a table, that includes a predetermined amount of each active ingredient.	Form suitable for administration to a mammal.

GSK contends, first, that this limitation should be limited to the treatment of humans only and, second, that the "dosage unit" should have a "predetermined amount of each ingredient." (See D.I. 32 at 16-17.) The Court will not adopt GSK's construction.

For the reasons stated immediately above, the Court will not limit this claim element to the treatment of only humans. (See Part II of this Memorandum Order.)

In support of the position that the "dosage unit" must have a "predetermined" amount of each active ingredient, GSK notes that the specification states that "[p]harmaceutical formulations suitable for oral administration may conveniently be presented as discrete units such as capsules, cachets or tablets each containing a predetermined amount of the active ingredient." ('021 patent at 5:17-21.) Based on this, GSK contends that the "specification clearly states that the 'form of a dosage unit' must contain a predetermined amount of each active ingredient." (D.I. 35 at 12 (emphasis added).) Unfortunately, this is not what the specification states. Rather, the specification merely states that one type of formulation (i.e., oral dosage forms) "may" be presented as units having a predetermined amount of the active ingredient. Thus, the statement in the specification relied upon by GSK is not a basis upon which to limit the claims. GSK further points to other exemplary dosage forms listed in the specification, such as ampoules, pre-filled syringes, and blister packs, and contends

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that "[t]here is not a single example" referring to dosage forms having something other than a predetermined amount of each active ingredient. (See D.I. 44:7-10; D.I. 35 at 13.)

However, GSK provides no evidence, such as expert witness testimony, that all of the disclosed dosage forms in fact contain a "pre-determined" amount of each active ingredient. Rather, GSK's evidence on this issue consists of little more than attorney argument and, perhaps, a dictionary definition. (See D.I. 32 at 16 (citing Webster's Third New Int'l Dictionary 676 (1986).) Attorney argument and extrinsic dictionary definitions carry little weight and are an insufficient basis upon which to introduce an extraneous limitation into claims. Indeed, "[i]t is improper for a court to add 'extraneous' limitations to a claim, that is, limitations added 'wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.'" Hoganas AB v. Dresser Indus., 9 F.3d 948, 950 (Fed. Cir. 1993) (quoting E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988).

Finally, GSK contends that Teva's construction "defies common sense" because it would allow a dosage unit to "contain an arbitrary and uncontrolled amount of the active ingredients." (Id. at 13.) However, in the Court's view, GSK fails to fully explain why the claims cannot, in fact, encompass dosage units in which there is variability in the relative amount of each active ingredient, such as where dosage units are prepared as a dry powder mixture containing rough amounts of each ingredient or as an aerosol in which the concentration of each agent varies with administration. 4 Furthermore, the Court is concerned that GSK's proposed construction will not clarify the claims, but introduce ambiguity. Indeed, GSK's construction does not explain when or by whom the amounts of each active ingredient must be "predetermined," nor does it set forth the level of precision with which the amount of each active ingredient must be "predetermined."

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4 GSK argued at the Markman hearing that failure to administer a "predetermined" amount of drug could lead to a "whole host of problems" and cited toxicity and resistance problems, identifying "peripheral neuropathy" as a particular example. (See D.I. 44 at 91:19-92:20.) However, this was not buttressed by any evidence and is therefore nothing more than attorney argument, which the cannot credit.

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Accordingly, the Court will construe the claim term "form of a dosage unit" to mean, as Teva contends, a "form suitable for administration to a mammal."
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C. Formaldehyde

The R & R found that formaldehyde, as used in the '973 patent, "includes 'all synthetically useful forms of formaldehyde including solid forms of formaldehyde such as paraformaldehyde and trioxane.'" 64 Defendants object, arguing that "formaldehyde" should be interpreted to mean monomeric formaldehyde (HCHO) only. Monomeric formaldehyde is a gas at room temperature. 65 According to defendants, use of the R & R's construction requires different definitions of the same term throughout the claims and would render certain claims superfluous.

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64 R & R at l0.

65 Pl. Ex. E P 34.

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"'The descriptive part of the specification aids in ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based on the description. The specification is, thus, the primary basis for construing claims'" 66 and "'[t]he best source for understanding a technical term'" 67 used in the claims. As Magistrate Judge Ellis correctly found,

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when the term is understood within the context of the patent as a whole, it is clear that "formaldehyde: was intended include forms other than monomeric formaldehyde.

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66 Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985)).

67 Id. (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)) (alteration in original).

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The specification describes one step of the invented process as requiring the "subsequent addition of formaldehyde to the mixture." 68 Later, in the "detailed description of the invention" section, the patent specifies that "[a]ccording to a preferred embodiment of the process of the present invention, formaldehyde is used in one of its solid forms, currently in form of its precursor 1,3,5-trioxane." 69 This indicates that the patent writers intended to use the term "formaldehyde" to refer to the compound in more than just its monomeric form.

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68 Pl. Ex. B. at col. 2:20-21.

69 Id. at col. 2:49-52.

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Further supporting this construction is the fact that the claims explicitly include formaldehyde precursors as a type of formaldehyde. For example, Claim 1 requires "adding formaldehyde." 70 Claims 2 and 3, which are dependent on Claim 1, describe "[a] process according to claim 1 in which formaldehyde is used in form of its precursor 1,3,5-trioxane" and "[a] process according to claim 1 in which formaldehyde is used in form of its precursor paraformadehyde." 71 Thus, Claims 2 and 3 describe more specific restrictions on the broader Claim 1 by specifying the particular form of formaldehyde used.

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70 Id. at col. 7:12.

71 Id. at col. 7:28-38.

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Defendants contend that this construction renders claims and parts of claims superfluous. Claim 23 states in relevant part, "[a] process for the preparation of 5-carboxyphthalide of formula A which comprises adding formaldehyde (or a formaldehyde precursor)." Here, the phrase "or a formaldehyde precursor" is merely an explanatory parenthetical intended to assist understanding and reinforces the definition of formaldehyde used in the patent as a whole. This use of additional words "to help not hinder understanding" is not superfluous. 72

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72 Bell & Howell, 132 F.3d at 707 (mutually reinforcing definitions not superfluous).

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Defendants contend also that the R & R's construction would render Claim 22 superfluous in its entirety because the only substantive difference between that claim and Claim 23 is the phrase "or a formaldehyde precursor." 73 However, as Magistrate Judge Ellis noted, the doctrine of claim differentiation "'is a guide, not a rigid rule.'" 74 Indeed, "'[i]t is not

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unusual that separate claims may define [an] invention using different terminology, especially where . . . independent claims are involved.'" 75 Here, Claim 22 depends from independent Claim 1. Claim 23 is independent. Where the claims are independent and the drafters' intentions are otherwise clearly evidenced by the specification as a whole, the doctrine of claim differentiation does not control. 76

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73 Def. Obj. at 20-21.

74 Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006) (quoting Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed. Cir. 1991)).

75 Id. (quoting Hormone Research Foundation, Inc. v. Genentech, Inc., 904 F.2d 1558, 1567 n. 15 (Fed. Cir. 1990)).

76 See, e.g., Hormone Research Found., 904 F.2d at 1567 n.15.

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II

T.F.H. argues that the district court erred in its construction of the claim limitation "a polyurethane elastomeric body formed by the reaction of aliphatic dicarboxylic acid and aromatic diisocyanate" in Claim 1. The district court construed this limitation to mean that "the polyurethane must be formed by the reaction of an aliphatic dicarboxylic acid directly with an aromatic diisocyanate." Order, slip op. at 2. The parties agree that polyurethane cannot in fact be formed by the direct reaction of an aliphatic dicarboxylic acid and an aromatic diisocyanate. In order to produce a polyester polyurethane, the dicarboxylic acid is first reacted with a dihydroxy compound, and the resulting polyester is then reacted with the isocyanate to produce the polyurethane. T.F.H. argues that the limitation should have been construed to mean the two chemicals are simply "reacted in the course of forming a polyester polyurethane." We disagree.

The process a court follows in construing claims is well known from our precedent, and we will touch on it only briefly here. Claim terms are to be given their ordinary and accustomed meaning. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999). Dictionaries may serve as "reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art." Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002). The context of the surrounding words in a claim must be considered in determining the ordinary and customary meaning of a disputed claim limitation. Brookhill-Wilk 1, LLC, v. Intuitive Surgical, Inc., 326 F.3d 1215, 1220, 66 USPQ2d 1517, 1520 (Fed. Cir. 2003). The intrinsic record, comprising the claims, the specification, and the prosecution history if in evidence, "must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted." Tex. Digital Sys., 308 F.3d at 1204, 64 USPQ2d at 1819. A patentee may rebut this presumption by "defining claim terminology in a manner inconsistent with its ordinary meaning," Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1301, 57 USPQ2d 1813, 1816 (Fed. Cir. 2001), or by disclaiming a particular interpretation of a claim term during prosecution, Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 863, 20 USPQ2d 1252, 1262 (Fed. Cir. 1991).

T.F.H.'s argument is based on what it characterizes as the "plain meaning" of the claim limitation; it contends that the district court erred "by changing the actual words used from 'and' to 'directly with.'" We find T.F.H.'s purported recourse to the plain meaning of the limitation incongruous with the construction it seeks. T.F.H. maintains that the limitation embraces a series of reactions involving aliphatic dicarboxylic acid and aromatic diisocyanate, in the course of which those two ingredients are not directly reacted with each other. In other words, T.F.H. asserts that "the reaction of A and B" means "reactions involving A and B, but not the direct reaction of A with B." For the following reasons, the plain meaning of the limitation will not bear this interpretation.

T.F.H. focuses its attention on the single word "and" and provides us with general dictionary definitions indicating the word

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can mean both "as well as" and "together with." By focusing on the meaning of the single word "and," T.F.H. loses sight of the context in which it is used in the claim expression at issue. The context in which a word is used in a claim cannot be ignored in determining the ordinary and customary meaning of a claim limitation containing that word. See Brookhill-Wilk 1, 326 F.3d at 1220, 66 USPQ2d at 1520.

The claim limitation "a polyurethane elastomeric body formed by the reaction of aliphatic dicarboxylic acid and aromatic diisocyanate" describes a product formed by "the reaction of" the two chemical compounds recited. The unambiguous meaning of the words themselves--"the reaction of" A "and" B--precludes any construction that might embrace the presence of an intermediate compound or intervening step. Simply put, there can be no reaction of A and B if A reacts first with an intermediary to form a different compound that is then reacted with B. The dictionary definitions offered by T.F.H. in the abstract for the word "and" do not alter this conclusion. The claim thus necessarily covers the direct reaction of the recited two reactants: aliphatic dicarboxylic acid and aromatic diisocyanate. T.F.H. chose to employ these words and cannot argue that a proper construction requires us to ignore their plain meaning.

Neither does the intrinsic record support the construction T.F.H. advances. The record does not show that "the specification uses the words in a manner clearly inconsistent with the ordinary meaning." Tex. Digital Sys., 308 F.3d at 1204, 64 USPQ2d at 1819. Indeed, the specification describes the polyurethane in terms similar to those of the claim limitation itself: "the preferred polyurethane is a polyester polyurethane formed by the reaction of aliphatic polycarboxylic acids . . . and polyfunction isocyanates." '733 patent, col. 2, ll. 34-37. Neither does the specification "use words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Tex. Digital Sys., 308 F.3d at 1204, 64 USPQ2d at 1819.

III

T.F.H. notes that the written description of the '733 patent refers to "polyester polyurethane" as a preferred material. It is also undisputed that the direct reaction of an aliphatic dicarboxylic acid and an aromatic diisocyanate produces a polyamide, not a polyurethane. T.F.H. conceded at oral argument that the claims would be invalid if we were to affirm the district court's construction of the "formed by the reaction of" limitation to require a direct reaction of the two listed components. T.F.H. argues that the district court's construction cannot be sustained as it both excludes the preferred embodiment and renders the claims invalid.

It is true that "construing a claim to exclude a preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support.'" Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, __, __ USPQ2d __, __ (Fed. Cir. 2003) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1578 (Fed. Cir. 1996)). It is also true that where claims are amenable to more than one claim construction, courts should not adopt a construction that would render a claim invalid. Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1557, 37 USPQ2d 1609, 1617 (Fed. Cir. 1996). In this case, however, the ordinary meaning of the terms used, together with the intrinsic record, render the claim limitation susceptible to only one construction. Thus, we must conclude that this is "the rare case in which such an interpretation is compelled." Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1308, 54 USPQ2d 1910, 1914 (Fed. Cir. 2000). Moreover, we are unwilling to adopt T.F.H.'s reading of the claim limitation simply to save it from its injudicious word choices. To do so, we would have to rewrite the claim limitation to cover a series of reactions involving aliphatic dicarboxylic acid and aromatic diisocyanate, in the course of which those two ingredients are not directly reacted with each other. We may not rewrite claims to preserve validity in this manner. Rhine v. Casio, Inc., 183 F.3d 1342, 1345, 51 USPQ2d 1377, 1379 (Fed. Cir. 1999); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584, 36 USPQ2d 1162, 1168 (Fed. Cir. 1995) ("Although we construe claims, if possible, so as to sustain their validity, it is well settled that . . . courts do not redraft claims." (citations omitted)).

IV

For the foregoing reasons, we hold that the district court did not err in construing "a polyurethane elastomeric body formed by the reaction of aliphatic dicarboxylic acid and aromatic diisocyanate" to mean that "the polyurethane must be formed by the reaction of an aliphatic dicarboxylic acid directly with an aromatic diisocyanate." Based on T.F.H.'s concession at oral argument, we hold all claims of the '733 patent invalid under 35 U.S.C. § 112, paragraph 2, for failure to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 (2000). In light of our holdings, T.F.H.'s other claim construction arguments are moot, and we decline to address them. We accordingly

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affirm the district court's dismissal of T.F.H.'s Complaint.
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b. "formed on"

The parties dispute whether the claim language requires that each successive layer be "formed on" the prior layer in such a way that nothing is interposed between each layer. As described above, however, the court has determined that the claim language and the specification permit the presence of interlayers between layers. Notably, the claim does not state that each layer is "formed directly on" the preceding layer. Accordingly, we determine that "formed on" does not mean "directly in contact with."
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6. The fractions

Next, Plaintiff disputes Defendants' proposed instructions regarding the meaning of the terms "a rest molasses fraction," "a betaine fraction," and "a sucrose fraction." Defendants advocate definitions of the terms that include purity ranges. For example, Defendants submit that "a sucrose fraction" means "a product fraction that is substantially separate from the other two fractions…and from all other components in the beet molasses. Its purity on a dry solids basis would vary from about 80 % to about 95 % sucrose when using beet molasses containing about 60 % of sucrose and 4.5 % of betaine on a dry solids basis. (Joint Stmt. p. 10). For support of this interpretation, Defendants refer to the specification wherein the purity ranges of the fractions are described. (DTX 2, Col. 5./ln. 50-68; Hearing Tpt. p. 233). The court agrees with Plaintiff that the terms as described in the claim language do not need to be defined with purity ranges.

First, the language in the specification that Defendants refer to for support does not require that each product fraction to have a certain purity range. For example, the specification states "the sucrose content of the sucrose fraction obtained by the method of the present invention may vary from about 80% to about 95% … These values, however, do not represent actual limits of the performance of the new methods; they are mere examples…" (DTX 2, Col.5/ln. 50-60). Moreover, the Federal Circuit has stated that "ordinarily a claim element that is claimed in general descriptive words, where a numerical range appears in the specification and in other claims, is not limited to the numbers in the specification or other claims." Specialty Composites, 845 F.2d at 987.

In the present case, the claim language describes the terms in general descriptive words. When numerical ranges are described in the specification, they are not constructed as limits but as examples. Accordingly, the court construes the three terms in dispute as follows: "a rest molasses fraction" means "a product fraction that is separate from the other two fractions (the sucrose fraction and betaine fraction);" "a betaine fraction" means "a product fraction that is substantially separate from the other two fractions (the sucrose fraction and the rest molasses fraction);" and "a sucrose fraction" means "a product fraction that is substantially separate from the other two fractions (the betaine fraction and the rest molasses fraction). (Joint Stmt. pp. 9-10).
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H. "being free flowing to an extent of at least 10 times greater than in powder form"

1. The Parties' Proposed Constructions

Rhodia asserts that PPG does "not directly dispute Rhodia's construction" of "being free flowing to an extent of at least 10 times greater than in powder form". (D.I. 108 at 17.) Instead, Rhodia maintains that PPG's contention with respect to the phrase centers on the language "free-flowing" and "powder form". (Id.) Rhodia asserts further that "the '234 patent defines a test for flowability." (Id. at 18.) That test, argues Rhodia, establishes that the meaning of the contested language is "a

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relative time for the precipitated silica particulates to flow through an aperature [sic] under vibration." (Id. (citing '234 Patent at col. 4 ll. 29-34).) Therefore, Rhodia asserts that "claim 9 calls for a flow of at least ten times less than the time it takes silica powder to pass through the same aperature [sic] under the same vibration." (Id.)

Similarly, PPG contends that the term "flowability" in the phrase should be construed consistently with the disclosure provided in the '234 patent written description. (D.I. 106 at 23.) Specifically, PPG asserts that flowability should be "'defined herein … as the time required for the product to flow into appropriate receptacle having a calibrated aperture while under slight vibration.'" (Id. (quoting '234 Patent at col. 4 II. 29-31).) Therefore, suggests PPG, the phrase should be construed in claim 9 "to mean that the silica particulates have a flowability as measured by the cited test that is 10 times better than the measured flowability of the particulates when milled into a powder form." (Id. at 24.)

2. The Court's Construction

I construe the phrase "being free flowing to an extent of at least 10 times greater than in powder form" to mean that the silica particulates of the '234 patent flow into an appropriate receptacle having a calibrated aperture while under slight vibration to an extent of at least 10 times greater than does silica in powder form. In other words, "flowability" is defined in accordance with the test provided by the inventors in the '234 patent written description.

The parties cite the same portion of the '234 patent written description as the appropriate source for determining the meaning of the phrase "being free flowing to an extent of at least 10 times greater than in powder form". That portion of the '234 patent written description provides as follows: "Flowability as defined herein is determined as the time required for the product to flow into appropriate receptable having a calibrated aperture while under slight vibration." (D.I. 1, '234 Patent at col. 4 II. 29-31.) This disclosure informs those of ordinary skill in the art as to the meaning of "being free flowing to an extent of at least 10 times greater than in powder form", as that phrase is used in the patent.
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C. "FREE FROM" ('939 PATENT).

King proposes that the phrase "an opioid antagonist composition . . . free from an opioid agonist" in claims 1 and 2 of the '939 patent be construed as "a multilayered particle containing opioid antagonist and completely free of opioid agonist at all times." (Pls.' '939 Opening Markman Br. 14.) Purdue, on the other hand, argues that it should mean simply, "the opioid antagonist composition does not contain an opioid agonist." (Def.'s '939 Opening Cl. Constr. Br. 4.) I find King's interpretation is without merit.

First, there is no basis for including the phrase "at all times." The text of claims 1 and 2 describe the opioid antagonist composition as "comprising an inert core, a first layerand a second layer" and that "the composition is free from an opioid agonist." '939 patent, col. 52, ll. 22-23, 39-40. Thus, there is no question that the entire antagonist composition -- the inert core, the first layer, and the second layer -- is "free from" any opioid agonist. However, King asserts that "free from" covers more than just these three parts of the antagonist composition. King admits that the antagonist particles can be "interdispersed with agonist-containing particles" in a dosage form but argues that when the antagonist composition is combined in dosage form with an agonist, "the agonist and antagonist must be contained in separate particles." (Pls.' '939 Opening Markman Br. 20.) I do not agree with this limitation.

Nothing in the claims or the specification supports such a requirement. Over a dozen of the remaining twenty-two claims state the opioid antagonist composition is to be combined with opioid agonists to create working dosage forms of opioid analgesics, and none of them imply that the two must be in separate particles. Several claims require that the opioid agonist and antagonist must be separated by the second layer of the composition, the hydrophobic material,but notably, they do not add that the agonist and antagonist are in different particles when separated. See, e.g., '939 patent, col. 52, ll. 61-64, ("An oral dosage form comprising an opioid agonist and the opioid antagonist composition of claim 1, wherein the hydrophobic material separates the opioid antagonist from the opioid agonist."); id., col. 53, ll. 24-29 (same). Additionally, the specification states broadly, "Once the opioid antagonist in a substantially non-releasable form is prepared, it may be combined with an opioid agonist, along with conventional excipients known in the art, to prepare the oral dosage form of the present invention." ('939 patent, col. 20, ll. 64-67.)

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There is also nothing that King points to in the prosecution history that supports its position that "at all times" should be part of the definition of "free from." The inventors wrote to the patent examiner, "Applicants respectfully submit that because the claims [1 and 2] explicitly recite a disclaimer that 'the opioid antagonist composition is free from an opioid agonist,' the claims make it clear that opioid agonists are not part of the opioid antagonist compositions of claims [1] and [2]." (Pls.' '939Opening Markman Br., Ex. 13 at 11.) King asserts that this implies that the opioid agonist must be in separate particles. However, that is a strained reading of the statement, and I find the statement actually conveys a meaning of "free from" closely analogous to the definition Purdue presently puts forth.

Also, King's proposal to define opioid antagonist composition as a multilayered particle containing opioid antagonist is unnecessary, as the composition is defined fully, and more accurately, by claims 1 and 2. King's clarification of the phrase "free from" to "completely free of" seems even less necessary as the modifier "completely" is redundant. If the inventors intended "completely free of," they could have used that phrase just as easily, but they chose "free from."

Purdue's definition on the other hand conveys the customary and ordinary meaning of "free from," and it is supported by the claims, specification, and prosecution history of the '939 patent. Therefore, I accept its definition and construe "free from" as "does not contain."
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A. Claim Construction

1. The parties at bar argue that the phrase "ripe human growth hormone" requires a protein having the same amino acid sequence as hGH produced by the pituitary gland. (D.I. 202 at 5) Plaintiffs argue that the phrase also requires that the hGH be biologically active and substantially pure. In response, defendants assert that neither the intrinsic nor extrinsic evidence imposes either of the latter two limitations.

2. Claim construction is question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc).

3. In interpreting the claims, a court should begin with the intrinsic evidence of record (i.e., the patent itself, including the claims, the specification, and the prosecution history). Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Id.

4. First, a court should look to words of the claims themselves to define the scope of the patented invention. Id. There is a heavy presumption that the claim terms carry their ordinary and customary meanings as would be understood by one of ordinary skill in the art. Markman, 52 F.3d at 986. Put differently, the court must determine how a person of experience in the field of this invention would, upon reading the patent documents, understand the words used to define the invention. Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Dictionaries and scientific treatises may help to supply the pertinent context and usage for claim construction. Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201, 1202 (Fed. Cir. 2002).

5. Second, because a patentee may choose to be his own lexicographer and use a term in a manner either more or less expansive than its general usage in the relevant art, the court also should review the specification to determine whether an inventor has used any term in a manner other than its ordinary meaning. Vitronics, 90 F.3d at 1582. The specification may act as a dictionary when it either expressly defines terms used in the claims or when it defines terms by implication. Id.

6. Third, a court may consider the prosecution history of a patent, if in evidence. Id. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id. (quoting Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)). That is, a court must look to the prosecution history to determine if the patentee has limited the scope of the claims by disclaiming a particular interpretation during prosecution. Biodex Corp. v. Loredan Biomed, Inc., 946 F.2d 850, 862 (Fed. Cir. 1991).

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7. Additionally, if the meaning of a term is not clear from the intrinsic evidence, then a court may consult extrinsic evidence, such as expert testimony, in construing claim terms as they would be understood in the relevant art. Markman, 52 F.3d at 980-81.

8. When construing the claims, courts must take great care to avoid importing unnecessary limitations into the claims from the specification. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003). "If we once begin to include elements not mentioned in the claim in order to limit such claim . . . we should never know where to stop." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (quoting McCarty v. Lehigh Val. R.R., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240, 1895 Dec. Comm'r Pat. 721 (1895)). Nevertheless, a court should look to the specification to determine whether it refers to a limitation only as a part of less than all possible embodiments or whether it suggests that the very character of the invention requires the limitation be a part of every embodiment. It is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002). On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345 (Fed. Cir. 2001).

9. After reviewing the language of claim 1 (i.e., biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone) in accordance with the above principles of claim construction, the court construes this claim to mean a protein produced by recombinant DNA techniques composed of a 191 amino acid sequence identical to that of hGH produced by the human pituitary gland with the full biological activity of hGH produced by the human pituitary gland, and free of the contaminants present in hGH produced by the human pituitary gland.

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E. 'FREE OF PORE-FORMING AGENT"

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Free of Pore-Forming Agent	"Free of pore-forming agent" means lacking a particulate non-polymeric water soluble species capable of being eluted from a coating to form a pore therein.	"Free of pore-forming agent" means the tablet does not contain a substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.	"Free of pore-forming agent" means the tablet does not contain a non-polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.

The background of the invention states:

U.Pat. No. 4,687,660 (the '"660 patent") and EP-A 017457 (the '"457 patent") disclose a tablet formed of a core and a coating, where the core comprises bupropion hydrochloride together with excipients(a) and optionally as osmotic enhancing agent and where the coating compromises a water-insoluble, water-permeable film-forming polymer (such as cellulose acetate), a pore-forming agent (such as impalpable lactose and sodium carbonate), and optionally a so-called water-permeability enhancing agent (such as polyethyleneglycol) and again optionally a plasticizer.

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(Ex. 1, Col. 1:28-36; emphasis provided)

The summary of the invention indicates that the '341 patent is "free of (monomoeric) pore-forming agent." (Ex. 1, Col. 1:57-58.)

Biovail asserts two reasons for adopting its narrower construction which would exclude polymeric water soluble species from the claimed scope of pore-forming agents. First, it looks to the discussion of prior art. Second, it asserts that a construction which failed to exclude polymeric water soluble species would render each of the examples of preferred embodiment outside the scope of the patent. The Court does not find the first argument persuasive, but does find that second argument is persuasive and controlling, particularly in light of the discussion of prior art in the patent.

Prior Art.

Biovail contends that the term "pore-forming agent" is defined by reference to certain prior art references in existence at the time of the filing of the '341 patent, and that those definitions apply to this term. (Biovail's Preliminary Claim Construction, p. 18.) Specifically, Biovail asserts that one skilled in the art would look to the '660 patent and the '457 application, in addition to the '341 patent specification, to comprehend the meaning of the term "pore-forming agent." (Id., p. 16.)

Biovail further contends that the '660 patent provides that a "pore-forming agent" is a particulate, non-polymeric, water soluble species. (JEM Decl., Ex. T, Ex. U.) In addition, Biovail asserts that the '457 application discloses a pharmaceutical composition comprising a formulation containing a water-soluble active ingredient, a semipermeable membrane surrounding the formulation, "and a particulate water-soluble pore-forming material dispersed within the membrane, whereby, in use in an aqueous environment, the pore forming material is dissolved forming pores in the semipermeable membrane . . ." (Response to Anchen's Opening Claim Construction, Ex. E, p. 2, P 2.)

Anchen points out that while Biovail relies on the '660 patent, the term in the '660 documents is "particulate, water-soluble, pore-forming material," and not a "pore-forming agent." (JEM Decl., Ex. T, '660 patent, Claim 1; Ex. U, '457 patent, Claim 1.) Anchen contends that while a "particulate, water-soluble, pore-forming material" would be a pore-forming agent, the two terms are not co-extensive. (Anchen's Opening Claim Construction Brief, p. 19.) Anchen states that "[t]he use of the more precise phrase 'particulate, water-soluble, pore-forming materials,' in the prior art patents establishes that the unlimited term 'pore-forming agent' in the '341 patent is not restricted to 'particulate non-polymeric species.'" (Id.) Anchen concludes that if the applicant of the '341 patent wanted to limit the disclaimer of the pore-forming species to a narrow class of particulate non-polymeric materials, the applicant could have done so by using BiovaiPs proposed definitions. (Id.)

Anchen further points out that Dr. Williams has admitted that the '341 patent does not state anywhere that it is incorporating by reference the definition of pore-forming agent in the '660 patent. (DJM Decl., Ex. W, 108:8-15.)

The state of knowledge generally at the time would not lead to the conclusion that polymers should be excluded. Anchen points out that Dr. Williams admitted that in 1998 a person of ordinary skill in the art would have known that water-soluble polymers could be used as pore-forming agents. (DJM Decl., Ex. W, 107:7-20.) Anchen explains that formulators often add a water-soluble component to the coating mixture to increase the permeability of the film, and therefore increase the release rate. (JEM Decl., Ex. F, Pharmaceutical Dosage Forms at 216-17.) Anchen shows that the use of water-soluble additives to create pores in water-insoluble polymeric coatings was a' well-established method of increasing the rate of drug release through the coating. (Anchen's Opening Claim Construction Brief, p. 17; JEM Decl., Ex. F.)

At least standing alone, the discussion in the '457 and '660 patents does not support the limitation for which Biovail argues. The Court rejects the incorporation notion for same reason it rejected similar arguments in interpreting the term "free of stabilizer."

Exclusion of Preferred Embodiment.

Biovail argues that because povidone, a pore-forming agent, is included in each of the patent's preferred embodiments, none of the examples would be covered by Claim 30. (Response to Anchen's Opening Claim Construction, p. 15.) Anchen's own showing establishes that water-soluble polymers, including polyvinyl pyrrolidone ("povidone" or "PVP"), and polyethylene

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glycol ("PEG"), are known pore-forming agents. (JEM Decl., Ex. F, Pharmaceutical Dosage Forms at 216-17.)

Each of the 11 examples in the '341 patent includes the following ingredient in the coating: Kollidon 90F (povidone USP). As a general rule, a claim construction is unlikely to be correct if it excludes the preferred embodiments. Amgen Inc. v. Hoechst Marion Roussel, INC., 314 F.3d 1313, 1349 (Fed. Cir. 2003), and cases cited by Biovail in its Post-Hearing Claim Construction Submission, pp. 2-3.) Anchen, however, counters that '341 patent provides examples and claims coatings using ethylcellulose, PVP, and PEG. That not does erase the point that all 11 examples also include povidone.

To be sure, the case law will entertain constructions which exclude some preferred embodiments. For example, when the claims are narrowed during the prosecution process, the narrowing may remove a preferred embodiments from the scope of the claim in the patent as issued. North American Container, Inc. v. Plastipak, Inc., 415 F.3d 1335, 1346 (Fed. Cir. 2005); Elekta Instrument S.A. v. O.U.R. Scientific International, Inc., 214 F.3d 1302, 1308 (Fed. Cir. 2000). However, that is not this case.

In this context, it is difficult to believe that one skilled in art reading the patent would not give particular weight to the statement that the invention was "free of (monomeric) pore-forming agent[s]." (Ex. 1, col. 1:58.) While the claim 30 might have been drafted with greater clarity, the Court cannot say that the totality of the patent did not put one skilled in the art on notice that a narrowed definition of pore-forming agent was being claimed.

Accordingly, the Court adopts a modified version Biovail's proposed construction.
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C. "Free of Pore-Forming Agent"

The parties also disagree on the proper construction of the term "free of pore-forming agent" in claim 30. Biovail asserts that it means "lacking a particulate monomeric water soluble species capable of being eluted from a coating to form a pore therein." (Biovail Opening Br. at 3.) Impax claims that it means "wherein the tablet lacks a monomeric water-soluble species capable of being eluted from a coating to form minute openings or interstices in the barrier membrane to enhance diffusion through the coating." (Impax Opening Br. at 35.) The central disputes between the parties over this term are: (1) whether the "pore-forming material" that the invention must be "free of" must be "particulate" (Biovail's position), (2) whether "pores" should be further defined as "minute openings or interstices in the barrier membrane" (Impax's position) and (3) whether the additional phrase "to enhance diffusion through the coating" is necessary (Impax's position).

The word "particulate" appears nowhere in the '341 patent. However, Biovail supports its assertion that the "pore forming material" must be "particulate" by pointing to two prior art references cited in the "Background of the Invention" section of the '341 patent, U.S. Pat. No. 4,687,660 ("the '660 patent") and European Published Patent Application No. EP-A-0171457 ("the '457 application"), as well as to U.S. Pat. No. 4,769,027 ("the '027 patent"), which was discussed in the '341 patent's prosecution history. According to Biovail, because the patentee referred to these prior art references in the specification and prosecution history in connection with the term "pore-forming agent," and because they involve pore-forming material that is particulate, one skilled in the art would look to these references to determine that "pore-forming agent" necessarily means a particulate substance. It is true that "prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence," which a court can consider along with the patent's claims themselves, the specification, and the prosecution history in defining a claim term. Kumar v. Ovonic Battery Co., Inc., 351 F.3d 1364, 1368 (Fed. Cir. 2003). However, the prior art references on which Biovail relies do not provide definitions of the term "pore-forming agent," but merely limit the type of pore-forming material to be used in their respective inventions. For instance, the '660 patent and the '027 patent both involve a pore-forming agent and state that "the pore-forming agent must be particulate in nature, with a maximum particle size preferably not exceeding about 500 :m . . . ." ('660 patent, Col. 4, lns. 28-30; '027 patent, col. 4, lns. 62-64.) Similarly, the '457 application states that "[t]he particulate water-soluble pore-forming material of use in the composition of the present invention, preferably, has a maximum particle size not exceeding 500 :m . . . ." ('457 application at 5, P2.) This is the language of limitation, not definition. Moreover, as Impax points out, the fact that the adjective "particulate" is used to modify "pore-forming material" in the '457 application would seem to indicate that in general, pore-forming agent may be either particulate or non-particulate. n20

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n20 Biovail agrees that "pore-forming agent" and "pore-forming material" are used interchangeably in these prior art references. (Biovail Resp. Br. at 25.)

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Furthermore, to conclude that the pore-forming agent must be "particulate" would be to say that a tablet need not actually be "free of pore-forming agent" to fall within the scope of claim 30. Under Biovail's construction, claim 30 covers tablets that are not free of pore-forming agent, so long as the pore-forming agent they include is not particulate in nature. The patentee knew how to include express limitations on what could be considered "pore-forming agent" for purposes of the '341 patent: for instance, he noted that the tablet's semi-permeable release coating was to be "free of (monomeric) pore-forming agent." (Col. 1, ln. 58.) The Anchen court, agreeing with Biovail that "free of pore-forming agent" as used in the '341 patent did not mean free of polymeric pore-forming agent, noted that "it is difficult to believe that one skilled in [the] art reading the patent would not give particular weight to the statement that the invention was 'free of (monomeric) pore-forming agent." Anchen, at 18. In the absence of a similarly express statement that "pore-forming agent" is limited to "particulate" matter, I must give the phrase "free of pore-forming agent" its ordinary and accustomed meaning. As noted above, the ordinary English meaning of the phrase "free of" is simply "not having or using" or "lacking." Webster's at 905.

With respect to polymeric pore-forming agent, it can be said that the patentee acted as his own lexicographer in the specification, explicitly carving out polymeric water-soluble species from the definition of "pore-forming agent." The same cannot be said with respect to non-particulate pore-forming agent. Thus, I reject Biovail's argument insofar as it would interpret the '341 patent to cover tablets containing monomeric pore-forming agents so long as these pore-forming agents are not "particulate," contrary to the specification's directive that the invention described in claim 30 is free of pore-forming agent. However, I also reject Impax's attempts to add elements to the definition of "free of pore-forming agent" that are not reflected in the intrinsic evidence. The '341 patent speaks nowhere of a "barrier membrane," nor does it define "pore-forming agent" as a substance meant "to enhance diffusion through the coating."

Finally, as with "stabilizer," I see no reason to deviate from the ordinary and accustomed meaning of "pore." Biovail faults Impax for relying on dictionary definitions of "pore," but does not suggest its own definition of the word. Because I do not believe the term "pore" is entirely self-defining in this context, I turn to technical and general dictionaries for insight into the term's ordinary and accustomed meaning. See Vitronics, 90 F.3d at 1584 n.6 (court "may . . . rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents"). Hawley's Chemical Dictionary provides, as one definition of "pore": "A void or interstice between particles of a solid such as sand minerals or powdered metals, that permits passage of liquids or gases through the material in either direction." Hawley's at 910. As "void" and "interstice" are somewhat nebulous ways of defining "pore," I turn also to Webster's Dictionary, which provides, as one meaning of "pore," "a minute opening . . . by which matter passes through a membrane." Webster's at 1766.

I therefore adopt a modified version of Impax's proposed construction of "free of pore-forming agent," a similar version of which was approved by the Central District of California in the Anchen litigation: "lacking a monomeric water-soluble species capable of being eluted from a coating to form minute openings that permit the passage of liquids or gases in either direction."

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Claim 1 provides that the "core" of the tablet be "free of stabilizer," and Claim 30 requires that the "tablet" be "free of stabilizer."

The term "free of is a "negative limitation," which defines the claimed invention by what it is not. See generally Upsher-Smith Labs., Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1321-23 (Fed. Cir. 2005).

The background of the invention states:

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As bupropion hydrochloride is unstable, the product described in the above two patents [U.S. Patent Nos. 5,358,970 (the "'970 patent") and 5,427,798 (the "'798 patent")] requires a stabilizer to achieve sufficient stability. This stabilizer is an acidic compound, preferably cysteine hydrochloride.

(Ex. 1, Col. 1, 24-27; emphasis provided)

The summary of the invention states, "[t]he invention thus provides a new bupropion hydrochloride controlled release composition under the form of a tablet free of stabilizer of any kind including those with acidic pH or with antioxidant properties." (Ex. 1, Col. 1:55-56; emphasis provided)

Biovail contends that the term "stabilizer" is defined by reference to certain prior art references in existence at the time of the filing of the '341 patent, specifically the '970 patent and the '798 patent, and that those definitions apply to this term. (Biovail's Preliminary Claim Construction, p. 18.)

Biovail argues that based on the '341 patent specification and the patents cited in the background section of the '341 patent, a person who is skilled in the art would understand free of stabilizer to mean: "lacking an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or liquid under ambient conditions." (Williams Decl., P 14.)

Biovail asserts that "all of the examples of stabilizers contained in the '341 patent, the '970 patent and the '798 patent are organic or inorganic acids that exist as solids or liquids under ambient conditions." (Williams Decl., P 13; Ex. 1, Col. 1:24-25.)

Moreover, Biovail avers that by virtue of the specific disclosure of the '970 patent, "it is clear that a core is free of stabilizer when there is not sufficient stabilizer in the core to stabilize bupropion hydrochloride. Thus, when there is no measurable amount of stabilizer in the core, it is, by definition, 'free of stabilizer.'" (Response to Anchen's Opening Claim Construction Brief, p. 8.)

Anchen contends that the terms "free of and "stabilizer" are not ambiguous, and therefore there should be no genuine dispute concerning the ordinary meaning of the phrase "free of stabilizer." (Anchen's Opening Claim Construction, p. 11.)

Anchen avers that "free of" is not a term that has a special meaning within the context of pharmaceuticals, and therefore should be defined in a way that is consistent with its ordinary English meaning: "not united with or not present as an element in other substances," "chemically uncombined or readily obtained in an uncombined form." (JEM Decl., Ex. I, Webster's Third New Int'l Dict, of the English Language Unabrid., 904-05 (1981).

Further, Anchen claims that the word "stabilizer" is a concept well understood in the pharmaceutical art as something that may provide stability. (Anchen's Opening Claim Construction Brief, pp. 7, 11.) "The term 'stability,' with respect to a drug dosage form refers to the chemical and physical integrity of the dosage unit, and when appropriate, the ability of the dosage unit to maintain protection against microbiological contamination." (United States Pharmacopeia-National Formulary ("USP"); JEM, Decl., Ex. H at 1940.)

Anchen avers that its proposed ordinary meaning of the term "free of stabilizer" is supported by and consistent with the specification of the '341 patent, and specifically the summary of the invention. As Anchen stresses, the summary of the invention informs the public that the claimed invention is "free of stabilizer of any kind." (Ex. 1, Col. 1:55-56.)

However, Biovail avers that Anchen's reliance on Webster's has been rejected by the Federal Circuit in Phillips. The Court finds that Biovail's interpretation of Phillips is misplaced. In Phillips, the court held that when the ordinary meaning of claim language, as understood by a person of skill in the art is readily apparent even to lay judges, and claim constructions involves little more than the application of the widely accepted meaning of commonly understood words, then general purpose dictionaries may be helpful. 415 F.3d at 1314. Hence the Court finds that Anchen's reliance on Webster's dictionary is proper in this case.

Further as Anchen points out, Biovail's expert, Dr. Williams, admitted that a person of skill in the art would consider the USP to be a "reliable authority," (11/22/05 Decl. of Don J. Mizerk ("DJM Decl."), Ex. W (11/15/05 Williams Depo.) at

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70:13-16) and that the USP is the "first place to go" to determine stability parameters. (Id. at 84:7-20.)

Moreover, as Anchen points out Dr. Williams admitted that a person of skill in the art in 1998 who was not aware of the '341 patent would agree with Anchen's proposed definition of the phrase "free of stabilizer." (Id. at 72:25-73:19.) However, the Court notes that Dr. Williams then stated that one of ordinary skill in the art would have been narrowed in the definition of the stabilizer because of the discussion in the background section and the content of the two patents that are discussed there. (Id. at 74:11-17.)

The Court, however, does not find that the discussion in the background section nor the content of the two patents narrows the definition of the claim.

Finally, as Dr. Williams admitted that a certain substance would be in the definition of stabilizer. (Id. at 74:7-10.)

Anchen avers that Biovail has not overcome the heavy presumption in favor of a claim term's ordinary meaning, and that the '341 patent does not incorporate patents '970 and '798. "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282-83 (Fed. Cir. 2000). As Anchen points out, there is nothing in the '341 patent specification that expressly incorporates both of those two patents.

Further, Dr. Williams admits that the '341 patent does not explicitly incorporate any definition of the term 'stabilizer' from the '970 or '798 patents. (DIM Decl., Ex. W at 76:16-77:3.) Importantly, Biovail's proposed definition of "stabilizer" is not found anywhere in the '341 patent, and actually contradicts the summary of the invention.

In addition, the Court does not find that the patentee has acted as his own lexicographer merely by mentioning the '970 or '798 patents in the background of the invention. The Court does not find that the patentee has set out a different meaning in the specification in a manner sufficient to provide notice of the meaning to a person of ordinary skill in the art. In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

For the foregoing reasons the Court finds that Anchen's proposed construction follows the directives in Phillips, However, the Court does not find that it is necessary to construe the term "free of."
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B. "Free of Stabilizer"

The parties also disagree on the proper construction of the term "free of stabilizer" in claims 1 and 30 of the '341 patent. n19 Biovail asserts that "free of stabilizer" means "that the core and tablet lack an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or liquid under ambient conditions." (Biovail Opening Br. at 3.) Impax claims that "free of stabilizer" means "wherein the core (claim 1) or the tablet (claim 30) is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." (Impax Opening Br. at 31.) The central disputes between the parties over this term are: (1) whether the invention must be completely free of stabilizer (Impax's position) or need only "lack an effective stabilizing amount" of a stabilizer (Biovail's position), (2) whether the stabilizer must be either an organic or inorganic acid (Biovail's position), (3) whether the stabilizer must exist as a solid or liquid under ambient conditions (Biovail's position), and (4) whether a "stabilizer" is properly defined as a "substance or agent that tends to prevent changes to the chemical integrity of the tablet" (Impax's position).

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n19 "Free of stabilizer" and "free of pore-forming agent" in the '341 patent are both "negative limitations" that define the claimed invention by what it is not. See Upsher-Smith Labs., Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1321-23 (Fed. Cir. 2005). Thus, a narrower construction of these limiting terms results in a broader construction of the claim and vice versa.

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Biovail contends that "free of stabilizer" means "lacking an effective stabilizing amount" of stabilizer. This argument must be rejected. As the Central District of California recognized in the related Anchen litigation, the specification of the '341 patent explicitly provides that the invention is "free of stabilizer of any kind." (Col. 1 line 55.) The specification is "the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315. Biovail argues that if a stabilizer were not present in the invention in an amount sufficient to stabilize the tablet, then it would not really be acting as a "stabilizer," and the tablet would still be "free of stabilizer." While this argument may be of philosophical interest, it does not comport with the ordinary and accustomed meaning of "free of stabilizer." When construing a claim involves "application of the widely accepted meaning of commonly understood words," general purpose dictionaries may prove helpful in determining a term's ordinary and accustomed meaning. Phillips, 415 F.3d at 1314. As the Anchen court noted, there is no reason not to apply the ordinary English meaning of "free of" when construing "free of stabilizer": "not having or using"; "lacking." Webster's Third New Int'l Dict. of the English Language Unabrid. 905 (1993) (hereinafter "Webster's"). If the tablet did in fact contain a compound used for stabilizing the tablet, but simply not enough of it, one would not call it "free of stabilizer," but rather "lacking sufficient stabilizer." Nor is this a case where the patentee acted as his own lexicographer in the specification to define "free of," contrary to its ordinary and accustomed meaning, as "lacking an effective amount of." In light of the specification's clear statement that the claimed invention is "free of stabilizer of any kind," I must reject Biovail's proposed construction of "free of stabilizer."

For the same reason, I reject Biovail's arguments that "free of stabilizer" means free of stabilizers that are organic or inorganic acids and are solids or liquids under ambient conditions. Such constructions would interpret the '341 patent to cover tablets containing stabilizers that are not organic or inorganic acids, or are not solids or liquids under ambient conditions, contrary to the specification's directive that the invention is free of stabilizer of any kind.

Because a specialized meaning for "stabilizer" in the '341 patent is not suggested by the claims, the specification, or the prosecution history, I see no reason not to construe "stabilizer" according to its ordinary and accustomed meaning. The Federal Circuit has noted that technical dictionaries can be of use to a court in determining the meaning of claim terms to one of ordinary skill in the art. See Phillips, 415 F.3d at 1318 ("We have especially noted the help that technical dictionaries may provide to a court to better understand the underlying technology and the way in which one of skill in the art might use the claim terms.") (citations omitted). Hawley's Chemical Dictionary defines "stabilizer" as "[a]ny substance that tends to keep a compound, mixture, or solution from changing its form or chemical nature." Hawley's Condensed Chemical Dictionary 1042 (13th ed. 1997) (hereinafter "Hawley's").

For these reasons, I construe "free of stabilizer" in claims 1 and 30 of the '341 patent to mean "lacking any substance or agent that tends to prevent bupropion hydrochloride from changing its form or chemical nature."

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2. Friable Reaction Product

During the Sevenson litigation, Sevenson sought a construction of "friable" that would require the reaction product be dry. The court rejected Sevenson's proposed construction, finding it was not supported by the claims or the specification. Instead, the court construed the term "friable" to mean "easily crumbled, pulverized, or reduced to powder." This construction was taken from Webster's Third New International Dictionary, 910 (1986). Sevenson did not appeal the court's construction of "friable."

All three defendants argue that during the post-Sevenson reexamination, Manchak argued to the PTO that the reaction product created by his invention must be processed into a "dry state." Therefore, those defendants seek to have "friable" construed to mean "dry," among the other components of its definition.

In the Patent Owner's Response to the Office Action in Reexamination, Manchak repeatedly used the word "dry" to describe Fryklind's reaction product. For example, in explaining how Fryklind is distinguished by its use of an external heat source, Manchak stated "'an outer heat supply' is added to make it possible to control the dryness of the night soil." However, Manchak also used "dry" to describe the reaction product of the '003 patent on at least two occasions. For example, he stated "Fryklind describes . . ., but does not describe using a rate of longitudinal movement that will allow the exothermic reaction to reduce the mixture to a dry solid reaction product by the time it has reached the end of the confined space." (emphasis

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added). Because his reference to the rate of longitudinal movement was a reference to the workings of the '003 patent, Manchak described the '003 patent's reaction product as dry. In the later Request for Reconsideration and Record of Interview, Manchak again referred to the dryness of the '003 patent's reaction product. He stated that "there is no suggested in Fryklind for relating the rate of movement of the mixture through the confined space to the exothermic reaction in such a way that the mixture would be transformed to a dry or friable condition by the time the reaction product reached the second end." (emphasis added).

Manchak argues that the term "dry" was used to distinguish the Fryklind patent because Fryklind repeatedly uses that word to describe the reaction product of his process. While that is true, it is nonetheless evident from the cited quotations that Manchak also described the reaction product of the '003 patent as "dry" or "dry or friable." Dry and friable are related terms. As the court noted in its prior opinion, "friable" describes how an item reacts with another force; it is "easily crumbled, pulverized or reduced to powder." "Dry," on the other hand, is defined as "free or relatively free of liquid." Webster's Ninth New Collegiate Dictionary 386 (1991). Thus, while "dry" describes a particular characteristic of the substance, "friable" is a functional adjective explaining how it reacts when acted upon. It is undisputed that the relative dryness of a substance effects how friable it is, but the two terms nonetheless describe different characteristics of the substance.

Generally, the prosecution history of a patent aids the construction of a claim term when the examiner and patentee have an exchange relating to a claim's meaning. Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998) ("The prosecution history is relevant because it may contain contemporaneous exchanges between the patent applicant and the PTO about what the claims mean."). The prosecution history can also "limit[] the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995). In this case, the exchanges between the PTO and Manchak did not relate to the construction of the term "friable," but were instead directed to other claimed distinctions between the patents. Nor did Manchak limit the construction of "friable" by disclaiming any particular construction of that term.

Manchak merely used the adjective "dry," in conjunction with "friable," to characterize the reaction product of the '003 patent. This is not the type of "definitive statement" on which the public would rely in reviewing the '003 patent. Digital Biometrics, Inc., 149 F.3d at 1347 (noting the public has a right to rely on definitive statements construing claim terms made during prosecution). Not every adjective used in characterizing a claim element must necessarily become part of the claim itself. Instead, the court's focus must remain on the claim language itself. Thermalloy, Inc. v. Aavid Eng'g, Inc., 121 F.3d 691, 693 (Fed. Cir.1997) ("Nonetheless, throughout the interpretation process, the focus remains on the meaning of claim language."). In this case, Manchak chose to use the term "friable" to describe his reaction product. While the adjective "dry" is related to "friable," the reexamination history of the '003 patent does not require that "friable" be construed to have the special meaning "dry." Therefore, the court will adhere to its earlier construction of friable -- "easily crumbled, pulverized, or reduced to powder."

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2. Average particle size/diameter of from about 2 to about 10 microns

The term "an average particle size of from about 2 to about 10 microns" appears in claims 7 and 8 of the '540 Patent and claim 6 of the '972 Patent. Claim 8 of the '540 Patent, quoted above, provides an example of the term's use. The term "an average particle diameter of from about 2 to about 10 microns" appears in claim 9 of the '540 Patent, quoted above. The glucan particles in claims 7, 8, and 9 of the '540 Patent and claim 6 of the '972 Patent are spherical. Plaintiffs propose that the disputed terms be construed as "the glucans have an average diameter of from about 2 to about 10 microns." Immudyne proposes this construction: "The most frequently occurring particle size is from 1.5 to 10.4 microns in diameter."

As to "average," its ordinary meaning is an arithmetic mean. See Webster's Third New International Dictionary 118, 150 (2002). The Court rejects Immudyne's construction of "average" as "mode."

With regard to the construction of "about," Plaintiffs and Immudyne essentially repeat their arguments addressed above in connection with "less than about one percent, by weight, protein." The Court does not discern intrinsic evidence that would precisely identify the parameters of the range "about 2 to about 10 microns." No variation from the limitation appears in the '972 Patent's and the '540 Patent's claims. The specifications do not specify the permissible deviations from 2 or 10 microns.

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The Summary of the Invention gives ranges of particle sizes associated with yeast strains:

The yeast is preferably a strain of Saccharomyces cerevisiae, but any strain of yeast can be used. These pure whole glucan particles are typically spherical, and exhibit a high water holding capacity, as exhibited by their viscosity in aqueous solutions. For example, an aqueous suspension of whole glucan particles derived from strain Saccharomyces cerevisiae A364A, having a particle size of approximately 2 to approximately 4 microns containing about 5.5 grams of glucan per deciliter has a viscosity of about 1000 centipoise. A Saccharomyces cerevisiae 374 derived glucan, having a particle size of from about 2.5 to about 6.3 microns, has a viscosity of about 2630 centipoise in an aqueous suspension containing about 3.5 grams of glucan per deciliter.

'540 Patent, col. 2, ll. 24-37; '972 Patent, col. 2, ll. 22-35. Later, the Detailed Description of the Invention in the '540 Patent reiterates the claimed range: "Preferably, the whole glucan particles are spherical in shape with a diameter of about 2 to about 10 microns . . . ." '540 Patent, col. 6, ll. 32-34. In the '972 Patent, the preferred ranges is "about 2 to about 4 microns." '972 Patent, col. 6, l. 32. Without evidence that would provide a basis to specify the permissible deviation from 2 or 10 microns, the Court gives the term "about" its ordinary meaning of "approximately." See Merck, 395 F.3d at 1369-72 & n.7. Accordingly, the Court construes "an average particle size of from about 2 to about 10 microns" and "an average particle diameter of from about 2 to about 10 microns" as "the arithmetic mean of the diameters of the particles is approximately 2 to approximately 10 microns."

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B. "From Human Acceptor Immunoglobulin"

Where the specification provides an express definition for a claim term, "the inventor's lexicography governs." Phillips, 415 F.3d at 1316. It is undisputed that the specification expressly defines acceptor: "the 5 human immunoglobulin providing the framework is called the 'acceptor.'" '370 Patent Col. 12:6-7. The parties' dispute concerns whether a variety of different human framework regions may be used in combination as a basis for the humanized immunoglobulins of Claim 28, as asserted by PDL, or whether the human acceptor immunoglobulin must come from a single naturally occurring human immunoglobulin, as argued by MedImmune.

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5 MedImmune contends that the presence of the article "the" before the word "human"in the specification's definition of acceptor indicates that only a single, naturally occurring human immunoglobulin can provide the framework. The Federal Circuit has rejected the argument that "the" necessarily implies singularity. Free Motion Fitness v. Cybex, Inc., 423 F.3d 1343, 1350-51 (Fed. Cir. 2005) ("reject[ing the]…argument that use of the word 'the' in connection with the word 'cable' later in the claim shows that the earlier reference to 'a' denotes singularity. Like the words 'a' and 'an,' the word 'the' is afforded the same presumptive meaning of 'one or more' when used with the transitional phrase 'comprising'"). While in this case "comprising" is not used in conjunction with "the," "the" still does not necessarily imply singularity. Because it concludes that the use of "the" does not support either party's proposed construction, the Court relies upon other language within the specification in determining the meaning of the contested term.

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MedImmune contends that the use of the word "human" assumes that the "human acceptor immunoglobulin" occurs naturally in the human body and is not subject to engineering. MedImmune also contends that every time the patent uses theterm "human acceptor," the term is synonymous with "naturally occurring human immunoglobulin." However, the specification teaches that "a variety of different human framework regions may be used singly or in combination as a basis for the humanized immunoglobulins of the present invention." '370 Patent Col. 17:17-19 (emphasis added). And, as PDL noted during the claim construction hearing, the specification also explains that "[a] principle is that as acceptor, a framework is used from a particular human immunoglobulin that is unusually homologous to the donor immunoglobulin to be humanized, or use a consensus framework from many human antibodies." '370 Patent 13:5-8.

MedImmune attempts to explain away this language in the specification, arguing that it refers only to the use of one human

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immunoglobulin to provide a light chain, and a different immunoglobulin to provide a heavy chain - not the engineering of one chain from different human immunoglobulins. MedImmune again relies upon the opinion of its expert, Dr. Lesk, as well as what it claims is the admission of PDL's expert, Dr. Strong, that "human" implies a single, naturally occurring human immunoglobulin. However, the law is clearthat while extrinsic evidence such as expert opinion may aid the claim construction analysis, it cannot be used to contradict the plain and ordinary meaning of a claim term as defined within the intrinsic record. Phillips, 415 F.3d at 1322-23. In this case, the language in columns 13 and 17 of the specification recognizes that the state of the art was such that human framework regions could be combined and contradicts MedImmune's position that "human" necessarily means a single, naturally occurring human immunoglobulin. 6

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6 MedImmune also asserts that the language in column 17 cannot be relied upon in this context because it refers to "substantially homologous modified immunoglobulins," '370 patent 17:9-10, which are separate and distinct from the humanized immunoglobulins of Claim 28. However, language found only a few lines below expressly contradicts this assertion. The patent reads "[m]oreover, a variety of different human framework regions may be used singly or in combination as a basis for the humanized immunoglobulins of the present invention." '370 Patent Col. 17:17-19.

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PDL also contends that MedImmune's suggested construction would impose a method limitation on a non-method claim."Courts must generally take care to avoid reading process limitations into an apparatus claim…because the process by which a product is made is irrelevant to the question of whether that product infringes a pure apparatus claims." Baldwin Graphic Systems, Inc. v. Siebert, Inc., 512 F.3d 1338, 1344 (Fed. Cir. 2008) (citations omitted). Claim 28 describes the invention of a humanized immunoglobulin and defines its characteristics, including the requisite degree of homology. Claim 28 does not define how that humanized immunoglobulin with those specified characteristics must be created. The language of the claim requires substantial homology, but it does not specify how that percent of identity must be achieved, whether by use of a single naturally occurring human immunoglobulin or an engineered combination.

MedImmune suggests that because all of the patent's preferred embodiments utilize a single naturally occurring human immunoglobulin, its proposed construction is more accurate. This argument lacks merit, for two reasons. First, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed asbeing limited to that embodiment." Phillips, 415 F.3d at 1323 (holding that "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments"). See also Kara Tech., Inc. v. Stamps.com, Inc., 582 F.3d 1341, 1347 (Fed. Cir. 2009) (citations omitted) ("In the only detailed embodiments in the patent, the key is embedded in the preestablished data. This is not enough, however, to limit the patentee's clear, broader claims…The claims, not specification embodiments, define the scope of patent protection"). Second, the patent itself recognizes that other embodiments of the invention exist outside those exemplified. '370 Patent Col. 17:8-19 ("in addition to the humanized immunoglobulin specifically described herein…").

Finally, MedImmune contends that PDL should be estopped from disowning the construction it persuaded the Alexion Court to adopt. MOB at 16. "The doctrine of judicial estoppel provides that '[w]here a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position…" Biomedical Patent Mgmt. Corp. v. Cal. Dep't of Health Servs., 505 F.3d 1328, 1341 (Fed. Cir. 2007).In Alexion, Judge Farnan concluded that "'Human acceptor immunoglobulin' and 'acceptor human immunoglobulin' are each construed to mean 'the human immunoglobulin providing the framework for the CDRs.'" PDL BioPharma, Inc. v. Alexion Pharmaceuticals, Inc., 568 F.Supp.2d 445, 456 (D. Del. 2008). MedImmune insists that the use of the word "the" in the Alexion court's construction of acceptor human immunoglobulin implies the use of a single human immunoglobulin - its suggested construction in the instant dispute. Like MedImmune's other arguments, this contention is unpersuasive.

In RF Delaware, Inc. v. Pacific Keystone Tech., 326 F.3d 1255 (Fed. Cir. 2003) the Federal Circuit held that

The party seeking to invoke collateral estoppel bears the burden to prove all necessary elements: (1) the issue at stake must be identical to the one involved in the prior litigation; (2) the issue must have been actually litigated in the prior suit; (3) the determination of the issue in the prior litigation must have been a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted must have had a full and fair opportunity to litigate the

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issuein the earlier proceeding.

Id., 326 F.3d at 1261.

None of these elements is present here. First, while Judge Farnan construed the term "human acceptor immunoglobulin," the issue disputed here-whether the human acceptor must be from a single human immunoglobulin-was not raised in Alexion. Second, there was no judgment in Alexion because the parties entered into a settlement agreement. Third as discussed above, this Court disagrees with MedImmune's assertion that the use of "the" in Alexion's construction of the term supports a conclusion in this case that only a single human immunoglobulin can be utilized.

For all of the foregoing reasons, this Court construes "from human acceptor immunoglobulin" to allow the use of a variety of different human framework regions in combination as a basis for the humanized immunoglobulins of Claim 28.
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b. "frozen uniformly"

Even if the ICE-CEL included the identical "opposite direction" flow as that described in the '078 patent, it would not infringe upon claim 16 because the phase change material in the ICE-CEL does not completely freeze as required by the claim.

Paragraph D of claim 16 states that the opposite flow system used in the ICE-BANK provides "generally uniform transfer of heat energy between the liquid in the respective pairs of conduits and the phase change material throughout said tank." The final clause of claim 16 states:

> whereby said phase change material may be alternately melted and frozen uniformly throughout the mass of said phase change material as heat is added to and withdrawn from the recirculating liquid in said system.

To accomplish this uniform freezing, the specification of the '078 patent provides for mat tubing to fill the entire volume of the tank "so that no region within the entire tank is more than a short distance away from the mat tubing." The specification further states:

> Therefore, ice advantageously builds uniformly on all tubes entirely throughout the whole tank of water. The water level rises in the tank because of the increased specific volume of the ice formed but there is no sideward expansion forces as the ice joins from one spiral layer to the other because the extra water volume has been squeezed upwards previously. The rise in water level provides a measure of the extent of the fusion process. The extra water on top is the last to freeze.

Focussing on these portions of claim 16 and the specification of the '078 patent, it is clear that claim 16 only encompasses systems wherein tubing is placed throughout the entire tank and the phase change material ("PCM") is entirely frozen. The prosecution history of claim 16 likewise mandates this interpretation. When pursuing the '078 patent, Calmac argued to the patent examiner that it "is able to freeze a plastic tank of water to solid ice without rupturing the tank." Amendment to Application for the '078 Patent at 17. Calmac went on to explain that "this is an astonishing result and is entirely unexpected." Id. Calmac emphasized that this system allows ice to build "on all of the tubes throughout the whole tank of water." Id. From this prosecution history, it is clear that claim 16 requires that the PCM freeze completely.

Calmac disputes this interpretation of claim 16. It argues that the patent language only states that the ICE-BANK is able to freeze a plastic tank of water to solid ice. This, it argues, does not mean that the patent excludes partially frozen tank systems from the invention. Calmac's proposed construction of claim 16 alters the true meaning of the claim as indicated through a review of its plain language, the specification, and the prosecution history. Claim 16 is limited to devices which freeze the PCM uniformly and completely. Any other construction of the claim distorts the undisputed patent record.

The ICE-CEL does not infringe upon this limitation of claim 16. First, the ICE-CEL is designed such that portions of the tank contain no coolant tubes. Second, the ICE-CEL is designed so that certain areas of the tank, specifically the sides, the center, and the top, do not freeze. These characteristics of the ICE-CEL are not in dispute. When these characteristics are

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compared with claim 16, it is evident that the ICE-CEL does not literally infringe upon the '078 patent.

Calmac concedes that the ICE-CEL does not have coolant tubes throughout the tank and that the PCM in the ICE-CEL does not normally freeze entirely. It insists, however, that the ICE-CEL nonetheless literally infringes upon the '078 patent. Although the ICE-CEL is designed to leave portions of the tank unfrozen, if the device is run improperly, all of the PCM in the tank will, in fact, freeze. For this reason, Calmac argues that the ICE-CEL literally infringes its patent. Calmac's argument on this point is frivolous. The PCM in the ICE-CEL may freeze entirely when it is improperly operated; however, it is undisputed that the ICE-CEL is not designed to operate in this manner. In fact, the warranty on the ICE-CEL does not apply if the consumer operates the device in such a way as to achieve 100% freezing. Misuse of a product by a consumer does not by itself transform an essential characteristic of that product. The PCM in the ICE-CEL does not freeze 100% under normal operation; it, therefore, does not literally infringe upon claim 16, which describes a device which "is able to freeze a plastic tank of water to solid ice without rupturing the tank." Amendment to the Application of the '078 Patent at 17.

In the alternative, Calmac argues that the ICE-CEL infringes on the 100% freeze portion of claim 16 under the doctrine of equivalents. Calmac, however, is precluded by prosecution history estoppel from asserting this argument. Initially, the '078 patent was rejected due to the state of the prior art. To overcome this rejection, Calmac argued to the examiner that the thermal storage system described in that claim is unique because it is able to freeze an entire tank of water. Calmac described this ability as an "astonishing result" which was "entirely unexpected." Amendment to the Application of the '078 Patent at 17. Calmac convinced the patent examiner to approve claim 16 by arguing the unique ability of the ICE-BANK to achieve 100% freezing. For this reason, Calmac is now estopped from asserting that claim 16 also includes thermal storage devices wherein the PCM does not freeze entirely. See, e.g., Hughes Aircraft Co., 717 F.2d at 1361.

As discussed above, the ICE-CEL does not literally infringe upon the 100% freezing element of claim 16. Also, Calmac is prevented by prosection history estoppel from asserting the doctrine of equivalents regarding this element. DB is entitled to summary judgment on the question of infringement. If there is no infringement, then no legal action can proceed against defendant Lake Taylor City Hospital Authority of Norfolk, DB's client.
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A. Adams' Motion for Reconsideration

To prevail on a motion for reconsideration, the movant must "not only demonstrate a palpable defect by which the Court and the parties have been mislead, but [must] also show that a different disposition of the case must result from a correction thereof." See LCivR 7.4(a). A motion for reconsideration may not be used to simply rehash rejected arguments or to introduce new arguments. See Westbrook v. Commissioner, 68 F.3d 868, 879 (5th Cir. 1995).

Adams argues that the Court should reconsider its construction of the term "an immediate release form which becomes fully bioavailable in the subject's stomach" as "the active pharmaceutical ingredient is thoroughly absorbed in the subject's stomach." Instead, it contends, the Court should adopt the construction proposed by its expert, Dr. Foster, which is "a dosage form that releases substantially all of the drug particles relatively quickly upon ingestion (i.e. in the stomach)." Adams contends that reconsideration is required because Perrigo's experts now admit that the claims, as this Court has construed them, do not literally cover the preferred embodiment, i.e., Mucinex(R), because: (1) it is generally understood in the pharmaceuticalfield that the small intestine is the primary site for absorption of all drugs with little, if any, drug absorption occurring in the stomach; and (2) no measurable amount of any guaifenesin formulation, including the preferred embodiment, is absorbed through the stomach. Adams contends that reconsideration is warranted because a construction which excludes the preferred embodiment, such as the Court's construction does in this case, is improper under Federal Circuit law. 1

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1 Adams' motion for reconsideration is authorized by this district's local rules, and a court retains the authority to reconsider prior claim construction rulings where appropriate. See Dexas Int'l, Ltd. v. Office Max Inc., No. 6:07cv396, 2009 U.S. Dist. LEXIS 6642, 2009 WL 252164, at *10 (E.D. Tex. Jan. 30, 2009).

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As Adams correctly notes, the Federal Circuit has held that a claim construction that excludes the preferred embodiment "is rarely, if ever correct and would require highly persuasive evidentiary support . . . ." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996). Nevertheless, this statement cannot be construed as a categorical rule against a construction that excludes the preferred embodiment. As the FederalCircuit has observed, "where we conclude that the claim language is unambiguous, we have construed the claims to exclude all disclosed embodiments." Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1215-16 (Fed. Cir. 2008). This is because the principal Adams cites generally applies when a claim "term has multiple ordinary meanings consistent with the intrinsic record." Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1383 (Fed. Cir. 2008). In such cases, a court must adopt the construction that aligns with the preferred embodiment. On the other hand, where the claim language is unambiguous and admits of only one meaning, a court must so construe the claim, even where the construction excludes the preferred embodiment, because "[c]ourts cannot rewrite claim language." Id.

In construing the phrase "fully bioavailable in the subject's stomach," the Court looked to the ordinary meaning of the term "bioavailable" within the art as referring to absorption rather than release of the drug. Specifically, the Court noted that the term "bioavailable" has a well-known meaning in the sciences of medicine and pharmacology pertaining to absorption. (Docket no. 176 at 28.) Adams contendsthat the Court's erroneous construction resulted from its consideration of extrinsic evidence (Perrigo's expert's claim construction declaration) "that has proven misleading and contrary to scientific principles." (Pls'. Br. Supp. Mot. Recons. at 9.) While it is true that the Court relied on extrinsic evidence, including the Merck Manual of Diagnosis and Therapy as well as the Code of Federal Regulations, the Court also considered the intrinsic evidence, including the claim language, the specification, and the file history, and concluded that the term "bioavailable" was intended to have its ordinary meaning. For example, in its Claim Construction, the Court noted that the specification recognized the distinction between release and absorption by stating that "'quick[] release [of] the guaifenesin . . . results in rapid bioavailablity.'" (Docket no. 176 at 29, quoting '252 Patent, Col. 1, ll. 50-52.) Similarly, at the final pretrial conference held on December 15, 2009, the Court cited other language in the specification recognizing the distinction between dissolution and absorption, or bioavailability. (12/15/09 Hr'g Tr. at 16-20 (citing Col. 2, ll. 50-52 ("Furthermore, every medicamenthas different solubility properties and pH dependencies which affect its dissolution rate, and hence bioavailability" (italics added).) Nothing Adams offers in support of its motion suggests that the term "bioavailable" had a meaning other than that which the Court adopted.

Adams further argues:

> Contrary to what Perrigo and Dr. Chambliss told the Court during claim construction, one of ordinary skill in the art could not understand the claims to require 100% absorption, or even "thorough" absorption, in the stomach. This is true because to so construe the claims, a person of ordinary skill in the art would have to ignore the fact that the intestine is the main site of drug absorption and conclude that the inventors intended, for some inexplicable and self-defeating reason, to define the scope of their invention so as to literally exclude any guaifenesin formulation, including the preferred embodiment expressly described in the '252 patent, which would be inconsistent with scientific principles.

(Pls.' Br. Supp. Mot. Recons. at 8.) In other words, why would the inventors do such a thing? The same question was probably raised by the patentee in Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004),in which the claimed invention was a process for precooking a dough product that would have a light, flaky texture upon final cooking at a later time. The claim at issue required "heating the resulting batter-coated dough to a temperature in the range of about 400[degrees] F. to 850[degrees]." Id. at 1373. The court observed that literal application of this claim language, consisting of "ordinary, simple English words whose meaning is clear and unquestionable," would produce a dough product "burned to a crisp" and "resembl[ing] a charcoal briquet" -- something the inventor would never have intended. Id. Applying the oft-repeated rule that "courts may not redraft claims, whether to make them operable or to sustain their validity," the court held that it was compelled to "construe the claim as written, not as the patentees wish they had written it." Id. at 1374.

So, why would the inventors of the '252 Patent define their invention by saying that the guaifenesin is fully bioavailable, i.e., absorbed, in the stomach? This Court can only speculate. Only the inventors and their lawyers who prosecuted the patent application know the answer. Regardless, in construing this language, the Courtconsidered all available evidence -- both intrinsic and extrinsic -- and concluded that "bioavailable" has a well-recognized meaning that always refers to absorption into the body. Adams has still not offered any evidence to the contrary. As the Federal Circuit stated in Chef

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America, courts may not redraft a claim that is subject to only one reasonable interpretation, even if the construction is "nonsensical." Id. at 1374. Because the term "bioavailable" has a meaning that is well known in the art, the Court concludes that it did not err in construing that term as referring to absorption rather than release or dissolution.
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III. Bioavailable

Perrigo asserts that we have an alternative basis to affirm the judgment of noninfringement. Perrigo argues that claim 24 requires an IR portion of guaifenesin that becomes "fully bioavailable in the subject's stomach." Perrigo asserts that Adams can not establish that Perrigo's ANDA product would meet this limitation either literally or under the doctrine of equivalents.

In its initial Claim Construction Order, the court construed "fully bioavailable in the subject's stomach" as "the active pharmaceutical ingredient is thoroughly absorbed in the subject's stomach." Claim Construction Order at 31. When granting summary judgment of noninfringement, the court concluded that a finding of infringement based on absorption at a site other than the stomach would entirely vitiate the claim term. Adams, 2010 U.S. Dist. LEXIS 12008, 2010 WL 565195, at *11. However, the court later sua sponte reconsidered its construction of the term "fully bioavailable in the subject's stomach." Adams, 1:07-cv-993, 2010 U.S. Dist. LEXIS 76163, *7 (W.D. Mich. Mar. 3, 2010) (Reconsideration Order). The court concluded that it erred by equating bioavailabilityto absorption. 2010 U.S. Dist. LEXIS 76163 at *5. The court explained that the specification "generally referred to the bioavailability in connection with the rate of release of the drug." 2010 U.S. Dist. LEXIS 76163 at *5. The court determined that "the inventors, acting as their own lexicographers, used the term 'bioavailable' to encompass both release and availability in the stomach for absorption, wherever that absorption might occur." Id. The court thus construed "immediate release form which becomes fully bioavailable in the subject's stomach" as "a form intended to rapidly release in the stomach substantially all of the active pharmaceutical ingredient for absorption." 2010 U.S. Dist. LEXIS 76163 at *8. Thus, the court vacated the portion of its earlier opinion granting summary judgment on the basis of bioavailability. 2010 U.S. Dist. LEXIS 76163 at *8-9.

On appeal, Perrigo asserts that "bioavailable" is commonly understood by those of skill in the art to mean absorption. Perrigo asserts that construing bioavailability in terms of release would require us to rewrite every single claim of the '252 patent by crossing out "bioavailable" and inserting "release." It cites Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374-75 (Fed. Cir. 2004), in which we concluded thatthe court may not rewrite unambiguous patent claim language.

Adams asserts that bioavailable in the context of the patent means release into the stomach, rather than absorption into the body. Adams points out that the specification repeatedly states that the IR portion of guaifenesin is released in the stomach, but it never states that it is absorbed in the stomach. Adams further notes that the district court's construction covers the preferred embodiment, while Perrigo's proposed construction would exclude all formulations because guaifenesin is primarily absorbed in the small intestine.

The district court correctly construed the term "immediate release form which becomes fully bioavailable in the subject's stomach" to mean "a form intended to rapidly release in the stomach substantially all of the active pharmaceutical ingredient for absorption." Perrigo and Adams each proposed a reasonable construction of the term bioavailable in the abstract. Adams' construction is consistent with the use of this term in the specification; Perrigo's is not. HN6Go to this Headnote in the case.Claim terms are not construed in a vacuum divorced from the specification. Although the specification never expressly defines bioavailable, ituses the term when describing the availability of the drug for absorption, not the actual absorption. For example, the specification explains that "every medicament has different solubility properties and pH dependencies which affect its dissolution rate, and hence its bioavailability." '252 patent col.2 ll.51-53. It further explains that "[t]he immediate release portion of the bi-layer tablet is formulated to dissolve in aqueous media of low pH, such as that found in the stomach, to quickly release the guaifenesin contained within the portion. This results in rapid bioavailability of a high concentration of guaifenesin." Id. col.10 ll.48-52. The specification says nothing about absorption of guaifenesin in the stomach; in fact, it explains that "[g]uaifenesin is readily absorbed from the intestinal tract." Id. col.2 ll.3-4. Thus, as used in the specification, bioavailability refers to the availability of guaifenesin for absorption, not the subsequent actual absorption itself.

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Adams' construction--requiring release and availability for absorption--covers the preferred embodiment. Perrigo's construction--requiring both release and actual absorption--excludes the preferred embodimentand essentially all guaifenesin formulations, as the specification explains that absorption occurs in the intestinal tract. HN7Go to this Headnote in the case.A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1583-84 (Fed. Cir. 1996). We therefore agree with the district court that one of skill in the art would understand bioavailable in this invention to require release and availability for absorption.

Perrigo argues that even if we construe the term bioavailable to refer to release, we should construe the term "fully" to have its ordinary meaning: "thoroughly," "completely," "entirely." We agree that nothing in the specification imparts any special meaning to the term "fully." This term should be given its plain and ordinary meaning. In light of these constructions, the district court properly denied summary judgment of noninfringement on the limitation "immediate release form which becomes fully bioavailable in the subject's stomach."
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D. Fuming Sulfuric Acid

Fuming sulfuric acid, or oleum, is a mixture of sulfuric acid (H[2]SO[4]) and sulfur trioxide. 77 The R & R recommends construing the phrase "fuming sulfuric acid containing at least 20% SO[3]" to mean "20% SO[3] up to an amount to which sulfuric acid would be considered an impurity." 78 Defendants object to this construction for several reasons, none of which is persuasive.

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77 See Pl. Ex. H at 91; Pl. Ex. B at col. 2:19; Def. Ex. EE at 36150.

78 R & R at 25.

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First, defendants argue that the term "impurity" is ambiguous. They contend that the issue of dispute -- the permitted upper limit of SO[3] or minimum amount of sulfuric acid in "fuming sulfuric acid" -- improperly will be left for the jury. But defendants' would define "fuming sulfuric acid," a mixture of sulfur trioxide and sulfuric acid, to include otherwise pure sulfur trioxide SO[3] containing a single molecule of water. 79 In other words, the real issue here is not a supposed ambiguity in the recommended definition, but that defendants would define fuming sulfuric acid to include SO[3] that contains only the slightest impurity. The R & R notes correctly that defendants' evidence does not support such a definition. For example, the deposition testimony cited by the defendants indicates that the properties of SO[3] would be affected by the presence of protons, i.e. the presence of sulfuric acid or water, but not that the presence of any protons would transform SO[3] to fuming sulfuric acid. 80 For example, defendants' expert, Dr. Williams, testified that "commercial grade Sulfan B, liquid sulfur trioxide, contain[s] enough sulfuric acid" that it could prove problematic in a "reaction that is sensitive to the presence of protons," but not that this presence transforms Sulfan B into fuming sulfuric acid. 81

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79 Def. Obj. at 27.

The water molecule combines with the sulfur trioxide to form sulfuric acid. See Def. Ex. Q at 106:4-10.

80 See Def. Ex. Q at 107-09; see also Def. Ex. HH PP 46-47 (Sulfan B is SO[3] not oleum or fuming sulfuric acid).

81 Def. Ex. Q at 107-09.

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The defendants object also to what they characterize as the R & R's "undue reliance" on the decision of the European Opposition Division. However, as the R & R demonstrates, Magistrate Judge Ellis did not place undue weight on the decision of a foreign patent office. The R & R notes merely that following its review of plaintiff's European counterpart to the '973 patent, the European patent office's construction of the phrase "fuming sulfuric acid" supported Magistrate Judge Ellis' own. This is not improper. 82

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82 See, e.g., Minerals Separation v. Hyde, 242 U.S. 261, 269, 37 S. Ct. 82, 61 L. Ed. 286, 1917 Dec. Comm'r Pat. 381 (1916) (noting agreement with House of Lords on an equivalent patent application).

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Theparties alternately dispute whether the nitrogen that is injected into the foam concentrate mixture can contain oxygen. US Foam seeks to give "gas consisting essentially of nitrogen," "nitrogen containing gas," and "gas comprising nitrogen" equivalent meanings: "a gas, other than air, that includes nitrogen and may include additional gases." US Foam makes a distinction for "gas consisting essentially of nitrogen," by adding the limitation that it does not contain combustible amounts of oxygen. Defendants argue that "gas comprising nitrogen" and "gas consisting essentially of nitrogen" are very different things. Importantly, Defendants contend that "gas comprising nitrogen" can include air, which is 78% nitrogen and contains sufficient oxygen to support combustion. Defendants argue that "comprising" is a broad and open-ended term that can include anything else whereas "consisting essentially of" is much narrower and contains very little else. According to Defendants, the patentee knew how to draft narrowly and broadly and chose to do both.

US Foam argues that the patentee expressly disclaimed air as the foam-producing gas. See '965 patent, 4:48-53 ("Conventionally air is used as thegas in forming high expansion foams. However, in view of the need to reduce the oxygen content in the mine at the area involved in the fire, contributing to the oxygen content in the sealed area by the expanded foam is undesirable. Accordingly, a gas consisting essentially of nitrogen is employed as the expanding gas."). In that passage, the patentee describes "gas consisting essentially of nitrogen" as a gas that will not contribute oxygen to the fire. If the foam were to be expanded with air, the substantial concentration of oxygen in the air would "add[] a highly combustible substance to the fire that becomes available to support combustion as the foam breaks down." '965 patent, 4:3-5. The Court construes "gas consisting essentially of nitrogen" and "nitrogen containing gas" to mean "gas containing mainly of nitrogen without other gases in sufficient concentrations to support combustion."

Even though there is no express disclaimer of air for the more broadly-claimed "gas comprising nitrogen," the patentee made clear throughout the specification that the invention does not use air. See '965 patent, 4:3-5; 4:48-53. The Court construes "gas comprising nitrogen" to mean "a gas, otherthan air, that includes nitrogen and may include additional gases that are not present in sufficient concentrations to support combustion."

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B. Claim language to be construed from Claim 3 -- "a gas impermeable enclosure receiving the electrically conductive portions of said thermocouple" -- col. 2, ll. 36-37

HEN contends that "gas impermeable enclosure" should be construed to mean "a receptacle made of a material which gas cannot pass through." (HEN CC Br. at 16.) HEN contends that the claim itself and the specification support its proposed construction, and that the claim language does not contain any language requiring the enclosure to be completely closed on all sides and gas tight. Minco, on the other hand, argues that "gas impermeable enclosure" should be construed to mean "a gas tight enclosure, into which or out of which gas cannot move or flow, such as a body of silicone surrounded by a small plastic casing." (Minco CC Br. at 16.) Minco argues that according to the specification, the purpose of the gas impermeable

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enclosure is to provide protection for the cold welds located inside the enclosure from heat or temperature differences. Furthermore, Minco argues that the patent specification describes the gas impermeable enclosure as follows: "The cold joints of the thermocouple 5 are embedded in a gas tight enclosure such as a body of silicone 8 surrounded by a small plastic casing 9. The conductors at the cold joints 7 are V-shaped with the apexes adjacent one another but electrically insulated from one another by the silicone 8." (Minco Ex. A, col. 2, ll. 39-44.) Minco argues that use of the word "embedded" supports the conclusion that the cold welds are encapsulated inside a body of silicone, which is known to be gas tight.

HEN's argument regarding the construction of "gas impermeable enclosure" is predicated on the fact that the enclosure is represented in the specification only by the small plastic casing, (see HEN Ex. A at Figure 1, number 9) which HEN construes as a receptacle that can be open on top. However, we understand the enclosure, based on the specification, as being an enclosure "such as a body of silicone 8 surrounded by a small plastic casing 9," (see HEN Ex. A at col. 2, ll. 40-41), and that this entire enclosure, not just the small plastic casing, must be gas impermeable. Consequently, we reject HEN's use of the word "receptacle" in its proposed construction and its related argument that the enclosure need not be closed on all sides as this is inconsistent with how the applicants understood the term "gas impermeable enclosure" as indicated in the specification. Additionally, HEN's construction of "impermeable" would make more sense if it were used to modify something that was typically two-dimensional, such as a barrier. In such a context, an impermeable barrier means that gas cannot pass through it. However, in the context of this invention, "impermeable" modifies "enclosure," which is something that connotes a three-dimensional element, and an impermeable enclosure means that gas cannot pass into or out of the enclosure. We believe, therefore, that HEN's proposed construction of an impermeable enclosure as a receptacle that is open on the top is not consistent with the understanding of these terms held by an ordinary person skilled in the art. An impermeable enclosure means that gas cannot enter the enclosure from any attitude -- from the bottom, the sides, or the top. Consequently, we construe "gas impermeable enclosure" to mean "an enclosure, into which and out of which gas cannot move or pass." 4

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4 The parties have relied in their arguments on extrinsic evidence such as the mechanics of the flow of gases in the area of the enclosure during the immersion of the probe in molten metal and dictionary definitions. However, we need not address this extrinsic evidence as we are able to construe the claim term based on the intrinsic evidence alone. See Phillips, 415 F.3d at 1319 (stating that courts in their discretion may use extrinsic evidence to determine claim meaning). Moreover, even if we rely on the dictionary definition of impermeable supplied by HEN, this would not support its position because "impermeable" is defined, in part, as "(of substances) not permitting the passage of a fluid through the pores, interstices, etc." See Webster's Encyclopedic Unabridged Dictionary of the English Language (1989). Allowing a substance, such as gas, to enter through the top of the enclosure would not be consistent with this definition.

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1. "a fire extinguishing chemical of a gas type that comprises argon and nitrogen"

Disputed term	On Site
a fire extinguishing chemical of a gas type that comprises argon and nitrogen	A gas that contains argon and nitrogen, optionally with other components

Claims 1, 6

Disputed term	US Foam
a fire extinguishing chemical of a gas	A fire extinguishing chemical of a gas type that includes nitrogen and argon and may include additional gases,

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type that comprises argon and nitrogen	however the source of the argon is a source other than the argon that is isolated from air during generation of the nitrogen.

Claims 1, 6

Theparties dispute whether the gas must include nitrogen and argon, and whether the argon gas, if included, must have an independent source. On Site relies on the specification to argue that the fire extinguishing chemical can use a gas that is selected from argon, nitrogen, or other component. See '558 patent, 1:46-59. On Site also argues that neither the claims nor the specification require limiting argon to an independent source.

US Foam argues that the patentee disavowed the scope of a nitrogen-air mixture when it amended the claims to overcome prior art. As originally drafted, the claim recited "a fire extinguishing chemical of a gas type comprising at least one member selected from a group consisting of argon, nitrogen, and carbon dioxide." Amendment, February 25, 2005, at p. 2. The patentee amended the claim to overcome the examiner's rejection because "[the prior art reference] shows a device and teaches [a] method of extinguishing a fire using a gas type chemical, nitrogen using a foam formed by water containing a synthetic surface-active agent." Office Action, Nov. 29, 2004, at 4. Amending the claim, the patentee distinguished over the prior art reference, explaining that it "failsto disclose the use of a fire extinguishing chemical that comprises argon and nitrogen." Amendment, Feb. 25, 2005, at 9-10. US Foam argues that On Site's proposal would permit air, which would recapture the prior art that included a nitrogen-air mixture.

"Just as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under § 112, ¶ 6." Ballard Medical Products v. Allegiance Healthcare Corp., 268 F.3d 1352, 1359 (Fed. Cir. 2001) (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998)). According to the examiner, the prior art taught mixing nitrogen with the air, such that "the addition of the nitrogen into the system would inherently reduce the oxygen concentration below 21% and would normally reduce the[] oxygen concentration to ranges claimed." Office Action, Dec. 1, 2004, at 4. [Dkt. 76-7] The patentee amended the claims to require nitrogen and argon and explained that the prior art did not disclose using both nitrogen and argon to reduce the concentration of oxygen. If the argon in this limitation was the argon in air, thenthe argon would serve no purpose to reduce the concentration of oxygen as it would necessarily be accompanied by the oxygen in gas. The Court agrees that the gas cannot be air. The Court finds no support for US Foam's proposal, however, that further limits the source of the argon such that it cannot be created or generated from the air. The Court construes the phrase to mean, "a gas other than air that contains argon and nitrogen, optionally with other components."

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None of the following elements are disputed and each term is assigned its plain and ordinary meaning as understood by a skilled artisan. The term "pharmaceutical composition" means an aggregated product formed from two or more substances for use as a drug in medical treatment. The term "gastrointestinal environment" means the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus. The term "mean fluctuation index" means the average degree of fluctuation ((Cmax-Cmin)/Cavg) over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma.

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1. Intrinsic Evidence

a. Claim Language

The Court first considers the intrinsic evidence to determine the proper meaning and scope of the disputed terms "liquid," "gel," and "liquid containing pack" as used in the Sereboff patent. In analyzing the intrinsic evidence, the Court first considers the language of all the claims, both asserted and nonasserted. See Bell Communications Research, Inc. v. Vitalink

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Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). Although the words in a claim are usually given their ordinary and customary meaning, a patentee may act as a lexicographer, giving the claim language a meaning different from the ordinary and customary usage of the words. See Vitronics, 90 F.3d at 1582. In this case, Fellowes essentially argues that all "gels" are subsumed within the term "liquid," and that "liquid" is specially defined by the written description of the Sereboff patent to include 3M's elastomeric gel. (See Def.'s Mem. in Opp'n at 6-7, 10.) 3M offers an interpretation in which the term "liquid" includes only "liquid gels," while "solid gels" are not included within the term "liquid." (See Pl.'s Mem. in Supp. at 5-7, 15.)

The Court first examines the relationship between independent claim 1, which includes the term "liquid," and dependent claims 3 and 20, which include the term "gel." A dependent claim can only further define (i.e., add narrowing limitations to) an independent claim; it cannot substitute one element for another specified in the independent claim. See Manual of Patent Examining Practice § 608.01(n) (7th ed. 1998). This convention of patent practice means only that "liquid" and "gel" cannot be mutually exclusive, for that would improperly substitute "gel" in dependent claims 3 and 20 for "liquid" in independent claim 1. Moreover, under the doctrine of claim differentiation, different claims are presumed to have different scopes. See Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998). This suggests that the term "liquid" in claim 1 is broader than the term "gel" in claims 3 and 20. For example, "liquid" in claim 1 includes water, which is not a "gel" within the scope of claims 3 and 20. These observations, however, while helpful in construing the claim language, do not resolve the dispute over whether all "gels" are completely subsumed under the term "liquid."

b. Written Description

Accordingly, the Court turns to the Sereboff patent's written description, which is also sometimes referred to as the patent specification. For the patentee to use terms in a claim differently from their ordinary meaning, the special definition of the claim term must be clearly enunciated in the written description or prosecution history of the patent. See Vitronics, 90 F.3d at 1582. Fellowes argues that the written description clearly indicates that the term "liquid" includes elastomeric gels because the written description of the Sereboff patent includes a reference to U.S. Patent Number 5,173,963 ("the Greenberg patent"), which discloses an elastomeric nonflowing gel. (See Def.'s Mem. in Opp'n at 6-7.) This argument is without merit.

The Sereboff patent's mere reference to the Greenberg patent fails to satisfy the Vitronics requirement of providing a clear and explicit special definition of any special usage of a claim term. First, the Greenberg patent is discussed only in the "Background of the Invention" section of the Sereboff patent, and is mentioned only in the context of identifying possibly relevant prior art, not to identify the actual subject matter of Sereboff's claimed invention. (See Sereboff patent at column 1, lines 35-41.) Moreover, the Sereboff patent fails to identify nonflowing elastomeric gels as being the important feature of the Greenberg patent for which reference to the Greenberg patent is made. (See id.) Furthermore, the Sereboff patent fails to incorporate the subject matter of the Greenberg patent by reference, such that the disclosure in the Greenberg patent is not considered to be part of the disclosure of the Sereboff patent. See In re Howarth, 654 F.2d 103, 107 (C.C.P.A. 1981) (requiring a patent applicant to either "set forth the information in his specification or incorporate it by reference to a reasonably accessible source"); In re De Seversky, 474 F.2d 671, 673 (C.C.P.A. 1973) (refusing incorporation where no "incorporation-by-reference" language existed in the application); Manual of Patent Application Practice and Procedure § 608.01(p) (7th ed. 1998) ("Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph."). For these reasons, the Court finds that the Sereboff patent's mere reference to the Greenberg patent does not provide a special definition of the term "liquid" that includes elastomeric gels.

Other portions of the Sereboff patent's written description must also be considered in interpreting the term "liquid." Fellowes argues for attaching a special meaning to "liquid" based on the following portion of the Sereboff patent's written description:

As is seen in FIG. 3, pack 30 includes a substantially liquid type composition 34 which may be in the form of a liquid having a viscosity approximating the viscosity of water, or may include a gel composition contained therein having a viscosity substantially above that of water.

(Sereboff patent at column 3, lines 53-68, emphasis in original.) The Court finds that this explicit language is sufficiently clear to constitute a special definition of the claim term "liquid." Under this special definition, the "liquid" of claim 1 of the Sereboff patent includes both a substance at about the viscosity of water and also gels having a viscosity substantially above

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that of water. (See id.) The written description of the Sereboff patent does not impose an upper bound on the viscosity of gels considered to be within the special definition of the claim term "liquid." (See id.) Thus, the written description of the Sereboff patent indicates that the term "liquid" appears to include all "gels" that can be regarded as having a viscosity.

c. Prosecution History

Having decided, based on its written description, that the Sereboff patent created special definitions of the terms "liquid" and "gel" at the time the patent application was filed, the Court next turns to the prosecution history to determine if this understanding of the meaning of "liquid" and "gel" was later modified during prosecution of the Sereboff patent application before the U.S. Patent & Trademark Office. Both claim amendments and mere arguments for patentability, along with other aspects of the prosecution history, must be examined to determine the meaning of terms in the claims. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995). The patentee cannot treat the claim as a "nose of wax," having one meaning during prosecution, and yet another altogether during litigation. See Senmed, Inc. v. Richard-Allan Med. Indus., 888 F.2d 815, 819 n.8 (Fed. Cir. 1989)(citing White v. Dunbar, 119 U.S. 47, 51-52, 30 L. Ed. 303, 7 S. Ct. 72 (1886)).

During prosecution of the Sereboff patent application, the claims were rejected as being obvious 4 based on U.S. Patent Number 5,228,665 ("the Garcia patent," disclosing a foam slab wrist rest) in view of U.S. Patent Number 4,896,388 ("the Bard patent," disclosing a pillow using both a compressible filling and a water filling). In arguing for patentability, Sereboff stated:

Unlike the Garcia system, the inventive concept of the [Sereboff] Application is not directed to a support system which provides firmness sufficient to restrict the movement of a user's wrists, nor to one which urges the user's wrists to maintain a fixed desirable position. Rather, it is directed to accommodating the free movement of the user's wrists and palms by the use of a fluid support mechanism which resiliently conforms to the contours of the user's wrists and palms, even while they are moving.

(Witt Decl. Ex. 7 at 47 ("Sereboff prosecution history").) (emphasis added) The Court finds that these explicit arguments during prosecution of the Sereboff patent created two additional constraints on the claims. First, the support mechanism must be fluid. (See id.) Second, the support mechanism must dynamically conform to the user's wrists while they are moving. (See id.) The first constraint provides additional insight into the proper interpretation of the claim terms "liquid" and "gel," i.e., the support mechanism must be "fluid." The second constraint does not affect the Court's literal infringement analysis.

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4 A patent cannot be obtained for subject matter sought to be patented that is deemed "obvious" by the patent examiner. See 35 U.S.C. § 103.

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The term "fluid" limits the "gels" included within the claim term "liquid" to only those gels that flow. Gels that do not flow are not "liquid," as that term was defined by the Sereboff patent application and further limited by Sereboff during prosecution. Stated differently, use of the term "fluid" during prosecution of the Sereboff patent allows the Court to conclude that the term "gel" is not subsumed within the term "liquid." The intrinsic evidence indicates that the term "liquid" in independent claim 1 limits the "gels" in claims 3 and 20 to only those gels that flow; nonflowing gels are not within the scope of the Sereboff patent claims.

2. Extrinsic Evidence

When the intrinsic evidence does not resolve a disputed claim term, the Court may also receive extrinsic evidence to aid in claim interpretation. See Markman, 52 F.3d at 980; Vitronics, 90 F.3d at 1583. In this case, the intrinsic evidence clearly limits the claimed "liquid" to include only those gels that flow. However, an examination of the extrinsic evidence provided by Fellowes' own expert, Dr. Larson, confirms the above claim construction based on the intrinsic evidence.

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Dr. Larson submitted an expert report in which he stated that "both the ordinary and scientific meanings [of 'liquid'] describe it as a substance that flows. . . . The term 'liquid' can refer to substances that flow or deform reversibly only when modestly large forces are imposed." (Larson Decl. P 3.) "If a gel is flowable, then the network structure must be capable of being broken down under a load or force, and to reform itself once that load is removed. Block copolymer formulations possess this property. . . ." (Id. P 10.) "The [3M] block copolymer formulation . . . fits within the range of gel possibilities envisioned by Sereboff." (Id. P 12.) "The [term] . . . liquid . . . as used in claim 1 of the Sereboff patent [is] intended to exclude substances like foam rubber that cannot deform irreversibly or 'flow,' but instead spring back into a predetermined shape after the deforming force is removed." (Id. P 17.) This terminology is also "intended to exclude nonflowable elastic substances. . . ." (Id. P 19.)

These statements by Dr. Larson clearly limit the claimed "liquid" to only those substances that flow. Dr. Larson admits that "nonflowable elastic substances" are not included within the scope of the Sereboff patent claims. (Id. P 19.) Thus, if the 3M gel is either nonflowable or elastic, it does not infringe the Sereboff patent. Dr. Larson also sheds further light on the meaning of "flow" and "flowable." If the 3M gel "springs back into a predetermined shape after [a] deforming force is removed," it does not flow and does not infringe the Sereboff patent. (See id. P 17.) Moreover, if the 3M gel is incapable of reforming itself after being broken down, then it does not infringe. (See id. P 10.) (emphasis added). The Court interprets the words "reforming itself," based on their plain meaning, to mean "reforming on its own accord" rather than "capable of being reformed." Thus, if reforming the 3M gel back to its predetermined shape (after the gel is broken down) requires an externally applied force, then the 3M gel does not infringe. 5 In summary, the Court finds that the extrinsic evidence offered by Fellowes also indicates that the claimed "liquid" must flow. The Court further finds that the claimed "liquid" must be inelastic, and it must be capable of reforming itself back into a predetermined shape after being broken down.

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5 Although Dr. Larson states that block copolymer formulations are able to reform themselves, he does not state that all block copolymer formulations act this way, or that the accused 3M elastomeric gel acts this way. (See id. P 10.)

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3. "gelling agent" as used in claims 9 and 19 of the '240 patent and claims 1, 3-6, 11 and 13-15 of the '579 patent

Plaintiff's construction: No construction necessary

Defendant's construction: An ingredient in the tooth whitening substance that causes the tooth whitening substance to form a gel

The parties agree that a "gelling agent" is an agent that has the ability to cause another substance to become a gel. However, defendant argues that a gelling agent as used in the '240 and '579 patent must cause a gel to be formed. Once again, defendant contends that the plain meaning of the term requires its proposed construction. Although I agree that the plain meaning of the term should be applied, I conclude that the plain meaning does not require that the gelling agent cause a gel to be formed in every instance.

The claim language of the '240 patent and the '579 patent offers no guidance on this issue. In both patents, a gelling agent is described as part of either a tooth whitening composition or a tooth whitening substance. Pat. '240, col. 18, lns. 1-3; Pat. '579, col. 14, lns. 38-40. Neither patent says that the tooth whitening composition or substance is formed into a gel.

In support of its construction, defendant cites the specification of the '579 patent and plaintiff's "internal documents" for the proposition that an agent is a gelling agent only when it forms a gel. According to defendant, the specification explains that a "gel" is formed by "gelling agents": "The gel is a high viscosity matrix formed from gelling agents known in the art." '579 Pat., col. 11, lns. 1-3. However, this does not prove that gelling agents must always cause a gel to be formed or that a tooth whitening composition or substance always forms a gel. Moreover, the specification of the '579 patent explains that the use of a gel is only a preferred embodiment, stating that "the oral care substance of the present invention can be in a variety [of]

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forms, but, most preferable is a gel, particularly an aqueous gel." '579 Pat., col. 10, ln. 66 - col. 11, ln. 1 (emphasis added). In other words, the oral care substance is not always formed into "gel." Defendant cites nothing in the specification that indicates that when a gel is not formed a gelling agent is not present.

Contrary to defendant's suggestion, common sense does not dictate that the presence of a gelling agent shows that a gel must be formed. As plaintiff argues, there will be instances in which certain compounds cause a substance to change or alter only when a certain amount of that object is present. For example, one drop of colored dye might not visibly change the color of water but a number of drops will. Does that mean that the single drop of dye is not a dyeing agent? Perhaps a "gelling agent" is different from a dyeing agent. If it is, defendant has offered no evidence to show that it is. Therefore, I will not adopt defendant's proposed construction.

Court's construction: an agent that has the ability to form a gel

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Gene Associated with Drug Resistance	A gene which encodes a protein that, when expressed at some level or concentration, allows eucaryotic cells expressing the gene to survive or proliferate in the presence of a chemical compound, such as a drug, which would otherwise kill the cells

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2. Gene Fragment - Single or Double Stranded

The parties hotly dispute whether "gene fragment" as used in the '832 patent refers to single-stranded DNA, double-stranded DNA, or both. BM contends that the term, as used in the claim of the '832 patent, should be limited to double-stranded DNA, which would exclude from the patent claim the techniques of SDM and PCR. Genentech contends that the '832 patent claim uses the term "gene fragments" to refer to both single and double-stranded DNA.

a. Intrinsic Evidence

The language of the claim, by itself, does not define "gene fragments" as either single or double-stranded DNA. There are numerous references to a double-stranded composite of oligonucleotides as a "gene fragment." (See Patent Figure 1; col. 4, ll. 40, 45, 47, 56, 58; col. 5, ll. 1, 3, 9; col. 9, ll. 63-64.) In other instances, the '832 specification depicts single-stranded DNA fragments (Figure 2) and describes single-stranded fragments as single-stranded "DNA fragments," "fragments," "primers" or "oligonucleutides," but never "gene fragments." (See Col. 4, ll. 39-60 and col. 10, 11. 10, 13.) Two publications cited in the prosecution history also use the term "fragment" -- without the modifier "gene" -- to include single-stranded synthetic DNA: K. Itakura, et al., Expression in Escherichia Coli of a Chemically Synthesized Gene for the Hormone Somatostatin, 198 Sci. 1056 (1977) and R. Crea, Chemical Synthesis of Genes for Human Insulin, 75 Proc. Natl. Acad. Sci. 5765 (1978).

The intrinsic evidence is ambiguous with respect to the definition of gene fragment. On the one hand, the patent specification and prosecution history expressly depict and discuss single-stranded DNA, most notably in Figure 2. This supports Genentech's argument that the term gene fragment encompasses single and double strands of DNA. On the other hand, nowhere is a single-stranded DNA fragment referred to as a "gene fragment."

b. Extrinsic Evidence

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Because the term "gene fragment" is unclear, the Court must resort to extrinsic evidence. BM's expert, Dr. Webb, testified that as used in 1979, the term "fragment" meant either double- or single-stranded DNA, but when modified by the word "gene" in the patent, the term "gene fragment" should be construed to mean double-stranded DNA. In support of this interpretation, Webb testified that the method described in the '832 patent claim covers only a "way to cut and paste double-stranded DNA fragments of hGH [human growth hormone] together for the purpose of cloning them." (Defendants' Exhibit A at 8.) BM also points out that Genentech's own expert stated that when the term "gene fragment" is used in Step (a) of Claim 1, it refers to double-stranded DNA. (Falkinham Aff. P 34.)

Genentech's expert, Dr. Ravetch, testified that in 1979 the term gene fragment was used "to describe a piece of DNA, whether double-stranded or single-stranded." (Tr. 1-44.) The Court-appointed expert, Cepko, also agreed that one of skill in the art in 1979 would have used the term "gene fragment" to refer to either single or double-stranded DNA, since either could carry "all the important information that you need for whatever it is you wish to do with that DNA." (Tr. 3-15.) Moreover, she testified, "you can join [a single strand] up to double strands, you can ligate it into a double-stranded molecule, you can do quite a lot with it." (Tr. 3-29.) Cepko also acknowledged, however, that attempting to carry out the steps described in the '832 patent with a single-stranded DNA fragment is "typically not done" and "is very low efficiency." (Tr. 3-32.)

3. Gene Fragment -- Length of Fragment

With respect to the length of the synthetic fragment, BM first argues that the '832 patent is limited to ligating a significant number of synthetic codons to cDNA fragments. Its first argument rests on the term "sequence." Claim 1 of the '832 patent requires a synthetic gene fragment encoding "the remainder of the amino acid sequence" of the known polypeptide. Quoting a standard dictionary definition of "sequence," BM argues that the synthetic gene fragment must code for more than one amino acid. The problem with this argument is that "sequence" is not one of the terms which BM flagged as a subject of the Markman hearing, and it is too late to raise this issue in a post-hearing brief.

BM also argues that Step (c) is practiced only if a "significant portion" of the structural gene is provided by organic synthesis. This argument rests on the prosecution history. The claims of '832 were initially rejected on February 26, 1981, pursuant to 35 U.S.C. § 103, as being obvious in light of prior art which taught the chemical synthesis of genes that code for polypeptide hormones. Rejecting the patent claim, the examiner stated:
It would be obvious to remove the additional leader nucleotide sequences so as to provide for the transcription of active protein since microbial cells unlike eucaryotic cells cannot remove the precursor leader sequences. Where the removal results in the loss of essential parts of the coding sequence, it would be obvious to replace them by chemical synthesis such as that disclosed by Itakura et al or Crea et al.

(P. Ex. 2 at 88.)

Genentech responded by stating that the prior art taught away from the approach proposed by the examiner. Id. at 106. Rather, according to the inventors, one article taught that double stranded cDNA made from a mature messenger was the "material of choice" and the other noted that the size of the growth hormone prevented applying synthetic techniques. (P. Ex. 2, p. 107.) Because the prior art stated that the DNA sequence must be derived from RNA, Genentech told the Examiner that none of the prior art "proposes at any point that any significant portion of the structural gene itself be synthetically fashioned." Id. (emphasis added). Further, to refute the rejection for obviousness, the inventors distinguished other prior art as follows:
Never once is it proposed [in the prior art] that codons for the first 23 amino acids, reported as "missing" in the earlier clone, be supplied synthetically. And once further work had led to a clone comprising the entire sequence for human growth hormone, as well as additional sequences, it is nowhere proposed that codons for the superfluous protein be removed and the bioactive product expressed directly, after replacement of any needed codons lost in removing the presequence.

(Id. at 110.) (emphasis added).

BM relies on the expert testimony of Dr. Webb, who stated that small synthetic fragments of DNA, which he called linkers, were used in the prior art, and that methodologically, the claimed invention "differed from the prior art only in that it relied on the 'marriage' of a cDNA fragment made by the enzyme reverse transcriptase with a long, organically synthesized DNA fragment." (D. Ex. A PP 17-19.)

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While Dr. Webb may well be correct in describing prior art, an analysis of the prosecution history as a whole does not support BM's reliance on the doctrine of prosecution history estoppel. The thrust of Genentech's argument to the examiner is that none of the prior art taught any organic synthesis of the missing portion of the structural gene, regardless of whether the missing portion was significant or just a missing codon. Steps (a) and (b) state that the first gene fragment procured by reverse transcription is subject to no size limitation other than that it be less than the entire coding sequence. Moreover, the inventors described the claims which were amended to deal with the examiner's indefiniteness concern as claims "which now encompass every situation in which any portion of the subject genes (albeit less than all of it) is derived by reverse transcription from messenger RNA." (Id. at 101.) Accordingly, the Court concludes that Genentech is not bound to the limitation that a "significant portion" of the structural gene must be achieved through organic synthesis.

c. Claim Construction

Based on the patent specification and prosecution history, the Court construes the term "gene fragment" in the '832 patent claim to refer to either single or double-stranded DNA, of any length. n2

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n2 BM argues that such a construction leaves unresolved the issue of enablement because the '832 does not enable the use of single strand DNA without undue experimentation. See Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (invalidating patent for failure of specification to enable practice of claimed method), cert. denied, 139 L. Ed. 2d 310, 118 S. Ct. 397 (1997); Genentech, Inc. v. Wellcome Foundation, Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994) (refusing to construe patent in way that would require undue experimentation). BM also argues that SDM and PCR do not infringe the patent claims because they operate by enzymatic synthesis. Those arguments will have to await another day.

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6. Construction Of "Generates A Base Call Identifying Said Unknown Base"

Affymetrix's proposed construction of "generates a base call identifying said unknown base" is "determines which nucleotide is most likely to be present at a particular position in a nucleic acid sequence." (D.I. 243 at 37.) Illumina's proposed construction is "identifies a nucleotide as A, C, G or T (or U)." (D.I. 240 at 38.) The dispute here is over the specificity with which a nucleotide must be identified. The Court concludes that Affymetrix's proposed construction is more accurate.

As described in the specification, the invention does not necessarily call bases by identifying an unknown base as simply A, C, T, or G (or U). While it may call a base as a specific nucleotide, it may also call it "as being ambiguously one of two or more bases . . . ." ('716 patent, col. 9, 11. 22-25; see also Id., col. 8, 11. 8-30 (listing the various codes that may be assigned to bases by a base call).) Therefore, the Court construes "generates a base call identifying said unknown base" to mean "determines which nucleotide is most likely to be present at a particular position in a nucleic acid sequence."
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1. Claim Construction

7.It is the court's "power and obligation to construe as a matter of law the meaning of language used in the patent claim." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). Courts are directed to consider three sources to ascertain the meaning of a claim: The literal language of the claim, the patent specification, and the prosecution history. When interpreting the words of the claim, the court should "ascribe [to the words] their ordinary meaning unless it appears the inventor used them otherwise." Bell Communications

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Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). The words of the claim must be construed in the light of the specification, whose "description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." Markman, 52 F.3d at 979. The court should also consider the patent's prosecution history, as it constitutes an "undisputed public . . ." expression of what the patentee understood in terms of claim construction. Id. at 980. The court may, in its discretion, consider extrinsic evidence "to assist in its construction of the written document, a task it is required to perform." Id. at 981. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. at 980. Neither the patent's prosecution history nor any extrinsic evidence considered can "enlarge, diminish, or vary" the limitations in the claims. Id.

8. "Genes controlling the synthesis of a selected aminoacid." The parties dispute the meaning of the phrase "genes controlling the synthesis of a selected aminoacid" which appears in claim 1 of the '765 patent. Claim 1 requires the chromosome DNA fragment of the donor bacterium that is to be used to form the hybrid plasmid to contain "genes controlling the synthesis of a selected aminoacid." ADM argues that the phrase should be construed to mean all genes controlling the synthesis of a selected amino acid, and that ABP's strains do not literally infringe claim 1 because ABP's plasmids do not carry the asd gene. According to ADM's construction, the threonine operon would not satisfy the claims and, thus, the threonine producing E. coli described in the specification do not fall within the scope of claim 1. Ajinomoto takes the position that the phrase "genes controlling the synthesis of a selected aminoacid" and the term "operon" are equivalent.

9. ADM supports its position that the phrase "genes controlling the synthesis of a selected aminoacid" should be construed to include all genes controlling the synthesis of a selected amino acid by reference to the '765 patent specification, the claims, and expert testimony. The '765 patent specification states:

For further work in constructing the strain producing an aminoacid use is made of hybrid plasmids containing all the selected genes controlling the synthesis of the given aminoacid. In this case, if the isolated plasmids do not contain all the required genes, the above-mentioned operations are repeated by modifying the fragmentation of DNA, e.g., by using another specific endonuclease.

(JX 1 at col.5, lines 21-28) (emphasis added). Claim 1 of the '765 patent uses the phrase "genes controlling the synthesis of a selected aminoacid," (JX 1 at col. 12, line 5), whereas claims 3 and 4 refer to the threonine operon, (JX 1 at col. 12, lines 28-29, 45-46). ADM points out that operons do not invariably contain all the genes controlling the synthesis of an amino acid, and not all species have genes controlling the synthesis of any particular amino acid which are organized as an operon. (P 59)

10. Ajinomoto seeks to interpret the phrase as meaning the operon. The term "operon" is defined in the '765 patent as "a jointly controlled group of genes generally monitoring the synthesis of a single product, e.g. aminoacid." (JX 1 at col. 1, lines 49-51) In supporting its position, Ajinomoto argues that the threonine operon is encompassed in the phrase "genes controlling the synthesis of a selected aminoacid" because the operon controls the synthesis of threonine. In the examples set forth in the '765 patent and ABP's construct, once a plasmid that contained the threonine operon was inserted into an auxotrophic host, the strain was able to produce threonine. Dr. Falkinham testified that "in using the word operon, we would also include those genes involved in the regulation of expression of the -- those -- genes for threonine synthesis." (D.I. 308 at 322) On cross examination, Dr. Rudolph agreed that "in the ordinary course of business that we call the science of microbiology, when one refers to the genes controlling the synthesis of the selected amino acid, they refer to in the fashion you have with regard to Tribe . . . the structural genes that are involved in the expression of that aminoacid." (D.I. 317 at 1649)

11. Neither Ajinomoto nor ADM introduced specific evidence regarding the use of the term "operon" and the phrase "genes controlling the synthesis of a selected aminoacid" by one skilled in the art at the time of the invention.

12. Based on this evidence and the specification, the court concludes that the phrase "genes controlling the synthesis of a selected aminoacid" refers to the amino acid operon.
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b. "Method of genotyping"

The parties have proposed a total of three possible constructions of the term "method of genotyping." Plaintiff proposed:
A method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype.

Defendant proposed the following construction:
A method for identifying a desired type or subtype of HCV present in biological tissue or fluid;

or, in the alternative,
A method for identifying any and all types and subtypes of HCV that may be present in biological tissue or fluid.

Read in light of the patent claims and specifications, plaintiff's proposal comes closest to defining the term in a way that conveys the meaning intended by the inventors. The two proposals submitted by defendant omit the concept of distinguishing among types or subtypes of HCV and classifying them that is at the heart of the '704 patent. "[T]he am of the present invention is to provide a method for the rapid and indisputable determination of the presence of one or several genotypes of HCV present in a biological sample and indisputably classifying the determined isolate(s)." '704 Pat., col 2, Ins. 39-43. Defendant's first proposal describes only a method for identifying a desired type or subtype of HCV. Defendant comes closer in its second proposal, which is a method for identifying any and all types or subtypes of HCV. However, neither proposal captures the sense of distinguishing among types or subtypes an classifying the determined isolate or isolates. Therefore, I will use plaintiff's proposed construction: "A method that distinguishes among types and/or subtypes of hepatitis C virus (HCV) and classifies the HCV into a genotype or subtype."
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The first patent for which RPA seeks to have its five scientists declared joint inventors is the '497 patent or "Spencer patent". For present purposes, the crucial claim in the '497 patent is claim 46, which reads as follows:

A glyphosate resistant, hybrid maize plant comprising a chromosomally integrated expression cassette comprising (a) a modified maize EPSPS gene encoding an EPSPS protein having isoleucine at position 102 and serine at position 106 and (b) a promoter active in maize operably linked to said EPSPS gene, wherein said hybrid maize plant comprises a transformation event selected from the group consisting of GA21, seed comprising said GA21 transformation event having been deposited as ATCC Accession Number 209033, FI117, seed comprising said FI117 transformation event having been deposited as ATCC Accession Number 209031, GG25, seed comprising said GG25 transformation event having been deposited as ATCC Accession Number 209032, and GJ11, seed comprising said GJ11 transformation event having been deposited as ATCC Accession Number 209030.

('497 Patent, col.64, II.58 -- col.65, II.4.)

The parties have agreed on the proper construction of this claim. Specifically, they have agreed to the following construction:

The phrase "[a] glyphosate resistant, hybrid maize plant" means a hybrid corn plant that provides the level of glyphosate resistance provided by one of the four specifically identified transformation events. A hybrid corn plant is a cross of two different genotypes of corn, which are sometimes called the "parents" of the hybrid corn plant.

Because the four specifically identified transformation events already include (a) a modified maize EPSPS gene encoding

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an EPSPS protein having isoleucine at position 102 and serine at position 106 and (b) a promoter active in maize operably linked to said EPSPS gene, the claimed hybrid corn plant must have as one of its parents one of the four transformation events discussed below. A transformation event is a plant or seed which has a specific DNA cassette in a specific location somewhere within the chromosome of the corn cells.

The specific transformation events are identified by the phrase "GA21, seed comprising said GA21 transformation event having been deposited as ATCC Accession Number 209033, FI117, seed comprising said FI117 transformation event having been deposited as ATCC Accession Number 209031, GG25, seed comprising said GG25 transformation event having been deposited as ATCC Accession Number 209032, and GJ11, seed comprising said GJ11 transformation event having been deposited as ATCC Accession Number 209030." The seeds of the specific transformation events are made available to the public at the American Type Culture Collection, or "ATCC," and the accession numbers identify where the seeds are indexed at the ATCC.

Because the parties have agreed to this construction, and because the construction appears consistent with the language of the claim, the Court adopts this construction in its entirety.
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B. Claim Construction

Neither ConAgra's generalized request that the district court conduct a Markman hearing nor its insistence on appeal that many complex issues lurk in various unnamed claim terms creates a disputed issue of material fact. As noted, the district court construed the only term that ConAgra disputed explicitly: "golden brown." Presumably, all other claim terms were undisputed because one of ordinary skill in the art would understand their plain meanings. In the context of jury instructions, we have doubted "that Markman requires the trial judge to instruct as to an undisputed 'claim construction' for every term, by simply parroting the words of the claim. . . ." U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1567 (Fed. Cir. 1997). We doubt even more strongly that a district court is obliged to construe undisputed claim terms prior to issuing a summary judgment of invalidity. See also PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1357 ("Although an infringement analysis typically begins with claim construction, the district court here did not construe the claims. . . because their meaning is not disputed."). ConAgra's attempt to preserve its right to identify new "disputed" claims on appeal by requesting a generalized Markman hearing must therefore fail. See United States Surgical, 103 F.3d at 1567.

As to the content of the district court's construction, colors can indeed pose challenging construction tasks. At one level, they are commonly used terms with well-accepted plain definitions that rarely need construction. At another, they are precise scientific terms corresponding to very specific portions of the spectrum that require precise definitions and constructions. ConAgra argued below--and argues again on appeal--that the court should extract the range of Hunter-Lab Color Meter measurements from the '027 Patent's examples, and construe the term "golden brown" to include colors falling between "about" the low end and the high end of the illustrated ranges.

This dispute follows a classic pattern. The district court found no specific definition in the intrinsic evidence, and used a dictionary to find the term's plain meaning; ConAgra would have us extract a more technical construction by reading limitations into the claims from the examples. We discussed both the nature and the appropriate resolution of such disputes in Texas Digital Systems v. Telegenix, Inc., 308 F.3d 1193, 1202-04 (Fed. Cir. 2002):

It has been long recognized in our precedent and in the precedent of our predecessor court, the Court of Customs and Patent Appeals, that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms. . . .

[But] the intrinsic record also must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted. . . . [This] presumption . . . will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope. . . .

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Id. (emphasis added).

The district court here did not consult a dictionary prior to searching the intrinsic evidence for a definition. To the contrary, the district court explicitly concluded that "the '027 patentee did not act as his own 'lexicographer' and failed to specifically define the term 'golden brown'" as a precursor to concluding that the proper construction of "golden brown" flowed from its plain meaning. Given that conclusion, the district court then consulted a dictionary to affix a legal definition at least somewhat more precise than an intuitive understanding of a color. The district court's approach is proper. We have often noted that "[judges may] rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996). Such is the case here; the dictionary definition that the district court adopted did not contradict any definition that one of ordinary skill in the art could ascertain from the intrinsic evidence in the record.

The district court's adoption of a plain meaning construction is therefore presumptively correct. To overcome that presumption, ConAgra must demonstrate that the intrinsic evidence provides both a clear and explicit disclaimer of the plain meaning and substitutes a more specific, technical construction of "golden brown." See Tex. Digital, 308 F.3d at 1203. ConAgra's suggestion that we glean numeric ranges from examples represents neither clear nor explicit disavowal of the common meaning. In fact, the examples are precisely what they purport to be: examples of Hunter-Lab Color Meter measurements falling within the commonly understood range of "golden brown." ConAgra does little other than "invite[] a violation of our precedent counseling against importing limitations into the claims." Id. at 1204.

We recently reversed a district court's claim construction for doing precisely as ConAgra urges--reading a limitation from an example into a claim term:

Because the plain language of the claim was clear and uncontradicted by anything in the written description or the figures, the district court should not have relied upon the written description, the figures, or the prosecution history to add limitations to the claim. Under such circumstances, relying on the written description and prosecution history to reject the ordinary and customary meanings of the words themselves is impermissible.

Liquid Dynamics, 355 F.3d at 1368 (citations omitted). This admonition was hardly new. We have often stated that while . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims. We recognize that there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.

Comark Communications v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (citations omitted). See also CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (explaining that a patentee cannot rebut the presumption of ordinary meaning "simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history").

In short, the district court properly considered all intrinsic evidence before determining that none of it could overcome the presumption favoring plain meaning, and only then turned to a dictionary to affix the plain meaning that one of ordinary skill in the art would assign to the color "golden brown." The district court therefore correctly construed the only disputed term according to its plain meaning as one of ordinary skill in the art would understand it, and we affirm its claim construction.

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A. Patent '128

Patent '128 describes a "Pressure-Sensitive Adhesive," Specifically, what is claimed is:

A pressure sensitive adhesive which comprises in admixture:

(a) natural rubber graft copolymerized with styrene and methyl methacrylate in the form of a latex; and

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(b) a finely divided hard particulate matter having no thermoplasticity dispersed in the latex.

This is the only independent claim of the patent. Central States contends that this Court must interpret the term "graft copolymerization." However, the parties seem to be in agreement over the definition of the term. Each party relies upon dictionary definitions that are substantially the same. This Court adopts the definition found in Hawley's Condensed Chemical Dictionary 573 (12th ed. 1997); "Polymer having branches of varying length made up of different monomeric units on a common trunk chain."

It is instead the word "and" that links styrene and methyl methacrylate ("MMA") which causes disagreement between the parties. In the '128 patent, the common trunk chain is the natural rubber. The branches are styrene and methyl methacrylate. Moore argues that two types of graft polymeric molecules would be covered by the claim so long as they are both within the same latex admixture: (1) a group with a trunk of natural rubber grafted solely with styrene and (2) a group with a trunk of natural rubber grafted solely with MMA. Essentially, Moore argues that the claim should be interpreted to mean "natural rubber graft copolymerized with styrene and natural rubber graft copolymerized with methyl methacrylate commingled in the form of a latex." (Added terms emphasized).

Central States argues that Claim I requires that the styrene and MMA branches be attached to the same trunks of rubber. Central States' asserted claim interpretation can be stated as "natural rubber simultaneously graft copolymerized with both styrene and methyl methacrylate in the form of a latex." 2 (Added terms emphasized).

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2 Central States does not specifically use the word "simultaneous" in its briefs. Moore characterized Central States' interpretation as such. See Plaintiff's Markman Brief at 6. However, Central States did not dispute Moore's characterization and it is clear that this is an accurate representation of Central States' interpretation of the claim. See generally, Defendant's Reply at 3.

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While Moore's proposed interpretation is plausible, it is not the most straightforward reading of the claim language. The term "and" is a nontechnical term which will be given its ordinary meaning. The common meaning of the word "and" means "together with" or "in addition to." The American Heritage Dictionary of the English Language (3d. ed. 1996). Therefore, the natural rubber must be graft copolymerized with styrene in addition to MMA (i.e., present simultaneously on the same natural rubber backbone).

There is little in the other claims, specifications, or prosecution history to suggest a different meaning. Though the specifications indicate two "Comparative Example[s]" that include MMA as the only graft copolymer, see Patent '128, col. 3, lines 27-44, this is not evidence that Claim 1 cannot incorporate the mixture contained in the comparative example. The prosecution history indicates that Plaintiff declined the patent examiner's request to more completely describe the graft copolymerization of the invention. See Moore's Markman Brief, Ex. B. A response to the examiner's request may have been beneficial to interpreting the claim at issue. Absent this type of intrinsic evidence, the Court is constrained to limit its construction of the word "and" in Claim 1 to its ordinary meaning.

Moore also asks this Court to find that there is no requirement that the branches of styrene and methyl methacrylate be in pure form. Moore argues that the patent should be read to merely include branches of chemical compounds containing styrene or MMA. However, Moore's claim interpretation excessively broadens the scope of the claims and would treat the claims as the oft cited "nose of wax." 3 See White v. Dunbar, 119 U.S. 47, 30 L. Ed. 303, 7 S. Ct. 72, 74 (1886). Notice concerns weigh strongly against finding in favor of Moore's proposed interpretation. Moore has proffered no plausible arguments why Claim 1 should be interpreted to include a rubber backbone of either styrene or MMA. Based upon a plain reading, Claim 1 should be read to disclose an invention containing branches of MMA and styrene in their pure form only.

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3 As the Court in White stated: "The claim is a statutory requirement, prescribed for the very purpose of making the

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patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." White v. Dunbar, 119 U.S. 47, 30 L. Ed. 303, 7 S. Ct. 72, 75 (1886).

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B. Extent to Which the Grain Protein is Denatured

Defendants' next proposed claim construction relates to claim language concerning denaturation of the grain protein. They contend that the court should construe the claim term "grain protein" used as the starting material in step [i] of the claimed method to mean substantially undenatured and, furthermore, construe substantially undenatured in this context to mean less than about 10% by weight denaturation of said protein; construe the claim language in step [ii] "while avoiding any substantial heat denaturation of grain protein" to mean less than about 10% by weight denaturation of the previously substantially undenatured grain protein; and construe the claim language in step [iii] "substantially denaturing said grain protein" to mean the previously substantially undenatured grain protein is denatured such that there is less than about 10% by weight undenatured protein remaining. MGPI objects to this proposed claim construction on the grounds that it ignores the multifaceted nature of protein denaturation. Specifically, MGPI explains that the claims refer explicitly only to the use of heat denaturation, whereas there are many other types of protein denaturation such as shear, 1 hydrostatic pressure, and chemicals (e.g., extreme pH values, organic solvents and solutes, detergents, etc.). Thus, the parties' point of disagreement on this issue concerns when, and to what extent, the grain protein is denatured during the steps of the claimed method. 2

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1 Shear refers to shaking, kneading, whipping, and the like. Food Chemistry 362 (Owen R. Fennema ed., 3d ed. 1996) ("High mechanical shear generated by shaking, kneading, whipping, etc. can cause denaturation of proteins.").2 Denaturation is a one-way street: undenatured protein can be denatured, but once denatured it cannot be undenatured to return to its native state.

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Claim 1 3 provides, in relevant part, as follows:

A method of forming a biodegradable article comprising the steps of:

[i] providing a formulation comprising from about 20-85% by weight of grain protein . . . and at least about 0.01% by weight of a reducing agent operable for cleaving disulfide bonds present in said grain protein; and

[ii] heating said formulation . . . in order to render the formulation substantially homogeneous and flowable while avoiding any substantial heat denaturation of said grain protein; and

[iii] molding said heated formulation . . ., including the step of substantially denaturing said grain protein during said molding.

'152 Patent, col. 5, ll. 55-67 to col. 6, ll. 1-3 (emphasis added). The prosecution history establishes that the underlined language was added to distinguish the method claimed in the '152 Patent over Mullen. The reasons for allowance state that the prior art (i.e., Mullen) "fails to teach or suggest the improvement wherein the grain protein article is denatured only in the molding step."

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3 The parties seem to agree that although step [iii] is expressly included in claim 1 and not claim 24, it may be included in claim 24 because (1) that claim is a "comprising claim," which means that other steps may be added, and (2) claim 45, which is dependent on claim 24, expressly adds step [iii].

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Defendants also direct the court's attention to language in the specification which speaks to the issue of denaturation of the grain protein. One of the paragraphs in the Description of the Prior Art states as follows:

Grain proteins normally exhibit better moisture resistance than starch, but exhibit significant processing problems such as altered rheology and flow characteristics, especially under conditions of heat denaturation. As a consequence, it can be very difficult to economically process grain protein-based plastics using conventional extrusion and injection molding equipment. These problems are believed to stem in part from the highly branched and networked structure of grain proteins and their ease of denaturation under normal processing temperatures.

'152 Patent, col. 1, ll. 67 to col. 2, ll. 9. The Summary of the Invention set forth in the '152 Patent continues to address this issue:

Broadly speaking, the method of the invention first comprises the step of providing a formulation especially designed to have flow and rheology properties allowing the formulation to be processed using conventional plastics forming equipment. This formulation is then heated under moderate temperature conditions, usually with shear, to create a substantially homogeneous and flowable formulation. The heated formulation can then be formed into desired articles using injection molding, extrusion or other forming equipment. Very importantly, the formulation is prepared as a substantially homogeneous and flowable product with the avoidance of any substantial heat denaturation of the grain protein (normally less than about 10% by weight denaturation of such protein). Thereafter, during the formation of the desired articles, the substantially undenatured protein is denatured. Thus in the context of injection molding, the preferred temperature conditions of molding assure essentially complete protein denaturation.

Id. at col. 2, ll. 28-46 (emphasis added). The language underlined above was added during the prosecution history in connection with the narrowing amendment to distinguish over Mullen. Defendants rely heavily on this specification language to support their claim interpretation.

MGPI contends that the claim language and the portion of the specification cited by defendants speak only in terms of heat denaturation, and that defendants have ignored the disclosure of denaturation by the addition of a reducing agent (i.e., a chemical) to the formulation introduced into the extruder as well as the fact that the specification also states that the formulation can be "heated under moderate temperature conditions, usually with shear . . ." '152 Patent, col. 2, ll. 33-35 (emphasis added). Plaintiffs contend that they made the narrowing amendment to distinguish Mullen's high temperatures, which had the practical effect of causing nearly complete heat denaturation in the extruder. They contend that under the '152 Patent the only type of "undesirable" denaturation in the extruder is the heat denaturation. MGPI relies on another excerpt from the Summary of Invention which states as follows:

Normally, the reducing agent is simply added to the other components of the formulation prior to or as a part of the extrusion process. Alternately, the reducing agent can be used to preliminarily treat the selected grain protein(s) prior to preparation of the starting formulation. . . . In any case, the reducing agent should be used in an amount to cleave from about 10-100% of the disulfide bonds in the grain protein.

Id. at col. 3, ll. 38-47. MGPI contends that this teaches that the grain protein may be pretreated with a reducing agent to denature the protein by severing up to 100% of its disulfide bonds.

After careful consideration of the parties' arguments on this issue, the court largely agrees with plaintiffs' characterization of the intrinsic record, which is essentially that the narrowing amendment was made to limit the claim such that the addition of any heat to the formulation in the extruder in step [ii] may be only moderate so as to avoid "substantial heat denaturation of said grain protein" (emphasis added), as stated by the claim language. Neither the claim language nor the specification addresses the possibility of denaturation by other means such as pressure or chemicals. The written description indicates that "the reducing agent can be used to preliminarily treat the selected grain protein(s) prior to preparation of the starting formulation." Thus, this obviously permits the grain to be denatured in step [i], at least to some extent, by methods other than heat. To the extent that the starting grain protein is denatured in step [i], step [ii] simply prohibits any further substantial denaturation by virtue of heat. In fact, the specification states that the reducing agent can be used to treat the grain protein (i.e., denaturation by using chemicals) prior to step [i]. Defendants infer based on this argument that because

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the specification states that a reducing agent should be used to cleave from about 10-100% of the disulfide bonds in the grain protein, MGPI is contending that completely denatured protein can be provided for use in the claimed formulation. The court does not understand MGPI to be advocating such a claim construction, however. Instead, the court understands MGPI's argument in this regard to be targeted to explaining why defendants' proposed claim construction is wrong--namely, because it fails to account for other factors which may denature the grain protein throughout the claimed method.

On the other hand, based largely on the "[v]ery importantly" excerpt from the specification added to distinguish over Mullen, the court does agree with defendants to the limited extent that the grain protein in step [i] must be substantially undenatured. But, the "very importantly" language added to the specification to distinguish over Mullen, again, was addressed only to preventing heat denaturation of the grain protein in the extruder, i.e., before step [iii]. Indeed, this tracks with step [ii] of the claim language, which states that the formulation must be heated to render the formulation substantially homogenous and flowable "while avoiding any substantial heat denaturation of said grain protein." Thus, the court construes the term "grain protein" in step [i] to mean grain protein that has not been substantially denatured by heat.

The remaining aspect of defendants' proposed claim construction relates to importing the 10% limitation from the specification. It is well settled, however, that "when a claim term is expressed in a general descriptive word, the court will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1358 (Fed. Cir. 2006). This is particularly so where, as here, the patentee used numerical ranges and numbers throughout the claims of the patent and notably did not do so with respect to the degree of denaturation. 4 Accordingly, the court finds defendants' argument in this respect to be without merit. The court, then, rejects defendants' proposed claim construction concerning importing the less-than-10%-denaturation limitation from the specification. The court finds that the claim terms concerning denaturation of the grain protein require no further construction beyond construing the term "grain protein" in step [i] to mean grain protein that has not been substantially denatured by heat.

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4 Additionally, the parenthetical "(normally less than about 10% by weight denaturation of such protein)" once again follows a reference to "the avoidance of any substantial heat denaturation of the grain protein." Thus, even if the court were to find the less than 10% by weight denaturation limitation to be warranted (which the court does not), that number would apply only to denaturation by virtue of heat, not other factors.

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D. "granuate"

Claim 1 of the '552 patent, which is representative of the use of this term in the Stamm patents, is as follows:

A fenofribrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate having a particle size below 20 [mu] m, inert hydrosoluble carrier particles and at least 20% by weight of at least one hydrophilic polymer, wherein the weight ratio of fenofibrate to hydrophilic polymer is from 1/10 to 4/1.

('552 patent, col. 9 l. 66-col. 10 l. 4 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "granulate" to mean "a small grain or pellet, or small particles forming a larger unit." (D.I. 238 at 6, C.A. 02-1512-KAJ; D.I. 167 at 5, C.A. 03-120-KAJ.) Abbott argues that its proposed construction is consistent with the ordinary and customary meaning of "granulate." (D.I. 237 at 11.) Teva proposes that I construe "granulate" to mean "the carrier to which the hydrophilic polymer and fenofibrate are adhered as single particles or as agglomerates, forming a coated-core structure." (D.I. 238 at 6, C.A. 02-1512-KAJ.) Impax proposes that I construe "granulate" to mean "the product generated from a granulation process having structures consisting of an inert hydrosoluble carrier coated with micronized fenofibrate and a hydrophilic polymer or (the remnants of) some solvent for fenofibrate.

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(D.I. 167 at 5-6, C.A. 03-120-KAJ.) Teva and Impax each assert that based on disclosures in the specification, the "very character of the invention" is the coated-core structure, and, as such, it should be a part of every embodiment. (D.I. 223 at 35-36, C.A. 02-1512-KAJ; D.I. 169 at 12-13, C.A. 03-120-KAJ.)

2. The Court's Construction

As earlier noted, if patent claim language has an ordinary and accustomed meaning, there is a heavy presumption that the inventor intended that meaning to apply. Bell Atlantic, 262 F.3d at 1268. The ordinary meaning of "granulate," as a verb, is "to form ... into ... granules." Webster's Third New International Dictionary 989 (3d ed. 1986). In the context of the Stamm patents, however, the patentee clearly intends to use the term "granulate" as a noun, synonymous with "granule," whose ordinary and plain meaning is "one of a number of particles forming a larger unit." Id.

Neither Teva nor Impax has presented sufficient evidence to demonstrate that the patentee intended another meaning to apply. First, as noted in the foregoing discussion, see supra Parts IV.A. and IV.C., when the patentees intended to give a word or phrase a particular meaning, rather than simply relying on an ordinary and customary meaning, they did so in unmistakable terms. Second, Impax's proposed construction includes structural features of the preferred embodiment formed by the preferred process described in the specification. Specifically, Impax cites two statements in the specification regarding "the composition according to the invention." which refer to methods of preparing the composition. (See D.I. 169 at 13, C.A. 03-120-KAJ (citing D.I. 170, Ex. 4 at 6:3-7; 6:43-47).) Each of these statements, however, is part of the detailed description of the preferred embodiment. Further, product claims are generally not limited to the process by which the product is made. See Vanguard Prods. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed. Cir. 2000) (noting that product claims are not generally limited to the process by which such product is made); 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1374 (Fed. Cir. 2003) (construing the term "embossed" as referring to an embossed pattern without "limiting how the embossed pattern, as defined in the specification, is created") (emphasis omitted). Third, "granulate" is a "general descriptive term," defined subsequently in the claim which does not impose the limitations Teva and Impax seek to impart. Therefore, I construe the term "granulate," synonymously with granule, to mean "one of a number of particles forming a larger unit."

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D. "A Method for Providing Granulocytopoietic Therapy to a Mammal" ("Granulocytopoietic Therapy") (Claim 2 of the '823 patent)

Claim Term	Amgen's Construction	Teva's Construction
"granulocytopoietic therapy"	therapeutically treating a mammal by stimulating the production of granulocytes	roweatment that causes an increase in the number of, or development of, granulocytes

Claim 2 of the '823 patent is directed to "a method for providing granulocytopoietic therapy to a mammal." Teva proposes that we construe "granulocytopoietic therapy" as "treatment that causes an increase in the number of, or development of, granulocytes." Teva Br. at 26. Amgen proposes that the limitation means "a method for therapeutically treating a mammal by stimulating the production of granulocytes." Amgen Br. at 30. Teva notes that this leaves the definition of "therapy" undefined. Teva Br. at 27.

Teva argues that we should reject Amgen's proposed construction because it does not provide a complete definition of the limitation. Id. Teva claims that a person of ordinary skill in the art would understand that the term "granulocytopoietic" refers to the production/proliferation of granulocytes. Id. Teva claimsthat the term therapy has its plain and ordinary meaning, i.e., treatment. Id. at 28. Thus, Teva argues, "granulocytopoietic therapy" should be construed as the treatment that causes an increase in the number, or development of, granulocytes. Id. at 29.

Amgen agrees that "granulocytopoietic" means "the development of granulocytes." Amgen Br. at 31. But the parties differ on the definition of "therapy." Amgen argues that Teva's proposed construction improperly equates "therapy" with "treatment" and argues that Teva's construction would expand the claim scope to cover any increase in the number or

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development of granulocytes, regardless of whether the method achieves a therapeutic or remedial benefit to a mammal, as required by the claim language. Amgen Resp. at 23. Amgen contends that Teva's definition could theoretically involve nothing more than a medically inconsequential increase in the number of granulocytes, or a harmful and detrimental overproduction of granulocytes, neither of which constitute "therapy" as the claims require. Id. Amgen argues that "treatment" does not go far enough. It is "treatment" to alleviate or cure a condition. Medical dictionaries define "therapy" as the"treatment of disease." Id. Amgen claims that its construction embodies the therapeutic requirement of the claim but Teva's construction does not. Id.

Amgen also argues that Teva's construction reads the term "mammal" out of the claim, changing the meaning of the phrase from therapeutically treating a mammal to a definition that encompasses treating cells in a petri dish. Id. at 24. Finally, Amgen disputes the relevance of Teva's contention that the specification does not disclose examples of providing treatment to mammals, thus implying that the claim cannot be directed to providing therapy to a mammal. Id. at 25.

The term "granulocytopoietic therapy" does not appear in the specification (except in the claim itself). But in fair summary, the preamble states that the method must provide therapy to a mammal granulocytopoietically (i.e., by stimulating the production of granulocytes). In general, a claim preamble is limiting if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Intirtool, Ltd. v. Texar Corp., 369 F.3d 1289, 1295 (Fed. Cir. 2004). Here, the preamble is "necessary to give life, meaning, and vitality" to theclaim and it must be construed as a claim limitation. Catalina MarketingCatalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). Thus, the word "mammal" cannot be read out of the claim, and the term must encompass the limitation of providing therapy to a mammal.

In addition, although the examples in the specification do not disclose examples of providing therapy to a mammal, a claimed invention is not limited to the examples provided in the specification, but rather is defined by the words in the claims. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)(finding that the patent is not restricted to the examples, but rather is defined by the words in the claim); Dow Chemical Co. v. United States, 226 F.3d 1334, 1342 (Fed. Cir. 2000)(noting that, as a general rule, claims of a patent are not limited to the examples listed within the patent specification).

Amgen does ultimately define "therapy" in its response as "a medical or therapeutic benefit." Amgen Resp. at 23. Amgen stated that the present invention "has been proven to be clinically effective, and is the first therapeutic product which can be used to effectively treat the hundredsof thousands of chemotherapy patients who suffer from a dangerous drop in white blood cell counts, and to treat other disorders involving low white blood cell counts." Amgen's Br., Ex. 13 at AMT 00002363 ('755 Prosecution History, 5/29/90 Amendment D, Paper No. 9). We will adopt Amgen's construction because "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Amgen's product is meant to treat mammals therapeutically, and its construction encompasses that aim.
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2. "greater anabolic state in the mammal than achieved using an equivalent dose of IGF-I"

Plaintiffs contend that this phrase means to "promote total body weight gain or statural growth that is greater than whatever total body weight gain or statural growth would be observed if the same amount of IGF-I as present in the IGF-I/IGFBP-3 mixture were administered by the same route, regimen, and schedule of administration as is used in the administration of the IGF-I/ IGFBP-3 mixture." In short, Plaintiffs state that it requires "that the doses compared, i.e., complexed IGF-I/IGFBP-3 versus IGF-I alone, must contain the same quantity of IGF-I and they must be administered following the same dosing regimen." Defendants contend that this phrase means that "a greater state of constructive metabolism is produced in the mammal when an IGFI/ IGFBP-3 complex is administered than when an 'equivalent dose' of 'IGF-I' is administered alone." Defendants separately define equivalent dose as a dose of IGF-I alone which has, within the measurement error, the same number of molecules of IGF-I as the dose of IGFBP-3/IGF-I complex to which it is being compared. Plaintiffs believe that no separate construction of equivalent dose is necessary because it should be construed as part of the phrase.

Both parties rely on the specification to support their constructions. Plaintiffs point to language, under the heading "Modes

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for Carrying Out the Invention," stating that the "amounts administered will promote a greater anabolic state in the treated patient over the anabolic effect obtained using the same amount of IGF-I administered by the same protocol, regimen, and route, but without IGFBP being also administered." '151 patent, col. 7:20-25. As Plaintiffs note, the '151 patent does not purport to teach, or claim, benefits based on different amounts of IGF-I, different protocols, different doses, or different routes of administration. Defendants note that the language Plaintiffs quote from the specification relates to the term "effective amounts," which the parties have stipulated means "the amounts of IGF-I and IGFBP-3 co-administered produce a 'greater anabolic state in the mammal than that achieved using an equivalent dose of IGF-I alone.'" Regardless, the specification language quoted above is not to be ignored just because it concerns a different phrase. See ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003). The specification language Plaintiffs quote concerning the "same protocol, regimen, and route" is more useful in construing the phrase "greater anabolic state in the mammal than achieved using an equivalent dose of IGF-I" than the language to which Defendants point. For example, in their section on equivalent doses, Defendants contend that the patent refers to dose as the amount delivered per day, not per injection. Although this is true, the patent provides how many injections are to be given daily, e.g., "IGF-I delivery at 0.3 mg/kg/day (two injections of 15 pg per day)." '151 patent, col. 12:4-5. The experiments described in the patent illustrate that the '151 patent compares forms of the drug, not different doses or numbers of injunctions.

Defendants' other two arguments in support of their construction are based on their expert's report and English grammar. Neither argument is persuasive. Their expert states that, when making comparisons between two different treatments, "clinicians often compare total daily dosage of a drug, without regard to whether the drug is administered in one injection per day or two injections per day" and "comparison of daily dosages is scientifically relevant." 2d Spencer Report at P 47. This is extrinsic evidence, regarding what clinicians often compare, does not pertain to the patent at issue and is not useful. Defendants further argue that the phrase uses a past participle -- the word achieved -- and thus requires that a direct comparison have been made between the effect "achieved" using a complex of IGF-I and IGFBP-3 and that "achieved" using IGF-I alone. According to Defendants, Plaintiffs seek to rewrite the claim by adding the words I' if I' "were" and "would," to change the claim to require only a theoretical comparison of the effects of the complex and IGF-I alone that has not yet occurred and that may never occur. This argument is unavailing as well.

Based on the intrinsic evidence presented, the Court construes the phrase "greater anabolic state in the mammal than achieved using an equivalent dose of IGF-I" to mean promote total body weight gain or statural growth that is greater than whatever total body weight gain or statural growth would be observed if the same amount of IGF-I as is present in the IGF-I/IGFBP-3 mixture were administered by the same route, regimen, and schedule of administration as used in the administration of the IGF-I/IGFBP-3 mixture. The Court will not separately construe the term "equivalent dose" because it is construed as part of the above phrase.

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Claim Construction

Claim construction is a question of law. Kopykake Enters., Inc. v. Lucks Co., 264 F.3d 1377, 1381 (Fed. Cir. 2001). Claim construction "is the process of giving proper meaning to the claim language", which defines the scope of the claim. Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed. Cir. 1997). "All terms in a patent claim are to be given their plain, ordinary and accustomed meaning to one of ordinary skill in the relevant art." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). Absent compelling circumstances, "a court will give a claim term the full range of its ordinary meaning as understood by an artisan of ordinary skill." Rexnord, 274 F.3d at 1342. Claim terms will be construed in a way that is consistent with their appearance in other claims of the same patent or other parts of the same claim. Rexnord, 274 F.3d at 1342.

The claim language is the focus of determining the meaning of disputed claim terms. Abtox, 122 F.3d at 1023. However, courts will consider intrinsic evidence, the claims, the specification, and the prosecution history. Kopykake Enters., 264 F.3d at 1381. If the meaning of the disputed terms are still ambiguous after consideration of intrinsic evidence, courts will consider extrinsic evidence. Kopykake Enters., 264 F.3d at 1381. Although a dictionary is considered extrinsic evidence, "judges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d

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1576, 1584 n.6 (Fed. Cir. 1996).

Once the court has ascertained the meaning to one of ordinary skill in the art of the disputed term, the court will examine the written description and drawings to be certain that the patentee's use of the term is consistent with the meaning determined by the court. Rexnord, 274 F.3d at 1342. A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Rexnord, 274 F.3d at 1342 (quoting Vitronics, 90 F.3d at 1583). The drawings and written description are examined "to determine whether the patentee has disclaimed subject matter or has otherwise limited the scope of the claims." Rexnord, 274 F.3d at 1343. The court should also examine the prosecution history to determine whether the patentee has ascribed a special meaning to the term that is inconsistent with the term's ordinary meaning. Vitronics, 90 F.3d at 1582. Furthermore, any meaning that was disclaimed during the prosecution of the patent as revealed by the prosecution history is excluded. Vitronics, 90 F.3d at 1583.

The parties dispute the meaning of the language "greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone" as it is used in Claims 1 and 2 of the '252 patent.

The '252 patent claims:

1. A process for treating pain in a mammal which comprises administering to the mammal the amount of a pharmaceutical composition effective to provide an analgesic effect, said pharmaceutical composition comprising hydrocodone or a pharmaceutically acceptable acid addition salt thereof and ibuprofen or a pharmaceutically acceptable acid addition salt thereof, the ration of hydrocodone to ibuprofen being within the range that the administration of a therapeutic amount of said composition to a mammal will provide a greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone.

2. A pharmaceutical composition which comprises hydrocodone or a pharmaceutically acceptable acid addition salt thereof and ibuprofen or a pharmaceutically acceptable acid addition salt thereof in amounts that are sufficient to provide an analgesic effect, the ratio of hydrocodone to ibuprofen being within the range that the administration of a therapeutic amount of said composition will provide a greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone.

'252 Patent, Col. 5, ll. 12-34; Col. 6, ll. 1-3.

Plaintiffs argue that this language should be construed as "describing a composition consisting of hydrocodone and ibuprofen in a ratio sufficient to provide a 'greater analgesic effect' than the effect obtained by using either hydrocodone or ibuprofen alone" at the same dose. (Pls.' Mem. Supp. Mot. Summ. J. Patent Infringement at 7-8.) Plaintiffs argue that this is the proper construction of the terms because the language is unambiguous, and one of ordinary skill in the art would understand the terms "greater analgesic effect" to mean greater than the analgesic effect at the same dose.

Teva argues that the language in Claims 1 through 6 "indicates that the combination [of hydrocodone and ibuprofen] is to be compared against whatever therapeutic dose of hydrocodone alone and ibuprofen alone that provides the maximum analgesic effect." (Teva's Opp'n Pls.' Mot. Summ. J. Patent Infringement at 8.) Teva argues that because the specification states that the therapeutic dosage range in humans of ibuprofen is 200 to 400 mg and that of hydrocodone is 5 to 10 mg, the claim language should be construed to mean that "the combination [of hydrocodone and ibuprofen] outperforms the maximum therapeutic dose of ibuprofen alone (400 mg) and hydrocodone alone (10 mg), not merely ibuprofen or hydrocodone in the 'same dose' as in the combination." (Id. at 8-9.) This meaning is based on (1) the use of the claim term "obtainable", which Teva argues indicates that the combination should be compared to the therapeutic doses of the drugs providing the maximum practical analgesic effect and (2) representations that Dr. Arnold made to the PTO, the EPO, and the Israeli Patent Office ("IPO") that the combination was novel because it provided a greater analgesic effect than either constituent at an increased dose.

"Obtainable" is defined as "capable of being obtained [;] available." Webster's Third International Dictionary 1559 (3d ed. 1986). This language, in Claims 1 and 2, does not suggest that the "greater analgesic effect" means that the claimed

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combination must outperform the maximum dosages of the component drugs in humans.

Neither the '252 patent's claims nor the specification contain any language that the terms "greater analgesic effect" have a plain meaning that would require the combination to outperform the component drugs at a maximum dose or any other increased dose. The plain language of the claims does not state that the combination provides a greater analgesic effect than the component drugs at an increased dose or a maximum dose. No dose or dose range is mentioned at all. Rather, Claims 1 and 2 clearly state that the combination provides a greater analgesic effect than either hydrocodone or ibuprofen alone.

Moreover, nothing in the claim language or the specification supports a construction that requires the claimed combination to provide a "greater analgesic effect" than a maximum dosage in humans. The plain language of the patent claims "a process for treating pain in a mammal which comprises administering to the mammal," '252 Patent, col. 5, ll. 12-13; "the ratio of hydrocodone to ibuprofen being within the range that the administration of a therapeutic amount … to a mammal will provide a greater analgesic effect," Id., col. 5, ll. 18-21, 30-33. The use of the term "mammal" rather than "human" indicates that the "greater analgesic effect" of the claimed combination should not be limited to human doses because humans are merely a subset of mammals. Moreover, in describing the preferred embodiment, the '252 patent states "the regimen will be prescribed by the physician or veterinarian[,] depending on the needs of the individual patient" which indicates that the patentee did not limit the claim terms by or to any human doses.

Furthermore, the prosecution history does not contain "any limiting definitional arguments or concessions that would require the [terms "alone" and "greater analgesic effect"] to be interpreted with the added requirements" Teva seeks to impose. Burke, Inc. v. Bruno Independent Living Aids, Inc., 183 F.3d 1334, 1341 (Fed. Cir. 1999).

Therefore, based on the foregoing, a "greater analgesic effect" is construed to mean "a greater analgesic effect than the effect capable of being obtained by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone at the same dose."

Claims 3 through 6 do not use the "greater analgesic effect" term, and neither party appears to dispute the meaning of any terms in those claims. Thus, based on the plain language of the terms, the remaining claims are construed as follows.

Claim 3 is construed to claim "a process for treatment of pain in a mammal which comprises administration to the mammal one part by weight of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and about twenty to eighty parts by weight of ibuprofen or a pharmaceutically acceptable salt thereof."

Claim 4 is construed to claim "a pharmaceutical composition comprising a pharmaceutically acceptable carrier and an analgesically effective amount of (1) one part by weight of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and (2) about twenty to eighty parts by weight of ibuprofen or a pharmaceutically acceptable salt thereof."

Claim 5 is construed to claim "a process for treating pain in a mammal which comprises the administration to the mammal of a dosage unit of (1) 5 to 10 mg of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and (2) 200 to 400 mg of ibuprofen or pharmaceutically acceptable acid addition salt thereof."

Claim 6 is construed to claim a "pharmaceutical composition in unit dosage form comprising a pharmaceutically acceptable carrier and (1) 5 to 10 mg of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and (2) 200 to 400 mg of ibuprofen or a pharmaceutically acceptable salt thereof."
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5. "greater number"

Claims 1, 2, 13, and 14 of the '600 patent contain the phrase "greater number of codons preferred by the intended plant host." DeKalb claims that this "greater number" limitation means that the synthetic gene uses codons that more closely resemble the overall distribution of codons in the intended plant host. DeKalb claims that any codon is "preferred" if its addition to the Bt gene makes its frequency closer to the frequency in plant genes. Mycogen disputes this interpretation, claiming that DeKalb's construction would make the "greater number" limitation no different from the "frequency"

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limitation in its other claims. DeKalb admits this. DeKalb argues that the two phrases are synonymous.

The main point of contention is in the meaning of "codons preferred. " Mycogen claims that this term refers to those codons that appear most frequently for each individual amino acid in the starting gene. In other words, if GCT is the most frequent codon for specifying the amino acid alanine in dicot plants, then GCT is a "preferred codon." Since there are 20 amino acids, under Mycogen's definition exactly 20 of the 61 existing codons are "preferred" in any specific organism. It claims that the "greater number" limitation is satisfied if there is a higher total of these 20 "preferred" codons in the synthetic gene than there was in the initial coding sequence.

A determination of the proper construction of the term "codons preferred" will resolve the dispute about the "greater number" claim. If Mycogen is correct in its interpretation that there are 20 specific preferred codons, then DeKalb's position that the claim is referring to the overall distribution of all codons cannot be correct. On the other hand, if DeKalb is correct that any codon is preferred if its addition brings the codon usage frequency closer to that of the intended host, then Mycogen's position that the claim requires a simple summation of 20 specific codons would be incorrect.

The evidence relating to the proper meaning of the term "codons preferred" supports the positions of both parties. The court will discuss the relative strength of the parties' proposed constructions in light of the language of the patent, the prosecution history, and the doctrine of claim differentiation.

a. Patent language

Mycogen first points to the claim language to support its position. Under the plain meaning of the phrase "greater number," Mycogen argues, these preferred codons are something that can be counted. Its claim interpretation involves the counting of the codons most frequently used for specifying each individual amino acid. Mycogen argues that DeKalb's interpretation is not amenable to a counting of codons, because the only relevant consideration in DeKalb's interpretation is frequency of codons, not total occurrences of each codon.

DeKalb counters that the only counting technique offered by Mycogen in its specification is one for calculating the percent deviation of the frequency of preferred codon usage for a synthetic gene from that of a host cell. Col. 7, lines 15-43. This calculation does not involve simple counting, but rather sums up the differences between the frequency of each codon as used in the synthetic gene and the frequency of the same codon as used in the plant host, and divides by the total number of codons. DeKalb argues that Mycogen's suggestion that one simply add up the number of appearances of specific codons is never disclosed or described in the patent or its specification.

The patent specification uses the phrase "codons preferred" or "preferred codons" several times, and in ways that support both parties' arguments. Mycogen points to the portion which reads:
In designing a synthetic gene encoding the Bt crystal protein, individual amino acid codons found in the original Bt gene are altered to reflect the codons preferred by dicot genes for a particular amino acid.

Col. 22, lines 25-29 (emphasis added). This is followed by the statement that:
In the case of alanine, it can be seen from Table 1 that the codon GCA is used in Bt proteins with a frequency of 50%, whereas the codon GCT is the preferred codon in dicot proteins.

Col. 22, lines 32-35 (emphasis added). Table 1 indicates that GCT is used 42% of the time that alanine is specified in dicot plant genes, more often than the other three alanine-specifying codons. Thus, it would appear that the term "preferred codon" is used in this section of the specification in a way consistent with Mycogen's proffered definition.

Mycogen also cites the specification's use of the term "least preferred codon" to describe codons ending in CG (col. 4, lines 21-22) as another example that is consistent with its definition of the term "preferred codon." According to Table 1, each codon ending in CG appears least frequently for the amino acid it specifies.

DeKalb points to different sections in the specification. When explaining how to calculate the difference in frequencies of codon usage between the synthetic gene and the plant host, the specification refers to the percent deviation of the frequency of preferred codon usage. Col. 7, lines 15-16 (emphasis added). This calculation measures the difference in frequency of codon usage for every codon - not just the 20 that Mycogen claims are defined as preferred codons.

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DeKalb also argues that the teaching of the specification consistently refers to the frequency of codon usage, not simply increasing the raw number of specific codons. In the very section of the specification that Mycogen quotes to support its definition, it also states that
Attention is given to maintaining the overall distribution of codons for each amino acid within the coding region of the gene. . . . Not all codons for alanine in the original Bt gene are replaced by GCT; instead, only some alanine codons are changed to GCT while others are replaced with different alanine codons in an attempt to preserve the overall distribution of codons for alanine used in dicot proteins.

Col. 22, lines 29-41.

The patent specification contains an example of a gene produced by the patented method. In this example, of the 20 codons that Mycogen defines as preferred codons, 7 of them occur a fewer number of times in the synthetic gene than they did in the native gene prior to modification. Mycogen points out that the other 13 codons occur more frequently, and that the total number of these 20 codons is greater in the synthetic gene than in the native Bt gene. However, DeKalb claims that nothing in the teaching of the patent dictates this result.

b. Prosecution history

DeKalb also points to evidence in the prosecution history that the "greater number" claim was meant to refer to the overall codon distribution. During the application process of the '831 patent, in his declaration, Dr. Murray explains that the method taught involves modification to the Bt sequence that "will result in a frequency of codon usage that more closely reflects that of the intended plant host." Id. at P4(G). He states that by comparing the frequency of codon usage of the Bt gene and the intended plant host, one "would easily be able to determine those codons which were unfavored by the plant, and be aware of possible nucleotide substitutions which could convert selected unfavored codons into codons which are more preferred by the plant host." Id. (emphasis added). Dr. Murray also states that "there is no 'right' or 'wrong' synthetic sequence, so long as [it] more closely reflects the frequency of codon usage of the intended plant host." Thus, DeKalb argues that Dr. Murray viewed the "codons preferred" as those that most closely reflect the overall distribution of codons in plant genes.

Mycogen argues that the prosecution history supports its claim construction, and not DeKalb's. In October, 1995, during the prosecution of the '862 patent, the patent examiner suggested that the "greater number" and "frequency" claims were anticipated by two references that disclosed the truncating of the native Bt gene. Mycogen responded that a mere shortening of the Bt sequence could not possibly modify a native Bt sequence so that it would have a "greater number of codons preferred." Rather, Mycogen claimed that such a truncation could only result in a reduction in the number of plant-preferred codons or no change in the number. In response to a concern raised by the patent examiner in January, 1996, Mycogen reiterated that "while a mere truncation, not involving substitution of codons . . . could affect the frequency of codon usage, it can in no way result in an increase in the number of plant preferred codons." (emphasis in original). Mycogen argues that this is evidence that the greater number claims must refer to something different than the distribution of all codons in the gene, and evidence that the "greater number" limitation is not synonymous with the "frequency" limitation.

c. Claim differentiation

Mycogen argues that DeKalb's interpretation is contrary to the doctrine of claim differentiation, which states that:

There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.

United States v. Telectronics, Inc., 857 F.2d 778, 783 (Fed. Cir. 1988) (quoting Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987). Mycogen claims that DeKalb's interpretation of the "greater number" limitation makes claims containing the limitation superfluous, since they would then be identical in meaning to claims containing the "frequency" limitation.

DeKalb responds that the doctrine of claim differentiation is not an automatic bar to their proposed construction. It cites

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case language that states that "two claims which read differently can cover the same subject matter." Tandon Corp., 831 F.2d at 1017. DeKalb argues that the differently phrased limitations simply define the invention using different terminology, and that the Federal Circuit has observed that this "is not unusual." Hormone Research Foundation v. Genentech, Inc., 904 F.2d 1558, 1567 n.15 (Fed. Cir. 1990).

d. The court's construction

Neither the doctrine of claim differentiation, nor the evidence in the prosecution history that Mycogen considers the "greater number" limitation to have a different meaning than the "frequency" limitation, supports Mycogen's proposed construction of the phrase "codons preferred." The court finds that these two limitations are slightly different, consistent with Mycogen's representations in the prosecution history. The difference is demonstrated by the example of the truncated gene. Mycogen argued in the prosecution of the '862 patent that such a gene could not possibly contain a greater number of codons preferred by the intended plant host. This statement does not preclude DeKalb's proposed construction. It is possible that a truncation might eliminate some codons that are more frequent in the Bt gene that they are in the plant gene, and thus make the overall frequency of codon usage more like that of the plant. However, that same truncation would not add codons to the gene, and thus there would not be a greater number of any codons, including those that are "preferred."

The court finds, after considering the claims, the specification, and the prosecution history, that DeKalb's construction of the term "greater number" is correct. Mycogen can only point to a single reference in the specification to support its position that the phrase "codons preferred" refers to the group of codons that are each the most frequently used to specify one of the amino acids. The one reference in the specification is not a definition of that term, but a use of the term "preferred codon" to describe GGA, the most frequently occurring codon for alanine in dicot plants. However, the specification also uses the phrase "preferred codon" in the language explaining how to calculate the percent deviation of codon usage. In that passage, "preferred codon" apparently refers to all codons, since the frequency of every codon is included in the calculation.

The list of the 20 codons that Mycogen considers to be the "preferred codons" does not appear anywhere in the prosecution history. Mycogen does not offer any evidence that their definition of the term is a common one in the field of genetics. Patent law places upon inventors the duty of "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. If Mycogen intended that "codons preferred" have this specific definition, it could have defined the term in the specification. Thus, the court finds that the term "codons preferred" does not refer to the codons that are most frequently occurring for each individual amino acid. Rather, a codon is "preferred" if its addition to the native gene makes its frequency in that gene more like the frequency of that codon in the gene of the intended plant host.

Therefore, the limitation "greater number of codons preferred" is satisfied where the newly-created synthetic gene has a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the intended plant host, and where the synthetic gene has an overall distribution of codon usage that is closer to that of the intended plant host.
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The '797 patent claims a process for making E. coli cells with an enhanced capacity to accept foreign DNA. A cell that accepts foreign DNA is called a transformable cell. The transformable cell's capacity to accept foreign DNA is called its competence. The '797 patent thus claims a method of producing transformable E. coli cells with improved competence. The foreign DNA is generally plasmid DNA -- a relatively small DNA molecule having a looped circular shape. Claim 1 of the '797 patent states:

1. A process for producing transformable E. coli cells of improved competence by a process comprising the following steps in order:

(a) growing E. coli cells in a growth-conducive medium at a temperature of 18 sdegreessC. to 32 sdegreessC.;

(b) rendering said E. coli cells competent; and

(c) freezing the cells.

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'797 patent, col. 10, ll. 26-32 (emphases added).

Invitrogen accused Stratagene of infringing claims 1-5, 7-11, and 13-16 of the '797 patent. Stratagene makes and sells competent E. coli cell lines. Stratagene makes its cell lines by a process that includes the steps of incubating cells at 37 sdegreessC, growing the cells in a fermenter at 26 sdegreessC, and freezing the cells.

On March 12, 2001, Invitrogen filed a complaint against Stratagene in the District Court for the Western District of Texas. On August 16, 2001, the district court held a Markman hearing to construe the claims. On August 30, 2001, the district court issued an order construing the preamble term "improved competence" and the growing step (a). On September 11, 2001, Stratagene filed a motion for summary judgment of noninfringement based on the district court's claim construction. On November 2, 2001, the district court granted Stratagene's summary judgment motion. On January 31, 2002, the district court issued a final judgment dismissing the action.

Invitrogen appealed the district court's summary judgment of noninfringement. Invitrogen asserts that the district court erred in concluding that the growing step (a) excludes all cell growth carried out above 32 sdegreessC. Invitrogen also disputes that the preamble term "improved competence" limits the claims. Stratagene cross-appealed. Stratagene asserts that the district court erred in concluding that the preamble term "improved competence" means that competence is "generally increased" with no numerical limitation.

This court has jurisdiction under 28 U.S.C. § 1295(a)(1) (2000).

II.

This court reviews without deference a district court's grant of summary judgment, and draws all reasonable factual inferences in favor of the non-movant. Cortland Line Co. v. Orvis Co., 203 F.3d 1351, 1355-56, 53 USPQ2d 1734, 1736 (Fed. Cir. 2000). This court decides for itself whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

A court determines patent infringement by first construing the claims and then applying the construed claims to the accused process or product. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). This court reviews a district court's claim construction without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc).

Claim language generally carries the ordinary meaning of the words in their normal usage in the field of invention. Toro Co. v. White Consol. Indus., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999). While this "ordinary meaning" rule is usually expressed as a pat formula, the context supplied by the field of invention, the prior art, and the understanding of skilled artisans generally is key to discerning the normal usage of words in any claim. See, e.g., Hoechst Celanese Corp. v. BP Chems., Ltd., 78 F.3d 1575, 1579 (Fed. Cir. 1996).

The applicant may also act as his own lexicographer and use the specification to implicitly or explicitly supply new meanings for terms. Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268, 59 USPQ2d 1865, 1870-71 (Fed. Cir. 2001). While prosecution history estoppel does not apply to determining literal claim scope, statements to an examiner during prosecution before the United States Patent and Trademark Office (PTO) may also illuminate the scope of the claims. See Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1358, 60 USPQ2d 1493, 1498 (Fed. Cir. 2001). Moreover, an applicant may actually disclaim claim scope during prosecution. Ballard, 268 F.3d at 1361. The applicant, however, must clearly and unambiguously express any such surrender of subject matter during prosecution. See Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388, 65 USPQ2d 1138, 1141 (Fed. Cir. 2002); Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1372, 64 USPQ2d 1926, 1932 (Fed. Cir. 2002).

A. The "Growing" Step

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The district court construed the growing step (a) to mean that "growth must be performed at a temperature within 18 sdegreessC to 32 sdegreessC, inclusive, and that at no time prior to freezing can the temperature of the cells exceed 32 sdegreessC." Invitrogen Corp.v. Biocrest Mfg., L.P., No. A 01 CA 167 SS, slip op. at 10 (W.D. Tex. Aug. 30, 2001) (Claim Construction Order). The district court rejected Invitrogen's argument that the term "comprising" in the preamble meant that claim 1 was open-ended and thus allowed an additional step of growing cells at 37 sdegreessC before the growing step (a). The district court instead read the prosecution history of the '797 patent to disclaim all growth outside the range in step (a). In other words, the district court's claim interpretation foreclosed any growth other than growth in the claimed temperature range.

When entering a rejection during prosecution of the application that led to the '797 patent, the PTO examiner stated that 18 sdegreessC to 32 sdegreessC was essential to the invention. The applicants then amended the claims to replace "less than 37 sdegreessC" with "18 sdegreessC to 32 sdegreessC" in claim 1. The applicants then stated that their amendment ensures that the claimed invention is different from prior art showing growth at 37 sdegreessC. Furthermore, the applicants noted that the invention avoids undesirable effects of growth at 37 sdegreessC. On the basis of this rather sketchy record, the district court concluded that the applicants had disclaimed all growth outside the range of 18 sdegreessC to 32 sdegreessC. Therefore the district court interpreted the claim to exclude any growth outside that range.

To the contrary, claim 1 does not address and therefore permits growth before the steps disclosed in the claim at temperatures outside the range of 18 sdegreessC to 32 sdegreessC. At the outset, the claim language itself does not preclude growth in advance of the first step in the claim. Step (a) of claim 1 specifies E. coli population growth at 18 sdegreessC to 32 sdegreessC. Step (b) specifies rendering competent the cells that immediately result from step (a). Step (b) conveys this by stating "rendering said E. coli cells competent" (emphasis added). The cells that are rendered competent in step (b) include specific cells formed at 18 sdegreessC to 32 sdegreessC in step (a). At no point has this claim addressed or limited any activities that may have occurred before steps (a) and (b).

The transition "comprising" in a method claim indicates that the claim is open-ended and allows for additional steps. See Vivid Techs., Inc., v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 811, 53 USPQ2d 1289, 1301 (Fed. Cir. 1999) (citing Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed. Cir. 1986)). Claim 1 uses the open-ended transition "comprising" to introduce the recited steps. Thus the claim signals to patent practitioners that claim 1 allows activity, even activity that produces E. coli cell growth, before the recited steps. Such activity outside the claim, of course, is not limited by the temperature range recited in claim 1. Thus, the district court erred by extending the claim's temperature restrictions beyond the reach of the claims. The claim language and its form do not restrict activities to prepare the cells that occur before the claimed method.

As noted earlier, the context of this scientific field illuminates the claim's meaning and reach. The '797 patent discusses the field of invention. In this discussion, the patent discloses that skilled artisans in this field grow and store E. coli cells at temperatures outside the range 18 degrees C to 32 degrees C in preparation for the claimed method. For example, the '797 patent discusses preparation of master seeds by a process involving growing E. coli cells at 37 degrees C (col. 5, ll. 49-50). Master seeds are frozen E. coli strains stored long-term at -70 degrees C. These master seeds must undergo preparation before becoming the primary seeds for use in the claimed method. The '797 patent discloses the growth or preparation of primary seeds at 18 degrees C to 32 degrees C, but notes that artisans may use higher temperatures because the resulting primary seeds "can be used to prepare competent cells from a culture grown at a lower temperature" (col. 6, ll. 5-13). The specification thus supplies context about the understanding of skilled artisans and the field of invention that confirms that claim 1 does not preclude growth before the first step in the inventive process.

The prosecution history does not show any clear and unambiguous disavowal of steps in advance of the step of growing E. coli cells in the claimed temperature range. By amending the claims to replace "less than 37 sdegreessC" with "18 sdegreessC to 32 sdegreessC" the applicants did not exclude all cells with ancestral growth above 32 sdegreessC. Instead, the applicants simply specified the requirement of growth of primary cells within the required range to render the cells competent in the following step (b). In context, the applicants' statements about the undesirable effects of growth at 37 sdegreessC refer to growth at 37 sdegreessC that immediately precedes rendering the E. coli competent. The applicants did not address growth at 37 sdegreessC that occurs before initiation of the claimed method. As the inventors stated in a declaration submitted to the PTO during prosecution, the invention provided improved competence "by growing the cells at 18 sdegreessC to 32 sdegreessC before rendering the cells competent" compared to an otherwise identical process with growth at 37 sdegreessC. The applicants did not disclaim all growth above 32 sdegreessC but instead emphasized the

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advantages of growth at 18 sdegreessC to 32 sdegreessC immediately before rendering the E. coli competent.

The district court's construction would also effectively exclude the embodiment of Example 3 of the '797 patent. This court has held that construing a claim to exclude a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1578 (Fed. Cir. 1996). This court finds no highly persuasive evidentiary support for excluding Example 3. Example 3 shows initial growth at 37 sdegreessC followed by growth at 23 sdegreessC before rendering the resulting cells competent. Specifically, Example 3 shows cells grown in a flask at 37 sdegreessC. Next Example 3 cooled the flask to about 23 sdegreessC. Finally, samples were removed at 30-minute intervals between 0 and 120 minutes before being rendered competent and transformed.

Example 3 also is not a comparative example meant to show the deleterious effect of growth at 37 sdegreessC. Table 3 shows the results of Example 3. The '797 patent describes the results as follows: "The results of this experiment indicate that shifting strain RR1 from 37sdegreess C. to 23sdegreess C. for two hours results in a 60 fold increase in the efficiency of transformation compared to a sample which does not undergo a temperature shift" (col. 10, ll. 20-24). The comparative example is the sample that "does not undergo a temperature shift," i.e., the sample removed at 0 minutes without spending any time at 23 sdegreessC. Thus, the entire context of the patent and its field of invention show that Example 3 demonstrates that even a small amount of growth in the claimed range (e.g., for 30 minutes) increases competence. Indeed the district court's construction would also exclude other embodiments disclosed in the '797 because ancestral cells are often grown at 37 sdegreessC at some stage.

Thus, an examination of the claim language in its proper scientific context, as well as a proper reading of the prosecution history, shows that step (a) encompasses only growth immediately preceding step (b). As the claim specifies, this growth must fall in the range of 18 sdegreessC to 32 sdegreessC. Growing the E. coli at 18 sdegreessC to 32 sdegreessC in step (a) yields a mass of cells that step (b) renders competent. The claim scope thus does not preclude preparatory steps in advance of step (a), including growth of E. coli at a temperature outside the step (a) range.
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4. "Haplotypic Pattern"

GTG proposes the construction "data, from an analytical method, that is characteristic of a particular haplotype." Applera proposes "a pattern of DNA fragments that have been separated according to mobility and visualized, and which is uniquely indicative of the presence of a particular haplotype," based on its reading of the prosecution history.

While it is true that in the prosecution history of the '762 patent, the patent examiner found the previously-proposed claims overbroad and unsupported by the specification, Applera Exh. U at 4, those findings were in relation to claims that did not contain the term "haplotypic pattern" but merely stated generally that a locus would be "identified." See, e.g., Applera Exh. S at 68. Those claims were then cancelled and newer, more specific claims describing the type of identification to be made, involving "haplotypic patterns," were substituted in their place on January 2, 1997. GTG Exh. N (also located at Applera Exh. W). Based on this file history, it is clear that GTG has not disclaimed coverage for haplotypic patterns that are not visualized, and that the claim covers any identification made through the comparison of haplotypic patterns in any way.

Furthermore, nothing in the specification or prosecution history implies that the identification made must be "uniquely indicative" of a particular haplotype, so that element of Applera's proposed construction is incorrect as well.

The court thus adopts GTG's construction, and construes the term "haplotypic pattern" as: data, from an analytical method, that is characteristic of a particular haplotype, without requiring that the data identify a haplotype to 100% accuracy or further specifying the analytical methods to be used.
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F. '928 Patent, Claims 1 and 2, and '955 Patent, Claim 5: Compound Having the Structure"

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Claim 5 of the '955 Patent claims "[a] compound having the structure. . ." according to a particular diagram. Claim 1 of the '928 Patent also claims a "compound useful as a probe for detecting the presence or absence of a nucleic acid, said compound having the [same] structure."

Plaintiffs would construe the phrase "having the structure" identically to the phrase "comprising the structure," including "any compound having the recited structure," even if the compound also has additional elements to those recited. Pl. Mem. of Law [Doc. # 89] at 27 (emphasis added). Defendants argue that "comprising" and "having" have different meanings depending on the context, and specifically that the inventors used "comprising" in an open sense and in conjunction with those signaling moieties that could have additional elements, but used "having the structure" where the structure was set and could not have additional elements. See discussion supra at 9. For instance, Claim 1 of the '955 patent claims a "nucleotide or oligo- or polynucleotide sequence comprising at least one of a moiety having the structure. . . ," and Claim 9 of that patent uses the same language.

According to the Federal Circuit,

When a patent claim uses the word "comprising" as its transitional phrase, the use of "comprising" creates a presumption that the body of the claim is open. In the parlance of patent law, the transition "comprising" creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements.

The transition "having" can also make a claim open. However, the term "having" does not convey the open-ended meaning as strongly as "comprising." "Having," for instance, does not create a presumption that the body of the claim is open.

Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l., 246 F.3d 1336, 1348 (Fed. Cir. 2001); see also Lampi Corp. v. American Power Products, Inc., 228 F.3d 1365, 1376 (Fed. Cir. 2000) ("Transitional phrases such as . . . 'having' . . . must be interpreted in light of the specification to determine whether open or closed language is intended.").

Here, the Court agrees with the parties that no assistance can be found in the specification. However, the claim language, and particularly the evident differences in the inventors' use of "having" and "comprising," lead to the conclusion that "having" is meant to be a closed term in the context of the '955 and '928 Patents. Specifically, the inventors signaled that they intended the term "comprising" to be open by language indicating that more than one moiety could "comprise" the claimed sequence or compound: "comprising at least one of a moiety. . . ," '955 Pat. 31:35; 32:54-55, or "comprising a detectable polypeptide complexed with a compound. . . ." '928 Pat. 31:26-27, 32:19-20 (emphases added). By contrast, they did not modify the term "having," which is always stated in the form, "a compound having the structure. . . ." See, e.g., '955 Pat. 31:35, 31:68, 32:55, '928 Pat. 30:5, 30:49. n5

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n5 Defendants' argument that open bonds, shown by "-," indicate an open claim element is not entirely persuasive. While this does appear to be the case in the '955 Patent, where Claims 9 and 15 use the word "comprising" and also indicate open bonds in the diagrams, in Claims 3 and 6 of the '928 Patent, which use the term "comprising," diagrams without open bonds are used. The better evidence, therefore, comes from the claim language itself, not the diagrams.

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Accordingly, in the context of these patents, the Court construes the term "having" to be intended by the inventors to be a closed term precluding additional elements, while "comprising" was intended to be an open term.
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Dr. Pieczenik argues that "having" is open-ended and, thus, equivalent to "comprising." While "having" may mean, in certain contexts, "comprising," this court has never equated the two:

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The transition "having" can also make a claim open. However, the term "having" does not convey the open-ended meaning as strongly as "comprising." "Having," for instance, does not create a presumption that the body of the claim is open.

Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001) (citation omitted). Examining the term within context of the claims, this court concludes that this usage of "having" is closed.

The asserted independent claims of the '363 patent, namely claim 24 and 34, contain the phrases "said oligonucleotide population has a coding region having a length from about 4 to about 12 nucleotide triplets" and "each structural gene having inserted therein one member of an oligonucleotide population wherein each member of said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets." '363 patent, col. 46, ll. 55-57; col. 47, ll. 56-60. Because the claims refer to a coding region that designates multiple nucleotide triplets, i.e., about 4 to about 12, the claims manifest an objective intent to close their scope to oligonucleotide populations consisting of members of specified lengths. In other words, substituting "comprising" for "having" would read the specificity--in particular, the upper bound of "about 12"--out of the claim. See Tex. Instruments, Inc. v. United States ITC, 988 F.2d 1165, 1171 (Fed. Cir. 1993). Thus, "having," in this context, is closed.
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having a molecular weight of at least approximately 500,000 to approximately 3,000,000

The Court modifies Defendants' proposed construction and construes the phrase as "a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000 as measure by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." Plaintiffs argue that the phrase should be construed as "measuring greater than about 1,000 cps at a concentration of about 50% in water." Defendants argue that the phrase should be construed as "a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000." Both Plaintiffs and Defendants re-urge the arguments set forth in support of their proposed constructions of the term "molecular weight." For the reasons discussed above with regard to "molecular weight," the Court rejects Plaintiffs' proposed construction and modifies Defendants' proposed construction to include various measurement techniques for determining molecular weight.
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b. Infringement

Defendants move for summary judgment of non-infringement of the Donzis Patents on the ground that neither Immutol nor Immupet satisfies the particle size limitations of the asserted claims. Plaintiffs oppose Defendants' motion on the ground that the allegedly infringing components of Immutol and Immupet contain particles of the requisite size. Claim 1 of the '015 Patent, the patent's sole independent claim, recites:

A method for improving the growth and survival of animals comprising:

administering an effective amount of a nutritional supplement to an animal, said nutritional supplement comprising a water-insoluble yeast cell wall extract comprising purified beta (1,3) glucan having a particle size of about 1.0 micron or less.

Claim 1 of the '719 Patent, the patent's lone independent claim, recites: "A composition suitable for nutritional supplementation comprising a water-insoluble yeast cell wall extract comprising substantially purified beta (1,3) glucans having a particle size of about 1.0 microns or less." The Court discerned that "about" had a narrow meaning and construed "a particle size of about 1.0 micron or less" in claim 1 of the '015 Patent and "a particle size of about 1.0 microns or less" in claim 1 of the '719 Patent as "a particle size of approximately 1.0 micron or less." From the parties' present arguments, the Court discerns the need to construe the term "having." 6 Cf. Ballard Med. Prods., 268 F.3d at 1358 ("As long as the trial

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court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best.").

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6 Before the Markman hearing, Plaintiffs proposed that "particle size of about 1.0 micron or less" be construed to mean that the "yeast cell wall extract includes beta (1,3) glucan particles that have a size of about 1 micron or less."

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Depending on its context, "having" may be closed or open. Compare Osram GmbH v. Int'l Trade Comm'n, 505 F.3d 1351, 1354, 1358 (Fed. Cir. 2007) (stating that "said luminous substance pigments having grain sizes <= 20 [mu] m" in claim "require[s] that all particles be below 20 [mu] m"), and Pieczenik v. Dyax Corp., 76 F. App'x 293, 296 (Fed. Cir. 2003) (unpublished) ("Examining the term within context of the claims, this court concludes that this usage of 'having' is closed."), with Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001) (stating that use of "having" as a transitional phrase can make a claim open but does not create a presumption that body of claim is open). Here, the claims use "having" to limit the particle size of the beta (1,3) glucan, suggesting that all glucan particles themselves are about one micron or less. 7

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7 The '719 Patent issued from a divisional application of the application that resulted in the '015 Patent. Their specifications are essentially the same. The Court applies a single construction of "having" to the patents. See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1333-34 (Fed. Cir. 2003).

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The specifications are consistent with this interpretation. The Summary of the Invention states that the "present invention is related to the use of purified beta (1,3) yeast extract glucan particles, in particular finely ground, as nutritional supplements." '015 Patent, col. 1, Il. 64-66; '719 Patent, col. 1, Il. 64-66. Similarly, the Detailed Description of the Preferred Embodiment(s) states that the "present invention is directed to substantially purified, beta (1,3) yeast extract glucans, in particular glucans having a fine particle size, which are useful in . . . nutritional applications"; that beta (1,3) glucans may be isolated from yeast cell walls by methods known by those of ordinary skill in the art; and that "[a]n improved glucan product is obtained when the average particle size is preferably about 1.0 microns or less, and more preferably about 0.20 microns or less." '015 Patent, col. 2, Il. 17-32; '719 Patent, col. 2, Il. 17-34. The beta (1,3) glucan is ground in a blender or ball mill to "obtain the desired smaller particle size." '015 Patent, col. 2, Il. 33-35; '719 Patent, col. 2, Il. 35-37. "One preferred grinding or particle size reduction method utilizes a blender having blunt blades, wherein the glucan mixture is blended for a sufficient amount of time . . . to completely grind the particles to the desired size without overheating the mixture." '015 Patent, col. 2, 11. 35-40; '719 Patent, col. 2, 11. 37-42. Before grinding, the glucan mixture is preferably passed through sieves to separate larger particles from smaller particles. '015 Patent, col. 2, Il. 45-50; '719 Patent, col. 2, Il. 46-51. The larger particles are ground and passed through sieves again. '015 Patent, col. 2, Il. 51-53; '719 Patent, col. 2, Il. 52-54. The process of sieving and grinding repeats itself until a final mesh size of 80 is obtained. '015 Patent, col. 2, 11. 53-55; '719 Patent, col. 2, Il. 54-56. The sieved particles are combined and further ground "until the desired particle size is obtained preferably about 1.0 micron or less, more preferably about 0.20 microns or less." '015 Patent, col. 2, Il. 55-58; '719 Patent, col. 2, Il. 56-59.

The prosecution history of the '015 Patent also supports a closed construction of "having." The patent examiner rejected claims "as being unpatentable over Schoenherr et al. (MacroGard Publication)":

Schoenherr et al. disclose the use of Beta 1,3 glucans as a nutritional supplement. The supplement is used as feed on various animals, and includes a teaching of its use on pigs and fish. The feed may be administered either orally or parenterally by injection . . . . Those of ordinary skill would have found it well within their skill to use such an additive on any number of animals given the animal models taught therein. However, Schoenherr et al. differs in that the particle size of the Beta 1,3 glucan is not taught.

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However, given the general teaching of its art accepted use for the same method of nutritional supplementation, it would have been well within the skill of the ordinary practitioner to claim the instant formulation for its instantly claimed method of nutritional supplementation as taught by Schoenherr et al. Indeed, there are no unusual and/or unexpected results which would rebut the instant prima facie obviousness. It is therefore deemed that it would have been obvious to claim the instant method given the clear teaching of Schoenherr et al. to use beta 1,3-glucans as a nutritional supplement.

(Citations omitted.) The applicant first responded by distinguishing the particle size taught in the MacroGuard publication. Under the heading, "MacroGuard and the art does teach a Particle Size: It is different from Applicant's, a Thousand Times Larger," the applicant wrote: "Claim 5 [claim 1 of the '015 Patent] specifies a particle size of about 1.0 micron or less. Clearly, the MacroGuard article teaches away from Applicant's invention. The MacroGuard article teaches a particle size over a thousand times larger than the particle size claimed in the instant application." The applicant next asserted that the application taught finely ground glucan particles, i.e., glucans having a fine particle size:

Under "detailed description of the preferred embodiment" the invention directs itself to substantially purified, beta (1,3) yeast extract glucans, in particular glucans having a fine particle size. An improved glucan is taught when the average particle size is preferably about 1.0 microns or less, and more preferably about 0.20 microns or less. The specification teaches a method for producing substantially purified beta (1,3) yeast extract glucan of the requisite 1.0 or 0.2 micron or less size.

The applicant continued by noting that the prior art does not teach use of particles of such a small size or grinding particles to such a small size:

Nowhere in the art does the examiner point to a teaching or suggestion of using a beta (1,3) yeast extract glucan having a fine particle size, and more particularly, a particle size of 1.0 micron or 0.2 microns or less. . . .

Applicant attaches hereto U.S. Patent No. 5,401,727 to Rorstad that has recently come to the attention of the inventor. Apparently, the Rorstad patent describes the research referred to in the MacroGuard article, referenced above. Nowhere in the Rorstad patent is there a teaching or suggestion of grinding the glucan product such that its particle size is about the size of one micron or less, or of any benefit to be achieved from a small particle size.

The applicant also highlighted the advantages of use of the smaller particles: "Applicant's 'fine grind' glucan has proven to enhance the immunopotentiating effect of the glucan while avoiding toxic effects." The applicant concluded by noting that he was "in the process of comparing the inventor's own 'nonground' product with his 'fine grind' glucan to exhibit enhanced and improved results." The applicant nevertheless submitted that "such results are not necessary since it is clear that the Rorstad patent and MacroGuard reference do not teach or suggest applicant's invention." The applicant closed his response, "Applicant's 'fine grind' results are enhanced, vis-a-vis the results repeated by MacroGuard and/or Rorstad." The examiner withdrew the rejection.

As the Court noted in its construction of "a particle size of about 1.0 micron or less," the particle size itself is essential to the inventions claimed in the '015 and '719 Patents. Based on the claims, specification, and prosecution history, the Court construes "having" as closed. Thus, "purified beta (1,3) glucan having a particle size of about 1.0 micron or less" in claim 1 of the '015 Patent and "substantially purified beta (1,3) glucans having a particle size of about 1.0 microns or less" in claim 1 of the '719 Patent require all beta (1,3) glucan particles to be approximately 1.0 micron or less.
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C. "Having CDRs from a Donor Immunoglobulin"

The remaining disputed claim terms concern the material supplied by the non-human "donor" immunoglobulin that is utilized to prepare humanized immunoglobulins.

1. "Having CDRs"

A. Numerosity

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i. Specification v. Ordinary Meaning

PDL proposes a construction requiring that one or more CDRs in each chain be transferred; Medlmmuneasserts that Claim 28 requires that all three CDRs be transferred. A term's accepted meaning in the art is dispositive unless the specification or file history demonstrates a clear intent to deviate from this ordinary meaning. Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1328 (Fed. Cir. 2006). Medlmmune contends that to persons having ordinary skill in the art in 1989, "CDRs" had an agreed-upon, accepted meaning of "all three CDRs in an immunoglobulin chain (six in two chains)." MOB at 20, citing Lesk Rep. PP 96-107; Lesk Rebuttal Report ("Lesk Reb.") PP 14-15; 27-38; Lesk Transcript ("Tr."). 89:6-11.

PDL does not dispute that in isolation, "CDRs" refers to the three CDRs in the heavy chain and the three CDRs in the light chain. It also recognizes that the glossary in the file history defined "CDRs" as such. Lesk Rep., Ex. 27 at 1 (defining CDRs as "the six short segments of an immunoglobulin, three in the light chain variable region and three in the heavy chain variable region, which fold up together in 3-dimensional space to form the binding site for the target antigen"). Nonetheless, PDL contends that in the context of the phrase "CDRs from a donor" in the'370 patent, "having CDRs" means that one or more CDRs in each chain need be transferred.

In On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331 (Fed. Cir. 2006), the Federal Circuit held that "each term must be construed to implement the invention described in the specification….Care must be taken lest word-by-word definition, removed from the context of the invention, leads to an overall result that departs significantly from the patented invention." Id. at 1344. The Court has adopted PDL's construction of the term "humanized immunoglobulin" - that definition, which is found in column 12 of the specification, states that "the term 'humanized' immunoglobulin refers to an immunoglobulin comprising a human framework region and one or more CDR's from a non-human (usually a mouse or rat) immunoglobulin." '370 Patent Col. 12:1-4 (emphasis added). In fact, the patent asserts repeatedly-in the abstract, the summary of the invention, the detailed description of the invention, and in many other places-that humanized immunoglobulins involve "one or more complementarity determining regions (CDR's)." '370 Patent Abstract (57) ("Novel methods for producing, and compositions of, humanizedimmunoglobulins having one or more complementarity determining regions (CDR's) and possible additional amino acids from a donor immunoglobulin"); Col. 2:35-39 ("Summary of the Invention: [t]he present invention provides novel methods for preparing humanized immunoglobulin chains having generally one or more complementarity determining regions (CDR's) from a donor immunoglobulin…"); Col. 10:63-67 (the detailed description of the invention states, "[t]he humanized immunoglobulins will have a human framework and have one or more complementary determining regions (CDR's)…from a donor immunoglobulin…"). The Court is not required to accept expert testimony that is inconsistent with the intrinsic evidence. Here, the intrinsic evidence consistently supports a construction of "CDRs" as "one or more CDRs from a non-human immunoglobulin." Kara Tech., Inc. v. Stamps.com, Inc., 582 F.3d at 1348 (rejecting expert testimony inconsistent with the specification).

Despite this abundant intrinsic evidence, Medlmmune claims that the specification always uses the unmodified term "CDRs" to mean each and every CDR. For example, column 11 of the patent explains that "an immunoglobulin light or heavy chainvariable region consists of a "framework" region interrupted by three hypervariable regions, also called CDR's." '370 Patent Col. 11:38-40. However, other language in the patent refutes Medlmmune's contention. The Abstract describes:

> Novel methods for producing, and compositions of, humanized immunoglobulins having one or more complementarity determining regions (CDR's) and possible additional amino acids from a donor immunoglobulin and a framework region from an accepting human immunoglobulin are provided. Each humanized immunoglobulin chain will usually comprise, in addition to the CDR's, amino acids from the donor immunoglobulin framework that are, e.g., capable of interacting with the CDR's to effect binding affinity, such as one or more amino acids which are immediately adjacent to a CDR in the donor immunoglobulin or those within about 3 A as predicted by molecular modeling.

'370 Patent at (57) Abstract. In fact, the '370 patent uses the unmodified term "CDR's," interchangeably with the phrase, "one or more complementarity determining regions." MedImmune's proposed construction of "CDRs" as always meaning "all three CDRs" would make the patent's other invocations of the phrase "threeCDR's" redundant. '370 Patent Col. 3:67. 4:10, 4:20, 4:30; 4:40; 4:50 ("the three CDR's in each chain are underlined").

PDL also refers to a related patent, U.S. Patent No. 7,022,500 ("the '500 Patent"), which shares the same specification as the

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claim in dispute. Claims should be interpreted consistently across patents that originate from the same parent application. NTP Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1293 (Fed. Cir. 2005). The '500 patent makes clear that the unmodified term "CDR's" does not mean "all CDRs." Although the '500 patent contains several dependent claims that add the limitation that each chain of the humanized immunoglobulin has three CDRs from the donor, the independent claim simply refers, as does Claim 28, to "CDRs from a donor immunoglobulin." Declaration of Peter Sandel ("Sandel Decl."), Ex. 13 ('500 Patent). PDL also calls attention to other relevant claims in the '500 patent. Independent Claim 67 describes "a humanized immunoglobulin having complementarity determining regions (CDRs) from a donor immunoglobulin…" '500 Patent Col. 153:1-3. Then, in the dependent Claim 69, the patent reads, "[a] humanized immunoglobulin according to claim 67 or 68having three CDRs from the heavy chain of the donor immunoglobulin and three CDRs from the light chain of the donor immunoglobulin." '500 Patent Col. 153:18-21. Dependent Claims 25, 61, 78, and 87 share similar language. '500 Patent Col. 151:29-32; Col. 152:53-56; Col. 153:53-56; Col. 154:34-37.

"[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. If MedImmune's construction of "CDRs from a donor" were correct, there would be no need to specify the transfer of all three CDRs from each chain in dependent Claim 69 because the independent Claim 67 necessarily would have conveyed the same meaning. Moreover, as PDL argues, the doctrine of claim differentiation is "especially strong when [as here] the limitation in dispute is the only meaningful difference between an independent and dependent claim." Sunrace Roots Enter., Co. v. SRAM Corp., 336 F.3d 1298, 1303 (Fed. Cir. 2003).

MedImmune contends that the claim differentiation doctrine has no application in the context of the '370 patent because the use of claim differentiation in a later-issuedpatent to construe an earlier-issued patent has been rejected repeatedly by the Federal Circuit. MedImmune Reply Brief at 16, citing ICU Med. Sys., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1376 (Fed. Cir. 2009). However, while the '500 patent issued more than five years later than the '370 patent, its filing date preceded the issuance of the '370 patent. Compare Sandel Decl., Ex. 6 ('370 Patent) with Sandel Decl., Ex. 13 ('500 Patent). Under these circumstances, the claim differentiation doctrine is at least instructive in construing the term "CDRs from a donor immunoglobulin." 7

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7 PDL also draws the Court's attention to Kara Tech., Inc., 582 F.3d at 1347, in which the Federal Circuit utilized a later-issued patent in applying the claim differentiation doctrine to determine the proper construction of a disputed term.

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Finally, MedImmune contends that the claim differentiation doctrine should be rejected when it results in a construction inconsistent with the specification and file history. However, as should be clear from the foregoing discussion, the Court finds that differentiation among the claims of the '500 patent is consistent with the specification and file history of the '370 patentand supports PDL's proposed construction.

ii. Preferred Embodiments

MedImmune also points out that all of the preferred embodiments in the '370 patent utilize all three CDRs from each chain. While this is true, it does not support MedImmune's legal position. As discussed previously in connection with the construction of "human acceptor immunoglobulin," the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Phillips, 415 F.3d at 1323 (holding that "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.") See also Kara Tech., 582 F.3d at 1347 ("In the only detailed embodiments in the patent, the key is embedded in the preestablished data. This is not enough, however, to limit the patentee's clear, broader claims…The claims, not specification embodiments, define the scope of patent protection"). Moreover, the patent itself states that other embodiments of the invention exist beyond those exemplified. '370 Patent 17:8-19 ("in addition to the humanized immunoglobulinspecifically described herein…").

iii. Prior Art

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Finally, MedImmune argues that based on the prior art that existed when PDL filed its application for the '370 patent, persons having ordinary skill in the art always would have transferred all six CDRs. MOB at 20-22. However, this argument is refuted by prior art cited in the patent itself. The '370 patent, at column 1, line 65, to column 2, line 5, cites Winter's European Patent 0 239 400. The latter teaches in relevant part that "[t]hus, in order to transfer the antigen binding capacity of one variable domain to another, it may not be necessary to replace all the CDRs with complete CDRs from the donor variable region." Sandel Decl., Ex. 14 at 7. Another patent application from Winter's group describes, "[a]n antibody having at least one CDR (complementarity determining region) which is foreign with respect to the constant region of the antibody, said at least one foreign CDR being selected from CDRs substantially as identified in Figure 2…" Sandel Decl., Ex. 15 at 15 (Clark et al., EP 0 328 404). 8

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8 MedImmune points out that in 1999 opposition proceedings in the European Patent Office, PDL endorsed the statement that "substitutions ofless than a complete set of CDRs (i.e. less than the three CDR sequences representing the Kabat-defined hypervariable regions) are not deemed to be encompassed by the [Winter] claims since…[s]uch modifications would require a significant amount of additional teachings not found in [Winter's] specification." Berl Ex. U at 33. MedImmune claims that PDL now seeks to rely upon Winter patent for exactly the opposite principle. However, even assuming that this claim has some historical significance, it does not undermine the overall strength of the intrinsic evidence in the '370 patent

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The parties also dispute whether the prior art cited by the '370 patent is properly incorporated by reference. MedImmune asserts that PDL's reference to Winter is improper because the '370 patent refers only to the general concept that Winter used recombinant DNA technology to produce "immunoglobulins which have human framework regions combined with complementarity determining regions (CDR's) from a donor mouse or rat immunoglobulin." '370 patent, Col. 1:67-2:2. MedImmune contends that this reference provides no identification "with particularity" of "what specific material" is incorporated or where that "materialis found." However, in the present context the Court need not determine whether the prior art was incorporated properly, as it looks to the Winter patent not as intrinsic evidence but rather as extrinsic evidence of the fact that persons having skill in the art at the time of the '370 application contemplated the transfer of less than the complete set of three CDRs in creating humanized immunoglobulins.

Accordingly, the Court concludes that the '370 patent did not limit the invention of Claim 28 to the transfer of all three CDRs from each chain, and that it allows the transfer of one or more CDRs from a chain in creating a humanized immunoglobulin.
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1. "Heating"

HISI requests that "heating" not be limited to any particular temperature range in Claims 1 and 67. (HISI Brief 18.) TPI, on the other hand, requests that "heating" be "limited to the temperature 510 [degrees] centigrade or less." (TPI Opp. 13.) TPI bases this construction on the specifications of the patent, which state that the "manufacturing process" includes combusting wood sawdust "at temperatures in an operable temperature range of 400 to 950 degrees Fahrenheit (204 to 510 degrees Centigrade)." (Kowalski Patent, Col. 11, at 44-49.) TPI argues that HISI's claim is limited by what the Kowalski Patent has defined as the operable range of the invention.

While claims need not be limited to their preferred embodiments, "claims may be no broader than the supporting disclosure" made in the specifications. Gentry Gallery v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998) (finding a claim invalid where it extended beyond the scope of what was disclosed in the patent's specifications); see also Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1323 (Fed. Cir. 2002) (stating that "a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope").

Here, it is not only the preferred embodiment of the patent, but nearly every section of the specification that discloses an

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operable temperature range of 204 [degrees] to 510 [degrees] C for the Kowalski Patent. First, after discussing the formation of deleterious compounds in the "Background Art" section of the patent, Kowalski states that "[t]o minimize formation of these compounds and to conform to empirical data from our laboratory tests, an operable combustion temperature range of 400 to 950 degrees Fahrenheit (204 to 510 degrees Centrigade), a preferred range of 500 to 800 degrees Fahrenheit . . . [is] established for the process described herein." (Kowalski Patent Col. 6-7.) Second, as mentioned above, the "Summary of the Invention" section of the patent states that the "manufacturing process" includes combusting wood sawdust "at temperatures in an operable temperature range of 400 to 950 degrees Fahrenheit (204 to 510 degrees Centigrade)." (Kowalski Patent, Col. 11, at 44-49.) Third, the "Best Mode" section specifies that the sawdust "is combusted by heating the cylinders with the natural gas burner to an operable temperature range of 400 to 950 degrees Fahrenheit (204 to 510 degrees centigrade)." (Kowalski Patent, Col. 16, at 39-41.)

Here, then, just as in Gentry, the "entirety of the specification clearly indicates that the invention is of a much narrower scope," Cooper Cameron Corp., 291 F.3d at 1323, than what is claimed in Claims 1 and 67. The specifications do not support the broad claim language of "heating"; accordingly these claims are deemed invalid on this ground. See Gentry Gallery, 134 F.3d at 1479.
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ORDER GRANTING MOTION FOR CLARIFICATION AND RECONSIDERATION OF CLAIMS CONSTRUCTION ORDER

Before the Court is the motion of William R. Kowalski ("Kowalski") and Hawaii International Seafood ("HISI") to clarify and reconsider the Court's claims construction order filed on October 17, 2007, in the above-captioned cases. Specifically, Kowalski and HISI request the Court to (1) clarify that the word "heating," as used in Claims 1 and 67 of the Kowalski Patent, is not limited to a specific numerical temperature range, and (2) to vacate the finding of invalidity of those claims. After careful consideration of the motion, the supporting and opposing memoranda, and the relevant case law, the motion for clarification and reconsideration is hereby GRANTED.
DISCUSSION

On August 31, 2007, the Court held a Markman hearing to construe certain claims of U.S. Patent 5,972,401, titled "Process for Manufacturing Tasteless Super-Purified Smoke for Treating Seafood to be Frozen and Thawed," originally awarded to Kowalski on October 26, 1999 (hereinafter "Kowalski Patent"). During claims construction, HISI and Kowalski urged that the word "heating" in Claims 1 and 67 of the Kowalski Patent not be given the specific numerical temperature limitation requested by Plaintiff and Counterclaim Defendant Tuna Processors, Inc., and by Defendants Mommy Gina Tuna Resources, King Tuna, Inc., Joaquin Lu, Seafriend, Richard Friend, Citra Mina Corporation, and Integral Seafood LLC (collectively, "TPI"). The Court ruled that the specifications, which "disclose[d] an operable temperature range of 204[degree] to 510[degree] C," did not support the broad language of the claim of "heating." (Claims Construction Order 19.) On this basis, the Court invalidated Claims 1 and 67 for violating the written description requirement of 35 U.S.C. § 112. It is this portion of the Claims Construction Order for which HISI and Kowalski request clarification and reconsideration.

Motions for reconsideration may only be brought if there has been (1) "[d]iscovery of new material facts not previously available," (2) "[i]ntervening changes in law," or (3) a "[m]anifest error of law or fact." Local Rule 60.1. Here, Kowalski and HISI assert that the Court made a manifest error of law by invalidating the claims during the claims construction process. Kowalski and HISI agree with the Court's implied finding that "heating" is broadly defined in Claims 1 and 67, but contend that the Court overstepped its bounds in taking the next step of invalidating those claims based on the specifications' failure to describe such a broad claim. The Court agrees.

Each claim of a patent is presumed to be valid. 35 U.S.C. § 282; Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1357 (Fed. Cir. 2003). Patents may be held invalid for failure to meet the written description requirement of 35 U.S.C. § 112 when narrow specifications fail to support a broad claim. Gentry Gallery, Inc. v. Berkline Corporation, 134 F.3d 1473, 1479 (Fed. Cir. 1998). However, invalidity under § 112 is a question of fact. Cordis Corp. V. Medtronic Ave., Inc., 339 F.3d 1352, 1364. To obtain a finding of invalidity under § 112 prior to trial, a party "must submit such clear and convincing evidence of invalidity such that no reasonable jury could find otherwise." Eli Lilly & Co. v. Barr Labs., 251 F.3d 955, 962 (Fed. Cir.

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2001).

Here, in addressing the validity issue in the context of claims construction, the Court did not allow the parties the same opportunity to present facts that would have been afforded them in a summary judgment proceeding. In addition, the Court did not take into consideration whether invalidity had been demonstrated by clear and convincing evidence.

TPI argues that the Court's finding of invalidity was nonetheless appropriate because sua sponte summary judgment can be proper where no material dispute of facts exists, and there has been adequate time to develop necessary facts. (TPI Mem. Opp. (citing Fuller v. City of Oakland, 47 F.3d 1522, 1533 (9th Cir. 1995).) Here, however, the Court does not believe that the parties were given adequate time to develop necessary facts, or to make the sorts of arguments that would have been raised in a summary judgment proceeding. In addition, TPI was never forced to prove invalidity with clear and convincing evidence. C.f. Fin Control Sys. Pty, Ltd. v. OAM Inc., 265 F.3d 1311, 1312 (Fed. Cir. 2001) (stating that "the district court's sua sponte grant of summary judgment of invalidity and unenforceability was procedurally improper because it did not provide the parties with adequate notice or an opportunity for FCS to present evidence and argument in opposition to the motion"). Accordingly, the Court hereby VACATES that portion of its Claims Construction Order that found Claims 1 and 67 of the Kowalski Patent to be invalid under § 112.

Kowalski and HISI have also requested that the Court clarify that it has construed the word "heating," as used in Claims 1 and 67 of the Kowalski Patent, as not limited to any specific numerical range. This is correct. While the Court continues to believe that the specifications of the Kowalski Patent describe a process significantly more limited than the "heating" claimed in Claims 1 and 67, these limitations may not be read into the broad claim. See Conoco, Inc. v Energy & Envtl., 460 F.3d 1349, 1358 (Fed. Cir. 2006) (affirming that "when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims") (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998)). If TPI wishes to challenge the validity of this claim based on the failure to adequately describe "heating" in the specifications, TPI may do so at the proper time. For the moment, however, the Court CLARIFIES that the word "heating," as used in Claims 1 and 67 of the Kowalski Patent, is not limited to any specific temperature range.
CONCLUSION

The Court's Claims Construction Order for the Yamaoka and Kowalski Patents, filed on September 17, 2007, is hereby reconsidered and amended such that (1) the portion of the order invalidating the Kowalski Patent's Claims 1 and 67 is VACATED; and, (2) the Court clarifies that "heating," as used in Claims 1 and 67 is not limited to any specific numerical temperature range.
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1. "hematopoietic stem cells"

"hematopoietic stem cells" is construed to mean "cells capable of effecting repopulation of blood and other hematopoeietic organs."
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D. Claim Construction Of The '995 Patent

Pfizer asserts claim 6 of the '995 patent against Ranbaxy's ANDA product. Claim 6 is a dependent claim, which depends on claim 2, which in turn depends on claim 1. Claim 1 is the only independent claim of the '995 patent. The relevant claims provide:

1. [R-(R*, R*)] -2- (4-fluorophenyl)- [beta], [delta] - dihydroxy-5- (1-methylethyl) -3-phenyl-4- [(phenylamino) - carbonyl] -1H-pyrrole-1-heptanoic acid or (2R-trans) -5- (4-fluorophenyl) -2- (1-methylethyl) -N, 4-diphenyl-1 - [2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl] -1H-pyrrole-3-carboxamide; or pharmaceutically acceptable salts thereof.

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2. A compound of claim 1 which is [R- (R*,R*)] -2- (4 - fluorophenyl) - [beta], [delta] - dihydroxy-5-(1-methylethyl) -3-phenyl-4- [(phenylamino) -carbonyl] -1H-pyrrole-1-heptanoic acid.

* * *

6. The hemicalcium salt of the compound of claim 2.

DTX-35, col. 16, 1. 60 - col. 17, 1. 12 (emphasis added).

The parties' claim construction dispute regarding claim 6 is whether claim 6 can be construed to cover the salt atorvastatin calcium. Ranbaxy contends that claim 6 cannot be construed to cover the salt, because claim 6 depends on claim 2 and claim 2 narrows the subject matter of claim 1 from atorvastatin acid or atorvastatin lactone, or pharmaceutically acceptable salts thereof to the single compound, atorvastatin acid. Ranbaxy argues that because claim 2 does not encompass salts, dependent claim 6 cannot cover the salt atorvastatin calcium. According to Ranbaxy, a reading of claim 6 to include the salt would render the patent invalid under Section 112, paragraph 4.

In response, Pfizer contends that Ranbaxy's claim construction is erroneous, because Ranbaxy incorrectly assumes that claim 6, a dependent claim, must incorporate all of the limitations of claim 2, from which it depends regardless of the actual language of claim 6. Because claim 6 expressly claims the hemicalcium salt of the compound of claim 2, Pfizer contends that claim 6 is properly construed to encompass the salt atorvastatin calcium.

The Court finds the language of claim 6 to be unambiguous to the extent that claim 6 is meant to claim the salt, atrovastatin calcium. The Court's conclusion is consistent with the express language of the claim and the understanding of the claim language to one skilled in the art. Claim 6 recites "the hemicalcium salt of the compound of claim 2." Claim 2, on which claim 6 depends, defines atorvastatin acid. Thus, claim 6 effectively reads, "the hemicalcium salt of atorvastatin acid." As a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form. Roush Tr. 910:3-912:4, 914:7-18. The specification of the '995 patent and claim 6 of the '995 patent comport with this standard practice by reciting the full name of the parent acid and then separately identifying the salt-forming ion. DTX-35, col. 4, 11. 3-6; Roush Tr. 914:7-18; Clive Tr. 1510:1-1517:2. Indeed, Ranbaxy utilizes this standard nomenclature in its ANDA application, as well. PTX-1011A at RA011211. Moreover, Ranbaxy's expert, Dr. Clive, had no difficulty understanding the language of claim 6 as referring to atorvastatin calcium. Clive Tr. 1507:7-1508:2; 1508:14-1509:24.

Despite this standard use of chemical nomenclature and the fact that the meaning of claim 6 is clear to those skilled in the art, Ranbaxy contends that the Court should not interpret claim 6 to refer to atorvastatin calcium, because such an interpretation would render the claim invalid for failure to adhere to the drafting requirements for dependent claims set forth in Section 112. Pursuant to Section 112, paragraph 4, "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed." Ranbaxy contends that there is a technical problem in the drafting of claim 6, because claim 1, from which claim 6 and claim 2 depend, recites three separate compositions: (1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts of these two compounds. Claim 1 differentiates among these three compositions using the disjunctive "or." As a dependent claim, claim 2 narrows the subject matter of claim 1 from atorvastatin acid; or atorvastin lactone; or pharmaceutically acceptable salts thereof, to the single compound atorvastatin acid. If claim 2 is limited to atorvastatin acid and it excludes the limitation from claim 1 referring to "pharmaceutically acceptable salts thereof," then Ranbaxy argues that claim 6 cannot be read to encompass that which it expressly names, the hemicalcium salt of atorvastatin.

While the Court recognizes that there may be a technical problem in the drafting of claim 6, the question presented to the Court is whether this drafting problem is sufficient to render the claim invalid if the claim is read consistently with its meaning to those skilled in the art. To reach this conclusion, the Court would be required to declare an issued claim invalid because of the failure to adhere to the drafting technicalities for dependent claims under Section 112, paragraph 4. n4 The Court has been unable to locate any precedent applying Section 112, paragraph 4 to invalidate a patent n5, and based on the legislative history of Section 112, paragraph 4, the Court understands the provision to be limited to matters of form, rather than matters of substance. Legislative history concerning this statutory section suggests that its provisions were meant to increase the fees payable to the Patent Office and expedite the prosecution of patent applications to make new technology

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available to the public more quickly. See S. Rep. No. 89-301 (1965), reprinted in 1965 U.S.C.C.A.N. 2315, 2319-2323. There is no indication in this legislative history that paragraph 4 was intended to be an invalidating provision. The Manual of Patent Examining Procedure ("MPEP") takes an approach consistent with the legislative history by viewing the failure to comply with paragraph 4 as a matter to be addressed through an objection to the claim and not a rejection of the claim's patentability under 35 U.S.C. § 112, 4. n6 Because the PTO considers improper dependent claims in this manner, the Court is not persuaded that the law of invalidity should be extended to reach Section 112, paragraph 4. Thus, the Court concludes that Section 112, paragraph 4 should not be used to invalidate an issued patent claim. n7 See 35 U.S.C. § 282 (recognizing that issued patent has statutory presumption of validity); Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 960 (Fed. Cir. 1997) ("Procedural lapses during examination, should they occur, do not provide grounds of invalidity. Absent proof of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.").

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n4 The Court is not persuaded that claim 6 can be read in any other manner, and Ranbaxy has not offered a plausible alternative reading for claim 6. Because the Court cannot construe the claim in any other manner, the question for the Court is whether claim 6 is invalid. See Phillips v. AWH Corp., 415 F.3d 1303, 1328 (Fed. Cir. 2005) (reaffirming the principle that construing claims so as to maintain their validity is only applicable when the claim language is ambiguous and recognizing that claims cannot be construed differently from their plain meaning to uphold their validity); Nazomi Communications, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368-1371 (Fed. Cir. 2005) (stating that "courts should not rewrite claims to preserve validity"); Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) (recognizing that if "the only claim construction that is consistent with the claim's language and the written description renders the claim invalid," then "the claim is simply invalid").

n5 In arguing that Section 112, paragraph 4 should be considered an invalidating provision, Ranbaxy refers the Court to cases that applied Section 112, paragraph 1 to invalidate a patent for lack of written description and enablement and Section 112, paragraph 2 to invalidate a patent for indefiniteness. Ranbaxy contends that paragraph 4 should not be treated differently from paragraphs 1 and 2 of Section 112. The Court understands that the Federal Circuit has applied Section 112, paragraph 1 to invalidate a claim; however, the Court also understands that even this limited use of Section 112, paragraph 1 has not been embraced by all members of the Court. For example, there is significant disagreement over whether "written description" should be divorced from "enablement" and considered a separate and independent ground for invalidity. See e.g. University of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1307-1314 (Fed. Cir. 2004) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976-987 (Fed. Cir. 2002) (Rader, J. dissenting and joined by Gajarsa, J. and Linn, J.). In light of this split among the Circuit judges, the Court is not persuaded that a further extension of invalidity principles to paragraph 4 should be made by this Court.

n6 MPEP 608.01(n) provides:

Where a claim in dependent form is not considered to be a proper dependent claim under 37 C.F.R. 1.75(c), the examiner should object to such claim under 37 C.F.R. 1.75(c) and require cancellation of such improper dependent claim or rewriting of such improper dependent claim in independent form. See Ex parte Porter, 25 U.S.P.Q.2d 1144, 1147 (Bd. of Pat. App. & Inter. 1992) (A claim determined to be an improper dependent claim should be treated as a formal matter, in that the claim should be objected to and applicant should be required to cancel the claim (or replace the improper dependent claim with an independent claim) rather than treated by a rejection of the claim under 35 U.S.C. Section 112, fourth paragraph.). The applicant may thereupon amend the claims to place them in proper dependent form, or may redraft them as independent claims, upon payment of any necessary additional fee.

MPEP § 608.01(n) at 600-80 (8th ed. rev. 2, May 2004).

n7 The Court further notes that the PTO raised no objections to the format or dependency of claim 6 or any of the other, similarly-worded claims to atovastatin salts, all of which depend on claim 2. DTX 139 at RA014772-74, RA014784, RA0147804-806, RA014813-14, RA014828-833.

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In sum, the Court interprets claim 6 of the patent to mean the salt of atorvastatin calcium. The Court's claim construction is consistent with the express language of the claim and the understanding of the claim to those skilled in the art. To the extent that the Court's claim construction conflicts with the requirements for dependent claims set forth in Section 112, paragraph 4, the Court concludes that this statutory provision provides no basis to invalidate a claim.
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A. An Herbicidally Effective Amount (Claims 1 and 3).

Claims 1 and 3 of the patent in suit, the composition claims, describe an "herbicidal composition comprising" an "herbicidally effective amount" of a particular 4-benzoylisoxazole (or "4-b") herbicidal compound. According to the patent specification, which is generally the "single best guide to the meaning of a disputed term," see CCPI, 966 F. Supp. at 278-79 (quoting Vitronics, 90 F.3d 1576 at 1582), an "herbicidally effective amount" is the "amount of an herbicide compound which adversely controls or modifies plant growth."

Apparently seizing upon this language, the specification's broad definition of the word "plant," 1 and certain statements made during the patent's prosecution history, the defendants argue that the term "herbicidally effective amount" means the amount of an herbicide compound actually applied to the corn crop which adversely controls or modifies the growth of not only the weeds which infest the crop but also the corn itself. In this respect, the defendants contend that the term requires the herbicide to actually be applied to the corn and, then, inherently injure it. The court declines to adopt this interpretation for the following reasons.

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1 The patent specification defines the word "plant" as encompassing "all physical parts of a plant, including seeds, seedlings, saplings, roots, tubers, stems, stalks, foliage, and fruits." The specification then goes on to define "plant growth" as "all phases of development from seed germination to natural or induced cessation of life."

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First, an interpretation that requires the herbicide to actually be applied to the corn crop would seem to render the composition claims meaningless by ignoring the reality that a "composition exists at the moment the ingredients are mixed together" and, therefore, that composition claims "read[] on any product at any time that contains the claimed proportions of ingredients." See Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1558 (Fed. Cir. 1995).

Second, as the patent specification clearly states,

(1) "herbicides are generally used to control or eradicate weed pests,"

(2) "the actual amount [of an herbicide] used depends upon several considerations, including particular weed susceptibility and overall cost limitations," and

(3) "4-b[] compounds have been found to be very effective herbicides with broad general herbicidal activity against broad-leafed and grass weeds . . . . The method of controlling vegetation with these compounds comprises applying an herbicidally effective amount of the compounds . . . to the area where herbicidal control is desired." (emphasis added).

In light of the specification's emphasis on weed control, the court concludes that the "plant growth" which the herbicide need only adversely control or modify is the growth of weeds.

For these reasons, the court concludes that, as used in Claims 1 and 3 of the 131 patent, the term "herbicidally effective amount" means the "amount of an herbicide compound which adversely controls or modifies weed growth."
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I. "heterogeneous mixture"

The phrase "heterogeneous mixture" appears throughout the shared Specification and the claims of the '479 patent. Abbott argues that the phrase, when applied to nucleic acid fragments, should be construed to mean "a mixture containing many copies each of fragments having different base compositions and/or sizes." Dako argues that the phrase should be construed to mean a "mixture of labeled nucleic acid fragments, such that application of the mixture to a chromosome results in a substantially uniform distribution of fragments (i.e., interrupted only be repetitive sequences) hybridized to the chromosomal DNA." The parties' constructions differ in two respects: Dako's construction requires that the heterogeneous mixture yield a substantially uniform distribution of fragments, and further requires that the uniform distribution cover only the unique portions of the chromosomal DNA.

Although claim construction generally begins with the plain meaning of claim terms as understood by one of ordinary skill in the art, a patentee is free to act as his own lexicographer to define terms used in the claims. Here, the Specification includes an express definition of "heterogeneous mixture":
Heterogeneous in reference to the mixture of labeled nucleic acid fragments means that the staining reagents comprise many copies each of fragments having different base compositions and/or sizes, such that application of the staining reagent to a chromosome results in a substantially uniform distribution of fragments hybridized to the chromosomal DNA.

Spec. at 4:2-9. Both parties rely on this definition in advancing their proposed constructions.

With respect to the first difference in the parties' constructions, the definition in the specification supports Dako's argument that the mixture must result in a substantially uniform distribution of fragments hybridized to the chromosomal DNA. Indeed, Abbott appears to concede in its brief that the Specification "explain[s] that application of the heterogeneous mixture to a chromosome results in a substantially uniform distribution of fragments hybridized to the chromosomal DNA." The court therefore finds that the resulting distribution must be substantially uniform.

With respect to the second difference in the parties' construction, Dako's proposed definition would exclude heterogeneous mixtures which include some repetitive segments, a possibility expressly contemplated by the Specification: "preferably the heterogeneous mixtures are substantially free from so-called repetitive sequences." Spec. at 4:20-22 (emphasis added). The court therefore construes "heterogeneous mixture," when used in the context of labeled nucleic acid fragments, to mean "a mixture of labeled fragments comprising many copies each of labeled fragments having different base compositions and/or sizes, such that application of the labeled fragments to a chromosome results in a substantially uniform distribution of fragments hybridized to the chromosomal DNA."
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1. "Heterologous DNA construct"

DeKalb proposes that heterologous DNA construct encoding EPSP synthase means "DNA (1) that is not normally found in the plant, but parts of the heterologous DNA construct may be identical to DNA sequences originally present in the corn plant and (2) that has the necessary components to produce EPSP synthase. " Syngenta takes issue with DeKalb's position that such heterologous DNA construct must contain the "necessary components" to produce EPSP synthase. Syngenta argues that no such limitation is found in the claim language and therefore, the addition of such a limitation is improper.

The Court first looks at the specification for guidance, which states:

As used herein, the term "heterologous DNA" refers to a DNA segment that has been derived or isolated from one genotype, preferably amplified and/or chemically altered, and later introduced into a Zea mays genotype that may be the same Zea mays genotype from which the DNA was first isolated or derived. "Heterologous DNA" also includes completely

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synthetic DNA, and DNA derived from introduced RNA. Generally, the heterologous DNA is not originally resident in the Zea mays genotype which is the recipient of the DNA, but it is within the scope of the invention to isolate a gene from a given Zea mays genotype, and to subsequently introduce multiple copies of the gene into the same genotype, e.g., to enhance production of the amino acid.

Therefore, "heterologous DNA" is used herein to include synthetic, semi-synthetic, or biologically derived DNA which is introduced into the Zea mays genotype, and retained by the transformed Zea mays genotype. The DNA includes but is not limited to, non-plant genes such as those from bacteria, yeasts, animals or viruses; modified genes, portions of genes, chimeric genes, as well as genes from the same or different Zea mays genotype.

United States Patent 5,554,798, column 6, lines 30-52. The patent further states that "[s]uitable heterologous DNA for use herein includes all DNA which provides for, or enhances, a beneficial feature of the resultant transgenic corn plant." United States Patent 5,554,798, column 8, lines 1-3. This is clearly a broad definition of Heterologous DNA construct, and would include any DNA construct which could "encode for EPSP synthase[,] " the remainder of the sentence of Claim 1 of the '798 patent. United States Patent 5,554,798, claim 1 ("A fertile transgenic Zea mays plant containing an isolated heterologous DNA construct encoding EPSP synthase . . . . " (emphasis added)).

From the claim language, DeKalb's definition of Heterologous DNA construct, to mean that it contains the "necessary components" to produce EPSP synthase is not unreasonable. While the Court recognizes the description in the patent specification states that the DNA may encode for any beneficial feature, the language of the claim itself limits the heterologous DNA construct, as one that "encodes for EPSP synthase. If the DNA construct does not contain the necessary components to produce EPSP synthase, then it cannot encode for it. Therefore, the Court adopts DeKalb's definition of "Heterologous DNA construct."

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D. "Heterogeneously Branched Linear Ethylene Polymer"

Dow's Construction	NOVA's Construction
A polymer having a distribution of branching different from and broader than the homogeneously branched ethylene/[alpha]-olefin.	Ethylene polymer having a distribution of branching different from and broader than the homogeneously branched ethylene/[alpha]-olefin, including having a highly branched portion, a medium branched portion and an essentially linear portion.

Though the parties are in partial agreement as to the meaning of the term "heterogeneously branched linear ethylene polymer," NOVA contends that the term should be understood to further require a distribution of polymers having three distinct portions: "a highly branched portion, a medium branched portion and an essentially linear portion." As principle support for this limitation, NOVA points to the following passage in the specification of the '053 patent:

Heterogeneously branched ethylene/a-olefin interpolymers differ from the homogeneously branched ethylene/a-olefin interpolymers primarily in their branching distribution. For example, heterogeneously branched LLDPE [linear low density polyethylene] polymers have a distribution of branching, including a highly branched portion (similar to a very low density polyethylene), a medium branched portion (similar to a medium branched polyethylene) and an essentially linear portion (similar to linear homopolymer polyethylene). The amount of each of these fractions varies depending upon the whole polymer properties desired. For example, linear homopolymer polyethylene has neither branched nor highly branched fractions, but is linear. A very low density heterogeneous polyethylene having a density from about 0.9 g/cm 3 to about 0.915 g/cm 3 (such as Attane(R) copolymers, sold by The Dow Chemical Company and Flexomer(R) sold by Union Carbide Corporation) has a higher percentage of the highly short chain branched fraction, thus lowering the density of the whole polymer.

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('053 patent at 7:33-51 (emphasis added); D.I. 127 at 18-19.) NOVA further notes that in describing "heterogeneously branched ethylene polymers" the specification explains, with reference to examples, that "[t]he amount of each of these [three] fractions varies depending upon the whole polymer properties desired." ('053 patent at 7:41-43.) Based on this, NOVA contends that "the specification actually makes clear that what differs among heterogeneously branched polymers is not whether or not they contain these three components. It's just the relative proportions of these three components." (D.I. 194 at 119:7-12.)

Dow responds that NOVA's relied upon passage refers only to an exemplary "heterogeneously branched linear ethylene polymer" - specifically, linear low density polyethylene ("LLDPE"). Indeed, Dow notes that in describing the three polymer fractions present in LLDPE it explicitly introduces LLDPE as an "example" of a "heterogeneously branched linear ethylene polymer." Dow further notes that the specification nowhere states that all types of "heterogeneously branched linear ethylene polymers" must have all three types of branched polymers. In fact, Dow contends, the '053 patent claims polymer compositions including a range of "heterogeneously branched linear ethylene polymers." High density polyethylene ("HDPE"), for example, though possibly including a medium branched polymer fraction and an essentially linear polymer fraction, does not necessarily include a highly branched portion, but is nevertheless still a "heterogeneously branched linear ethylene polymer."

The Court does not import mere examples from the specification into the claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005). In addition, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004)(quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)). The Court agrees with Dow that when the specification refers to the three polymer fractions in LLDPE, it is merely describing an exemplary embodiment of one component of the invention. Indeed, as set forth above, LLDPE is explicitly introduced as an "example." Furthermore, on reviewing the specification, the Court is unable to identify any "clear intention" to limit this claim term to only a polymer having three distinct portions with different branching properties. Accordingly, the Court will construe the term "heterogeneously branched linear ethylene polymer," to mean, as Dow contends, "a polymer having a distribution of branching different from and broader than the homogeneously branched ethylene/[alpha]-olefin."
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4. High browning flavorless aqueous composition

Plaintiff argues that the phrase "high browning flavorless aqueous composition" as used in the 541 patent and 582 patent should be construed to mean "a composition capable of imparting a brown color to foodstuffs without imparting virtually any detectable flavor to foodstuffs (whether a composition is flavorless is determined by comparing treated foodstuffs to untreated foodstuffs by taste, not smell)." 57 Defendant counters that the proper construction is "a virtually flavorless water containing composition or product capable of imparting a brown color to foodstuffs, considering smell as well as taste of the product (the product applied to the meat must have virtually no flavor)."

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57 Docket Entry 69 at 4.

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The parties' dispute turns on the meaning of the word "flavorless" as used in the claim. Plaintiff contends that flavorless refers to the compositions effect on foodstuffs to which it is applied. In short, the composition adds virtually no flavor to the foodstuffs. Defendants argue that "flavorless" refers to the composition itself. The composition has virtually no flavor.

The customary and ordinary usage of "high browning flavorless aqueous composition" supports defendants' construction insofar as they argue that "flavorless" refers to the composition and not the foodstuffs treated. There is no dispute among the parties that aqueous describes composition, nor do they dispute that "high browning" refers to the composition's ability to impart color to the treated foodstuffs.

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"Flavorless" is an adjective, 58 which immediately precedes the noun, "composition" in the claims at issue. The ordinary usage of an adjective would dictate that the preceding adjective commonly describes the following noun. Accordingly, "flavorless" would describe "composition." Therefore, the customary and ordinary construction of claim 20 of the 541 patent and claim 16 of the 582 patent is that the aqueous composition is flavorless.

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58 See Defendants' claim construction hearing Exhibit 11 at 3.

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Notwithstanding this unambiguous construction, plaintiff argues that the patentees acted as their own lexicographers and defined the "high browning flavorless" composition in a manner other than its ordinary and customary usage. However, the patentees did not expressly define the terms in the specification. Rather, plaintiff argues that the terms, high browning flavorless composition, are defined by the reference of the composition's effect on the foodstuffs.

While it is true that the patentees make clear that the purpose of the invention is to provide coloring to foodstuffs without adding smoke flavor, it is likewise true that the patentees claimed that the pyrolysis liquid produced from the claimed method is flavorless. Such a construction is supported not only by the claims language and the specification examples, but also by the selected portions of the prosecution history provided above.

Plaintiff argues that defendants have "cherry picked" selected portions of the prosecution history and read the selections out of context to support defendants' construction that the term "flavorless" refers to the browning liquid. However, plaintiff's contention is not supported by the record. The above cited portions of the prosecution history were all made in appeal of the patent examiner's rejection of claims originally numbered 1-4 and 7-27. 59 The patentees made the arguments to persuade the Commissioner of Patents that the examiner erred in rejecting the patent claims 1-4 and 7-27. These selections show that the patentees took the position that the browning liquid did not impart flavor to the treated foodstuffs because the liquid itself was flavorless. The prosecution history contains additional instances of the patentee arguing that the browning liquid is flavorless and therefore, does not impart flavor to the treated foodstuff. 60

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59 Docket Entry 46, Ech. 3, RTI 0266.60 See Docket Entry 46, Ech. 3, RTI 0283, 0284, 0288, and 0293.

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Finally, plaintiff argues that defendants improperly construe the claims by adding the additional components of taste and smell. However, to the extent that defendants construe flavor to include the sensory perceptions of taste and smell, they are correct that a person of ordinary skill in the art would understand flavor to encompass both senses.

In considering the patent applications, the patent examiner cited a number of reference sources relevant to the art. Pertinent to the issue of "flavor," the examiner referred to the text Food Chemistry. Food Chemistry explains the ordinary and customary usage of "flavor" in the art:

The term "flavor" has evolved to a usage that implies an overall integrated perception of all the contributing senses (smell, taste, sight, feeling, and sound) at the time of food consumption. The ability of specialized cells of the olfactory epithelium of the nasal cavity to detect trace amounts of volatile odorants accounts for the nearly unlimited variations in intensity and quality . . . Taste buds located on the tongue and back of the oral cavity enable humans to sense sweetness, sourness, saltiness, and bitterness, and these sensations contribute to the taste component of flavor. Nonspecific or trigeminal neural responses also provide important contributions to flavor perception through detection of pungency, cooling, umami or delicious attributes, as well as other chemically induced sensations that are incompletely understood. 61

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61 Food Chemistry, 586 (Owen R. Fennema ed., Marcel Dekker, Inc., 2d ed. 1985)

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The patent examiner included the above passage in his analysis of the claims in question. The patentee did not contest the usage of flavor contained in the above passage, but rather addressed the patent examiner's reliance on the work to reject the claims. Accordingly, the quoted passage constitutes intrinsic evidence of the meaning of the term "flavor" as understood by one of ordinary skill in the art. Even if Food Chemistry constitutes extrinsic evidence, the text is a technical work that holds a favored position and provides the accepted meaning of flavor in the art.

Accordingly, the District Court should construe the phrase "high browning flavorless aqueous composition" to mean "a virtually flavorless water containing composition or product capable of imparting a brown color to foodstuffs, considering smell as well as taste of the product (the product applied to the meat must have virtually no flavor)."
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4. A high browning, low flavor liquid composition

Plaintiff contends that the phrase "a high browning, low flavor liquid composition" recited in the claims at issue should be construed as "a liquid composition capable of imparting a brown color to foodstuffs without imparting strong flavor to the foodstuffs (whether a composition is low flavor is determined by comparing treated foodstuffs to untreated foodstuffs by taste, not smell)." Defendants counter that the phrase should be construed as "a low flavor liquid solution with substantially no smoke flavoring ability, considering smell as well as taste."

The parties dispute whether "low flavor" refers to the liquid composition or the foodstuffs which are encased by the casings treated with the liquid composition. They parties also disagree as to whether "flavor," as used in the claims, encompasses smell as well as taste.

A plain reading of "high browning, low flavor liquid composition" supports defendants' construction. In the context of the claim statements, the customary and ordinary usage of both "high browning" and "low flavor" are as compound adjectives. 98 Liquid is also an adjective in the context of the claims. Each of the adjectives describes the immediately following noun, in this case, composition. Accordingly, it is the composition that is "high-browning," "low-flavor," and "liquid."

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98 Using "high" and "low" in conjunction with other descriptive terms create compound adjectives. Compound adjectives that are formed by using "high" or "low" are generally hyphenated. Accordingly, the claim terms should be read as "low-flavor" and "high-browning." See The American Heritage(R) Book of English Usage, 255 (Houghton Mifflin Company 1996).

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This construction is supported by the patent specification. The specification describes the invention as a "method of making a food casing in which the casing has high browning capabilities and less intense flavor properties compared to previously reported food casings." 99 According to the patentees, the advantages of the invention are due in part to the characteristics of the browning composition used to treat the casings. Importantly, the browning composition has low levels of phenols. Phenols are the class of chemicals that researchers skilled in the art of smoke solutions have concluded are primarily flavoring and aroma compounds. 100 Consequently, the liquid composition, which is low in levels of phenols, is also low in flavor.

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99 "067 patent, Col. 3, lines 62-65.100 537 patent, Col 2, lines 49-56. Note that the 067 patent is a continuation in part of the 537 patent, Docket Entry 56, Ech. 1F, RA 2313.

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As noted in the analysis of the 541 and 582 patents, a person of ordinary skill in the art would understand the term "flavor"

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to include all the contributing senses (smell, taste, sight, feeling, and sound) at the time the food is consumed. The specialized cells of the olfactory system detect trace amounts of odors and account for variations in quality and intensity. The taste buds of the tongue and back of the mouth sense sweetness, sourness, saltiness, and bitterness. 101

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101 Food Chemistry, 586 (Owen R. Fennema ed., Marcel Dekker, Inc., 2d ed. 1985)

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In the context of the 067 patent claims, the description of flavor provided by Food Chemistry constitutes extrinsic evidence of the term. Nonetheless, the text constitutes a learned authority that has been cited by a patent examiner as the state of the art in the course of the prosecution of patent of a similar nature. Therefore, the definition of "flavor" contained in the cited text holds a favored place in this claims construction context.

Accordingly, the District Court should construe the phrase "high browning, low flavor liquid composition" to mean "a low flavor liquid solution with substantially no smoke flavoring ability, considering smell as well as taste."
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high molecular weight di-allyl di-methyl ammonium chloride

The Court modifies Defendants' proposed construction and construes the phrase as "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having a molecular weight range of about 1,000,000 or greater." Relying on the same arguments they urged with regard to "molecular weight," Plaintiffs argue that the term should be construed as "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water." For the same reasons discussed above with regard to "high molecular weight quaternized ammonium polymer" and "molecular weight," the Court rejects Plaintiffs' proposed construction.

Defendants argue that the phrase should be construed as "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having an average molecular weight range of about 1,000,000 or greater." For the same reasons discussed above with regard to "high molecular weight quaternized ammonium polymer," the Court does not include the word "average" in its construction of the phrase.
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high molecular weight epichlorohydrin d-methyl amine (Epi-DMA)

The Court modifies Defendants' proposed construction and construes the phrase as "a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." Since the parties have agreed on the definition of epichlorohydrin d-methyl amine (Epi-DMA), only the "high molecular weight" portion of the phrase is in dispute. Plaintiffs argue that the term should be construed as "a high-molecular weight Epi-DMA measures greater than about 1000 cps at a concentration of about 50% in water." Defendants argue that the term should be construed as "a high molecular weight Epi-DMA having a molecular weight range of greater than about 500,000 and less than about 3,000,000." Both Plaintiffs and Defendants re-urge the arguments set forth in support of their proposed constructions of the term "molecular weight." For the reasons discussed above with regard to "molecular weight," the Court rejects Plaintiffs' proposed construction and modifies Defendants' proposed construction to include various measurement techniques for determining molecular weight.
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high molecular weight quaternized ammonium polymer

The Court modifies Defendants' proposed construction and construes the phrase as "a quaternized ammonium polymer having a viscosity of about 1,000 cps or greater at a concentration of about 20% in water, depending on repeating unit moiety and a molecular weight range of about 1,000,000 or greater." Relying on the same arguments they urged with regard to "molecular weight," Plaintiffs argue that the phrase should be construed as "a quaternized ammonium polymer having a viscosity of about 1,000 cps or greater at a concentration of about 20% in water, depending on repeating unit moiety." The specification clearly describes the high molecular weight quaternized polymer in terms of both its molecular weight and its viscosity. See Col. 3:1-4 ("The quaternized polymer has a molecular weight of greater than approximately 1,000,000 and has a viscosity greater than about 1,000 cps at a concentration of approximately 20% in water."). Plaintiffs attempt to improperly exclude the molecular weight characteristics of the high molecular weight quaternized polymer as it is described in the specification. Accordingly, and for the reasons discussed above with regard to "molecular weight," the term is construed to include a reference to its molecular weight range.

Defendants contend that the term should be construed as "a quaternized ammonium polymer having a viscosity of about 1,000 cps or greater at a concentration of about 20% in water, depending on repeating unit moiety and an average molecular weight range of about 1,000,000 or greater." Defendants argue that the term "average" should be included to prevent an alleged infringer from being found to infringe because a few of the polymers being used fall within the molecular weight range of about 1,000,000 or greater. Although this may be a concern Defendants will have to address at trial, there is no intrinsic or extrinsic evidence to support a construction that includes the word "average." Accordingly, the word "average" is not included in the construction of the phrase "high molecular weight quaternized ammonium polymer."
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C. Infringement of the '833 Patent

Apotex's arguments as to the proper claim construction for the '833 patent fail on the same logic as the '181 patent. Apotex argues that the district court erred in construing the term "pure" to mean the absence of impurities, where excipients are not considered to be impurities. Under Apotex's definition of "pure," Claim 1 of the '833 patent would cover methods of spray drying where the solution to be spray dried contained only highly pure CA. Because the term "pure" should be construed such that it is consistent with the ordinary meaning of that term, we construe the '833 patent consistently with the '181 patent and affirm the district court's construction. Based on this construction, a "highly pure solution of cefuroxime axetil" may include a solution that contains excipients along with pure CA. Apotex's method of producing its amorphous CA product by spray drying excipients and pure CA therefore infringes the claims of the '833 patent.
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C. Hollow

"Hollow" appears in several asserted claims of the '324 Patent. Claims 9 and 13, quoted above, provide examples. After describing the process to obtain whole [beta] - glucan--extracting non-glucan components without disrupting a cell wall--the '324 Patent's specification states: "These hollow, three-dimensional particles are conducive to a high water holding capacity, in that they become filled with water upon hydration." '324 Patent, col. 4, ll. 11-13. The '324 Patent's use of "hollow" is consistent with the term's common meaning of having an empty space within. See Webster's Third New International Dictionary 1080 (2002). The Court construes the term accordingly. See Phillips, 415 F.3d at 1314.
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A. "Assessing . . . a Homocysteine Co-Substrate"

The specification of the '127 patent defines "homocysteine co-substrate" as "a compound which reacts with homocysteine in

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the enzyme-catalysed, e.g. a SAH-hydrolase catalysed, homocysteine conversion reaction." '127 patent, 2:43-45. Axis Shield argues that this definition indicates that "homocysteine co-substrate" is not limited to the specific co-substrate used in a particular assay, but that it may be a homocysteine co-substrate for any conceivable enzymic reaction that uses homocysteine as a substrate. For example, Axis Shield argues that SAH, which is not a homocysteine co-substrate in the General Atomics assay, nonetheless constitutes a homocysteine co-substrate under claim 1 of the '127 patent because there may be other enzymic reactions in which SAH acts as a homocysteine co-substrate.

The Court rejects Axis Shield's proposed construction of homocysteine co-substrate. The passage quoted above makes clear that "homocysteine co-substrate" is specific to the enzyme used, and is not any potential co-substrate of homocysteine. Indeed, in its proposed construction Axis Shield changes "the enzyme catalyzed . . . homocysteine conversion reaction" to "an enzyme catalyzed homocysteine conversion reaction." Def. Oppo. Br. at 15. Axis Shield provides no reason why this change is warranted by the specification. Accordingly, the Court adopts General Atomics' proposed construction of "homocysteine co-substrate": "a compound which reacts with homocysteine in the homocysteine conversion reaction of the assay."

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B. "Assessing . . . the Homocysteine Conversion Products of the Enzymic Conversion of Homocysteine"

Claim 1 of both the '127 patent and the '717 patent includes the step of "assessing . . . the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." Axis Shield argues that General Atomics' assay contains this claim limitation. Alternatively, it argues that even under General Atomics' construction of the phrase, the assay infringes under the doctrine of equivalents.

1. Proper Construction

The dispute over the meaning of "homocysteine conversion products of the enzymic conversion of homocysteine" centers on whether "homocysteine conversion products" must be the products of the enzymic reaction that derive specifically from homocysteine, or whether they include all products of the homocysteine conversion reaction. Axis Shield argues that the term includes all of the products of the enzymic reaction, including the products that derive from the homocysteine co-substrate. General Atomics, on the other hand, argues that "homocysteine conversion products" are limited to the "conversion products derived from homocysteine in the reaction catalyzed by the homocysteine converting enzyme of the assay." See Borchardt Decl., P 36. Under General Atomics' interpretation, its assay would not infringe because the only "homocysteine conversion product" of the HMTase reaction is methionine; SAH is a conversion product of SAM, not homocysteine.

The Court agrees with General Atomics that the plain language of the claims limits "homocysteine conversion products" to those products of the homocysteine conversion reaction that are derived from homocysteine. The claims at issue clearly state that the reaction products to be assessed are "products of the enzymic conversion of homocysteine." Elsewhere, the specification generally uses "homocysteine conversion reaction" or just "reaction" to refer to the reaction as a whole; the more narrow language of the claims does not appear. See, e.g., '127 patent, 2:45 ("homocysteine conversion reaction"); 2:59-63 (referring to "direct or indirect reaction product of the enzymic conversion of the analyte"); 3:3-4 ("[SAH-hydrolase] catalyses the homocysteine reaction"). Even the claims of the '127 patent use the language "homocysteine conversion reaction." Id. at 24:6-12. Aside from the abstract, the closest the specification comes to the language at issue is "products of the enzymic conversion of homocysteine," language not as limited as that found in the patents' claims. See '127 patent, 2:29-30; see also '127 patent, 12:39-42. The specification therefore demonstrates that Axis Shield chose narrower language for its claimed invention than the language it had available to it. The Court finds that, by limiting the analyte to the "homocysteine conversion products of the enzymic conversion of homocysteine," the patents' claims confine the possible analytes to those that derive from homocysteine itself, not those that derive from the reaction generally.

Axis Shield disagrees with this reading of the '127 patent, and argues that the plain language of the claims indicates that "homocysteine conversion products" may be any products of the conversion reaction. This argument is difficult to follow, but Axis Shield apparently argues that the phrase "of the enzymic conversion of homocysteine by said enzyme" modifies both "homocysteine co-substrate" and "homocysteine conversion products." Under this reading, Axis Shield argues that the

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phrase "of the enzymic conversion of homocysteine by said enzyme" means "associated with the enzyme-catalyzed homocysteine reaction." Oppo. Br. at 16. The Court finds this reading of the claim language strained; referring to a co-substrate of a reaction is awkward phrasing, at best. The patents do not use such language to modify "homocysteine co-substrate" in other areas of their specifications. See, e.g., '127 patent, 3:11 ("In the above scheme, adenosine is the homocysteine co-substrate."). Rather, the specifications refer to co-substrates in the manner identified by General Atomics' expert. See Borchardt Reply Decl., P 10 ("The correct way to identify a co-substrate is to name another substrate with which it reacts."). In addition, other claim language refers to a "substrate . . . for the homocysteine conversion reaction," a much more sensible method of referring to the substrate than "a homocysteine co-substrate . . . of the enzymic conversion of homocysteine." See '127 patent, 24:9-10 (emphasis added). Thus, the Court rejects Axis Shield's argument that "enzymic conversion of homocysteine" modifies both "homocysteine conversion products" and "homocysteine co-substrate," and that the phrase should therefore mean "associated with the enzyme-catalyzed homocysteine reaction."

Axis Shield also raises a number of arguments against General Atomics' construction of "homocysteine conversion products." First, it points to a single disclosure in the patents' specifications that refers to using the "products of . . . [homocysteine conversion] reactions . . . as analytes." See '127 patent, 4:5-8 ("The co-substrates and the conversion products of these various reactions may be used as the analytes in the assay of the invention."). Axis Shield argues that this disclosure indicates that the patent was not intended to be limited to assessing products derived from homocysteine. n7 This single disclosure, however, unlimited by the more specific phrasing of the patent's claims, only serves to demonstrate language that would have achieved Axis Shield's proposed construction. Instead of referring to the products of the "homocysteine conversion reaction," however, the claims limit their reach to "homocysteine conversion products of the enzymic conversion of homocysteine." Further, read in context, the quoted language was not intended to specify the scope of the invention. Rather, it was a reference to a number of homocysteine conversion reactions documented in the scientific literature, establishing the possibility that those reactions could be utilized in the invention. The Court finds that the above disclosure in the specification is insufficient to broaden the plain meaning of the claim terms. See Superguide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004) ("The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language.").

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n7 Another portion of the specification contains language more similar to, but arguably broader than, the claim language: "In one aspect the present invention therefore provides a method for assaying homocysteine in a sample, said method comprising the steps of . . . assessing (preferably photometrically) a non-labelled analyte selected from the homocysteine co-substrate and the products of the enzymic conversion of homocysteine by said enzyme." '127 patent, 2:21-31.

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Axis Shield also argues that General Atomics' construction is inconsistent with a number of embodiments disclosed in the specification. The first such embodiment is a betaine reaction in which an enzyme named BHMase converts homocysteine and betaine into methionine and dimethylglycine. '127 patent, 2:38-39; Green Decl., PP 10-11. Because the enzyme in this reaction transfers a methyl group from the betaine to the homocysteine, the enzyme effectively acts in an identical manner as the HMTase in General Atomics' assay. Thus, Axis Shield argues that its patent should be read broadly enough to cover similar reactions.

Setting aside the fact that the patents only contain cursory references to the betaine reaction, Axis Shield's argument fails because there is no indication of how the assessment of the betaine reaction is performed. Indeed, the patents' specifications reference the betaine reaction in conjunction with a number of other potential enzymic reactions then state simply, "[t]he co-substrates and the conversion products of these various reactions may be used as the analytes in the assay of the invention." '127 patent, 4:5-10. There is no indication that dimethylglycine should be used as the analyte; if betaine were used as the analyte the reaction would fall within the patents' scope. Thus, the Court does not believe that its construction of "homocysteine conversion products" removes the betaine reaction from the reach of the patents' claims.

A second embodiment that Axis Shield argues this Court's construction overlooks is the disclosure of a method for "indirect assessment" of the analyte. The patents teach that "the chemical species actually detected need not of course be the analyte itself but may for example be a derivative thereof or some further substance." '127 patent, 2:52-55. Because the patents teach detecting a substance other than a homocysteine conversion product, Axis Shield argues, there is no need to limit the

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analyte to those reaction products that were derived from homocysteine. This argument misses the point, however; it is not what is ultimately detected that is important to the patent, it is the method of measuring homocysteine by assessing the level of homocysteine-derived products in the sample. Indirect assessment still operates in this same basic manner.

The final embodiment that Axis Shield contends is excluded by this Court's construction of "homocysteine conversion products" is the "inhibition" embodiment in the specification. The inhibition embodiment measures the level of homocysteine in a sample by adding the enzyme SAH-hydrolase and either adenosine and SAH. SAH-hydrolase is an enzyme that creates a reversible reaction; it converts SAH into homocysteine and adenosine, and also converts homocysteine and adenosine back into SAH. Thus, the level of homocysteine in a sample can be monitored either by adding adenosine or SAH. If adenosine is added, the SAH hydrolase creates SAH from the adenosine and homocysteine, allowing the level of homocysteine to be determined by monitoring the decrease of adenosine in the sample. If SAH is added, the enzyme acts to split it into homocysteine and adenosine. Because the reaction is reversible, however, "any homocysteine present in the test sample will counteract this net reaction, and thus inhibit the formation of adenosine." '127 patent, 3:48-55. By monitoring the increase in the level of adenosine formed in the sample, one can therefore determine the amount of homocysteine. Id.

Neither of these embodiments is excluded from the claims of the '127 patent by General Atomics' construction because they involve assessing adenosine, a co-substrate of homocysteine for the SAH-hydrolase enzyme. n8 Both embodiments, however, are excluded from the claims of the '717 patent, because the analyte disclosed is adenosine. Even under Axis Shield's construction of the term, adenosine is not a "homocysteine conversion product" because it is not a product of the homocysteine conversion reaction; it is a product only of the conversion of SAH. Thus, the inhibition embodiments are simply unclaimed subject matter, and do not establish that General Atomics' construction is incorrect. Although a claim interpretation that excludes a preferred embodiment is "rarely, if ever, correct, Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1374 (Fed. Cir. 2005), here there is no dispute that the inhibition embodiment does not fall within the '717 patent's scope under either party's interpretation of the phrase "homocysteine conversion products."

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n8 Axis Shield also argues that the patents teach assessing SAH in this reaction, instead of assessing adenosine. See Green Decl., P 18. While SAH could undoubtedly be monitored, given that it has a one-to-one relationship with homocysteine, the patents do not disclose using it as an analyte. The passage Axis Shield relies on states: "The SAH-hydrolase substrates used in the method of the invention may thus be SAH or adenosine or analogues and precursors thereof." '127 patent, 3:56-58. This passage follows the description of the alternative SAH-hydrolase reactions, as described above, and discloses only that SAH or adenosine may be added to the sample. The Court does not read this passage as disclosing that SAH may be used as the analyte. Even if the Court were to accept Axis Shield's contention that the patents disclose using SAH as the analyte, it would agree with General Atomics that SAH would constitute a "homocysteine conversion product" because it is actually derived from homocysteine in the enzymic reaction, and that the embodiment is therefore consistent with General Atomics' construction.

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Finally, Axis Shield also raises two other arguments that can be quickly disposed of. First, Axis Shield argues that General Atomics' construction is incorrect because it is inconsistent with the requirement that the analyte be "non-labelled." As General Atomics responds, however, the selection of a particular detection method is unrelated to the choice of which analyte to assess. See Borchardt Reply Decl., P 13. While the Court's construction of "homocysteine conversion products" may render the invention more similar to prior techniques that utilized radioactive labeling, there is no requirement that the inventions use labeling; in fact, they specifically prohibit it. Second, Axis Shield argues that the use of the plural "homocysteine conversion products" indicates that the analyte may be any of the products of the reaction. The Court disagrees. Axis Shield's use of the plural is more easily explained by the existence of reactions in which homocysteine is converted into multiple products. See Aannestad Reply Decl., Exh. 20 at 2 (describing conversion of homocysteine and water into three products through the use of the homocysteinase enzyme).

Accordingly, the Court adopts General Atomics' proposed construction. The "homocysteine conversion products" must be products that actually derive from homocysteine in the enzymic reaction.
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A. "homocysteine converting enzyme"

Axis-Shield seeks a broad construction of this term: an "enzyme that catalyzes a reaction between homocysteine and a co-substrate (if any) that is not homocysteine to produce one or more products that do not include homocysteine." Axis-Shield's construction would thus include any enzyme that could potentially catalyze a reaction involving homocysteine, even if the enzyme does not in fact act on homocysteine in the assay at issue. General Atomics' proposed construction is much more narrow: "an enzyme that acts on the sample homocysteine being assayed." General Atomics' construction would thus include only enzymes that act on the homocysteine existing in the original sample, and not enzymes that act only on homocysteine produced at some other point in the assay.

A natural reading of claim 1, at first blush, favors General Atomics' proposed construction. If the assay method is to result in "the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme," then the enzyme must convert the homocysteine in the sample. Axis-Shield argues that this logic, however, ignores the ability of the claimed assay to run "in reverse."

The "forward" reaction is as follows: The sample containing homocysteine is contacted with a co-substrate, adenosine, and an enzyme, SAH-hydrolase. The SAH-hydrolase catalyzes a reaction between the homocysteine and the adenosine, forming SAH. The amount of SAH or remaining adenosine is then measured, by which the amount of homocysteine in the original sample can be determined. See Patent '127, 3:40-47.

The reverse or "inhibition" (or "hydrolytic") embodiment of claim 1 functions differently. See Patent '127, 3:16-33, 3:48-55. The sample containing homocysteine is contacted with SAH and SAH-hydrolase. Some of the SAH-hydrolase acts to break apart SAH into its component parts, adenosine and homocysteine. Other SAH-hydrolase molecules, however, bind to the homocysteine in the sample, and are unavailable to break up the SAH. Therefore, if the assay begins, for example, with equal parts SAH and SAH-hydrolase, not all of the SAH will be broken up, as some of the SAH-hydrolase will be occupied with the homocysteine. The amount of adenosine is then measured, and compared to the amount of adenosine that would be found if all of the SAH-hydrolase had been engaged to break up SAH. The difference will be proportionate to the amount of homocysteine in the sample. In this "reverse" reaction, the homocysteine converting enzyme, SAH-hydrolase, does not actually convert any of the homocysteine in the sample. Axis therefore argues that General Atomics' proposed construction is too narrow, as it would preclude this embodiment.

This "reverse" embodiment, however, standing alone, is inconsistent with claim 1. The natural reading of the last step of claim 1, "without chromatographic separation assessing a non-labelled analyte selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme," is that homocysteine is, at some point, converted into other products by the enzyme. See Order Granting Summ. J. 9-14 (Docket No. 83). In the "reverse" reaction described above, homocysteine is never converted; some is bound to the SAH-hydrolase, but absent a co-substrate, SAH-hydrolase effects no change on the homocysteine.

At oral argument, Axis-Shield asserted that the reverse reaction does not occur in isolation, but rather is part of simultaneous forward and reverse reactions, and in that context, the assay is consistent with claim 1, because SAH serves as both a substrate and a homocysteine conversion product. The simultaneous, forward and reverse, "inhibition" embodiment functions as follows. As in the pure "reverse" reaction, the homocysteine sample, SAH, and SAH-hydrolase, are placed together. Some of the SAH-hydrolase breaks up the SAH, and some bonds to the homocysteine. As the SAH is broken into homocysteine and adenosine, the newly-freed adenosine can bond with the SAH-hydrolase, to which homocysteine is already bound, thereby forming new SAH particles (this is the "forward" reaction). As this process continues, the rate of adenosine formation will change. The rate of change in adenosine formation will be proportionate to the amount of homocysteine in the sample. In this "inhibition" embodiment, SAH is both a substrate, because SAH-hydrolase acts on it, and is a homocysteine conversion product, because the freed adenosine combines with homocysteine to create new SAH.

This "inhibition" reaction is clearly described in the patent as a possible embodiment of the claims. See patent '127 at 3:16-38, 3:48-55. The Court also finds that this embodiment does not conflict with claim 1, as SAH acts as both a substrate and a homocysteine conversion product. However, this finding does not compel the Court to agree with Axis-Shield's broad

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construction of "homocysteine converting enzyme." Axis-Shield argues that General Atomics' construction, which is the natural construction, is too narrow because in the reverse reaction the enzyme does not actually act on the sample homocysteine. However, as discussed, the reverse reaction alone is inconsistent with claim 1. Only in the context of a continuous forward-reverse, "inhibition" embodiment, is the reverse reaction consistent with claim 1. In this context, the enzyme does catalyze the homocysteine in the sample. As adenosine is freed, it combines with homocysteine, using the SAH-hydrolase enzyme, forming new SAH. The freed adenosine makes no distinction between the homocysteine which is in the sample to begin with, and the homocysteine freed from SAH. The "homocysteine converting enzyme" in the inhibition embodiment thus does in fact convert homocysteine from the sample. There is therefore nothing to prevent the Court from adopting the natural reading of "homocysteine converting enzyme," which is "an enzyme that acts on the sample homocysteine being assayed." This construction encompasses both the "forward" and "inhibition" embodiments of the assay, without being over-broad.
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D. "homogeneous"

1. The Parties' Proposed Constructions

Rhodia proposes that "homogeneous" be construed to mean "the similarity in the nature, or consistency, of the population of particulates." (D.I. 108 at 13.) Rhodia supports its proposed construction with reference to the specification of the '234 patent and the assertion that "homogeneous" refers to the "more uniform morphology" of the patented silica particulates over "previously known silica particulates," and with the argument that the word "homogeneous" does not imply that each individual silica particulate is uniform, but, instead, that the population demonstrates more uniformity than prior art silica forms. (Id. at 13-14.)

PPG proposes that I construe "homogeneous" "to mean that the precipitated silica particulates all have the same or similar size and shape." (D.I. 106 at 16 (emphasis removed).) PPG argues that Rhodia's proposed construction "leaves open to question" the meaning of "'similar in nature throughout'." PPG claims that its own, proposed construction should be adopted because it makes clear that the inventors intended the size and shape of the particles to be "homogeneous". (Id. at 17.) In support, PPG directs attention to portions of the '234 patent specification which PPG says show that the size and shape of the particulates are "homogeneous" within a specified range. PPG also notes statements the inventors made during patent prosecution describing the particulates as "completely homogeneous". (Id. at 15-17.)

2. The Court's Construction

I construed "homogeneous" to mean "of the same or a similar kind or nature … of uniform structure or composition throughout …." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 554 (10 ed. 2002). From the context in which the word appears, the word "homogeneous" has an ordinary, non-technical meaning. The intrinsic record does not contradict that ordinary meaning. Accordingly, I adopt a standard dictionary definition of the word "homogeneous".
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54. The term "homogeneous" means that samples of the product taken anywhere throughout the product should have the same compositions.
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The parties dispute whether the claim term "homogeneously branched linear ethylene/[alpha]-olefin interpolymers" should be explicitly characterized as having a composition distribution branch index ("CDBI") of greater than about 30 percent (Nova's position) or not (Dow's position). In an effort to resolve this dispute, the Court requested clarification as to whether the specification's guidance that "substantially all of the interpolymer molecules" in "homogeneously branched linear

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ethylene/[alpha]-olefin interpolymers" have "the same ethylene/comonomer ratio within that interpolymer" could be squared with its guidance that such interpolymers could have a CDBI as low as 30 percent. (See D.I. 270 at 26.) More specifically, the Court expressed concern that requiring "substantially all" interpolymer molecules to have "the same" ethylene comonomer ratio was unduly stringent and, to those of skill in the art, irreconcilable with a CDBI as broad as 30 percent. (See id.)

II. DECISION

The Court agrees with Dow that "homogeneously branched linear ethylene/[alpha]-olefin interpolymers" should not be construed in terms of CDBI, a parameter the patents-in-suit define as the "weight percent of the polymer molecules having a comonomer content within 50 percent of the median total molar comonomer content." '053 patent at 3:38-40. Although CDBI is often used in the art to characterize interpolymers, the Court concludes that the CDBI parameter alone does not carry sufficient information to consistently and accurately distinguish between homogeneous and heterogeneous interpolymers. In particular, because the CDBI is defined relative to the "median total molar comonomer content," interpolymers having comonomer distributions of similar width may nonetheless have very different CDBI values. (See D.I. 291 at 6.) Thus, although, as NOVA notes, during prosecution the patentee referred to CDBI when distinguishing the polymers of the patents-in-suit from those of the prior art, (see D.I. 143, Exh. U at 103), the Court cannot conclude that this necessitates a definition of "homogeneously branched linear ethylene/[alpha]-olefin interpolymer" in terms of the CDBI parameter.

In this regard, the Court cannot agree with NOVA that the specification characterizes the CDBI parameter as a tool that can be used to establish a bright line between homogeneous and heterogeneous polymers. Indeed, the specification explains only that the "homogeneity of the interpolymers is typically described" by the CDBI. '053 patent at 3:35-36 (emphasis added). Likewise, the specification explains that the "CDBI for linear and for the substantially linear olefin polymers of the present invention is preferably greater than about 30 percent, especially greater than about 50 percent." Id. at 3:49-51 (emphasis added). In the Court's view, this, at most, indicates that the CDBI parameter has some utility in characterizing polymers, not that the claims of the patents-in-suit should be limited to particular CDBI ranges.

Having concluded that the term "homogeneously branched linear ethylene/[alpha]-olefin interpolymer" should not be construed in terms of CDBI, the Court must now consider whether it is appropriate to define it as being, in part, an "interpolymer in which the comonomer is randomly distributed within a given interpolymer molecule and wherein substantially all of the interpolymer molecules have the same ethylene/comonomer ratio within that interpolymer." This definition is supported by the specifications of the patents-in-suit, which state that "[t]he homogeneously branched ethylene/[alpha]-olefin interpolymers useful for forming the compositions described herein are those in which the comonomer is randomly distributed within a given interpolymer molecule and wherein substantially all of the interpolymer molecules have the same ethylene/comonomer ratio within that interpolymer." Id. at 3:29-35.

Although the Court expressed reservations that this definition does not adequately reflect that interpolymers contain a distribution of polymer molecules, on reviewing the parties' supplemental claim construction briefing, the Court is satisfied that, in context, those of skill in the art would not understand this definition so narrowly. Indeed, though maintaining that the term "homogeneously branched linear ethylene/[alpha]-olefin interpolymer" should be defined in terms of CDBI, NOVA directs the Court to literature in the field of polymer science explaining that "the statistical nature of polymerization . . . forces the composition of any synthetic copolymer chain to be always distributed around a certain average value." (D.I. 296, Exh. AM at 4.) Likewise, NOVA explains that "[f]undamentally, the short chain branching within a group of interpolymer molecules, even those considered to have 'homogeneous' branching, can never be identical." (D.I. 296 at 3.) Similarly, Dow explains that "[p]ersons skilled in the art in 1993 and now understand that all polyethylene polymers have a distribution of branching. That is true for homogeneously branched polymers." (D.I. 297 at 9.) In view of the above, the Court concludes that, in the context of the relevant art, it is not inappropriate to define "homogeneously branched linear ethylene/[alpha]-olefin interpolymers" as being interpolymers in which "substantially all" of the interpolymer molecules have "the same" ethylene/comonomer ratio.

III. CONCLUSION

For the reasons discussed, the Court will construe the term "homogeneously branched linear ethylene/[alpha]-olefin interpolymer" to mean "ethylene [alpha]-olefin interpolymer in which the comonomer is randomly distributed within a

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given interpolymer molecule and wherein substantially all of the interpolymer molecules have the same ethylene/comonomer ratio within that interpolymer. Such interpolymer has no long chain branching."
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2. "% Homology"

a. The Parties' Proposed Constructions

28. Novozymes proposes that "% homology" means "a percent identity calculation according to the standard whereby the number of exactly matching amino acid residues in two sequences is compared to the total number of residue positions that are present in both sequences, expressed as a percent, e.g., as implemented by the GAP GCG program." (D.I. 118 at 19.)

29. Defendants argue that the calculation of homology "requires use of any method that accounts for all substitutions, insertions, and deletions, including internal and terminal deletions, over the entire amino acid sequences of the variant and parent alpha-amylases identified in the claims." (D.I. 115 at 63, P 16.) That calculation is not consistent with Novozymes's proposed construction, primarily because Novozymes's calculation method does not count deletions.

b. The Court's Construction

30. Because Novozymes's proposed construction is consistent with unambiguous instructions given in the '031 patent, I conclude that it is the correct construction.

31. According to the patent:

> An amino acid sequence is considered to be X % homologous to the parent [alpha]-amylase if a comparison of the respective amino acid sequences, performed via known algorithms, such as the one described by Lipman and Pearson in Science 227 (1985) p. 1435, reveals an identity of X %. The GAP computer program from the GCG package, version 7.3 (June 1993), may suitably be used, employing default values for GAP penalties [Genetic Computer Group (1991) Programme Manual for the GCG Package, version 7, 575 Science Drive, Madison, Wis., USA 53711].

('031 patent, 4:36-45.) Thus, according to that passage, "% homology" is equivalent to percent identity. (Devereux, Tr. at 124:22-25, 128:9-13; Arnold, Tr. at 140:6-14; Alber, Tr. at 294:5-9.) Also, the passage sets forth a methodology that, first, aligns the sequences and, second, calculates the percent identity from the alignment. (Devereux, Tr. at 126:9-12; Arnold, Tr. at 145:14-20; Alber, Tr. at 233:22-24.) Finally, a software package is suggested that "may suitably be used" to perform the alignment and calculation of identity.

32. Novozymes's construction is based on the methodology used by that software package. In the GAP program, identity is calculated by counting the number of exact matches of amino acid residues between two aligned sequences and dividing by the number of positions where there are residues present in both sequences. (Devereux, Tr. at 109:22-110:6.) When one sequence has a residue with no corresponding residue in the other sequence, the program allows a gap in the alignment, and that position is not counted in the denominator of the identity calculation. (Id. at 109:13-21, 110:7-111:12.)

33. Defendants argue that even though the patent states that GAP is suitable for the calculation, a person having ordinary skill in the art would understand that using GAP would be incorrect. (D.I. 116 at 11-14.) First, Defendants note that while GAP "may suitably be used," it is not required, and that other methods for doing the calculation were available when the specification was written, methods that might give a different result. (Id. at 11-12 (citing Arnold, Tr. at 181:12-182:10, 190:19-191:3; Alber, Tr. at 234:25-235:8).)

34. Second, Defendants argue (D.I. 116 at 13-14) that the '031 specification teaches that deletions, which will cause gaps in an alignment, are important modifications that can be made by protein engineers. Indeed, the patent includes deletions in its general description of possible modifications ('031 patent, 3:59-65) and the claims themselves require deletions at positions

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179 and 180 (id., 65:11-17, 65:21-66:12, 66:16-19). In addition, Defendants cite extrinsic evidence to support the proposition that a person having ordinary skill in the art would understand that deletions were important in the field of protein engineering. (TX 511, D.I. 122 at A-8886, P 30; Alber, Tr. at 216:9-217:6, 217:20-218:20.) Because of that importance, Defendants contend, those skilled in the art would know that deletions should be included in the calculation of percent identity.

35. While I agree that the '031 patent discloses that deletions are relevant modifications, those general statements, which are not made in the context of a discussion of percent identity, are not sufficient to overcome the express instruction that GAP may suitably be used. Indeed, the presence of both the commentary on deletions and the instruction regarding GAP shows that the patentee gave the instructions with full understanding about the importance of deletions. It was no oversight or mistake. While the patent does not instruct that GAP is the only way to do the calculation, that does not imply, as Defendants suggest, that GAP should not be used. A construction that requires that GAP not be used would be contrary to the express language of the patent.

36. I conclude that the construction proposed by Novozymes is correct, because it is consistent with those unambiguous instructions in the patent. "% homology" means "a percent identity calculation according to the standard whereby the number of exactly matching amino acid residues in two sequences is compared to the total number of residue positions that are present in both sequences, expressed as a percent, e.g., as implemented by the GAP GCG program."
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A. "HPV DNA"

At the claim construction hearing, the parties agreed that the term HPV DNA refers to a full length genome of the human papillomavirus. See, e.g., "wherein the HPV 52 DNA consists of all or a fragment of HPV DNA . . . ." Claim 8, col. 16, lns. 46-47. The only dispute they had was whether the word "the" preceding human papillomavirus should be changed to "one," as defendant proposed. Defendant's proposal is sensible because it is obvious that the term human papillomavirus does not refer to more than one human papillomavirus; one could not have a full length genome of two human papillomaviruses). The word adds clarity to the term and it is consistent with the prosecution history and the canons of construction.

The prosecution history shows that the applicant told the examiner in April 1996 and again in September 1996 that "the claimed HPV 52 DNA is all or a part of an HPV DNA, that is the DNA of an entire human papillomavirus . . ." FH 0342, 0372 (emphasis added). Such a representation is binding on the applicant. Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) (prosecution history includes "all express representations made by or on behalf of the applicant to the examiner to induce a patent grant," including "amendments to the claims and arguments made to convince the examiner that the claimed invention meets the statutory requirements of novelty, utility, and nonobviousness"); Coleco Industries, Inc. v. U.S. International Trade Comm'n, 573 F.2d 1247, 1257, 65 C.C.P.A. 105 (Cust. & Pat. App. 1978).

It is a canon of construction that "a" or "an" following the phrase "consisting of" is generally read as meaning one. Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1359 (Fed. Cir. 2005) ("In particular, this court has interpreted the word "a" in its singular sense when, as in this case, it has been used in conjunction with the closed transitional phrase "consisting of.") (citing Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 334 F.3d 1274, 1281 (Fed. Cir. 2003). It is another canon of construction that "'closed' transition phrases such as 'consisting of' are understood to exclude any elements, steps, or ingredients not specified in the claim." AFG Industries, Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1245 (Fed. Cir. 2001) (citing PPG Industries v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998)).

The wording of independent claims 1, 8, 18, 24 and 26 supports the interpretation of "the" as "an." All of the independent claims refer to HPV 52 DNA that "consists of all or a fragment of an HPV DNA." (Emphasis added.).

Plaintiff argued in its pre-hearing briefs that the claims do not require HPV DNA to be only a "full length HPV genome," but it abandoned this argument at the claims construction hearing. Transcript, dkt. # 45, at 31, ln. 19, 33, lns. 19-25 - 34, lns. 1-4. This was a wise decision in light of the inventor's repeated statements to the examiner that the HPV DNA to which the patent application referred is the DNA of an entire human papillomavirus. FH 342, 372. Such a statement is not ambiguous, as plaintiff characterized it in its pre-hearing briefs, but definite and clear. Therefore, I conclude that the term "HPV DNA"

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should be construed as "a full length genome of one human papillomavirus."
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G. "HPV DNA Hybridization Probe"

As with the previous claim term, plaintiff contends that no construction is necessary. Defendant proposes "nucleic acid molecule that is specific for the DNA of any one type of HPV and differentiates the DNA of that type from DNA of all other HPV types."

The initial difficulty in understanding the parties' disagreement on this claim term is identifying the term they are discussing. The only reference to "HPV hybridization probe" is in dependent claim 19 (where the term seems clearly to encompass the "HPV 52 hybridization probe" that is the object of independent claim 18). Claim 21 talks about an "HPV hybridization probe composition." For the purpose of this order, I will assume that the hybridization probe at issue is the one of those making up the "hybridization probe composition." On that assumption, I find defendant's proposal persuasive because it is consistent with the claim language and the specification. As explained above, the hybridization probes work, separately or in composition with other probes, only if they are made up of molecules specific for a particular type of HPV.

Therefore, I will adopt the construction, "nucleic acid molecule that is specific for the DNA of any one type of HPV and differentiates the DNA of that type from DNA of all other HPV types."
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C. "HPV 52 hybridization probe" and "HPV hybridization probe"

Plaintiff objects to the constructions given these two separate terms in the July 23 order. (The first term was construed as "a nucleic acid molecule that is specific for HPV 52 DNA and differentiates HPV 52 DNA from the DNA of all other HPV types"; the second was construed as "nucleic acid molecule that is specific for the DNA of any one type of HPV and differentiates the DNA of that type from DNA of all other HPV types."). Plaintiff takes issue with the specificity and differentiation requirements the constructions impose upon the probes. However, nothing in its arguments for reconsideration convinces me that the construction was incorrect.

Plaintiff makes much of the fact that specificity for HPV 52 DNA is not necessary when a probe is used in a sample that might not reasonably be expected to include HPV 52 DNA. Apparently, in that situation, a probe that is non-specific for HPV 52 DNA would serve the purpose of determining whether any HPV is present. Such a probe, however, would not be the one claimed in claim 18; that one must be specific for HPV 52 DNA, for all the reasons set out in the July 23 order.
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B. "HPA 52 DNA"

Plaintiff's proposed construction is "DNA that consists of all or a fragment of type 52 HPV." Defendant suggests "DNA molecule derived from only type 52 HPV." The parties argued their competing constructions at some length in their briefs. At the hearing, however, they agreed that the term means a "DNA molecule that is type 52 HPV" and limited their disagreement to the word "only." As agreed upon, the parties' construction eliminates the word "derived," which plaintiff found objectionable both because it limited HPV 52 DNA to the way it is manufactured and because it appeared to be an "attempt to limit HPV 52 DNA to nucleic acids that would otherwise be expressly encompassed by the literal claim language and the functional limitations of the claims." Plt.'s Response Br., dkt. # 38, at 2.

Plaintiff's first objection to "derived" is odd in view of its own assertion to the examiner that "the claimed HPV 52 DNA must be derived from only type 52 HPV DNA." FH 0343 (emphasis added). However, its objection is mooted by the

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elimination of this word from the construed term.

Plaintiff's second objection extends beyond the word derived to the inclusion of the word "only" in the construction. Plaintiff maintains that the term HPV 52 DNA should not be construed to exclude DNA that is also found in an HPV type of a number higher than 52, so long as the HPV 52 DNA consists of a fragment of type 52 DNA. Plaintiff concedes that the term cannot be construed to include HPV types 1-51 because the applicant amended claim 6 (now claim 8) to add the phrase, "the HPV 52 DNA does not hybridize to DNA from HPV types 1 through 51 under stringent conditions." FH 0342. However, plaintiff argues that when the applicant proposed this amendment, he preserved the possibility that HPV 52 DNA could hybridize or detect HPV types yet to be identified (types 53 and higher).

To support this argument, plaintiff quotes a portion of the applicant's April 1996 amendment and response to office action. Plt.'s Response Br., dkt. # 38, at 6. In doing so, plaintiff omits an important sentence: "Since the HPV portion of clone pCD 15 is the HPV genome of the type 52 HPV discovered by applicant, and since cross-hybridization of an HPV to this type 52 HPV to greater than 50% under moderately stringent conditions identifies it, by definition, as an HPV of type 52, the claimed HPV 52 DNA must be derived from only type 52 HPV DNA." FH 0342 (emphasis added).

Before the applicant filed his April 1996 amendment, he might have had grounds for an argument that claim 6 encompassed fragments of all HPV strains known at the time of the invention (1-51) and as yet unknown HPV types, such as HPV 53, 54, etc. Once he filed the amendment, however, he gave up those grounds and the possibility of a claim encompassing fragments of HPV types of as yet unknown composition. Not only did he tell the examiner that the claimed HPV 52 DNA must be derived from only type 52 HPV DNA, but he changed the term "comprising" to "consisting of" in the relevant claims. ("wherein the HPV 52 DNA consists of all or a fragment of an HPV DNA . . ." FH 0336-40.). In doing so, he chose to narrow the claim. Promega Corp. v. Applera Corp., 2002 U.S. Dist. LEXIS 26927, 2002 WL 32355680 *7 (W.D. Wis. 2002) ("In contrast to the open transitional term "comprising," "consisting of" is a closed transitional phrase that is 'understood to exclude any elements, steps, or ingredients not specified in the claim.'") (quoting AFC Industries, Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1245 (Fed. Cir. 2001)).

The applicant's representations to the examiner are binding on him and bind plaintiff by extension. Coleco Industries, Inc., 573 F.2d at 1257; see also Southwall Technologies Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 USPQ2d 1673, 1676 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."); Spectrum International, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998) ("explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim").

In light of the facts that the independent claims all contain the language "wherein the HPV 52 DNA consists of all or a fragment of an HPV DNA" and that plaintiff argued to the examiner that "the claimed HPV 52 DNA must be derived from only type 52 HPV DNA," FH 0343, thereby disclaiming HPV 52 DNA derived from any other type, I agree with defendant that the word "only" belongs in the construed claim term to make it clear that the DNA molecule is only type 52 HPV. I conclude that the proper construction of HPV 52 DNA is "a DNA molecule that is only type 52 HPV."
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To determine the meaning of "HPV 52 DNA," we begin by considering the language of the claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The claims of the '715 patent that recite HPV 52 DNA all recite additionally three distinguishing characteristics that Digene points out are essential to the definition of its invention. See '715 patent col.16 l.13--col.18 l.65. Those distinguishing characteristics emphasize the specificity of the definition of HPV 52 DNA. Moreover, the definition of the term "HPV 52 DNA" is further limited by other claim language. As Third Wave points out, the language of claim 21 distinguishes "HPV 52 DNA" from DNA of other HPV types by reciting both "HPV 52 DNA" and "DNA or RNA of at least one other HPV type." The applicant therefore distinguished HPV 52 DNA from the DNA of other HPV types. Thus, the claim language provides support for Third Wave's position that "HPV 52 DNA" means "a DNA molecule that is only type 52 HPV."

The prosecution history further supports the limited scope of "HPV 52 DNA," and the district court permissibly found the prosecution history conclusive in this case. "[A] court should also consider the patent's prosecution history, if it is in

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evidence. . . . Like the specification, the prosecution history provides evidence of how the [Patent Office] and the inventor understood the patent." Phillips, 415 F.3d at 1317 (citations and quotation marks omitted). During prosecution, the applicant explained, with reference to a claim amendment, that "the HPV 52 DNA is defined by three characteristics." In explaining the second characteristic, the applicant stated that "[s]ince the HPV portion of clone pCD15 is the HPV genome of the type 52 HPV discovered by applicant, and since cross-hybridization of an HPV to this type 52 HPV to greater than 50% under moderately stringent conditions identifies it, by definition, as an HPV of type 52, the claimed HPV 52 DNA must be derived from only type 52 HPV DNA." Claim Construction Opinion, 2007 U.S. Dist. Lexis 53882, *17. The applicant therefore disclaimed a meaning of "HPV 52 DNA" that was derived from anything but HPV 52 DNA. See Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998) ("[E]xplicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim."); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). Digene argues that the applicant's statement, using the word "derived," simply described the origin of the DNA, not its specific structure. However, the statement, including the word "only," unequivocally limited the makeup of "HPV 52 DNA" to that specific type, not allowing it to include any other type of DNA. We therefore affirm the district court's construction of "HPV 52 DNA" as meaning "a DNA molecule that is only type 52 HPV."

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F. "HPV 52 Hybrididation Probe"

Claim 18 of the patent begins: "An HPV 52 hybridization probe comprising a member selected from the group consisting of. . . ." Defendant contends that the introduction to claim 18 should be read as a "nucleic acid molecule that is specific for HPV 52 DNA and differentiates HPV 52 DNA from DNA of all other HPV types." Plaintiff opposes this construction, arguing that the term needs no construction because the claim is drawn to HPV 52 DNA or HPV 52 RNA, "which are structurally defined by the claim itself." Plt.'s Response Br., dkt. # 38, at 19. Plaintiff contends that if the claim term is construed, it should not be read as limiting the probe to a nucleic acid molecule specific for HPV 52 DNA.

The initial inquiry is to determine whether any construction is necessary. It is if the introductory words are "additional structural limitations of the claim" rather than being merely a statement of purpose or description of intended use for the claimed structure. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). Deciding the effect to be given preamble language "can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Id.

A review of the '715 patent shows that it describes the patented invention as one that relates to nucleic acid hybridization probes "particularly for human papillomavirus type 52. The patent abstract reads "Nucleic acid hybridization probes for human papillomavirus types and particularly human papillomavirus type 52; and methods for applying the same." The Field of the Invention reads: "The present invention relates to nucleic acid hybidization probes for human papillomavirus and particularly for human papillomarvirus type 52 (hereinafter "HPV 52") and methods for employing the same." Col. 1, lns. 15-18.

The Summary of the Invention includes the sentence, "Accordingly, an object of the present invention is to provide nucleic acid hybridization probes which are specific for HPV type 52." Col. 4, lns. 30-32. In the November 1992 amendment, the applicant described the invention as including "[p]robes specific for HPV 52," which could be used for early diagnosis and treatment of papillimavirus infection. FH 0201. In a later response, filed in May 1993, the applicant made the same point about probes specific for HPV 52. FH 0249.

The statements in the patent and prosecution history are strong evidence that the applicant's purpose was the development of an HPV DNA hybridization probe that was specific for HPV 52 DNA and capable of differentiating HPV 52 DNA from the DNA of other HPV types. However, plaintiff points out additional statements in the specification, including the sentence, "Still another object of the present invention is to provide a method for detecting HPV DNA or RNA in general and HPV type 52 in particular, in an unknown sample of DNA or RNA, particularly an unknown sample of DNA or RNA derived from a genital lesion so as to determine the risk of cervical cancer development," id. at lns. 34-39. It notes that the specification describes two methods of employing hybridization probes: to test a tissue sample for the presence of HPV

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DNA or RNA in general or to test for a particular DNA or RNA or both, depending on the stringency of the hybridization conditions. Plaintiff asserts that this is support for its position that the hybridization probe that constitutes HPV 52 DNA of claim 18 need not be a nucleic acid that is specific for HPA 52 DNA and that differentiates HPV 52 DNA from DNA of all other HPV types.

Plaintiff's argument seems to be as follows: Both claims 24 and 26 recite the hybridization of the nucleic acids of an unknown sample to HPV 52 DNA that is defined identically to the nucleic acids of claim 18, yet claims 24 and 26 are describing two entirely different processes for entirely different purposes. In claim 24, the method described is detecting HPV DNA under non-stringent conditions, which would be useful with crude genital extracts, whereas in claim 26, the described method is detecting HPV 52 DNA specifically, under stringent hybridization conditions. Thus, plaintiff argues, "the specification makes clear that the hybridization probe that comprises HPV 52 DNA need not be a nucleic acid that is 1) 'specific for HPV 52 DNA' and 2) 'differentiates HPV 52 DNA from DNA of all other HPV types,' as required by [defendant's] proposed construction for the term "HPV 52 hybridization probe." Plt.'s Response Br., dkt. # 38, at 20.

Plaintiff does not explain why the use of an HPV 52 hybridization probe to detect HPV DNA in general (that is, without differentiating HPV 52 from other HPV types) makes defendant's proposed construction improper. The HPV 52 probe does not change its character when it is used for general HPV DNA detection in non-stringent conditions; it simply does not utilize the greater differentiation capability it has under moderately stringent and stringent conditions. Nevertheless, its differentiation capability and its molecular structure specific for HPV 52 DNA remain critical for detecting general HPV DNA. If this were not the case, why would the patent specification tell persons of ordinary skill that it is advantageous to use type 52 along with sequences representative of HPV types 6, 11, 16, 18, 31 and 33 when the unknown sample of DNA is derived from genital lesions and these types of HPV are most likely to be found in genital lesions? '715 pat., col. 8, lns. 38-43. It is the specificness of the molecule that makes it useful for this purpose.

I conclude that when the applicant used the term "HPV 52 DNA hybridization probe" in claim 18, he intended to claim and encompass a nucleic acid molecule that is specific for HPV 52 DNA and that differentiates HPV 52 DNA from DNA of all other types. This claim term discloses "'a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim itself.'" Poly-America, L.P. v. GSE Lining Technology, 383 F.3d 1303, 1310 (Fed. Cir. 2004 (quoting Poly-America, Inc. v. Serrot International, Inc., 2001 U.S. Dist. LEXIS 17078, 2001 WL 1335793, *2 (N.D. Tex. 2001)). Therefore, I will adopt the construction of this term proposed by defendant: "nucleic acid molecule that is specific for HPV 52 DNA and that differentiates HPV 52 DNA from DNA of all other types."
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C. "HPV 52 hybridization probe" and "HPV hybridization probe"

Plaintiff objects to the constructions given these two separate terms in the July 23 order. (The first term was construed as "a nucleic acid molecule that is specific for HPV 52 DNA and differentiates HPV 52 DNA from the DNA of all other HPV types"; the second was construed as "nucleic acid molecule that is specific for the DNA of any one type of HPV and differentiates the DNA of that type from DNA of all other HPV types."). Plaintiff takes issue with the specificity and differentiation requirements the constructions impose upon the probes. However, nothing in its arguments for reconsideration convinces me that the construction was incorrect.

Plaintiff makes much of the fact that specificity for HPV 52 DNA is not necessary when a probe is used in a sample that might not reasonably be expected to include HPV 52 DNA. Apparently, in that situation, a probe that is non-specific for HPV 52 DNA would serve the purpose of determining whether any HPV is present. Such a probe, however, would not be the one claimed in claim 18; that one must be specific for HPV 52 DNA, for all the reasons set out in the July 23 order.
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E. "HPV 52 DNA Labeled with a Detectable Label"

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According to plaintiff, this is another term that does not need construction. During the course of the claims construction hearing, however, it became evident that the parties have a dispute about the nature of the detectable label. Defendant proposed the construction: "HPV 52 DNA that incorporates an atom or different compound that gives the DNA a new detectable property." Although plaintiff opposed a construction that eliminated the possibility that the label could be DNA, it agreed that if this is not a possibility (and it is not, given the constructions I have given to other claim terms), it would accept the construction "HPV 52 DNA labeled with a detectable label that is not DNA." I will adopt this construction. It is not necessary to construe the term "detectable label." Its meaning is not in dispute now that it has been construed as not including DNA and it can be explained to the jury.

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A. "HPV 52 DNA labelled with a detectable label"

The dispute between the parties turns on the nature of the detectable label on a hybridization probe. (The point of a hybridization probe is to detect the presence of a particular molecule and bind to it; because the binding itself cannot be seen, a label is used to signal to the researcher that the binding has occurred and the molecule detected.). Plaintiff contends that a detectable label could be DNA and not necessarily HPV 52 DNA; defendant disagrees that it could be either. In support of its contention, plaintiff asserts that nothing in the patent or prosecution history says that the label cannot be DNA; the specification makes it implicit that DNA can be a detectable label because the specification refers to ligands, a term that encompasses DNA and any other molecule or atom that binds to something else; in addition, the patent explains that a probe may be labeled using radionucleotides, which are simply pieces of radioactive DNA; and persons of ordinary skill in the art would have known from articles published in 1988 or earlier that DNA could be used as a detectable label.

Defendant denies that the specification implies the use of DNA for a label; to the contrary, the specification's list of possible labels includes only those things that add a new detectable property to the DNA probe, which eliminates DNA as a candidate. It argues that construing the term to include DNA would be erroneous for a number of reasons, if only because it would read out of the claim the term "labeled," which has a meaning separate from "detectable label." Defendant takes issue with plaintiff's characterization of the pre-application articles, asserting that no person of ordinary skill in the art would have known from these articles that DNA could be used as a label for an HPV 52 DNA. Moreover, even if such persons would have understood as a general proposition that DNA could be used for this purpose in some circumstances, they would not have read the term detectable label in the '715 patent as referring to DNA.

The claim term, "HPV 52 DNA labeled with a detectable label" is used in independent claims 18, 21, 24 and 26. (Claim 18 is directed to a hybridization probe; claim 21 is directed to a hybridization probe composition and claims 24 and 26 are method claims.). Claim 18 is representative of the four claims. It reads as follows:

An HPV 52 hybridization probe comprising a member selected from the group consisting of

(i) HPV 52 DNA labelled with a detectable label, and

(ii) HPV 52 RNA labelled with a detectable label,

wherein the length of the HPV 52 DNA or HPV 52 RNA is between approximately 15 and 8000 necleotide bases,

wherein the HPV 52 DNA or HPV 52 RNA consists of all or a fragment of an HPV DNA, wherein the HPV DNA cross-hybridizes to the HPV portion of clone pCD15 to greater than 50% under moderately stringent conditions,

wherein the HPV 52 RNA consists of all or a fragment of an HPV RNA, wherein the HPV RNA cross-hybridizes to the HPV portion of clone pCD15 to greater than 50% under moderately stringent conditions,

wherein the HPV 52 DNA and HPV 52 RNA do not hybridize to DNA from HPV types 1 through 51 under stringent conditions.

Claim 18 says nothing about the form the "detectable label" may take. However, the patent specification includes the

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following information:

The polynucleotide or oligonucleotide probe may be labeled with an atom or inorganic radical, most commonly using radionucleotides, but also perhaps heavy metals. In some situations, it may also be possible to employ an antibody which will bind specifically to the probe hybridized to the single-stranded DNA. Oligonucleotide probe technology is disclosed by Szostak, J.W., et al., Meth. Enzymol. 68:419-428 (1979), incorporated by reference herein.

More commonly, a radioactive label is employed, suitable radioactive labels including <32>P, <3>H, <14>C, <35>S, <125>I, or the like. Any radioactive label may be employed which provides for an adequate signal and has sufficient half-life. Other labels include ligands, fluorescers, chemiluminescers, enzymes, antibodies, and the like.

'715 pat., col. 10, lns. 35-48.

It is unnecessary to spend any time on plaintiff's first argument, that nothing in the patent specifications says that the detectable label could not be DNA, because it is irrelevant unless plaintiff can demonstrate that persons of ordinary skill in the art would have known that DNA could be a detectable label. I suspect that plaintiff makes this argument as part of its theory that even if the use of DNA as a label was not known at the time of the filing of the application, the patent specifications are open-ended enough to encompass the use of later-discovered materials for labeling. For reasons set out hereafter, I am not persuaded that DNA could ever be a label in the context of the '715 patent.

I turn then to plaintiff's second argument, which is that persons of ordinary skill would have understood in 1988 that because the specification refers to ligands and ligand is a term that encompasses DNA and any other molecule or atom that binds to something else, a detectable label could consist of DNA. This argument rests on the flawed syllogism that a ligand is a molecule; DNA is a molecule; DNA can be a ligand; the '715 patent says that a ligand can serve as a label; therefore, the patent anticipates that DNA can serve as a ligand. It is not necessary to decide whether DNA can ever be a label; I will assume that there are circumstances in which such a use is not only possible but helpful to the researcher. It does not follow, however, that the '715 patent can be read to cover DNA as a label.

If all that is required for a "label" is a single-stranded DNA binding to another strand of DNA, then, according to the terms of the patent, the claimed DNA would always be "labeled" because HPV 52 DNA is made up of at least 15 nucleotides bound to each other. Such a reading would eliminate any independent meaning for the "labeled with a detectable label" language in the relevant patent claims. Or, to take another example of incoherence, a sequence that is not HPV 52 DNA could include a portion homologous to HPV 52 DNA. Could the non-homologous portion be characterized as the label and if so, would it come within the claim terms? And finally, if plaintiff is asserting that the patent claim could be read as suggesting the use of HPV 52 DNA as a "detectable label," how would plaintiff avoid the risk that the claim will be unpatentable because it would cover the wild form of HPV 52 DNA? (The full length of the genome could fall within the claim if "label" is construed to include DNA and part of the viral genome is called the label.). Would this make claim 18 fail because it can be read as extending to a naturally occurring organism which is inherently unpatentable?

The natural reading of the list of possible labels in the specification is that each adds a new detectable property to the DNA probe that would help probe users know when they had detected HPV 52 DNA and not another form of DNA. This conclusion derives from the nature of the materials listed in the specification, all of which add a new property to the HPV 52 DNA that assists detection. For example, fluorescers emit light; heavy metals produce a change in electron density; radioactive labels give off radioactive signals; biotins, antibodies and ligands bind specifically to other molecules; and enzymes produce catalyzing reactions. By contrast, DNA does not add a new property to the HPV 52 DNA.

Plaintiff does not accept the proposition that the potential labels listed in the specification call for adding on a new property. It maintains, for example, that radioactive labels are not "added on," but are an integral part of the DNA bases within the oligonucleotides. It is true that once the nucleotides are made radioactive and reinserted into the DNA bases they form an integral part of those bases, but it does not follow that nothing has been added to them. After all, they do not start out as radioactive. They become so after a radioactive isotope such as <32>P is attached to them. In the same way, an antibody is "added" by attachment to a probe hybridized to single-stranded DNA and heavy metals and fluorescers are "added" to the probe. None of these is part of the original probe.

It is noteworthy that in denying that the HPV 52 DNA hybridization probe could include naturally occurring HPV 52 DNA,

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plaintiff points out that such "HPV 52 is not 'labeled' in any way--nothing has been done to it to make it distinct from other, unlabeled naturally occurring HPV 52 in the sample." Plt.'s Resp. Br., dkt. # 65, at 14. (Emphasis added.) In other words, plaintiff acknowledges that labeling consists of adding a distinctive new property to existing DNA.

Plaintiff argues that the court "should bear in mind that the DNA that can be part of a detectable label may or may not be HPV 52 DNA. Only the DNA considered part of the HPV 52 DNA needs 'to consist[] of all or a fragment of an HPV 52 DNA,' while the DNA that forms a detectable label can be any DNA." Plt.'s Br. in Supp. of M. for Recons., dkt. # 57, at 7. Plaintiff adds that the detectable label is not constrained in the same way as HPV 52 DNA. Id. This is argument in the form of ipse dixit. Plaintiff does not refer to anything in the patent or prosecution history that supports such a reading of the patent; it does not explain why a person of ordinary skill would contemplate using DNA as a label for a detection probe designed to distinguish particular DNA types accurately; and it does not address the apparent conflict between the use of DNA for this purpose and the emphasis in the prosecution history on eliminating DNA fragments that could interfere with the detection process. E.g., FH 0202-03. Moreover, plaintiff leaves unexplained how an HPV 52 DNA probe would be "labeled with a detection label" if the label were DNA, that is, what would have been done to the probe to make it distinct from an unlabeled probe. If plaintiff believes that some portion of the HPV 52 DNA or of another form of DNA can act as the label, it must explain how the probe itself is labeled. It cannot read the word "labeled" out of the claim term without violating the rules of claim construction. Merck & Co. v. Teva Pharms, USA, Inc., 395 F.3d 1364, 1410 (Fed. Cir. 2004) (claim construction should not render claim terms superfluous).

With the exception of claim 1 and dependent claims 2-7, which claim a recombinant DNA of HPV 52 comprising a cloning vector and HPV 52 DNA, all of the '715 patent claims are limited to HPV 52 DNA. I conclude that reading the claims as including a different form of DNA, even as a label, would be reading in something the inventor did not intend and the patent office did not authorize.

Plaintiff turns next to extrinsic evidence offered by an expert witness to the effect that persons of ordinary skill in the art would have read the patent as covering labels consisting of DNA. Such extrinsic evidence is not a starting point for claim construction, but becomes relevant only when intrinsic sources of evidence are inadequate. Phillips v. AWH Corp., 415 F.3d 1303, 1317-18 (Fed. Cir. 2005) (en banc) (in general extrinsic evidence is less reliable than patent and prosecution history). Although plaintiff has not shown that the intrinsic evidence is inadequate, I will consider whether the extrinsic evidence would change my view of the proper construction of the disputed term.

In fact, the evidence in question is of little help. The expert does not explain what he considers the necessary level of ordinary skill in the art or what the person of ordinary skill would have known in 1988. (Plaintiff suggests that the operative time is 1997, when the patent issued, but the law does not support the suggestion. Id. at 1312-13 ("We have made clear, moreover, that the ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.").) The expert does not address the essential point, which is not whether DNA can ever be a detectable label, as a general proposition, but whether a person of ordinary skill in the art would understand from reading the '715 patent that it is claiming the use of DNA as a detectable label.

In addition to its expert's opinion, plaintiff has cited two publications that it contends described the use of DNA as a label in a probe before 1988, one of which is an article by J.E. Arrand, "Preparation of Nucleic Acid Probes," Chapter 2 of Nucleic Acid Hybridization, B.D. James and S.J. Higgins, Eds., IRL Press, Washington, D.C. 1985. The patent applicant cited the reference for its explanation of choosing a piece of DNA for use as a probe and its protocol for eliminating fragments that may cross-hybridize non-specifically with the DNA or RNA being probed, FH 0203; he did not cite it for its explanation of the use of DNA as a label. Id. The article's author describes adding DNA onto the 3' ends of DNA fragments and does not suggest that the addition of DNA to probe sequences is undesirable in and of itself. Instead, the author says that the content of the DNA sequences must be considered carefully. FH 216. Given the article's focus on radioactive labeling methods, FH 0219, it falls short of showing that persons of ordinary skill would have known that DNA could be used as a label for an HPV 52 DNA hybridization probe. To take an example, plaintiff does not explain how adding DNA to the 3' ends of DNA fragments proves that the author was describing the use of DNA as a label or was even aware of such a use. Instead, it appears that the end labeling was to be done with radioactive phosphorous isotope <32>P. FH 0222.

Plaintiff cites another article, this one by C. Vinson, et al, "In Situ Detection of Sequence-Specific DNA Binding Activity Specified by a Recombinant Bacteriophage," Gene & Bacteriology Development 2:801-06 (1988), which refers to using a

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specific DNA sequence as a ligand. Id. at 801. Although this article was published before the application for the '715 patent was filed, nothing in it suggests using DNA as a ligand for labeling purposes.

I conclude that plaintiff has failed to show that the construction I adopted for the claim term "HPV 52 DNA labeled with a detectable label" is erroneous. Therefore, its motion for reconsideration will be denied.
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3. "Human"

Hoodlums defines "human" as "[b]elonging to or having the qualities of man or mankind including but not limited to the human qualities shown in Figures 5, 8 and 9 of the '972 patent." (Doc. 37, Ex. B at 3-4.) Redtail defines "human" as "[a]n erect bipedal primate mammal with the capacity for articulate speech and abstract reasoning." (Id.) Both definitions are based on dictionary definitions.

The term "human" is only found in claim 3, in reference to "human facial features." (Doc. 44, Ex. B at 8.) In the specification, the patent notes that Figures 5, 8 and 9 show one embodiment "having a human skull shape 34." (Id. at 7.) Under Federal Circuit law, any construction should include the preferred embodiment. See On-Line Techs., Inc., 386 F.3d at 1138. Only the plaintiff's definition includes a reference to this embodiment. In addition, the defendant's definition includes a requirement that a human have the capacity for articulate speech and abstract reasoning. Infants and the disabled may lack the ability for articulate speech, but they are no less human because of it. Redtail's definition, therefore, does not capture the ordinary and customary meaning of the word "human." Instead, the court finds "belonging to, or having the qualities of, man or mankind" more accurately captures the ordinary and customary meaning of the word "human." New Webster's Dictionary and Thesaurus, 187.

Looking to the claims, the specification, Federal Circuit law, and the dictionary, the court defines human as "belonging to, or having the qualities of, man or mankind, including, but not limited to, the human qualities shown in Figures 5, 8 and 9 of the '972 patent."
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1. "Human erythropoietin" ('422 claim 1)

Amgen	Roche/Hoffmann	This Court(earlier case)
A protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine	A glycoprotein having the amino acid sequence of erythropoietin isolated from human urine having the structure that would be produced in mammalian cells as of the invention date	Did not address

The Court adopted Amgen's construction of the term "human erythropoietin." Fundamentally, the difference between the parties' constructions of this term is that Roche/Hoffmann sought to include 1) a glycosanation process and 2)a description of the structure of erythropoietin. Tr. 9:5-40:6. The Court declined to work these two limitations into the construction because such a construction would render this claim inconsistent with the other claims, the patent specification, and the prosecution history.

First, the specification itself describes human erythropoietin as a polypeptide having a certain structure. See '933 Patent

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10:9-15, 13:50-53. The specification does not define "erythropoietin" by reference to the presence or absence of any attached molecules, such as the carbohydrate that can be attached to EPO proteins for glycosylated EPO. '933 Patent 10:28-33. In fact, the specification expressly contemplates that additional molecules maybe attached to "human erythropoietin." By implication, therefore, those additional molecules are not part of the amino acid structure that comprises the claimed product. Id.

Second, this Court does not think it ought alter the open construction of the term "human erythropoietin" found in the patent. The patent itself is silent as to the presence or absence of any structural characteristic beyond the required amino acid sequence. Reading, as Roche/Hoffmann proposes, all the characteristics of "erythropoietin isolated from human urine … produced in mammalian cells as of the invention date" would unnecessarily narrow the claims.

As to this last point, at oral argument the Court expressed its concern about interpreting claims of inventions that at the time of filing were considered "seminal" or "ground braking." Tr. 17:20-19:14. Essentially, the Court was troubled by the fact that since those patents are generally broad on their face, later products or inventions would find it hard to differentiate themselves from the sweep of such general claims. Upon much reflection, however, the Court gives weight to Amgen's argument that as much as an inventor has reasons to claim broadly (to exclude as many future competitors as possible), there are also reasons to claim narrowly. By claiming narrowly, the first inventor not only avoids anticipation but also delimits the essential requirements that an accused embodiment must have in order to infringe. Tr. 26:1-20. Regardless of an inventor's assumed motivation, a district court must interpret the claims as having the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13.

Therefore, following the Federal's Circuit mandate on claim construction, the Court adopts the following construction:

Human erythropoietin: A protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine

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(1) The meaning of "Human Growth Hormone" in the '980 Patent

35. The '980 patent has the headings "BACKGROUND OF THE INVENTION," "SUMMARY OF THE INVENTION," "DETAINED DESCRIPTION OF THE INVENTION" and "CONSTRUCTION AND EXPRESSION OF A CLONING VEHICLE FOR HUMAN GROWTH HORMONE". (Def. Ex. 1). Under the heading "Background of the Invention", and its subheading "Human Growth Hormone," the '980 patent defines pit-hGH as consisting of 191 amino acids.

36. Under the heading "Detailed Description of the Invention", the inventors disclose that:

"Of course, the expression product will in every case commence with the amino acid coded for by the translation start signal (in the case of ATG, F-Methionine). One can expect this to be removed intracellularly or in any event to leave the bioactivity of the ultimate product essentially unaffected."

(Def. Ex. 1.). Thus in the '980 Patent, the inventors indicated that the met could stay onto the ultimate product.
37. Genentech's experts, Drs. Chamberlin, Falkinham and Peet all testified that the '980 patent defined hGH as either with or without "met" attached to the amino acid sequence 1-191. (Tr. 58. Chamberlin; 155, 215-220. Falkinham: 1916 Peet).

38. The Court finds that the term "human growth hormone" in Claim 2 includes "met-hGH" and "hGH".

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Claim 2 of the '980 patent, the only claim asserted to be infringed, reads as follows:

2. A method for producing human growth hormone which method comprises culturing bacterial transformants containing

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recombinant plasmids which will, in a transformant bacterium, express a gene for human growth hormone unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto, and isolating and purifying said expressed human growth hormone.

The parties dispute the meaning of the claim term "human growth hormone," which appears four times in claim 2. Genentech argues that the term encompasses either met-hGH or hGH. Novo argues that the term encompasses only hGH (191 amino acids), as found in nature, and that the production of that material is not enabled. Novo points out that the '980 specification, in the background section, states that naturally occurring "human growth hormone ('HGH') is secreted in the human pituitary. It consists of 191 amino acids . . . ." Col. 3, ll. 45-46. This is true. However, it has been long accepted that a patentee can be his own lexicographer, provided that he defines his terms. E.g., Beachcombers, Int'l, Inc. v. WildeWood Creative Prods., Inc., 31 F.3d 1154, 1158, 31 U.S.P.Q.2D (BNA) 1653, 1656 (Fed. Cir. 1994). In light of the specification, we do not consider that claim 2 is limited to a method of producing natural hGH; it defines a method for recombinantly producing, in a bacterial host, an expression product, i.e., "said expressed human growth hormone."

The specification defines the expression product produced by the process as follows:
Of course, the expression product will in every case commence with the amino acid coded for by the translation start signal (in the case of ATG, f-methionine). One can expect this to be removed intracellularly, or in any event to leave the bioactivity of the ultimate product essentially unaffected.

Col. 7, ll. 52-57. Thus, the specification teaches that the expression product will be either met-hGH or hGH, depending on whether or not the extra methionine residue is cleaved intracellularly in the bacterial host. Whether the extra methionine is in fact cleaved intracellularly is not important, according to the specification, because met-hGH and hGH were believed to be biologically equivalent.

While the specification indicates that natural hGH has 191 amino acids, the specification has made clear that, in using the term "human growth hormone," the inventors meant either met-hGH or hGH. Therefore, because "claims must be read in view of the specification, of which they are a part," Markman, 52 F.3d at 979, 34 U.S.P.Q.2D (BNA) at 1329, and the specification makes clear that what is initially expressed must have a methionine residue, but may be cleaved to hGH, we construe the claim term "human growth hormone" to encompass both met-hGH and hGH.

The parties also dispute whether claim 2 covers only the direct expression of human growth hormone or both the direct expression and cleavable fusion expression of the hormone. Novo argues that the claim only covers direct expression. Genentech contends, as it did before the district court, that claim 2 covers both the direct expression and cleavable fusion expression of human growth hormone. In support, Genentech points to the following language in the '980 specification:

Alternatively, the synthetic remainder may yield a proteolysis-resistant conjugate so engineered as to permit extra-cellular cleavage of extraneous protein, yielding the bioactive form.

. . . .

Applications will appear in which it is desirable to express not only the amino acid sequence of the intended product, but also a measure of extraneous but specifically engineered protein. . . . Extraneous conjugate designed to permit specific cleavage extracellularly may be employed to compartmentalize intended products otherwise susceptible to degradation by proteases endogenous to the microbial host.

Col. 4, ll. 11-14; col. 7, ll. 3-6 and 20-24.

It is true, as Genentech states, that the specification refers to both direct expression and cleavable fusion expression of human growth hormone. The specification teaches, for example, that the invention allows the "expression of either the intended product absent extraneous conjugated protein [i.e., by direct expression], or intended product conjugated to but specifically cleavable from extraneous protein [i.e., by cleavable fusion expression]." Col. 7, ll. 48-51. The claims, however, not the specification, measure the protected patent right to exclude others. E.g., Environmental Designs Ltd. v. Union Oil Co., 713 F.2d 693, 699, 218 U.S.P.Q. (BNA) 865, 871 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043, 79 L. Ed. 2d 173, 104 S. Ct. 709 (1984). While claims are to be interpreted in light of the specification, all that appears in the specification is not necessarily within the scope of the claims and thus entitled to protection. What is not claimed, even though disclosed as

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part of the "invention," cannot be enjoined. See infra note 8. Significantly, claim 2 unquestionably specifies the expression of "human growth hormone unaccompanied by . . . extraneous protein." The specification defines this as direct expression. In contrast, cleavable fusion expression, according to the specification, produces an expression product that includes "extraneous protein." Thus, it is apparent from the claim language, read in light of the specification, that claim 2 covers only a method of directly expressing human growth hormone and does not encompass a cleavable fusion expression process.

The prosecution history also supports this claim construction. In an October 28, 1982 Office Action, the U.S. Patent and Trademark Office ("PTO") rejected the pending claims as unpatentable over prior art showing the preparation of certain highly relevant fusion proteins. Genentech responded, in a January 14, 1983 Amendment, with the following statements: The work of the inventors . . . represents the first occasion upon which a medically significant human polypeptide was directly expressed microbially rather than in conjunction with extraneous protein. The direct expression of product was made possible by the conjoint use of synthetic DNA and cDNA derived from messenger RNA. This . . . achievement--making possible the microbial production of a human polypeptide in mature form, that is, unaccompanied by any extraneous conjugated protein--was made possible, inter alia, by the marrying of DNA of artificial and natural source.

Thus, it contrasts sharply with work conducted by previous workers, including the work reported by the cited reference of Itakura et al. which focused on the preparation of fusion proteins wherein the desired portion was covalently linked with a portion of a microbial protein which protected the desired protein from proteolytic cleavage within the microbial cell. The fusion proteins, however, require further processing in order to arrive at [the] desired protein in mature form. This is not always possible to achieve because a lytic enzyme designed to cleave the produced polypeptide at the desired locus where desired protein is linked to the extraneous protein may, in addition, cleave the molecule at other locations so as to produce a protein which is incomplete and therefore probably largely useless. In any event, the extra cleavage step represents additional processing which, from an economic point of view, is to be avoided if possible.

The present invention provides the basis for dispensing with the necessity of an additional processing step. It, for the first time, provides a convenient method for producing in a host system a protein which is in mature form, having been expressed directly by means of this invention. [Emphasis in original].

Furthermore, Genentech distinguished the prior art by arguing that the patentable invention "produced [the] desired protein unaccompanied by extraneous conjugated protein, thus for the first time achieving success in producing [the] desired protein in a direct manner." Similar assertions were made throughout the patent's lengthy prosecution. In an August 25, 1983 Response, Genentech argued that "the present application represents the first occasion upon which a medically significant human polypeptide was prepared microbially directly expressed rather than as a fusion protein." Similarly, in its September 25, 1984 Amendment, Genentech represented to the PTO that "the work of the inventors underlying the present application demonstrated the first occasion upon which a medically significant human polypeptide was directly expressed microbially rather than in conjunction with extraneous (fusion) protein." Genentech then distinguished certain highly relevant prior art references (Itakura et al.) as disclosing the proper assembly of DNA sequences so as to effect expression of a heterologous DNA insert, both as a fusion protein and directly, under control of a homologous regulon.

The disclosure in the Itakura et al. applications, therefore, teaches one skilled in the art not only how to produce a polypeptide as a fusion product, but also how to achieve direct expression of a desired polypeptide unaccompanied by an unwanted fusion protein. The work underlying the invention claimed by the present Applicants, however, represents the most facile means of achieving this result (by constructing the desired gene by combining cDNA and synthetic DNA) and represents the first instance in which the direct expression of a desired medically significant protein was clearly demonstrated.

Genentech consistently argued during prosecution that the patentable invention was a method of directly expressing human growth hormone; it never argued that the invention included cleavable fusion expression. n8 It is thus clear that claim 2 is limited to a method of directly expressing human growth hormone. The district court erred in adopting Genentech's broader reading of claim 2, which is not supported by the claim language, specification, or prosecution history of the patent.

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n8 As a practical matter, Genentech's retreat during prosecution from its reference to cleavable fusion expression is unsurprising, given the numerous PTO rejections of the claims as unpatentable over known fusion protein processes, and the

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fact that the '980 specification contains little, if any, specific disclosure of how to obtain the expression product by cleavable fusion expression. It appears that Genentech wrote a broader disclosure, but settled for patent protection for its preferred embodiment.

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Thus, properly construed, claim 2 is a process for the direct expression of met-hGH or hGH. It is undisputed, however, that Novo does not directly express met-hGH or hGH; it uses a cleavable fusion process to produce hGH. Accordingly, Novo does not express "human growth hormone unaccompanied by . . . extraneous protein," and does not literally infringe claim 2. See Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1282, 230 U.S.P.Q. (BNA) 45, 46 (Fed. Cir. 1986) (literal infringement requires that every limitation of the patent claim be met); Johnston v. IVAC Corp., 885 F.2d 1574, 12 U.S.P.Q.2D (BNA) 1382 (Fed. Cir. 1989) (same). We conclude, therefore, that the district court clearly erred in finding that Genentech established literal infringement of claim 2.
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b. Human IGF-I

The parties also dispute the construction of the term "human IGF-I." Plaintiffs contend that human IGF-I means "a polypeptide that corresponds in amino acid sequence to mature human insulin-like growth factor-I (IGF-I) naturally occurring in human blood, and optionally can include an additional amino acid at the N terminal end." Defendants construe this term to mean a polypeptide having the same amino acid sequence and disulfide bond configuration as human IGF-I isolated from human blood or serum and to exclude IGF-I fusion proteins. The Court agrees that this term excludes IGF-I fusion proteins, but it will not use the term Defendants propose. Instead, it will use the definition provided in the patent. Thus, the Court construes the term "human IGF-I" as comprising the amino acid sequence corresponding to human IGF native to human tissue; human IGF-I does not include fusion proteins. See col. 4:64-2.
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3. Bioactivity

Defendants assert that the human IGF-I, in claim 1, and the mature human IGF-I, in claim 9, require proper disulfide configuration. Plaintiffs contend that Defendants are reading additional limitations into claims 1 and 9. According to Plaintiffs, human IGF-I and mature human IGF-I are defined by their primary amino acid sequence and do not require any disulfide bond configuration.

The patent does not include the phrase "disulfide bond configuration." But it does stress bioactivity, and, according to Defendants' expert, IGF-I that does not have proper disulfide bonds formed are likely to be inactive. Defendants contend that the only utility disclosed in the '414 patent for human IGF-I is its use as a therapeutic agent, and thus bioactivity is required. In discussing the present invention, the patent states, "All such products have been found to be biologically active, hence useful as intended." '414 patent, col. 1:44-53. The goal of the invention was to produce human IGF as a product of recombinant DNA technology from a host organism: "Such materials would exhibit bioactivity admitting of their use clinically in the treatment of various growth affect conditions." Id. at col. 2:226-32. In addition to the specification, Defendants point to the prosecution history, which reinforces the bioactivity requirement.

Plaintiffs point to other parts of the specification. They note that the specification teaches that the claimed IGF proteins are "defined by means of DNA, gene and deductive sequencing," not only bioactivity. Id. at col. 5:2-5. The specification further describes the invention as "directed to the preparation of polypeptides comprising the amino acid sequence of IGF." Id. at 3:56-61. The parts of the specification Plaintiffs cite, however, do not show that there is no bioactivity requirement. And Plaintiffs fail to address the portions of the specification emphasizing the need for bioactivity. Nor do Plaintiffs adequately address the prosecution history. For example, in response to an office action, Plaintiff Genentech stated that undue experimentation would not be required "to determine whether a given IGF-I or IGF-II protein, expressed directly, secreted

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or as a fusion protein, is biologically active and thus falls within the scope of the present claims." '414 Patent Stipulated File History, Tab. 8 at 18.

The Court construes the term "human IGF-I," in claim 1, and term "mature human IGF-I," in claim 9, to refer to bioactive material.
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Human patient

The Court construes the term as "a recipient of any various personal health services." MRI argues that "human patient" means "any person to whom the formulation-in-question has been, is, and/or will be administered." BSN argues that the term means "a human under medical care and treatment."

The intrinsic record does not support either proposed construction. The Court is not persuaded by MRI's argument that a person who elects to take the formulation is a "patient" simply because he administers the formulation to himself. The patentee included "patient" in the '707 patent without providing a definition. The normal and customary meaning of "patient" is a person who receives health-related services from another. See WEBSTER'S NEW WORLD DICTIONARY 990 (3d college ed. 1991). Furthermore, the Court construes the term to give every word meaning, and MRI's interpretation renders "patient" redundant to "human." See Exxon Chem. Patents, 64 F.3d at 1557.

Similarly, the Court is not persuaded by BSN that the term requires administration under a physician's direction. There is no indication in the '707 patent that the method was contemplated for use only under a physician's care. However, the Court is persuaded by BSN to the extent that "patient" implies treatment by a qualified health service provider--e.g., physician, nurse practitioner, nutritionist, physical therapist--and therefore construes the term as "the recipient of any of various health service providers."
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Disputed claim language	Plaintiffs' construction	Defendants' construction
in a human patient in need thereof	The preamble is clear on its face, and therefore the court should decline to construe it.	in a human diabetic patient who has an above-normal blood glucose level, or is expected to suffer an increase in blood glucose level above a normal level. A "patient" is one who is suffering from any disease or behavioral disorder and is under treatment for it.

This disputed claim language also appears in the preamble. The parties agree that this phrase is limiting, but disagree that it needs to be construed. At the hearing, Defendants submitted documents from the prosecution history of United States Patent No. 6,485,760 and of the '459 divisional patent to demonstrate that Plaintiffs differentiated prior art by emphasizing that these patents envisioned use of the corosolic acid in human beings. See Declaration of Sri Sankaran Regarding Exhibits Used at Claim Construction Hearing ("Sankaran Decl.") Ex. A at 7-8 ("It is respectfully submitted that it is and would be totally improper to conclude that one skilled in the art would learn or believe from Murakami that corosolic acid would be effective in treating blood sugar imbalances in human patients much less what a suitable dosage should be for this utility.

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That is, the disclosure of Murakami is limited to the results of in vitro tests using tumor cells and rats. . . . one skilled in the art would not try to and could not predict whether the concentrate would be effective to inhibit an increase in or reduction in human blood sugar level when an undisclosed dosage amount of concentrate is orally administered to a human being.") (emphasis in original); Ex. B at 2 ("Applicants note that claims drawn to methods of treating a human diabetic patient have been allowed in the priority application. The presently filed divisional application is directed to the patentable compositions used in the allowed methods."). Defendants argue that a human patient as referenced in the patent is a diabetic patient, one whose blood sugar level is elevated or is expected to be elevated. Plaintiffs object to this proposed construction because it is too restrictive; they argue that a "patient" could be someone who desires to inhibit from rising or to lower a blood sugar level without having a diabetes diagnosis or being at risk for diabetes, for example, to slow down weight gain. Plaintiffs point to the prosecution history of the '760 patent submitted by Defendants, which at one point references a human being, not a human patient. See Sankaran Decl. Ex. A at 8.

The Court is not convinced that this phrase needs construction. Defendants point to no intrinsic or extrinsic evidence to support limiting the term "patient" to the definition proposed by Defendants. The patentee could have specified in the claims that the human patient be diabetic, but chose not to and instead made the claim more broad. The specification contains numerous references to treatment of diabetes using corosolic acid. See, e.g. '459 patent at col. 1, lines 32, 45, 61; col. 2, lines 16. However, importing Defendants' restrictive proposed construction would improperly read limitations from the specification into the claim. Moreover, a person may be a "patient" without necessarily having a particular confirmed diagnosis or being under current treatment. Defendants' proposed construction would simply invite more questions about what constitutes "under treatment" in terms of frequency of contact with and type of treatment provider.

Indeed, Defendants' proposed construction of "patient" is subsumed within the plain language of the last portion of this claim phrase, "in need thereof." If a patient has or is expected to have an above-normal blood glucose level, then that patient would be "in need thereof" of the patent invention, which purports to inhibit an increase in or lower blood sugar levels. This is evident from the context of the claims themselves and from the specification. If a person has normal blood sugar level and no reason to try to prevent an increase in blood sugar, then he or she is not "in need thereof" under the patent, and would therefore not fall within the claim language.

Finally, this phrase is not beyond the understanding of a typical juror. The Court finds no reason to import a more restrictive construction of the phrase "in a human patient in need thereof" than its ordinary meaning. Accordingly, the Court declines to construe this phrase.
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J. Human Urinary Erythropoietin

The '933 patent employs the phrase "human urinary erythropoietin" in Claims 1 and 2 and dependent Claim 9. Trial Ex. 2 at 38:21, 38:23, 39:3. Amgen contended that the term means "human EPO isolated from pooled urine of aplastic anemia patients isolated using any method used in the prior art," Pl.'s Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. Amgen's '933 Patent: The Parties Constructions (emphasis omitted), whereas TKT argued that it means "all EPO preparations that can be isolated or purified from human urine by any method," Defs.' Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. 2. The dispute, then, is essentially one of scope: Does the claim term encompass all erythropoietin preparations obtained from human urine or is it limited to only EPO obtained from the pooled urine of aplastic anemia patients?

In order to support its construction, Amgen relied on the specification and prosecution history. The specification, for instance, identifies and briefly describes the "Miyake procedure" 18 for "purifying human erythropoietin from urine of patients with aplastic anemia." Trial Ex. 1 at 7:10-17. The patent cites other prior art sources that describe the isolation of human urinary erythropoietin from the pooled urine of aplastic anemia patients. Id. at 8:13-16. The specification also reports the results relating to molecular weight comparisons of CHO-produced EPO, COS-produced EPO, and the "pooled source human urinary extract." 19 Id. at 28:33-41. Similarly, Amgen pointed to comparisons between its recombinant erythropoietin and human urinary erythropoietin purified by the Miyake procedure as evidence of novelty. Trial Ex. 2 Tab 6 at 11.

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18 The Miyake procedure is a particular method for purifying urinary EPO.19 CHO, or Chinese hamster ovary, cells are, as their name suggests, derived from hamsters. COS cells are, in contrast, derived from monkeys.

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Though Amgen's construction may be supported by these aspects of the specification and prosecution history, Amgen's narrow interpretation of this claim limitation is not faithful to the plain and ordinary meaning of the claim language. The claim terms themselves do not specify which type of human urinary erythropoietin is contemplated. Instead, the plain and ordinary meaning of the phrase "human urinary erythropoietin" broadly encompasses all urinary EPOs. As a result, "on this one, in all candor, the shoe is on the other foot . . . ." Tr. of Markman Hr'g, Vol. III at 106:11-12. Thus, adhering to the plain meaning of the terms, the Court concluded that "human urinary erythropoietin" means "erythropoietin derived from human urine." Id. at 112:23-24.
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D. The Term "Hybrid DNA Molecule"

In the '765 patent claims, the term "hybrid DNA molecule" (sometimes referred to as a "hybrid plasmid" in the specification and in claims 3 and 4) is defined as being produced by combining a chromosome DNA fragment with a plasmid DNA molecule. ADM argues that the term "hybrid DNA molecule" should be interpreted to mean molecules that are made by both "in vivo" and "in vitro" methods. n11 (D.I. 240 at 11) Ajinomoto has argued that only hybrid DNA molecules made in vitro can be considered to fall within the scope of the claims of the '765 patent. (D.I. 191 at 15) ADM claims that the '765 patent specification makes references to both in vivo and in vitro preparation of hybrid molecules. (D.I. 240 at 12)

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n11 "In vitro" refers to events that occur in a test tube, while "in vivo" refers to events that occur in a cell or organism. (D.I. 240, Ex. C at 974)

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The court notes, however, that the reference to in vivo preparation of hybrid molecules in the '765 patent specification appears in a discussion of another patent:

Certain practical aspects of applying of [sic] genetic engineering methods are revealed in the method for preparing the strains Pseudomonas involving degradation of complex organic compounds (petroleum hydrocarbons) (cf. U.S. Pat. No. 3,923,603) This patent teaches in vivo preparation of hybrid molecules by way of intracellular recombination.

However, methods of preparing strains producing aminoacids [sic] with the use of genetic engineering techniques are hitherto unknown.

(D.I. 240, Ex. A, col. 2, lines 59-68) Given this limited reference to in vivo methods, the court concludes that the term "hybrid DNA molecule" refers only to molecules prepared in vitro.
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With regard to the '824 and '767 patents, the term "hybridization" has a definite meaning. The district court correctly understood the term to mean "the binding of two separate, complementary strands of nucleic acids to form nucleic acid hybrids." 2006 U.S. Dist. LEXIS 74570, [WL] at *1 n.1. The ambiguity, in the district court's view, was that a person of ordinary skill would not understand whether a linkage group interferes with hybridization "substantially."
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3. "under hybridisation conditions"

a. The Parties' Proposed Constructions

OGT proposes that I construe "under hybridisation conditions to mean "under conditions suitable for hybridization." (D.I. 174 at 21; D.I. 173 at 4.) Mergen proposes that I construe "under hybridisation conditions" to mean "conditions that permit discrimination between hybridization of oligonucleotide sequences that are exactly matched and mismatched to the polynucleotide sequence." (D.I. 175 at 23; D.I. 173 at 4.)

b. The Court's Construction

OGT argues that this claim term should be construed according to its plain and ordinary meaning. (D.I. 174 at 21.) Mergen encourages me to read in limitations from the specification. (D.I. 175 at 23-24.) I will not read in limitations from the specification when the term is easily construed according to its ordinary meaning as understood by a person of ordinary skill in the art. See Texas Digital Sys., Inc., 308 F.3d at 1205. I conclude that one of ordinary skill in the art would understand that the phrase "under hybridisation conditions" means "under conditions suitable for hybridization." Therefore, I construe the phrase "under hybridisation conditions" to mean "under conditions suitable for hybridization."
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1. "hybridizes, under stringent conditions"

Plaintiffs state that the parties largely agree to the construction of this term. Defendants contend that it means "single strands of DNA from two sources form a stable double-stranded structure that remains intact during manipulation in the following conditions: Hybridizing in 50% formamide at 5XSSC at a temperature of 42 [degrees] C. and washing the filters in 0.2XSSC at 60 [degrees] C. These conditions are intended to exclude sequences that hybridize to the BP28 sequence." According to Plaintiffs, the difference between the parties' constructions is Defendants' attempt to add the sentence on intent.

Plaintiffs argue that the intent sentence is from the specification and should not be imported to the definition of this term. Defendants contend that the intent sentence is an affirmative limitation that Plaintiff Genentech added to claim 1 during prosecution to overcome an enablement rejection. They note that the Examiner initially rejected claim 1 for lack of enablement because the specification did "not enable all DNAs which would hybridize to the DNA of Fig. 3 under stringent conditions." '287 Patent Stipulated File History, Tab 12 at 3. But Defendants include only a portion of the Examiner's sentence. The sentence in full reads: "The specification does not enable all DNAs which would hybridize to the DNA of Fig. 3 under stringent conditions wherein the sequence is at least 10 nucleotides in length as set forth in claim 1." Id. According to Plaintiffs, Plaintiff Genentech overcame this rejection by replacing the minimum length limitation with a limitation that the DNA molecules must encode a protein with

The Court construes the term "hybridizes, under stringent conditions" to mean that single strands of DNA from two sources form a stable double-stranded structure that remains intact during manipulation in the following conditions: Hybridizing in 50% formamide at SXSSC at a temperature of 420 C. and washing the filters in 0.2XSSC at 60 [degrees] C.
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c. "probes hybridizing to at least one domain"

Defendant contends that claims 6 and 7 require specific hybridization, meaning completely homologous base-pairing with no mismatches. ("Homologous" means "exhibiting biological homology; "homology" means "similarity of nucleotide or

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amino acid sequence." Merriam-Webster OnLine, http://m-w.com/dictionary/homology). Thus, defendant argues, a probe that hybridized to less than an entire domain would not be covered by the claim. Defendant notes that other claims of the '704 patent use more flexible language. For example, in claim 3, the method allows the target domain to comprise "at least 5 contiguous nucleotides" in a list of longer domains. Therefore, defendant argues, the absence of similar language in claims 6 and 7 supports a construction requiring the hybridization of complete domains. At the least, it maintains, the term is susceptible to two distinct meanings (either homologous base-pairing with some mismatches or completely homologous base-pairing with no mismatches) and would leave a person of ordinary skill in the art confused about the meaning of the term.

In response, plaintiff argues that the claim term "specifically," refers to hybridization to sequences of a specific type or subtype of HCV and not to other types or subtypes of HCV, as shown in Examples 10 and 11 of the patent specifications. These examples describe the genotype-specific regions a researcher could expect to find in variable regions of the 5' UTR and ways in which to obtain type-specific hybridization.

In its supplemental proposed finding of fact, defendant cites the testimony of one of the inventors of the '704 patent, Lieven J. Stuyver, to the effect that specific hybridization as used in the patented method "requires perfect matching between the nucleotides of a probe and the nucleotides of the HCV pairing such that there is completely homologous probe/target base pairing, with no mismatches." Stuyver's testimony suggests that perfect matching of the nucleotides must occur in all circumstances; if this is his reading, it contradicts the patent specifications. In Example 11, for example, the patent specifies that in certain hybridization conditions

it may also be preferable to elongate or shorten the contiguous HCV sequence and/or to reverse the sense of the probes to allow genotype-specific hybridization at a certain preferred temperature or salt concentration. However, in some cases, it may be preferable to include inosines or mismatching nucleotides to allow genotype-specific hybridization at a certain preferred temperature or salt concentration.

Col. 35, Ins. 32-34-col. 36, Ins. 1-4. The patent specifications are intrinsic evidence of the meaning of the patent language; in the evidentiary hierarchy, they take precedence over extrinsic evidence such as the opinions of outside experts. Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005) ("while extrinsic evidence 'can shed useful light on the relevant art,' we have explained that it is 'less significant than the intrinsic record in determining "the legally operative meaning of claim language"'")(quoting C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004)(quoting in turn Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Moreover, Stuyver does not fall into the category of an expert; he is an inventor discussing his subjective intent in using a particular term. The Court of Appeals for the Federal Circuit considers inventor testimony of little value when construing claim language. E-Pass Techs., Inc. v. 3COM Corp., 343 F.3d 1364, 1370 n.5 (Fed. Cir. 2003)("inventor testimony is of little probative value for purposes of claim construction"); Markman v. Westview Instruments, Inc., 52 F.3d 967, 985 (Fed. Cir. 1995).

Read in light of the specifications and claims, plaintiff's proposed construction is more convincing than defendant's. In order to produce the desired information, hybridization must be specific to the nucleotides that are unique for each genotype or subtype at given positions in the probe. Therefore, I will construe hybridization to mean "hybridizing a probe to a target sequence and not to a non-target sequence."

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14. "Hydroacrylic monomer units"

The plaintiff contends that this phrase should have the same meaning as "hydroxy acrylic monomer units." The defendants propose "a monomer unit having an acrylic moiety and a hydrophilic moiety." The plaintiff argues that this was a term resulted from a typographical error and that one of ordinary skill in the art would understand the phrase as "hydroxy acrylic monomer units." The defendants argue that this term can be understood as being broader than the hydroxy acrylic monomer units because it does not require a hydroxy group. According to the defendants, any error should not be corrected by the court.

The Court agrees with the plaintiff. Reading the term in the context of the patent, one of ordinary skill in the art would

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understand the term to mean "hydroxy acrylic monomer units." Accordingly, this term has the same construction as "hydroxy acrylic monomer units."
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The invention claimed by the patent involves hydrogen sulfide contamination. Hydrogen sulfide is a toxic gas found naturally in crude oil, derivative products such as petroleum residua and fuel oils, and waste water associated with crude oil production. See '991 patent, col. 1, l. 19 to col. 2, l. 2. Hydrogen sulfide vapors are slowly emitted from these liquids at all stages of production, transport, and storage. If uncontrolled, they pose a serious health problem. See id. The claims at issue are directed to processes and compositions for controlling these emissions. Claims 1-9 are process claims. Independent claim 1, from which claims 2-9 depend, reads in pertinent part as follows:

1. A process of inhibiting the liberation of hydrogen sulfide gas from a material comprising water or a hydrocarbon containing dissolved hydrogen sulfide comprising adding to said material a sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas evolution. . . .

Id. at col. 7, ll. 7-12.

Claims 17-25 and 35 are related composition claims. Independent claim 17, from which claims 18-25 and 35 depend, reads in pertinent part as follows:

17. A composition comprising

a. a material comprising water or a hydrocarbon, and

b. a sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas liberation. . . .

Id. at col. 8, ll. 34-38.

Claims 42-45, which were added during the reexamination proceeding, are also composition claims. Claim 42, from which claims 43-45 depend, reads in pertinent part as follows:

42. A composition comprising:

a. a liquid hydrocarbon material, and

b. a sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas liberation. . . .

Feb. 8, 1995 Response to Office Action at 2-3 (adding claims 42-45).

The two references upon which the Board relied in rejecting the claims at issue were the Doerges reference and U.S. Patent 4,244,703 (Kaspaul). The parties do not dispute what these references teach one of ordinary skill in the art.

The Doerges reference teaches a process for removing hydrogen sulfide and other acid gases from natural gas (a gaseous hydrocarbon) by "scrubbing" the natural gas with an absorbent liquid containing an organic solvent and an organic base such as a diaminomethane. See Doerges, col. 1, ll. 49 to col. 2, l. 28. Specifically, the absorbent liquid is circulated through a vertical column from the top to the bottom. See id. at col. 4, ll. 35-41. The natural gas is then pumped into the bottom of the column. See id. As the natural gas vapors rise to the top of the column, the hydrogen sulfide is absorbed by the absorbent liquid. See id. The natural gas then exits the top of the column with less hydrogen sulfide in it. See id.

The second reference, Kaspaul, teaches adding a diaminomethane compound to hydrocarbon fuels to improve fuel economy. See Kaspaul, col. 2, ll. 50-60. It does not teach inhibiting the liberation of hydrogen sulfide from a hydrocarbon. It does not refer to hydrogen sulfide at all.

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The Board held that process claims 1-9 and composition claims 17-25 would have been obvious over the Doerges reference. The Board held that the broadest reasonable interpretation of the term "hydrocarbon" included both gases and liquids in light of references in the written description to both gaseous and liquid hydrocarbons. See Petrolite, slip op. at 15, 21-27. The Board also held that the process of claim 1 would have been obvious over the Doerges reference because the amount of diaminomethane in the absorbent liquid in the column was sufficient to inhibit the evolution of hydrogen sulfide. See id. at 19. With regard to composition claim 17, the Board found that the process disclosed in the Doerges reference resulted in "a mixture containing a hydrocarbon gas, methanol, and a particular amount of the claimed diaminomethane compound . . . The Doerges reference describes the composition recited in claim 17." Id. at 32. The Board held that "the complete description of the claimed composition is the ultimate of obviousness." Id. The Board concluded that dependent claims 2-8 and 18-25 would have been obvious for the same reason.

The Board also concluded that composition claims 17-25, 35, and 42-45 would have been obvious over the Kaspaul reference. The Board construed independent claims 17 and 42 as not requiring the presence of hydrogen sulfide in the compositions. See id. at 37. The Board concluded that the compositions of claims 17 and 42 would have been obvious over the Kaspaul reference because the amount of diaminomethane described in that reference would effectively inhibit the evolution of hydrogen sulfide. See id. at 36-37. The Board concluded that dependent claims 18-25, 35, and 43-45 would have been obvious for the same reason.

Baker Hughes timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994).

DISCUSSION

* * *

Turning to the merits of the Board's decision, we agree with Baker Hughes that the Board erred in construing the term "hydrocarbon" as used in the claims to include gases. As the plain language of claims 1, 17, and 42 indicates, the claims are directed to inhibiting the "evolution" or "liberation" of hydrogen sulfide from either an aqueous or hydrocarbon material. The written description uses the terms "evolve" and "liberate" several times and, in each instance, the terms are used to describe the emission of hydrogen sulfide from a liquid hydrocarbon, particularly petroleum residua. See, e.g., '991 patent, col. 1, ll. 57-58. For example, in the Background of the Invention, the written description states:

The presence of the sulfur compounds in the residua gives rise to the generation of a gas having substantial portions of hydrogen sulfide gas. . . . During storage or [] transport [of residua], hydrogen sulfide gases become liberated. . . . Providing an effective chemical method for suppressing or inhibiting the liberation of hydrogen sulfide gases from residua are of considerable importance. Methods heretofore known for suppressing the liberation of hydrogen sulfide gases from residua suffer from the standpoint of effectiveness.

Id. at col. 1, l. 66 to col. 2, l. 17 (emphasis added). Similarly, in the Detailed Description of the Invention, the written description states that "the incorporation of the additive to suppress the evolution of hydrogen sulfide gases should be made before the residua are stored or transported." Id. at col. 3, ll. 62-65 (emphasis added). Although the Director points to various parts of the written description that describe hydrocarbons as gases and liquids, nowhere does the written description use the terms "evolution" or "liberation" to describe the separation of hydrogen sulfide from a gaseous hydrocarbon material. Moreover, the written description's use of the terms "evolution" and "liberation" to describe the emission of a hydrogen sulfide from a liquid hydrocarbon is consistent with the terms' common chemical definitions. See Webster's II New Riverside University Dictionary 690 (1988) ("liberate: to release from combination, as a gas"); id. at 449 ("evolve: to give off: emit"). Lastly, nowhere in the written description is there an example of the claimed process being used with a gaseous hydrocarbon. None of the embodiments of the invention described in the written description relate to gaseous hydrocarbons. We therefore conclude that the Board adopted a construction of the claim beyond that which was reasonable in light of the totality of the written description, and therefore erred in construing the claims to include gaseous hydrocarbons.

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E. Hydrocarbon fuel.

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Next, the court turns to the definition of "hydrocarbon fuel." The term "hydrocarbon fuel" appears only in the preamble of asserted claim 1. Nonetheless, the term is used consistently with the term "hydrocarbon-containing fuel" found elsewhere in the patent. See 082 patent, claim 29. Although the court has previously held that the preamble of claim 1 is not a limitation, the court will construe the terms "hydrocarbon fuel" and "hydrocarbon-containing fuel" consistently to provide guidance.

The plaintiff contends that the term means "a material that contains hydrocarbon and is capable of releasing energy or power by combustion." The defendant contends that the term means "a composition, such as gasoline or diesel fuel, capable of releasing energy or power by combustion or other chemical or physical reaction that is composed of organic compounds that contain only carbon and hydrogen and is not just one or more components of such composition that can be separated by further processing." The court has considered the arguments of the parties and is persuaded that the plaintiff's definition is correct. The defendant's proposed definition of this simple claim term is wrought with non-infringement arguments that are not properly the subject of claim construction. The court defines "hydrocarbon fuel" and "hydrocarbon-containing fuel" to mean "a material that contains hydrocarbon and is capable of releasing energy or power by combustion."
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1. "Ion bombardment . . . the ions being hydrogen ions" or "hydrogen ion bombardment" ('484 patent) means that hydrogen ions alone are implanted, i.e., the mono-implantation of hydrogen. Processes in which other gas ions are also introduced (before, after, or with hydrogen) do not satisfy this limitation. (JA-2370; Soitec, S.A. v. Silicon Genesis Corp., 81 Fed. Appx. 734, 738-39 (Fed. Cir. 2003) (unpublished))

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1 The parties have identified many disputed terms. The court has construed the terms most essential in view of the parties' infringement positions and positions regarding the validity of the patents in suit.

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3. "Implanting hydrogen ions" ('009 patent) means that hydrogen ions alone are implanted, i.e., the mono-implantation of hydrogen. Processes in which other gas ions are also introduced (before, after, or with hydrogen) do not satisfy this limitation. (MA-0934; MA-0937; Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Ltd., 535 U.S. 722, 736-37, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002))
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(2) "Hydrogenated Vegetable Oil"

241. Teva's proposed construction for "hydrogenated vegetable oil" is: "refined, bleached, hydrogenated, and deodorized vegetable oil stearins consisting mainly of the triglycerides of stearic and palmitic acids." (supra P 101).

242. Teva based its proposed construction for "hydrogenated vegetable oil" on the definition used in the USP/NF. Teva established that the USP/NF was a technical reference widely used by pharmaceutical formulators, and that USP/NF definition served as a baseline for formulators when discussing excipients.

243. Bristol's proposed construction for "hydrogenated vegetable oil" is: (1) a mixture (2) of mono-/di- and triglycerides (3) derived or isolated from plant sources (4) whose fatty acid moieties are partially or completely hydrogenated and (5) whose fatty acid carbon chain lengths range from 12 to 22. (supra P 103).

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244. Bristol based its proposed construction for "hydrogenated vegetable oil" by using a general chemical dictionary and a non-scientific dictionary for definitions of the terms "hydrogenated" and "vegetable oil" and then synthesizing those definitions. (See supra P 104). Bristol did not establish that a person of ordinary skill would look to these references to define excipients used in formulations. (See supra P 107).

245. Teva established that a pharmaceutical formulator would look to the USP/NF monographs for the plain and ordinary definition of excipients. The testimony of the '344 patent inventors at their depositions, where they applied the USP/NF definition of "hydrogenated vegetable oil" is highly persuasive evidence that the ordinary meaning of the term for pharmaceutical formulators as of July 10, 1989 was "refined, bleached, hydrogenated, and deodorized vegetable oil stearins consisting mainly of the triglycerides of stearic and palmitic acids."

246. Bristol's efforts to dismiss the USP/NF as simply "regulatory" are unconvincing. FDA approval is an essential part of the manufacture of pharmaceutical products and therefore that approval is an inherent part of the process of formulation. To the extent that Bristol raised any issue with excipient definitions based on the USP/NF, it is with imposing the details of specifications onto the claimed excipient, not utilizing the description of the compound, as Teva's proposed construction does.

247. Bristol provided no evidence, except the unsupported opinion of its expert, Dr. Klibanov, to suggest that a pharmaceutical formulator would instead look to a general chemical or non-scientific dictionary in defining excipients.

248. The Court therefore construes the term "hydrogenated vegetable oil" in Claim 1 as: "refined, bleached, hydrogenated, and deodorized vegetable oil stearins consisting mainly of the triglycerides of stearic and palmitic acids."
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3. Hydrophilic Gel System

Claim 12 provides: "A preparation according to claim 1 wherein the release is controlled by a hydrophilic gel system." (Emphasis added). The term hydrophilic gel system is also incorporated into dependent claims 14 and 15.

Mutual contends that the term is not well understood by the claim language alone and points to the specification in support of its argument that a hydrophilic gel system should be construed as one of a number of pharmaceutically-acceptable compositions which include one or more water-soluble polymers that form a gelatinous layer around a tablet into which they are incorporated after exposure of the tablet to an aqueous environment, e.g., hydroxypropyl methylcellulose (HPMC). Mutual cites to the following portion of the specification:

According to the invention the solubilized drug is preferably combined with a hydrophilic gel system, namely a hydrophilic swelling matrix e.g. HPMC. This form of controlled release mechanism is a suitable way to control the release of the micelles of drug and solubilizer. . . . Among the different hydrophilic materials tested, HPMC, hydroxypropyl methylcellulose, is the best gel-forming material.

(Col. 3, lns. 53-58, 60-62) (emphasis added).

Astra argues that this term is commonly used in the industry to mean a delivery system of a water soluble gel- and matrix-forming material. Astra points to the manufacturer's brochure for methocel, the commercially available brand of HPMC, in which the manufacturer explains that: "This handbook describes how to select and use METHOCEL products for controlled release of the drugs in hydrophilic matrix systems." (Pl.'s Ex. 26 at 3) (emphasis added). Astra also points out that Mutual's proposed invention uses HPMC, which is described in Mutual's Product Development Report as "the matrix forming agent." (Pl.'s Ex. 14 at M036589). Astra notes that the '081 patent specification, as quoted above, identifies HPMC as the preferred embodiment of hydrophilic gel systems. (Col. 3, lns. 53-58, 60-62) (see also Col. 2, lns. 44-53) (explaining how the hydrophilic gel systems work).

This Court concludes that those skilled in the art would recognize the term hydrophilic gel systems as recited in the '081 claims to mean a delivery system of a water soluble gel- and matrix-forming material and that Mutual has not directed this

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Court to any portion of the intrinsic record which indicates that this ordinary meaning should be varied.
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C. "hydrophilic polymer"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

An immediate-release fenofibrate composition comprising:

(a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 [mu]m, a hydrophilic polymer and a surfactant; and

(b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "hydrophilic polymer" to mean "any high molecular weight compound of repeating molecular units having an affinity towards water." (D.I. 238 at 5, C.A. 02-1512-KAJ; D.I. 167 at 4, C.A. 03-120-KAJ.) Abbott asserts that its proposed construction is consistent with the ordinary and customary meaning of the term. (D.I. 237 at 8, C.A. 02-1512-KAJ.) Teva and Impax each propose that I construe "hydrophilic polymer" to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." (D.I. 238 at 5, C.A. 02-1512-KAJ; D.I. 167 at 4, C.A. 03-120-KAJ.) Teva and Impax allege that the patentees acted as their own lexicographers because the specification clearly defines this term when it states, "the expression 'hydrophilic polymer' in the invention should be taken to mean any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." ('670 patent, col. 4 ll. 14-17; see D.I. 238 at 5, C.A. 02-1512-KAJ; D.I. 268 at 11, C.A. 02-1512-KAJ; D.I. 167 at 4, C.A. 03-120-KAJ.)

Abbott asserts that the construction proposed by Teva and Impax rests on a selective reading of the specification and is at odds with a passage in the specification which states "depending on polymer solubility, [the hydrophilic polymer] either dissolves in the solution or forms a gel or a suspension having varying degrees of thickness." (D.I. 270 at 13, C.A. 02-1512-KAJ; '670 patent, col. 6 ll. 25-27 (emphasis added).) Abbott argues that the definition provided in the specification is inconsistent with the usage of the term in the passage just quoted, because the definition requires that the hydrophilic polymer both dissolve in water and form a gel. (D.I. 270 at 12-13, C.A. 02-1512-KAJ.) Because of this alleged inconsistency, Abbott argues that the term should be construed according to its ordinary meaning. (Id.)

Teva and Impax assert that Abbott's alleged inconsistency is not an actual inconsistency at all. They argue that the sentence quoted by Abbott is consistent with the specification's definition of "hydrophilic polymer" because it states that the hydrophilic polymer can either dissolve or form a gel or a suspension "in the solution," which is a suspension of the active ingredient in a solvent, where the solvent can be aqueous or organic. (D.I. 268 at 10-11, C.A. 02-1512-KAJ; D.I. 205 at 10, C.A. 03-120-KAJ.) Thus, Teva and Impax argue that because PVP, the identified hydrophilic polymer, is known to be soluble in water, but insoluble in many organic solvents, such as hydrocarbons or mineral oil, the term "hydrophilic polymer" is used consistently throughout the specification. (Id.) Therefore, they assert that "hydrophilic polymer" should be construed as explicitly defined in the specification and Abbott's proposed construction should be rejected. (Id.)

2. The Court's Construction

For the same reasons expressed supra Part IV.A.2., I find that the patentees acted as their own lexicographers and specifically defined "hydrophilic polymer" in the specification to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." Furthermore, because I find

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that the specification uses this term consistently, I agree with Teva and Impax that the presumption, stating that a term should be construed according to its ordinary meaning, is overcome.

First, the specification clearly and explicitly defines the term "hydrophilic polymer," when it states "the expression 'hydrophilic polymer' in the invention should be taken to mean... ." ('670 patent, col. 4 ll. 14-15.) Second, the portion of the specification identified by Abbott, discussing polymer solubility, does not establish an inconsistency with regard to how the patentees used this term in the patent. This paragraph states in its entirety:

The significant starting product is the suspension of the active ingredient. This suspension is prepared by putting the micronized active ingredient into suspension in a solution comprising the hydrophilic polymer and, optionally, a surfactant, in solution in a solvent. If a surfactant is employed, it is put into solution in the solvent (beaker+magnetic or vane stirrer). Next, the hydrophilic polymer (PVP) is dispersed, while stirring, in the solution previously obtained. Depending on polymer solubility, this either dissolves in the solution or forms a get or a suspension having varying degrees of thickness. While still stirring, the micronized active ingredient is dispersed in the form of a fine shower into the above solution or suspension, to form a homogenous suspension. The order of these steps can be reversed. The solvent employed can be aqueous or organic (for example ethanol). For example demineralized water can be used.

('670 patent, col. 6, ll. 16-32 (emphasis added).)

As noted by Abbott, this portion of the specification states that the hydrophilic polymer "either dissolves in the solution or forms a gel or a suspension," but does not both dissolve and form a gel, as the portion of the specification defining the term requires. Counsel for Abbott, however, was unable to articulate for the court why the statement "the solvent employed can be aqueous or organic" does not relieve any perceived inconsistency in the use of the term hydrophilic polymer. (See D.I. 297 at 60:24-72:3, transcript of Markman hearing, Feb. 28, 2005.)

It is quite clear that when the polymer either dissolves or forms a gel or suspension, it is doing so in "the solution." "The solution" thus referred to is the suspension, which consists of the micronized active ingredient, the hydrophilic polymer, optionally a surfactant, and a solvent. Thus, the suspension contains a solvent. Further, the penultimate sentence in the paragraph makes clear that the solvent can be aqueous or organic. As noted by Teva, PVP, the hydrophilic polymer discussed in the quoted paragraph, "is known to be soluble in water but insoluble in many organic solvents." (D.I. 268 at 10, C.A. 02-1512-KAJ.) Thus, I agree with Teva and Impax, that if the suspension contained an aqueous solvent, the polymer would be affected differently than if the suspension contained an organic solvent. Such a difference would explain why this portion of the specification states that the hydrophilic polymer "either dissolves in the solution or forms a gel or a suspension," rather than stating that the hydrophilic polymer dissolves and forms a gel, as its definition requires it to do in water. Thus, the specification does not use the term "hydrophilic polymer" in a manner inconsistent with the explicit definition provided by the patentees acting as their own lexicographers, and, therefore, I construe it to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel."

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5."Hydrophobe Precursor"

Claim 16 of the '693 patent also refers to a "hydrophobe precursor." That claim states in part, "said pellicle having been formed by application of an aqueous mixture of a hydrophobe precursor to the surface of a sheet of absorbent material." (Emphasis added.) Fort James suggests that this term has plain meaning to a POSITA and requires no interpretation. 54 Coating Excellence suggests that the term should be construed to mean "any organic material combining a site reactive toward starch or cellulose with a long hydrophobic tail and having a surface energy of less than 35 dynes/cm when applied to fibers on the surface of the inner absorbent layer." 55

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54 Plaintiffs' Final Proposed Claim Constructions [Dkt. No. 175] at p. 3.55 Defendants' Amended Claim Construction Statement [Dkt. No. 176] at Ex. A, pp. 7-8.

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The specification for the '693 patent, in a number of locations, describes the use of a hydrophobe precursor to form the foraminous hydrophobic water-vapor-permeable pellicle. (E.g., '693 patent, col. 2, lines 7-9; col. 4, lines 60-65.) The specification describes "the most convenient method of forming" the pellicle. (Id., col. 7, lines 28-47.) The specification explains that "typically" there will be a surface energy of less than 35 dynes/cm. (Id., col. 7, lines 47-50.) The specification then goes on to describe broadly what a hydrophobe precursor "may be": "Broadly speaking, a hydrophobe precursor may be any organic material combining a site reactive toward starch or cellulose with a long hydrophobic tail such as, for example, a C14-C18 carbon chain length." ('693 patent, col. 8, lines 1-4.) The inventors further identify specific types of chemicals that should be considered "a hydrophobe precursor" and set forth a typical structure for a "hydrophobe precursor." ('693 patent, col. 8, lines 4-52.) 56

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56 Neither party identified any file history material pertinent to this construction.

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In short, while certain aspects of Coating Excellence's construction are mentioned as embodiments of the invention, the undersigned finds that the specification does not limit the term "hydrophobe precursor" to such embodiments.

The relationship between the hydrophobe precursor and the resulting pellicle is plain from the language of claim 16. It is, therefore, a close call whether any construction is necessary. However, to avoid any confusion by a juror regarding what a precursor is, the undersigned recommends the following construction: "A precursor is a material from which another material can be formed. A hydrophobe precursor may be, but is not limited to, any organic material combining a site reactive toward starch or cellulose with a long hydrophobic tail, as well as the specific hydrophobic precursors identified in the specification of the '693 patent and materials having the structure of the hydrophobe precursors disclosed in the specification of the '693 patent." 57

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57 Fort James submitted a dictionary definition of precursor that is consistent with the above. Plaintiffs' Response to Defendants' Amended Claim Construction Statement [Dkt. No. 178]. The above construction, however, was adduced from the statements in the specification and no consideration of extrinsic evidence is necessary.

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A. The Meaning Of The Disputed Term "Hydrosol"

Novartis contends that the term "hydrosol" should be construed to mean "solid particles, varying in size from 1 nanometer to 10,000 nanometers (10 microns) in diameter, dispersed in an aqueous (i.e., water-containing) medium" (D.I. 298 at 2, 6). Novartis contends that this definition is consistent with what one of ordinary skill in the art would construe the term "hydrosol" to mean, namely solid particles dispersed in any aqueous medium (i.e. a water-containing environment), which could include the stomach of a patient. (D.I. 298 at 6). Novartis also contends that this definition is supported by the '382 Patent specification, which requires that the solid particles range in size from 1 nanometer to 10,000 nanometers. (D.I. 298 at 6).

Eon contends that the term "hydrosol" should be construed to mean "a synthetic pharmaceutical preparation, i.e., it does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient; a formulation in which all the solid particles are smaller than 7 microns in diameter, and in any event smaller than about 10 microns in diameter; all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize." (D.I. 302 at 4). According to Eon, this definition is supported by the specification and prosecution history, which limit all solid particles to about seven microns in diameter, and confirm that the '382 Patent only contemplates synthetically stabilized hydrosols formed outside of the body. (D.I. 302 at 13, 15, 16).

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In construing the term "hydrosol," the Court has considered the claim language, specification, and prosecution history of the '382 Patent. (See D.I. 303, '382 Patent, col. 9, lns. 21-29, col. 1, lns. 21-23, 48-51, D.I. 303 at A59, A66). The specification of the '382 Patent indicates that the hydrosol contemplated in Claim 1 is in "intravenously" acceptable and "injectable" form. The specification does not support an interpretation regarding hydrosols formed naturally upon ingestion. (See, D.I. 303 at A3, '382 Patent, col. 1, lns. 21-23; at A5, col. 5, lns. 62-65). Moreover, in the applicants' Amendment dated March 17, 1989, they describe how the invention is prepared and administered:
. . . a solution of a difficulty [sic] water soluble drug compound in an organic solvent miscible with water is poured out into water[,] thus forming finely divided solid drug compound particles in amorphous colloid form . . .;

The removal of organic solvent from the colloidal aqueous dispersion is not detrimental, as the stabilization of the drug colloid particles is maintained. The protective colloid is, and remains absorbed on the solid drug particles. The resulting dispersion contains particles of such small diameters that they can be administered by intravenous injection. From the particles the drug compound is then immediately released without any measurable delay.

(D.I. 303 at A66) (emphasis added). When read together, the Court is persuaded that the specification and prosecution history require that the term "hydrosol" be limited in scope to synthetic pharmaceutical preparations which are not formed within the stomach of a patient. With regard to the parties' dispute concerning the size of the solid particles, the Court declines to provide a construction, because the specification of the '382 Patent unambiguously resolves the issue. (See D.I. 303 A3, '382 Patent, col. 1, lns. 14-18). As for the remaining issue, namely whether hydrosol is comprised of solid particles, it appears that the parties are in agreement, and thus, the Court will adopt Eon's proposed definition.

For all of the above reasons, the Court construes the term "hydrosol" to mean: a) a synthetic pharmaceutical preparation, i.e., it does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient; and b) all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize.
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The key issue on appeal is whether "hydrosol" as it appears in all of the '382 patent claims is limited to medicinal products prepared outside of the body or whether it also includes products formed within the stomach of a patient after a particular medicinal product has been ingested. Novartis argues that the plain meaning of hydrosol includes products formed inside the stomach and that this definition controls the outcome of this case. We disagree.

Neither party has suggested that hydrosol has a specialized meaning inconsistent with the ordinary dictionary definition, (see Br. for Pls.-Appellants at 9 (urging definitions "consistent with the definitions found in dictionaries"); Br. for Def.-Appellee at 21-22 (urging a definition consistent with the dictionary definition)), thus under our precedent, we begin our claim construction analysis with an examination of general purpose dictionary definitions. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203-04 (Fed. Cir. 2002); see also Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378 (Fed. Cir. 2002). Webster's Third New International Dictionary (2002) ("Webster's") 1 defines the term "hydrosol" as "a sol in which the liquid is water." Webster's at 1110. In turn a "sol" is "a dispersion of solid particles in a liquid colloidal solution." Id. at 2167. 2 The term "solution" has two pertinent definitions. These are: "(1): a liquid containing a dissolved substance" and "(2): a liquid and usu. aqueous medicinal preparation with the solid ingredients soluble." Id. at 2170. The first of these definitions is broad enough to include a solution (i.e., the liquid medium in which the solid particles are dispersed) within the body, but, as explained below, the second definition is not. 3

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1 Neither party contends that the relevant definitions in this case have changed since the '382 patent application was filed and the patent issued.

2 The dissent relies on the Merriam Webster Medical Dictionary (2003), available at http://www.intelihealth.com ("Merriam

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Webster"), which defines "sol" as "a fluid colloidal system; especially: one in which the dispersion medium is a liquid." Post at 3-4; see also Dorland's Illustrated Medical Dictionary 1718 (30th ed. 2003) ("Dorland's") (defining "sol" as "a colloid system in which the dispersion medium is a liquid"). Contrary to the dissent, we are not foreclosed from referring to the definition of "solution" simply because the medical dictionary it cites refers to a "fluid colloidal system" and does not use the word "solution." See post at 4. Other medical dictionaries make clear that "sol" is often used synonymously with "colloidal solution." Stedman's Medical Dictionary 528, 1653 (27th ed. 2000) ("Stedman's") (defining "sol" as "a colloidal dispersion of a solid in a liquid" and further indicating that "colloidal dispersion" is a synonym for "colloidal solution"); see also 4 Attorneys' Dictionary of Medicine, Vol. S-139 (1995) ("Some scientists refer to a sol as a colloidal solution, rather than a dispersion. . . ."). Thus, there is no indication that the general purpose dictionary definition is inconsistent with the medical dictionary definition.

3 The dissent mistakenly suggests that the majority is equating the meaning of "hydrosol" with the meaning of the term "solution." Post at 4. We are doing no such thing. Rather, we recognize that a hydrosol consists of two things: (1) solid particles (here the cyclosporin) suspended in (2) an aqueous solution. In this context we are simply holding that the solution component of the hydrosol can mean a medicinal preparation. We are unaware of any evidence that one of ordinary skill in the art would consider the solution dispersing the solid particles of cyclosporin to no longer be a "solution," as the dissent suggests here. Indeed, the patentee's brief informs us that "there is no dispute that injectable solutions [including the cyclosporin] are one particular embodiment of the claimed invention." (Pls.-Appellants Br. at 11 (emphasis added).) Thus, contrary to the dissent's view, the narrower definition of solution is entirely consistent with the claim language.

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"Medicinal" means "of or relating to medicine" and the relevant definition of "medicine" is "a substance or preparation used in treating disease." Webster's at 1402. The Oxford English Dictionary, offers a similar definition of "medicine" as "any substance or preparation used in the treatment of disease; a medicament . . . . Now commonly restricted to medicaments taken internally." 9 The Oxford English Dictionary 549 (2d ed. 1989). Medical dictionaries define "preparation" in terms of a substance that is made prior to being administered. See Merriam Webster (defining preparation as "something that is prepared; specifically: a medicinal substance made ready for use); Dorland's at 1502 (defining "preparation" as "a medicine made ready for use"); Stedman's at 1440 (defining "preparation" as "something made ready, as a medicinal or other mixture, or a histologic specimen"). Thus, contrary to the suggestion in the dissent, post at 5-6, a "medicinal preparation" is a preexisting product that is administered to treat disease and therefore must necessarily be prepared outside the body. Indeed, Novartis (the patentee) conceded at oral argument that the normal connotation of medicinal preparation would lead you to believe it was something prepared outside the body.

Our analysis of the dictionary definition of hydrosol therefore yields a range of possible meanings consisting of two competing definitions. The claim term "hydrosol" is either broadly defined to include a dispersion of solid particles in aqueous colloidal solution formed in a patient's stomach, or limited to a medicinal preparation consisting of a dispersion of solid particles in an aqueous colloidal solution formed outside the body.

II

For more than 45 years we, and our predecessor court, have looked to the intrinsic record to determine as a matter of claim interpretation which of the available, relevant definitions should be applied to the claim term at issue. As our predecessor court explained, "one need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended as the word is used in a given claim. The subject matter, the context, etc., will more often then not lead to the correct conclusion." Liebscher v. Boothroyd, 46 C.C.P.A. 701, 258 F.2d 948, 951, 1958 Dec. Comm'r Pat. 437 (CCPA 1958); see also, e.g., Inverness, 309 F.3d at 1379 ("We must determine whether the specification or prosecution history clearly demonstrates that only one of the multiple meanings was intended."); Texas Digital, 308 F.3d at 1203 ("Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor."); Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning.").

In the present case, the specification describes the claimed hydrosol in terms of a pharmaceutical composition and makes no

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mention of the term in any other context. Novartis concedes "that the specification contains no description or examples of making hydrosols in the patient's body." (Reply Br. for Plaintiffs-Appellants at 4.) Rather, the abstract states that "the invention provides a hydrosol of a pharmacological active agent in an intravenous applicable, stabilised, pharmaceutically acceptable form." '382 patent, abstract; see also id. at col. 4, l.32; col. 5, ll.26-27 (describing the hydrosol as comprising solid particles of the drug "in an intravenously applicable, stabilised, pharmaceutically acceptable form."). The specification repeatedly describes the invention as a "pharmaceutical composition," see id. at col. 6, ll.66-68; col. 7, ll.1-2; col. 7, l.8, a method for "preparation of a pharmaceutical composition," id. at col. 6, l.65, and a "method of treatment using the corresponding pharmaceutical compositions," id. at col. 7, ll.10. Since the dictionary defines "pharmaceutical" as a "medicinal drug," Webster's at 1694, these descriptions support adoption of the narrower definition of hydrosol. Moreover, another aspect of the claimed hydrosol, an "injectable solution" is distinguished from the prior art on the ground that "it was never [previously] proposed to use pharmacologically active agent particles in an aqueous hydrosol form for intravenous injection purposes." '382 patent col. 1, ll.51, 56-58. 4 Because an injectable hydrosol must necessarily be prepared outside the body, these statements further support adoption of the more limited definition of "hydrosol" as a medicinal preparation prepared outside the body.

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4 In addition, the specification teaches that the water portion of the hydrosol may be removed leaving the cyclosporin particles in a dry form that "is a starting material for preparation of pharmaceutical compositions," which after being "redispersed with distilled water . . . may be intravenously administrable." '382 patent, col. 6, ll. 50-60.

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The prosecution history of the '382 patent points to the same conclusion. The examiner initially rejected Novartis's claims as obvious. Novartis distinguished the prior art, arguing that its invention "formed finely divided solid drug compound particles in amorphous colloid form." (App. at 974.) Novartis argued that this "dispersion contains particles of such small diameters that they can be administered by intravenous injection." Id. This description likewise supports the narrower definition of hydrosol as it clearly suggests that the hydrosol is a "pharmaceutical composition" that can be injected into a patient.

In light of the specification and prosecution history, we conclude that the narrower definition of "hydrosol" applies; that is, the term "hydrosol" is limited to a medicinal preparation consisting of a dispersion of solid particles in a liquid colloidal solution prepared outside the body. While none of the statements in the intrinsic record is an explicit disclaimer of subject matter sufficient to vary the scope of the claim from its ordinary meaning, 5 these statements are helpful in guiding us to choose between competing dictionary definitions of a claim term.

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5 Cf. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003) ("Where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender."); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001) (construing the claims to include a "coaxial" limitation, despite their ordinary meaning, because "portions of the . . . specification lead to the inescapable conclusion that the references . . . to an inflation lumen 'separate from' the guide wire lumen must be understood as referring to coaxial lumens"); see also Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906-08 (Fed. Cir. 2004) (discussing the appropriateness of limiting unambiguous claim language based on the intrinsic record).

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In this regard, the present case is different from Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994), where we held that the claimed compound was not limited to its pre-ingested form. Id. at 1422. There the claim at issue was drafted to a specific chemical compound, cefadroxil monohydrate, in a crystalline form characterized by specific x-ray diffraction properties. See Id. at 1420. Since the plain meaning of the claim language was clear and there was no express or implied pre-ingestion limitation, we found no basis for so limiting the claim. Thus, we held that "while the claim . . . is limited to the crystalline form of cefadroxil exhibiting the specified x-ray diffraction pattern, it is not limited to

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the compound in its pre-ingested form." Id. at 1422. However, in the present case the plain meaning of "hydrosol" is not clear, and nothing in Zenith purports to change the long-standing precedent that we look to statements made in the specification and prosecution history to choose between competing dictionary definitions.

Likewise our more recent decision in Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373 (Fed. Cir. 2003), does not require us to construe the '382 patent to encompass hydrosols formed only after ingestion. In Schering the parties agreed that the claims at issue covered a metabolite of the drug Loratadine, i.e., "the compound formed in the patient's body upon ingestion of [that] pharmaceutical." Id. at 1375. We held that these claims were anticipated by an earlier patent for the drug itself. Id. at 1382. This conclusion was based in part on the assumption that ingesting the earlier claimed pharmaceutical would create the metabolite and thus infringe the metabolite patent. Id. at 1380. However, in the present case there is no agreement that the claim encompasses the product formed after ingestion (in Schering the metabolite). Here that is at the heart of the dispute.

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CLEVENGER, Circuit Judge, dissenting.

At trial, the parties disputed the meaning of "hydrosol" as it appears in the '382 patent. Novartis argued that the term should have its accepted normal meaning, i.e., solid particles dispersed in any aqueous medium. Eon did not disagree with this meaning of the term, but insisted that "hydrosol" as claimed in the patent must be limited to hydrosols made outside the body, and exclude any hydrosol that is formed in the stomach. Eon claimed support for its view from the references in the specification and the file history describing the invention as directed to a hydrosol that is intravenously acceptable and in injectable form. Since the specification and file history made no reference to formation of the claimed hydrosol anywhere other than outside the body, the district court agreed with Eon that the "intravenous-injectable" connotations required the term to be restricted to the preferred embodiments shown in the patent.

On appeal, Novartis again asks why it is denied the ordinary meaning of hydrosol, which of course is not restricted to hydrosols made in any particular place, whether it be in a factory or in a human stomach. See, e.g., Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 318 F.3d 1143, 1148-52 (Fed. Cir. 2003). Novartis challenges the rationale of the district court as contrary to our established law, which precludes narrowing a claim term simply because the specification and file history describe examples of embodiments that reflect the use of a contested term in a specific way. See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 2004 WL 241482, at *6-*10 (Fed. Cir. 2004) (holding that claim terms are given the full breadth of their ordinary meaning unless a clear disavowal of scope is stated in the specification). The majority makes no attempt to defend the incorrect rationale of the district court's claim interpretation analysis. Instead, the majority uses multiple dictionaries to find an ambiguity in the meaning of "hydrosol" as claimed. With more than one possible pertinent meaning for "hydrosol" on the table, the majority can properly apply our precedent to look to the specification and file history of the patent to determine whether the patentee has eliminated the apparent ambiguity by choosing one definition over the other. The majority concludes that the specification teaches that the inventor here clearly limited the claimed hydrosol to medicinal varieties of the same prepared outside the body.

I differ not with the majority over the tools of claim interpretation to be applied; my difference is in how the majority has used those tools to arrive at its perceived ambiguity. Let me explain.

The majority starts with its dictionaries in hand, and goes first, as makes sense, to the word "hydrosol." It uses Webster's Third New International Dictionary to learn that "hydrosol" means "a sol in which the liquid is water." Other dictionaries could be used to arrive at the same definition, and in each instance the definition covers "hydrosol" no matter where it gets made. See, e.g., Dorland's Illustrated Medical Dictionary 873 (30th ed. 2003) ("a sol in which the dispersion medium is water"); Stedman's Medical Dictionary 385 (1995) ("a colloid with water as the dispersing medium"); Webster's Ninth New Collegiate Dictionary 590 (1985) ("a sol in which the liquid is water"). We all agree that this is a suitable definition of "hydrosol." For certain, the ordinary meaning of "hydrosol" carries no manufacturing site limitation with it. That being so, one would have thought that the majority would have applied our settled law to allow the term its full breadth, unless the patentee had made an explicit disclaimer or clear disavowal of scope to alter the ordinary broad meaning of the term. See, e.g., Liebel-Flarsheim, 358 F.3d 898, 2004 WL 241482, at *6-*10; Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1341-48 (Fed. Cir. 2001); Specialty Composites v. Cabot Corp., 845 F.2d 981, 986-88 (Fed. Cir. 1988). As the majority correctly and

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candidly concedes, the patentee in this case did not make any explicit disclaimer or disavowal of hydrosols made inside the body, so under our precedent Novartis would appear to be correct in its understanding of the disputed term.

But not so, according to the majority. It pursues the search in the dictionary, relying on Webster's Third New International Dictionary (2002). There, it finds as a definition for "sol" the following: a "dispersion of solid particles in a liquid colloidal solution." For the majority, this definition from this particular chosen dictionary is crucial, for it permits the court to move to a further degree of separation away from the word "hydrosol" to investigate the meaning of "solution." Had the majority used the Merriam Webster Medical Dictionary (2003), available at http://www.intelihealth.com, definition of "sol," it would have been deprived of the opportunity to pursue the meaning of "solution," because the more pertinent medical dictionary defines "sol" simply as "a fluid colloidal system; especially: one in which the dispersion medium is a liquid." Id. The pursuit of the meaning of "solution" is also blocked if one had turned to Webster's Ninth New Collegiate Dictionary (1984) (the copy provided to my chambers by the court), which defines "sol" as "a fluid colloidal system; esp: one in which the continuous phase is a liquid." Id. at 1121; see also Merriam-Webster's Collegiate Dictionary 1117 (10th ed. 1998); id. at 1186 (11th ed. 2003).

Having found a need to define "solution"--remember, the need is in order to know the meaning of "hydrosol"--the majority again relies on its dictionary in the next degree of separation to produce two meanings for "solution." One meaning, "a liquid containing a dissolved substance" is deemed by the majority, correctly, to be broad enough to relate back to "hydrosol" without imposing any restrictions on the manufacturing site of the hydrosol. The other meaning, however, is pay dirt for the majority. That second definition of "solution" is "a liquid and usu. aqueous medicinal preparation with the solid ingredients soluble" (emphasis added).

At this stage in the dictionary expedition, the majority should have noticed the error of its ways. This is so, because the definition it adopts for "solution" requires that the solid ingredients be soluble. A purpose if not the purpose of the claimed hydrosol is to address the problem of cyclosporin's insolubility. A hydrosol solves the problem by finely dispersing the insoluble solid ingredient (cyclosporin) in a liquid. Cyclosporin is no more soluble than before. Indeed, Appellee Eon's brief informs us of this very fact: "Hydrosols are distinguishable from solutions in that in a solution there are no solid particles . . . ." (Appellee's Br. at 4). For this reason, the claimed hydrosol is not a "medicinal preparation with the solid ingredients soluble," and the preferred definition of "solution" cannot be tied back to the claim language. When such a disconnect occurs in the dictionary pathway, the dictionary exercise has gone too far. 1

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1 The majority's attempted escape from our reasoning on this point also fails. Jumping away from the chosen dictionary definition (the one that allows a pursuit of the meaning of "medicinal preparation") because of the "solution" roadblock it presents, the majority finds another definition presenting the concept of dispersion, and uses that concept to read back into "solution" a fluid containing solid particles, such as the claimed hydrosol. This chase through the dictionary establishes one point with sparkling clarity: the majority eschews the preferred meaning of common terms, (i.e., solution means "a liquid containing a dissolved substance," Majority op. at 5), in favor of secondary, or tertiary, etc. meanings of the word in question.

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In the next degree of separation, the majority embraces the term "medicinal preparation," and forthwith abandons Webster's in favor of The Oxford English Dictionary 548-49 (2d ed. 1989), to plumb the depths of the meaning of the word "medicine." (The reader should not forget that the word we are trying to define is "hydrosol," not "medicine."). But The Oxford English Dictionary clearly does not state that a "medicine" must be manufactured outside the body, as the majority claims. Indeed, that dictionary emphasizes that "medicine" is taken internally, as is the case with Eon's alleged infringing substance. By no stretch does The Oxford English Dictionary require a medicine to be made in a pharmaceutical factory. As a matter of fact, the primary definition of "medicine" in that dictionary ("any substance or preparation used in the treatment of a disease") is broad enough to cover a hydrosol made in the body. The secondary definition of medicine, "medicament," leads to the concept of internal consumption on which the majority relies. Note also, that the definition of "medicine" in The Oxford English Dictionary, being restricted to "medicaments taken internally," is suspect, since many medicines are topically applied. Furthermore, appropriate medical dictionaries do not similarly restrict the ordinary definition of the word "medicine," i.e., "a substance or preparation used in treating disease." See Merriam Webster Medical Dictionary (2003),

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available at http://www.intelihealth.com; see also Stedman's Medical Dictionary (27th ed. 1999) (defining "medicine" as "[a] drug"); Dorland's Illustrated Medical Dictionary (30th ed. 2003) (defining "medicine" as "any drug or remedy"). In short, the ordinary meaning of "medicine" includes a hydrosol of cyclosporin formed in the stomach.

At the end of the long search in various dictionaries, the majority concludes that "hydrosol" is ambiguous because of "multiple possible" conflicting dictionary definitions. I am at a loss to understand why this dictionary search creates such an ambiguity. Indeed, at the end of the dictionary exercise, the majority narrows "medicine" to things made outside the body, even though the very dictionary on which the majority relies offers a primary meaning for the term that reaches hydrosols made anywhere. The majority's decision depends entirely on a suspect secondary meaning for "medicine" found in only a single dictionary.

"Hydrosol" simply means "a sol in which the liquid is water." Nothing in the dictionary listed under the word "hydrosol" speaks to the site where hydrosols are made. A "hydrosol" can be made anywhere, and manufacture outside the body is just a narrower subset of anywhere, with anywhere including inside the body. The existence of the narrower subset does not create ambiguity. It simply tells us what we know-that terms frequently have broad and narrow meanings. We then look to the specification and file history to determine whether the patentee made a clear disclaimer of the broader meaning. If not, the patentee is not taxed with narrowing references by way of examples (such as the intravenous and injection examples in the patent in suit) to narrow the broad scope.

Our case law has long recognized that medicines claimed in patents can be made inside or outside the body, and that infringement will lie in either case if the proper proofs are made. These cases are no less concerned with patient treatment than the instant case. In all of them, we have a "medicine" whose ordinary meaning carries no manufacturing site limitations. See Schering Corp. v. Geneva Pharms. Inc., 339 F.3d 1373 (Fed. Cir. 2003); Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756, 759 (Fed. Cir. 1997); Zenith Labs., 19 F.3d at 1421-22. Each of these precedents involved medical preparations. But until this case, no one had suggested that a suspect dictionary definition of the term "medicine" should be used to deny a patentee the right to prove infringement when the claimed composition is formed as a medicine in the body following the ingestion of a different composition that was manufactured outside the body.

In short, the majority should have ended its dictionary analysis at the word "hydrosol." Only by pressing on through several degrees of separation can the majority get to the definition of "medicine" on which it relies to confirm the existence of a second competing pertinent definition of "hydrosol." Dictionaries are fine tools to assist in the exercise of claim interpretation, for sure, but in this case the majority has simply overworked the dictionaries to a point of error.

My preference is to use our standard tools of claim interpretation, including proper use of dictionaries, in this case, and let it fit comfortably, as it should, in our body of law that recognizes that medicinal preparations made in the body can infringe valid claims. For the reasons set forth above, Novartis's patent should not be limited to injectable hydrosols of cyclosporin made outside the body. Novartis is entitled to a trial in which it can bring forward its proof of infringement.

With respect, I therefore dissent.
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B. "hydrosoluble carrier"

Claim 1 of the '405 patent, which is representative of the use of this term in the Stamm patents, is as follows:

A composition comprising a hydrosoluble carrier and micronized fenofibrate having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025M sodium lauryl sulfate.

('405 patent, col. 10 ll. 29-36 (emphasis added).)

1. The Parties' Proposed Constructions

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The parties propose the same meanings for the term "hydrosoluble carrier" as they did for "inert hydrosoluble carrier," except without it being "pharmaceutically inert." (See D.I. 238 at 4, C.A. 02-1512-KAJ; D.I. 167 at 3, C.A. 03-120-KAJ.) Thus, Abbott proposes that I construe "hydrosoluble carrier" to mean "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium." (D.I. 238 at 4, C.A. 02-1512-KAJ.) Teva and Impax have not specifically set out their proposed meanings for this term, but I understand that their proposals would contain the same functional descriptions following the meaning proposed by Abbott. (See D.I. 238 at 4, C.A. 02-1512-KAJ; D.I. 167 at 3, C.A. 03-120-KAJ.)

2. The Court's Construction

Based on my construction of "inert hydrosoluble carrier," supra Part IV.A.2., and for the same reasons expressed therein, I construe "hydrosoluble carrier" to mean "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium."
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"Hydroxyl-containing replacement for water vapor"

ASM contends that "hydroxyl-containing replacement for water vapor" is limited to ethyl alcohol, methyl alcohol or isopropyl alcohol. Genus argues that the phrase is not limited to those three substances.

The specification is ambiguous. The relevant language from the specification provides:

> While the invention has been described above with reference to HF vapor and water vapor or HF vapor, HCl vapor and water vapor as the vapor etchant, other hydroxyl-containing substances could serve as a replacement for the water. Appropriate hydroxyl-containing replacements are ethyl alcohol, methyl alcohol and isopropyl alcohol.

(Id. 7:14-20.) The parties dispute whether the last sentence is a limitation or whether it merely sets forth three examples. ASM contends that it means "The only appropriate hydroxyl-containing replacements are ethyl alcohol, methyl alcohol and isopropyl alcohol," while Genus contends that it means "Appropriate hydroxyl-containing replacements include, but are not limited to, ethyl alcohol, methyl alcohol and isopropyl alcohol." The meaning of the sentence is ambiguous on its face.

The parties agree that a "hydroxyl-containing" substance is one that contains an OH group (an oxygen atom bonded to a hydrogen atom). The parties dispute, however, whether any substance with an OH group can be considered to be a "replacement for water vapor." ASM argues that there are thousands of substances that contain a hydroxyl group, and that it would be inappropriate to include all of them in the definition. (Brown Decl., Ex. I, Hammond Rebuttal Report at 4.) ASM does not attempt to explain why any of these other hydroxyl-containing substances would not be an adequate replacement for water vapor in the context of the invention, however, other than to point out, in the abstract, some differences between water and other hydroxyl-containing substances.

Genus points out that the "summary of the invention" portion of the specification states that "other hydroxyl containing substances can serve as replacements for the water" ('568 patent 3:13-14), without limiting those substances to the three types (ethyl alcohol, methyl alcohol and isopropyl alcohol) that appear later in the patent. Genus' expert, William G. Oldham, explains that the purpose of water in the context of the invention is to serve as a solvent to ionize the hydrogen halide so that the etching reaction can proceed. (Brown Decl., Ex. E, Oldham Rebuttal Report at 15.) Thus, the water serves as a catalyst to initiate the etching process. (Id.) Oldham states that ethyl alcohol, methyl alcohol and isopropyl alcohol also act in the same fashion, as does acetic acid, a hydroxyl-containing substance that is not mentioned in the specification. (Id. at 16.)

Hammond does not dispute Oldham's conclusion that acetic acid also acts as a solvent that can serve as a catalyst to initiate the etching process. Hammond does set forth some ways in which acetic acid is different from ethyl alcohol, methyl alcohol and isopropyl alcohol, but he does not argue that acetic acid cannot serve the same function as those substances in the context of the process used in the invention. Instead, Hammond points out that a later-issued patent exists for the use of HF

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vapor and glacial acetic acid vapor to etch silicon oxide, and thus Hammond essentially concedes that acetic acid can be used in the process. (Brown Decl., Ex. F, Hammond Expert Report at 16.) It is clear from Oldham's rebuttal expert report, however, that while the pK[a] (which uses a logarithmic scale) of water, methyl alcohol, ethyl alcohol, and isopropyl alcohol all hover around 16, the pK[a] of acetic acid is approximately 5, and thus would appear to be much less effective as a solvent that ionizes the hydrogen halide so that the etching reaction can proceed. (Oldham Rebuttal Expert Report at 16 n.31 and n.32.) The Court therefore declines to find, at this time, based on the current record, that acetic acid serves as an adequate substitute for water vapor.

Nonetheless, the Court agrees with Genus that "hydroxyl-containing replacement for water vapor" is not limited to ethyl alcohol, methyl alcohol or isopropyl alcohol, but includes other substances containing an OH group which serve as a solvent to ionize the hydrogen halide so that the etching reaction can proceed.
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a. "Hydroxy acrylic monomer"

Both parties agree that this phrase corresponds to the following formula:

[SEE FORMULA IN ORIGINAL]

The parties also agree that the term (also known as HAM) is defined in the specification. '327 patent, 4:8-22. Both parties, however, have added additional language in their proposed constructions. The plaintiff has added two explanatory sentences to set forth the definitions of "(unsubstituted) alkyl group" and "substituted alkyl group." The defendants argue that there is no intrinsic support for further explanation of terms.

The defendants' proposed construction adds further limitation based on other portions of the intrinsic record. The defendants add a limitation that HAM units must be hydrophilic. The defendants contend that the specification states that the purpose of the HAM units is to improve wettability, which means that the HAM units must be hydrophilic. The plaintiff, however, argues that the definition of HAM in the specification encompasses unsubstituted alkyl groups which are known to be hydrophobic, and, therefore, HAM units may be hydrophobic.

The defendants add another limitation that HAM units do not include polymerizable vinylic siloxane monomers (or PVS monomers). The plaintiff, however, contends that the specification states that a HAM unit may contain a substituted alkyl in the X group where the substituent contains a siloxanyl (Si-O) group, which would constitute a PVS monomer. According to the plaintiff, this means that HAM units encompass PVS monomers.

The Court agrees with the plaintiff that the term should be construed as described in the specification. "Hydroxy acrylic monomer" means "a molecule corresponding to the following formula:

[SEE FORMULA IN ORIGINAL]

wherein R is H or a substituted or unsubstituted alkyl; and X is a radical selected from the group consisting of hydroxyalkyloxy, hydroxalkyl amine, and hydroxy; with the alkyl being substituted or unsubstituted, and with the hydroxy on the alkyl being either a single hydroxy or a multiple hydroxy. An (unsubstituted) alkyl group is a hydrocarbon molecule containing only carbon and hydrogen atoms (C and H). A substituted alkyl group has an atom or group of atoms replaced by one or more different atoms or groups." 2

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2 The defendants appear to only dispute the inclusion of the plaintiff's explanatory language, but not its accuracy.

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b. "Hydroxy acrylic monomer units"

For "hydroxy acrylic monomer units," the defendants propose the same construction as "hydroxy acrylic monomer" while the plaintiff proposes "chemical structures that are part of a polymer and correspond to the structures of hydroxy acrylic monomers in polymerized form, an example of which is shown below. The R and X in the formula are as defined above and may also be sites through with the monomer units are connected to the polymer:

[SEE FORMULA IN ORIGINAL]

The Court agrees with the plaintiff that monomer units are part of a polymer and that the structure shown by the plaintiff is a more appropriate representation of the HAM unit as part of a larger polymer molecule. Accordingly, the Court adopts the plaintiff's proposed construction.
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D. "Hydroxy-protecting groups"

Independent process claims 1, 14 and 16 of the '277 Patent, contain the limitation: "R[2] is a hydroxy-protecting group" and claim 1 also contains the limitation "R[3] is a hydroxy-protecting group."

According to BMS, it has "consistently argued that claims 1, 14 and 16 of he '277 Patent included any R[2] protecting group and that claim 1 includes any R[3] protecting group, because the claims contain no limitation as to any specific protecting group, or class or category of protecting group." (Bristol Post-Hearing Memo., p. 5)

BMS points out that in RPR's initial Markman submission, RPR seemingly agreed with BMS (RPR February 2 Br. 14, emphasis added):

"The 'R' group can be varied in accordance with and to the degree recited in the claims. For example, in claim 1, both 'R[2] and R[3] are defined generally as 'hydroxy-protecting groups.' Thus, each derivative "referred to in Claim 1 can result from the use of any hydroxy-protecting group."

Next, BMS cites testimony by Dr. Martin at the Markman hearing (Martin Hrg. Tr., p. 98) in support of its position:

Q. Now, sir, in claim 1, the R[2] is a hydroxy-protecting group. There are no restrictions on the hydroxy-protecting group, right?

A. That is correct.

Q. For the R[3] protecting group, the hydroxy-protecting group on the baccatin reactant, there are no restrictions on the R[3] protecting group, right?

A. In claim 1, yes, that is correct.

Again, Dr. Martin's testimony is direct, to the point, and supports BMS's position on the issue. Furthermore, I agree with BMS's analysis of the intrinsic evidence as it relates to the meaning of the terms "hydroxy-protecting groups" and reproduce it here in full:

"Claim 1 of the '277 Patent starts with reactants already having the protecting groups attached, and identifies the R[2] and R[3] groups as 'hydroxy protecting group[s]. There is no limitation as to the class or type of hydroxy protecting group. The claim subsequently requires that the hydroxy protecting groups are 'replaced by hydrogen', but does not specify how that

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deprotection occurs, and so encompasses any deprotection method.

Claim 2 Specifies the R[2] and R[3] protecting (including MOM, EOE, BOM, etc.) and describing the R[3] groups as 'trialkylsilyl groups in which each alkyl portion contains 1 to 3 carbons.'

The specification of the '277 Patent reiterates the general statements that R[2] and R[3] are 'hydroxy protecting groups' ('277 Patent, col. 2, ll. 46, 61, Tab 2), and then provides the more narrow preferred or more especially used groups, including TMS, BOM and MOM ('277 Patent, col. 2, l. 67-col. 3, l. 9, Tab 2). 2 The specification also provides a general statement that deprotection 'is generally accomplished by treatment in an acid medium' ('277 Patent, col. 3, l. 43, Tab 2), and provides one specific example of the esterification and subsequent removal of the protecting groups (esterification: '277 Patent, col. 4, ll. 43-53, Tab 2; deprotection: '277 Patent, col. 5, ll. 43-48, Tab 2).

There is, no other disclosure or guidance in the '277 Patent concerning how to use the protecting groups identified, or what tests to use to determine whether some other protecting group works." (BMS Post-Hearing Br., pp. 5-7).

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2 TMS is trialkylsilyl with each of the three alkyl groups being methyl.

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The relevant portions of RPR's position on the issue are as follows:

"'OH' groups are one of the most common functional groups in organic chemistry. An organic chemist would understand that a 'hydroxy protecting group' means a chemical group attached to the oxygen of an 'OH' group (by replacing the hydrogen), which temporarily 'locks up' the 'OH' group (in the form of a 'O-protected' group) (id., [Martin] pp. 39-40, 52, 58). This protection effectively removes, and thus makes, the OH group thus inert to a particular reaction (id., pp. 31-35). The protection can be removed to regenerate the 'OH' (id.).

* * *

Protecting groups are frequently used in the synthesis of complex natural products such as taxanes, and the skilled synthetic, organic chemist knows what they are and how to select them (Corey, p. 265 (Ex. 1)). Thus, there is nothing about the term 'hydroxy protecting group' which requires interpretation." (RPR Post-hearing Br., p. 15).

RPR's statement that a POSA in 1988 (indeed even today) understood how hydroxy-protection groups functioned to protect and make the OH group inert in a reaction is accurate. Dr. Corey's testimony on the issue provides a complete and undisputed statement of the knowledge and resources available to a POSA on the subject: "As of 1988 there were many, many protecting groups that were known for protecting hydroxy groups and also there was a huge amount of literature, background of the use of these various protecting groups. So, one of ordinary skill would not only be able to find within the covers of one book a complete compilation of suitable protecting groups, but be able to find the supporting literature, the background literature for the use of these protecting groups." (Corey Hrg. Tr., p. 265).

The foregoing accurate statements concerning the knowledge and resources available to a POSA in 1988, regarding hydroxy-protection groups, in general, does not, however, dictate a construction that changes the plain meaning of hydroxy-protecting groups as used in the claims and specification of the '277 Patent. In other words, a re-statement of the well known function of the "hydroxy-protecting groups" in general chemical reactions is not the same as defining the terms as used in the particular taxol process claimed in the '277 Patent. Likewise, a POSA's knowledge of the existence and identity of this large group available for hydroxy-protection in general chemical reactions would not cause a POSA to interpret the terms in a way different from that dictated by the plain and unambiguous language used in the claims and specification.

Indeed, a POSA, with this background knowledge, would necessarily conclude from the language in the claims and the specification, that the inventors were directing him/her to this large hydroxy-protection group without restriction. As noted earlier, Dr. Martin agrees with this statement. Further, there is nothing in the '277 Patent, other than the preferred subset of this larger group claimed in claim 2 and 17, which points a POSA to a subset of the larger groups to use in the invention as

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claimed. Finally, there is nothing in the intrinsic or extrinsic evidence which even hints at how a POSA would determine, without experimentation, which of the remaining subset of the hydroxy-protecting groups would work in the claimed process for taxol production.

In RPR's final Post-Hearing Brief on the issue, RPR is more direct and argues (Br., pp. 11-13) that "those skilled in the art of organic chemistry clearly and indisputably understand the term 'hydroxy-protecting group,' in structural and functional terms." RPR also asserts that the terms hydroxy-protecting group "encompasses only protecting groups capable of protecting as needed and then being removed." Obviously, again, a reference to RPR's position that a functional definition is required for the terms. Finally, leaving no doubt about its position, RPR states: "Therefore, claim 1 when read as a whole by the skilled organic chemist, clearly is intended to cover only hydroxy-protecting groups that work to produce taxol." (emphasis added)

Over time RPR has moved from its original contention that no interpretation of "hydroxy-protection groups" was required to a direct request that the Court rewrite the plain language of the claims "R[2]/R[3] is a hydroxy-protecting group" to read "R[2]/R[3] is any group that works to protect the OH." This requested change in the straight forward claim language -- obviously well understood by Dr. Martin as meaning "no restrictions"-- to language which specifically narrows 3 and restricts the terms to mean just those groups that "work to protect," has no basis in Federal Circuit law. RPR cites no cases to support its position.

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3 RPR's request to "narrow" and restrict the meaning of hydroxy-protecting groups is inconsistent with the overall position it has taken in its Markman briefings -- namely, that its claims should be given the broadest possible interpretation. See the following argument sections of its post-hearing brief: A. The Language Of The Patent Claims Is Clear and Unambiguous And Compels A Broad Interpretation" (which includes arguments re: hydrogen-protecting groups); B. The Doctrine Of Claim Differentiation Also Compels A Broad Claim Interpretation; C. The Patent Specification Confirms That The Patent Claims Should Be Interpreted Broadly; and D. The Prior Art And The JACS Article Do Not Support A Narrow Interpretation Of The Patent Claims (RPR Post-Hearing Br. pp. 12, 23, 26 and 29).

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It is also clear that the Patent Office would have had no legal basis to issue claims written in the functional or results oriented language proposed by RPR, unless such claims had been written according to the strict requirements of 35 U.S.C. § 112, P 6. This section of the patent code reads as follows:

"An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material or acts described in the specification and equivalence thereof."

The claims of the '277 Patent are not written in compliance with § 112, P 6 and it would be inappropriate for the Court to rewrite the claims in this fashion.

Finally, I agree with BMS's position that if RPR's interpretation were adopted by the Court, "a chemist would have to laboriously carry out the entire process, including the esterification and the protection steps, to determine if a protecting group is covered by the claim. Moreover, even if the results are negative, that would not mean that a protecting group was outside the claims, because there might be some other conditions under which it would "work." Thus, to confirm that a group is outside the claims the reader would have to test every possible set of reaction conditions -- plainly a Herculean, if not an impossible, task." (BMS post-hearing brief, p. 9.)

In conclusion, in light of the fact that BMS's requested interpretation for the "hydroxy-protecting group" terms is supported by the intrinsic and extrinsic evidence and that RPR's requested interpretation is without support in either the evidence or law, I recommend the Court adopt the following construction of the terms:

"Hydroxy-protecting groups" means any protecting group, or class or category without limitations as to any specific protecting group or class or category.

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11. "Hydroxyalkyl acrylate" or "hydroxyalkyl methacrylate"

The plaintiff proposes that "hydroxyalkyl acrylate" means "a type of hydroxy acrylic monomer unit where R may be a hydrogen atom (H) and where X is a hydroxyalkyloxy radical. Like other HAM units, X may have a substituted or unsubstituted alkyl as part of it and may also include more than one hydroxyl group. X may also be a site through which the monomer unit is connected to the polymer." 3 The defendants propose "a hydroxy acrylic monomer unit having a hydrocarbon group with 10 or fewer carbon atoms and at least one hydroxy group."

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3 Hydroxyalkyl methacrylate is a subset of hydroxy acrylic monomer units. The parties appear to agree that it should have the same construction as hydroxyalkyl acrylate except that R should be defined as a methyl group (-CH[3]).

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The plaintiff argues that the defendants' proposal limits the construction to the preferred embodiment. The plaintiff also argues that the defendants' construction fails to capture the fact that the alkyl in the X group may be substituted and would constitute a non-hydrocarbon. The defendants argue that the applicants did not provide a description to include a hydroxyl alkyl having an unlimited number of carbon atoms and, therefore, one of ordinary skill in the art would understand that the applicant limited to carbon chain to 10 or fewer carbon atoms. The Court has considered the parties' positions and adopts the plaintiff's proposed constructions for both terms.

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The issues of claim construction and infringement focused on the controlled release agent, hydroxypropyl methylcellulose (HPMC). HPMC is defined in the Handbook of Pharmaceutical Additives as follows:
Definition: Propylene glycol ether of methyl cellulose

Properties: White powd.; swells in water to produce a clear to opalescent visc. colloidal sol'n.; nonionic, insol. in anhyd. alcohol, ether, chloroform; sol. in most polar solvs.

Trade Names: Benecel7 Hydroxypropyl Methylcellulose; Methocel7 E3 Premium; Methocel7 E4M Premium; Methocel7 E5P; Methocel7 E6 Premium; Methocel7 E10MP CR; Methocel7 E15LV Premium; Methocel7 E50LV Premium; Methocel7 E50P; Methocel7 E Premium; Methocel7 F4M Premium . . . .

M. & I. Ash, Handbook of Pharmaceutical Additives 552 (1995).

A

The specification describes the hydroxypropyl methylcellulose release agent as follows:

This invention is directed to control sustained release (SR) tablets containing bupropion hydrochloride (as the drug or active ingredient), preferably hydroxypropyl methylcellulose (Methocel7) for controlling drug release rate, and cysteine hydrochloride or glycine hydrochloride.

* * *

Methocel7 is the brand name for hydroxypropyl methylcellulose (HPMC) from Dow Chemical. Other companies also supply HPMC.

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* * *

In order to prepare the controlled sustained release (SR) tablets of this invention, particles of bupropion hydrochloride are preferably blended with microcrystalline cellulose and hydroxypropyl methylcellulose (Methocel7) to form an admixture of blended powders.

* * *

In the practice of this invention, for every part by weight of bupropion hydrochloride, the amount of hydroxypropyl methylcellulose is 0.19 to 1.1 and more preferably 0.267 to 0.68 parts by weight . . . .

'798 patent, col.1:67 - col.3:14. The specification describes the HPMC used in the examples as follows:

Hydroxypropyl Methylcellulose 2910, USP used in the examples, conforms to 28.0 to 30.00% methoxyl substitution and 7.0 to 12.0% hydroxypropyl substitution. The preferred nominal viscosity of 2% solution in water is not less than 3,000 centipoise and not more than 5,600 centipoise. It is supplied by Dow Chemical Company, Midland, Mich. as Methocel E4M Premium CR.

'798 patent, col.5:13-20.

During prosecution of the '798 patent, the examiner required that all the claims be limited to hydroxypropyl methylcellulose as the release agent. For example, claim 14, as originally submitted, was as follows:

14. A controlled sustained release tablet comprising an admixture of 100mg of bupropion hydrochloride and means for providing a shelf life of at least one year and after oral administration of a single one of said tablets in adult men producing plasma levels of bupropion as free base ranging substantially between the minimum and maximum levels as shown in Fig. 5 over twenty four hours.

The examiner stated:
The rate of release is directly related to the release retarding effect of hydroxypropylmethylcellulose. While other excipients have been disclosed, the particular cellulose is considered critical for controlled and/or sustained release and should be incorporated into the independent claims. The disclosure of a single species does not provide a basis for claiming a generic concept.

The applicant acquiesced, and limited all the claims to hydroxypropyl methylcellulose. However, the examiner did not require limiting the hydroxypropyl methylcellulose to any specific grade or molecular weight. What the examiner required was:

Applicants are claiming a tablet which provides a distinct release profile. The advantages provided by the unique tablet differ from an instant release tablet. The limitations of claims 2-3 are considered critical and should be incorporated into claim 1 for proper enablement.

In response, the applicant amended claim 1 to include the limitations: "said tablet releasing between about 20 and 60 percent of bupropion hydrochloride in water in 1 hour, between about 50 and 90 percent in 4 hours and not less than about 75 percent in 8 hours."

The examiner did not require "a particular grade" of HPMC. The district court erred in holding that the amendment adding the release rate data to the claim limited the claim to the grade of HPMC in the example. The district court stated: "All grades of HPMC could no longer be read into the Glaxo claims to a certainty after the amendment which recognized that a particular grade was critical for controlled or sustained release, therefore an invitation was extended to refer elsewhere for particular grade information." Neither the applicant nor the examiner stated that "a particular grade was critical"; the amendment stated the parameters of the claimed release, not a particular grade of hydroxypropyl methylcellulose. The HPMC was not limited to the specific example of grade 2910.

Andrx states that its HPMC has a significantly lower molecular weight and viscosity than those of grade 2910, and that the

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Andrx HPMC does not affect the rate of release because it is readily soluble. Andrx states that it controls the release of bupropion in other ways, not by way of the HPMC in its tablets. Andrx states: "In the Andrx ANDA products, the Eudragit7E100/Ethocel7100 layer is the release controlling means. This polymer mixture forms a polymeric membrane that regulates the amount of drug that is allowed to release from the pellets by diffusion through the membrane." Andrx also states that its tablets do not exhibit the dissolution and blood plasma profiles required by the claims. Glaxo challenges these statements, pointing out that Andrx was unable to produce a satisfactory controlled release product without using HPMC, and that Andrx has represented to the FDA that its tablets are bioequivalent to the Glaxo tablets, as is required for an ANDA, and thus necessarily match the release rate, dissolution, and blood plasma profiles of the federally approved formulation.

Glaxo states that hydroxypropyl methylcellulose is a polymer and exists in a range of molecular weights, that it is incorrect to construe the claims as limited to a particular grade of hydroxypropyl methylcellulose, and that the specification contains no basis for either a molecular weight or a viscosity limitation. Glaxo argues that while the specification shows the HPMC 2910 (supplied as Methocel7 E4M Premium CR) that Glaxo used, the description of the invention does not limit the HPMC to a particular grade.

Glaxo states that hydroxypropyl methylcellulose is a gel-forming material known for use in pharmaceutical formulations. There was extensive evidence to this effect. Professor Kathryn E. Uhrich (Rutgers University) testified as follows:

Significantly, all grades of HPMC are capable of forming a hydrogel that contributes to sustained release when exposed to aqueous media, including the HPMC E5 grade of the Andrx ANDA products. Andrx's products use HPMC E5 and clearly fall within the patented claim element for HPMC. The accused products contain admixtures of HPMC E5 with bupropion and the resulting tablets are sustained release tablets where the HPMC E5 contributes to the release.

* * *

The hydroxypropyl methylcellulose [in the Andrx products] is essential for the sustained or extended release of bupropion hydrochloride as a result of, among other things, the interactions of the hydroxypropyl methylcellulose with the adjacent bupropion/hydroxypropyl methylcellulose, as well as with the other polymers in the formulation during both manufacture and drug release. The hydrophilic properties of hydroxypropyl methylcellulose and its ability to swell in the presence of solvents such as water and certain organic solvents are also important in controlling release. Therefore, in Andrx's proposed 100 mg and 150 mg products, a means for releasing bupropion hydrochloride is hydroxypropyl methylcellulose as required by Claims 18 and 19.

Dr. Banakar, Andrx's expert, described by Andrx as world renowned, testified that a person of ordinary skill in the art of drug formulation reading the '798 patent would understand that hydroxypropyl methylcellulose only includes certain grades of HPMC which are high-viscosity and hydrogel-forming. Dr. Banakar stated:

If the term "hydroxypropyl methyl cellulose" as used in Claims 1, 14, 15, 18 and 19 of the '798 patent includes low-viscosity, low molecular weight grades of HPMC, then the '798 patent is not enabling of the claimed invention because it does not teach or enable one skilled in the art to make a sustained-release bupropion formulation having the dissolution profiles of Claims 1, 18 or 19 or the blood plasma drug levels of Claims 14 or 15. That is, for a product to exhibit the dissolution profile recited in Claim 1 of the '798 patent, and only require the use of bupropion and HPMC, at the specified ratio, the HPMC must be of a high molecular weight, high-viscosity release-controlling grade. Use of a low-viscosity, low molecular weight soluble grade of HPMC such as the E5 grade at the recited ratios without some other sort of release-controlling technology added would make it impossible for one of ordinary skill in the art to obtain the required dissolution profile.

In fact, in order to obtain a suitable sustained release formulation, which uses HPMC E5 as a binding agent and/or seal coat, constituent, Andrx needed to employ a completely different and novel release technology. . . . The Andrx ANDA products do not employ hydrogel technology to control the release of bupropion. Instead, the Andrx ANDA products employ pellets (compressed into a tablet) having certain polymer coatings thereon, which control bupropion release by diffusion.

Dr. Nicholas Peppas (Professor of Pharmacology, Purdue University) described by Glaxo as one of the world's leading scientific experts in hydrogels, disagreed with Dr. Banakar:

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Each of Andrx's products comprises hydroxypropyl methylcellulose and bupropion hydrochloride and the hydroxypropyl methylcellulose is an essential component for the extended and sustained release of bupropion hydrochloride. Its presence in Andrx's formulations and the interactions of the hydroxypropyl methylcellulose with other components inside of this formulation lead to the formation of a gel region in the polymer matrix, which, as I have shown in paragraphs 31, 32 and 36, is a controlling step of the overall release process.

I disagree with Dr. Banakar's opinion [Andrx's expert] with respect to the characteristics of hydroxypropyl methylcellulose and with Dr. Banakar's opinion that a person working in drug formulation or pharmaceutics would interpret Claims 1, 13, 14, 15, 17 and 19 of the '798 patent as limited only to hydroxypropyl methylcellulose grades that form "hydrogels" and would not include "low viscosity grades" of hydroxypropyl methylcellulose. In my opinion, and based on my experience, Dr. Banakar is incorrect in defining "low viscosity" grades of hydroxypropyl methylcellulose as not being "hydrogels."

* * * *

For lower viscosity hydroxypropyl methylcellulose grades, these gels may be somewhat less dense than for higher viscosity hydroxypropyl methylcellulose grades, but the gels formed during swelling definitely control the drug release process in Andrx's products.

Although the expert testimony is facially in conflict, it was not disputed that the mechanism whereby HPMC affects the release of materials with which it is mixed is the swelling of the HPMC in contact with water. It was not disputed that Andrx mixes the bupropion with HPMC in the interior portion of its tablets. Andrx did not establish that the HPMC it used to mix with the bupropion did not swell in water and affect the rate of release of the bupropion, while arguing that other chemicals affect diffusion. Glaxo stresses that in the Andrx formulation the HPMC is mixed with the bupropion at the core of the tablet, as in the '798 patent.

Andrx in turn stresses that both Andrx and Glaxo use a rapidly soluble grade of HPMC as outer coatings of the tablet. The '798 patent describes the Glaxo outer coating as a thin film of HPMC that does not "substantially affect the release rate of the bupropion hydrochloride from the tablet, since the coating is instant release which rapidly dissolves in the stomach." The '798 specification explains that "because of the nature of the film coating, the release rate will be substantially the same whether or not the tablets are film-coated."

Andrx states that it uses this same grade inside its tablet in admixture with the bupropion, and therefore that it cannot contribute to controlling the rate of bupropion release. Glaxo responds with the testimony of Andrx's formulation scientist, Mr. Jianbo Xie, that he and others at Andrx had been unable to produce a sustained release bupropion product without using HPMC, although they had tried to do so because of the Glaxo patent. By deposition Mr. Xie stated:
Q: I'm asking what you were thinking when you were doing this development work in the first half of 1997. Whatever the lawyers think or didn't think, weren't you trying to stay away from HPMC to avoid the patents?

A: If we could, we tried to -- how do you say that -- can you repeat your question again?

* * *

Q: You perceived your job so as to stay away from using HPMC if you could so that you could avoid infringement, that is what you were trying to do in early 1997; isn't that correct?

A: Yes, that was a part of the reason, part of the reason.

As a matter of claim construction, the intrinsic and extrinsic evidence lead to the conclusion that the HPMC mixed with the bupropion at the core of the tablet is not limited to a particular grade and molecular weight, provided only that the claimed limitations of release rate and plasma levels are met. When a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67, 62 USPQ2d 1658, 1662-63 (Fed. Cir. 2002). It is established that "as a general rule claims of a patent are not limited to the preferred embodiment . . . or to the examples listed within the patent specification." Dow Chemical Co. v. United States, 226 F.3d 1334, 1342, 56 USPQ2d 1014, 1019 (Fed. Cir. 2000); Northern Telecom Ltd. v. Samsung

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Electronics Co., Ltd., 215 F.3d 1281, 1293, 55 USPQ2d 1065, 1074 (Fed. Cir. 2000) ("preferred embodiments, without more, do not limit claim terms").

In this case the properties and use of hydroxypropyl methylcellulose to control release were well known. The examination record showed that patentability turned on the ratio of the HPMC to the bupropion, the shelf life, the rate of release, the duration of release, and the plasma levels. The hydroxypropyl methylcellulose used in admixture with the bupropion hydrochloride is not limited to the grade and molecular weight of HPMC in the specific examples, but the claims, correctly construed, require that HPMC be present in the stated amount, and that the product have the release rate and duration and plasma levels and other properties set forth in the claims.
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"Hyperglycemia"

In the Joint Claim Construction Chart, Nutrition 21 construes this term, which appears in Claims 1 and 7 the '623 Patent, to mean "a symptom of diabetes." GNC does not propose any construction for the term. Neither party addresses the term's construction in its briefs.

Construing the term will be helpful to the jury, who may not otherwise be familiar with the term's meaning. Further, the specification identifies hyperglycemia as a symptom of diabetes. '623 Patent, col. 1:35. Therefore, the Court construes "hyperglycemia" as "a symptom of diabetes."
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D. Hyperparathyroidism

Plaintiffs contend that the term "hyperparathyroidism" should be construed as "increased (i.e., above normal) secretion of PTH by the parathyroid gland." Defendants object to Plaintiffs' use of the term "secretion." According to Defendants, the increased PTH levels in patients with hyperparathyroidism secondary to ESRD are caused by more than increased PTH secretion bythe parathyroid glands. Therefore, Defendants propose construing the claim term "hyperparathyroidism" as "substantially elevated serum PTH." 2

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2 As noted above, the Court declines to construe claim 7 as limited to patients with substantially elevated serum PTH.

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Plaintiffs' proposed construction is consistent with the '116 patent specification, which explains that "[r]educed serum levels of 1 [alpha],25-(OH)2D cause increased, and ultimately excessive, secretion of PTH by direct and indirect mechanisms," which in turn results in "hyperparathyroidism." '116 patent, col. 2, ll. 55-57. Plaintiffs' construction also finds support in a scientific dictionary. The Oxford Companion to Medicine (Oxford: 1986) defines "hyperparathyroidism" as "increased activity of the parathyroid glands," and states that "[s]econdary hyperparathyroidism occurs in response to conditions like vitamin D deficiency and chronic renal disease which tend to depress serum calcium levels." The Federal Circuit has approved the use of "dictionaries, and especially technical dictionaries," by "court[s] in determining the meaning of particular terminology to those of skill in the art of the invention" where "the court deemsit helpful in determining 'the true meaning of language used in the patent claims.'" Phillips, 415 F.3d at 1318 (citation omitted).

Defendants do not appear to dispute Plaintiffs' position that the term "hyperparathyroidism" refers to increased secretion by the parathyroid glands. Indeed, Defendants' own experts testified that the term "hyperparathyroidism" refers to increased secretion of PTH by the parathyroid glands. See Deftos CC Decl., Exh. F, P 5 ("substantially elevated levels of PTH in the blood of patients with hyperparathyroidism secondary to end stage renal disease ('ESRD') are due not only to the increased

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secretion of PTH by the parathyroid glands (the secondary hyperparathyroidism), but also to the accumulation of fragments of PTH because of their decreasing excretion by the ailing kidney") (emphasis added); Deftos expert report, Exh. C, P 30 (explaining that secondary hyperparathyroidism occurs where "blood calcium is low and signals the parathyroid gland to produce more PTH"); Segre expert report, Exh. B, P 37 (defining secondary hyperparathyroidism as occurring where "the parathyroid glands secrete excessive amounts of PTH because of extrinsic factors"). Rather, Defendants'point is that other factors also contribute to the increased PTH levels in patients with hyperparathyroidism secondary to ESRD. See Segre CC Decl., Exh. 0, PP 2-3 ("the increased serum PTH concentrations in ESRD patients with secondary hyperparathyroidism are not simply the result of increased secretions from the PTH glands, but also result from reduced clearance of PTH and PTH fragments from serum"). But the Court's task is to construe the term "hyperparathyroidism secondary to ESRD," not to describe all of the causes of increased PTH levels in patients with hyperparathyroidism secondary to ESRD. Nor does Plaintiffs' proposed construction purport to describe all of those causes. Therefore, Plaintiffs' proposed construction is not inconsistent with Defendants' observation regarding the additional causes of increased PTH levels in patients with hyperparathyroidism secondary to ESRD.

The Court sees no need to address the other causes of increased PTH levels in patients with hyperparathyroidism secondary to ESRD. Therefore, it construes "hyperparathyroidism" as "increased (i.e., above normal) secretion of PTH by the parathyroid gland."
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D. "Imbalance of neuronal stimulation after Alzheimer's disease"

Plaintiffs construe this term as: "a pathophysiological situation characterized by an excessive inflow of calcium through NMDA receptor channels after Alzheimer's disease." They assert that the patentee defined the term in the following portion of the specification:

cerebral ischemia is characterized by a pathophysiological situation defined by an imbalance of neuronal stimulation mechanisms. In this context, the excessive inflow of calcium through NMDA receptor channels finally leads to the destruction of brain cells in specific brain areas.

(D.I. 223 at 18 (citing JA2 at col. 2 lines 46-52)) Plaintiffs also point to a portion of the reexamination prosecution history, in which the patentee stated that the imbalance of neuronal stimulation that is cerebral ischemia "can be initiated by various conditions, including Alzheimer's disease (col. 3, lines 10-16), and is characterized by a substantial increase in excitatory amino acids, which allows for an excessive influx of calcium through NMDA receptor channels leading to loss of brain cells (col. 2, lines 46-52)." (JA760-61)

Most of the Defendants, relying on the same portion of the specification cited by Plaintiffs, propose to construe the term in a manner incorporating many of the same concepts as Plaintiffs: "The destruction of brain cells, that results from an excessive influx of calcium through NMDA receptor channels (but not an imbalance of the dopamine/acetylcholine system), wherein said excessive influx is caused by an acute interruption of blood supply to the brain occurring after Alzheimer's disease." 9

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9 The Lupin and Sun Defendants propose the following construction: "A pathophysiological situation caused by cerebral ischemia occurring after Alzheimer's disease." (D.I. 222 at 27-28) Defendants Apotex and Upsher-Smith Laboratories, Inc. contend that the term need not be construed because, in their view, the claims in which it appears (claims 17 through 19) are invalid under Section 305, as these claims are impermissibly broader than original claim 1. (D.I. 222 at 23 n.15) For the reasons noted in the text, I recommend Plaintiffs' proposed construction, which is supported by the cited portion of the specification and the reexamination prosecution history. I will not address Defendants' Section 305 arguments in connection with claim construction.

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This dispute, as with others already discussed, turns on whether the focus of the patent is on an interruption of blood supply

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or a neuronal imbalance, and further on whether the term deals with a neuronal imbalance or on the loss of brain cells that follows it. Just as I have largely sided with Plaintiffs above, and for the same reasons, I do so here as well. The "imbalance" referred to in this term is a neuronal imbalance, not an interruption in blood supply, and not the consequences of a neuronal imbalance.

Therefore, I recommend that "imbalance of neuronal stimulation after Alzheimer's disease" be construed as "a pathophysiological situation characterized by an excessive inflow of calcium through the NMDA receptor channels after Alzheimer's disease."

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E. Immunoassay

The term "immunoassay" is used in claims 2, 4, 10, 12, 20, and 22 to describe the procedure used to determine strong staining. Magistrate Judge Hollows adopted Chiron's proposed construction of the term:
The term "immunoassay" refers to a laboratory technique that makes use of the binding between an antigen and an antibody in order to identify or quantify the specific antigen, and more particularly, to a protocol which uses the minimal concentration of the antibody which provides strong staining of the positive control.

Genentech first argues that this construction is too narrow, because an immunoassay measures interactions between antibodies and a sample of cells or tissue, which include but are not limited to antibody-antigen binding. Although immunoassays can be used to measure things other than antibody-antigen binding, the '561 patent is exclusively concerned with antibody-antigen binding. This fact is apparent from the claims themselves, which describe the immunoassay technique in connection with strong staining, the purpose of which is to measure antigen-antibody interactions.

Genentech next argues that the construction recommended by Magistrate Judge Hollows improperly limits the term "immunoassay" to a protocol using minimal concentrations of the relevant antibody. This protocol is set forth in the specification. See '561 Patent, at 18:31-40 (describing an immunoperoxidase staining procedure in which "pure antibodies were first titrated to find the minimal concentration giving strong immunoperoxidase staining on breast cancer sections"). Although limitations from the specification may not be read into the claims, the claims must be read in light of the specification. Bell Atlantic, 262 F.3d at 1269. Given the purposes of the patent and the uses toward which the immunoassays of the patent claims are directed, it would be important to use a minimal concentration of the antibody of interest. Use of a high concentration of the antibody may flood the tissue and give strong staining everywhere, thus making it impossible to determine the extent of actual binding. n26 Therefore, the court adopts the recommended construction in full.

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n26 Genentech states that Chiron's expert, Dr. Parslow, "conceded that an immunoassay can be performed using either a minimal concentration or a higher concentration." (Genentech Opp'n to F & R's, at 19.) Because the specification and the purposes of the patent support Magistrate Judge Hollows' interpretation, the court need not consider this extrinsic evidence. In any case, the fact that an immunoassay can be performed using a higher than minimal concentration of antibodies does not make it useful for purposes of the patent. Dr. Parslow never testified that effective staining results could be achieved by using higher than minimal concentrations. (See Transcript, Vol II, at 206:23 - 207:12)("Q: In fact, when IMPATH did its tests, it used the maximum concentration of the antibody that did not give unduly high background staining; right? A: I believe Dr. Cote testified in the deposition that the two concentrations would be effectively the same in his view, that there wouldn't be very much difference in the concentration that you arrived at by those two methods.")(emphasis added).

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2. "Immunoassay"

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Biosite contends an "immunoassay" is a test that uses antibody specificity to detect the presence (or absence) of a compound of interest in a test sample. Although Dade Behring does not disagree with Biosite's definition, it believes the definition is incomplete. Dade Behring additionally states that the "immunoassay" performed in the '241 Patent is non-chromatographic in that it does not require the flow of fluid for a distance along a membrane to obtain the result; rather the assay involves the immediate contact of the sample solution with the bound mips. The dispute between the parties therefore revolves around whether this claim language should be limited by the descriptive terminology, "non-chromatographic."

Starting, as the Court must, with the language of the claim, there is no mention of the term "non-chromatographic." See Col. 1, lines 28-32. Nevertheless, the specification describes the invention as "novel non-chromatographic assay devices and methods employing such devices are described for the determination of members of an immunological pair (mip)." See Col. 2, lines 20-22. As the Federal Circuit Court of Appeals has observed, "interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." See Ekchian, 104 F.3d at 1303; see also Electro Medical Systems v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994) ("claims are not to be interpreted by adding limitations appearing only in the specification."); See Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1422 (Fed.Cir.), cert. denied, 513 U.S. 995, 130 L. Ed. 2d 409, 115 S. Ct. 500 (1994) ("It is axiomatic that terms in the specification cannot simply be read into the claims where they do not appear.").

The parties do not dispute that an immunoassay may be either chromatographic or non-chromatographic. Consequently, interpreting the term "immunoassay" in the claim does not inherently require a distinction to be made between chromatographic and non-chromatographic techniques. By appending the limitation "non-chromatographic" to the definition of "immunoassay," the Court would be impermissibly adding an extraneous limitation only appearing in the specification. As the Federal Circuit has warned district courts in performing claim constructions, "no matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them." See Intervet Am., 887 F.2d at 1053 (Fed.Cir.1989). Accordingly, the Court finds the specification cannot be used to import the term "non-chromatographic" into the definition of the claim term "immunoassay."

Dade Behring next argues that the prosecution history supports its position. Specifically, in an Amendment dated February 18, 1982, the patent applicants stated: "Deutsch and Grubb [prior art references] are both chromatographic techniques . . . . In the subject invention, there is a different kind of movement of the sample." See D.I. 129, Ex.3 at 9. Further, in an Amendment dated August 28, 1981, applicants described Grubb as "immunochromatography," while "the technique employed in the subject invention is contrary to the manner in which Grubb's invention is performed." D.I. 129, Ex.4 at 5. In spite of this seemingly compelling evidence, the Court adheres to the well-established claim construction principle that "although the prosecution history can and should be used to understand the language used in the claim, it too cannot enlarge, diminish or vary the limitations in the claims." See Markman, 52 F.3d at 980. The Court therefore declines to enlarge the claim limitations by importing post hoc explanations, and inferences therefrom, from the prosecution history into the claim language.

In short, the simple fact of the matter is that the patentees left out of the claims, for one reason or another, the word "non-chromatographic." It is not proper, nor the Court's role, to supply an extraneous limitation appearing only in the specification and/or the prosecution history. See Intervet Am., 887 F.2d at 1053. Accordingly, the Court declines to add "non-chromatographic" to the definition of the "immunoassay" claim term. The Court therefore holds an "immunoassay" is a test that uses antibody specificity to detect the presence (or absence) of a compound of interest in a test sample.
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8. "Immunosorbing Zone Is Immersed In Said Sample Solution"

This claim dispute boils down to what "immersed" means. Biosite maintains the claim language must be construed to mean the immunosorbing zone must be dipped into solution, while Dade Behring contends the Claim language is not limited to a dipping process, but allows any process by which the immunosorbing structure is completely covered or surrounded.

In support of its limited reading, Biosite asserts the specification explicitly distinguishes its use of the word "immersion" from an alternative process of dropping or pouring liquid onto the immunosorbing zone. The relevant specification reads:

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. . . the assay device may be conveniently immersed in a solution.

Alternatively, the solutions may be applied to the immunosorbing zone in a horizontal position, either dropwise, as a slowly flowing stream, or in a container surrounding the immunosorbing zone.

Col. 6, lines 33-39 (emphasis added). The specification explicitly contrasts the immersion method from other horizontal methods, such as dropping or pouring liquid on the immunosorbing zone. Dade Behring contends the word "alternatively" just refers to methods of immersion and does not contrast immersion by plunging and immersion by the dropwise or pouring method. The Court is not persuaded. The word "alternatively" commences a new paragraph and is being used as a conjunction to signify that the terms connected are to be taken not together but one in place of the other. See Webster's at 63. The specification therefore supports limiting the word "immerse" to dipping the immunoassay into solution.

However, because neither the specification nor the prosecution history 19 provides a special or unique definition for immersion, the Court will adopt the customary and ordinary meaning of immersion. See Vitronics, 90 F.3d at 1582. "Immerse" is defined as "to plunge or to dip into liquid." See Webster's Dictionary at 1130. Thus, as it turns out, the dictionary definition is consistent with the use of "immersion" in the specification.

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19 Although the prosecution history makes clear "the immunosorbing zone can be in a horizontal or vertical position," see D.I. 129, Ex. 11 at 29; see also id. at Ex. 5 at 17, the prosecution history supports the definition supplied in the specification by implication when in distinguishing prior art it states, "the immunosorbing zone of Grubb is not immersed in the sample solution. Rather, Grubb exposes only a small portion of the immunosorbing zone to the sample solution." Hence, the applicants for the '241 Patent specifically distinguished between immersion, which requires the plunging or dipping the whole assay device into solution, and only exposing a small portion of the zone, as in a dropwise method. The prosecution history therefore also supports "immersion" to mean the dipping or plunging into liquid.

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Accordingly the Court construes the Claim language "immunosorbing zone is immersed in said sample solution" as requiring the immunosorbing zone to be plunged or dipped into the sample solution. 20

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20 Dade Behring attempts to point to Biosite's own documents to support its broad construction of "immersed." The Court is at a loss, however, to understand why the accused infringer's documents should be relevant to how claim language in the allegedly infringed patent should be interpreted. Nor does the Court find it proper to rely on a former case construing this claim language, see Syva v. Hybritech, 1989 U.S. Dist. LEXIS 16678, 1989 WL 418546 (S.D.Cal. June 29, 1989), inasmuch as such extrinsic evidence is improper to consider when the intrinsic evidence of the patent record unambiguously and completely defines this term. See Bell & Howell, 132 F.3d at 706.

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E. "impermeable" and "impermeably coated famotidine granules"

Claim 1 recites the following composition:
A solid oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of impermeably coated famotidine granules [and antacids] . . . separated by said impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide.

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Claim 5 recites the following method:
b) coating the granules with a coating impermeable to aluminum hydroxide or magnesium hydroxide to form impermeably coated famotidine granules; c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a compression mixture . . .

(Emphasis added.) According to Plaintiffs, "impermeable" refers to "a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide," and "impermeably coated famotidine granules" means "famotidine granules that are coated with a material that is impermeable to the aluminum hydroxide or magnesium hydroxide." Plaintiffs' construction does not require that the impermeable coating cover the entire surface area of the granules, and instead describes a property of the coating material itself.

Perrigo contends that "impermeable" and "impermeably coated famotidine granules" refer to granules with coating that is "completely impermeable to the antacid and prevents any contact or interaction between any of the famotidine and any of the antacid." According to Perrigo, this construction would include only granules whose surface area is completely coated by the impermeable material.

The plain language of the claim is ambiguous. Some of the claim language focuses on the nature of the coating material. Claim 1 recites "impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide." (Emphasis added.) Likewise, claim 5 recites a method of "coating the granules with a coating impermeable to aluminum hydroxide or magnesium hydroxide." (Emphasis added.) At the same time, claims 1 and 5 each refer to "impermeably coated famotidine granules." This language arguably indicates that not only must the coating material be impermeable, but also that each famotidine granule must be completely encapsulated by the material.

The ambiguity arising from the claim language is resolved by the intrinsic evidence. The specification reveals that the inventors contemplated at least some interaction between the famotidine and the antacids. Famotidine degrades in small amounts even when isolated from the antacids. ('340 Patent, Fig. 5.) According to the specification, combining the "impermeably" coated famotidine with antacid could result in "an additional 1% by weight" degradation. ('340 Patent col. 4, ll. 5-14.) The "additional" degradation is caused by interaction between the famotidine and the antacids. Thus, "[t]he examples in the patents demonstrate that the inventors did not contemplate that each and every particle of [famotidine] must be enclosed perfectly . . ." Astra Aktiebolag v. Andrx Pharms., Inc. (In re Omeprazole Patent Litig.), 222 F. Supp. 2d 423, 461 (S.D.N.Y. 2002) (rejecting a claim construction that would disallow any imperfection in the coating of omeprazole particles).

Perrigo's proposed construction also contradicts the principle that claims be construed in the way that one of ordinary skill in the art would understand them. At the Markman hearing, Plaintiffs asserted, without objection from Defendants, that the coating procedures identified by the parties cannot achieve 100% coating on each famotidine granule. (Tr. at 30, 33-34.) "[O]ne of ordinary skill in the art would understand the terms ['impermable' and 'impermeably coated famotidine'] to include not only the perfect manifestations of these terms, but also objects that are as close to perfection as available technology can reasonably achieve." John Mezzalingua Assocs. v. Arris Int'l, Inc., 2003 U.S. Dist. LEXIS 24730, No. 03 Civ. 353, 2003 WL 23282752, at *7 (W.D. Wisc. Nov. 14, 2003). To require perfectly coated famotidine granules would be "inconsistent with the intrinsic evidence and the real world . . ." Astra Aktiebolag, 222 F. Supp. 2d at 471.

Defendants rely on statements in the examiner's Notice of Allowability to support their position. (Kiel Decl. Ex. 2: Paper No. 39, at 3-4.) There, the examiner required that claim 1 be edited to remove the term "substantially" from the phrase "coating on the famotidine granules which is substantially impermeable to the aluminum hydroxide or magnesium hydroxide." (Kiel Decl. Ex. 2: Paper No. 39, at 2.) Yet, as noted above, the quoted language refers to a property of the coating material, not the extent of coverage on the granule. Therefore, the removal of the word "substantially" is consistent with McNeil's view that only the coating material need be completely impermeable.

Defendants also highlight the examiner's amendment changing the phrase "coated famotidine granules" to "impermeably coated famotidine granules." (Kiel. Decl. Ex. 2: Paper No. 39, at 2.) However, this amendment was adopted to eliminate a potential indefiniteness problem under 35 U.S.C. § 112. As the examiner explained:
The instant claims have been amended to recite an "impermeable coating" or "impermeably coated" granules so that

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inconsistently narrow and broad references in the claims to what is apparently the same coating would be eliminated and a rejection under 35 U.S.C. 112 . . . would thereby be avoided.

(Kiel Decl. Ex. 2: Paper No. 39, at 4.) Prior to the examiner's revision, the claims merely recited "coated famotidine granules" without explaining what material would be used for the coating.

Indeed, the prosecution history--and the Roche declaration in particular-- supports Plaintiffs' construction of the terms. The examiner found the results of the Roche test sufficiently convincing to allow certain of McNeil's original claims. Yet it is undisputed that the coated famotidine in the Roche test experienced approximately 2% degradation, at least part of which resulted from interaction with the antacids. (Kiel Decl., Ex. 2: Paper No. 32, Figs. 4-5; Defendants' Claim Interpretation Brief, dated Feb. 24, 2006, at 9.) In other words, the coating used by Roche could not have precluded all interaction between the famotidine and the antacids because the coated famotidine experienced degradation that could only have been caused by the antacids. Defendants' papers rely heavily on the Roche test, but that test demonstrates that a person of ordinary skill would reject their proposed constructions of "impermeable" and "impermeably coated famotidine granules."

Finally, the sole dictionary definition of "impermeable" provided by the parties is: "not permeable: not permitting passage (as of a fluid) through its substance." Webster's, at 1133. This definition indicates that the word "impermeable" relates to the property of a substance, rather than the application of that substance to a surface.

This Court construes "impermeable" to refer to "a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide," and "impermeably coated famotidine granules" to refer to "famotidine granules that are coated with a material that is impermeable to the aluminum or magnesium hydroxide, using Wurster coating, rotocoating or another coating process acceptable to a person of ordinary skill in the art."
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III. Claim Construction

Defendants request that the Court withdraw its Markman ruling to take into account Defendants' expert testimony on claim interpretation. Yet none of the expert evidence presented on this motion was identified to the Court when the July 27 Order was issued. A motion for reconsideration may not be used "to advance new facts, issues or arguments not previously presented to the court." Bank Leumi Trust Co. of New York v. Istim, Inc., 902 F. Supp. 46, 48 (S.D.N.Y. 1995). Because Defendants cannot point to any evidence that this Court "overlooked" in the July 27 Order, the motion to withdraw this Court's Markman ruling is denied. See Shrader, 70 F.3d at 257; Harris v. Wu-Tang Prods., No. 05 Civ. 3157 (WHP), 2006 U.S. Dist. LEXIS 40527, 2006 WL 1677127, at *2-4 (S.D.N.Y. June 16, 2006); Valentine v. Metro. Life Ins. Co., No. 85 Civ. 3006 (CSH), 2005 U.S. Dist. LEXIS 10352, 2005 WL 1278524, at *2 (S.D.N.Y. May 31, 2005).

Defendants urge this Court to revisit the Markman ruling pursuant to the principle of "rolling claim construction." See Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1345 n.3 (Fed. Cir. 2003); Guttman v. Kopykake Enters., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002). However, rolling claim construction is most often applied when the Court issues "tentative" constructions when "faced with construing highly technical claim language on an expedited basis," such as on a preliminary injunction motion. Oakley, 316 F.3d at 1345 n.3 (quoting Guttman, 302 F.3d at 1361-62); see also Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996). Here, the Court construed the claims after a protracted briefing schedule and a day-long hearing. As one court has noted:

Where there is, as here, an extensive record with a procedure embodying the formality for the claim construction proceedings, it is appropriate to view the standard of review to be used in considering a motion for reconsideration in a stricter manner in consideration of the interests of judicial economy. Having devoted several days to hearings and after reviewing an extensive record, the court issued its opinion on claim construction. This court will, therefore, examine the motion in light of the record and traditional standards of review for motions for reconsideration.

Manders v. McGhan Med. Corp. No. 02 Civ. 1341, 2006 U.S. Dist. LEXIS 57467, 2006 WL 2372136, at *2 (W.D. Pa. Aug. 15, 2006). Moreover, Defendants could have presented expert evidence during the Markman proceedings. They chose not

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to, and offer no principled reason why they deserve a second bite at the apple.

Leaving aside the applicable standard, the expert evidence Defendants now proffer simply repackages arguments previously made by Defendants and rejected by this Court. Regarding the construction of "impermeable" and "impermeably coated famotidine granules," the July 27 Order held that the intrinsic evidence unambiguously permitted some imperfections in the coating of famotidine. The Court therefore rejected Defendants' proposed construction of the terms that would require a coating that "prevents any contact or interaction between any of the famotidine and any of the antacid." McNeil, 443 F.2d at 510. Defendants have identified nothing that contradicts the unambiguous intrinsic evidence. Extrinsic evidence such as Defendants' proposed expert testimony may not be relied on during claim construction when the intrinsic evidence unambiguously defines the disputed claim language. See Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997).

Defendants' purported expert, Metin Celik, offers conclusory testimony about the coating required by the '340 patent's claims. (See Rebuttal Report of Dr. Metin Celik ("Celik Rebuttal") at 9-10). Celik identifies no method that is capable of applying a perfect coating to the famotidine granules. Celik does not even attempt to reconcile the absence of such evidence with the requirement that claims be construed in a way that one of ordinary skill in the art understands them. See Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("[T]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation."); Markman v. Westview Instrs., Inc., 52 F.3d 967, 986 (Fed. Cir. 1995) (In construing claims the courts focus on "what one of ordinary skill in the art at the time of the invention would have understood the term to mean."). Accordingly, the construction of "impermeable" and "impermeably coated famotidine granules" adopted by this Court in the July 27 Order will not be altered.
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6. "so as to elicit an improved antisecretory effect"

The term "so as to elicit" appears in claims 5 and 6. The term "an improved antisecretory effect" appears in claims 5 and 17. Plaintiff contends that "so as to elicit" should be construed to mean "to bring about." Plaintiff further asserts that "an improved antisecretory effect" means "an enhanced ability to decrease gastric acid secretion." DRL, on the other hand, argues that construction of the phrase "so as to elicit an improved antisecretory effect" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: "the observed inherent antisecretory effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl] sulfinyl]-1Hbenzimidazole during treatment of gastric acid related diseases, where the improved antisecretory effect is sufficiently better than that of omeprazole such that it would support a claim of superiority that the FDA would allow in advertising and product literature." For reasons discussed above, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of certain terms within this phrase is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

First, Plaintiff proposed construction for the term "so as to elicit" is "to bring about." As best as the Court can construe from Astra's papers, Astra relies primarily on the dictionary definition of "elicit," which means "to draw forth or bring out." Miriam Webster's Dictionary, 10th ed., 1993 at 374. However, because there is no ambiguity as to the meaning of the phrase "so as to elicit" and because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.

Next is the phrase "an improved antisecretory effect," which Astra contends should be construed as "an enhanced ability to decrease gastric acid secretion." With regard to intrinsic evidence, Astra asserts that both the claim language and the '192 specification support its proposed construction. The Court agrees that a person skilled in the art reading the plain language of the claim would understand that the term "improved" referred to a comparison to omeprazole. This is further supported by the specification. For example, the specification discloses that "[i]n rapid metabolisers the mean AUC at steady state … of the (-)-enantiomer of omeprazole was almost 90% higher than that of omeprazole [which] resulted in a more pronounced

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gastric acid antisecretory effect for the (-)-enantiomer of omeprazole compared to that of omeprazole." '192 patent, col. 5, lines 17-20. The Court, therefore, shall construe the term "an improved antisecretory effect," consistent with Plaintiff's proposed construction, namely, "an enhanced ability to decrease gastric acid secretion."
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B. "Improved Competence"

In its claim construction order, the district court construed the term "improved competence":
The phrase "improved competence" means that the number or quantity of E. coli cells that take up and establish exogenous DNA is generally increased as compared with the number or quantity generally obtained when cells are prepared by either (1) growing the cells at 37 sdegreessC, rendering them competent, and freezing them, or (2) growing the cells at 37 sdegreessC, rendering them competent, and not freezing them.

Claim Construction Order at 10. Invitrogen asserts that the preamble term "improved competence" should not limit the claims because the term simply states an intended advantage. Stratagene counters that while the district court correctly concluded that "improved competence" limits the claims, the district court should have also construed "improved competence" to require at least a ten-fold competence increase and to require that repeated freezing and thawing does not decrease competence.

In the first place, the district court correctly discerned that the preamble in this patent acts as a limitation. The district court reasoned: "In response to the Examiner's rejection, the applicants for the '797 patent amended the claims to include the 'improved competence' language" and "cannot now disavow the claim limitation of 'improved competence' because it was clearly essential for procuring the patent." Id. at 4. This court has stated that "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808-809, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002) (citing Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed. Cir. 2001)).

In an official action dated March 22, 1988, the PTO examiner rejected all claims over D. Hanahan, DNA Cloning (1985) (Hanahan), because "the claims do not require increased competency." In response, the applicants replaced "competent E. coli cells" in the preamble with "E. coli cells of improved competence." The applicants stated "new claim 29 corresponds to canceled claim 1 but has been rewritten to make clear that the process gives E. coli cells of improved competence." The applicants distinguished Hanahan by arguing that the reference "does not teach the preparation of E. coli cells of improved competence" and "the cells produced according to the claimed methods have improved competence." By the amendment and the accompanying statements, the applicants clearly relied on the preamble term "improved competence" to distinguish Hanahan. "Improved competence" thus limits the claims and is not merely a statement of intended advantage. Thus, the district court properly consulted the context of the preamble language, in this case its prosecution history, to note that it operates as a limit on claim scope.

To determine the limiting effect of the language, the district court again correctly consulted the overall context of the language. The test data in the prosecution history and the patent itself show that the claimed process provided varying amounts of increased competence. Therefore, relying on this scientific data, the district court adopted a general definition of the term "improved." The district court properly declined to read into the claim any specific numerical improvement, such as a ten-fold increase in competence. At the outset, the claim language itself includes no specific numerical limitation for the "improved competence." Moreover neither the specification nor the prosecution history supplies any specific improvement measure. Thus "improved competence" requires no specific numerical limitation. This court also finds no basis for construing "improved competence" to require that repeated freezing and thawing does not decrease competence. The district court correctly construed the term "improved competence."
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A. "in a first compartment inactive SAH-hydrolase"

General Atomics suggests that this term be construed to mean "the kit does not contain an active SAH-hydrolase before the kit is used." However, nothing in the claims or specifications requires that the inactive SAH-hydrolase be completely inactive. The Court therefore adopts Axis-Shield's proposed construction, which is, "the contents of a first compartment of the kit includes inactive SAH-hydrolase."
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B. Defendant's New Claim Construction Argument

Now, following Judge Reed's claim construction, in response to Plaintiff's motion for summary judgment, Defendant raises a new issue of claim interpretation, concerning the following phrase within claim 1 of the patent: "a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer." Defendant's new position is that the word "in" should be construed to mean "in and only in." Defendant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ("Def. Brief") at 6. Defendant contends that, under the proper interpretation of "in," the patent is limited to a solution in which an effective amount of the active compound is dissolved in and only in the solubilizer, and in nothing else. 4

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4 Plaintiff asserts that it is too late for Defendant to raise new arguments concerning claim construction. However, because a complete and proper understanding of the patent claims is necessary in order for this Court to determine whether Defendant has infringed those claims, this Court will consider Defendant's new arguments.

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This is significant, Defendant claims, because in Defendant's formulations, the active compound felodipine is "intermixed" with not only PEG 400 (which may or may not function as a solubilizer), but also with one or more additional substances, such as ethanol (a volatile solvent) or polyvinyl pyrrolidone ("povidone" or "PVP"). Id. at 1. Defendant stresses that, in its formulations, the felodipine, the PEG 400, and various other components (i.e. ethanol and PVP) are all mixed together into a "homogenous composition," which is then dried. See id. at 7. Thus, Defendant argues, in its products the felodipine and the PEG 400 "are never intermingled in the absence of another component." Id. Under Defendant's suggested interpretation of the word "in," the '081 patent would cover only formulations in which an "effective amount" of the active compound is entirely dissolved or dispersed in the nonionic solubilizer alone.

Defendant highlights two statements made by the inventor in an amendment filed with the PTO. Defendant claims that these two statements prove the inventor limited its invention to a formulation in which the active compound is entirely dissolved in a solubilizer only, and not in any third substance. See Def. Brief at 6. Both of these statements were apparently made in attempting to distinguish the invention of the '081 patent from the prior art Kawata patent. As explained above, Kawata teaches a "first component" and an optional "second component;" the second component can be, as an example, PEG 400. Though PEG 400 can be used, generally, as a solubilizer, the Kawata patent specifically teaches that solubilizers should not be used. See supra Part III.A.3.

The first statement at issue was made in relation to a May 11, 1988 claim amendment, in response to an initial rejection by the PTO based, in part, on Kawata's prior art. See Def. Brief, Ex. F. The inventor sought to distinguish Kawata by demonstrating that Kawata does not even make use of solubilizers, at least not in any appreciable amount. See id. at 5, lns. 7-11, 19-21. The inventor pointed out, to the PTO, that Kawata teaches against using any "substance improving the solubility in the intestines." Id. (quoting Kawata, United States Patent 4,673,564 (col. 3, lns. 49-52)). Of course, the use of a solubilizer is a major element in the '081 patent. Thus, the inventor argued, Kawata "provides no guidance toward the present invention." See id., lns. 23-24.

The inventor also argued, in the alternative, that even if the second component in Kawata were used as a solubilizer, the active compound would be "principally" dissolved in the first component.

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Only one component of [Kawata's] formulations could be a "nonionic solubilizer" . . . i.e. Kawata's optional 2nd component of the basic substance. Even if the drug in Kawata's formulations can be said to be dissolved or dispersed, however, it is not in the 2nd component alone, but principally in the required 1st component of the basic substance.

Id., Ex. F at 4-5. Defendant wishes to lift this remark out of context, to show that, in order to overcome Kawata, the '081 patent's inventor limited its coverage to solutions in which the active compound is dissolved entirely in the solubilizer, and not also in something else. More specifically, Defendant suggests that because Kawata describes a solution in which an active compound is mingled with several different components (including a volatile solvent), the '081 patent's inventor was compelled to disclaim any solution in which the active compound is not dissolved 100-percent in the solubilizer alone. This Court is satisfied that the inventor made no such disclaimer.

The inventor's remarks to the PTO were seemingly made in the context of distinguishing Kawata as an entirely different process, in that Kawata did not even utilize solubilizers. The inventor set forth an alternative argument that, even if Kawata used solubilizers, the active compound would not be "principally" in the solubilizer. All that the inventor conceded was that, if Kawata contains a solubilizer as its second component, the Kawata active compound is principally dissolved in the first component, not the solubilizer. That is entirely different from a wholesale disclaimer of all solutions in which the active compound is dissolved in both a solubilizer and another substance, such as a volatile solvent. Accordingly, the prosecution history excerpt relied upon by Defendant does not clearly establish that the inventor surrendered coverage "with reasonable clarity and deliberateness," with respect to solutions in which the active compound is not 100-percent dissolved in the solubilizer alone. Schumer, supra, 308 F.3d at 1313.

Defendant cites a second passage from the same claim amendment filed with the PTO, which Defendant claims establishes a disclaimer of "volatile solvents." In the amendment, the inventor asserted that "manufacture of the preparations of the invention does not involve the use of volatile solvents as does Hegasy [another prior art patent]." Def. Brief, Ex. F, at 8, lns. 16-17. This statement, on its face, demonstrates a limited disclaimer, only in that the '081 patent does not incorporate volatile solvents.

The disclaimer of volatile solvents is consistent with Plaintiff's position, throughout the prosecution and throughout this litigation, that the Kawata patent is distinguishable as an entirely different process from the '081 patent. Just as the inventor pointed out to the PTO that Kawata does not use solubilizers, the inventor also pointed out that Kawata utilizes volatile solvents, whereas the '081 patent does not. But the inventor never told the PTO that the '081 patent should exclude all preparations in which a volatile solvent is used at all.

Claim 1's express limitation, "in a semi-solid or liquid nonionic solubilizer" applies to all solutions in which the active compound is dissolved or dispersed in a nonionic solubilizer. The specification and prosecution history do not suggest that a narrower interpretation should apply. Thus, an accused formulation will meet this claim element even though the alleged infringer has also added to the accused formulation some extra ingredients, such as PVP or a volatile solvent like ethanol. Cf. Mannesmann, supra, 793 F.2d at 1283 ("The presence of additional elements is irrelevant if all the claimed elements are present in the accused structure."); A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 702 (Fed. Cir. 1983) ("It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device.").

As noted above, courts interpret claim language with a "heavy presumption" in favor of the "ordinary meaning" of terms. Prima Tek, supra, 318 f.3D 1143, 2003 WL 245558, at *3. Defendant has failed to cite any case law justifying a conclusion that the preposition "in" is synonymous with the phrase "in and only in;" as every college student studying logic knows, they are not considered synonymous.

Defendant cites Key Pharmaceuticals v. Hercon Laboratories Corp., 161 F.3d 709 (Fed. Cir. 1998), in which the Federal Circuit construed the term "pharmaceutically effective amount." However, the Key Pharmaceuticals decision pertains to a patent for a transdermal adhesive patch, not an oral pharmaceutical formulation. After reviewing the facts and analysis in Key Pharmaceuticals, this Court is convinced that that case is totally inapposite to the question before this Court, i.e., whether the '081 patent, which is limited to an "effective amount" of the active compound "in" a solubilizer, can cover only solutions in which the active compound is totally dissolved in the solubilizer alone.

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Likewise, Defendant relies on Hazani v. U.S. Intern. Trade Com'n, 126 F.3d 1473 (Fed. Cir. 1997), in which the court construed the phrase "integrally formed in":

Although the term "integrally formed in" is not defined in the written description portion of the specification, the word "integral" means "complete" or "entire," and the word "in," as used in this context, means "indicating a point or place thought of as spatially surrounded or bounded." See Webster's New International Dictionary 1253, 1290 (2d ed.1939).

Hazani has not given us any reason to depart from the ordinary meaning of those words. Accordingly, the term "integrally formed in," as used in claim 14, requires that the bit line be formed entirely within the substrate.

Id. at 1480. Hazani is irrelevant to the instant case not only because it involved a semiconductor memory cell technology bearing no comparison to the invention of the '081 patent, but also because the Hazani court interpreted the word "in" within the context of the larger phrase "integrally formed in."

In sum, the intrinsic evidence presented to this Court with respect to the '081 patent does not suggest, as Defendant contends, that the word "in" must be read as "in and only in." Def. Brief at 6. Nothing in the patent or prosecution history suggests that the patent can only cover solutions in which the active compound is dissolved in and only in the solubilizer, and in nothing else. Nor does the intrinsic evidence cited by Defendant prove that an accused product can escape infringement simply because it includes a third ingredient (such as ethanol or PVP), intermixed with the active compound and solubilizer.

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The district court held a Markman hearing and issued a Claim Construction Order. In construing two disputed claim n7 terms of the '493 patent, the district court ruled that the term "in a stabilizing amount" in cl aim 1 was not a limitation, but merely described the intended results of using octoxynol 40 in an "amount between 0.001% and 1.0% wt/vol." '493 patent, col. 8, line 55. The claim term makes clear that combining the recited ingredients in the claimed weight to volume ratio will stabilize the compound.

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n7 The district court's conclusion that the claim term "antimicrobially effective" is not a claim limitation is not being appealed.

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Syntex moved for summary judgment of infringement based upon the court's specific claim construction. Apotex did not oppose Syntex's motion. The district court compared the claims of the '493 patent with the drug formulation and uses set forth in Apotex's ANDA 76-109 application and determined that there was no factual dispute. The district court found that the generic version of ACULAR identified in the ANDA 76-109 submission would infringe each claim of the '493 patent, and granted Syntex's motion for partial summary judgment that Apotex had literally infringed each claim of the '493 patent.

After a bench trial on the issues of invalidity and unenforceablity, the district court restated its determination that Apotex's proposed generic version of ACULAR infringed all of the claims of the '493 patent. The district court found that ACULAR is coextensive with the method claims of the '493 patent. The district court also determined that Apotex's proposed generic drug is virtually identical to ACULAR in its composition, preservative system, and intended uses. On the basis of these findings, the district court reiterated that the formulation defined by ANDA 76-109 directly infringed claims 1-6, 8-13, and 15-16 of the '493 patent. The district court further stated that claims 7 and 14 were infringed under the doctrine of equivalents. n8

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n8 Claims 7 and 14, the district court observed, specified a sodium chloride concentration of 0.79. The ANDA formulation contains 0.8 sodium chloride. The court concluded this minor difference would not permit the ANDA formulation to escape

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infringement under the doctrine of equivalents.

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The district court held that the '493 patent was not invalid, rejecting Apotex's invalidity arguments based on obviousness. Moreover, the district court concluded that Syntex had overcome the PTO examiner's obviousness objection by making a showing that the prior art taught away from the use of octoxynol 40 in ophthalmic solutions containing BAC and NSAIDs, and that the use of octoxynol 40 generated unexpected results. The district court also found that the substantial success of ACULAR on the market confirmed that the '493 patent claims were non-obvious. Finally, the district court found no inequitable conduct. The court rejected Apotex's contentions that Syntex had affirmatively misrepresented the unexpected nature of octoxynol 40's ability to stabilize the KT/BAC combination by deliberately withholding test results concerning the ability of octoxynol 12.5 to accomplish the same objectives as the claimed surfactant. The district court found that the test results concerning octoxynol 12.5 were not material, and that Syntex lacked intent to deceive the PTO.

Apotex appeals the district court's claim construction ruling, its judgment of infringement, its non-obviousness determination, and its finding of no inequitable conduct. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Standard of Review

This court reviews de novo the grant of summary judgment. Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1096 (Fed. Cir. 2003). Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). A determination of patent infringement consists of two steps: (1) the court must first interpret the claim, and (2) it must then compare the properly construed claims to the allegedly infringing device. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). Claim construction, the first step, is a matter of law that this court reviews de novo. Id. at 1456. Generally, the second step is a factual question that we review for clear error. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). However, factual inferences that are material to the grant of a summary judgment are not accorded such deference-they are reviewed to ascertain whet her there is a genuine issue of material fact. Lemelson v. TRW, Inc., 760 F.2d 1254, 1260 (Fed. Cir. 1985).

This court reviews for clear error the district court's determination of the factual inquiries underlying obviousness, while it reviews de novo the legal conclusion that a claim is invalid as obvious. McNeil-PPC, Inc. v. L. Perrigo Co., 337 F.3d 1362, 1368 (Fed. Cir. 2003), cert. denied, 540 U.S. 1107, 157 L. Ed. 2d 893, 124 S. Ct. 1068 (2004). The factual determinations relevant to the obviousness inquiry include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations, if any, such as commercial success, unexpected results, copying, long-felt but unresolved need, and the failure of others to develop the invention. Graham v. John Deere Co., 383 U.S. 1, 17-18, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966). "What the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references are questions of fact." In re Fulton, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004).

A finding of inequitable conduct is committed to the trial judge's discretion and is reviewed under an abuse of discretion standard. Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988). "To overturn such a determination, the appellant must establish that the ruling is based on clearly erroneous findings of fact or on a misapplication or misinterpretation of applicable law, or evidences a clear error of judgment on the part of the district court." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995) (citing Kings down Medical Consultants, 863 F.2d at 876. Findings of materiality and intent are factual findings subject to the clearly erroneous standard and, therefore, will not be disturbed on appeal unless this court has a definite and firm conviction that a mistake has been committed. Id.

B. Claim Construction

Apotex challenges the district court's claim construction on the ground that the term "in a stabilizing amount" should properly be read as a claim limitation. We agree with the district court that the term "in a stabilizing amount" simply describes the intended result of using the weight to volume ratios recited in the claims. Accordingly, we conclude that the

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district court correctly construed the disputed term of the '493 patent and correctly determined that Apotex's proposed generic version of ACULAR would infringe all of the claims of the '493 patent. We now turn to Apotex's assertions of invalidity and unenforceability.
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2. "In an aqueous hydrogen peroxide solution having a water content of at least 25%"

Again, the court begins with the plain language of the claim. The terms in the phrase themselves are self-explanatory. Aqueous means "of, relating to, or resembling water." WEBSTER'S COLLEGIATE DICTIONARY 58 (10th Ed. 1999). "Hydrogen peroxide" is the name of a particular chemical compound having the structure H2O2 Id. at 568. In this context, "solution" means "a homogenous mixture formed" when "a solid, liquid or gaseous substance is homogeneously mixed with a liquid or sometimes a gas or solid." Id. at 1119. The question for the court is the meaning of these terms when read as a part of the entirety of Claim 1 and, in particular, how these terms relate to the remainder of this phrase "having a water content of at least 25%."

Reilly argues that the entire phrase requires that the PVP oxidation reaction must take place with the ingredients, including hydrogen peroxide, water, and PVP, in an aqueous solution state. Reilly Response Br., p. 13. BASF, on the other hand, contends that the phrase does not require that the oxidation reaction take place in a solution, but rather that the oxidation of the PVPs in the "mixture" of contents in the reaction vessel, which may be in [redacted], or solution state, take place using a solution of hydrogen peroxide. Plaintiff BASF AG's Memorandum in Opposition to Reilly's Motion for Summary Judgment of Non-Infringement ("BASF's Opposition"), p. 28. Thus, the dispute about this phrase centers upon what the patentee claimed in Claim 1 with regard to the state of matter in the reaction vessel at the time of the oxidation reaction.

Because the meaning of this phrase is not apparent on the face of the claim, the court must look at the specification and prosecution history to properly construe it. In the specification of the 684 patent, the inventor described the "aqueous hydrogen peroxide solutions used in the process according to the invention" as having a particular hydrogen peroxide concentration. 684 Patent, Col. 2, 11. 4-7. In this discussion, however, there is no reference to water content in the hydrogen peroxide solution. Thus, while this may be the most logical reading of the actual words of Claim 1, nothing in the specification suggests that it is the hydrogen peroxide solution which is required to contain at least 25% water.

In addition, BASF specifically denies that the water requirement refers to the hydrogen peroxide solution. Plaintiff BASF's Reply Paper in Support of Its Motion for Summary Judgment and in Opposition to Reilly's Motion for Summary Judgment of Noninfringement, p. 10. Instead, it points to the specification's explicit statement that the water content requirement refers to the "water content in the reaction mixture at the start of the oxidation," 684 Patent, Col. 2, 11. 43-48, and argues that as a result it is impossible to read the patent as requiring a certain water content in anything other than the mixture in the reaction vessel at the beginning of the reaction.

The "reaction mixture," as referenced repeatedly throughout the specification, is the patentee's description of the entire contents of the reaction vessel at the time of the oxidation process. See e.g., id., Col. 6, 11. 26-29 ("The process of claim 1, wherein said oxidation is conducted at a temperature from 20 [degree] to 140 [degree] and the polymer concentration in the reaction mixture ranges from 5 to 70% by weight."); Col. 2, 11. 43-46 ("The oxidation of the polyvinylpyridine in the process according to the invention preferably takes place with a water content in the reaction mixture at the start. . . ."); Col. 3, 11. 43-44 ("The polymer concentration in the reaction mixture can be 5 to 70%. . . ."). The word "mixture," however, is a vague term that could be used to refer to many states of matter including a solution, [redacted]. Dubin Dep., p. 126, 1. 19 -- p. 130, 1. 2. Thus, proper scientific understanding may certainly suggest a difference between the hydrogen peroxide solution, 684 Patent, Col. 2, 11. 4-7, and the "reaction mixture," 684 Patent, Col. 2, 11. 43-46, as those terms are used throughout the specification. See also Dubin Dep., p. 126, 1. 22 -- p. 127, 1. 9. The use of the term "mixture," however, is sufficiently imprecise that it does not answer the questions the parties raise regarding the exact state of the matter in the reaction vessel at the time of the oxidation reaction, whether [redacted] or solution, and the court must look elsewhere to resolve this issue. 5

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5 Reilly also argues that the question is resolved because the examples in the 684 patent each include starting with PVP in an aqueous solution. As stated above, however, the Federal Circuit strongly warns courts to avoid reading limitations from the specification into the claims of the patent based solely on the specific examples disclosed. See Texas Digital Systems, Inc., 308 F.3d at 1205. Thus, even if the examples were limited to depicting only situations in which the PVPs were dissolved into a solution, the court will not use this as evidence that the claim is also so limited.

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The court next turns to the patent's prosecution history. After the PTO rejected the original application covering this invention as unpatentable over prior patents, BASF filed an amendment to its application that included changes to the rejected claims as well as clarifying remarks. Prosecution History, p. BASF 0916-23. As stated previously, one of the changes BASF made from the original rejected claims was to change the wording of Claim 1 from stating that the oxidation reaction must be done "with aqueous solutions of hydrogen peroxide" to read that the process must be done "in an aqueous solution of hydrogen peroxide." Id., p. BASF 0872 and BASF 0916 (emphasis added). Reilly argues that this change clearly demonstrates the patentee's intention that the reaction take place in the solution rather than simply with the solution present as the original claim suggested. BASF contends, on the other hand, that these terms are instead interchangeable because they have the same meaning. The importance of this alteration when examined alone, removed from the rest of the comments in the amendment, is ambiguous to the court and thus the court cannot not end its consideration of the patent's prosecution history here.

Beyond this change in actual claim language, as a part of the effort to overcome the PTO's obviousness rejection, the patentee included a section of remarks further explaining the invention and detailing the reasons that it is not obvious in light of prior patents. The patentee begins his remarks by noting that "there are two embodiments to the process, the first which involves the oxidation of polyvinylpyridines in the aqueous hydrogen peroxide acid solution, wherein the amount of water in the solution is 25%." Prosecution History, p. BASF 0919 (emphasis added). As the court has previously found and BASF has admitted, the specification explicitly tells the reader that 25% refers to the water content in the "mixture" present in the reaction vessel at the beginning of the oxidation reaction and not simply to the hydrogen peroxide solution alone. See 684 Patent, Col. 2, 11. 43-48. Clearly then, from a plain meaning of the patentee's remarks to the PTO, there are two solutions present -- the first, a hydrogen peroxide solution, and the second, one in which the water content is 25%. Thus, it appears to the court that BASF stated to the PTO that the mixture in the reaction vessel at the time the oxidation process begins is in fact a solution in which the water content is 25%.

Once BASF made this statement, all other remarks must be read in light of this fact. Consequently, when, as BASF points out, the patentee states that the invention is "an oxidation reaction which occurs in an aqueous medium with hydrogen peroxide," the reader, the court or the PTO, understands this to mean that the oxidation reaction occurs in an aqueous solution with hydrogen peroxide. Prosecution History, p. BASF 0920 (emphasis added). In addition, when the patentee explains that this invention is different from the prior patent because the claims here require "oxidation occurring in an acidic medium with hydrogen peroxide" and that the "aqueous medium must contain at least 25% water," the reader again understands that this invention, unlike that disclosed in the prior patent, requires a solution in the reaction vessel that includes at least 25% water by weight and hydrogen peroxide as well as the PVPs to be oxidized. Id., p. BASF 0921.

For these reasons, the court concludes that although the meaning of the phrase "in an aqueous hydrogen peroxide solution having a water content of at least 25%" is not clear on the face of the plain language of the claim, or by viewing the specification alone, the reader may determine the meaning by viewing the language and specification in combination with the prosecution history. Therefore, the court finds that the phrase means that the reaction vessel, at the beginning of the oxidation reaction, contains a solution that includes PVPs, at least 25% water by weight, and hydrogen peroxide.
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The ordinary meaning of "reducing NF- [kappa] B activity in cells" is unclear. The phrase cannot simply reflect that the NF- [kappa] B activity must occur within cells because this would be redundant. There is no dispute NF- [kappa] B activity can occur only within cells, and this limit is already included in the claim construction of "NF- [kappa] B activity." Amgen, 577 F. Supp. 2d at 727. As Amgen argues, "reducing NF- [kappa] B activity in cells" could mean that the reducing act must occur within the cell. But as Ariad suggests, it could also mean simply that the method must be performed on cells in which

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NF- [kappa] B is present, without regard to the situs of the reducing agent.

The specification of the '516 patent divides external influences (e.g., TNF- [alpha]) and intracellular transducers (e.g., NF- [kappa] B). That division is at the cell membrane, and the claim language "reducing NF- [kappa] B activity in cells" is consistent with this division. The specification repeatedly frames NF- [kappa] B as an intracellular transducer of external influences:

As a result of this finding, it is now possible to alter or modify the activity of NF- [kappa] B as an intracellular messenger and, as a result, to alter or modify the effect of a variety of external influences, referred to as inducing substances, whose messages are transduced within cells through NF- [kappa] B activity. Alteration or modification, whether to enhance or reduce NF- [kappa] B activity or to change its binding activity (e.g., affinity, specificity), is referred to herein as regulation of NF-KB activity. The present invention relates to a method of regulating or influencing transduction, by NF- [kappa] B, of extracellular signals into specific patterns of gene expression and, thus, of regulating NF- [kappa] B-mediated gene expression in the cells and systems in which it occurs.

In particular, the present invention relates to a method of regulating (enhancing or diminishing) the activity of NF- [kappa] B in cells in which it is present and capable of acting as an intracellular messenger, as well as to substances or composition useful in such a method.

'516 patent col.3 l.59 -- col.4 l.9. For example, TNF- [alpha] is an "inducing substance" because its "messages are transduced within cells through NF- [kappa] B activity." Decoy molecules are designed to "alter or modify the activity of NF- [kappa] B as an intracellular messenger" by binding active NF- [kappa] B and preventing it from inducing DNA expression. Consequently, the administration of decoy molecules would "alter or modify the effect of" TNF- [alpha] by blocking, within the cell, the signal that was initiated by TNF- [alpha] at the receptor on the surface of the cell.

Thus, the specification assumes the existence of an external influence whose effect can be modified by acting within the cell. In contrast, Enbrel acts to stop the external influence (TNF- [alpha]) from reaching the cell. Enbrel does not "alter or modify the activity of NF- [kappa] B as an intracellular messenger and, as a result, . . . alter or modify the effect of a variety of external influences." Rather, it directly blocks one of the "variety of external influences." While the specification proposes several agents that act within the cell to reduce NF- [kappa] B activity, there is no mention whatsoever of agents that act outside the cell to reduce NF- [kappa] B activity.

In its arguments made to the PTO during reexamination of the '516 patent, Ariad further reinforced the division between actions taken inside and outside of the cells:

Broadly speaking, there are the two types of methods to obtain a cell exhibiting reduced NF- [kappa] B activity [which are] as follows: (a) reducing the induced NF- [kappa] B activity by intervening in the signaling pathway by which NF- [kappa] B activity is manifested including particularly intervening intracellularly at a specific segment within the signaling pathway; and (b) preventing the external inducing stimuli from inducing the intracellular signaling pathway through which NF- [kappa] B activity is manifested. Certain claims of the '516 patent as issued covered both types of methods. However, as discussed further in this response applicants maintain that the rejected claims now pending [which include claims 6, 18, 70-72 and 183-184] are directed only to type (a) above.

The category (a) methods described above indisputably include decoy molecules and the other examples in the specification because those agents "interven[e] intracellularly." And the category (b) methods indisputably include antibiotics because they "prevent[] the external inducing stimuli from inducing" NF- [kappa] B activity. Enbrel, which acts outside the cell, and acts by blocking the external inducing stimuli from reaching the cell, would seem a far better fit in category (b) than category (a). Ariad's difficulty in making its argument to the PTO, and in this case, is that it lacks a basis in the specification to distinguish Enbrel from antibiotics. Rather, the patent creates a category of "external influences" that are simply the backdrop for the invention, and Enbrel and antibiotics impact only this category. Ariad argues that the "signaling pathway" should include the event of TNF- [alpha] binding to the receptor on the outside of the cell, and as such Enbrel should fit into category (a). But again, there is nothing whatsoever in the specification to support this view--not even a single mention of an NF- [kappa] B signaling pathway.

Although the ordinary meaning of the term "reducing NF- [kappa] B activity in cells" admits alternative views, the

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specification and prosecution history unequivocally point to the conclusion that the term limits the asserted claims to methods wherein the action that reduces NF- [kappa] B activity is taken inside the cell. As such, we conclude that "reducing NF- [kappa] B activity in cells" means "taking action inside cells to inhibit (interfere or block) an NF- [kappa] B activity." We therefore affirm the summary judgment of noninfringement. Ariad also appealed the construction of numerous other claim terms, but the parties agree that none of these has any impact on the summary judgment of noninfringement on appeal. Therefore, we decline to reach them.
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C. "in contact with"

Claim 1 recites a tablet with:
said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by said impermeable coating on the famotidine granules . . .

(Emphasis added.) Plaintiffs urge this Court to construe "in contact with" to mean "a union or junction of body surfaces, a touching or meeting," which would be broad enough to encompass both a one-layer and a two-layer embodiment. Defendants propose the following construction: "The coated famotidine granules and the magnesium or aluminum hydroxide have been mixed together and then pressed together in a solid oral dosage form, such that a therapeutically effective amount of the famotidine and magnesium or aluminum hydroxide are in contact with each other in the solid oral dosage form." According to Defendants, this definition would cover only a one-layer tablet because the full therapeutically effective amount of the famotidine granules would not be in contact with the antacid inside a two-layer tablet.

Only Plaintiffs' proposed construction is consistent with this Court's construction of the terms "mixing" and "compression mixture." Indeed, the evidence from the specification and prosecution history discussed above supports McNeil's construction of "in contact with." Defendants argue that a 1998 revision to the claims compels a narrower construction. When the examiner rejected several of McNeil's proposed claims following the submission of the Roche declaration, McNeil amended the claims further to recite for all composition claims:
1. [A] therapeutically effective amount of coated famotidine granules suitable for the treatment of gastric disorders and pharmacologically acceptable acid addition salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide . . . [and]

2. Wherein the oral dosage form has the coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by the coating on the famotidine granules which is substantially impermeable to the aluminum hydroxide or magnesium hydroxide.

(Kiel Decl. Ex. 2: Paper No. 37, at 1-2 (emphasis added).) The examiner required the highlighted word "the" in the quoted claim proposal to be replaced with the word "said." (Kiel Decl. Ex. 2: Paper No. 39, at 2.) As issued, the '340 patent recites:

1. [A] therapeutically effective amount of impermeably coated famotidine granules for the treatment of gastric disorders and pharmacologically acceptable salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide . . .

2. Wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by said impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide.

(Emphasis added.) Because "said" coated famotidine granules refer to "a therapeutically effective amount of famotidine granules," Defendants claim that the examiner required a therapeutically effective number of famotidine granules to be in contact with the antacids. According to Defendants, this can only be achieved in a single-layer tablet.

The prosecution history does not support Perrigo's contentions. When the proposed claim recited "the coated famotidine granules," the word "the" clearly referred to the previous recital of "therapeutically effective amount of coated famotidine." The language required by the examiner--"said coated famotidine granules"--makes precisely the same reference back to the

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"therapeutically effective" language. The amendment, therefore, did not affect the meaning of the proposed claims. Indeed, the examiner explicitly regarded the amendment as a "matter[] relating only to the form of the claims and not the substance . . ." (Kiel Decl. Ex. 2: Paper Nos. 38-39.)

Regardless, Defendants implicitly argue that unless the claims require only "some of the coated famotidine granules" to be in contact with the aluminum or magnesium hydroxide, every granule of therapeutically effective famotidine must touch the antacid. This argument is unavailing. The amended language ("said coated famotidine granules") could refer to a singular group of therapeutically effective famotidine granules, requiring only some portion of that group to be in contact with the antacids. This Court cannot conclude that McNeil "clearly and unambiguously" disclaimed the two-layer coated granule embodiment. Sandisk, 415 F.3d at 1287.

Finally, the dictionary definition of "contact" undisputedly supports McNeil's construction. Webster's defines "contact" as a "union or junction of body surfaces: a touching or meeting." Webster's, at 490. In a two-layer coated granule tablet, the coated famotidine granules and the aluminum hydroxide or magnesium hydroxide are in contact when they touch or meet at the interface of the layers. Defendants offer no competing definition from a dictionary, treatise or encyclopedia. In light of the above, this Court construes the term "in contact with" in claim 1 to mean "a union or junction of body surfaces, a touching or meeting."

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Here, to determine the scope and meaning of the '953 patent, the Court first analyzes the intrinsic evidence in the record. The parties agree that the person of ordinary skill in the field to which the '953 patent is directed would have a doctorate degree in chemistry, pharmaceutics, pharmacy, or pharmaceutical science and some industry or postgraduate experience, or would have a lesser academic degree and a longer period of experience. V2-100:10-14; V9-59:16-24; V7-104:17-105:9; see also V9-59:16-60:1. Claim 1 of the '953 patent recites: "The compound 2-(2-amino-1,6-dihydro-6-oxo-purin-9-yl)methoxy-3-hydroxy-1-propanyl-L-valinate hydrochloride in crystalline form." DTX-1, col. 30, ll. 42-44. The parties further agree for purposes of this case that the chemical name refers to valganciclovir HCl, and the Court agrees that claim 1 unambiguously means the compound valganciclovir HCl. 42 SF-21. As discussed herein, the parties disagree as to the meaning of only one claim term: the requirement that the compound be "in crystalline form."

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42 Dependent claim 2 of the '953 patent reads: "An antiviral pharmaceutical composition comprising the compound of claim 1 and a pharmaceutically acceptable excipient." When claim 2 recites "the compound of claim 1," it is referring to valganciclovir HCl in crystalline form, as defined in claim 1. There is no dispute that an "excipient" is a "substance[] other than the active ingredient that. . . [can be] added to the formulation in manufacturing the drug." Warner-Lambert Co. v. Teva Pharms. USA, 418 F.3d 1326, 1330 n. 1 (Fed. Cir. 2005). "'Pharmaceutically acceptable' means generally safe and non-toxic and . . . acceptable for . . . human pharmaceutical use." PTX-1, col. 10, ll. 1-4. The word "comprising" is a term of art which means that the claim does not exclude additional, unrecited elements. Accordingly, claim 2 requires the presence of valganciclovir HCl in crystalline form and a pharmaceutically acceptable excipient, but does not exclude the presence of other materials, such as amorphous valganciclovir HCl.

Dependent claims 3, 4, 5, and 6 of the '953 patent are directed to methods of treating an "animal" infected with a virus by administering a therapeutically effective amount of "the compound of Claim 1," i.e., valganciclovir HCl in crystalline form. The term "animal" in claim 3 includes humans. PTX-1, col. 10, ll. 63-65. The other terms in claims 3-6 do not require separate analysis. In claim 4, the reference to "the method of claim 2" is an obvious typographical error. In Hoffer v. Microsoft Corp., 405 F.3d 1326, 1331 (Fed Cir. 2005), the court found that a district court can correct a harmless obvious error in a patent when it is not subject to reasonable debate, as it may for other legal documents. In this case, claim 4 is referring back to a method claim. Claim 2, however, is not a method claim, and claim 3 is the only method claim that appears prior to claim 4. Therefore, it is obvious that claim 4 was intended to recite "the method of claim 3." V3-51:14-16, 52:8-54:14. Accordingly, the Court corrects this typographical error to reflect "the method of claim 3" in claim 4. None of these claims, however, are in dispute nor do they help the Court in determining the validity or scope of claim 1 of the '953 patent.

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Claim 1 of the '953 patent is a "product" or "composition of matter" claim. RoCL 2. Such claims define the claimed subject matter solely in terms of its structure or other physical characteristics. Id. Claim 1 is directed to a chemical compound per se and not a method of manufacturing such a compound. SF-21; V2-108:11-21; V7-182:7-184:18; PTX-1; DTX-8 at 171. The language "in crystalline form" means that the valganciclovir HCl molecules are arranged in a regularly repeating three dimensional pattern. RoCL 3; V2-80:2-8; V6-25:12-17. According to Roche, claim 1 means "nothing more nothing less" than this construction. RoCL 3. This definition, however, does not indicate whether in crystalline form means the presence of a single crystal or something more.

The Court must determine what "in crystalline form" in claim 1 of the patent-in-suit encompasses. In SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1339-41 (Fed. Cir. 2005), the Federal Circuit determined that the claim, which contained the four words "crystalline paroxetine hydrochloride hemihydrate," unambiguously described a specific product -- the structural compound of the single crystal of hemihydrate. Id. at 1339. This differs from the instant claim because that compound could not be produced without the presence of at least one single crystal. Id. at 1346. In this case, there is no dispute that amorphous valganciclovir HCl exists, 43 and that it can be produced without the presence of a single crystal.

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43 Roche concedes that the amorphous form does not infringe. See RoCL 6.

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While the compound within claim 1 of the '953 patent unambiguously refers to alganciclovir HCl, the requirement that the compound be "in crystalline form" is ambiguous. Specifically, the Court cannot discern from the plain language of claim 1 whether it encompasses pure crystalline valganciclovir HCl or other semi-amorphous forms containing partially ordered solids. While the claims themselves do not provide any insight into the meaning of "in crystalline form," the written description does provide some guidance. The '953 patent states that:

The compound of the invention can be, and has been, produced in crystalline form. This is a decisive advantage over the compounds disclosed in the prior art which have been described as non-crystalline materials. The advantage resides in the fact that pharmaceutical formulations can be more easily produced with a crystalline material. A crystalline material can be processed efficiently and is susceptible of being more reproducibly characterized than a non-crystalline material, and the quality of the crystalline materials of the invention can be much more readily ascertained than that of non-crystalline materials.

DTX-1, col. 21, ll. 21-31. Therefore, in its patent, Roche describes that the HCl and acetate salts of valganciclovir "can be prepared as crystalline materials and therefore can be easily manufactured into stable oral formulations." DTX-1, col. 15, ll. 7-9. On the other hand, the patent explains that prior art compounds were "non-crystalline materials which are difficult to process for the manufacture of oral pharmaceutical dosage forms." Id., col. 3, ll. 32-34; V6-70:6-25. The patent itself equates in crystalline form with crystalline material, and distinguishes crystalline from noncrystalline material based upon the relative ease with which crystalline material permits a formulation chemist to make a stable oral dosage form. While the manufacturing or storage advantages of crystalline material should not be read into the patent's claims, the stability of the compound in crystalline form helps to inform the Court of the properties of what Roche meant and the PTO understood claim 1 of the proposed patent to encompass.

The prosecution history provides further insight into the meaning of the terms. Roche's March 1996 Preformulation Book stated that "[t]here are two crystalline forms (X and Y) and two metastable forms (A and B) of the racemic mixture of the diastereomers of [valganciclovir HCl]." DTX-589 at 9; V6-38:13-39:20; V3-65:18-66:2. 44 Roche contrasted the two crystalline forms of valganciclovir HCl, Forms X and Y, with the two metastable forms of valganciclovir HCl, Forms A and B. V6-38:25-39:7, 46:1-9; V3-66:22-25. Roche determined that the metastable forms, A and B, were unstable, semi-amorphous materials that converted to crystalline, Form X, under certain conditions. DTX-589 at 15, 26; DTX-104 at 16. In its 2000 NDA submission to the FDA for Valcyte, Roche stated that "[t]here are two crystalline forms of valganciclovir HCl (termed X and Y) and an amorphous form" and that "[n]o crystalline forms other than form X and Y have been observed." DTX-659 at 1. After it obtained the '953 patent, Roche essentially re-characterized Forms A and B as merely amorphous

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material containing low amounts of crystalline material. Id. at 1-2. However, at the time it applied for the '953 patent, Roche believed that Forms A and B were neither crystalline nor stable, but amorphous and converted to crystalline under certain conditions. DTX-589 at 15, 26.

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44 Ranbaxy asserts, and Roche does not dispute, that Roche submitted its Preformulation Book to the PTO during the '953 patent prosecution. RaFF 13.

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Prior to the issuance of the '953 patent, Roche had tried to obtain a patent over the valganciclovir HCl compound. Roche did not distinguish between the crystalline and noncrystalline forms in that attempt. The patent examiner rejected Roche's proposed patent based, inter alia, on the fact that it was anticipated by the '339 patent and obvious in light of this prior art. DTX-8 at 170-71. In the '339 patent, Beauchamp taught a genus of compounds, which would make the existence of valganciclovir HCl obvious to one of ordinary skill in the art. Id. Thus, the claim of valganciclovir HCl without any limitations is overly broad because it covers "both crystalline and non-crystalline" forms of the compound, which would result in double-patenting. Id. at 174. However, after Roche limited its application to valganciclovir HCl in crystalline form, the PTO allowed the patent based on the fact that the prior art did not specify the "crystalline form" of valganciclovir HCl, and such a distinction should not be read into the patent. The PTO issued the '953 patent based on the inventors' representations that the crystalline form was not naturally occurring nor easily produced "without undue effort, if at all." Id. at 181-83, 215. Thus, the PTO determined that crystallinity was not obvious or anticipated by the '339 patent or the prior art.

The importance of these determinations is that (i) Roche and the PTO were aware of at least two different forms of valganciclovir HCl, amorphous and crystalline, when Roche sought the '953 patent, (ii) Roche knew that the stability of valganciclovir HCl varied based on which form the compound was in, and argued that the stable crystalline forms were not obvious and required undue experimentation, and thus, (iii) the '953 patent only covered valganciclovir HCl in crystalline form, the known crystalline Forms X and Y. In fact, Roche does not assert that the amorphous form of the compound spontaneously converts to the crystalline form nor does Roche contend that the only natural state of the compound is the crystalline form. Indeed, Roche cannot make these arguments because such positions would contradict the inventors' assertions that producing this form was difficult, and thus, that the crystalline form was not obvious nor expected. Further, such an argument or claim construction would provide a patent over the entire valgancyclovir HCl compound, which the PTO already rejected. Therefore, the Court construes claim 1 to include only the stable, crystalline forms of the compound valganciclovir HCl. See E.I. Du Pont de Nemours, 849 F.2d at 1433 (finding that a court can only interpret claims).

Roche argues that the patent also covers the crystalline material found in a mixture with amorphous or semi-amorphous forms of the valganciclovir HCl compound. The Court agrees. While the '953 patent does not refer to trace amounts of crystalline material in an otherwise noncrystalline material, V3-74:21-75:1; V6-71:4-7, a person of ordinary skill in the field may understand valganciclovir HCl "in crystalline form" to mean even a single crystal. But this does not mean that other possible semi-amorphous forms are necessarily covered by the patent. In its submission to the PTO, Roche admitted that there were other noncrystalline forms of valganciclovir HCl, which the '953 patent excludes. See RoCL 6. Roche even defined Form A as semi-amorphous and unstable, and excluded it from the known crystalline forms mentioned in the patent prosecution history and its Preformulation Book. DTX-104 at 16; see also DTX-659 at 1-2. It is clear that the nonobviousness of the crystallinity of valganciclovir HCl was the basis for the '953 patent's issuance. DTX-8 at 178-88, 214-15. The language in the '953 patent indicates that the claimed compound is more stable than its noncrystalline counterpart. DTX-1, col. 21, ll. 21-31. The patent specifically excluded those unstable forms that were noncrystalline; based upon Roche's own representation at the time, this would necessarily exclude Forms A and B. DTX-8 at 168-74, 214-15. Therefore, while the Court agrees with Roche that a mixture containing any amount of detectable crystalline material (namely Forms X and Y) is covered by the '953 patent, the Court also finds that other possible semi-amorphous forms of valganciclovir HCl may exist, but are noncrystalline and not covered by the patent. See E.I. Du Pont de Nemours, 849 F.2d at 1433 (finding that the court cannot broaden nor narrow claims to give the patentee something different than what it has set forth). Thus, the Court finds that the patent language and prosecution history lead to a claim construction that "in crystalline form" covers only the stable, crystalline forms of valganciclovir HCl, Forms X and Y, whether as a pure crystalline solid or in a mixture with other amorphous forms, but any other forms of valganciclovir HCl, specifically amorphous and other possible semi-amorphous forms of valganciclovir HCl, are not covered by the patent.

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The parties further dispute how to determine whether a product is "in crystalline form:" whether the valganciclovir HCl is in crystalline form X or Y or in other possible semi-amorphous forms. In this case, Roche offers XRD testing to prove crystallinity. The parties do not dispute that the '953 patent never refers to XRD, never identifies XRD as the sole technique for determining whether a material is crystalline, nor does it provide an XRD pattern or "fingerprint" to assist in determining which XRD feature, if any, might indicate the presence of valganciclovir HCl in crystalline form. DTX-1; V3-72:21-78:9; V6-71:1-3. Accordingly, the patent never suggests that XRD would be necessary to detect valganciclovir HCl in crystalline form

Ranbaxy argues that the patent points to crystalline material's handling properties, not its XRD pattern, and the prosecution history reveals that those properties would have been apparent to a medicinal or formulation chemist without resort to a more sensitive XRD analysis. The Court disagrees. While the stability of the compound is a characteristic of the defined form, even Drs. Rogers and Cockcroft admitted that XRD is a standard technique for detecting material in crystalline form. Further, the evidence establishes that the person of ordinary skill at the time the patent was issued would know that the best way to identify whether a sample is "in crystalline form" is to subject it to XRD, and that such a person would send the sample to an analytical lab for such testing, which in fact is what the '953 inventors did. See Part II.G.4., supra. Indeed, Ranbaxy's scientists do the same. See Id. Thus, the Court finds that XRD testing is an appropriate way to determine whether a given sample is valganciclovir HCl "in crystalline form." 45

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45 Relying on the distinctions between crystalline and noncrystalline materials, as emphasized in the '953 patent and its prosecution history, Ranbaxy contends that "in crystalline form" means exhibiting the properties of a crystalline material, specifically defined by the multi-peaked fingerprint and the stability of the compound. V6-67:1-70:25. Roche contends that "in crystalline form" means crystalline as determined by the presence of at least a single peak in an XRD pattern. V2-103:21-104:2, 104:13-22. Because, however, the patent is silent with regard to the XRD pattern for valganciclovir HCl "in crystalline form," it is not part of the claim construction. Rather, the XRD pattern is more appropriately analyzed under the infringement analysis. See Part III.B.1., infra.

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3. "In Genetic Linkage"

GTG proposes that the term "in genetic linkage" be construed as "a tendency of DNA sequences on the same chromosome to be linked together," and Applera proposes "DNA sequences that are on the same chromosome and are inherited together." Both parties agree that the dictionary definition of the term "genetic linkage" requires only a tendency for traits to be inherited together. However, Applera claims that prosecution history estoppel limits the breadth of the claims.

Prosecution history estoppel only occurs when a patentee clearly and unmistakably disavows the breadth of a claim. See, e.g., Omega Eng'g Inc. v. Raytek Corp., 334 F.3d 1314, 1326 (Fed. Cir. 2003). While the statement that "DNA sequences which are in genetic linkage are regions of genomic DNA that are inherited together" in the prosecution history could potentially be read as stating that 100% certainty of linkage is necessary, see Applera Exh. L at 5, that reading does not demonstrate the necessary "clear and unmistakable surrender" of subject matter for that reading of the prosecution history to apply. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1359 (Fed. Cir. 2003), cert. denied, 540 U.S. 1213, 124 S. Ct. 1426, 158 L. Ed. 2d 141 (2004).

Furthermore, the next sentence of that section of the prosecution history reaffirms that "[s]ince the meaning of the term 'genetic linkage' is well known in the art and is used in the specification and claims in a manner consistent with that definition, the meaning of the claims is clear." Applera Exh. L. at 5. On this record, Applera cannot show "clear and unmistakable" intent to require 100% certainty of linkage beyond the dictionary definition of the term.

The court thus adopts GTG's definition, and construes the term "in genetic linkage" as: a tendency of DNA sequences on the

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same chromosome to be linked together.
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"In need thereof" and "in need of"

These terms appear in several claims from all the patents-in-suit. Nutrition 21 proposes a consistent construction of the terms: "if a person administers CP, s/he is in need of CP." GNC's proposed constructions are particular to the claims in which the terms appear and are worded in reference to the methods articulated in those claims. For Claims 1 and 7 of the '623 Patent, GNC proposes construing "in need thereof" to mean "one who knows that he/she has a need to reduce hyperglycemia and stabilize serum glucose." For the '624 Patent, GNC proposes the construction "one who knows he/she has a need to increase lean body mass." For the '156 Patent, GNC proposes the construction "one who knows he/she has a need to treat undesirable high levels of blood serum lipids." For each of the patents, the parties' dispute centers on the type of knowledge one must have, or the determination that must be made, before CP is administered. However, both parties' proposed constructions are deficient.

During prosecution, the patent examiner rejected several of the inventors' original claims under 35 U.S.C. § 112, P 1 and required the addition of "in need of" and "in need thereof." Nutrition 21 notes that after the inventors' claim amendments, "the Examiner ultimately conceded the term 'in need' to cover both a 'subjective need' and an 'objective need' of a person taking CP, which is the position the inventors advocated from the beginning." See Sept. 1991 Amendment to U.S. Patent Application No. 07/553,184 ("Sept. 1991 Amendment") at 4-6. Nevertheless, Nutrition 21's proposed construction renders the terms meaningless because under that construction any person who "administers" CP is automatically deemed to "need" the compound. Construing the terms in this fashion ignores both the subjective and objective needs for CP referenced in the prosecution history.

GNC's argument that the ordinary meaning of "in need thereof" / "in need of" requires there to be an objective medical determination that a subject needs CP also fails. GNC argues that the language Nutrition 21 quotes from the prosecution history file indicates only what the inventors' attorneys intended when amending the patents-in-suit, not the patent examiner's understanding. However, the record before the PTO can inform the meaning of claim language because statements made during prosecution are probative of what the inventors and examiner understood claim terms to mean. See Phillips, 415 F.3d at 1317; Vitrionics Corp., 90 F.3d at 1582. When adding the terms after the examiner's rejection of their claims, the inventors noted the examiner's finding that "'in need thereof / 'in need of" encompassed a "subjective perceived need." See Sept. 1991 Amendment at 4-5. The examiner never challenged this contention and subsequently allowed the amended claims. No reasonable competitor reviewing and relying on this prosecution history would believe the terms do not cover an individual's subjective need for CP. See Vitronics Corp., 90 F.3d at 1583 ("[C]ompetitors are entitled to review the public record, apply the established rules of claim construction, [and] ascertain the scope of the patentee's claimed invention. . . .").

The intrinsic record does not support either side's proposed constructions. In light of the prosecution history, for all the patents-in-suit the Court construes "in need thereof" and "in need of" to mean "one who has a specific perceived need."
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2. In sequence

Defendants argue that when the inventors spoke of steps "in sequence," they meant that the chemicals leading to the increase in divalent cations and then to the reduction in phosphorylation must be added in sequence. They maintain that no other reading of the claim language is logical, particularly, because in their view, scientists did not understand the sequential reaction of these two processes in 1993.

Claim 1 claims a process for in vitro parthenogenic activation of an oocyte "comprising the following steps in sequence": the increase of intracellular levels of divalent cations in the oocyte and the reduction of phosphorylation of cellular proteins

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in the oocyte. Contrary to defendants' assertion, the plain meaning of the language is that the steps occur in sequence; that is, step a occurs before step b. The claim recites a result. The claim says nothing about the administration of chemicals to achieve the reactions or the order in which such chemicals might be administered. Therefore, it is not limited to a method in which the chemicals are administered in sequence, rather than simultaneously, so long as the resulting reactions occur sequentially. As to the argument that scientists would not have understood the sequential nature of the reactions when the '720 patent application was filed, the patent specifications includes the inventors' observation that the initial calcium transient "appears to be an upstream event." Col. 6, ln. 61-62.

The language of other claims in the patent does not demonstrate that the inventors intended that claim 1 refer to both treatments and results. Claims 8 and 9 are claims that depend on claim 1. They recite specific processes to achieve the results claimed in claim 1. Claim 18 is an independent claim. Like claims 8 and 9, it claims specific ways of achieving the result claimed in claim 1. The legal presumption is that the use of different words or phrases in separate claims implies a significant distinction between the claims. See Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987).

The specification language does not mandate a different meaning of "in sequence." In describing one of the experiments, the inventors refer to sequential treatment and describe the time it takes for the sequential steps to occur after administration of particular chemicals, '720 pat., col. 10, ln. 54-55, but they do so using very different language from the language they use in claim 1. Instead of reciting the steps as they occur in sequence, as they do in claim 1, they refer explicitly to the timing of the treatments administered.

The prosecution history does not mandate a different understanding of the term "in sequence." Although the term was added during the prosecution of the application, there is no indication that it was added to refer to the timing of the administration of chemicals rather than to the order in which the steps described in (a) and (b) occur. Rather, the evidence is that it was added in response to a comment by the examiner that it was unclear whether "step (a) and step (b) occur simultaneously or in sequence."

Defendants have a final argument on this point that they raise for the first time in their reply brief and fail to develop. Relying on a concurring opinion in one case from the Federal Circuit, Seal-Flex, Inc. v. Athletic Track and Court Construction, 172 F.3d 836 (Fed. Cir. 1999) (Rader, J., concurring), they argue that as claim 1 is written, it is a "step-plus-function" within the scope of 35 U.S.C. § 112, P 6. Paragraph 6 provides that

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claims shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Defendants maintain that under this provision, claim 1 must be read as covering the corresponding acts described in the specification because the claim is written to cover functions without specifying how the functions are to be achieved. It may be that defendants are correct. It is not possible to know from the scant fifteen lines in their brief or the twelve sentences of their argument at the evidentiary hearing exactly what their theory is on this complex question of patent construction. The law in this circuit is that "arguments that are not developed in any meaningful way are waived." Central States, Southeast and Southwest Areas Pension Fund v. Midwest Motor Express, Inc., 181 F.3d 799, 1999 U.S. App. LEXIS 11890, *20, 1999 WL 371671, *7 (7th Cir. 1999); see also Finance Investment Co. (Bermuda) Ltd. v. Geberit AG, 165 F.3d 526, 528 (7th Cir. 1998).

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1. The Term "In Situ"

According to the claim language itself, the core material lies on one side of the separating layer, while the enteric coating lies on the other side: "thereby forming in situ a separating layer as a water soluble salt product between the alkaline compound and the enteric coating polymer." (P3, col. 16:7-9 (emphasis added).) "In situ" is a scientific or technical term of Latin origin that literally means "in place," or, in the original location. (Astra's Cl. Constr. Mem. of 11/5/01, Ex. 31, McGraw Hill Dictionary of Scientific and Technical Terms, 5th ed. at 1023 (1994).) A person of ordinary skill in the art

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would understand the term "in situ" to have that meaning. (See Langer Tr. 5245:19-5246:1.)

"In situ" in the context of claim 1 of the '281 patent refers to the formation of the separating layer within the formulation, as compared to its separate application, a process covered by the claims of the '505 and '230 patents. This construction of "in situ" is supported by the specification:

According to a second aspect[,] the present invention provides a process for the manufacture of two functionally different layers in one manufacturing step. By such a process a separating layer comprising a water soluble salt of an enteric coating polymer is obtained, as well as the enteric coating layer itself.

….

According to said process the separating layer is formed by an in situ reaction between the enteric coating polymer and the alkaline core material comprising the pharmaceutically active substance.

(P3, col. 5:44-58.) Thus, the separating layer is created within the formulation--in place--by the chemical reaction of an alkaline reacting compound and the enteric coating.

The patent specifications repeatedly describe the separating layer as forming "spontaneously" during the enteric-coating process. (See id., col. 9:49-50 ("separating layer is spontaneously formed in situ during the process"), col. 10:32-33, col. 11:2-3, col. 12:6-7, col. 13:46-47, col. 14:45-46.) Citing the testimony of its expert Dr. Banakar concerning that language in the specification, Andrx argues that a person of ordinary skill in the art of pharmaceutical formulation would have understood the term "forming in situ" to mean forming immediately during the enteric-coating process. (See Banakar Tr. 5217:16-17 ("The plain meaning of the word 'spontaneous' is right away, immediately.").) However, there is no temporal requirement in either the claims or the specification for when the separating layer must form. The fact that the specification refers to the separating layer forming spontaneously means that it forms without additional human effort. (Langer Tr. 5251:14-23.)
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Claim 22

The process according to claim 1, wherein the solid ladle metallurgy additive is in the form of a briquette.

Plaintiff argues that the claim is silent as to how the briquette is formed and simply requires the additive to be "in the form of a briquette." In other words, Plaintiff's position is that the claim is only concerned with the shape of the additive and not how it is formed (Tr. 49). The Court agrees.

Defendant argues that the Court should import the definition of briquette from the specification which details how a briquette is made (Tr. 50). But the Court need only go to the specification if the claim language needs clarification. Here, the language is straightforward: namely, that the additive needs to be in the form of a briquette. To accept Defendant's definition would be to render the phrase "in the form of" meaningless. In other words, Defendant would have the Court read out the words "in the form of" and import from the specification how a briquette is made (p. 50). But that is not the plain reading of the phrase.
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A. Whether Claim 6 Of The '314 patent Should Be Read As A Unitary Term

Claim 6 of the '314 patent provides:

6. The compound 7-(4-(4-fluorophenyl)-6-isopropyl-2 -(N-methyl-methylsulfonylamino)pyrimidin-5-yl)-(3R, 5S)-

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dihydroxy-(E)-6-heptenoic acid in the form of a non-toxic pharmaceutically acceptable salt thereof.

In construing this term, Judge Stark took a unitary approach to the claim and recommended that claim 6 be construed as:

A non-toxic pharmaceutically acceptable salt of the compound 7-(4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl)-(3R, 5S)-dihydroxy-(E)-6-heptenoic acid.

In objecting to this claim construction, Mylan contends that the Federal Circuit has never applied a "unitary" approach to claim construction and that the application of such an approach here results in rewriting the claims to delete from them the words "in the form of" and "thereof." Mylan contends that the failure to construe each component of the claim, namely the terms "acid," "salt," "in the form of" and "thereof," impermissibly broadens the claim to embrace a larger set of compounds. According to Mylan, this larger set of compounds was not considered part of the '314 patent during the reissue proceedings, and Shionogi, who requested the reissue, abandoned these broader claims such that claim 6 should be limited to the much narrower set of compounds that are an " . . . acid in the form of a . . . salt thereof." (D.I. 142 in Civ. Act. No. 07-805-JJF at 7-8).

In response, Plaintiffs contend that the words of claim 6 parceled out by Mylan are akin to phrases, and therefore, the word-by-word construction proposed by Mylan will depart from the context of the invention. More specifically, Plaintiffs contend that there is no need to define the term "acid" separately from the rest of the claim, because the term "acid" is used only as part of the definition of the compound which is claimed in the salt form. Plaintiffs further contend that under their proposed construction, as adopted by the Magistrate Judge, claim 6 is not broadened from the scope of the '440 patent, the original patent from which the '314 patent was reissued.

Reviewing the claim language, specification and prosecution history related to the disputed claim, the Court adopts the claim construction proposed by Judge Stark. The Federal Circuit has cautioned against a word-by-word approach to claim construction when such an approach to construction divorces itself from the context of the invention. See e.g., On Demand Machine Corp. v. Ingram Industries, Inc., 442 F.3d 1331, 1344 (Fed. Cir. 2006). In this case, the plain language of the disputed claim recites a heptenoic acid in salt form. This construction is consistent with the specification which provides eight examples disclosing a heptenoic acid in salt form. In this context, the Court agrees with Judge Stark that the term "acid" does not require an individualized claim construction because it is part of the compound named in the claim. The Court's conclusion is further supported by the prosecution history of the '314 patent, which demonstrates that once Shionogi took measures to draft the acid out of the claim, by limiting the claim to the "acid in the form of a salt," the PTO allowed the claim. From this context, it is evident that the PTO and Shionogi viewed the acid of the claimed compound to be different from the salt of the claimed compound.

Mylan contends that use of the phrase "in the form of" renders the claim ambiguous, but the Court disagrees in light of the prosecution history. It is evident that the "in the form of" language was derived from back and forth discussions between Shionogi and the PTO to yield the agreed upon result that Shionogi claim the pharmaceutically acceptable salt of the acid recited in the claim 6 compound and remove from the scope of the claim the acid itself. (D.I. 52 in MDL NO. 08-1949, Exh. 4 at AZ00411430.) It is further evident from the prosecution history, that the PTO did not view this amendment to the '314 reissued patent to broaden the scope of the claim beyond the original '440 patent. (Id.)

The Court agrees with Judge Stark that Mylan's proposed claim construction impermissibly reads into the claim a process that was not recited by the patentee. As Judge Stark explained, such a construction would exclude one of the preferred embodiments which describes a different process of forming the calcium salt of the claimed compound. '314 patent, col. 13, 1. 59-col. 14, 1.8 (describing rosuvastatin calcium salt as being formed from the sodium salt of rosuvastatin, and not from the heptenoic acid). As the Federal Circuit has noted, a claim construction which excludes a preferred embodiment is rarely the correct construction. See, e.g., Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("[I]t is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.")

In sum, the Court agrees with and will adopt the proposed construction of Judge Stark for claim 5 of the '314 patent, as well as the rationale provided by Judge Stark in making his recommendation. Accordingly, the Court will overrule Mylan's Objection as it pertains to claim 6 of the '314 patent.
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3. "In the presence of acid"

The plain ordinary meanings of the words of this phrase are self-evident. Reilly argues that despite the seeming simplicity of the statement, it is unclear and requires the court to examine both the specification and prosecution history to determine its meaning. After reviewing these sources, Reilly concludes that the term in fact means "sufficient acid to dissolve the polyvinylpyridine starting material in the aqueous reaction medium." Reilly Br. In Support, pp. 24-26. BASF, on the other hand, contends that the phrase means what it says and the court should not add qualifications to this term not apparent in the plain language of the claim.

In this context, an "acid" is "any of various typically water-soluble and sour compounds that in solution are capable of reacting with a base to form a salt, redden litmus, and have a pH less than 7, that are hydrogen-containing molecules or ions able to give up a proton to a base or that are substances able to accept an unshared pair of electrons from a base." WEBSTER'S COLLEGIATE DICTIONARY 10 (10th Ed. 1999). Thus, the ordinary meaning of this phrase is that during the reaction described in Claim 1, acid, as defined above, is present, or involved. This is certainly not a precise phrase. Nothing indicates the type or quantity of acid required. Dependent Claims 3 and 4 provide some narrowing of the term acid. These claims indicate that the acid to which Claim 1 refers may be organic acid, including "formic acid, acetic acid, propionic acid, coconut fatty acid, stearic acid, benzenesulfonic acid, p-toluenesulfonic acid, or an alkyl sulfonic acid," or inorganic acid, including "sulfuric acid or phosphoric acid." 684 Patent, col. 6, 11. 13-19. To further narrow the term, the court must, however, look to other sources including the specification and prosecution history. The court views these other sources with caution, however, remembering the heavy presumption that the court will give the words their plain, ordinary meaning, without modifications. See Johnson Worldwide Associates, Inc., 175 F.3d at 989-90. This presumption is only overcome if a party can "point to a term or terms in the claim with which to draw in" statements in the written description that Affect the claim's scope. Id. ("That is, claim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources.").

The specification provides little evidence to support an understanding of the term other than that of its ordinary meaning. The patentee does use the specification to repeat the limitations on type of acid stated in Dependent Claims 3 and 4. See 684 Patent, Col. 2, 11. 8-13. It does not, however, provide any additional information about the type of acid.

In support of their arguments regarding the quantity of acid required, both parties cite the portion of the specification that provides,

> The oxidation can in principal also be carried out in the absence of acids. However, a procedure in which the oxidation is carried out in the presence of acids is preferred because the polymers containing vinylpyridine units then dissolve partially or even completely in the aqueous reaction medium. If the polyvinylpyridines which are to be oxidized are insoluble in water, the polymer is suspended in the aqueous reaction medium. As the oxidation of the polymer advances, it dissolves partially or completely in the reaction medium.

684 Patent, Col. 3, 11. 7-15. Contrary to Reilly's argument, this quotation does not provide evidence of any particular quantity of acid contemplated in Claim 1. It simply states that it is preferred that the reaction take place "in the presence of acid" because the polymers "then dissolve partially or even completely in the aqueous reaction medium." Id. Without reading more into these sentences than the words actually state, the court cannot conclude anything about the quantity of acid. Nothing in this statement, or in the remainder of the specification explicitly requires the reader to limit the invention to a narrower embodiment than the words of Claim 1 otherwise imply.

It is true, as Reilly argues, that if a specification "makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims." Alloc Inc. v. ITC, 342 F.3d 1361, 68 U.S.P.Q.2d 1161, 1167 (Fed. Cir. 2003). As stated previously, however, the court will not import limitations to the claims based solely on the description, preferred embodiments, or even examples set forth in specification without a reason to do so. See Id. ("It is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention."); Johnson Worldwide Associates, Inc., 175 F.3d at 989-90. Here, the statement cited above provides no such reason, it simply tells the reader that the presence of acid is preferred during the oxidation

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process because of its effect on the polymers in the reaction medium. Contra Scimed Life Sys. Inc., 242 F.3d at 1342-44 (finding that the inventor limited the invention to a specific embodiment through repeated reference to only this embodiment and an explicit statement that "all embodiments of the present invention are contemplated and disclosed herein"); Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) (noting that although technically covered by the claim terms, certain embodiments of the invention were explicitly disclaimed by the inventor's definition of a term in the specification).

Further, the court's finding that the invention is limited to a process in which the oxidation reaction takes place in a solution does not alone provide a sufficient reason to read such a limitation on the invention. The court sees nothing to suggest that a particular quantity of acid is necessary to produce this solution state and finds no direct evidence in the specification, prosecution history, or the testimony of experts skilled in the art that would require it to conclude that the invention claimed in the 684 patent is narrowed to include only embodiments with a particular quantity of acid.

Finally, nothing in the prosecution history indicates a clear intention to limit the language of Claim 1 to any particular quantity or type of acid. In the prosecution history, like in the specification, the patentee simply notes the presence of acid and its effect on the oxidation reaction. See Prosecution History, pp. BASF 0916, BASF 0919. The prosecution history does not however, provide any specific directions to the court to read any limitations into the ordinary meaning of this phrase.

For these reasons, the court finds that the phrase "in the presence of acid" should be given its plain ordinary meaning as limited by Dependent Claims 3 and 4, but without limitation as to quantity. That is, it means that acid, as defined above, is present during the oxidation of PVP.
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1. "in the presence of . . . an ionic suspension stabilizer"

In the present case, a review of the claim language, the patent specification, and the prosecution and re-examination histories establishes that the "ionic" limitation does not cover in situ formation of the ionic character of the stabilizer, but rather requires that the stabilizer be ionic when it is added to the reaction. As an initial matter, the language of the asserted claims specifically call for an "ionic" suspension stabilizer. The term "ionic" is the opposite of "non-ionic," and has a definite and distinct meaning to a person having ordinary skill in the relevant art. "Ionic" material carries an overall charge, either positive or negative, while "non-ionic" material is neutral and carries no charge. Thus it follows that the words of the claims themselves foreclose an interpretation of the "ionic" limitation which encompasses non-ionic stabilizers. Indeed, to construe the claims otherwise would render the term "ionic" superfluous.

This understanding of the Baker-Ketola claims -- that it does not cover in situ formation of the stabilizer but requires the stabilizer to be ionic when introduced to the reaction -- is reinforced by the specification. The Background of the Invention section specifically refers to the suspension stabilizer as an "essential ingredient," which suggests that the inventors viewed the stabilizer as a separate, discrete, ready-to-use, externally added component of the claimed invention, rather than an element created in situ during the polymerization process.

The particular embodiments contained in the specification further confirm that the Baker-Ketola claims require that the stabilizer be ionic when it is introduced to the reaction. The exemplary stabilizers disclosed in the specification are all ionic. 14 In addition, each of the representative reactions uses an ionic suspension stabilizer that is externally added during the process. 15

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14 These exemplary stabilizers also all have interfacial tensions above 15.0 dynes per centimeter.

15 3M's reliance on Example 1 in the specification as demonstrating that the Baker-Ketola claims cover in situ formation of the ionic character of the stabilizer is misplaced for substantially the reasons set forth in Beautone's Reply Brief. Example 1 complies with the patent's disclosure of only ionic, external, ready-to-use stabilizers. It differs from the other examples only in so far as the ionic character of the stabilizer is brought about by neutralizing the polyacrylic acid, a step that is

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specifically called for in the specification. Example 1 merely shows the requisite neutralization first, which yields the external, ready-to-use stabilizer, to which the remainder of the reaction ingredients are then added. Therefore, there is no in situ transformation of a non-ionic stabilizer to an ionic stabilizer in the Baker-Ketola patent.

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3M's assertion that this interpretation -- that the stabilizer be ionic when added to the reaction -- impermissibly limits the scope of the asserted claims to the particular embodiments is without merit. There is no difference in scope between the claims and the exemplary stabilizers and representative reactions contained in the specification. As discussed above, the claim terms specifically call for the use of an ionic suspension stabilizer. Therefore, the fact that all of the stabilizers disclosed in the specification are ionic and that each of the representative reactions uses an externally added ionic stabilizer confirms that the Baker-Ketola claims demand that the stabilizer is an externally added ingredient and is ionic when mixed into the reaction vessel. Cf. Specialty Composites v. Cabot Corp., 845 F.2d 981 (Fed. Cir. 1988) (declining to limit the word "plasticizers" to external plasticizers even though only external plasticizers were exemplified in the specification where neither the claims nor the specification specified between "internal and external" plasticizers); Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (concluding district court did not err in adopting broader construction even though the particular embodiments disclosed in the specification may have suggested a narrower interpretation); SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121-22 (Fed. Cir. 1985) (holding district court erroneously relied on specification in reading limitations from other claims into the disputed claims).

Nor does the prosecution history require a different interpretation. During the prosecution, 3M added the stabilizer limitation that was contained in claim 7 (a claim that is not currently in dispute) to claims 1 and 4. On the one hand, because claim 7 specified that the stabilizer was to be "charged" to the reaction vessel, it is arguable that this meaning necessarily followed when claims 1 and 4 were amended, even though as amended they did not expressly call for "charging" the stabilizer to the reaction vessel. On the other hand, it is also possible to argue that 3M specifically omitted the element requiring the stabilizer to be "charged" to the reaction when it amended claims 1 and 4 to conform with claim 7 and therefore infer that claims 1 and 4 encompass in situ formation of the ionic character of the stabilizer. Accordingly, the prosecution history does not provide useful guidance in determining the meaning and scope of the disputed Baker-Ketola claims. 16

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16 Application of the doctrine of claim differentiation also does not warrant a different construction. While the difference between claim 7, which specifically requires "charging" the ionic suspension stabilizer to the reaction vessel, and claims 1 and 4, which only specify that the polymerization take place "in the presence of" an ionic suspension stabilizer, may imply a difference in scope, the claims and the specification, as discussed above, only support a single construction of the "ionic" limitation; namely that the claims conceive of the ionic stabilizer as a separate and distinct ingredient that is to be "externally added to" the reaction vessel.

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On the other hand, however, 3M's 1994 reexamination remarks do not advance Beautone's interpretation. Although 3M characterized the stabilizer as "externally added" and referred to a prior art stabilizer as formed "in situ," these statements were not made to distinguish the proposed Baker-Ketola claims from the prior art. Rather a closer look establishes that 3M used the phrase "externally added" to draw a distinction between stabilizers, such as Silver's comonomer, which polymerized with other monomers to form the microspheres, and Baker-Ketola's ionic suspension stabilizers, which were external to the polymerization and did not become part of the microspheres. Moreover, 3M's in situ remarks simply involved recognizing that the Renfrew patent covered in situ formation of the suspension stabilizer. 3M then went on to argue that it would not be obvious to substitute Renfrew's in situ suspension stabilizer for Silver's comonomer because Renfrew's stabilizer homopolymerizes while Silver's comonomer copolymerizes with the other comonomers to form the adhesive microspheres.

In sum, the claim terms and the specification demonstrate that the ionic limitation of the Baker-Ketola claims requires that the suspension stabilizer be externally added to the reaction vessel and be ionic when so added.
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1. '540 Patent and '972 Patent

"Substantially retaining the in vivo glucan morphology," "having substantially the in vivo glucan morphology," and "retaining the in vivo glucan morphology" appear in several asserted claims of the '540 Patent and the '972 Patent. Claim 1 of the '540 Patent and claim 1 of the '972 Patent, quoted above, provide examples of the first phrase's use. Plaintiffs construe "substantially retaining the in vivo glucan morphology" as "the non glucan components (e.g., protein, chitin and glycogen) are extracted from the glucan thereby producing whole glucan particles that have substantially intact cell walls." The portion of Immudyne's proposed construction of "whole glucan particles substantially retaining the in vivo glucan morphology" that relates to the present dispute is "that substantially retains the in vivo, three dimensional morphology of the yeast cell." Immunocorp and Biotec construe "substantially retaining the in vivo glucan morphology" as "substantially and consistently retaining the intact three dimensional structure, typically spherical, of the beta glucan in the cell wall of a living cell." They propose similar constructions of the other phrases.

Beginning with the words of the patents' claims, the Court notes that one claim, claim 9 of the '540 Patent, uses "morphology" to refer to the shape of the whole glucan particles. The claim states: "Whole glucan particles derived from yeast cells, said particles being alkali-insoluble and having substantially the in vivo glucan morphology, said particles also having a spherical morphology with an average particle diameter of from about 2 to about 10 microns and containing greater than 85%, by weight, hexose sugars and less than about one percent, by weight, protein." The claim's reference to a "spherical morphology" suggests that morphology refers to particle shape. See Phillips, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims."). Although other claims in the '540 Patent and the '972 Patent refer to whole glucan particles being spherical in shape or having a spherical shape, "[d]ifferent terms or phrases in separate claims may be construed to cover the same subject matter where the written description and prosecution history indicate that such a reading of the terms or phrases is proper." Nystrom v. Trex Co., 424 F.3d 1136, 1143 (Fed. Cir. 2005).

The specifications support the suggestion that morphology refers to shape. According to the Background of the Invention, [beta] -linked glucan "is responsible for the shape and mechanical strength of the cell walls." '540 Patent, col. 1, ll. 38-39; '972 Patent, col. 1, ll. 37-38. The Summary of the Invention indicates that the glucan obtained from the present invention retains the "three dimensional morphology of the intact yeast cell wall":

By processing yeast cells and the glucans derived therefrom according to the techniques of the present invention, a glucan product which retains the three dimensional morphology of the intact yeast cell wall and having high water holding capacity is formed, which in turn may be further processed to give glucans having improved or novel functional properties.

'540 Patent, col. 2, ll. 6-12; '972 Patent, col. 2, ll. 5-11. "These pure whole glucan particles are typically spherical . . . ." '540 Patent, col. 2, ll. 25-26; '972 Patent, col. 2, ll. 24-25.

The specifications also distinguish morphological properties from structural properties: "This process yields a product which maintains the morphological and structural properties of the glucan as found in vivo . . . ." '540 Patent, col. 3, ll. 24-26; '972 Patent, col. 3, ll. 22-24. In addition, as noted above, [beta] - linked glucan is responsible for the shape of the cell walls.

The Court turns to the prosecution history. As originally filed, the claims of the '540 Patent did not include the phrase "in vivo glucan morphology." For example, the applicant initially claimed "[g]lucan particles having substantially the three-dimensional structure of glucan in vivo." The examiner rejected the claims "as being clearly anticipated by Manners et al." At an interview, the examiner and the applicant agreed on the following claim to avoid Manners: "Whole glucan particles isolated from glucan-containing cell walls and substantially retaining their in vivo three dimensional structure." Notwithstanding this agreement, the applicant's amended claim appeared as: "Whole glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology." The applicant characterized the modification as a "slight change":

The newly submitted claims are based upon the suggested claim discussed between the Examiner and Applicants'

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Attorney at the interview. There is a slight change in language relating to the retention by whole glucan particles of the in vivo glucan morphology because one of the inventors . . . believes this to be more scientifically accurate than the previously suggested language stated in terms of the retention of three-dimensional structure.

The amended claims were allowed. During the prosecution of the '972 Patent, the applicant relied on the allowance of the '540 Patent's claims as amended to argue for allowance. The examiner allowed the claims: "The primary reason for allowance of the claims is the requirement thereof that the glucan contained in the food formulation is glucan comprising whole [beta] - glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology."

From the words of the claims, the specifications, and the prosecution history, a person of ordinary skill in the art would understand that "in vivo glucan morphology" refers to the shape that the glucan had in the cell from which the glucan is derived. The Court construes "substantially retaining the in vivo glucan morphology" as "substantially retaining the shape that the glucan had in the cell from which the glucan is derived"; "having substantially the in vivo glucan morphology" as "having substantially the shape that the glucan had in the cell from which the glucan is derived"; and "retaining the in vivo glucan morphology" as "retaining the shape that the glucan had in the cell from which the glucan is derived."
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The invention is claimed using non-restrictive terminology. The memory system "includes" an array of "non-volatile floating gate memory cells" which are "partitioned into a plurality of sectors." The claimed method requires "partitioning the memory cells within the individual sectors into at least a user data portion and an overhead portion." As a patent law term of art, "includes" means "comprising." See Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1344-45 (Fed. Cir. 2003); Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., Inc., 123 F.3d 1445, 1451 (Fed. Cir. 1997). Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations. Nor does the choice of articles-"an array" of memory cells, "a plurality of sectors," "said array of memory cells," "the memory cells," or "the individual sectors" - compel a different conclusion. These groupings of Flash EEprom memory cells provide an antecedent basis for various steps of the claimed method, but nothing in their recitation excludes other configurations of memory cells on a physical device that, in some part, practices the claimed methods. Thus, nothing in the language of claims 1 or 10 prevents the use of Flash EEproms containing cells that are not grouped into partitioned sectors.
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7. "pH in a range 4.5 to 6.0, inclusively": "Inclusively" means including but not exceeding the endpoints of the range.

('062 patent, col. 6, ll. 22-27)
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Incorporated	Stably integrated into the chromosomal DNA within the nucleus of a cotransformed or transformed eucaryotic cell

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3. Incorporating

Genentech contends that the term "incorporating" should be given its plain English meaning. It argues that the phrase

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"incorporating argininium ion in said composition" means "the pharmaceutical composition contains at least argininium ions and tissue plasminogen activator, or analogs, however and whenever incorporated." (Genentech Memo at 14.) BM contends that the phrase "incorporating" refers to "adding arginine to a pharmaceutical composition." Specifically, BM argues that because the '225 patent is a "method" patent, rather than a composition patent, the term "incorporating" must be construed as a "process for increasing the solubility of t-PA in a pharmaceutical composition by adding arginine."

This issue is relevant because the BM's product, BM 06.022, "first encounters argininium ions when it is not purified" and "when it is not native in its folding pattern." (Cepko report at 7.) BM thus uses argininium ions for the purpose of refolding denatured, but soluble, t-PA. BM does not remove the argininium ions from its product and, therefore, Reteplase contains argininium ions in the pharmaceutical composition that is administered to patients. (Cepko report at 8.)

a. Intrinsic Evidence

The term "incorporating" is not expressly defined in the '225 patent. To begin with, the plain English language meaning of "incorporating" includes the following definitions:

to put or introduce into a body or mass as an integral part or parts; to take in or include as a part or parts, as the body or a mass does; to form or combine into one body or uniform substance, as ingredients; to unite or combine so as to form one body; combined into one body, mass, or substance.

Random House Unabridged Dictionary 968 (2d ed. 1993). The word "incorporating" directly follows the open-ended term "comprising." The Federal Circuit has defined "comprising" as follows: "'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Chiron, 112 F.3d at 501.

The '225 specification states that the purpose of incorporating argininium ions in a buffer composition is to increase the "stability and solubility characteristics for the t-PA component." ('225 Patent, col. 1, ll. 14-16; col. 2, ll. 12-14; 18-19.) There is no mention in the '225 patent of using argininium ions to allow the refolding of denatured t-PA.

The '225 patent does not explicitly define the exact point at which t-PA is placed in the solution ("buffer") with argininium ions. Nonetheless, in "each example given in the '225 patent, and in the methods for production of Figures 1-3, purified t-PA was used." (Cepko report at 7.)

The prosecution history, likewise, provides guidance. In the patent application, for example, Genentech states that the invention is based on the discovery that the "inclusion of arginine (as argininium ion) in a pharmaceutically acceptable composition" of t-PA "significantly increases the stability and solubility of t-PA . . . ." (Patent application at p. 3, ll. 14-18; page 5, ll. 15-16.) Finally, Genentech's March 13, 1990 preliminary amendment to the '225 application states that "the claim of the present invention is directed to increasing the solubility of t-PA via the addition of argininium ion as such." (March 13, 1990 amendment, p. 2.)

The grammatical structure of the claim itself contains a key clue to the meaning of incorporate. To construe a claim, courts must look at the language as a whole and consider the grammatical structure and syntax. Chiron, 112 F.3d at 500. The term cannot simply mean that the composition contains argininium because that construction would make "incorporating" and "comprising" redundant. Also, if "incorporating" meant containing, without connecting a sequence of events, there would be no need for the phrase "in said composition."

b. Claim Construction

Based on the language of the claim, the purpose of the invention, the specification, and the prosecution history, I conclude that the term "incorporating" refers to adding argininium to a pharmaceutical composition of t-PA.
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1. "Increase"

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Iovate asserts that the term "increase" should be construed to mean a "statistically significant increase." It offers expert testimony as proof that someone skilled in the art would understand the term in that way. In addition, it argues that Examples 1 and 2 in the patent specification used a standard measure of statistical significance when showing "increased" blood plasma insulin and muscle creatine concentrations.

Allmax, on the other hand, rejects any further construction of "increase" by the Court. It contends that Iovate is attempting to import an unnecessary limitation into a term that is already unambiguous. In support of its position, Allmax cites Abbott Labs. v. Sandoz, Inc., 529 F. Supp. 2d 893, 911 (N.D. Ill. 2007), where the court refused to read a "statistically significant" requirement into the construction of the word "lower" because the ordinary and plain meaning of that word is simply "less than." The court explained that a word is not meaningless (and in need of construction as a matter of law) just because an expert may understand it to have a more "helpful" meaning.

Iovate responds that in Abbott one disputed claim included the term "statistically significant" whereas another did not and the court found it noteworthy in construing "lower" that the patentee could easily have added the "statistical significance" limitation if it had intended for that limitation to exist. Therefore, Iovate contends that Abbott is inapposite here where "statistically significant" does not appear at all in the patent-in-suit.

In further support of its position against the addition of a "statistical significance" limitation, Allmax also points out that Examples 3 and 4 in the '900 Patent do not use a standard measure of statistical significance. Iovate responds that those examples do not refer to an increase in creatine retention at all except tangentially by way of a reference to an increase in plasma insulin concentration that exhibited such a large increase as to be obviously statistically significant.

Iovate's further construction of "increase" is unwarranted. An "increase" and a "statistically significant increase" would have two different meanings (presumably even to a person skilled in the art). For example, a 0.01% increase may not be statistically significant but is, nevertheless, an increase. Particularly because the term "statistical significance" is used in the specification to describe the kind of "increase" observed but is omitted from the disputed claims, "increase" will be read as just that and without the limitation of being "statistically significant."

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3. "increased average plasma levels (AUC)", "per dosage unit", "per unit dosage"

These terms are found in the phrases "an increased average plasma levels (AUC) per dosage unit" in claim 2 and "an increased average plasma level (AUC) per unit dosage" in claim 14. Astra contends that the phrase "an increased average plasma levels (AUC)" should be construed to mean "greater blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve." Astra further proposes that "per dosage unit" or "per unit dosage" be construed as "for every specified quantity administered." DRL argues that construction of the phrases "an increased average plasma levels (AUC) per dosage unit" and "an increased average plasma level (AUC) per unit dosage" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: the observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl] -1H-benzimidazole that the average AUC for individuals treated with that compound is greater than that for individuals treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature." For the same reasons expressed earlier, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of this term is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

In support of its proposed construction of "an increased average plasma levels (AUC) per dosage unit", Astra points to various portions of the '192 patent specification:

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In rapid metabolisers the mean AUC at steady state (Day 7) of the (-)-enantiomer of omeprazole was almost 90% higher than that of omeprazole. This resulted in a more pronounced gastric acid antisecretory effect for the (-)-enantiomer of omeprazole compared to that of omeprazole. The inhibition of pentagastrin simulated gastric acid secretion was 62% for omeprazole and 79% for the (-)-enantiomer of omeprazole following administration of 15 mg doses of each substance.

'192 patent, col. 5, lines 17-23.

Higher average AUC results in a more pronounced inhibitory effect on gastric-acid secretion and is expected to result in better overall clinical effect. Thus, the alkaline salts of (-)-omeprazole can provide an improved, alternative pharmaceutical formulation and method for the treatment of gastric acid-related diseases."

'192 patent, col. 7, lines 3-16. See also '192 patent, col. 2, lines 38-46. Astra also points to the testimony of Dr. Andersson referred to above. The Court finds such evidence clearly supports the construction proposed by Astra and its position that the term "increased" references a comparison to omeprazole, and therefore shall construe "an increased average plasma levels (AUC)" to mean "greater blood levels of (-)-omeprazole, as measured by the area under the concentration-time curve, compared to the typical or usual blood levels for omeprazole, as measured by the area under the concentration-time curve."

With respect to the terms "per dosage unit" or "per unit dosage," Astra fails to provide adequate support for its proposed construction. Moreover, because the ordinary and customary meaning of these terms would be clear to one skilled in the art, the Court declines to construe the phrase as it is used in the '192 patent.
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(A) "such that the seal has increased resistance to chemical attack"

Possessing the property of being more resistant to deterioration when exposed to a broad range of harsh chemical agents when compared to the closest prior art seals known as of the filing date of the '107 patent, measured and analyzed according to accepted scientific standards set forth by the scientific community, such as those set forth in ASTM standards.
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"Increasing"

Neither party addresses this term in its briefs. In the Joint Claim Construction Chart, Nutrition 21 identifies "increasing" as a distinct term in certain claims from the '624 Patent and asks that the term "be given its plain and ordinary meaning." GNC does not ask the Court to construe this term. This term does not require construction.
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4. Construction of "Indicating An Extent Of Hybridization"

Affymetrix's construction of "indicating an extent of hybridization" is "relating to the relative binding of." (D.I. 243 at 35.) Illumina's proposed construction is "indicating the strength of binding so as to distinguish a single-base mismatch." (D.I. 240 at 35.) The proposed constructions of both parties construe "hybridization" as "binding." Both parties also agree that "extent of hybridization" refers to the relative strength or amount of binding. (D.I. 243 at 35; D.I. 240 at 35.) The dispute here, then, concerns Illumina's proposed addition of the limitation "so as to distinguish a single-base mismatch." The Court concludes that such a limitation is not required.

Claim 1 requires that the nucleic acid probes "differ[] from each other by at least a single base . . . ." ('716 patent, col. 42, ll. 59-60 (emphasis added).) The use of the language "at least" indicates that the inventors contemplated embodiments in which

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the probes differ from each other by more than a single base. In such embodiments the limitation "so as to distinguish a single-base mismatch" would be wholly misplaced. Therefore, the Court construes "indicating an extent of hybridization" to mean "indicating the relative strength of binding."
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9. "Indication"

GTG proposes this term be construed as "suggestion or sign of," while Applera proposes "positive identification of said central selected chromosomal region as being associated with the trait."

The court adopts GTG's position. As previously discussed, the patent and prosecution history do not require "positive identification" of the region in question. "Indication" is thus construed as: suggestion or sign of.
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A. "inert hydrosoluble carrier"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

An immediate-release fenofibrate composition comprising:

(a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 [mu]m, a hydrophilic polymer and a surfactant; and

(b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott argues that the specification explicitly defines this claim term as follows: "In the framework of this invention, the expression 'inert hydrosoluble carrier' means any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium." (D.I. 237 at 6, C.A. 02-1512-KAJ; '670 patent, col. 4 ll. 3-9.) Based on that language, Abbott asserts that "the patentees acted as their own lexicographer[s] by expressly defining the term in the patent specification and by using their definition in a consistent way throughout the patent." (D.I. 237 at 6, C.A. 02-1512-KAJ.) Abbott therefore proposes that I construe "inert hydrosoluble carrier" in accordance with the definition stated in the specification (D.I. 238 at 1, C.A. 02-1512-KAJ; D.I. 167 at 1, C.A. 03-120-KAJ), because "under well-settled law, this express definition 'controls' the meaning of the claim term" (D.I. 237 at 6, C.A. 02-1512-KAJ).

Teva proposes that I construe "an inert hydrosoluble carrier" to mean "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, which is soluble in an aqueous medium, notable in a gastric acid medium, and which functions as a support for particles of micronized fenofibrate and polymer." (D.I. 238 at 1-2, C.A. 02-1512-KAJ.) Teva asserts that the addition of the phrase "and which functions as a support for particles of micronized fenofibrate and polymer" is necessary because "the inert hydrosoluble carrier is a specific material that carries or supports particles of micronized fenofibrate that adhere to the surface of the carrier," and, as such, the meaning of the term should include this functional description in addition to the definition provided in the specification of the Stamm patents. (D.I. 223 at 29-30, C.A. 02-1512-KAJ.) In support, Teva cites several Federal Circuit decisions in which the Court construed disputed claim language to

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include functional characteristics. n7

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n7 In support of its argument, Teva cites Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc., 384 F.3d 1333, 1338-39 (Fed. Cir. 2004), Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003), Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001), and Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216-17 (Fed. Cir. 1995). (D.I. 268 at 12, C.A. 02-1512-KAJ.)

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Impax proposes that I construe "an inert hydrosoluble carrier" in essentially the same way, with this slightly different wording: "an excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, which is soluble in an aqueous medium, notably in a gastric acid medium, and having material coated or layered onto the excipient, which acts as a support." (D.I. 167 at 1, C.A. 03-120-KAJ.) Impax asserts that Abbott's proposed construction "fails to account for the meaning of the term 'carrier,' ... [which] must be construed to require that the excipient ... have material coated or layered onto it ... [because] it is acting as the support for the material." (D.I. 169 at 11, C.A. 03-120-KAJ.)

2. The Court's Construction

"Patent law permits the patentee to choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). A patentee acts as his own lexicographer where he "clearly set[s] forth a definition of the disputed claim term in the specification." Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1304 (Fed. Cir. 2003). In so doing, "the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1370 (Fed. Cir. 2005) (internal citations omitted).

The patentees here acted as their own lexicographers in defining the meaning of the term "inert hydrosoluble carrier." The specification clearly states, "in the context of this invention, the expression 'inert hydrosoluble carrier' means... ." n8 ('670 patent, col. 4 ll. 3-5.) I cannot imagine a clearer way of expressing the intention that a particular term be given a particular meaning. Abbott proposes that such meaning defines the term in its entirety, whereas Teva and Impax argue that the meaning is incomplete because it does not describe the function of the carrier as a support. (D.I. 237 at 6, C.A. 02-1512-KAJ; D.I. 223 at 29-30, C.A. 02-1512-KAJ; D.I. 169 at 11, C.A. 03-120-KAJ.) In acting as their own lexicographers, the patentees identified "inert hydrosoluble carrier" as the term they intended to define. ('670 patent, col. 4. ll 3-4 (emphasis added).) Thus, the definition explicitly identified in the specification, was intended to include the term "carrier," and, as such, it does not require its own independent construction based on its intended function. n9 Therefore, I construe "inert hydrosoluble carrier" to mean "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium."

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n8 Because each of the Stamm patents has the same written description, citations are directed to the patent specification containing the specific claim chosen to represent the context of the disputed claim term at issue.

n9 In support of its argument, Teva cites Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc., where the Federal Circuit held that the patentee had acted as his own lexicographer because the specification stated that "the solubilizers suitable according to the invention are defined below" and then stated that "the solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents... ." Astrazeneca, 384 F.3d 1333, 1339 (Fed. Cir. 2004). Based on this disclosure in the specification, the Court determined that the term "solubilizer" was intentionally limited to "surfactants." Id. at 1339-40. Thus, if anything, this case supports Abbott's argument that the patentees acted as their own lexicographers in defining the term "inert hydrosoluble carrier," as expressed in the specification. In Alloc, Inc. v. International Trade Commission, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003), Netword, LLC v.

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Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001), and Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216-17 (Fed. Cir. 1995), also cited by Teva, the patentee had not acted as his own lexicographer by explicitly defining a claim term. Those cases therefore do not support the particular arguments asserted by Teva and Impax, that the explicit definition provided by the patentee is somehow deficient because it does not encompass the full meaning of the term as used in the patents, and, therefore, the court should alter the definition provided.

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6. The Term "Inert"

Subparagraphs (b) of claims 1 of the '505 and '230 patents require that the subcoating be "inert." (Pl, col. 16:48; P2A, col. 13:10.) The inventors nowhere defined the term "inert" to have any specialized meaning; "inert" is not expressly defined in the '505 and '230 patents, or in their file histories. That means that the ordinary meaning of the term controls, and the ordinary meaning of "inert" is very clear. At the time of the patents, a person of ordinary skill in the art of pharmaceutical formulation would have understood the term "inert" to mean pharmaceutically, chemically, and pharmacologically inactive. (Banakar Tr. 3220:24-3221:1.) This is consistent with the common understanding of the term set forth in dictionaries and technical treatises. See, e.g., Oxford University Press (1974) (defining "inert" as "without active chemical properties"); Oxford University Press (1973) (defining "inert" as "without active chemical, physiological or other properties; neutral"; Random House (defining "inert" as "having little or no ability to react"; "Pharm. having no pharmacological action, as the excipient of a pill"); A55 at 635 (Hawley's Condensed Chemical Dictionary (12th ed.) ("Inert: A term used to indicate chemical inactivity in an element or compound.")).) In Remington's Pharmaceutical Sciences, for example, the term "inert" is used as follows: "in addition to the active or therapeutic ingredient, tablets contain a number of inert materials. The latter are known as additives or excipients." Remington's Pharmaceutical Sciences, 17th ed. at 1605 (1985) (emphasis added) (Andrx Reply Mem. Regarding Cl. Constr. of 11/12/01, Ex. Q). These terms, which are widely used in pharmaceutical science, are terms of art meaning an inactive material in a pharmaceutical dosage form. Handbook of Pharmaceutical Excipients, Arthur H. Kibbe, Ph.D., Ed., Preface at xv, 3d ed. (2000) (Andrx Reply Mem. Regarding Cl. Constr. of 11/12/01, Ex. R). The Handbook of Pharmaceutical Excipients does not list any pharmaceutically active substance as an additive or excipient. Thus, the court adopts the construction proffered by Defendants, which is grounded entirely in the ordinary meaning of the term. See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999) (holding that the ordinary meaning of claim language is heavily presumed and that party seeking to use statements in the written description to affect a patent's scope must at the very least identify a claim term that is susceptible to clarification); see also Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248-49 (Fed. Cir. 1998).

Reliance on the ordinary meaning of the term, however, does not require blindfolding oneself to reality, as Defendants have done. Just as Defendant Andrx argued that the subcoating had to be 100% continuous, among other things, Defendants argue that the term "inert" requires the absolute absence of any pharmaceutically active or chemically reactive substances in any infringing subcoating. Under Defendants' proposed construction, this absence of reactivity is to be determined in a vacuum, based solely upon the known characteristics of a particular substance found to be in a subcoating and without reference to the invention or consideration of the materials with which that particular substance interacts. Defendants' construction would bar even a single molecule of omeprazole from appearing in the subcoating of an infringing formulation. Once again Defendants' claim construction theory attempts to read an unattainable "perfection" limitation into the claims. Indeed, since almost no substance is totally inert under all conditions, Defendants' construction would vitiate any possibility of proving infringement and thereby render the claims meaningless. The law is plain, infringement need not be perfect to be infringement. Shamrock Techns., Inc. v. Medical Sterilization, Inc., 903 F.2d 789, 792 (Fed. Cir. 1990). Moreover, the term "substantially," unless expressly excluded, is understood as being incorporated into a patent claim. See AFG Indus., Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1250 (Fed. Cir. 2001) (stating that, with respect to a patent for which the parties generally agreed that a 'layer' requires a "uniform" chemical composition, absent any specific statement in the patent of chemical uniformity as a characteristic of a layer, the layer must be understood as only "substantially" uniform.). A subcoat that is "substantially" inert will also meet the claim limitation of "inert subcoat." Genpharm's Andrx's and Cheminor's contention that "inert" must mean totally and absolutely inert is simply wrong as a matter of law.

The claim language and other disclosures in the patent support the position that the use of the word "inert" to modify the

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term "subcoating" was not intended to cut off all possibility of reactivity. In fact, the claim language "said subcoating comprising . . . materials selected from . . ." permits the presence of additional components in the subcoating. See Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001). In addition, the patent claims and specifications themselves make it clear that the subcoating can contain chemically reactive substances, like alkaline reacting compounds. Defendant's definition is inconsistent with claim 11 of the '505 patent, which expressly requires that the subcoating of claim 1 include an ARC, (Pl, col. 18:1-3), and the '505 patent specification, which expressly permits ARCs in the subcoating, (Pl, col. 4:14-27). Any doubt that the "inert subcoating" of claim 1 can include reactive compounds and pharmaceutically active compounds is directly addressed by reviewing claim 1 in the context of claim 11. Claim 11 expressly calls for "[a] preparation according to claim 1, wherein the subcoating further comprises an alkaline buffering compound." (P1, Col. 18:1-3.) In other words, subcoats may include "alkaline buffering compounds," like disodium hydrogen phosphate, which is not only an ARC but also a pharmaceutically active compound. (Astra's Cl. Constr. Mem. Ex. 11, 1996 Merck Index 12th ed. at 1481 (DHP listed with therapeutic activity in humans).)

The patent prosecution histories also teach that the subcoating can contain pharmaceutically active substances, like omeprazole. During the prosecution of the '230 patent, the examiner rejected Astra's claims as indefinite, asserting that acid labile compounds and ARCs could be the same thing. ('230 Prosecution History, at 216 ("The language 'acid labile compound' and 'alkaline reacting compound' read on the same compound whereas applicants specification specifically identifies precise and exact compounds that are not related.").) In its response, Astra pointed out that the examiner was correct, that ARCs can also be acid-labile compounds. ('230 Prosecution History at 256 ("this is precisely what applicants intended").) That part of the prosecution history shows that ARCs may be pharmaceutically active, acid labile compounds, and the specification expressly states that a subcoating may contain such compounds. (P2A, col. 9:23-25 ("The separating layer consists of one or more water soluble inert layers, optionally containing pH-buffering substances.").)

Credible extrinsic evidence supports the court's construction as well. For example, Defendants' experts Dr. Auslander and Dr. Porter opined that formulators understand the term "inert" to mean not having an adverse affect on the formulation and to encompass situations where there is a small amount of interaction. (See Astra's 11/12/01 Cl. Constr. Resp., Exs. 34, 70.) 32 Even the prior art relied on by Defendants shows that the term "inert" means substantially non-reactive. (See G31, GB 760 403 at 2, col. 2:67-70 ("By 'inert mineral solid' is meant a mineral solid which is substantially non-reactive with either the coating substance [enteric coating] or the medicament and is inert to acid medium.").) For these additional reasons, the aspects of Defendants' claim construction requiring that every molecule of every substance in the subcoating be utterly devoid of all reactivity are inconsistent with the patents' claim language, specifications, and prosecution histories.

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32 The text of the depositions referenced by Astra in support of its claim construction arguments reads as follows:

Q: Would you utilize formulation studies to determine which materials were inert in the context of that particular formulation that you were developing?

A: Yes.

Q: And would you conclude that materials that were inert were the materials that didn't have an adverse effect on the formulation that you were developing?

A: That's correct.

(Astra's 11/12/01 Cl. Constr. Resp., Ex. 70, Auslander Dep. Tr. 75:15-24.)

Q: What is your understanding of the definition of inert?

A: That is a very broad question because I think my understanding would be in a given circumstance does the material have any likely interaction with ingredients in the formulation that would be compromising to performance or stability of that formulation.

Q: Would you in real life practice understand that while there might be some small amount of interaction, that as long as

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that interaction isn't so great as to compromise the performance or stability of that formulation that it would be inert?

. . . .

A. I would think yes.

(Astra's 11/12/01 Cl. Constr. Resp., Ex. 34, Porter Dep. Tr. 42:14-43:6.)

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Defendants worry about the slippery slope; they ask, if the materials in the subcoating do not have to be completely inert, just how "inert" is enough to qualify as "inert?" Defendants' fear is unwarranted. A person of ordinary skill reviewing the '505 and '230 patent specifications would understand that the invention is a stable formulation. That requires a subcoating that protects the omeprazole and maintains the integrity of the enteric coating. (See, e.g., Pl, col. 15:34-38; see also Pl, col. 15:7-16.) The meaning of "inert" flows directly from the invention described in the specification--the subcoating layer cannot adversely affect the properties of the omeprazole or the enteric coating. The patent specification provides that "not adversely affecting . . . the enteric coating" means that the formulation retains gastric acid resistance. (See, e.g., Pl, col. 5:33-53 ("Without this separating layer the resistance towards gastric juice would be too short and/or the storage stability of the dosage form would be unacceptably short.").) This construction of the term "inert" is also supported by the file histories of the two patents. For example, United States Patent 4,685,918 ("Amidon"), a document referenced in the prosecution history for the '505 patent, discusses "inert inorganic and organic solvents" that "do not adversely harm the core, wall, and the materials forming the final wall." (Astra's Cl. Constr. Mem., Ex. 19, '505 Pros. History at 295, Amidon, col. 10:4-8 (emphasis added).)

The patent specifications describe the properties the subcoating should have in terms of stability. The subcoating must provide increased gastric acid resistance and storage stability. (See, e.g., Pl, col. 5:33-53.) Thus, the patent teaches that the subcoating must be inert under those conditions, which allows for the possibility that some inconsequential amounts of different components may react under some conditions or to such a limited extent that gastric acid resistance and storage stability remain uncompromised for practical purposes. Therefore, the court construes the term "inert" in claims 1 of the '505 and '230 patents, when modifying "subcoating," to require that the subcoating be chemically, pharmaceutically, and pharmacologically inactive such that the subcoating does not adversely affect the properties of the active ingredient or the enteric coating material in the formulation.

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The invention claimed by the patent involves hydrogen sulfide contamination. Hydrogen sulfide is a toxic gas found naturally in crude oil, derivative products such as petroleum residua and fuel oils, and waste water associated with crude oil production. See '991 patent, col. 1, l. 19 to col. 2, l. 2. Hydrogen sulfide vapors are slowly emitted from these liquids at all stages of production, transport, and storage. If uncontrolled, they pose a serious health problem. See id. The claims at issue are directed to processes and compositions for controlling these emissions. Claims 1-9 are process claims. Independent claim 1, from which claims 2-9 depend, reads in pertinent part as follows:

1. A process of inhibiting the liberation of hydrogen sulfide gas from a material comprising water or a hydrocarbon containing dissolved hydrogen sulfide comprising adding to said material a sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas evolution. . . .

Id. at col. 7, ll. 7-12.

Claims 17-25 and 35 are related composition claims. Independent claim 17, from which claims 18-25 and 35 depend, reads in pertinent part as follows:

17. A composition comprising

a. a material comprising water or a hydrocarbon, and

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b. a sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas liberation. . . .

Id. at col. 8, ll. 34-38.

Claims 42-45, which were added during the reexamination proceeding, are also composition claims. Claim 42, from which claims 43-45 depend, reads in pertinent part as follows:

42. A composition comprising:

a. a liquid hydrocarbon material, and

b. a sufficient amount of the following diaminomethane compound to inhibit hydrogen sulfide gas liberation. . . .

Feb. 8, 1995 Response to Office Action at 2-3 (adding claims 42-45).

The two references upon which the Board relied in rejecting the claims at issue were the Doerges reference and U.S. Patent 4,244,703 (Kaspaul). The parties do not dispute what these references teach one of ordinary skill in the art.

The Doerges reference teaches a process for removing hydrogen sulfide and other acid gases from natural gas (a gaseous hydrocarbon) by "scrubbing" the natural gas with an absorbent liquid containing an organic solvent and an organic base such as a diaminomethane. See Doerges, col. 1, ll. 49 to col. 2, l. 28. Specifically, the absorbent liquid is circulated through a vertical column from the top to the bottom. See id. at col. 4, ll. 35-41. The natural gas is then pumped into the bottom of the column. See id. As the natural gas vapors rise to the top of the column, the hydrogen sulfide is absorbed by the absorbent liquid. See id. The natural gas then exits the top of the column with less hydrogen sulfide in it. See id.

The second reference, Kaspaul, teaches adding a diaminomethane compound to hydrocarbon fuels to improve fuel economy. See Kaspaul, col. 2, ll. 50-60. It does not teach inhibiting the liberation of hydrogen sulfide from a hydrocarbon. It does not refer to hydrogen sulfide at all.

The Board held that process claims 1-9 and composition claims 17-25 would have been obvious over the Doerges reference. The Board held that the broadest reasonable interpretation of the term "hydrocarbon" included both gases and liquids in light of references in the written description to both gaseous and liquid hydrocarbons. See Petrolite, slip op. at 15, 21-27. The Board also held that the process of claim 1 would have been obvious over the Doerges reference because the amount of diaminomethane in the absorbent liquid in the column was sufficient to inhibit the evolution of hydrogen sulfide. See id. at 19. With regard to composition claim 17, the Board found that the process disclosed in the Doerges reference resulted in "a mixture containing a hydrocarbon gas, methanol, and a particular amount of the claimed diaminomethane compound . . . The Doerges reference describes the composition recited in claim 17." Id. at 32. The Board held that "the complete description of the claimed composition is the ultimate of obviousness." Id. The Board concluded that dependent claims 2-8 and 18-25 would have been obvious for the same reason.

The Board also concluded that composition claims 17-25, 35, and 42-45 would have been obvious over the Kaspaul reference. The Board construed independent claims 17 and 42 as not requiring the presence of hydrogen sulfide in the compositions. See id. at 37. The Board concluded that the compositions of claims 17 and 42 would have been obvious over the Kaspaul reference because the amount of diaminomethane described in that reference would effectively inhibit the evolution of hydrogen sulfide. See id. at 36-37. The Board concluded that dependent claims 18-25, 35, and 43-45 would have been obvious for the same reason.

Baker Hughes timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994).

DISCUSSION

* * *

Turning to the merits of the Board's decision, we agree with Baker Hughes that the Board erred in construing the term

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"hydrocarbon" as used in the claims to include gases. As the plain language of claims 1, 17, and 42 indicates, the claims are directed to inhibiting the "evolution" or "liberation" of hydrogen sulfide from either an aqueous or hydrocarbon material. The written description uses the terms "evolve" and "liberate" several times and, in each instance, the terms are used to describe the emission of hydrogen sulfide from a liquid hydrocarbon, particularly petroleum residua. See, e.g., '991 patent, col. 1, ll. 57-58. For example, in the Background of the Invention, the written description states:

The presence of the sulfur compounds in the residua gives rise to the generation of a gas having substantial portions of hydrogen sulfide gas. . . . During storage or [] transport [of residua], hydrogen sulfide gases become liberated. . . . Providing an effective chemical method for suppressing or inhibiting the liberation of hydrogen sulfide gases from residua are of considerable importance. Methods heretofore known for suppressing the liberation of hydrogen sulfide gases from residua suffer from the standpoint of effectiveness.

Id. at col. 1, l. 66 to col. 2, l. 17 (emphasis added). Similarly, in the Detailed Description of the Invention, the written description states that "the incorporation of the additive to suppress the evolution of hydrogen sulfide gases should be made before the residua are stored or transported." Id. at col. 3, ll. 62-65 (emphasis added). Although the Director points to various parts of the written description that describe hydrocarbons as gases and liquids, nowhere does the written description use the terms "evolution" or "liberation" to describe the separation of hydrogen sulfide from a gaseous hydrocarbon material. Moreover, the written description's use of the terms "evolution" and "liberation" to describe the emission of a hydrogen sulfide from a liquid hydrocarbon is consistent with the terms' common chemical definitions. See Webster's II New Riverside University Dictionary 690 (1988) ("liberate: to release from combination, as a gas"); id. at 449 ("evolve: to give off: emit"). Lastly, nowhere in the written description is there an example of the claimed process being used with a gaseous hydrocarbon. None of the embodiments of the invention described in the written description relate to gaseous hydrocarbons. We therefore conclude that the Board adopted a construction of the claim beyond that which was reasonable in light of the totality of the written description, and therefore erred in construing the claims to include gaseous hydrocarbons.

While in many cases a reversal on claim construction would necessitate a remand, we need not remand for the PTO to determine whether the change of construction renders claim 1 nonobvious over the Doerges reference. We agree with Baker Hughes that the process of claim 1 would not have been obvious over the Doerges reference. The differences between the processes are readily apparent. The Doerges reference teaches how to extract hydrogen sulfide from a gaseous hydrocarbon with a diaminomethane solution, whereas claim 1 teaches how to inhibit the liberation of hydrogen sulfide from a liquid hydrocarbon by adding diaminomethane directly. Thus, the results are opposite. In the Doerges reference the hydrogen sulfide is removed; in claim 1, it is retained. Moreover, in claim 1, the diaminomethane is added to a liquid hydrocarbon, whereas in the Doerges reference a gaseous hydrocarbon bubbles through the diaminomethane solution.

In its reexamination decision, the examiner allowed another claim, claim 37 (added during reexamination), that is identical to claim 1 except that it explicitly recites a "liquid hydrocarbon." See Petrolite, slip op. at 2 (allowing claim 37); Feb. 8, 1995 Response to Office Action at 1-2 (adding claim 37). Since the examiner concluded that claim 37 would not have been obvious over the Doerges reference, we can safely assume that he would have concluded that claim 1 would not have been obvious over the Doerges reference had he construed the claim as we have. In addition, since we have concluded that the process of claim 1 would not have been obvious over the Doerges reference, the processes of claims 2-9, containing additional limitations, similarly would not have been obvious. The Board's rejection of claims 1-9 over the Doerges reference is therefore reversed.

We also agree with Baker Hughes that the compositions of claim 17 would not have been obvious over the Doerges reference. The differences between the compositions of claim 17 and the mixture described in the Doerges reference are readily apparent. The Doerges reference describes a gaseous hydrocarbon, whereas claim 17 describes a liquid hydrocarbon. As with claim 1, we can also assume that the examiner would not have found claim 17 obvious over the Doerges reference had he construed the claim to cover only liquid hydrocarbons because he did not reject claim 42 (also added during reexamination) over the Doerges reference. Claim 42 is similar to claim 17 except that it also explicitly recites a "liquid hydrocarbon." In addition, since we have concluded that the compositions of claim 17 would not have been obvious over the Doerges reference, the compositions of claims 18-25 and 35, containing additional limitations, similarly would not have been obvious. The Board's rejection of claims 17-25 and 35 over the Doerges reference is therefore also reversed.

Finally, we agree with Baker Hughes that the Board erroneously construed composition claims 17 and 42 as not requiring

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the presence of hydrogen sulfide. Both claims require "a sufficient amount of [] diaminomethane compound to inhibit hydrogen sulfide gas liberation." This language implicitly requires the presence of hydrogen sulfide in the compositions for two reasons. First, the liberation of hydrogen sulfide from a composition cannot be inhibited if it is not present. Second, it would be futile to determine how much diaminomethane would be "sufficient" to inhibit hydrogen sulfide liberation if hydrogen sulfide were not present.

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Disputed claim language	Plaintiffs' construction	Defendants' construction
A composition for inhibiting an increase in, or lowering, a blood sugar level	The preamble of this patent is clear and unambiguous and therefore is not in need of construction.	A mixture made up of one or more ingredients that has the effect of preventing blood glucose from rising above a normal level, or lowering blood glucose to a normal level.

Language in a claim's preamble is appropriate for construction when it limits the claimed invention. A preamble generally limits the claimed invention if it "recites essential structure or steps, or if it is necessary to give life, meaning and vitality to the claim." NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1305 (Fed. Cir. 2005) (quoting Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) ("Additionally, dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention. [citation omitted] Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope. [citation omitted] Further, when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation. [citation omitted]"). However, preamble language is generally not limiting "'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" Catalina Mktg, 289 F.3d at 808 (quoting Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997)). Here, the parties agreed at the hearing that the preamble language is limiting. They disagree, however, on whether the language needs to be construed.

The disagreement focuses on Defendants' proposed substitution of the word "preventing" for "inhibiting." Plaintiffs argue that the use of "preventing" is too limiting, and that the word "inhibiting," as used in the claim language, is clear and not in need of construction. The Court agrees that "preventing" is different from, and more restrictive than, the term "inhibiting." Defendants have made no showing, based on any intrinsic or extrinsic evidence, that "inhibiting" should be given a construction that is more restrictive than its ordinary meaning. For example, the specification does not contain the term "preventing," nor does the context of the claim language warrant use of this term. The specification includes language regarding keeping blood sugar at a normal level, but because the Court may not read limitations from the specification into the claims, the use of "preventing" would improperly impose limitations on the claim that are not found in the claims themselves. Finally, no party presented any prosecution history as to the meaning of "inhibiting" that would justify giving it a limited meaning.

In this context, inhibiting means slowing down or impeding, in whole or in part, a person's blood sugar level from increasing or going up higher than it otherwise would but for the method employed. See Pl.'s Reply at 2:14-16. This definition, however, only reiterates the plain meaning of "inhibiting," and therefore does not clarify or aid in understanding a disputed term. See United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claims construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what a patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."). Accordingly, the Court declines to construe this language.

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The district court conducted a Markman hearing and construed five claim terms disputed by the parties, including "inhibitor or activator of a protein," n2 which was held to mean "a substance that has a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all."

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n2 The district court's constructions of the other four disputed claim terms are contested either by Housey in its appeal, or by the defendants in a conditional cross-appeal. Because our holding on the construction of "inhibitor or activator of a protein" is dispositive by virtue of Housey's stipulation, we do not address these other terms.

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The district court considered and expressly rejected Housey's argument that an "activator or inhibitor of a protein" was limited to substances that "directly interact [with], i.e., bind to, the target protein." The interpretation adopted by the district court includes within an "inhibitor or activator of a protein" substances that affect the test cell's "responsive change in a phenotypic characteristic" through the direct-binding concept to which Housey argues the term is absolutely limited. In addition, however, it is broader: it includes substances that operate through other indirect concepts of molecular interaction. For example, under the district court's interpretation, a substance being screened may still be an "inhibitor or activator of a protein" if it binds to and alters the metabolic functioning of a molecule other than the POI that is essential to either a biochemical pathway required to produce the POI in the first place or a biochemical pathway in which the fully formed POI participates in the cell in order to trigger the "phenotypic response." In other words, the district court's definition includes within the scope of an "inhibitor or activator of a protein" substances that inhibit or activate the biological activity of the POI in the cell without binding to the POI itself.

Housey stipulated that, "based upon the Court's construction of the claim limitation 'inhibitor or activator of a protein,' . . . [and] subject to its right to appeal the Court's claim construction and any final judgment based thereon, that the Court may enter an order stating that the patents in suit are invalid and not infringed." Housey and the defendants, however, "reserved all of their claims, counterclaims, arguments and defenses" if "the Court's determinations on . . . issues of claim construction [related to 'inhibitor or activator of a protein'] are reversed or modified on appeal such that the matter is remanded for further consideration." Based on the stipulation, the district court entered final judgment in favor of the defendants.

Housey appealed to us, and we have jurisdiction to hear the appeal pursuant to 28 U.S.C. § 1295(a)(1).

III

We review the district court's claim construction de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Claim construction begins with the language of the claims. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). When construing patent claims, there is a "heavy presumption" that the language in the claim "carries its ordinary and customary meaning," CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002), "amongst artisans of ordinary skill in the relevant art at the time of the invention," ResQNet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1378 (Fed. Cir. 2003). Dictionaries and treatises may provide insight into a term's ordinary meaning thus defined. Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202-03 (Fed. Cir. 2002). However, a claim must also be considered in the context of the intrinsic evidence, namely the claims, the specification, and the prosecution history. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342-43 (Fed. Cir. 2001). If there is a discernable plain and ordinary meaning of the claim language, then this meaning usually defines the scope of the claims unless the patentee has explicitly disclaimed or clearly disavowed this meaning in the specification or prosecution history. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (requiring "words or expressions of manifest exclusion or restriction" before broad terms in a claim will be read narrowly in light of a narrow specification (quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2000)); Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) ("This court also considers the prosecution history ... to determine whether the applicant clearly and unambiguously 'disclaimed or disavowed [any interpretation] during prosecution in order to obtain claim allowance.'" (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985) (alteration in original))). For example, the patentee may act as his own lexicographer and expressly define the term in the specification. See Tex. Digital Sys., 308 F.3d at 1204; Rexnord, 274 F.3d at 1342.

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A

The language of claim 1 of the '281 patent clearly supports the district court's construction and is inimical to any narrower construction. The claim recites "[a] method of determining whether a substance is an inhibitor or activator of a protein." '281 patent, col. 24, ll. 46-47. The steps of the method in turn permit a determination of whether substances affect phenotypic response to the POI in the test and control cells differently. Thus, if "a substance . . . has a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all," the substance is, as defined by the claimed method itself, an inhibitor or activator of the protein of interest.

Furthermore, the specification expressly defines an "inhibitor or activator of a protein" as a substance that yields a positive response to the claimed method, just as the district court did. See id. at col. 3, ll. 5-10 ("Substances which specifically inhibit or inactivate [sic] the POI may be distinguished from substances which affect cell morphology or growth by other mechanisms in that they will have a greater effect on the test lines than on the control line."); id. at col. 4, ll. 48-50 ("Inhibitors or activators are identified by their greater effect on the phenotype of the higher producing cell line.").

Housey argues that the district court's construction "confuses the method of distinguishing activators or inhibitors with the definition of activators or inhibitors." We disagree. The claim addresses a method of determining whether a compound is an inhibitor or activator that is conducted by observing whether a particular event occurs when the method is performed. It is therefore logical to construe an "inhibitor or activator of a protein" as a substance that precipitates that event, especially given that the specification, too, defines an inhibitor or activator in the same way.

B

Housey's principal argument on appeal with respect to the construction of "inhibitor or activator of a protein" is the same one that was rejected by the district court: Housey argues that this limitation is "properly construed to mean substances that interact with, i.e., bind to, the POI in order to exert their inhibiting or activating effect on the cellular functioning of the POI." We do not agree that, as used in the '281 patent, an "inhibitor or activator of a protein" is limited to substances that achieve their effect on the biological activity of the POI through a particular reaction mechanism, namely binding to the POI. A substance need only have "a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all" to be an "inhibitor or activator of a protein," and an inhibitor or activator of a POI may alter the biological activity of the POI through a direct POI-binding mechanism or an indirect pathway-binding mechanism. The word "bind" or "binding" appears nowhere in the '281 patent in conjunction with an "inhibitor or activator of a protein."

At oral argument (and thus on the late side of things), Housey produced definitions of "inhibitor" and "activator" from technical dictionaries to argue for the first time on appeal that the plain meaning of an "inhibitor or activator of a protein" is limited to a substance that binds to the protein. With respect to an inhibitor or activator of an enzyme, these definitions do include a direct-binding limitation. See Chambers Dictionary of Science and Technology 13 (1999) (defining "activator" as "of an enzyme, a small molecule which binds to it and increases its activity"); Henderson's Dictionary of Biological Terms 284 (11th ed. 1995) (defining "inhibitor" as "a substance which . . . prevents the normal action of an enzyme . . . by binding to the active site . . . [or] by binding to other parts of the enzyme"). However, the claim language is an "inhibitor or activator of a protein," not of an enzyme, n3 and the dictionaries also include a more appropriate general definition of both "activator" and "inhibitor" that requires only an effect on the biological activity of the protein, regardless of the mechanism used to achieve that effect. See Chambers Dictionary of Science and Technology 13 (defining "activator" as "any agent . . . whose presence stimulates biochemical or physiological changes"); Henderson's Dictionary of Biological Terms 284 (defining "inhibitor" as "any agent which checks or prevents an action or process"). Thus, according to the evidence submitted by Housey, the plain meaning of "inhibitor or activator of a protein" does not support the inclusion of the direct-binding concept as a limitation on the claimed method.

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n3 Enzymes are only one of many types of proteins. See Henderson's Dictionary of Biological Terms 474 (noting that proteins are "essential in living organisms as enzymes, structural constitutents of cells and tissues and in control of gene

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expression etc.").

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The intrinsic evidence of the '281 patent does not clearly disavow this broad plain meaning. In fact, even if the plain meaning were considered to be ambiguous, supporting both a narrower definition limited to inhibitors and activators that bind to the POI and a broader definition of inhibitors and activators that need only affect the biological activity of the POI, the district court was correct because the specification and prosecution history affirmatively demonstrate that Housey intended the broader meaning that is not limited to direct binding.

The specification foresaw the possibility of a substance affecting the "responsive change in a phenotypic characteristic" in the cell line with the greater amount of POI without the substance binding to the POI. See '281 patent, col. 6, ll. 29-33 ("Cell lines will be sensitive in their growth properties [i.e. in the their relevant phenotypic characteristic] to chemical agents which are capable of binding to, or modifying the biological effects of, the POI." (emphasis added)). n4 The specification also expressly defines the terms "inhibitors" and "activators" in terms of the biological activity of the POI without any reference to binding. See id. at ll. 40-42 ("The term 'inhibitors' includes both substances which reduce the activity of the POI and those which nullify it altogether."); id. at ll. 37-40 ("The term 'activators,' as used herein, includes both substances necessary for the POI to become active in the first place, and substances which merely accentuate its activity.").

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n4 Housey's argument that the "or" in this passage from the specification is explanatory, not disjunctive, is strained. "Binding to" is unquestionably narrower than "modifying the biological effects of." Rarely does one use "or" in the explanatory sense to define a word as simple as "bind," and even less frequently does one use a broad, general term to explain the meaning of a narrow, precise term.

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Housey's statements in the prosecution history of the '281 patent also support this conclusion. In distinguishing prior art during prosecution, Housey repeatedly characterized his invention as one that could determine whether a substance interacted with the biological pathway in which a particular protein functioned: The prior art did "not provide the target protein/biochemical pathway specificity of the present invention." Because biological pathways usually involve more than one protein, a substance can clearly interact with the POI's biological pathway without binding with the POI itself, and Housey stated as much in the process of distinguishing another prior art reference:

Substances . . . identified or characterized using the teachings of the Housey patents will be found to interact directly with the target protein itself and/or with other proteins in which the target protein also interacts in the form of dimeric or multimeric complexes. In this fashion, the approach disclosed in the Housey patents provides a specificity between a target protein and its attendant biochemical pathways within the cell that is impossible to achieve with other assay systems.

Housey argues that an inhibitor or activator is limited to substances that bind to the POI because the claim language specifies an inhibitor or activator "of a protein." The fact that the biological activity "of a protein" is affected by a screened substance, however, lends no insight into whether the effect must be attributed to binding to the protein or some other type of influence on the biological pathways through which the protein is created and in which the protein functions.

Similarly, Housey argues that the recurring presence of the terms "specific" and "specifically" in the specification and the prosecution history conclusively demonstrates that the inhibitor or activator operates by binding with the POI. See, e.g., '281 patent, col. 1, ll. 10-12 ("In particular, [the invention] is concerned with a method of screening for substances which specifically inhibit or activate a particular protein." (emphasis added)); id. at col. 2, ll. 27-28 (describing the invention as having a "specificity for detecting an active agent exceeding that of" the prior art assays); id. at ll. 28-32 ("The method which we describe herein involves the generation of a cell line purposefully engineered to detect both stimulatory and inhibitory agents which are absolutely specific for any given protein which affects the cultural of morphological characteristics of a cell." (emphasis added)); id. at col. 9, ll. 30-31 (stating that the method was screening for "substances which may contain biologically active agents specific to the POI" (emphasis added)). Leaving aside the absence of the word "specific" in the claim language (and our repeated warnings not to import limitations from the specification that are not

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present in the claims, Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003) ("The danger of improperly importing a limitation is even greater when the purported limitation is based upon a term not appearing in the claim.")), this language from the specification does not lead to a strong inference of direct binding to the POI. As the above-quoted sections of the prosecution history demonstrate, the use of "specific" suggests equally as strongly that the biological activity of the POI is affected, through a direct or indirect mechanism, when the biological activity of other proteins in other biochemical pathways is not. Furthermore, the specification, too, equates specificity with the biological effect of the inhibitor or activator, not with any particular mechanism of action. See '281 patent, col. 3, ll. 5-10 ("Substances which specifically inhibit or inactivate the POI may be distinguished from substances which affect cell morphology or growth by other mechanisms in that they will have a greater effect on the test lines than on the control line." (emphasis added)). n5

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n5 Housey's reference to the definition of the term "specific binding" is not relevant to the use of "specific" in the patent, as "specific binding" presupposes the presence of binding, the very limitation which is in question here.

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Finally, Housey points to language at the end of one of the specific embodiments in the specification and argues that it demonstrates that the patented assay must be able to detect substances that bind to the POI: "This work establishes, for the first time, the fact that stable overproduction of a protein in mammalian cells can result in a novel cellular phenotype(s) . . . which can be directly modulated by chemical agents which interact with the protein." Id. at col. 18, ll. 30-36 (emphasis added). First, this passage does not indicate that the interaction between the agent being screened and the POI must be in the form of direct binding; another protein or cellular component may provide the mechanism through which the agent interacts with the POI. Second, not only does this passage describe only a single embodiment (and limitations on specific embodiments are not to be imported into the claims, see Electro Med. Sys., S.A. v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994)), but it describes an embodiment in which there is "a direct relationship between the molar amount of inhibitor [or activator] required to prevent [or stimulate] [the phenotypic response] and the molar amount of [the POI] present in each cell line." '281 patent, col. 18, ll. 22-24, 28-30. This additional fact notes a direct relationship between the amount of POI overexpressed in the test cell and the amount of inhibitor or activator required to eliminate the "responsive change in a phenotypic characteristic." If true, this fact may or may not permit one of skill in the art to use the claimed method to divine that the inhibitor or activator binds directly to the POI, but it unquestionably is not a claimed limitation in the "method of determining whether a substance is an inhibitor or activator of a protein" of claim 1 of the '281 patent.

C

Housey invokes two canons of claim construction to support limiting an "inhibitor or activator of a protein" to a substance that binds to that protein, but neither is persuasive. First, Housey cites Athletic Alternatives, Inc. v. Prince Manfacturing, Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996), for the proposition that in the event of a tie between a broader and narrower meaning, the notice function of patent law requires that the narrower meaning prevails. Housey misreads Athletic Alternatives. In that unusual case, one patent applicant made two contradictory and irreconcilable affirmative representations of the contested limitation. In those circumstances, we held that the narrower interpretation trumps the broader interpretation. In this case, there are no contradictory and irreconcilable choices for the meaning of "inhibitor or activator of a protein." Second, Housey relies on the axiom that "claims should be so construed, if possible, as to sustain their validity." Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) (quoting Carman Indus., Inc. v. Wahl, 724 F.2d 932, 937 n.5 (Fed. Cir. 1983)). Here, we have not been asked to review validity, and the district court did not pass on validity. Housey's stipulation of invalidity alone is insufficient to invoke this canon. In any event, the canon lacks dispositive effect in this case. See Liebel-Flarsheim Co., 358 F.3d at 911 ("Unless the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous, the axiom regarding the construction to preserve the validity of the claim does not apply.").

IV

We agree with the district court's construction of the "activator or inhibitor of a protein" limitation, and we therefore affirm the judgment of the district court.
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E. "inhibits a pathological activity of human TNF [alpha]"

Claim term, phrase or clause	Centocor's Proposed Construction
"inhibits a pathological activity of human TNF [alpha]"	"Inhibits a TNF-[alpha]-mediated biological activity associated with a clinical problem such as disease, infection and/or malignancy"

Claim term, phrase or clause	Defendants' Proposed Construction
"inhibits a pathological activity of human TNF [alpha]"	"Inhibits a biological activity such as cytotoxicity, inflammation, or other activity associated with human TNF [alpha] mediated disease or damage."

This term appears in claim 11 of the '239 patent. The claim reads as follows:

11. The antibody or antigen-binding fragment of claim 9, wherein said binding of the antibody or antigen-binding fragment to human TNF [alpha] inhibits a pathological activity of human TNF [alpha]. '239 Patent, cl. 11 (emphasis added).

The defendants dispute only the inclusion of "clinical" in the plaintiffs' proposed construction. They argue that such limitation suggests that clinical testing, rather than in vitro testing, is required to show inhibitions of pathological activity of TNF-[alpha]. The defendants cite to a portion of the specification that discloses in vitro assays that show antibodies inhibiting cell death caused by TNF-[alpha], concluding that such antibodies have therapeutic use for treating TNF-[alpha]-mediated pathologies. See '775 Patent, col. 50, l. 1-col. 51, l. 57.

The plaintiffs' proposed construction unnecessarily limits the inhibition of pathological activity to clinical problems, especially when the specification expressly allows for testing of inhibition through in vitro assays. The inclusion of "clinical" in the plaintiff's construction unnecessarily limits the claim scope.

Accordingly, the court construes the disputed phrase as follows: "inhibits a TNF-[alpha]-mediated biological activity such as cytotoxicity or inflammation, or one associated with a clinical problem such as disease, infection and/or malignancy."
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Claim 1 of the '329 Patent, with disputed terms underlined and agreed construction in brackets, recites:

1. A stiff heterophase naturally transparent gel candle, said candle comprising a transparent gel made of from about 70% to about 98% by weight of a hydrocarbon oil, and up to about 30% by weight of a copolymer selected from the group consisting of a triblock, radial block, and multiblock copolymer, and optionally from 0 to about 10% by weight of a diblock copolymer, a wick contained in said gel; and one or more ornamental insoluble objects embedded in said gel; wherein said candle additionally comprises at least one additive selected from the group consisting of an anti-oxidant, stabilizer, fragrance, colorant, insect repellant, and flame retardant.

Penreco argues for the following construction of the term "insoluble" as used in the phrase "one or more ornamental insoluble objects embedded in said gel" in claim 1: "one or more ornamental objects not uniformly blended in said gel." This construction, Penreco argues, requires use of a visual test to determine whether an embedded object is insoluble.

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According to Penreco, a visual test comports with the claim language of the '329 Patent--specifically that of dependent claim 9, which provides specific examples of insoluble ornamental objects--including "stars, glitter, sparkles, ribbons, swirls or layers of colorant or combination of shaped objects." United States Patent No. 6,066,329, Document No. 88, ex. 2, at col. 11, 11. 19-20. Penreco argues, moreover, that a visual test is appropriate and necessary in light of the purpose or function of having an ornamental object embedded in the gel, namely, to improve the aesthetic or decorative properties of the candle.

Hanna's criticizes Penreco's contention that "insoluble" means "not uniformly blended," by arguing that Penreco's definition eliminates restrictions that the word "insoluble" imparts on the word "objects." In other words, according to Hanna's, if the ornamental objects are blended uniformly into the gel, then there are no ornamental "objects." Likewise, if there are ornamental objects in the gel, then necessarily they are not uniformly blended into the gel. Hence, the word "insoluble" is meaningless as a modifier of the word "objects" in claim 1. Hanna's points out that this criticism is bolstered by the written description of the '329 Patent, in which the inventors contemplated that the embedded ornamental features "may be either insoluble or soluble in the gel composition of the candle, as desired." U.S. Patent No. 6,066,329, Doc. No. 88, ex. 2, at col. 8, 11. 9-11 (emphasis added). Claim 1, however, covers only "one or more ornamental insoluble objects embedded in said gel." (Emphasis added.) Hanna's correctly observes that Penreco's construction cannot be correct because it would eviscerate the inventors' belief that both soluble ornamental features and insoluble ornamental features can be embedded in the gel candle. If the insoluble ornamental objects include everything that is "not uniformly blended" into the gel, however, no conceptual room is left for any distinction to be made between soluble and insoluble ornamental objects. Again, the word "insoluble" is rendered meaningless.

Hanna's, on the other hand, proposes to construe the phrase as "one or more ornamental objects incapable of dissolving under any. condition during the life of the candle embedded in said gel." Hanna's construction is derived from several dictionaries and chemistry treatises, which define "insoluble" as "1. That cannot be dissolved: insoluble matter," THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed., 2000), Document No. 87 ex. 2, at 907, and "That the solubility is less than about .1 g per 100 ml (roughly 0.01 M) , "LINUS PAULING, GENERAL CHEMISTRY (1 9 7 0) , id. ex. 3, at § 13-4 . Dr. Eric Wigg, a chemist designated by Hanna's as its expert witness, defines insoluble as "a negligible quantity of the compound dissolves." Document No. 87 ex. 7, at 150:5-7. 2

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2 Dr. Wigg states in his deposition that his proffered definition is taken from the Chemical Rubber Publishing Co.'s Handbook of Chemistry and Physics (1963), which states that "[t]he term insoluble (i.) must be interpreted to mean that a negligible quantity of the compound dissolves." See HANDBOOK OF CHEMISTRY AND PHYSICS (Chemical Rubber Publishing Co., 1963), Document No. 88 ex. 10, at 763.

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Hanna's rigid definition of insoluble, which is rooted in the science of chemistry, would not seem to apply in the context of purely decorative objects embedded in gel candles to serve an ornamental or aesthetic purpose. In fact, neither of the parties' proposed constructions fully considers the function of the insoluble objects embedded in the gel as indicated by the written description of the '329 Patent--namely, that the objects are ornamental or decorative features. A claim term must be interpreted in light of the teachings of the written description and purpose of the invention described therein. Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 25 (Fed. Cir. 2000). See also Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 956 (Fed. Cir. 2000); Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998) (relying, in part, on the stated purpose of the invention in construing the claims); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim.").

WEBSTER' S NINTH NEW COLLEGIATE DICTIONARY (1990) , Which WaS in popular use in the few years immediately preceding this patent application, defines "insoluble" as "soluble only with difficulty or to a slight degree." This definition provides a sensible and commonplace understanding of the word when applied to an ornamental object placed in a transparent gel candle for aesthetic purposes. If the ornamental object is soluble only with difficulty or to a slight degree when embedded in a gel candle, it fulfills the ornamental purpose of the invention. This does not require chemical or scientific analysis of the embedded ornamental object(s), but only a visual test. Therefore, and taking into account the purpose of the invention, the claim term "insoluble" in "one or more ornamental insoluble objects embedded in said gel" is

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construed to mean "soluble only with difficulty or to a slight degree, so that the object(s) when embedded in the gel retains its intended ornamental feature."
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B. Claim 1 of the '323 and '535 Patents

Here, Becton and Novo disagree as to the proper construction of Claim 1 of the '323 and '535 patents. 20 Claim 1 of the '323 patent states:

A needle assembly comprising:

(a) a needle hub having a base and a standard insulin needle fitting for removably mounting said needle assembly on a pen-type insulin syringe having a standard mounting and which accepts cartridges containing only insulin types that may flow freely through a G30 needle; and

(b) a G30 needle secured in said base and having first and second needle portions extending from said base in opposite directions.

'323 Patent, Becton Ex. 7.

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20 As previously indicated, Claim 1 is the only independent claim in both the '323 and '535 patents.

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Claim 1 of the '535 patent provides:

An insulin injection system comprising a pen shaped syringe comprising a cartridge with insulin and an injection needle, wherein the needle is a G30 needle and the cartridge contains an insulin type which may freely flow through the G30 needle.

'535 Patent, Becton Ex. 1.

At issue here is the meaning of the language "insulin types that may flow freely through a G30 needle" contained in the '323 patent, and the similar language "an insulin type which may freely flow through the G30 needle," contained in the '535 patent. Novo argues that this language applies to both insulin solutions and insulin suspensions. Becton counters that this language must be interpreted as applying only to insulin suspensions.
C. Construing the Patents

Having reviewed the specifications and prosecution histories of the patents, the Court agrees with Novo's reading of the claims. That is, for the limited purpose of ruling on Novo's motion for a preliminary injunction, the Court construes the language of Claim 1 of the '323 and '535 patents to apply to both insulin suspensions and solutions.

Column 3, Line 10 of the '323 patent, and Column 3, Line 7 of the '535 patent explicitly refer to both insulin solutions and suspensions. Likewise, the Abstracts 21 of both the '323 and '535 patents state in relevant part: "The needle is a G30 needle and the insulin is a type which may freely flow through a G30 needle. When the insulin is the type comprising suspended crystals the maximum dimension of any crystal is 15 [mu] m." 22 '323 and '535 Patent Abstracts, Becton Exs. 1, 7 (emphasis added). The clear implication from these Abstracts is that insulin that may flow freely through a G30 needle can be insulin solutions or suspensions.

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21 Patent Abstracts are relevant to claim construction. See, e.g., Al-Site Corp. v. Cable Car Sunglasses, 911 F. Supp. 410, 415 (N.D. Cal. 1994). 22 The symbol [mu] represents microns. One micron is equal to 0.001 mm.

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Moreover, the prosecution histories of both patents indicate that the patents apply to both insulin suspensions and solutions. See Declaration of Benjamin S. Lee, Ex. D at 3; '535 Patent Reexamination Request, Becton Ex. 14.

Accordingly, the Court concludes that the words "insulin types" and "insulin type" as used in Claim 1 of the '323 and '535 patents apply to both insulin solutions and insulin suspensions.

Having interpreted Claim 1 of Novo's patents, the Court now turns to whether the patents, as interpreted, are valid.
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E. "Intermediate release nicotinic acid formulation"

Term/Phrase (Claim Nos.)	Abbott's Proposed Construction	Lupin's Proposed Construction
"intermediate release nicotinic acid formulation" ('229 patent, claims 17 & 25) ('691 patent, claim 13) ('715 patent, claims 1, 3, 5, 7, 9, & 11) ('967 patent, claim 16)	A nicotinic acid formulation which, when administered to a patient to be treated, the active ingredient will be released for absorption into the blood stream over a period of time which is slower than that of immediate release niacin formulations, but faster and different than other sustained release niacin formulations	A dosage form not containing an internal hydrophobic component that releases an active ingredient, namely, nicotinic acid, in vitro or in vivo over a period of time which is greater than 1 hour but less than 24 hours

i. The Parties' Positions

With respect to the proper understanding of the temporal aspect of the disputed phrase, Abbott observes that the CIP patents' specifications all state that:

As indicated herein, "intermediate release" is understood to mean a composition or formulation which, when orally administered to a patient to be treated, the active ingredient will be released for absorption into the blood stream over a period of time which is slower than that of IR niacin formulations, but faster and different than SR niacin products.

('229 patent, col. 16 lines 33-40; '691 patent, col. 16 lines 30-38; '715 patent, col. 17 lines 2-9; '967 patent, col. 17 lines 2-9) The same specifications also state:

"[I]ntermediate release" … is used herein to characterize the nicotinic acid formulations of the present invention which release their medication in vitro or in vivo over a period of time which is greater than about 1 to 2 hours, i.e., slower than IR niacin, but less than about 10 to 24 hours, i.e., faster than SR niacin.

('229 patent, col. 5 lines 33-39; '691 patent, col. 5 lines 35-41; '715 patent, col. 5 lines 35-41; '967 patent, col. 5 lines 31-37) Abbott denies that the latter description'snumerical high and low endpoints should control (as they do in Lupin's construction), however, because the very purpose of using numerical time periods and the word "about" in describing them -- as opposed to fixed endpoints -- is to avoid numerical certainty. Abbott attests that "[i]t is axiomatic that the term 'about' avoids strict numerical limitations." (D.I. 55 at 43-44 n.9 (citing Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1368 (Fed. Cir. 2008))

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Lupin responds that the second quotation shown above should control, since it is more specific than the first. (D.I. 60 at 17) Additionally, the word "about" is not in the actual claim language being construed, just in the specifications, so precedents construing "about" as a claim term are inapposite. (Id. at 16) Lupin also objects that Abbott's proposed construction is ambiguous because it lacks limits. (Id. at 17) For example, the phrase "faster and different than other sustained release niacin formulations" in Abbott's proposal is ambiguous because there is no specified standard for assessing "different," and "other sustained release formulations" could refer to any number of SR products, including those disclosed in thespecification, those marketed at the time of the patent's issuance, or even those marketed at any time in the future. (Id. at 18) By contrast, Lupin insists that its proposed construction provides certainty and reflects the full range of time periods suggested in the CIP patents' specifications.

ii. Recommended Construction

I have concluded that neither Abbott nor Lupin has properly construed the disputed claim term "intermediate release nicotinic acid formulation." Instead, I recommend that the Court construe this term as "a nicotinic acid formulation which, when administered to a patient to be treated, the active ingredient will be released for absorption into the blood stream over a period of time which is greater than about 1 to 2 hours, i.e., slower than immediate release niacin, but less than about 10 to 24 hours, i.e., faster than sustained release niacin." 26

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26 For the reasons discussed previously, I do not believe the CIP patent claims (like those of the other claims in dispute) should be construed to include the limitation "not containing an internal hydrophobic component.

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This recommended construction is derived from the two specification excerpts quoted above, in which theinventor essentially defines the term "intermediate release" for purposes of the claims of these patents. The specifications' definitions are consistent with one another. Combining them, as I recommend, eliminates the ambiguity identified by Lupin in the phrase "different than other sustained release formulations." Additionally, while "about" does not appear in the disputed claim, it is appropriate here to include it in the construction, as it is part of the specifications' definitions. "About" is used in the specifications to show that the time periods within which SR and IR products are released vary based on metabolic factors and are thus difficult to predict, as is well known by those skilled in the art. (See, e.g,. '715 patent, col. 1 lines 54-67 ("[IR] nicotinic acid formulations generally release nearly all of their nicotinic acid within about 30 to 60 minutes following ingestion …. [SR] nicotinic acid formulations are designed to release significant quantities of drug for absorption into the bloodstream … over an extended period such as 12 or 24 hours after ingestion."); id. col. 4 lines 34-37 ("The difficulty of correctly predicting the appropriate release pattern [for SRproducts] is well known to those of skill in the art.").)
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3. "intratympanically injected through a puncture of the tympanic membrane"

Apotex argues that term "intratympanically injected through a puncture of the tympanic membrane," as used in Claim 7 of the patent, means "introduced into the middle ear with an instrument such as a syringe." (Apotex Br., at 25.) Daiichi urges a broader interpretation, in which the term means "forced into the middle ear through a puncture of, or a tympanostomy tube within, the tympanic membrane." (Daiichi Br., at 30.) The Court agrees with Apotex' interpretation of the disputed term.

Daiichi argues that Claim 7 should be read to include, but should not to be limited to, the use of a syringe. The basis for this argument is that since the '741 patent is directed to the treatment of otitis media with a perforated tympanic membrane, there would be no need to use a syringe to force the antibiotic into the middle ear cavity. According to Daiichi, Claim 7 should be construed to include the instillation of ofloxacin drops into the external auditory canal, as set forth in Claim 6, which are then forced, i.e. "injected," through the ruptured tympanic membrane using a method referred to as "pumping the tragus." n11

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n11 "Pumping the tragus" essentially means wiggling the ear so as to exert pressure on the fluid in the external auditory canal.

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Noting that the language of Claims 6 and 7 does nothing to support this interpretation, the Court finds that a close reading of the patent specification precludes this Court from adopting Daiichi's proposed construction. Specifically, in several sections of the specification, "intratympanic injections" are distinguished from the instillation of ear drops. The specification states: Dose forms of the topical preparation of the present invention include sprays, otic solutions, e.g. intratympanic injections and ear drops, ointments and the like.

* * *

In administration of the ofloxacin solution, several 0.5 ml-doses per day are applied to the external auditory canal by spreading, spraying or instillation, or intratympically injected through a puncture of the tympanic membrane.

(Krol Decl., Exh. A. (emphasis added).) Indeed, even Daiichi's own expert, Dr. Angelo Agro, testified at her deposition, that an ordinary person skilled in the art would not have known at the time the '741 patent was issued that "intratympanically injected" meant "pumping the tragus." As Agro testified:

Q: At the time of the invention, were any ototopical preparations being intratympanically injected in the fashion you are describing [pumping the tragus] ?
A. No.

(Krol Decl., Exh. M, Transcript of Deposition of Angelo Agro, M.D., 115:5-11.)

Had Daiichi intended the act as its own lexicographer and defined the term "intratympically injected" to mean "pumping the tragus," it was certainly free to do so by clearly defining the term in the patent specification. Having failed to do so, the Court finds that the most sensible construction of the term is, as Apotex argues, "introduced into the middle ear with an instrument such as a syringe," an interpretation that is consistent with the generally known meaning of the word "injection."
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After holding a Markman hearing on July 22, 2005, the Court held that a person ordinarily skilled in the art would have a medical degree, experience treating patients with ear infections, and knowledge of the pharmacology and use of antibiotics. Daiichi Pharm. Co., 380 F. Supp. 2d at 485. Additionally, that person would be a pediatrician or general practitioner-those doctors who are often the first line of defense in treating ear infections. Id. Furthermore, the Court construed the term "otopathy" to mean "bacterial ear infection," the words "effective to treat" to be interpreted as "safe and efficacious," and the phrase "intratympanically injected through a puncture of the tympanic membrane" to mean "introduced into the middle ear with an instrument such as a syringe." Id. at 485-89.
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(9) And being inverted with respect to said promoter segment and said termination segment . . . The Court concludes that this element requires an inverted gene segment, or, in other words, a "flipped" gene, or a gene that is placed in reverse orientation to the transcriptional promotor and transcription termination segments. The promoter and termination segments, however, must remain in ordinary position and order.
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Background

The '152 patent is directed to an adhesive for use on repositionable notes, such as 3M's Post-It (R) brand notes. The claimed adhesive, the key to repositionability, contains numerous inherently tacky, elastomeric microspheres. * Conventional flat film adhesives, used on tapes such as 3M's Scotch (R) brand tape, provide stickiness over the entire surface of the tape, resulting in very strong adhesive forces. Unlike the flat adhesive, only the tips of the claimed microsphere adhesive make contact with the surface. As a result of the reduced adhesive surface area, the adhesive forces are greatly reduced, permitting repositioning of the note.

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* Exemplary claim 1 recites (emphasis added):

Infusible, solvent-insoluble, solvent-dispersible, inherently tacky, elastomeric polymeric microspheres formed from non-ionic monomers and comprising a major portion of at least one oleophilic, water-emulsifiable alkyl acrylate or methacrylate ester, said polymeric microspheres having a glass transition temperature below about -20o C, and having been prepared by aqueous suspension polymerization in the presence of at least one anionic emulsifier at a concentration level above said emulsifier's critical micelle concentration and an ionic suspension stabilizer having an interfacial tension of at least about 15.0 dynes per centimeter.

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3M filed its complaint under section 337 alleging infringement of certain claims of the '152 patent by Beautone. Initial determinations were issued first by Chief ALJ Saxon and then, after a remand ordered by the Commission for additional findings, by ALJ Luckern. The Commission adopted Judge Luckern's initial determination, and then issued its final decision in which it affirmed Judge Saxon's finding that Beautone did not infringe the asserted claims, either literally or under the doctrine of equivalents. This appeal followed.
Discussion

On appeal, 3M assigns error to the Commission's claim construction, and to the finding of noninfringement under the doctrine of equivalents. In particular, 3M asserts the Commission erred in construing the phrase "in the presence of" as requiring the suspension stabilizer to be ionic when charged to the vessel, i.e., that under the claim the stabilizer can not be transformed from nonionic to ionic in situ. Regarding infringement, 3M contends that Beautone's product, which is prepared using two nonionic stabilizers having individual interfacial tensions of 9 and 13, is equivalent to the claimed product, which must have an interfacial tension "of at least about 15.0."

Under the Commission's interpretation that the stabilizer must be ionic when it is put into the vessel, we agree that a nonionic stabilizer is not an equivalent substituent. To so hold would effectively read the ionic limitation out of the claim. Conversely, if we were to give the claim the interpretation proffered by 3M--that the claims cover in situ formation of an ionic stabilizer--and further if we assume that Beautone's nonionic stabilizers actually become ionic in situ (there is no test so proving), 3M's infringement case nevertheless suffers fatally from a lack of proof.

3M offered no proof below that Beautone's product contained an ionic suspension stabilizer having an interfacial tension equivalent to at least 14.8. ** Indeed, the only evidence in the record regarding the interfacial tension claim limitation is that Beautone's two nonionic stabilizers have a combined interfacial tension of 11.0 at the start. 3M proffered no evidence regarding Beautone's actual in situ interfacial tension. While 3M's expert, Dr. Poehlein, did testify about the in situ reaction, his testimony was that the in situ reaction between ingredients would have the effect of lowering the interfacial tension from 11.0. On cross-exam, Dr. Poehlin testified that he did not know how far below 11.0 the interfacial tension would go because he "never measured that number." Nor was he aware that 3M ever measured Beautone's interfacial tension.

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** Judge Luckern construed the claim phrase "at least about 15.0" as literally meaning at least 14.8. Because 3M failed to

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raise the issue below, 3M can not now challenge that construction. Checkpoint Sys., Inc. v. United States Int'l Trade Comm'n, 54 F.3d 756, 760, 35 U.S.P.Q.2D (BNA) 1042, 1045-46 (Fed. Cir. 1995).

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Nevertheless, 3M contends that Beautone's products have an interfacial tension that is equivalent to that claimed. Yet, as pointed out above, 3M did not prove the actual value of the in situ interfacial tension of Beautone's combined stabilizers. It is impossible to determine equivalency without a value for Beautone's alleged in situ interfacial tension. 3M's brief is long on conclusory attorney argument regarding equivalency, but the record is woefully short on evidence. Absent preponderant evidence that Beautone's products contained an ionic suspension stabilizer with an interfacial tension that is equivalent to what was claimed, infringement can not be found.

We have considered 3M's other arguments, and find them unpersuasive. We need not consider Beautone's other defenses.
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III. 240 PATENT

As stated supra, the 240 process patent concerns the method of manufacturing the contact lenses described in the 477 patent. Specifically, the 240 patent refers to the method of printing the surface of a clear lens with a coloring substance so as to produce a lens of the type described in the 477 patent. To accomplish this process, the lens, which is constructed of polymer, 8 is coated with a coloring substance and a binding polymer. (Shull Decl., Ex. C at 61). The lens and binding polymer are then bonded to each other by the reaction of their functional groups. (Id.)

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8 A "polymer" is a very large molecule that is made up of a chain of repeating units derived from small molecules in the same sense that a wall is made up of bricks. (Shull Decl., Ex. D at 72).

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The Joint Statement of Disputed Terms indicates that the parties dispute three terms that appear in claims one and two of the 240 patent. These terms are as follows:

1. "coating at least a portion of a surface of the lens with a color coat comprising coloring substance, binding polymer having functional groups selected from at least one of -COOH, -OH, and -N-H-R, where R is hydrogen or C[1] to C[8] alkyl, and an additional compound having at least two groups per molecule selected from at least one of -NCO and epoxy,"

2. "binding the lens polymer to the binding polymer by the reaction of the functional groups selected from at least one -COOH, -OH, and -N-H-R, where R is hydrogen or C[1] to C[8] alkyl with the functional groups selected from at least one of -NCO and epoxy."

3. "The method of claim 1 wherein the additional compound contains two isocyanate groups."

The first two terms are in claim one and the third is in claim two.

Notwithstanding the Joint Statement, both parties acknowledge that the fundamental dispute involves the interpretation of the claim terms "isocyanate" and its chemical formula or abbreviation, "-NCO." (Pl.'s P&A at 16). 9 Because this is the fundamental dispute between the parties, the Court limits its order to construing those terms. At the hearing, the parties agreed to this approach. As Defendant points out, its accused process does not involve coating a contact lens with an unreacted isocyanate. (Def.'s P&A at 4). Thus, not surprisingly, Defendant interprets the 240 patent as requiring the use of "unreacted" or "free" -NCO. 10 Conversely, Plaintiff argues that no such limitation is present in the claim or the specification.

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9 Websters Third New International Dictionary defines "isocyanate" as "a compound containing the univalent radical -NCO consisting of an isocyano group united with oxygen." "Isocyano" is defined as "relating to or containing the groups -NC."

10 For background, an isocyanate group that is attached to a compound may be "free" or "blocked." (Pl.'s P&A at 20-21). An isocyanate group that is available to react with other compounds is "free." (Id.). An isocyanate group that is "blocked" has been reacted with a second compound so that the compound becomes attached to the isocyanate group, thereby essentially blocking or protecting the isocyanate group from further reactions with other compounds. (Id.). Thus, Defendant's position is that the isocyanate used in the 240 process patent must be available to react with other compounds.

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At the outset, the Court notes Defendant has failed to point to any language in the claims or the specification of the 240 patent which expressly limits the isocyanate used to "free" isocyanate. In fact, although the terms "-NCO" and "isocyanate" appear throughout the specification, at no place are those terms modified by the word "free." Moreover, the specification appears to provide for a broad definition of the type of isocyanate that may be used. It states, "Hexamethylene diisocyanate (OCN-(CH[2])[6]-NCO) is the preferred isocyanate compound. However, use of any isocyanate having the formula R<1>(NCO)[n] wherein n is greater than or equal to two (preferably two) is within the scope of this invention." (Shull Decl., Ex. C at 64, col. 6, ln. 15-19) (emphasis added). 11

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11 Defendant places great emphasis on the fact that the preferred isocyanate is hexamethylene diisocyanate, which, it argues, is a "free" isocyanate. (Def.'s P&A at 5, 6; Risen Decl. P28). However, as this language indicates, the invention reads on any isocyanate with the designated formula. Federal circuit law is clear that what is patented is not limited to the examples used in the specification unless such a limitation appears in the language of the claims or the specification. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1998).

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In asserting that the use of "isocyanate" and its chemical formula "-NCO" in the 240 patent is limited to "free" isocyanate or -NCO, Defendant argues, as its counsel put it at the hearing, that isocyanate (-NCO) can only mean, or can only consist of, "free" -NCO. In support of this argument, Defendant relies exclusively on expert testimony coupled with textbook definitions. 12 Specifically, Defendant puts forth the declaration and deposition testimony of William M. Risen, a Professor of Chemistry at Brown University. Mr. Risen's declaration states that "-NCO as used in the '240 patent claims, and as disclosed in the '240 patent specification means unreacted isocyanate (sometimes referred to as 'free' isocyanate)." (Risen Decl. P 26). Dr. Rosen also states that "-NCO" does not include the chemical formula "RNHCOOR," which is a urethane. (Risen Decl. P 27). In support of these claims, Dr. Risen cites a textbook on Organic Chemistry. (Risen Decl., Ex. F). However, apart from its dubious value in construing a claim, that textbook definition does not clearly support the opinion offered. Nor does the definition from Hackh's Chemical Dictionary, to which Defendant pointed at the hearing.

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12 Both at the hearing and in its brief, Defendant argued the prosecution history of the 240 patent indicates Plaintiff gave up any claim to a process using "blocked" isocyanates. (Def.'s P&A at 7-10). However, the Court does not find a basis in the prosecution history to conclude that Plaintiff is precluded from having the patent construed to include all isocyanates.

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Defendant's reliance on expert testimony results from the fact that there is no language in the claims or the specification which supports the conclusion that the 240 patent is limited to "free" isocyanate or -NCO. Indeed, as stated supra, the specification contains such broad language -- "use of any isocyanate having the formula R<1>(NCO)[n] wherein n is greater than or equal to two (preferably two) is within the scope of this invention" (Shull Decl., Ex. C at 64, col. 6, ln. 15-19) (emphasis added) -- that it supports Plaintiff's position. At the hearing, the Court asked the parties whether there can be an

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isocyanate with the chemical formulation R<1>(NCO)[n] that is blocked. (If so, Plaintiff's construction is correct; if not, as Defendant contends, the 240 patent is limited to "free" isocyanates). Their answers were far from illuminating and, predictably, at odds. Defendant's best argument was that the formula, in diagram form, expressly contemplates two isocyanates joined by a placeholder (R). The isocyanates, Defendant argued, are thus "free" to react with other functional groups, as shown in the diagram below.

[SEE DIAGRAM IN ORIGINAL]

Plaintiff's best argument makes use of a chemistry textbook, which points out that the "capping or blocking" of isocyanates is considered a special way of modifying isocyanates. (Shull Decl., Ex. G at 81). This "capping or blocking" can be reversed under certain conditions, such as heat, to produce a free isocyanate. (Id.). Thus, Plaintiff argues, any distinction between a "blocked" isocyanate and a "free" one can readily be eliminated, and the patent's reference to any isocyanate indicates that either "free" or "blocked" isocyanates may be used at points in the process.

The Court cannot conclude which, if either, of the alternative and rather confusing arguments the parties made in court is correct, but believes it need not reach such a determination. The language of the specification is plain: "any isocyanate" means "any isocyanate." That is, given that isocyanates may be "free" or "blocked," the use of the term "any" indicates that the claim includes the use of either "free" or "blocked" isocyanates. Thus, Defendant's position that the patent is restricted to the use of "free" isocyanates would impose a limitation not present in the specification. Federal Circuit law is clear that where the specification does not require a proposed limitation, that limitation should not be read into the claims. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988); Virginia Panel Corporation v. MAC Panel Co., 133 F.3d 860, 865-66 (Fed. Cir. 1997). The Court follows this rule and finds the 240 patent is not limited to a process using "free" isocyanates or its chemical formula, -NCO.

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C. "Isolated" (Claim 1 of the '755 patent)

Claim Term	Amgen's Construction	Teva's Construction
"isolated"	separate from forms of human G-CSF not having the amino acid sequences recited in the claim	separated from other substances

Teva argues that "isolated" means "separated from other substances." Teva Br. at 23. The specification acknowledges that "isolated" hpG-CSF was known: "[a]nother factor, designated human CSF-â, has also been isolated from human bladder carcinoma cellline 5637." Id. at 23;'755 patent, 6:5-9. Teva asserts that although "isolated" means "separated from other substances," this does not mean "free of impurities." Teva Br. at 24. Teva also argues that Amgen could have defined "isolated" however it wanted to but declined, and that when it filed new claims with the term "isolated" and removed "non-naturally occurring," Amgen made clear that the two phrases have different meanings. Id. at 25-26.

Amgen submits that the term "isolated" means "set apart" or "standing alone." Amgen claims that in the context of claim 1 of the '755 patent "isolated" modifies "hpG-CSF polypeptide," and therefore it reinforces that the claimed polypeptides are separated from hpG-CSF polypeptides not having the amino acid sequences recited in the claim, i.e., the claims do not encompass the 177 form. Amgen Br. at 30. Amgen points out that both parties agree that the plain meaning of the term "isolated" is "separated" or "set apart." The parties agree that "isolated" and "pure" are different concepts, and that "isolated" does not preclude the presence of at least some other substances in addition to the claimed polypeptides.

The parties disagree, however, on whether"isolated" is properly construed apart from the claim phrase it modifies. Amgen claims that Teva fails to specify exactly what it is that is separated and ignores a defining characteristic of Dr. Souza's claimed invention, namely, the isolation of a particular species of hpG-CSF polypeptide. Amgen Resp. at 11. Amgen proposes that "an isolated human pluripotent granulocyte colony stimulating factor (hpG-CSF) polypeptide" means a separated species of human polypeptide, designated hpG-CSF. That separate species is necessarily separate from hpG-CSF

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polypeptides not having one of the specified amino acid sequences, and therefore excludes the 177-amino acid species of hpG-CSF. Id.

Amgen claims that the intrinsic record supports its view because, before Dr. Souza's invention, the art lacked an ability to produce or obtain the claimed species of hpG-CSF polypeptides in isolation. Dr. Souza provided a means to produce and obtain that species of hpG-CSF polypeptides separate and apart (i.e., isolated) from all of the other polypeptides and substances produced in the human cancer cells that had thwarted prior attempts to achieve that result. Id. at 12. Amgen asserts that, properly construed, theterm "isolated" serves to reinforce the fact that the species of hpG-CSF polypeptide claimed by Dr. Souza is separate from other species of hpG-CSF polypeptides whose amino acid sequences differ from those recited in Dr. Souza's claims. Id. at 13.

Amgen argues that Teva's construction would render the second claim in the '755 patent 4 -- which is dependent upon the first claim -- meaningless because it is a composition claim that must contain the isolated polypeptide of claim 1 and a carrier, and expressly allows for the presence of additional substances. Teva's construction, "separated from other substances," would render claim 2 meaningless because it would require the polypeptide to be both separated from other substances and combined with other substances. The Federal Circuit has deemed this sort of construction impermissible. Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1362 (Fed. Cir. 2008)("this court strives to reach a claim construction that does not render claim language in dependent claims meaningless"). Thus, we agree with Amgen and will adopt its construction.

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4 The second claim of the '755 patent is "[a] composition comprising the hpG-CSF polypeptide ofclaim 1 and a carrier."

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A. "Isolated and Purified"

Defendants object to the Magistrate Judge's recommendation that the interpretation of the phrase "isolated and purified" should be "separated from other, unwanted substances." Although the Defendants urges that this interpretation is at least necessary to isolate and purify, Defendant argues that the interpretation of the claim should be more narrow: "individually separated from other, unwanted substances from a source by a process that achieves a desired level of concentration of each saccharide." (Pl. Cl. Constr. Br. at 18). Like the Magistrate Judge, this court first notes that nothing in the language of the patent suggests that each saccharide must be separated from all other saccharides.

1. Prosecution History

The Defendants' first objection to the interpretation of this claim is that the Plaintiff surrendered all other embodiments by using Example 2 as its only stated example to explain "isolated and purified" to the patent examiner in a phone conversation. (Defs.' Obj. to Recomm. at 5). The Defendants argue that the Magistrate Judge was wrong in stating that the Plaintiff had not surrendered all other embodiments. They first argue that although a prosecution disclaimer must be "clear and unmistakable disavowal," the disclaimer can be implicit, and the Magistrate Judge erred in his application of this rule. Id. The Defendants rely on one case to support their argument of an implicit disavowal and state that the Magistrate Judge's Recommendation is inconsistent with the authority. Id. at 6. That argument is not correct, because this situation is clearly distinguishable from the scenarios stated by Computer Docking Station Corp., which the Defendants relied upon to support their argument of implicit disavowal. (Defs.' Obj. to Recomm. at 6); See Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008). The scenarios that the Federal Circuit cited in that case all had explicitly clear disavowals, and the court even explicitly stated that a prosecution disavowal "does not apply to an ambiguous disavowal." Id. at 1374. In fact, the court emphasized that when a patentee describes a specific function in the prosecution phase, the description does not limit the claims further. Id. Also, that court stated that when a statement is amenable to multiple reasonable interpretations the statement is not a disavowal. Id. Thus, the Magistrate Judge's Recommendation concurs with the language of that court. For these reasons, the court does not find that the authority cited by the Defendants supports the

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lenient standard that they urge this court to adopt for this situation.

The Defendants argue that the prosecution history as a whole contains a clear disavowal. Defendants claim that the patentee differentiated prior art by stating that the prior art was distinguishable from the present invention, because the prior art did not make the saccharides bioavailable in individual forms. (Defs.' Obj. to Recomm. at 10). The Defendants choose to focus on the use of "individual forms" as their sole focus of their argument, but another reasonable interpretation is made possible by including the word "bioavailable" into the analysis. The Plaintiff states that the use of different compositions such as in animal or fiber form can prevent the body from absorbing the nutrients thus making them not bioavailable. (Pl.'s Response to Obj. at 16). Using those sources, the saccharides would have to be made into monosaccharides before being bioavailable. Id. Because the Plaintiff used different sources that did allow bioavailability without the further refinement, this is a reasonable interpretation of the statement in the alleged disavowal. And as the court in Computer Docking Station stated, when there are multiple reasonable interpretations of a patentee's statement in the prosecution period, the court should find that there was no prosecution disavowal. Computer Docking Station, 519 F.3d at 1374. Furthermore, although the patentee does refer to Example 2 in the response, patentee never said that Example 2 was the only embodiment. Therefore, this court agrees with the Magistrate Judge and finds that there was no "clear and unmistakable" prosecution disavowal and will interpret the patent on what is claimed in the patent.

2. The conflict of "isolated" and "purified"

The Defendants' other argument is that the words isolated and purified must be given different meanings. Although, it is true that two terms that are closely related should give a different meaning to the words, sometimes different words can be used to express similar concepts even if it is "poor drafting practice." See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed. Cir. 1996); Bancorp Servs., LLC v. Hartford Life Ins. Co., 359 F.3d 1367, 1373 (Fed. Cir. 2004). Additionally, there is nothing in the claims, specification, or prosecution history that states that the saccharides must be separated "from a source by a process that achieves a desired level of concentration of each saccharide." Instead, the specification shows a separation of the saccharides from unwanted materials and nothing more.

3. What "Isolated and Purified" Modifies

The Defendants' last contention with the Recommendation is that the Magistrate Judge did not address what the phrase "isolated and purified" modifies. (Defs.' Obj. to Recomm. to 19). Reading the patent, "isolated and purified" clearly modifies "saccharides" which this court has interpreted to mean "carbohydrates or sugars which can be in the form of mono-, oligo-, and/or polysaccharides." Furthermore, these saccharides can appear in polysaccharide form as a combination of sugars. Therefore, the sugars do not have to be individually isolated and separated as the Defendants urge, but rather may appear in their polysaccharide form.

4. Construction of "Isolated and Purified"

Thus, this court construes this phrase to be the portion of the claim construction to which both parties agreed and the Magistrate Judge ruled: "separated from other, unwanted substances." Furthermore, "isolated and purified" does not mean that the saccharides have to be individually isolated and separated from each other.
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B.

The first disputed claim term is "isolated and purified." Plaintiff asks the court to construe the term simply to mean "separated from other, unwanted substances." (See Plf. Cl. Constr. Br. at 17). While defendants agree that the "isolation" and "purification" of a substance at least requires separation from unwanted substances, they interpret the claim term to mean that each saccharide identified in the patent must be individually separated from the other saccharides in the patent. (See Def. Cl. Constr. Br. at 3, 9). Defendants further argue that the terms "isolated" and "purified" are not synonymous, and that the term "purified" requires each saccharide to be "further refined to a desired level of concentration." (Id, at 21). Thus, defendants ask the court to construe "isolated and purified" to mean "individually separated from other, unwanted substances from a source by a process that achieves a desired level of concentration of each saccharide." (Id. at 18).

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1.

The court initially observes that nothing in the language of the patent claims or the specification suggests that each saccharide must be individually separated from the other saccharides. In support of their proposed claim construction, defendants point to Claim 10 of the '807 Patent, which provides that:

[the] said galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose [of Claim I] are isolated and purified from predigested gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemicellulose, inulin, fructan or lactose.

(Plf. Cl. Constr. App. at 19, col. 19, ll. 1-11 & col. 10, ll. 1-2). However, this language limits only the source of the saccharides. It does not require that each saccharide be individually separated from every other saccharide in the source. Nor does it prevent several of the saccharides from being "isolated and purified" together, apart from other unwanted substances present in the natural source.

Similarly, Claim 8 of the '431 Patent requires that:

at least five isolated and purified saccharides are obtained from the group consisting of gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

(Id. at 35, col. 21, ll. 1-13 & col. 22, ll. 1-6). Again, this limitation merely identifies natural sources of the claimed saccharides. Claim 1 does not mention possible sources of the saccharides listed in the patent. Thus, contrary to defendants' argument, Claim I and Claim 8 are not superfluous. (See Def. Cl. Constr. Br. at 13).

In addition, the patent specification plainly states that the saccharides comprising the dietary supplement composition may be present "in monomeric, oligomeric or polymeric and derivatized or underivatized form." (Plf. Cl. Constr. App. at 12, col. 5, ll. 45-46). The specification explains that "the saccharides can be in the form of mono-, oligo- and/or polysaccharides, e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose." (Id. at 13, col. 8, ll. 42-46). This language directly contradicts defendants' argument that the saccharides must be obtained alone.

2.

Defendants also rely on Example 2 in the specification of the '807 Patent to support their proposed construction of "isolated and purified." Example 2 reads:

Another suitable composition for a product according to the present invention is as follows:

25 kilograms each of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose available from Florida Food Products as well as Aldrich Chemical Company and Sigma Chemical is charged into a stainless steel ribbon blender and mixed for five (5) minutes. Then 250 grams of Aerosil 380 (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. the powder is then encapsulated into size # 1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

(Plf. Cl. Constr. App. at 15, col. 12, ll. 30-46) (emphasis added). According to defendants, the term "isolated and purified"

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was added late in the prosecution of the '807 Patent after numerous rejections by the patent examiner in light of the prior art. (See Def. Cl. Constr. App., Exh. J). When challenged by the examiner to show support, by way of specific examples in the specification, "of the concept of a dietary supplement composition comprising a nutritionally effective amount of isolated and purified saccharides," counsel for the applicants cited to Example 2. (Id., Exh. K at 6). Because no other specific examples of "isolated and purified" saccharides were mentioned in response to the examiner's inquiry, defendants maintain that the applicants surrendered all other embodiments and that the invention claimed by the patent is limited to that described in Example 2. (Def. Cl. Constr. Reply Br. at 3-4).

This argument is virtually identical to the one rejected by the court in Mannatech I. In that case, which was decided by the undersigned magistrate judge with the consent of the parties, plaintiff alleged that a dietary supplement manufactured and sold by the defendant infringed one or more claims of the '807 and '431 Patents. The defendant argued, inter alia, that the term "isolated and purified" meant "obtained alone with other components removed therefrom." Mannatech I, 513 F.Supp.2d at 758. In support of its proposed claim construction, the defendant relied heavily on Example 2 of the '807 Patent. See id. at 758-59. The court rejected this selective reading of the claim language and refused to limit the claim to the specific embodiment disclosed in Example 2. As the court explained:

The Federal Circuit has cautioned against such an approach to claim construction, "even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.'" JVW Enterprises, Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005), quoting Phillips, 415 F.3d at 1323, Here, the patent specification makes clear that the invention includes sugars available from a wide variety of natural and synthetic sources, and that "the composition of the invention is not intended to be limited by the source from which the [sugars] are obtained."

Id. at 759. Based on the intrinsic evidence, including the specification and the prosecution history of the '807 Patent, the court construed the term "isolated and purified" to mean "separated from other, unwanted substances." Id. at 762. 4

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4 Although the court is not bound by a claim construction ruling in a prior suit, it may look to the ruling for guidance. See, e.g. Rambus, Inc. v. Hynix Semiconductor, Inc., 569 F.Supp.2d 946, 967 (N.D. Cal. 2008); Astrazeneca AB v. Mylan Labs., Inc. (In re Omeprazole Patent Litig.), 490 F. Supp. 2d 381, 419 (S.D.N.Y. 2007), aff'd, 281 Fed.Appx. 974, 2008 WL 2369864 (Fed. Cir. Jun. 10, 2008), citing Burke, Inc. v. Bruno Independent Living Aids, Inc., 183 F.3d 1334, 1338 (Fed. Cir. 1999).

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Like Mannatech I, there is no evidence in this case that the applicant intended for the claims and the embodiments in the specification "to be strictly co-extensive." To the contrary, the patent specification provides examples of several preferred embodiments and expressly states:

The carbohydrates included in the dietary supplement of the invention are available from a wide variety of natural and synthetic sources such as shrubs, trees, plants, yeasts, fungi, molds, gums, resins, starch and cellulose derivatives and natural mucin sources. Specifically, some of the natural sources include: (a) shrub or tree exudates which contain acacia, karaya, tragacanth, or ghatti; (b) marine guns which include agar, algin, or carrageenan; (c) seed gums which include guar['] locust bean, or psyllium; (d) plant extracts which contain pectins or acetylated polymannose; (e) starch and cellulose derivatives such as hetastarch, carboxymethylcellulose, ethylcellulose, hydroxypropyl methylcellulose, methylcellulose, oxidized cellulose; and microbial gums which contain dextrans, xanthan.

(Plf. Cl. Constr. App. at 13, col. 7, ll. 48-62; see also id. at 12, col. 5, 63-67 & col. 6, ll 1-7). Moreover, under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term only "by making a clear and unmistakable disavowal of scope during prosecution." Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006); see also Seachange Int'l, Inc. v. C-COR Inc., 413 F.3d 1361, 1372-73 (Fed. Cir. 2005). Here, the prosecution history fails to indicate that the applicant "clearly and unmistakably" gave up embodiments made using gums, extracts, and other sources that naturally include more than one saccharide. As counsel for the applicant told the patent examiner:

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[T]he present application includes an example directed to a composition of individual sugars. Specifically, please see Example 2 which is directed to a composition that includes 25 kilograms each of galactose, glucose, mannose, N-acetyleuraminic acid, fucose, N-acetylgalactosamine, N-acetylyglucosamine and xylose which would have to be isolated and purified at some point.

(Def. Cl. Constr. App., Exh. K at 6) (emphasis added). Nothing in this response unambiguously disclaims dietary supplement compositions comprised of saccharides drawn from sources other than those described in Example 2. The response merely provides "an example directed to a composition of individual sugars," without suggesting that it is the only example. There is no evidence that the applicant intended to disavow all the other examples or embodiments set forth in the specification in order to gain approval for the patent.

3.

Defendants further argue that plaintiff's proposed construction of "isolated and purified," which is the same construction given to the term by the court in Mannatech I, fails to give independent meaning to the term "purified." (See Def. Cl. Constr. Br. at l9). It is true that use of two terms in close proximity in the same claim gives rise to an inference that a different meaning should be assigned to each term. See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed. Cir. 1996). However, that inference is not conclusive. "[I]t is not unknown for different words to be used to express similar concepts, even though it may be poor drafting practice." Bancorp Services, L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1373 (Fed. Cir. 2004). Such is the case here. There is nothing in the claim language, the specification, or the prosecution history of the patents-in-suit to suggest that the saccharides must be refined to any particular level of concentration. See Mannatech I, 513 F.Supp.2d at 762 (expressly rejecting argument that "isolated and purified" saccharides were required to be at least 95%o pure). Accordingly, the court should follow Mannatech I and construe the term "isolated and purified" to mean "separated from other, unwanted substances."

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III.

The '807 and '431 Patents describe combinations of various saccharides, or sugars, used as a dietary supplement. (See Plf. Cl. Const. App. 6-21, 224-39). In their claim construction briefs, the parties seek construction of the term "isolated and purified," which appears in Claim 1 of the '807 Patent:

A dietary supplement composition, comprising: nutritionally effective amounts of isolated and purified galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(Id. at 20) (emphasis added). Similar language is used in Claim 1 of the '431 Patent:

A dietary supplement composition comprising: a nutritionally effective amount of isolated and purified acetylated mannose; and a nutritionally effective amount of at least five isolated and purified saccharides selected from: galactose, glucose, mannose, xylose, N-acetylneuraminic acid, fucose, N- acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, iduronic acid and arabinogalactan.

(Id. at 238) (emphasis added). 2 Plaintiff asks the court to construe "isolated and purified" to mean "performing one or more steps to exclude unwanted components and provide a nutritionally effective product." (See Plf. Cl. Const. Br. at 14). Defendant believes that the term means "obtained alone with other components removed therefrom." (See Def. Cl. Const. Br. at 3 & Def. Cl. Const. App. at 67-68). Thus, it appears that the parties generally agree that "isolated and purified," as used in the subject patents, means that the component sugars have been separated from other, unwanted components. However, defendant's proposed claim construction contains a further limitation that requires the isolated sugars to be "obtained alone" with a purity level of at least 95%. (Id.). Plaintiff opposes any numerical purity requirement, arguing instead for a broad construction of "isolated and purified" that teaches a process of excluding unwanted components from sugars obtained from both natural and chemical sources. (See Plf. Cl. Const. Br. at 14). The court will address the parties' respective arguments in turn.

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2 Claim 1 is the sole independent claim of the '807 and '431 Patents. The parties seek the same construction of "isolated and purified" where those terms appear either explicitly or by reference in the dependent claims of the patents-in-suit. See Forest Laboratories, Inc. v. Abbott Laboratories, 239 F.3d 1305, 1310 (Fed. Cir. 2001) ("We also construe independent claims consistently with the claims that depend from them.").

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A.

In support of its proposed claim construction, defendant relies on Example 2 in the specification of the '807 Patent, which reads:

Another suitable composition for a product according to the present invention is as follows:

25 kilograms each of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose available from Florida Food Products as well as Aldrich Chemical Company and Sigma Chemical is charged into a stainless steel ribbon blender and mixed for five (5) minutes. Then 250 grams of Aerosil 380 (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. The powder is then encapsulated into size # 1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

(Def. Cl. Const. App. at 12) (emphasis added). 3 Defendant focuses on Example 2 because it was cited by counsel for the applicants when challenged by the patent examiner to show support, by way of specific examples in the specification, "of the newly limited genus which would show possession of the concept of a dietary supplement composition comprising a nutritionally effective amount of 'isolated and purified saccharides.'" (See Plf. Cl. Const. App. at 181-82, 215). Although nothing in the patent itself or the prosecution history mentions the level of purity of the component sugars, product catalogs published by Aldrich Chemical Company and Sigma Chemical, two of the suppliers mentioned in Example 2, list compounds with a purity level of 95% or greater. (See Def. Cl. Const. App. at 58-61, 62-66). Defendant therefore reasons that the phrase "isolated and purified" requires the isolated sugars to be "obtained alone" with a purity level of at least 95%.

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3 Example 2 in the specification of the '431 Patent is identical in all respects. (Compare Def. Cl. Const. App. at 12 with id. at 28).

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The court rejects this selective reading of the claim language. Importing a purity requirement of 95% or more would limit the claim to the specific embodiment disclosed in the written description. The Federal Circuit has cautioned against such an approach to claim construction, "even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.'" JVW Enterprises, Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005), citing Phillips, 415 F.3d at 1323. Here, the patent specification makes clear that the invention includes sugars available from a wide variety of natural and synthetic sources, and that "the composition of the invention is not intended to be limited by the source from which the [sugars] are obtained." (See Plf. Cl. Const. App. at 15, 232). Specifically, Claim 8 of the '431 Patent states:

The dietary supplement composition of claim 1, wherein the acetylated mannose is obtained from the group consisting of aloe vera and acetylated polymannose, and the at least five isolated and purified saccharides are obtained from the group consisting of gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate,

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sucrose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

(Id. at 239). Table 3 included in both the '807 and '431 Patents lists more than one dozen natural sources of the claimed sugars. (Id. at 15, 232). Likewise, Example 1 refers to:

A suitable composition for a product according to the present invention is as follows: tragacanth gum (100 kg), a source of galacturonic acid, galactose, fucose, xylose, arabinose, and rhamnose, is charged into a stainless steel ribbon blender and guar gum (10 kg), a source of mannose and galactose, is charged into the stainless steel ribbon blender. The mixture of tragacanth gum and guar gum is mixed for five (5) minutes. Then 250 grams of Aerosil 380 (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler.

(Id. at 17, 234) (emphasis added). No specific source of the tragacanth gum, guar gum, or rice flour is mentioned. By contrast, Example 3 lists other suitable ingredients for the invention, including Gum Tragacanth T/3, Gum Ghatti No. 1, arabinogalactin, and MANAPOL, all of which are available from chemical supply companies. (Id. at 17-18, 235). Nowhere in the claim language, the specification, or the prosecution history of either patent is there any evidence of an intent to limit the source of sugars to those listed in the Aldrich Chemical and Sigma Chemical catalogs or to require that the sugars be at least 95% pure. See e.g. RF Delaware, Inc. v. Pacific Keystone Techologies, Inc., 326 F.3d 1255, 1263 (Fed. Cir. 2003) ("[W]hen a claim term is expressed in general descriptive words, it typically will not be limited to a numerical range that may appear in the written description as referring to a preferred embodiment or in other, narrower claims."); Modine Manufacturing Co. v. U.S. International Trade Comm'n, 75 F.3d 1545, 1557 (Fed. Cir.), cert. denied, 518 U.S. 1005, 116 S. Ct. 2523, 135 L. Ed. 2d 1048 (1996) ("Mathematical precision should not be imposed for its own sake."). The court therefore determines that the term "isolated and purified" does not include a numerical purity requirement.

B.

Nor can the court accept plaintiff's proposed construction of "isolated and purified," which requires that the product be "nutritionally effective" and describes a process of excluding unwanted components from the sugars that includes "predigestion to make the saccharides bioavailable to the host." (See Plf. Cl. Const. Br. at 14). The "nutritionally effective" requirement is already part of Claim 1, which describes a dietary supplement comprising "nutritionally effective amounts" of isolated and purified sugars. (See Plf. Cl. Const. App. at 20, 238). The patent specification defines "nutritionally effective amount" to mean "that amount which will provide a beneficial nutritional effect or response in a mammal." (Id. at 16, 233). Because the language of the claim itself requires the invention to be "nutritionally effective," it would be superfluous to impose such a limitation on the definition of "isolated and purified." See Power Mosfet Technologies, L.L.C. v. Siemens AG, 378 F.3d 1396, 1410 (Fed. Cir. 2004) (interpretations that render some portion of the claim language superfluous are disfavored).

To the extent plaintiff argues that the term "isolated and purified" specifically contemplates a process of "predigestion to make the saccharides bioavailable to the host," such an argument fails in light of the instrinsic evidence of record. During the prosecution of the '807 Patent, the applicants added the claim that ultimately issued as Claim 1:

A dietary supplement for providing nutritional product saccharides which saccharides are essential components of glycoproteins in a mammal, said dietary supplement comprising nutritionally effective amounts of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(Plf. Cl. Const. App. at 62-63). However, the PTO rejected this claim as being anticipated by the prior art. (Id. at 82). According to the examiner, the prior art taught that "sea urchin embryos comprise the instantly claimed saccharides" and that such embryos can be used as dietary supplements. (Id.). In an attempt to overcome this objection, the applicants rewrote the claim with the following limitation:

A dietary supplement composition comprising nutritionally effective amounts of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose; wherein said composition is preservative free and said saccharides are bioavailable as monosaccharides.

(Id. at 97) (emphasis added). The applicants argued that the proposed limitation distinguished their invention from the prior art because the prior art did not "disclose treating the hyaline layer or the sea urchin eggs to make the saccharides

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bioavailable as monosaccharides." (Id. at 100). The PTO responded that the new limitation had no support in the as-filed specification and rejected the insertion of the limitation as a new concept. (Id. at 114-15). The examiner specifically noted that "nowhere in the disclosure of Applicant can be found any teaching or suggestion of a treatment of sources of carbohydrates comprising the claimed saccharides to make the saccharides of the claimed invention bioavailable as monosaccharides." (Id. at 115).

The applicants made two more attempts to rewrite their claim. First, they deleted the language specifying that the sugars be "bioavailable as monosaccharides," substituting the following limitation:

A dietary supplement composition comprising nutritionally effective amounts of predigested forms of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(Id. at 129) (emphasis added). In support of this new limitation, the applicants relied on expert testimony to establish that "it is the predigestion of the saccharides that makes the saccharides bioavailable as monosaccharides." (Id. at 132). The applicants also pointed to their patent application, which described various techniques for accomplishing predigestion. (Id.). However, the examiner rejected the proposed claim as indefinite and uncertain. (Id. at 141). Finally, the applicants revised their claim to substitute the term "isolated and purified" for "predigested forms" of the component sugars:

A dietary supplement composition comprising a nutritionally effective amount of isolated and purified galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(Id. at 161) (emphasis added). Initially, the revised claim was rejected because the "isolated and purified" limitation, like the earlier proposed limitation requiring the sugars to be bioavailable as monosaccharides, had no literal support in the specification, either by way of generic disclosure or specific examples. (Id. at 182). The examiner reversed her decision after a telephone interview with an attorney for the applicants, wherein counsel relied on Example 2 to show that the component sugars "would have to be isolated and purified at some point." (Id. at 215). The '807 Patent issued shortly after that interview. (Id. at 220).

It is clear from the prosecution history of the '807 Patent that the PTO expressly rejected claim language that included a process of "predigestion to make the saccharides bioavailable to the host." Nor is there any intrinsic evidence to suggest that the term "isolated and purified" includes a process of "predigestion." 4 To the extent plaintiff relies on extrinsic evidence to reintroduce the concept of "predigestion" at the claim construction stage, such evidence cannot be used to arrive at a construction of the claim that is clearly contrary to the public record. See Phillips, 415 F.3d at 1318; Vitronics, 90 F.3d at 1584. Moreover, none of the expert opinions offered by plaintiff support a construction of "isolated and purified" that includes a process of "predigestion to make the saccharides bioavailable to the host." 5 Dr. Bill McAnalley, a pharmacology-toxicology expert and one of the named inventors of the '807 and '431 Patents, interprets the disputed claim term to mean "removed from nature and separated or detached by one or more steps from an unwanted substance or substances." (Plf. Cl. Const. App. at 316). Mark Tengler, the president of a Texas-based company that specializes in manufacturing nutracuetical and pharmaceutical products, states that "isolated and purified" means "removed from nature and then (or thus) separated or detached from unwanted components by human intervention." (Id. at 368, P 3 & 370, P 11). Dr. Garold S. Yost, a Professor of Pharmacology and Toxicology at the University of Utah who has conducted numerous studies on herbal supplements, opines that the disputed term means "performing one or more steps to exclude unwanted components from a natural source, while providing a nutritionally effective product." (Id. at 376-77, PP 3-4 & 378, P 11). Because there is no evidence that the phrase "isolated and purified" includes a process of "predigestion," the court declines to construe the claim in such a manner.

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4 The prosecution history of the '431 Patent reveals that the applicants participated in a personal interview with the patent examiner on February 27, 2006, six months after the '807 Patent was issued. During that interview, the applicants proposed an amendment to narrow the scope of several dependent claims, clarifying that "the isolated and purified acetylated manpose and the isolated and purified saccharides are obtained in nutritionally effective amounts by digestion from the sources listed in claim 28 and paragraphs [0031], [0033], [0042], [0043] and [0046] of the present application." (Plf. Cl. Const. App. at 293) (emphasis added). The PTO never responded to the proposed amendment and the prosecution history contains no further discussion of the interview between the applicants and the examiner. This lone reference to "digestion" is simply too vague to support plaintiff's argument that "isolated and purified" includes a process of "predigestion to make

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the saccharides bioavailable to the host."5 Defendant has filed a motion to strike the testimony of plaintiff's experts on the ground that their reliance on extrinsic evidence, rather than intrinsic evidence, is contrary to the hierarchy of analysis established in Phillips. The court has not relied on any of this testimony in construing the disputed claim terms, other than to show that the experts do not support the construction proposed by plaintiff. Consequently, the motion to strike is denied as moot. See Consortium Information Services, Inc. v. National Information Services, Inc., No. 3-99-CV-2509-BD, 2001 U.S. Dist. LEXIS 19390, 2001 WL 1516758 at *3 n.5 (N.D. Tex. Nov. 21, 2001) (Kaplan, J.) (overruling as moot objections to affidavits where none of the evidence was necessary to the disposition of pending motion).

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CONCLUSION

For these reasons, the court construes the term "isolated and purified," as used in the '807 and '431 Patents, to mean "separated from other, unwanted substances."
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Defendant argues that both the '807 and '431 Patents are invalid for indefiniteness. Under section 112 of the Patent Act:

[A patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." Miles Laboratories, Inc. v. Shandon Inc., 997 F.2d 870, 875 (Fed. Cir. 1993), cert. denied, 510 U.S. 1100, 114 S. Ct. 943, 127 L. Ed. 2d 232 (1994); see also North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1579 (Fed. Cir. 1993), cert. denied, 511 U.S. 1069, 114 S. Ct. 1645, 128 L. Ed. 2d 365 (1994). However, a patent that fails to meet this requirement is invalid for indefiniteness. See Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Indefiniteness is a question of law and must be proved by clear and convincing evidence. See Touchcom, Inc. v. Dresser, Inc., 427 F.Supp.2d 730,732-33 (E.D. Tex. 2005) (citing cases).

The '807 and '431 Patents require the component saccharides to be "isolated and purified," a term the court has construed to mean "separated from other, unwanted substances." Mannatech, 513 F.Supp.2d at 762. In light of this construction, defendant argues that the claim term is vague and indefinite because neither the patents themselves nor the intrinsic record provide an objective standard to determine the precise degree of "isolation" or "purification" or specify exactly what "unwanted substances" must be removed in order to practice the invention. See Def. MSJ Br. at 3-4. The court disagrees. Exact precision is not required to avoid invalidity on grounds of indefiniteness. Rather, the claim language need only be as accurate as the subject matter permits. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986); see also Power-One, Inc. v. Artesyn Technologies, Inc., No. 2-05-CV-0463, 2007 U.S. Dist. LEXIS 20458, 2007 WL 896093 at *5 (E.D. Tex. Mar. 22, 2007) (citing cases). Here, the intrinsic record demonstrates that the claimed invention is comprised of at least six different saccharides each available from a number of natural and synthetic sources. Other evidence shows that the degree of isolation and purification required, as well as the identity of any unwanted substances, differs depending on the source. Compare Plf. MSJ Resp. App. at 36-37 (describing simple cleansing and sorting required to separate gum ghatti and gum tragacanth from dirt and bark) with id. at 61 (describing multiple steps required to separate aloe vera gel from anthraquinones, a laxative, and fibrous plant material). The court therefore determines that the "isolated and purified" limitation is reasonably precise in light of the subject matter.

Nor is the court's construction of this claim term fatally indefinite. To the contrary, the court's construction of "isolated and purified" is consistent with interpretations of the claim term by expert witnesses skilled in the art of dietary supplements and related sciences. See Mannatech, 513 F.Supp.2d at 762. No expert has suggested that the term "isolated and purified" is so vague that it cannot be given any meaning at all. 4 Thus, the term is not "insolubly ambiguous" so as to be indefinite. See Amgen, 314 F.3d at 1342. Defendant is not entitled to summary judgment on its affirmative defense of invalidity for

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indefiniteness.

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4 In its claim construction brief, defendant proposed that "isolated and purified" meant "obtained alone with other components removed therefrom, i.e. with a purity level of at least 95%." See Mannatech, 513 F.Supp.2d at 758. Although this definition was not adopted by the court, the fact that defendant proffered a proposed construction of this claim term undermines its argument that the term is "insolubly ambiguous" and not amenable to construction. See Wireless Agents, L.L. C. v. Sony Ericsson Mobile Communications AB, No. 3-05-CV-0289-D, 2007 U.S. Dist. LEXIS 6888, 2007 WL 273568 at *3 (N.D. Tex. Jan. 31, 2007) (claim term not indefinite where party asserting invalidity had proffered a construction for the term); Power-One, 2007 U.S. Dist. LEXIS 20458, 2007 WL 896093 at *5 n.3 (same).

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Corresponding definitions for the related disputed claims terms and phrases naturally flow from this definition. Accordingly, the term "isolated compound of formula (3)," also used in claim 1 of the '481 patent, refers to:

"the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation."

* * *

The above definitions derive first from the plain language of the claims themselves. In this regard, claim 1 of the '481 patent describes a process that begins with "isolating from a crude reaction mixture compound of formula (3)." This statement, standing on its own, plainly refers to separating the compound of formula (3) from the crude reaction mixture. Significantly, the claim language teaches that it is the compound of formula (3) that is to be separated from the crude reaction mixture; the claim language does not teach separating the solvent or any component other than the compound of formula (3) from the crude reaction mixture. Nor does the claim language refer to separating the compound of formula (3) from only a single component of the crude reaction mixture, such as the solvent. Instead, the plain language of the patent requires that the compound of formula (3) itself be separated from the crude reaction mixture, namely from the other components of the crude reaction mixture. In other words, were the compound of formula (3) left in a mixture with the other components of the crude reaction mixture -- with the exception of any permissible amounts of impurities -- it would not be isolated from the crude reaction mixture as required by claim 1 of the '481 patent. n13

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n13 Synthon essentially conceded this point in the course of the prosecution history when it explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." See infra (discussion of prosecution history).

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This conclusion also comports with the relevant portions of the patents' specifications. In this regard, it should first be noted that despite the fact that the patents are clearly distinct from one another -- one claims a process and one claims a compound forming one part of the underlying process -- the specifications set forth in the '481 and '738 patents are virtually identical, including the examples set forth therein. This fact alone suggests that the applicants did not give careful, focused thought to the specification, as it might relate to each of the two distinct patents. But even more puzzling is the fact that only 3 of the 13 examples set forth in the specification even arguably pertain to isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this particular step in the claimed inventions.

Specifically, example 1 teaches that "[t]wo layers are formed in the reaction mixture; the upper one was separated and the

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lower organic layer was again washed with 200 ml of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent." See '481 Patent Specification, col. 15, ll. 1-5. Example 1A, in turn, provides that "[t]he solvent was decanted and the gum like solid washed with 2 x 5 ml of IPA...[and] the solvent was evaporated leaving an oil." Id. at col. 15, ll. 20-22. And finally, example 4 -- which is essentially identical to example 1 with the exception that a methyl rather than an ethyl is used as a starting material -- teaches that "[t]he isopropanolic layer was separated and the organic layer was again washed with 53 ml of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent." Id. at col. 17, ll. 31-34. Other than these three -- 1, 1A and 4 -- no other examples set forth in the specification describe isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this step to the claimed process and compound.

Significantly, the removal of the solvent reflected in each of these three examples serves to isolate the compound of formula (3) from only one component of the crude reaction mixture and leaves the compound of formula (3) remaining in a mixture with the other components. Put differently, the removal of the solvent taught in examples 1, 1A and 4 -- the only examples contained in the specification arguably dealing with isolating the compound of formula (3) n14 -- serves only to isolate the solvent, as opposed to the compound of formula (3), from the remaining components of the crude reaction mixture. Leaving the compound of formula (3) still mixed with the majority of the other components of the crude reaction mixture -- in levels in excess of the permissible amount of impurities permitted to remain following isolation -- cannot logically result in an "isolated form" of the compound of formula (3) consistent with the patent claims and specification. Indeed, to adopt this position put forth by Synthon would essentially deprive the "isolating" requirement of any significant meaning.

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n14 The remaining examples deal with subsequent steps in the amlodipine production process, including, inter alia, the formation of the compound of formula (2) and removal of the deprotecting agent.

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It is important to note that the relevant examples in the specification refer only to "the organic layer containing the desired product," rather than to the "isolated form" of the compound of formula (3), i.e., the "desired product" itself. In fact, none of the examples set forth in the specification specifically mention the isolating step or the isolation process. n15 And this is not surprising in the circumstances, given that the examples set forth in the specification are precisely those that were included in Synthon's original application to the PTO, prior to the insertion of the "isolating" requirement in the relevant claims. See infra (discussion of prosecution history). In fact, it appears from a review of the prosecution history that the specification was not changed, modified or updated in any respect following the "isolating" amendments, presumably to protect the applicant's priority date. For this reason, examples 1, 1A and 4 set forth in the specification are not particularly instructive or illuminating as to the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)."

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n15 The absence of a clear and detailed description of the isolating step in the specification is plainly obvious in some instances, as where the specification provides, for example, that "it is an advantage of this process that...the isolation and purification of the intermediate (3) is not necessary." '481 Patent Specification, col. 6, ll. 43-46.

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In an unsuccessful attempt to mask this inherent weakness in the available examples, Synthon assiduously avoids referring directly to isolating or separating the compound of formula (3) itself, as required by the plain language of the relevant claims. Instead, Synthon, throughout is pleadings, refers repeatedly to isolating or separating the "organic layer" or "oily layer" containing the compound of formula (3). n16 But significantly, the relevant claims of the '481 and '738 patents teach neither isolating the "oily layer" containing the compound of formula (3) from the crude reaction mixture, nor isolating merely a layer of solvent from the crude reaction mixture. Instead, the claims at issue expressly require isolating the compound of formula (3) from the other components of the crude reaction mixture.

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n16 See, e.g., Synthon's Supplemental Claim Construction Brief (Docket # 121), p.3 ("the patent references decanting (pouring off) of the solvent layers as one way to isolate the oily layer containing compound 3"); id. at p.4 ("[n]ot once does the specification suggest that the separated oily layer must contain a particular percentage of compound (3) as compared to other materials"); id. at p.4 ("there is only one reference in the entire patent to a particular percentage of any remaining starting materials or other impurities in the oily layer after isolation of compound (3)"); id. at p.5 ("one passage in the specification refers to the 'recovered' oily layer") (emphasis added).

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It is clear, then, that under claim 1 of the '481 patent, some act or step must be taken to separate the compound of formula (3) from the other components of the crude reaction mixture, which mixture the parties have agreed includes "any unreacted starting materials or side products or any catalysts or solvent." See supra p.14. Indeed, the specification also makes clear that the isolating step must involve more than removing the solvent from the crude reaction mixture, as it expressly states that "[t]he solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be separated from the rest of the unreacted starting materials and also from any potential side products." '481 Patent Specification, col. 6, ll. 22-25 (emphasis added). The specification further provides that

[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and the remaining starting materials can be easily removed. Recovery can be by any known technique and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product. It should be understood that such washing is not intended to be considered a 'purification step,' but rather merely part of the recovery.

'481 Patent Specification, col. 6, ll. 34-43 (emphasis added). And significantly, the specification summarizes the invention by recognizing that "the use of the compound (3) of our invention...allows for a reduction in side products by producing a stable intermediate that is easily separable from the rest of the reactive starting materials, thereby reducing the chance of side effects in subsequent reaction steps." '481 Patent Specification, col. 8, ll. 53-61 (emphasis added). Given these statements in the specification acknowledging removal of the starting materials and other side products, it is clear that merely pouring off from the crude reaction mixture a single layer of solvent, which Synthon contends is sufficient to meet the requirement of isolating, does not serve to separate the compound of formula (3) from the other components of the crude reaction mixture; rather, as illustrated above, this suggested step only serves to separate or isolate most of the solvent -- typically isopropanol -- from the crude reaction mixture, which mixture still contains the compound of formula (3).

The conclusion reached here is also consistent with the patents' prosecution histories, as well, which is plainly an important tool in claim construction. See, e.g, Phillips, 415 F.3d at 1317 (providing that "[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent"). n17 Thus, the '481 file wrapper reflects that the original process claims of the '481 patent did not include the terms "isolating from a crude reaction mixture" or "isolated compound of formula (3)." In fact, in February 2003, the patent examiner rejected Synthon's asserted claim 18 -- which ultimately matured into claim 1 of the '481 patent -- as being anticipated by the prior art on the basis that the compound of formula (3) would be formed during the reaction steps of Pfizer's '909 patent. To overcome this rejection, Sython amended its application claim 18 to include the step of "isolating from a crude reaction mixture compound of formula (3)." n18 Significantly, this amendment served to distinguish the claimed process from the prior art by making clear that the compound of formula (3) is required to be isolated or separated from the other materials of the crude reaction mixture prior to the next step of the claimed process. n19 The patent examiner thereafter allowed amended claim 18 on the ground that it "distincts from the art of record in that the starting material is novel," noting that "[a] process using a new starting material is patentable."

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n17 See also Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349-50 (Fed. Cir. 2004) (recognizing that "[t]he prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application").

n18 In this regard, Synthon's original application claim 18 -- prior to the addition of the "isolating" requirement -- simply claimed "[a] process, which comprises reacting a compound of formula (3)...with an alkyl 3-aminocrotonate of formula

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B...to form a compound of formula (2)." Significantly, this form of application claim 18 was rejected by the patent examiner as being anticipated by the prior art, in that the compound of formula (3) referenced in application claim 18 would be formed during the reaction steps of Pfizer's '909 patent. Synthon thereafter amended its application claim 18 to cover "[a] process, which comprises isolating from a crude reaction mixture a compound of formula (3)...and reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." (Emphasis added). And, in its supporting amendment papers, Synthon noted, inter alia, that "[s]uch an isolation step is not taught or suggested in...[the] '909 [patent]."

n19 In this regard, the applicants submitted various amendment papers to the patent examiner in July 2004 providing, inter alia, as follows:
[C]laim 18 as amended requires that the compound of formula (3) be isolated from a crude reaction mixture before being reacted with an amino crotonate. Such an isolation step is not taught or suggested in [the prior art] ...Why would a worker of ordinary skill in the art try to isolate an intermediate not shown or suggested to be isolated in [the prior art]? Clearly, such a modification is not suggested or rendered obvious by the teachings of [the prior art].

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Likewise, in the course of the prosecution of the '738 patent, the patent examiner rejected application claim 2 for indefiniteness, noting that it was a "substantial duplicate" of claim 1 in that it did not "limit the compounds" of claim 1. In this regard, while application claim 1 covered "a compound having the formula (3)," application claim 2 covered the compound of claim 1 in "isolated form." In response to this preliminary indefiniteness rejection, the applicants stated the following:

Claim 1 [of the '738 patent'] is directed to a compound per se. Accordingly it reads on the isolated, purified compound itself as well as the compound in compositions/mixtures with other ingredients. That is, claim 1 is not avoided simply because the compound of formula (3) is contained in a mixture with other compounds. Certainly any composition that contained the compound of formula (3) falls within the scope of claim 1. In contrast, claim 2 requires the compound of formula (3) to be in isolated form. A composition that contains a compound of formula (3) and, e.g., phthalimidoamlodipine of formula (2) would avoid claim 2, but not claim 1. Claim 2 is not a substantial duplicate of claim 1. Indeed, there is no reason to read claim 1 as requiring the compound of formula (3) to be in isolated form. Therefore, claim 2 is a proper dependent claim of clear and definite scope.

(Emphasis added). In other words, and of particular significance here, the applicants explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." n20 And significantly, this statement essentially amounts to an admission by Synthon that the compound of formula (3) is not "isolated" within the meaning of the relevant patent claims if it is still contained in a mixture with other ingredients or compounds. See, e.g., Omega Engineering, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) (recognizing that "[t]he doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretations specific meanings disclaimed during prosecution").

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n20 Following the applicant's clarification in this regard, the patent examiner withdrew the earlier indefiniteness rejection and allowed application claim 2 of the '738 patent.

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In sum, the definitions reached here make clear that some impurities are allowed to remain together with the compound of formula (3) following the isolation process, as the parties concede. But more importantly, by including the phrase "residual amounts of the other components," the definition also accurately requires that the compound of formula (3) be separated, at least to some extent, from the other components of the crude reaction mixture. n21 Nothing in the patent claims or specification provides any basis to quantify more specifically the amount of impurities or the residual amounts of the other components of the crude reaction mixture that are permitted to remain following isolation of the compound of formula (3).

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n21 Indeed, a standard dictionary defines the word "residual," in pertinent part, as "remaining after a part is taken." See Webster's Third New International Dictionary 1931 (1993).

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a. "DNA" and "isolatedDNA"

The parties approach the terms "DNA" and "isolated DNA" from opposing perspectives. 38 Plaintiffs contend that the term "DNA" means "a sequence of nucleic acids, also referred to as nucleotides" and therefore constitutes a "nucleotide sequence" or a "polynucleotide." Pl. Br. at 10. 39 Myriad disputes Plaintiffs' definition of "DNA" insofar as Plaintiffs' definition suggests that the term "DNA" refers merely to information, that is, "a description of the linear order of nucleotide units that make up the polynucleotide." Myriad Br. at 15. Myriad instead argues that "DNA" refers to "a real and tangible molecule, a chemical composition made up of deoxyribonucleotides linked by a phosphodiester backbone." Myriad Br. at 14.

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38 The degree to which the parties actually disagree on the meaning of the discussed claim terms is unclear; however, to the extent some disagreement has been noted by the parties, this section seeks to resolve them.

39 For purposes of this opinion, "Pl. Br." refers to Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment; "Myriad Br." refers to Myriad Defendants' Memorandum of Law (1) in Support of Their Motion for Summary Judgment and (2) in Oppositionto Plaintiffs' Motion for Summary Judgment; "Pl. Reply" refers to the Memorandum of Law (1) in Further Support of Plaintiffs' Motion for Summary Judgment Against All Defendants and (2) in Opposition to the Myriad Defendants' Motion for Summary Judgment and (3) in Opposition to Defendant United States Patent and Trademark Office's Motion for Judgment on the Pleadings; "Myriad Reply" refers to Myriad Defendants' Memorandum in Reply to Plaintiffs' Opposition to Myriad Defendants' Motion for Summary Judgment; and "USPTO Reply" refers to the Reply Memorandum of Law in Further Support of Defendant United States Patent and Trademark Office's Motion for Judgment on the Pleadings and in Opposition to Plaintiffs' Motion for Summary Judgment.

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As its name implies, DNA, or deoxyribonucleic acid, is an acid - a tangible, chemical compound. As Myriad correctly notes, the specifications make clear that "DNA," as used in the patents, refers to the physical manifestation of the acid, one that may be "substantially separated from other cellular components which naturally accompany a gene." '473 patent, col. 19:8-9; '282 patent, col. 19:10-11; '492 patent, col. 17:64-65. Despite the description of theterm "DNA" set forth in the briefs, this understanding of the meaning of "DNA" is shared by both Plaintiffs' and Myriad's declarants. See Kay P 125; Linck P 45; Schlessinger P 12; Grody P 10; Leonard P 30.

The term "isolated DNA" is defined by Plaintiffs as "a fragment of DNA substantially separated from other cellular components and other DNA." Pl. Br. at 10. Myriad disputes Plaintiffs' definition insofar as it implies that fragments of DNA exist free-floating in the cell, separate from other cellular components, such as proteins and the other DNA in the chromosome. Myriad Br. at 16. The patent specifications expressly define "isolated DNA" as a DNA molecule "which is substantially separated from other cellular components which naturally accompany a native human sequence [such as] human genome sequences and proteins" and "includes recombinant or cloned DNA isolates and chemically synthesized analogs or analogs biologically synthesized by heterologous systems." '473 patent, col. 19:6-15; '282 patent, col. 19:8-18; '492 patent, col. 17:62-18:5.

"Isolated DNA" is therefore construed to refer to a segment of DNA nucleotides existing separate from other cellular components normally associatedwith native DNA, including proteins and other DNA sequences comprising the remainder

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of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means.
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This same definition can likewise be used to describe the term "isolated form." That is, the "isolated form" of the compound of formula (3), used in claim 2 of the '738 patent, means:

"the form of the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation."

The above definitions derive first from the plain language of the claims themselves. In this regard, claim 1 of the '481 patent describes a process that begins with "isolating from a crude reaction mixture compound of formula (3)." This statement, standing on its own, plainly refers to separating the compound of formula (3) from the crude reaction mixture. Significantly, the claim language teaches that it is the compound of formula (3) that is to be separated from the crude reaction mixture; the claim language does not teach separating the solvent or any component other than the compound of formula (3) from the crude reaction mixture. Nor does the claim language refer to separating the compound of formula (3) from only a single component of the crude reaction mixture, such as the solvent. Instead, the plain language of the patent requires that the compound of formula (3) itself be separated from the crude reaction mixture, namely from the other components of the crude reaction mixture. In other words, were the compound of formula (3) left in a mixture with the other components of the crude reaction mixture -- with the exception of any permissible amounts of impurities -- it would not be isolated from the crude reaction mixture as required by claim 1 of the '481 patent. n13

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n13 Synthon essentially conceded this point in the course of the prosecution history when it explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." See infra (discussion of prosecution history).

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This conclusion also comports with the relevant portions of the patents' specifications. In this regard, it should first be noted that despite the fact that the patents are clearly distinct from one another -- one claims a process and one claims a compound forming one part of the underlying process -- the specifications set forth in the '481 and '738 patents are virtually identical, including the examples set forth therein. This fact alone suggests that the applicants did not give careful, focused thought to the specification, as it might relate to each of the two distinct patents. But even more puzzling is the fact that only 3 of the 13 examples set forth in the specification even arguably pertain to isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this particular step in the claimed inventions.

Specifically, example 1 teaches that "[t]wo layers are formed in the reaction mixture; the upper one was separated and the lower organic layer was again washed with 200 ml of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent." See '481 Patent Specification, col. 15, ll. 1-5. Example 1A, in turn, provides that "[t]he solvent was decanted and the gum like solid washed with 2 x 5 ml of IPA...[and] the solvent was evaporated leaving an oil." Id. at col. 15, ll. 20-22. And finally, example 4 -- which is essentially identical to example 1 with the exception that a methyl rather than an ethyl is used as a starting material -- teaches that "[t]he isopropanolic layer was separated and the organic layer was again washed with 53 ml of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent." Id. at col. 17, ll. 31-34. Other than these three -- 1, 1A and 4 -- no other examples set forth in the specification describe isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this step to the claimed process and compound.

Significantly, the removal of the solvent reflected in each of these three examples serves to isolate the compound of formula (3) from only one component of the crude reaction mixture and leaves the compound of formula (3) remaining in a mixture

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with the other components. Put differently, the removal of the solvent taught in examples 1, 1A and 4 -- the only examples contained in the specification arguably dealing with isolating the compound of formula (3) n14 -- serves only to isolate the solvent, as opposed to the compound of formula (3), from the remaining components of the crude reaction mixture. Leaving the compound of formula (3) still mixed with the majority of the other components of the crude reaction mixture -- in levels in excess of the permissible amount of impurities permitted to remain following isolation -- cannot logically result in an "isolated form" of the compound of formula (3) consistent with the patent claims and specification. Indeed, to adopt this position put forth by Synthon would essentially deprive the "isolating" requirement of any significant meaning.

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n14 The remaining examples deal with subsequent steps in the amlodipine production process, including, inter alia, the formation of the compound of formula (2) and removal of the deprotecting agent.

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It is important to note that the relevant examples in the specification refer only to "the organic layer containing the desired product," rather than to the "isolated form" of the compound of formula (3), i.e., the "desired product" itself. In fact, none of the examples set forth in the specification specifically mention the isolating step or the isolation process. n15 And this is not surprising in the circumstances, given that the examples set forth in the specification are precisely those that were included in Synthon's original application to the PTO, prior to the insertion of the "isolating" requirement in the relevant claims. See infra (discussion of prosecution history). In fact, it appears from a review of the prosecution history that the specification was not changed, modified or updated in any respect following the "isolating" amendments, presumably to protect the applicant's priority date. For this reason, examples 1, 1A and 4 set forth in the specification are not particularly instructive or illuminating as to the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)."

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n15 The absence of a clear and detailed description of the isolating step in the specification is plainly obvious in some instances, as where the specification provides, for example, that "it is an advantage of this process that...the isolation and purification of the intermediate (3) is not necessary." '481 Patent Specification, col. 6, ll. 43-46.

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In an unsuccessful attempt to mask this inherent weakness in the available examples, Synthon assiduously avoids referring directly to isolating or separating the compound of formula (3) itself, as required by the plain language of the relevant claims. Instead, Synthon, throughout is pleadings, refers repeatedly to isolating or separating the "organic layer" or "oily layer" containing the compound of formula (3). n16 But significantly, the relevant claims of the '481 and '738 patents teach neither isolating the "oily layer" containing the compound of formula (3) from the crude reaction mixture, nor isolating merely a layer of solvent from the crude reaction mixture. Instead, the claims at issue expressly require isolating the compound of formula (3) from the other components of the crude reaction mixture.

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n16 See, e.g., Synthon's Supplemental Claim Construction Brief (Docket # 121), p.3 ("the patent references decanting (pouring off) of the solvent layers as one way to isolate the oily layer containing compound 3"); id. at p.4 ("[n]ot once does the specification suggest that the separated oily layer must contain a particular percentage of compound (3) as compared to other materials"); id. at p.4 ("there is only one reference in the entire patent to a particular percentage of any remaining starting materials or other impurities in the oily layer after isolation of compound (3)"); id. at p.5 ("one passage in the specification refers to the 'recovered' oily layer") (emphasis added).

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It is clear, then, that under claim 1 of the '481 patent, some act or step must be taken to separate the compound of formula (3) from the other components of the crude reaction mixture, which mixture the parties have agreed includes "any unreacted starting materials or side products or any catalysts or solvent." See supra p.14. Indeed, the specification also makes clear

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that the isolating step must involve more than removing the solvent from the crude reaction mixture, as it expressly states that "[t]he solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be separated from the rest of the unreacted starting materials and also from any potential side products." '481 Patent Specification, col. 6, ll. 22-25 (emphasis added). The specification further provides that

[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and the remaining starting materials can be easily removed. Recovery can be by any known technique and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product. It should be understood that such washing is not intended to be considered a 'purification step,' but rather merely part of the recovery.

'481 Patent Specification, col. 6, ll. 34-43 (emphasis added). And significantly, the specification summarizes the invention by recognizing that "the use of the compound (3) of our invention...allows for a reduction in side products by producing a stable intermediate that is easily separable from the rest of the reactive starting materials, thereby reducing the chance of side effects in subsequent reaction steps." '481 Patent Specification, col. 8, ll. 53-61 (emphasis added). Given these statements in the specification acknowledging removal of the starting materials and other side products, it is clear that merely pouring off from the crude reaction mixture a single layer of solvent, which Synthon contends is sufficient to meet the requirement of isolating, does not serve to separate the compound of formula (3) from the other components of the crude reaction mixture; rather, as illustrated above, this suggested step only serves to separate or isolate most of the solvent -- typically isopropanol -- from the crude reaction mixture, which mixture still contains the compound of formula (3).

The conclusion reached here is also consistent with the patents' prosecution histories, as well, which is plainly an important tool in claim construction. See, e.g, Phillips, 415 F.3d at 1317 (providing that "[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent"). n17 Thus, the '481 file wrapper reflects that the original process claims of the '481 patent did not include the terms "isolating from a crude reaction mixture" or "isolated compound of formula (3)." In fact, in February 2003, the patent examiner rejected Synthon's asserted claim 18 -- which ultimately matured into claim 1 of the '481 patent -- as being anticipated by the prior art on the basis that the compound of formula (3) would be formed during the reaction steps of Pfizer's '909 patent. To overcome this rejection, Sython amended its application claim 18 to include the step of "isolating from a crude reaction mixture compound of formula (3)." n18 Significantly, this amendment served to distinguish the claimed process from the prior art by making clear that the compound of formula (3) is required to be isolated or separated from the other materials of the crude reaction mixture prior to the next step of the claimed process. n19 The patent examiner thereafter allowed amended claim 18 on the ground that it "distincts from the art of record in that the starting material is novel," noting that "[a] process using a new starting material is patentable."

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n17 See also Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349-50 (Fed. Cir. 2004) (recognizing that "[t]he prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application").

n18 In this regard, Synthon's original application claim 18 -- prior to the addition of the "isolating" requirement -- simply claimed "[a] process, which comprises reacting a compound of formula (3)...with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." Significantly, this form of application claim 18 was rejected by the patent examiner as being anticipated by the prior art, in that the compound of formula (3) referenced in application claim 18 would be formed during the reaction steps of Pfizer's '909 patent. Synthon thereafter amended its application claim 18 to cover "[a] process, which comprises isolating from a crude reaction mixture a compound of formula (3)...and reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." (Emphasis added). And, in its supporting amendment papers, Synthon noted, inter alia, that "[s]uch an isolation step is not taught or suggested in...[the] '909 [patent]."

n19 In this regard, the applicants submitted various amendment papers to the patent examiner in July 2004 providing, inter alia, as follows:
[C]laim 18 as amended requires that the compound of formula (3) be isolated from a crude reaction mixture before being reacted with an amino crotonate. Such an isolation step is not taught or suggested in [the prior art] ...Why would a worker of

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ordinary skill in the art try to isolate an intermediate not shown or suggested to be isolated in [the prior art]? Clearly, such a modification is not suggested or rendered obvious by the teachings of [the prior art].

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Likewise, in the course of the prosecution of the '738 patent, the patent examiner rejected application claim 2 for indefiniteness, noting that it was a "substantial duplicate" of claim 1 in that it did not "limit the compounds" of claim 1. In this regard, while application claim 1 covered "a compound having the formula (3)," application claim 2 covered the compound of claim 1 in "isolated form." In response to this preliminary indefiniteness rejection, the applicants stated the following:

Claim 1 [of the '738 patent'] is directed to a compound per se. Accordingly it reads on the isolated, purified compound itself as well as the compound in compositions/mixtures with other ingredients. That is, claim 1 is not avoided simply because the compound of formula (3) is contained in a mixture with other compounds. Certainly any composition that contained the compound of formula (3) falls within the scope of claim 1. In contrast, claim 2 requires the compound of formula (3) to be in isolated form. A composition that contains a compound of formula (3) and, e.g., phthalimidoamlodipine of formula (2) would avoid claim 2, but not claim 1. Claim 2 is not a substantial duplicate of claim 1. Indeed, there is no reason to read claim 1 as requiring the compound of formula (3) to be in isolated form. Therefore, claim 2 is a proper dependent claim of clear and definite scope.

(Emphasis added). In other words, and of particular significance here, the applicants explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." n20 And significantly, this statement essentially amounts to an admission by Synthon that the compound of formula (3) is not "isolated" within the meaning of the relevant patent claims if it is still contained in a mixture with other ingredients or compounds. See, e.g., Omega Engineering, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) (recognizing that "[t]he doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretations specific meanings disclaimed during prosecution").

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n20 Following the applicant's clarification in this regard, the patent examiner withdrew the earlier indefiniteness rejection and allowed application claim 2 of the '738 patent.

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In sum, the definitions reached here make clear that some impurities are allowed to remain together with the compound of formula (3) following the isolation process, as the parties concede. But more importantly, by including the phrase "residual amounts of the other components," the definition also accurately requires that the compound of formula (3) be separated, at least to some extent, from the other components of the crude reaction mixture. n21 Nothing in the patent claims or specification provides any basis to quantify more specifically the amount of impurities or the residual amounts of the other components of the crude reaction mixture that are permitted to remain following isolation of the compound of formula (3).

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n21 Indeed, a standard dictionary defines the word "residual," in pertinent part, as "remaining after a part is taken." See Webster's Third New International Dictionary 1931 (1993).

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Honeywell contends the district court erred in its alternative ruling granting summary judgment of infringement of claims 1, 5, 7, 10, and 11 of the '817 patent. Honeywell states that "[e]ither the court misapplied its construction of the 'isolating' limitation [of independent claim 1], or it misconstrued the 'isolating' limitation . . . by not limiting the gas stream containing the 'isolat[ed] [HFC-]245fa to only residual amounts of reaction mixture components." Appellee's Br. at 21. Honeywell argues that, applying the correct claim construction, it is entitled to a judgment of non-infringement of independent claim 1 and dependent claims 5, 7, 10, and 11. Honeywell's argument involves the construction of both claims 1 and 12 of the patent, for Honeywell asserts that "[h]ad the district court properly applied the construction it gave to 'isolating . . . [HFC-245fa] from the reaction mixture' for claim 12, it could only have concluded, as a matter of law, that the accused Honeywell process does not infringe claim 1 or its dependent claims." Id. at 57.

The district court construed the limitation "isolating . . . [HFC-245fa] from the reaction mixture by drawing off [HFC-245fa] and [HCI] in a gaseous phase as each of said [HFC-245fa] and [HC1] is being formed" in independent claim 1 as follows:

The process for making HFC-245fa includes a reaction at a temperature and under a pressure whereby HFC-245fa and HCI are produced in gaseous form and separated from the reaction mixture in a gas stream that can include other compounds, such as unconverted reactants and chlorofluoropropanes possibly formed by incomplete fluorination of HCC-240fa.

Solvay, S.A. v. Honeywell Specialty Materials LLC, 591 F. Supp. 2d 724, 2008 WL 5155629, at *2 (D. Del. 2008) ("Claim Construction Ruling") (emphasis added).

The corresponding limitation in independent claim 12 of the '817 patent reads "isolating said [HFC-245fa] from the reaction mixture . . . to keep in the reactor in the liquid state the unconverted [HCC-240fa], most of the [HF] and most of the products of partial fluorination of [HFC-245fa]." In construing this limitation, the district court stated:

I conclude that the "isolating" limitation found in claims 1 and 12 should be construed consistently. The fact that claim 12 discloses a device to accomplish the process, while claim 1 only describes the process, does not convince me that the patentee meant to use the same word ("isolate") to describe different processes.

Claim Construction Ruling, 591 F. Supp. 2d 724, 2008 WL 5155629, at *3. The court construed the "isolating" limitation of claim 12 as follows: "As the HFC-245fa and HCI are produced in gaseous form, they are separated from the reaction mixture in a gas stream by the device." 591 F. Supp. 2d at 729. Thus, the court construed "isolating" in independent claims 1 and 12 as meaning "separating."

In arriving at its construction of claim 1, the district court considered whether the term "isolating," as used in the claim, means that "only" HFC-245fa and HCI are drawn off from the reaction mixture in a gas stream as they are being formed, or whether the gas stream can include other components. The court reasoned that the patent specification uses "isolate," "separate," and "to draw off" interchangeably, as did the inventors during prosecution, and that "isolate" thus should not be construed to mean only HFC-245fa and HCI, even if the dictionary definition of "isolate" suggests separation of a "pure chemical substance." 591 F. Supp. 2d at 729. The court also reasoned that because claim 12's use of "isolate" clearly allows for "residual amounts" of products other than HFC-245fa and HCI to be in the gas stream, the isolating limitation of claim 1 "should be construed consistently." 7

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7 As seen, claim 12 recites that "most of the [HF] and most of the products of partial fluorination of [HFC-245fa]" are kept in the reactor in the liquid state (emphases added). '817 patent, col.6 ll.28-30.

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In its infringement ruling, the district court held that the Geismar process infringed claim 1 because it draws off a gas stream from the reaction mixture and thereby isolates, or separates, HFC-245fa from the mixture. See Non-infringement Ruling, 591 F. Supp. 2d at 727. The court noted that "although the gas stream in the Geismar process includes many compounds other than HFC-245fa and HCl," the process still infringed because "claim 1 has been construed very broadly . . . ." Id. at 727-28.

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Honeywell urges that the district court failed to appreciate that claim 1 requires that the gaseous product leaving the reactor include only "residual amounts of other non-reacting compounds," along with HFC-245fa and HCI. According to Honeywell, that is also what claim 12 requires. In support of its argument, Honeywell points to the expert testimony of Michael Doherty interpreting "isolating" as "purifying" HFC-245fa from all other reaction mixture components so that there are only residual, i.e., not measurable, amounts of other compounds in the gas stream. See Appellee's Br. at 59-60. Honeywell also points to dictionary definitions of "isolation" as "separation of a pure chemical substance from a compound or mixture," contending "isolating" thus means completely separating HFC-245fa from all other reaction mixture components, including HF. Id. at 60-61. Finally, Honeywell asserts that, during prosecution, the inventors limited the "isolating" step to being one that separates HFC-245fa and HCl from all reaction mixture components the first (and only) time they leave the reactor in a gas stream. Id. at 62. 8 Honeywell concludes that the district court's error--either in claim construction or claim construction application--resulted in an incorrect finding of infringement with respect to Honeywell's Geismar process because, in that process, more than "residual amounts" of other compounds leave the reactor. Honeywell contends that the Geismar process does not isolate from the reaction mixture the HFC-245fa and HCl as they are being formed, but, rather, draws off a gas stream which is mostly HF and which also contains partially fluorinated compounds. Id. at 58.

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8 Honeywell points to an amendment made during prosecution, in which the inventors added the "isolating" language in claim 1 and overcame prior art by describing their process as isolating HFC-245fa and HCl by drawing off each from the reaction mixture as they are being formed. Honeywell notes that the inventors said nothing about also drawing off reaction mixture components, such as HF. Id.

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Solvay responds that the district court erred in neither its claim construction nor its application of that claim construction. Solvay argues that the district court correctly construed claim 1 when it concluded that "isolating" does not mandate that HFC-245fa and HCl are the only materials in the gas stream that are drawn off, or isolated, from the reaction mixture. See Non-infringement Ruling, 591 F. Supp. 2d at 727-28. Solvay asserts that the district court correctly understood that the '817 patent teaches a process that separates gaseous HFC-245fa from the reaction mixture in the reactor by continuously drawing off a gaseous stream that includes HFC-245fa and HCl, as well as other components. See Appellant's Reply Br. at 29-30. Solvay contends that the district court properly construed the "isolating" limitation to include this teaching. See Non-infringement Ruling, 591 F. Supp. 2d at 728 (noting that the broad construction of claim 1 "reflect[s] the claim language and the intrinsic evidence"). See Appellant's Reply Br. at 30-31. Solvay also contends the district court properly applied the construction of the "isolating" limitation to find infringement, based on Honeywell's acknowledgement that its Geismar process includes many compounds other than HFC-245fa and HCl in the gas stream that are drawn off from the reaction mixture (e.g., HF and other partially fluorinated compounds). See id. at 31; Non-infringement Ruling at 727-28.

We see no error in the district court's infringement ruling. In our view, claim 1 is not limited to "isolating" only HFC-245fa and HCl and residual amounts of other compounds. The claim does not recite isolating HFC-245fa from all other components involved in the process, and it does not recite isolating HFC-245fa from everything beyond residual amounts of reaction mixture components in the gas stream. Neither does the specification require that the gaseous stream separated from the reaction mixture contain only HFC-245fa and HCl. The patent specification uses the terms "isolating," "separating," and "drawing off" interchangeably, as the district court noted. At the same time, we do not think any of the statements made during prosecution call for a construction of claim 1 that requires only "residual amounts" of other components in the gas stream. In the prosecution amendment to which Honeywell points, see footnote 8 above, the inventors simply described their process as isolating HFC-245fa and HCl by drawing off each from the reaction mixture as they are being formed. Such a description does not constitute a statement that the invention of the '817 patent involves a process in which only certain reactants (and no others) can be isolated from reaction mixture components or, in other words, one in which only residual amounts of other compounds are contained in the gas stream.

Honeywell's reliance on the testimony of Michael Doherty interpreting "isolating" as "purifying" HFC-245fa from all other reaction mixture components is misplaced. The term "purifying" is not used in the patent and is not to be considered synonymous with "isolation" based on extrinsic expert testimony alone. See Phillips v. AWH Corp., 415 F.3d 1303, 1317

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(Fed. Cir. 2005) (en banc) (extrinsic evidence such as expert testimony is "less significant than the intrinsic record in determining the legally operative meaning of claim language") (internal citations omitted); Kara Tech. Inc. v. Stamps.com Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("extrinsic sources like expert testimony cannot overcome more persuasive intrinsic evidence."); Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1347 (Fed. Cir. 2009) (district court erroneously relied on expert testimony and a dictionary definition to the exclusion of the intrinsic evidence of the specification language).

Finally, we do not view the district court's construction and application of claim 1 as inconsistent with its construction of claim 12. As noted, in construing claim 12's "isolating" limitation, the court stated that "[a]s the HFC-245fa and HCl are produced in gaseous form, they are separated from the reaction mixture in a gas stream by the device." Claim Construction Ruling, 591 F. Supp. 2d 724, 2008 WL 5155629, at *4. The court's construction of claim 1, in which "isolating" does not mean that the gas stream contains no more than residual amounts of components other than HFC-245fa and HF, is not at odds with its construction of claim 12's isolating limitation, in which "HFC-245fa and HCl are . . . separated from the reaction mixture in a gas stream . . . ."

The district court construed a different claim 12 limitation, "to keep in the reactor in the liquid state the unconverted [HCC-240fa], most of the HF and most of the products of partial fluorination of [HCC-240fa]," as follows:

> The gas stream can include residual amounts of other compounds, such as unconverted reactants and chlorofluoropropanes possibly formed by incomplete fluorination of HCC-240fa. However, the unconverted HCC-240fa, more than 50% of the HF, and more than 50% of the partially fluorinated intermediates must remain in the reactor vessel in the liquid state.

Claim Construction Ruling, 591 F. Supp. 2d 724, 2008 WL 5155629, at *4 (emphasis added). In urging an inconsistency between the court's construction of the "isolating" limitations in claims 1 and 12, Honeywell points to this claim construction language. It apparently contends that this construction of claim 12's "to keep in the reactor in the liquid state" limitation, combined with the court's statement that claims 1 and 12 are to be construed "consistently," means that "isolating" in claim 1 means that only "residual" amounts of compounds other than HFC-245fa and HCl may be in the gas stream. This language, however, does not relate to the "isolating" limitation of claim 12. Rather, it relates to the "keep in the reactor in the liquid state" limitation of the claim. As the discussion in section B below makes clear, this is a fundamentally different limitation from the "isolating" limitation.

We therefore reject Honeywell's argument with respect to claim 1, whether viewed as asserting an incorrect claim construction or the erroneous application of a correct claim construction. Because Honeywell does not dispute that its accused Geismar process has a gas stream with more than residual amounts of reaction mixture components, the district court did not err in ruling that claims 1, 5, 7, 10, and 11 of the '817 patent were infringed.

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While the parties, in the course of the claim construction proceedings, sensibly and correctly did not dispute two general points concerning the term "isolating" -- namely that "isolating" (1) generally means "separating" and (2) does not equate to "purifying" -- their fundamental dispute with respect to the meaning of this particular term in the context of the patents in issue never dissolved. And not surprisingly, this fundamental dispute was plainly driven by the parties' views on what definition would be most likely to lead to a victory on the hotly disputed infringement issue.

As an initial matter, the parties agree the term "isolating," standing alone, generally means "separating." Indeed, this equation of the terms "isolating" and "separating" finds firm support in the specification where the terms are used interchangeably. n10 Moreover, this general definition of the disputed term is also confirmed by reference to a standard dictionary. See Webster's Third New International Dictionary 1199 (1993) (providing that the term "isolate" means, inter alia, "to separate (as a chemical compound) from all other substances"). Yet, despite their agreement as to the general meaning of the term "isolate," the parties advance sharply divergent views on what it means to isolate or separate the compound of formula (3) from the crude reaction mixture, as required by the patent claims and specification.

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n10 See, e.g., '481 Patent Specification, col. 6, ll. 22-25 ("The solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be separated from the rest of the unreacted starting materials and also from any potential side products") (emphasis added).

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As the '481 patent teaches, the compound of formula (3) may be produced by reacting two starting materials -- one an ester or ketoester, and the other an aldehyde -- in a solvent, such as isopropanol, in the presence of a catalyst, such as piperidine. This chemical reaction creates a "crude reaction mixture" containing the compound of formula (3). The next step in the process is to "isolate" from the crude reaction mixture the compound of formula (3). The '481 patent then requires that "the isolated compound of formula (3)" be reacted with another organic compound -- an aminocrotonate -- to form the compound of formula (2), otherwise referred to as the phthalimidoamlodipine. The compound of formula (2) is a protected amlodipine compound that is essentially identical to the amlodipine compound itself, except that it also contains a phthalimide protecting group. The '481 patent further teaches that the phthalimide protecting group is ultimately removed from the compound of formula (2) by using a deprotecting agent, thereby resulting in the formation of the final amlodipine compound.

Particularly pertinent here is the '481 patent's disclosure in claim 1, the sole independent claim, of "[a] process, which comprises isolating from a crude reaction mixture compound of formula (3)," and then "reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B." '481 Patent, col. 25, ll. 50-51; col. 26, ll. 1-2. This specific claim language is the source of the parties' claim term definition disputes. Specifically, the parties initially disputed the meaning of (i) "crude reaction mixture;" (ii) "isolating;" (iii) "isolating from a crude reaction mixture compound of formula (3);" and (iv) "isolated compound of formula (3)." n2 As Synthon I reflects, application of the legal principles taught in Markman and its progeny to the intrinsic evidence resulted in the adoption of preliminary definitions for each of the disputed terms and phrases. These preliminary definitions, discussed in detail in Synthon I, were as follows:

(i) "crude reaction mixture" means "a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent;"

(ii) "isolating" means "separating," generally;

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i Isolating

The preamble to Claim 1 describes the patent as a "method of growing and isolating . . " Neither side disputes that "growing" means "propagation or cultivation of the virus, whereby the virus increases in number," but there is fervent debate over the term "isolating". Initially, Boehringer argues the position that as a general rule, preamble language never serves as a limitation. The preamble is that portion of the claim preceding the word "comprising." See Judin v. United States, 27 Fed. Cl. 759, 775 (Fed.Cl. 1993). While the significance of preamble language is a vexing issue for federal courts interpreting patent claims, Boehringer's position is untenable.

A "claim preamble has the import that the claim as a whole suggests for it" and when the drafter uses "both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). In other words, where the preamble language is "necessary to give life, meaning and vitality to the claim" or it is deemed "essential to point out the invention defined by the claim," the Federal Circuit has found that the language

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effectively limits the scope of the claim. Bell, supra, at 620-21. Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997).

In Bell Communications, the court clarified that the construction of preamble language does not present some "deep[] mystery." See Bell Communications, supra, at 621. Bell Communications dictates that the mechanics of preamble construction are the same as those for general claim construction. See Id. Therefore, this court must employ the interpretive principles elucidated in Markman and Vitronics, cited supra. First, I must look to the preamble language itself and then to the specification to further clarify the scope of the claim. See Bell Communications, supra, at 619-20. The court should also consider the prosecution history and when necessary, any extrinsic evidence. See Vitronics, supra.

The entire record in this case makes clear that Boehringer was working on the problem of both "growing" and "isolating" the PRRS virus. Boehringer has argued that "isolating" does not limit the scope of the claim because the body of the claim does not contain an isolation step. To some extent, that is true. When the claim language talks about "inoculating the virus . . . and incubating the inoculated cell sheet," that defines how to grow the virus and not necessarily how to isolate it. Nevertheless, to construe the claim as not involving "isolation" "would be divorced from reality." See Corning Glass Works, supra, at 1257. The specification makes clear that "isolation" is an integral part of the process which cannot be separated from the growing component. There is no question that steps involved in the body of claim 1 facilitate isolation. As will be discussed below, the specification anticipates that the claimed method will be repeated in several passages and while there are no isolation steps in the body of the claim, the elements of the claim facilitate isolation and the isolation step is necessary to be able to repeat the method. By introducing its claim as a "method of growing and isolating," Boehringer has defined the environment in which its process takes place. Once we understand that the term "isolating" impacts upon the scope of the claim, the construction of the term "isolating" becomes the more important task.

According to Schering, the clear meaning of the word "isolating" is recovering the causative (viral) agent from the tissue homogenate. Under that interpretation, the patent would cover the initial isolation of PRRS, but it would not cover "subsequent passages." In response. Boehringer argues that the term should be construed much broader. Boehringer posits that "isolation" is the "separation of the virus from its surroundings" -- a construction which encompasses "the initial recovery from a tissue sample [or homogenate] or separating or harvesting the virus from a cell culture system." Plaintiff's Finding No. 117. Certainly, the latter definition comports more with the common definition of isolation meaning: "to set or place apart, detach or separate. See RANDOM HOUSE COLLAGE DICTIONARY (1980). Moreover, nothing in the claim, specification, or prosecution history supports Schering's interpretation.

First and most importantly, when the claim refers to isolating the virus, it does not indicate whether the source of isolation is either the tissue homogenate from the diseased pig or the virus recovered from a previous passage. Second, under the heading, "Isolation," the specification discusses "initial isolation" and "subsequent passages." In that section, which discusses the use of serum in the process, the patent states that:
The presence of serum may be helpful for the initial isolation of the viral agent. Subsequent passages of the viral agent in the MA 104 cell line will produce the CPE without the presence of serum. However, more pronounced CPE is observed with the use of serum in the growth medium for the MA-104 cell line. See '778 Patent, Col. 3, lines 37-42 (emphasis added).

The specification language anticipates that there will be an "initial isolation" and other isolations "in subsequent passages." Schering does not believe that this is a valuable distinction because the specification does not mention "other isolations," just "subsequent passages." If the patent covered "other isolations," Schering intimates, the specification would need to distinguish between "initial isolation" and "subsequent" isolations, not just passages. However, such a degree of precision is not necessary. The language assumes that other isolations occur and therefore, the term "isolating" should not be limited to the initial isolation from the tissue homogenate. Finally, because the prosecution history does not suggest anything to the contrary, I find that the term "isolating" references the recovery of the virus from either the tissue homogenate or a previous passage.

A question remains as to how isolation is performed. In its post-trial briefs, Boehringer has argued that isolation means to recover the virus from its surroundings. At the hearing, Boehringer argued that isolation meant to "decant fluids containing virus and separate out debris." See Plaintiff's Ex. 10 (copy of chart demonstrating "Passaging PRRS Virus According to claim 1"). Looking at the specification. which is the most relevant indicator -- isolation is effected when, after incubation, the "fluid [containing the virus] is separated from the bottle, and passed into a new bottle." Although the differences

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between these definitions may be insignificant, the court will use the language of the specification because apart from the claim language itself, it is "the single best guide to the meaning of a disputed term." Vitronics, supra, at 1582.
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A. "Isolating"

The first dispute over claim construction concerns whether the term "isolating" recited in the claim's preamble imposes a limitation on the claim. While Schering, as we shall see, argues that the district court construed "isolating" too broadly, Boehringer asserts that the district court erred by treating "isolating" as a claim limitation at all. According to Boehringer, "isolating," as well as "growing," are mere recitations of purpose and as such do not impose any limitations on the method defined by the balance of the claim.

Boehringer is correct in that a preamble simply stating the intended use or purpose of the invention will usually not limit the scope of the claim, unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1350, 48 USPQ2d 1225, 1230-31 (Fed. Cir. 1998). Neither "growing" nor "isolating" is required to provide antecedent basis for subsequent claim language.

An intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates. But as we explained in Griffin v. Bertina, 285 F.3d 1029, 62 USPQ2d 1431 (Fed. Cir. 2002), preamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise. Id. at 1033, 62 USPQ2d at 1434. This principle holds true here, as it frequently does for method claims: "growing" and "isolating" are not merely circumstances in which the method may be useful, but instead are the raison d'etre of the claimed method itself. Divorced from the process of growing and isolating virus, the claimed method reduces to nothing more than a process for producing cytopathic effects in sheets of cultured MA-104 cells--a process whose absence of fathomable utility rather suggests the academic exercise. Gauging the effect of preamble language based on the claim as a whole, see Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1819-20 (Fed. Cir. 1995), it becomes apparent that claim 2 is in fact directed to a process for growing or isolating viruses. Accordingly, the district court properly recognized "isolating" as part of the definition of the claimed subject matter and thereby a limitation of the claim.

Having concluded that the district court correctly read "isolating" as imposing a limitation on the claim, we also conclude that the district court gave the term its proper construction. Essentially adopting Boehringer's interpretation, the district court held that the virus is "isolated" not only when the virus is cultured from tissues of an infected animal (the initial recovery of the virus), but also during subsequent serial passages of the virus, when the virus is cultured from an aliquot of an infected cell culture. Boehringer, 984 F. Supp. at 248. In other words, PRRS virus is "isolated" according to claim 2 each time the virus is propagated into a fresh tissue culture bottle, not just when the virus is initially isolated from an infected pig.

Schering, however, contends that "isolating" can refer only to the initial growth of virus from an infected tissue sample or other natural source, and not to subsequent passages in culture. Under such a construction, Schering would escape infringement because Schering "isolated" the virus from infected pigs in 1991, before the '778 patent issued. Moreover, while Schering grows its attenuated vaccine virus on MA-104 cells, Schering initially isolated the PRRS virus on cultured porcine lung cells, rather than the simian cells required by the '778 claims.

The first step in claim construction is to determine the ordinary and customary meaning, if any, that would be attributed to the term by those skilled in the art. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001). Dictionary definitions frequently are useful in this process, Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202-03, 64 USPQ2d 1812, 1818-19 (Fed. Cir. 2002), and in support of its construction the district court cited a "common definition" of "isolate" found in the Random House College Dictionary: "to set or place apart, detach or separate." Boehringer, 984 F. Supp. at 248. From this definition, the district court concluded that the PRRS virus was "isolated" in each serial passage, when the virus was separated from the infected cells.

According to Schering, however, the district court's reliance on this definition was erroneous. Because a term's ordinary

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meaning is that which it assumes in the field of the invention, Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999), Schering contends that the district court should have looked instead to narrower definitions found in dictionaries of microbiology and molecular biology--some of which define "isolation" as the process of obtaining a pure culture from a naturally occurring population. Under such a definition, serial passaging of a virus during cell culture would not constitute "isolating."

Boehringer points out that Schering's technical definitions were not introduced into the record at trial, nor, apparently, were they in any way presented to the district court. Like trial judges, we are free to consult dictionaries regardless of whether they have been offered by a party in evidence or not. Tex. Digital, 308 F.3d at 1203, 64 USPQ2d at 1819. Nonetheless, parties are obliged to make their claim construction arguments in the first instance to the district court, and we will rarely give weight to arguments that rely on sources brought forth for the first time on appeal. But Schering's technical dictionary definitions would carry little weight even if they had been first presented to the district court. Schering leads off its argument with the following technical definition of "isolation":

(microbiol.) Any procedure in which a given species of organism, present in a particular sample or environment, is obtained in pure culture.

Dictionary of Microbiology and Molecular Biology 468 (2d ed. 1987) (emphases added). Plainly, this definition does not require that the organism originate in a sample containing a natural or mixed population, and therefore easily encompasses propagation of a virus during serial passage, in which the virus is obtained from a culture comprising viruses, uninfected cells, infected cells, and dead cells. And while some of Schering's technical definitions do refer to obtaining organisms from natural populations, the remainder establish that the customary meaning of "isolating" in the field of the invention is broader than Schering maintains. The district court therefore properly determined that the ordinary meaning of "isolating" encompasses more than the initial isolation of a virus from an infected tissue sample.

While there is a strong presumption that the ordinary and accustomed meaning of a claim term governs its construction, this presumption may be overcome by evidence from the specification or prosecution history showing that the patentee employed the term in a manner inconsistent with its ordinary meaning. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325-26, 63 USPQ2d 1374, 1380-81 (Fed. Cir. 2002). Schering contends that both the patent's specification and prosecution history show reliance on a narrower meaning of "isolating," but its arguments are not persuasive. Under the heading "ISOLATION," the specification discloses both the culturing of tissue homogenate from infected animals, and several subsequent passages of the virus in culture. '778 patent, col. 2, l. 42 - col. 3, l. 54. Thus, to the extent that the specification uses a form of the verb "isolate," the specification supports the broader meaning of "isolating" advanced by Boehringer rather than the narrower construction advocated by Schering. Schering also points to the fact that the specification uses the word "recovered" as a synonym for "isolated," and uses the term "recover" only when referring to culture of the virus from tissue samples. But this observation strengthens Boehringer's position, not Schering's: the use of a different word to describe the isolation of PRRS virus from infected tissue samples--"recover"--suggests that "isolate" does not refer solely to this process.

Schering's prosecution history argument is similarly unavailing. During prosecution, Boehringer submitted several publications to the Patent and Trademark Office to establish that ATCC-VR2332 was the virus that caused PRRS. Because these references use the words "isolate" and "isolation" to refer to the recovery of the virus from tissues of infected animals, Schering contends that the term "isolating" in the claims should be so limited. But while references submitted during prosecution may shed light on the ordinary and accustomed meaning of a claim term, a patentee does not renounce the ordinary meaning of a term merely by submitting a reference that employs a different meaning. Absent a reliance on the narrower meaning by the patentee during prosecution, the references' use of "isolating" in a narrower sense does not preclude the claim term from also encompassing steps subsequent to the initial isolation. The district court construed this term correctly.

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In its opening claim construction brief, Synthon proposed that "isolating from a crude reaction mixture compound of formula (3)" should be defined simply as "separating the compound of formula (3) from a crude reaction mixture," with the additional condition that "this does not require that compound (3) be separated from all of the components of the crude

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reaction mixture (i.e., compound (3) need not be completely pure)." Similarly, Synthon initially proposed that the phrase "isolated compound of formula (3)" should be defined as "the compound of formula (3) that has been separated from a crude reaction mixture," and that the "isolated form" of the compound of formula (3) "does not require that compound (3) be completely pure."

Pfizer's initial proposal bore some resemblance to Synthon's, but was in fact significantly different. According to Pfizer, the phrase "isolating from a crude reaction mixture compound of formula (3)" must be construed to mean "separating the compound of formula (3) from the other materials in the crude reaction mixture." In other words, Pfizer, unlike Synthon, specified in its original proposed definition that the compound of formula (3) was required to be "separated from the other components of the crude reaction mixture." Similarly, Pfizer argued that the essentially synonymous terms "isolated compound of formula (3)," found in the '481 patent, and "isolated form," found in the '738 patent, required that the compound of formula (3) not be mixed with other compounds. Thus, Pfizer's original proffered definitions suggested the result of the isolating or separating step had to be the pure form of the compound of formula (3).

These divergent positions raised the question whether the various forms of the claim term "isolating" require the compound of formula (3) to be in a completely pure state following isolation and, if not, whether the patent claims or specification reveal any quantifiable manner in which to limit or describe the level of impurities permitted to remain together with the compound of formula (3) following the "isolating" step. In this regard, following significant oral and written argument, the parties ultimately reached their second and final general agreement regarding the disputed term "isolating," namely that the act of "isolating from a crude reaction mixture compound of formula (3)" does not require that the resulting form of compound of formula (3) be completely pure. In other words, the parties are in agreement that the act of isolation is not akin to purification of the compound of formula (3). Indeed, the embodiments and examples of the claimed process and compound disclosed in the specification make unmistakably clear that the isolated form of compound (3) includes some level of impurities, including some amount of unreacted starting materials. In other words, the specification acknowledges that the isolating process need not result in a pure form of the compound of formula (3). To illustrate this point, Example 1 of the specification describes the formation of the compound of formula (3), in part, as follows:
Two layers are formed in the reaction mixture; the upper one was separated and the lower organic layer was again washed with 200 ml of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent.

Yield: 350 g (84%), as the mixture of cis and trans isomers (6:4). Content of 2-chlorobenzaldehyde less than 5%.

'481 Patent Specification, col. 15, ll. 1-7. This particular example makes clear that even after separation of "the organic layer" containing the intermediate compound of formula (3), followed by evaporation of that layer to dryness, a quantity of unreacted starting material, namely the 2-chlorobenzaldehyde, remains present with the compound of formula (3).

Nor is this the only intrinsic evidence that the patent distinguishes between isolating or separating on the one hand, and purifying on the other. The specification is explicit that purification is an optional step that can be performed following isolation, and not a result achieved during or as part of isolation. n11 In this regard, it is important to note that the act of purification is set forth in a separate dependent claim of the '481 patent, namely claim 19, describing "[t]he process according to claim 1, which further comprises purifying said isolated compound of formula (3) before said reacting step... ." n12 Thus, under the doctrine of claim differentiation, isolation and purification must necessarily be viewed as separate and distinct acts, as both parties now appropriately concede. See Phillips, 415 F.3d at 1314-15 (recognizing that "[t]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim") (citations omitted).

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n11 See, e.g., '481 Patent Specification, col. 5, ll. 26-29 (stating that "[t]he compound (3) may be prepared in a sufficiently pure state and simply isolated from a crude reaction mixture by any conventional techniques. Such an isolated form of the compound (3) can be further purified if needed or used directly in the next synthetic step"); id., col. 6, ll. 34-38 (stating that "[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and the remaining starting materials can be easily removed").

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n12 Claim 20 of the '481 patent, also depending from claim 1, likewise adds the sole limitation that the "isolated compound of formula (3) is not purified before said reacting step." (Emphasis added).

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Given the parties' agreement that isolating or separating the compound of formula (3) from the crude reaction mixture need not result in compound of formula (3) that is completely pure, the next step in the analysis is to resolve the parties' dispute as to whether the patent reveals some quantifiable measure for the amount of impurities permitted to remain following the step of isolating the compound of formula (3). Pfizer, for its part, suggests that only "minor" amounts of impurities, including unreacted starting materials, are allowable following the act of isolation. In this regard, Pfizer modified its originally proposed constructions of the disputed terms to specify that "isolating from a crude reaction mixture compound of formula (3)" means "separating the compound of formula (3) from the other materials in the crude reaction mixture, but that after separation, the compound of formula (3) may contain only minor amounts of impurities, including impurities that may have been components of the crude reaction mixture." In support thereof, Pfizer cites to a passage from one of the preferred embodiments set forth in the patents' specifications, which provides, in pertinent part, that "[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and the remaining starting materials can be easily removed." '481 Patent Specification, col. 6, ll. 34-38 (emphasis added).

Yet, as Synthon correctly points out, other examples submitted during the course of the prosecution of the '481 patent confirm that the amount of unreacted starting materials and other impurities remaining following isolation of the compound of formula (3) from the crude reaction mixture can collectively reach levels as high as 40 percent. Moreover, the permissible levels of impurities following isolation cannot, as Pfizer suggests, be viewed categorically as "minor," as such a limitation is not contained in the patent claims. And, in any event, to read into the patent an undefined quantitative limitation (i.e. "minor amounts") on the level of allowable impurities following isolation -- particularly one that is not clear from the terms of the claims and specification -- would serve not to clarify a claim term, but simply to add yet another ambiguity to the disputed claim term. Imposition of a quantitative limitation such as "minor" or "small" to describe the permissible amounts of impurities following isolation of the compound of formula (3) is therefore not warranted in this instance.

To resolve the parties' remaining dispute, Synthon next proposes that the term "isolating from a crude reaction mixture compound of formula (3)" should be defined as "separating the compound of formula (3) from the crude reaction mixture by any conventional or known technique," with the latter descriptive phrase deriving from the lengthy description of the invention set forth in the specification. See '481 Patent Specification, col. 5, ll. 26-28 (providing that "[t]he compound (3) may be prepared in a sufficiently pure state and simply isolated from a crude reaction mixture by any conventional techniques") (emphasis added); id., col. 6, ll. 38-39 (providing that "[r]ecovery can be by any known technique and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product") (emphasis added).

Although initially appealing, this proposed definition is ultimately unpersuasive. First, and most importantly, to read the requirement into claim 1 that isolation of the compound of formula (3) from the crude reaction mixture must be performed "by any conventional or known technique" would essentially import a functional limitation into the claimed process that is not expressly contained in the claims themselves. To do so would clearly be improper under well-settled Markman principles. See Burke, 183 F.3d at 1340 (recognizing that limitations included in the specification, including functional limitations, cannot be imported into the claims where no such limitations exist in the claims). It is also significant to note that the phrase "by any conventional or known technique" is, by its nature, a term itself not free from ambiguity; a term with a meaning that changes over time. The universe of separation techniques that were considered "conventional" or "known" by persons skilled in the relevant art at the time the patents issued may not include techniques that are now, or in the future may become, conventional.

In the circumstances, given that neither parties' proposed definitions for the remaining disputed claim terms are appropriate in this instance--namely Pfizer's "minor impurities" argument nor Synthon's "conventional or known technique" argument -- an independent resolution of the disputed claim terms must be reached in light of the intrinsic evidence. And in the end, a careful review of the claims, the specification and the prosecution history teaches, as Pfizer argues, that isolating the compound of formula (3) from the crude reaction mixture necessarily involves separating the compound of formula (3) from the other components of the crude reaction mixture, with some impurities permitted to remain following the act of isolation. Thus, the phrase "isolating from a crude reaction mixture compound of formula (3)," used in claim 1 of the '481 patent, is

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appropriately defined as:

"separating the compound of formula (3) from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation."
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As the '481 patent teaches, the compound of formula (3) may be produced by reacting two starting materials -- one an ester or ketoester, and the other an aldehyde -- in a solvent, such as isopropanol, in the presence of a catalyst, such as piperidine. This chemical reaction creates a "crude reaction mixture" containing the compound of formula (3). The next step in the process is to "isolate" from the crude reaction mixture the compound of formula (3). The '481 patent then requires that "the isolated compound of formula (3)" be reacted with another organic compound -- an aminocrotonate -- to form the compound of formula (2), otherwise referred to as the phthalimidoamlodipine. The compound of formula (2) is a protected amlodipine compound that is essentially identical to the amlodipine compound itself, except that it also contains a phthalimide protecting group. The '481 patent further teaches that the phthalimide protecting group is ultimately removed from the compound of formula (2) by using a deprotecting agent, thereby resulting in the formation of the final amlodipine compound.

Particularly pertinent here is the '481 patent's disclosure in claim 1, the sole independent claim, of "[a] process, which comprises isolating from a crude reaction mixture compound of formula (3)," and then "reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B." '481 Patent, col. 25, ll. 50-51; col. 26, ll. 1-2. This specific claim language is the source of the parties' claim term definition disputes. Specifically, the parties initially disputed the meaning of (i) "crude reaction mixture;" (ii) "isolating;" (iii) "isolating from a crude reaction mixture compound of formula (3);" and (iv) "isolated compound of formula (3)." n2 As Synthon I reflects, application of the legal principles taught in Markman and its progeny to the intrinsic evidence resulted in the adoption of preliminary definitions for each of the disputed terms and phrases. These preliminary definitions, discussed in detail in Synthon I, were as follows:

(i) "crude reaction mixture" means "a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent;"

(ii) "isolating" means "separating," generally;

(iii) "isolating from a crude reaction mixture compound of formula (3)" means "separating the compound of formula (3) from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation;" and

[ILLEGIBLE TEXT] from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation."

See Synthon I, 437 F. Supp. 2d 565, 2006 WL 2669040, at **7, 11.

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n2 Although the parties also originally disputed a related claim phrase used in the derivative '738 compound patent, that patent has since been dismissed with prejudice from the litigation and thus need not be addressed here. See supra n. 1.

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As noted, the trial proceeded under two alternative definitions for the primary disputed claim phrase, specifically the phrase "isolating from a crude reaction mixture compound of formula (3)." In this regard, the first of these alternative definitions was initially to be the preliminary definition set forth in Synthon I, while the second alternative definition was identified as follows:

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"separating the compound of formula (3) from the crude reaction mixture, except that this does not require that the compound of formula (3) be separated from all of the components of the crude reaction mixture or that the compound of formula (3) be completely pure."

See Synthon IP, Inc. v. Pfizer, Inc., Civil Action No. 1:05cv1267, 2006 U.S. Dist. LEXIS 95004 (E.D. Va. June 30, 2006) (Order). Thereafter, however, in the course of a final pretrial conference on August 3, 2006, the first alternative definition for the phrase "isolating from a crude reaction mixture compound of formula (3)" -- that is, the definition set forth in Synthon I -- was clarified and amended in several minor respects to read as follows:

"separating the compound of formula (3) from the other known components of the crude reaction mixture, except that following the act of separation, the resulting compound of formula (3) need not be pure; it may contain known and unknown impurities, unknown side products, as well as residual amounts of the other known components of the crude reaction mixture."

See Synthon IP, Inc. v. Pfizer, Inc., Civil Action No. 1:05cv1267 (E.D. Va. Aug. 3, 2006) (Order). n3 One additional minor modification was made to the first alternative definition prior to the jury trial in this matter, n4 resulting in the following two alternative definitions being presented to the jury for separate consideration on each issue of infringement and validity remaining in the case:

Alternative Definition # 1
"separating the compound of formula (3) from the other known components of the crude reaction mixture, except that following the act of separation, the resulting compound of formula (3) need not be pure; there may be present known and unknown impurities, unknown side products, as well as residual amounts of the other known components of the crude reaction mixture;" and

Alternative Definition # 2
"separating the compound of formula (3) from the crude reaction mixture, except that this does not require that the compound of formula (3) be separated from all of the components of the crude reaction mixture or that the compound of formula (3) be pure."

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n3 These modifications were prompted primarily by Synthon's argument that the chemical reactions used in synthesizing compounds typically result in the formation of various unknown side products and unknown impurities and thus, it might prove impossible to determine whether in the course of the isolation step the compound of formula (3) had been separated from all of the side products that might be present in the crude reaction mixture.

n4 Specifically, the phrase "it may contain," appearing after the semi-colon in the first alternative definition, was amended to read "there may be present."

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As noted, the ensuing seven-day jury trial culminated in a jury verdict for Pfizer on all remaining infringement and validity issues under both of the alternative definitions for the disputed claim phrase "isolating from a crude reaction mixture compound of formula (3)." n5 This post-verdict Markman opinion now addresses several arguments raised by Synthon in a supplemental claim construction brief filed following issuance of Synthon I, but before commencement of the jury trial, and makes clear for the record the final claim construction definitions applicable to this case.

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n5 The 17-page special verdict form was divided into four separate sections, namely (i) infringement under Alternative Definition # 1, (ii) infringement under Alternative Definition # 2, (iii) validity under Alternative Definition # 1, and (iv) validity under Alternative Definition # 2. Only literal infringement was in issue.

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II.

Because the parties do not dispute the legal principles cited and relied on in Synthon I, it is unnecessary to do more here than to adopt and incorporate those principles by reference. See Synthon I, 437 F. Supp. 2d 565, 2006 WL 2669040, at **3-6. The essential dispute between the parties continues to focus on the meaning of the claim phrase "isolating from a crude reaction mixture compound of formula (3)." In this regard, Synthon continues to oppose, as it has from the outset, the argument offered by Pfizer and adopted in Synthon I that isolating the compound of formula (3) from the crude reaction mixture necessarily involves separating the compound of formula (3) from the other known components of the crude reaction mixture, as required by Alternative Definition # 1. Instead, Synthon contends that subjecting the crude reaction mixture to a "phase separation where two layers emerge" and then pouring off or decanting "the upper isopropanolic layer," leaving behind an oily layer containing the compound of formula (3) is sufficient to meet the isolation requirement of the patent claims in issue. Yet, as in the initial round of briefing and argument, Synthon is clearly mistaken in this regard, for the intrinsic evidence points persuasively to the claim construction set forth in Alternative Definition # 1. In other words, a careful review of the claims, the specification and the prosecution history teaches that isolating the compound of formula (3) from the crude reaction mixture necessarily involves separating the compound of formula (3) from the other known components of the crude reaction mixture, with some impurities, unknown side products and residual amounts of the other known components of the crude reaction mixture permitted to remain following the act of isolation. Thus, removal of only one of the other known components of the crude reaction mixture, i.e. the solvent, is not sufficient to isolate the compound of formula (3) from the crude reaction mixture.

Indeed, as explained in Synthon I, Alternative Definition # 1 derives first from the plain language of the claims themselves. To begin, claim 1 of the '481 patent describes a process that begins with "isolating from a crude reaction mixture compound of formula (3)." This statement, standing on its own, plainly refers to separating the compound of formula (3) from the crude reaction mixture. Significantly, the claim language teaches that it is the compound of formula (3) that is to be separated from the crude reaction mixture; the claim language does not teach separating the solvent or any component other than the compound of formula (3) from the crude reaction mixture. Nor does the claim language refer to separating the compound of formula (3) from only a single component of the crude reaction mixture, such as the solvent. Instead, the plain language of the patent requires that the compound of formula (3) itself be separated from the crude reaction mixture, namely from the other components of the crude reaction mixture. In other words, were the compound of formula (3) left in a mixture with the other components of the crude reaction mixture -- with the exception of any permissible amounts of impurities -- it would not be isolated from the crude reaction mixture as required by claim 1 of the '481 patent.

The specification also makes clear that the isolating step must involve more than removing the solvent from the crude reaction mixture, as it expressly states that "[t]he solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be separated from the rest of the unreacted starting materials and also from any potential side products." '481 Patent Specification, col. 6, ll. 22-25 (emphasis added). The specification further provides that

> [p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and the remaining starting materials can be easily removed. Recovery can be by any known technique and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product. It should be understood that such washing is not intended to be considered a 'purification step,' but rather merely part of the recovery.

'481 Patent Specification, col. 6, ll. 34-43 (emphasis added). Moreover, the specification summarizes the claimed process by recognizing that "the use of the compound (3) of our invention...allows for a reduction in side products by producing a stable intermediate that is easily separable from the rest of the reactive starting materials, thereby reducing the chance of side effects in subsequent reaction steps." '481 Patent Specification, col. 8, ll. 53-61 (emphasis added). Given these statements in the specification acknowledging removal of the starting materials and other side products, it is clear that merely pouring off from the crude reaction mixture a single layer of solvent, which Synthon contends is sufficient to meet the requirement of isolating, does not serve to separate the compound of formula (3) from the other components of the crude reaction mixture; rather, as illustrated above, this suggested step only serves to separate or isolate most of the solvent -- typically isopropanol--from the crude reaction mixture, which mixture still contains the compound of formula (3).

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Alternative Definition # 1 is also consistent with the patent's prosecution history. Thus, the '481 file wrapper reflects that the original process claims of the '481 patent did not include the phrases "isolating from a crude reaction mixture" or "isolated compound of formula (3)." In fact, in February 2003, the patent examiner rejected Synthon's asserted claim 18 -- which ultimately matured into claim 1 of the '481 patent -- as being anticipated by the prior art on the basis that the compound of formula (3) would be formed during the reaction steps of a prior art reference, namely U.S. Patent No. 4,572,909, a twenty-year old patent owned by Pfizer relating to the pharmaceutical compound amlodipine. To overcome this rejection, Synthon amended its application claim 18 to include the step of "isolating from a crude reaction mixture compound of formula (3)." n6 Significantly, this amendment served to distinguish the claimed process from the prior art by making clear that the compound of formula (3) is required to be separated from the other components of the crude reaction mixture prior to the next step of the claimed process.

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n6 In this regard, Synthon's original application claim 18 -- prior to the addition of the "isolating" requirement -- simply claimed "[a] process, which comprises reacting a compound of formula (3)...with an alky1 3-aminocrotonate of formula B...to form a compound of formula (2)." Significantly, this form of application claim 18 was rejected by the patent examiner as being anticipated by the prior art, in that the compound of formula (3) referenced in application claim 18 would be formed during the reaction steps of Pfizer's '909 patent. Synthon thereafter amended its application claim 18 to cover "[a] process, which comprises isolating from a crude reaction mixture a compound of formula (3)...and reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." (Emphasis added). And, in its supporting amendment papers, Synthon noted, inter alia, that "[s]uch an isolation step is not taught or suggested in...[the] '909 [patent]."

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Likewise, in the course of the prosecution of the derivative '738 patent, the patent examiner rejected application claim 2 for indefiniteness, noting that it was a "substantial duplicate" of claim 1 in that it did not "limit the compounds" of claim 1. In this regard, while application claim 1 covered "a compound having the formula (3)," application claim 2 covered the compound of claim 1 in "isolated form." In response to this preliminary indefiniteness rejection, the applicants stated the following:

Claim 1 [of the '738 patent'] is directed to a compound per se. Accordingly it reads on the isolated, purified compound itself as well as the compound in compositions/mixtures with other ingredients. That is, claim 1 is not avoided simply because the compound of formula (3) is contained in a mixture with other compounds. Certainly any composition that contained the compound of formula (3) falls within the scope of claim 1. In contrast, claim 2 requires the compound of formula (3) to be in isolated form. A composition that contains a compound of formula (3) and, e.g., phthalimidoamlodipine of formula (2) would avoid claim 2, but not claim 1. Claim 2 is not a substantial duplicate of claim 1. Indeed, there is no reason to read claim 1 as requiring the compound of formula (3) to be in isolated form. Therefore, claim 2 is a proper dependent claim of clear and definite scope.

In other words, and of particular significance here, Synthon explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." n7 This statement essentially amounts to an admission by Synthon that the compound of formula (3) is not "isolated" within the meaning of the relevant patent claims if it is still contained in a mixture with other ingredients or compounds. In other words, this admission made in the course of the patent's prosecution is wholly inconsistent with Synthon's proposed construction of the disputed claim phrase and fully consistent with the definition set forth in Synthon I, later modified to form Alternative Definition # 1.

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n7 Following the applicant's clarification in this regard, the patent examiner withdrew the earlier indefiniteness rejection and allowed application claim 2 of the '738 patent.

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Now, in its motion for reconsideration, Synthon reasserts several arguments that were already addressed and rejected in Synthon I, the primary one being that none of the examples set forth in the '481 patent specification support Alternative Definition # 1. This fact, however, was already acknowledged in Synthon I, where it was noted that "none of the examples set forth in the specification specifically mention the isolating step or the isolation process." See Synthon I, 437 F. Supp. 2d 565, 2006 WL 2669040, at *13. It was also noted in Synthon I that "only 3 of the 13 examples set forth in the specification even arguably pertain to isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this particular step in the claimed inventions." See 437 F. Supp. 2d 565, [WL] at *13. n8 And significantly, all of these examples refer only to "the organic layer containing the desired product," rather than to the "isolated form" of the compound of formula (3), i.e., the "desired product" itself.

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n8 Consistent with the parties' initial assertions, Synthon I noted that only 3 of the 13 examples set forth in the '481 patent specification specifically relate to the formation and alleged isolation of the compound of formula (3), namely examples 1, 1A and 4. Although example 12 also addresses the compound of formula (3) to a limited extent, that example is explicitly directed to the compound of formula (2) and contains no additional information or explanation material to the result reached here.

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As previously explained in Synthon I, this absence in the applicable examples of any specific treatment or discussion of isolation of the compound of formula (3) is not surprising in the circumstances given (i) that the "isolating" requirement was added to the claims in issue in the course of the patent's prosecution, see supra, and (ii) that the original specification and examples submitted to the Patent and Trademark Office (PTO) in Synthon's initial application were not changed, modified or updated in any respect following the "isolating" amendments, presumably to protect the applicant's priority date. For all of these reasons, it remains clear, as noted in Synthon I, that the relevant examples set forth in the patent's specification are not particularly instructive or illuminating as to the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)" given that Synthon's original application claims did not require the compound of formula (3) to be isolated from the crude reaction mixture.

Yet now, in an attempt to avoid the result in Synthon I, and hence application of Alternative Definition # 1, Synthon raises several new arguments in its motion for reconsideration that were not previously addressed in Synthon I. In this regard, Synthon first argues that the inventors contemplated from the outset -- at the time the original patent application was filed -- that the compound of formula (3) would be isolated from the crude reaction mixture and thus that the examples set forth in the original specification must be read as addressing the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)." In support of this new argument, Synthon claims that the word "isolated" was present in an originally-filed claim directed at the compound of formula (3) itself. Yet, a review of the prosecution history discloses that Synthon is clearly mistaken in this regard.

To be sure, Synthon correctly notes that the original patent application -- Application No. 09/809,351 (the '351 application) -- was filed with the Patent and Trademark Office (PTO) on March 16, 2001. This application contained not only process claims, but also additional claims directed to the compound of formula (3) itself. In the course of the prosecution history, however, the patent examiner, issued a restriction requirement requiring the applicants to split the originally-filed claims into multiple applications, all with a common specification. Thus, original application claims 18-34 of the '351 application were pursued first, ultimately maturing into the '481 process patent. Original application claims 1-17, in turn, were prosecuted at a later date and ultimately matured into the '738 derivative compound patent. Given their provenance, both patents share the identical specification.

Synthon's recitation of the prosecution history is correct in these preliminary respects, but then goes awry in contending that application claim 2, as originally filed in the '351 application, included the term "isolated" in connection with the compound of formula (3). Specifically, Synthon claims that original application claim 2 described "[t]he compound according to claim 1, wherein said compound is in isolated form." The record flatly refutes this contention; application claim 2, at the time the '351 application was originally filed, claimed something entirely different, namely "[t]he compound according to claim 1 in the form of an oil." And significantly, not a single claim in the entire original application was directed to the isolated form of the compound of formula (3). Indeed, it was not until August 27, 2001, when Synthon submitted a continuing-in-part

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application, that the claim that ultimately matured into claim 2 of the '738 derivative compound patent was added to the application, specifically "[t]he compound according to claim 1, wherein said compound is in isolated form." Indeed, the record reflects that prior to that amended application in August 2001, the isolation requirement for the compound of formula (3) appeared nowhere in the asserted claims. n9 This notable absence therefore casts significant doubt on Synthon's current position that the examples in the specification should be read as addressing the isolating step because the inventors contemplated isolating the compound of formula (3) from the crude reaction mixture from the outset, at the time the original patent application was filed.

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n9 The only claims of the original '351 application that used the term "isolating" were directed at "isolating" the compound of formula (2) -- the phthalimidoamlodipine -- as opposed to the compound of formula (3).

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In its motion for reconsideration, Synthon also argues that the "oily layer" referenced in the relevant specification examples n10 is, in fact, "the compound of formula (3) in isolated form." In other words, Synthon now contends that subjecting the crude reaction mixture to a "phase separation where two layers emerge" and then pouring off or decanting "the upper isopropanolic layer," leaving behind an oily layer containing the compound of formula (3) is equivalent to isolating the compound of formula (3) from the crude reaction mixture, as required by the claims in issue. The problem with this proposed construction, however, is that it would essentially deprive the "isolating" requirement of any significant meaning, as the oily layer undeniably contains all of the known components of the original crude reaction mixture with the exception of most of the solvent or isopropanol. Such a construction is thus contrary to the specification and the prosecution history, both of which teach that the compound of formula (3) is separated from the starting materials and side products during the isolation process and cannot remain in a mixture with other compounds or ingredients following the act of isolation, with the exception of various "known and unknown impurities, unknown side products, as well as residual amounts of the other known components of the crude reaction mixture." See supra, Alternative Definition # 1.

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n10 None of the examples actually use the precise term "oily layer," as argued by Synthon; rather, Examples 1 and 4 reference an "organic layer, containing the desired product," Example 1A refers to "an oil" or "gum like solid," and Example 12 simply references "an oil."

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In support of its argument that the oily layer containing the compound of formula (3) described in the relevant examples of the patent specification constitutes the "isolated compound of formula (3)," Synthon relies, in part, on a declaration submitted by the named inventors in the course of the prosecution history. Specifically, in September 2002, the patent examiner rejected Synthon's asserted application claim 18 as being anticipated by a Russian prior art reference, namely the RU 21611156 patent. To overcome that anticipation rejection, Synthon submitted a "Rule 131 declaration" from the named inventors in order to establish an earlier invention date and thus "swear behind" the publication date of RU 21611156. n11 As required by the applicable federal regulations, the inventors' Rule 131 declaration referred only to rejected application claim 18. And significantly, the Rule 131 declaration was signed by the inventors before application claim 18 was officially amended to add the "isolating" requirement. Indeed, the Rule 131 declaration was signed by the inventors between February 4 and 6, 2003, while Synthon did not file the amendment papers adding the "isolating" requirement to the claims in issue until February 10, 2003. For this reason, it is not surprising that the Rule 131 declaration nowhere explicitly refers to isolating the compound of formula (3); instead, similar to the original application claims, the declaration refers only to isolating the compound of formula (2).

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n11 Title 37 C.F.R. 1.131 provides that "[w]hen any claim of an application...is rejected, the inventor of the subject matter of the rejected claim...may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference."

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To be sure, the Rule 131 declaration provides that an experiment was performed by the named inventors of the '481 patent in the Czech Republic prior to the critical date applicable to RU 21611156. That experiment, according to the inventors, involved a "two-step reaction scheme," whereby in the first step, two starting materials are reacted to form an intermediate compound -- the compound of formula (3) -- and in the second step, "the formed intermediate...is reacted with methyl-3-aminocrotonate" to form an additional compound -- the compound of formula (2) -- elsewhere referred to as the phthalodipine or phthalimidoamlodipine. Nowhere in the Rule 131 declaration do the named inventors acknowledge that the intermediate compound of formula (3) is "isolated" prior to its reaction with the aminocrotonate. And this absence of any reference to isolating the compound of formula (3) does not appear to be inadvertent or insignificant, for the Rule 131 declaration does expressly mention isolating with respect to the compound of formula (2). n12 It follows, therefore, that if isolation of the compound of formula (3) was intended to be part of the claimed process from the outset, as Synthon unpersuasively argues in its motion for reconsideration, then such an isolation step would likewise have been expressly mentioned in the Rule 131 declaration. It was not.

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n12 Specifically, the Rule 131 declaration provides, in pertinent part, that "the yield of phthalodipine, after isolation of the product as crystals, is reported as 12.27 g. (47.2% of theoretical yield)." (Emphasis added).

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But this does not end the analysis, for Synthon offers one final argument in support of its assertion that the isolated form of the compound of formula (3) required by the claims in issue is the "oily layer" left behind following removal of the solvent from the crude reaction mixture. Specifically, Synthon points to a statement made by its prosecuting attorney in certain submissions filed with the patent examiner contemporaneously with the Rule 131 declaration that "[t]he invention, including the isolation of a compound of formula (3) (as an oil layer) and reacting it with an alkyl 3-aminocrotonate to successfully form a compound of formula (2), was performed in the Czech Republic" by the named inventors before the publication date of RU 21611156. While this single statement made by the prosecuting attorney arguably supports Synthon's assertion that the "oily layer" containing the compound of formula (3) constitutes the "isolated form" of the compound of formula (3), this does not alter the critical fact that there is no reference whatsoever to isolating the compound of formula (3) in the Rule 131 declaration itself, either as an oily layer or otherwise. Moreover, it is clear that a prosecuting lawyer's statement made in the course of the prosecution history cannot broaden the requirements of the actual patent claims themselves. See Biogen v. Berlex, 318 F.3d 1132, 1140 (Fed. Cir. 2003) (recognizing that "[r]epresentations during prosecution cannot enlarge the content of the specification"). Put differently, this single statement made by the prosecuting attorney cannot serve to make the "oily layer" containing the compound of formula (3) -- which layer is without question still a mixture of all of the known components of the crude reaction mixture with the exception of the majority of the solvent -- the "isolated form" of the compound of formula (3) required by claim 1 of the '481 patent. Indeed, it was the very same prosecuting attorney who later told the patent examiner, in order to overcome a preliminary indefiniteness rejection, that the compound of formula (3) would not be isolated within the meaning of the asserted claims if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." See supra, pp. 8-10.

III.

In the end, all of Synthon's arguments against application of Alternative Definition # 1, including those asserted both before and after issuance of Synthon I, are unpersuasive. Rather, a careful review of the intrinsic evidence compels the conclusion that Alternative Definition # 1 is the appropriate and final definition applicable to the disputed claim phrase "isolating from a crude reaction mixture compound of formula (3)." This final definition requires that the compound of formula (3) be separated from the other known components of the crude reaction mixture, with the understanding that following the act of separation, the resulting compound of formula (3) need not be pure, as there may be present (i) known and unknown impurities, (ii) unknown side products, as well as (iii) residual amounts of the other known components of the crude reaction mixture. Corresponding definitions for the related disputed claims terms and phrases naturally flow from this final definition.

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The sole dispute on claim construction for the '405 patent is the meaning of the term "isotonic" in claims 1-4. At issue is whether the term "isotonic" should be defined in its "conventional sense" to mean "compatible with body fluids," as EKR contends, or defined as a specific range of osmotic pressure as "corresponding to that of body fluids, approximately 275-300 mOsm/L," as advanced by Sun. Sun focuses on the '405 patent's reference to Remington's Pharmaceutical Sciences ("Remington's"), which explicitly sets forth a range of 275-300 mOsm/L. Thus, EKR argues for a definition based on physiological compatibility with bodily fluids whereas Sun seeks to add an osmotic pressure limitation imported from Remington's.

With regard to the definition of "isotonic," the '405 patent states:

The term "isotonic" is used in its conventional sense, as is described in "Remington's Pharmaceutical Sciences," Mack Publishing Company, Easton, Pa., 1985, Chapter 80, page 1455 et seq., especially page 1456, left column, 60 lines 24-33, to mean a fluid corresponding to body fluids including blood and lacrimal fluid, normally having an osmotic pressure which is often described as corresponding to that of a 0.9% solution of sodium chloride.

('405 Patent, Col. 3, ll.56-64.) The Federal Circuit in Phillips teaches that the "'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent," 415 F.3d at 1321, and that the Court should primarily consider the intrinsic evidence, including the claims, specification and prosecution history. 415 F.3d at 1312-17. Extrinsic evidence is considered less reliable in that it risks taking the meaning out of the patent specification's context and placing it into the abstract. Id. at 1318. The Federal Circuit in Phillips offers several reasons for the lesser importance of extrinsic evidence, the most relevant being that "extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning." Id.

Sun argues for construction based upon the specific osmotic pressure ranges set forth in Remington's, which is referenced in the '405 patent. ('405 patent, col. 3, l. 58.) Despite the explicit reference to Remington's, only the text of the patent can be considered intrinsic. The text of the patent, however, does not set forth specific osmotic ranges; those are found only by opening Remington's, which constitutes extrinsic evidence for purposes of a patent analysis. The '405 patent's claims embrace parenteral administration by injection or infusion of isotonic solution in mammals generally, including cattle, horses, and sheep, as well as human beings. While the '405 patent claims cover both infusion and injection, Sun's accused product can only be administered by infusion, and only after being rendered isotonic (because it would otherwise be potentially harmful if directly injected). Sun argues that its product is "50% below" the isotonic limitation--and is hypotonic--as formulated. But this argument assumes that isotonicity lies within the range of 275-300 mOsm/L. Before Sun's accused product in the ampul could ever be administered, it must necessarily be infused with fluids for intravenous drip, which alters the tonicity. Since the '405 patent covers administration to mammals, restricting a definition of the term "isotonic" to a specified osmolality range amenable to humans (as referenced in Remington's) does not make sense. Accordingly, the Court must reject Sun's construction of the term "isotonic" because it relies on ranges at the expense of capturing the variable meaning of isotonic depending on the situation.

The truer definition under Phillip's guidance is one that adheres to the intrinsic evidence contained in the '405 patent, covering isotonic's "conventional" meaning, which, according to the '405 patent, "mean[s] a fluid corresponding to body fluids including blood and lacrimal fluid." Moreover, extrinsic evidence would support a claim construction favorable to EKR's definition of compatibility with bodily fluids because even Remington's conveys that isotonicity relates to a qualitative "physiologic compatibility" and cannot be pinned down to a specific range of osmotic pressure. On the same page of Remington's as is referenced in the '405 patent, the treatise states: "isotonicity infers a sense of physiologic compatibility where isoosmoticity need not." (RW Decl., Ex. 16, Remington's, at 1456.) Dr. Bhowmick's testimony concerning the definition of "isotonic," which supports EKR's preferred construction, is in agreement, even though he is Sun's witness:

Q. I see. When you say "isotonic," what do you mean by that?

A. It's - isotonicity, same as the physiological solutions.

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Q. So compatible with body fluid?

A. Yes

(Bhowmick Tr. 63:11-16.)

EKR's definition for "isotonic" with respect to the '405 patent is more in keeping with the plain and ordinary reading of the patent language. The '405 patent did not mean to define isotonic as a particular range of osmotic pressure because isotonicity will change as necessary, whether a sheep, horse, or human is the subject for administration.

The Court construes isotonic as meaning "compatible with body fluids."
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2. "joined end-to-end outside of the living cells"

The dispute concerning this claim language is whether this phrase is a product-by-process claim. Amgen argues it is and therefore, this claim language is a process limitation that requires the joinder of DNA end-to-end outside of the living cell. Schering disagrees. It asserts this language is not in product-by-process form. Instead, Schering argues that it is only a structural limitation as to the term "recombinant DNA molecule," and therefore, this claim language may encompass an identical product made by a different process.

"Product-by-process claims" are claims which describe the product more by the process used to obtain it than by its structure. See Hazani v. United States Int'l Trade Comm., 126 F.3d 1473, 1479 (Fed. Cir. 1997). Although not referred to in the patent statute, product-by-process claims developed in response "to the need to enable an applicant to claim an otherwise patentable product that resists definition other than by the process by which it is made." See In re Thorpe, 777 F.2d 695, 697 (Fed.Cir.1985).

The Court, however, is not persuaded that the phrase "joined end-to-end outside of living cells" is in product-by-process form. Product-by-process claims recite how a product is made, not how it is used. See Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 997 (Fed. Cir. 1993). This claim language, however, is best characterized as a pure product claim since the product is described by its structure rather than by the process used to obtain it. See Hazani, 126 F.3d at 1479. Accordingly, the Court finds "joined end-to-end outside of living cells" to be a structural limitation which may encompass identical products made by different processes.
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D.

The pivotal issue on appeal is the proper construction of the count, which is a question of law. DeGeorge v. Bernier, 768 F.2d 1318, 1321, 226 U.S.P.Q. (BNA) 758, 760 (Fed. Cir. 1985). To construe the count we must look at the language as a whole and consider the grammatical structure and syntax. Credle v. Bond, 25 F.3d 1566, 1571, 30 U.S.P.Q.2D (BNA) 1911, 1915 (Fed. Cir. 1994).

In the absence of ambiguity, it is fundamental that the language of a count should be given the broadest reasonable interpretation it will support and should not be given a contrived, artificial, or narrow interpretation which fails to apply the language of the count in its most obvious sense. Only when counts are ambiguous may resort be had to the application where the counts originated, and this court does not look to the specification to determine whether there is an ambiguity.

In re Baxter, 656 F.2d 679, 686, 210 U.S.P.Q. (BNA) 795, 802 (CCPA 1981) (citations omitted).

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We agree with both parties that no ambiguity exists in the count. The district court interpreted the count based on the protein encoded by the DNA construct. Therefore, the district court concluded that a DNA construct is outside of the scope of the count if, when incorporated into an expression plasmid and transformed into a yeast cell, it secretes a fusion protein instead of mature human IGF-I. The plain language of the count, however, militates against this conclusion.

Although a close relationship exists between a DNA construct and the protein it encodes, the two are not equal. The count specifically defines a DNA construct, not the protein that is produced by expression from the construct. The specific elements enumerated in the count that necessarily must be included in any DNA construct within the count are a DNA sequence coding for the secretory leader, a processing signal sequence, and human IGF-I. No dispute exists that Genentech's DNA construct as described in the Lee application contains the complete DNA sequences for these three proteins in its DNA construct. The issue arises from the nine additional codons encoding the collagenase cleavage site inserted between the sequences coding for human IGF-I and the alpha-factor processing sequences. Therefore, the issue of claim construction is decided by the meaning of the phrase "joined in proper reading frame."

The term "reading frame" relates to the way in which a protein is expressed from a DNA construct. DNA is made up of a series of nucleotides. To express the DNA construct to yield a protein, the cell machinery reads nucleotides in sets of three, which are called triplets or codons, to incorporate specific amino acids into the protein. If an extra nucleotide is inserted or deleted from a DNA sequence, the series of triplets is changed and different amino acids are incorporated into the protein. The term "reading frame" describes this phenomenon. To maintain "proper reading frame," the triplets in the DNA sequence must be read so that the proper amino acids are incorporated into the resulting protein. See KARL DRLICA, UNDERSTANDING DNA AND GENE CLONING: A GUIDE FOR THE CURIOUS, 33-36 (2d ed. 1992).

In the DNA construct of the count at issue here, "in proper reading frame" means that the nucleotides must be read in such a way that the seventy amino acids of human IGF-I are incorporated in the proper sequence in the expressed protein. Nothing exists in the definition of "in proper reading frame" to exclude nucleotides coding for additional amino acids at the beginning of the seventy amino acid IGF-I sequence.

This interpretation of the count is consistent with the open-ended term "comprising." "Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim. In re Baxter, 656 F.2d at 686, 210 U.S.P.Q. (BNA) at 802.

The claim construction issue then becomes whether the term "joined" forecloses the possibility of additional nucleotides being inserted between the two joined elements, the alpha-factor processing sequences and human IGF-I sequence. We find that it does not.

The district court found that "joined" ordinarily means "connected." From this definition, the district court read into the term a requirement that the alpha-factor processing sequences and human IGF-I sequence should be directly joined with no intervening nucleotides.

We hold, however, that this interpretation of the term "joined" is not the broadest, reasonable interpretation of the count. To be joined or connected does not necessitate a direct joining or connection. Nothing in the count restricts it to direct joining. Therefore, we hold that the count encompasses DNA constructs such as Genentech's, that have intervening nucleotide sequences between the alpha-factor processing sequences and the human IGF-I sequence, as long as the proper reading frame is maintained between the two joined sequences.

This is not inconsistent with our opinion in Wellcome Foundation, 29 F.3d 1555, 31 U.S.P.Q.2D (BNA) 1161. In that case we defined the phrase "human tissue plasminogen activator" in the context of the claims of the patent at issue in that case. Because we found the term ambiguous, we examined the specification for guidance as to the meaning and sought to avoid definitions upon which the PTO could not have relied when it issued the patent. We found through this method that the phrase "human tissue plaminogen activator" meant t-PA produced through recombinant DNA technology but having the same structure as natural t-PA. We found this definition "most consistent with the limited form in which the claims are drafted and the others were hopelessly overbroad." 29 F.3d at 1564, 31 U.S.P.Q.2D (BNA) at 1168.

This definition is not inconsistent with our holding here. Genentech's DNA construct contains codons for all seventy amino acids of the mature human IGF-I protein. Therefore, Genentech's construct contains the structure of natural IGF-I. Again,

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we are examining a DNA construct and not a protein. Therefore, the addition of codons at the beginning of the DNA sequence for human IGF-I is irrelevant.
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1. "jojoba-derived material"

Plaintiff's proposed construction of "jojoba-derived material" is: "the combination of polar hydrophilic salts (i.e., alkali salts of jojoba) and relatively non-polar unsaponifiables (i.e., jojoba fatty alcohols) produced from the saponificationof jojoba oil starting material." Defendant's proposed construction is: "material derived from the jojoba plant or alternatively any material that is left following the application of the saponification process to jojoba oil."

Plaintiff's construction is not the ordinary meaning of "jojoba-derived material." Plaintiff essentially conceded this at the claim construction hearing:

If you're asking me if you walked up to a person on the street randomly and said, 'What do you think jojoba-derived material is?' They probably would give Desert Whale's definition, something that came from a jojoba plant.

(Doc. 62 at 16). Plaintiff argues the patentee provided a unique definition for "jojoba-derived material" in the claim itself, though Plaintiff concedes it could not find any case law showing a patentee can provide a unique definition different from the plain ordinary meaning for a claim term in the claim itself. (Doc. 62 art 16). In any case, there is no indication in the claims of the Patent that the patentee intended to provide a unique definition for the term "jojoba-derived material." See Markman, 52 F.3d at 979 ("[A]ny specialdefinition given to a word must be clearly defined in the specification."). The summary of the invention in the specification, moreover, clearly states:

Unless specifically noted, it is intended that the words and phrases in the specification and claims be given the ordinary and customary meaning to those of skill in the applicable art or arts. If any other meaning is intended, the specification will specifically state that a special meaning is being applied to a word or phrase.

(Doc. 32-1 at 20) (emphasis added). The specification nowhere expressly states that a special meaning is being applied to "jojoba-derived material." And there is a heavy presumption that claim terms mean what they say and have their ordinary meaning. Phillips, 415 F.3d at 1312-13. Defendant's plain language construction of the term will be adopted.
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2. "kinetic energy of ions"

Micromass posits that the "kinetic energy of ions" should be construed to mean "the energy associated with motion," as opposed to the ions' potential energy or internal energy.

AB/Sciex does not disagree, but argues that to the extent that Micromass attempts to add a further limitation to the claim language, it should be rejected. It does not explain, however, what further limitation might be added by Micromass's proposed construction.

"Kinetic" is defined as "of or relating to the motion of material bodies and the forces and energy associated therewith." Webster's Ninth New Collegiate Dictionary 662 (1991). This definition is consonant with that provided by Micromass and the court will therefore adopt Micromass's proposed construction of "kinetic energy of ions" as "energy associated with the motion of ions."
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"Known dose"

Nutrition 21 argues that "known dose," which appears in dependent Claim 13 of the '156 Patent, means "a predetermined quantity of chromic tripicolinate or chromium." In its brief, GNC argues that the term means "an effective amount," but provides no evidentiary support for its argument, intrinsic or otherwise. In the Joint Claim Construction Chart, GNC's proposed construction is "an amount of chromic tripicolinate determined to reduce the blood serum lipid content in the individual."

Claim 13 depends on Claim 3, which describes "[a] method for treating undesirable high levels of blood serum lipids" and includes administration of an "effective, blood serum lipid reducing dose of chromic tripicolinate." '156 Patent, col. 15:22-29. Claim 13 is directed to "[t]he method of [C]laim 3 wherein a known dose of chromic tripicolinate is administered on a plurality of days, the method additionally comprising reevaluating the level of blood serum lipids." Id. at col. 15:54-57. Skilled artisans would logically read the dose mentioned in Claim 13 to refer back to Claim 3's "effective, blood serum lipid reducing dose" of CP.

The Court has already construed the term "effective[,] blood serum lipid[-]reducing amount [dose]" to mean "an amount to reduce blood serum levels in the individual." Thus, GNC's chart proposal is correctly attuned to the specific function for which the doses are administered under Claim 3 and 13's methods: reduction of blood serum lipids in the individual. Moreover, GNC's chart proposal correctly acknowledges Claim 13's infusion of a knowledge element. Claim 13's use of the adjective "known" as opposed to, for example, the articles "said," "the," or "a"adds a limitation to the method of Claim 3. Unlike other terms in the '156 Patent for which GNC proposes a construction that employs the word "determined," here the adjective "known" provides intrinsic support for a predetermination of some kind.

However, GNC does not justify its implication that the patentees used "known" to mean that one must know the CP amount used will be effective. Based on the structure of the claim language, those skilled in the art would read the adjective "known" to modify the noun immediately following it: "dose." Thus, skilled artisans would read "known" to refer to quantity, not effect. Adopting GNC's chart proposal could result in a situation where an individual administers on a plurality of days an amount of CP, without ever knowing the actual dosage she administers. The CP could be effective in reducing the individual's blood serum lipids, thus fulfilling the practice of Claim 3. But, the individual's ignorance of the specific dose would defy the practice of Claim 13.

Nutrition 21's construction -- specifically its use of the words "predetermined quantity" -- correctly encapsulates the relationship between the term elements "known" and "dose." However, the construction does not place the term "known dose" in its proper context within dependent Claim 13. Nutrition 21 points to no support in the claims or specification for reading "known dose" to entail administration of pure chromium in the alternative to CP. Claim 13 is specifically directed only to a "known dose of chromic tripicolinate." Nutrition 21 seems to be advocating a general construction of "known dose." But as discussed, skilled artisans would construe the dose of Claim 13 to have a very specific meaning due to the relationship between Claims 3 and 13.

Accordingly, the Court construes the term "known dose" to mean an "a dose effective to reduce blood serum lipids and whose amount is known."

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i-STAT manufactures a portable, point-of-care analyzer used to measure the hematocrit level of blood. 1 Nova makes a similar nonportable device that is protected by U.S. Patent No. 4,686,479 (the '479 patent). The '479 patent teaches a method for analyzing hematocrit.

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1 Hematocrit is the percentage of the volume of a blood sample composed of cells of red blood.

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The i-STAT and Nova devices are based on a common principle. Red cells in the blood conduct electricity poorly while electrolytes in the blood (principally sodium and chloride) are highly efficient conductors. 2 The i-STAT and Nova devices measure the hematocrit value of a blood sample by comparing the conductivity of the sample to that of a known standardizing solution. The i-STAT and Nova devices also adjust the reading to account for differing concentrations of electrolytes in the two exemplars. Finally, both devices use an aqueous calibrating solution to overcome the physical limitations involved in using real blood as a reference.

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2 The conductivity of blood, in other words, is inversely influenced by the concentration of red blood cells. '479 patent, col. 1, lines 10-23.

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The dispute in this case centers on the meaning of the '479 patent term equating the conductivity of the '479 standardizing solution to a "known equivalent hematocrit value." See November 14, 1996 Hearing Tr., at 7. The '479 patent, at col. 1, lines 56-60, defines "known equivalent hematocrit value" to mean "the hematocrit level of a blood sample having a conductivity corresponding to that of the standardizing solution." i-STAT asks for the court's construction of this specific language.

On March 7, 1997, the court issued a tentative construction of the disputed patent language and invited the parties' comments on its understanding of the underlying scientific and technical issues, and on the relevance, if any of the Supreme Court's post-briefing decision in Warner Jenkinson Co. v. Hilton Davis Chemical Co., U.S. , 137 L. Ed. 2d 146, 117 S. Ct. 1040 (1997).
DISCUSSION

"A literal patent infringement analysis involves two steps: the proper construction of the asserted claim and a determination as to whether the accused method or product infringes the asserted claim as properly construed." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581-1582 (Fed. Cir. 1996), citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 1393, 134 L. Ed. 2d 577 (1996). "Construction of a patent claim is a matter of law exclusively for the court." 52 F.3d at 977 (citations omitted). In construing claims, a court should first "look to the words of the claims themselves, both asserted and non-asserted, to define the scope of the patented invention." Vitronics, 90 F.3d at 1582, citing Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). The court should also look to the patent specification. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make it and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582.

The claims, specifications and file history constitute the patent's "public record . . . on which the public is entitled to rely." Vitronics, 90 F.3d at 1583. Thus. it is inappropriate for a court to consider extrinsic evidence, such as expert testimony, unless the testimony is necessary to understand the meaning or scope of a technical term in the claims. Id., citing Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995); Markman, 52 F.3d at 980-981 (same). "Where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." Vitronics, 90 F.3d at 1583.

Interpretation of the Term "Known Equivalent Hematocrit Value"

The meaning of the term "known equivalent hematocrit value" is, as previously noted, at the heart of the dispute over the construction of the claims of the '479 patent. The court held a Markman hearing focused largely on this issue on November 14, 1996, and entertained a number of post-hearing submissions. Nova's argument, as it has been refined over the course of the litigation, seeks to delink the patent term "equivalent hematocrit value" from the hematocrit value of an actual blood sample.

The actual hematocrit of a standardizing solution is never negative or positive; because the standardizing solution contains no red blood cells, its actual hematocrit is, by definition zero . . . The conductivity of the standardizing solution is, as stated in the claims 'indicative' or 'representative' of an 'equivalent hematocrit value,' whether positive or negative. [Thus]

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conductivity and 'equivalent hematocrit value' simply are the starting points from which one can measure an actual hematocrit of real blood by performing a mathematical calculation using the relative conductivities of the blood and the standardizing solution. One of ordinary skill in the art, after reading the equations in the patent (Col. 10, lines 47-68), would immediately recognize this mathematical fact.

Nova Memorandum of April 14, 1994, at 5.

i-STAT argues that this is the way Nova now wishes the patent had been written, for had it been, it would clearly encompass i-STAT's calibrating solution. i-STAT, however, points to the following limiting definition in the '479 patent.

The standardizing solution has a known ion species concentration and a conductivity indicative of a known equivalent hematocrit value; 'equivalent' hematocrit value is used in this application to mean the hematocrit level of a blood sample having a conductivity corresponding to that of the standardizing solution, even though the standardizing solution contains no whole blood cells and has an actual hematocrit value of 0.

'479 patent, col. 1, lines 54-62.

The crux of contention, as both parties acknowledge, are the four words "of a blood sample." In the physical world, the hematocrit value of real blood is measured on a closed percentage scale of zero to 100. Zero represents pure blood plasma 3 containing no red blood cells; 100 represents a (probably theoretical) sample consisting entirely of red blood cells. 4 The scale of resistance values, while it can be plotted against the hematocrit scale, is not bounded by its minimum and maximum values. This means that it is possible to construct a standardizing solution with a negative hematocrit value, that is, a solution with a resistance lower (and a conductivity higher) than any value encountered in real blood. 5 i-STAT argues that, by definition, the hematocrit value of the '479 standardizing solution must be expressed as a positive number, because no other result is possible with a real blood reference, 6 that is, no hematocrit value found in an actual blood sample can be less than zero. 7 This reading of the patent is. I believe, correct.

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3 Plasma is the liquid component of blood.

4 In living patients actual hematocrit ranges from 10 to approximately 75. i-STAT claims that it is possible to construct a sample of physical blood with an hematocrit of 100. Whether this is true or not is not material to the construction of the '479 patent's claims.

5 Pure plasma with a hematocrit level of zero has a resistance value of 1.8k ohms. Real blood within the range of normal hematocrit levels (35-50) has an approximate resistance value of 4.1k ohms. i-STAT assets that its standardizing solution has a resistance value of 1.6k ohms, a value below that of plasma. As i-STAT views the method of the '479 patent, it teaches the substitution of a standardizing solution correlated to a hematocrit value derived from real blood, thus avoiding the "clotting, cleaning and resultant down time that the repeated use of reference blood would produce in the apparatus." Zelin Aff. P 15. If the i-STAT calibrant could be assigned an "equivalent hematocrit value," the number would necessarily be negative, that is. indicating a conductivity greater than pure plasma. Id., at P 18. A negative hematocrit value, i-STAT argues, is a wholly artificial construct, not unlike assigning a negative value to a scale measuring velocity. The negative number that can be assigned to the i-STAT calibrant is thus merely "the result of the equation that the [i-STAT] device uses which relates the hematocrit levels of real blood samples to their resistivities." Id., at P 19. In sum, "the i-STAT system's calibrant solution cannot correspond to a blood sample as required by the asserted claims [of the '479 patent]." Id., at P 20.

6 Michael Zelin, a vice-president of i-STAT, attests that the conductivity of i-STAT's calibrant solution corresponds to no blood or plasma sample which exists either physiologically or that can be construed by manipulation. "As such, i-STAT's calibrant solution has no 'equivalent hematocrit value' as per the explicit definition in the '479 patent." Zelin Reply Aff. P 6. "The 'equivalent hematocrit value' of i-STAT's calibrant solution is unknowable." Id., at P19. Zelin contends that the '479 device does not work with a standardizing solution like i-STAT's which has a conductivity greater than that corresponding to an "equivalent hematocrit value" of zero. Id., at PP 51-67.

7 While it is true that the preferred embodiment of Nova's invention utilizes a standardizing solution that provides an

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equivalent hematocrit value of less than 5%, that value is clearly keyed to a real blood reference, even if not to an actual sample that could be drawn from a living human being.

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Nova argues that the '479 patent, read holistically, with its various graphs and equations, defines "equivalent hematocrit values" to encompass conductivities not only below the range of the actual hematocrit values found in real blood, but negative hematocrit values as well. This argument effectively reads out of the '479 patent the express limitation equating "known equivalent hematocrit value" with the hematocrit level of "a blood sample." 8 Expanding on the claims of a patent by collapsing its limitations is something that patent law does not permit. See Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1105 (Fed. Cir. 1996) (a court cannot construe claims to read out an express limitation), citing Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed. Cir. 1993); Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1563 (Fed. Cir. 1991) (same). 9

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8 I am somewhat puzzled by Nova's insistence that the court confuses equivalent and actual hematocrit values. The issue is not whether the standardizing solution described in the '479 patent has an actual hematocrit value; no one is under the illusion that it does (or could have). A thermometer measures temperatures against a physical scale of relative degrees of hot and cold without necessarily reaching or exceeding the theoretical extremes of that scale (for example, absolute zero) or actually radiating the temperature it records. The issue rather is whether the '479 patent describes equivalent hematocrit value in such a fashion as to limit its claims to solutions calibrated against a real blood reference.

9 I simply cannot accept Nova's argument that Figure 12A in the '479 patent expands the express definition of equivalent hematocrit value to include negative values for two reasons. First, the patent itself describes Figure 12A as illustrating the relationship of resistance to actual hematocrit values. See col. 10, lines 48-54. Second, the figure as presented was mistakenly drawn, as Nova itself admitted in proceedings before the European Patent Office. I agree with i-STAT that Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc., 21 F.3d 1068 (Fed. Cir. 1994), is of no particular relevance as i-STAT is not seeking to rely on a decision of a foreign patent examiner, but only upon Nova's admissions in the foreign proceeding. See Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1116 (Fed. Cir. 1983).

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At issue is the proper construction of the following limitation: "standardizing solution . . . having a known concentration of [a particular] ion species and having a conductivity indicative of a known equivalent hematocrit value." Col. 14, ll. 58-61. "Claims must be construed in light of the specification and the prosecution history." Grain Processing, 840 F.2d at 908, 5 U.S.P.Q.2D (BNA) at 1793. "Claim terms are given their ordinary and customary meaning in the field of the invention, unless a special definition is clearly stated in the specification." Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1443, 43 U.S.P.Q.2D (BNA) 1837, 1840 (Fed. Cir. 1997); see also York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572, 40 U.S.P.Q.2D (BNA) 1619, 1622 (Fed. Cir. 1996) ("Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning."). Nevertheless, an inventor may "be his own lexicographer and . . . give terms uncommon meanings . . . [by] setting out his uncommon definition in some manner within the patent disclosure." Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388, 21 U.S.P.Q.2D (BNA) 1383, 1386 (Fed. Cir. 1992).

The court construed the "standardizing solution" limitation as a solution whose known equivalent hematocrit value is between zero and 100. The court reached this conclusion because the written description expressly defines "equivalent hematocrit value":

The standardizing solution has a known ion species concentration and a conductivity indicative of a known equivalent hematocrit value; "equivalent" hematocrit value is used in this application to mean the hematocrit level of a blood sample having a conductivity corresponding to that of the standardizing solution, even though the standardizing solution contains

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no whole blood cells and has an actual hematocrit value of 0.

Col. 1, ll. 54-62. The court reasoned that the inclusion of the phrase "of a blood sample" requires that "equivalent hematocrit values" correspond to values that a blood sample theoretically could have. "In the physical world, the hematocrit value of real blood is measured on a closed percentage scale of zero to 100," with zero representing pure blood plasma, which contains no red blood cells, and 100 representing a hypothetical sample composed of only red blood cells. Although actual blood drawn from a patient never has a hematocrit value of zero or 100, the court construed "blood sample" to include any sample whose hematocrit level is within the entire range of possible percentages.

Nova Biomedical argues that this interpretation is too narrow. According to Nova Biomedical, "equivalent hematocrit value" should be construed to include negative values, even though an actual blood sample could not have a negative value. It argues that construing "blood sample" to mean an actual blood sample conflicts with the written description. First, Nova Biomedical maintains that an actual blood sample cannot have a hematocrit level of five, but the written description discloses using a standardizing solution whose equivalent hematocrit value is five. Its expert, Dr. Young, refutes the premise of this argument, however, because he testified that "we are seeing some people survive even at 5 hematocrit." Therefore, the use of a solution having an equivalent hematocrit value of five does not suggest that "blood sample" has an uncommon meaning.

Next, Nova Biomedical argues that the written description discloses using a standardizing solution whose equivalent hematocrit value is negative. According to Nova Biomedical, FIG. 12A shows that equivalent hematocrit values may be negative. The written description explains, however, that FIG 12A shows actual hematocrit values because it states that "resistance (Rx) is related to hematocrit value" (Hx) of a blood sample. Col. 10, ll. 48-50; see also col. 5, ll. 34-35. Moreover, based on Nova Biomedical's statements before the European Patent Office, the court properly found that FIG. 12A is not accurate--the line plotted should not extend into negative hematocrit values. Therefore, the written description does not expressly disclose the use of negative equivalent hematocrit values.

Nova Biomedical also argues that the standardizing solution of the preferred embodiment has a negative equivalent hematocrit value. The preferred embodiment uses "EA" as the standardizing solution. The written description does not expressly state that EA has a negative equivalent hematocrit value. Nova Biomedical maintains, however, that one of ordinary skill in the art would know that EA is more conductive than plasma--i.e., that it has a negative equivalent hematocrit value. Accordingly, it argues that the written description inherently discloses the use of negative equivalent hematocrit values. "In order for a disclosure to be inherent, . . . the missing descriptive matter must necessarily be present in the . . . application's specification such that one skilled in the art would recognize such a disclosure." Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159, 47 U.S.P.Q.2D (BNA) 1829, 1834 (Fed. Cir. 1998); see also In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (CCPA 1981) ("Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (quoting Hansgirg v. Kemmer, 26 C.C.P.A. 937, 102 F.2d 212, 214, 40 U.S.P.Q. (BNA) 665, 667 (CCPA 1939))). Nova Biomedical admits that EA may be less conductive than plasma--and thus have a positive equivalent hematocrit value--if phosphate or bicarbonate ions are used instead of chlorine ions. Therefore, the use of EA alone does not inherently disclose using a standardizing solution having a negative equivalent hematocrit value.

Thus, nothing in the written description suggests that the court erred in defining "blood sample" as any sample whose hematocrit level is between zero and 100. The court properly looked to the express definition of "equivalent hematocrit value" in the written description and concluded that "equivalent hematocrit values" are those between zero and 100. Applying this construction to the accused device, we agree with the district court that no reasonable jury could find literal infringement. The parties themselves agree that i-STAT's device uses a standardizing solution that is more conductive than plasma (i.e., it has a negative equivalent hematocrit value). Therefore, this solution does not literally meet the standardizing solution limitation of the claims.

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2. known sequences is construed to mean sequences of monomers identified prior to attachment to the surface.

Affymetrix contends that "known sequences" means sequences of identified or identifiable monomers.

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Incyte contends that "known sequences" means a polymer synthesized monomer by monomer, and whose sequence is determined by the monomer by monomer synthesis process used to generate it.

The Court adopts the plain and ordinary meaning of the words, "known sequences," as there are no statements in the specification or prosecution history which indicate that the inventors intended the words to have a meaning inconsistent with the ordinary meaning. Accordingly, the Court finds that Affymetrix's assertion that unknown but identifiable sequences are encompassed by the ordinary meaning of "known sequences" is untenable, as this definition contradicts the ordinary meaning of "known."

Furthermore, for the reasons previously discussed, the Court finds that "known sequences" cannot be restricted only to those sequences which Incyte asserts are enabled by the specifications. "Known sequences" is not reasonably amenable to a definition restricting it to polymers synthesized monomer by monomer, whose sequence is determined by a monomer by monomer synthesis process, and the Court will not import this extraneous limitation into the claim.
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2. "[H]aving a peptide sequence of human factor VIII:C but lacking a peptide region selected from the group consisting of:" 3 Having the amino acid sequence of the human Factor VIII protein lackingonly the particular segment of the human Factor VIII protein in one of the specified alternatives (a), (b) or (c).

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3 '112 patent, claim 10.

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Plaintiff makes three arguments in support of its broad interpretation of the above (that is, "lacking a peptide region of at least the regions identified in (a), (b) or (c)"). First, in an interference, the PTO gives the claims their "broadest reasonable interpretation." When reviewing the case law cited by plaintiff, however, the above principle characterizes a proceeding under § 135(a) (an interference may be declared whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application), not in a § 291 proceeding. Aside from the different fora, the two proceedings "raise different issues," to wit, "[p]atent application claims are given their broadest reasonable interpretation during examination proceedings, for the simple reason that before a patent is granted the claims are readily amended as part of the examination process." Stampa v. Jackson, 65 U.S.P.Q.2d 1942, 1945-46 (B.P.A.I. 2002). Therefore, the ordinary rules governing claim construction should apply in this § 291 proceeding.

Second,plaintiff argues that the PTO necessarily followed plaintiff's proposed construction in granting a patent term extension for the '112 patent and, consistent with the above, the PTO's "determination [i.e., granting the extension], based on its construction of claim 10 of the '112 patent, is given great deference that can only be overcome by clear and convincing evidence that the term extension was invalid." Again, the case law cited by plaintiff does not support their argument. In Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290-91 (Fed. Cir. 2006), Ranbaxy argued that, when correctly construed, the patent did not cover Pfizer's commercial product. The Federal Circuit noted that Ranbaxy's argument depended on its proffered claim construction, which the Court had already rejected (in favor of and having accepted the district court's proffered claim construction). In Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990), the Court acknowledged that the Commissioner should be accorded significant deference, but only to the limited extent of his agency's technical expertise, to wit, "whether any patented chemical compound named in a patent term extension applicationfell within the statutory definition of 'product,' but not what 'product' was to mean." Claim construction is a matter of law and, therefore, does not fall within the PTO's technical expertise (assuming that the PTO went through the claim construction exercise in the first instance).

Finally, according to plaintiff, the use of the Markush claim language in claim 10 does not prevent the claim from reading on larger deletions, so long as one of the specifically stated regions is missing. Aside from broad language in the specification, 4 plaintiff relies on the prosecution history to support its construction. More specifically, new claim 29 was

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added disclosing "[a] procoagulant protein having a peptide sequence substantially the same as that of human Factor VIII:C but lacking a peptide region within the region selected from the group consisting of: . . ." (D.I. 84 at JA000212) In distinguishing his invention from the prior art, the applicant argued that the "FVIII deletion variants" identified in the specification not only were active but were expressed at surprisingly substantial levels (albeit for unknown reasons). (Id. at JA000218) The claims were again rejected, the examiner explainingthat, "[w]ith respect to applicant's arguments concerning the 'unexpected' level of expression . . ., it is reiterated that the claims are not limited to the DNA constructs which are expressed at the argued unexpected levels. Accordingly, the unexpected results are not relevant as the claims are not limited to the factors which result in the enhanced levels of expression." (Id. at JA000226) In response, the applicant further amended claim 29 by deleting the phrases "within a region" and "substantially the same as that" and adding the phrase "truncated human Factor VIII:C protein which is an" active procoagulant protein. 5 (Id. at JA000227 and JA000231) In his accompanying remarks, the applicant noted that "[t]he Examiner agreed in the interview that applicant was first in the art to make such deletions, and that the invention encompasses patentable subject matter, although the precise scope of the patentable subject matter was not agreed upon. The Examiner did agree that the claims would be allowable if limited to deletions of at least the size shown to yield the reported results. In order to expedite prosecution, applicant's attorney agreed to so limit the claims with the understandingthat applicant may pursue claims of broader scope in a continuing application." (D.I. 84 at JA000232)(emphasis added) Given the well known purpose of Markush groups, I interpret this analysis as one limiting, not expanding, the scope of the claim to more specifically define the operative regions of the Factor VIII protein known to the applicant at the time.

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4 "X represents a polypeptide sequence of up to 949 amino acids substantially duplicative of sequences of amino acids within the sequence Ser-760 through Arg-1708 . . . Protein domain X may comprise a continuous but shorter sequence selected from the region Ser-760 through Arg-1708." ('112 patent, col. 2:12-35)

5 "10 (29) (amended). A truncated human Factor VIII:C protein which is an active procoagulant protein having a peptide sequence [substantially the same as that] of human Factor VIII:C but lacking a peptide region [within a region] selected from the group consisting of:

(a) the region between Pro-1000 and Asp-1582;

(b) the region between Thr-778 and Pro-1659; and

(c) the region between Thr 778 and Glu-1694."

(D.I. 84 at JA000231)

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In sum, I decline to accept plaintiff's claim construction in this regard, as it is supported by neitherthe case law nor the intrinsic record.
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C. "laminated" and "laminate"

Sud-Chemie contends that the terms "laminated" and "laminate" must be given their ordinary meaning in the context of the '942 patent. Mulitsorb urges that these terms should be construed to mean formed from two or more layers attached by an adhesive.

The court must again start with the claim in which the term appears. Claim 1 recites a desiccant container comprising a dessicant material "surrounded by a laminated, water vapor permeable desiccant packaging material." This packaging material comprises "an uncoated microporous film having an inner and outer surface heat sealed to an uncoated laminate film..." The term "laminated" describes the "water vapor permeable packaging material" which is comprised of the laminate

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film heat sealed on its inner uncoated surface to the uncoated microporous film of Claim 1. The term "laminated" is not defined in Claim 1. The term "laminate" also lacks a particular definition in Claim 1. It merely modifies one "film" of the invention.

The parties agree that "laminated" and "laminate" mean "two or more bonded layers" when that term is applied to films. They diverge on the question of whether the patent defines the terms to more particularly require adhesive lamination of the films comprising this invention.

The inventors described adhesive lamination in the prior art in the Background of the Invention. In describing the prior art patent to Nawata, they stated that "[t]he lamination process utilizes a low melting temperature adhesive secured to the inside surface of a microporous material to laminate the microporous film to the gas permeable layer. Alternatively, a portion of the gas permeable sheet can be melted to secure it to the microporous layer." [emphasis added]. The inventors thus noted that lamination was the securing together of layers via various methods. Similarly, in referencing the prior art patent to Inoue, they described "[t]he plastic films that are laminated to the paper may comprise a laminate themselves comprised of a plastic film with a high softening point secured to a plastic film with a low softening point." [emphasis added]. This description noted that one plastic film was "secured to" another plastic film through a softening process. The inventors also stated that films laminated with adhesives do not form a strong bond between the layers, a problem that their invention addressed. In the Preferred Embodiment, they stated that the uncoated laminate film of the invention "can be comprised of different layers of the same or different materials laminated together." [emphasis added]. The patent specification does not contain a specialized definition of "laminated" or "laminate." Therefore, the ordinary meaning controls. As utilized in the '942 patent, "laminated" or "laminate" means "two or more bonded layers."
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2. What is the Proper Construction of the Term "Layer"?

A key issue in this case is how to distinguish between "layers" and "interlayers." It is undisputed that Cardinal's accused products contain deposits of titanium in addition to layers of silver and zinc oxide. Determining whether Cardinal's products infringe the patent requires ascertaining whether these titanium deposits constitute "interlayers," as would be covered by the patent claim, or additional "layers," which would not. Accordingly, it is necessary to define both "layer" and "interlayer" to determine how to categorize the titanium deposits.

a. the trial court's interpretation of "layer" and "interlayer"

The trial court noted that the patentee did not set forth an explicit definition of "layer" in the patent, and thus the court sought to construe "layer" according to its ordinary meaning. To do so, the court selected the definition of the term "layer" appearing in Webster's Third New International Dictionary: "one thickness, course, or fold laid or lying over another…." From the same dictionary, the trial court adopted the following definition of "interlayer": "a layer placed between other layers." The trial court appears to have retreated from adopting these definitions as a final claim construction, for it stated that these definitions were merely a "starting point." The court went on to quote our statement that "indiscriminate reliance on definitions found in dictionaries can often produce absurd results . . . . One need not arbitrarily pick and choose from the various accepted definitions of a word to decide which meaning was intended as the word is used in a given claim." Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1250, 48 U.S.P.Q.2D (BNA) 1117, 1122 (Fed. Cir. 1998). Nonetheless, the trial court offered no other construction for these disputed claim terms. It appears from the remainder of the court's order that it departed from the definitions set forth in the dictionary it quoted, but we cannot discern exactly what interpretation of "layer" and "interlayer" the court settled upon. It is critical for trial courts to set forth an express construction of the material claim terms in dispute, in part because the claim construction becomes the basis of the jury instructions, should the case go to trial. See IPPV Enters., LLC v. Echostar Communications Corp., 106 F. Supp. 2d 595, 601 (D. Del. 2000). It is also the necessary foundation of meaningful appellate review.

This court has repeatedly cautioned against using non-scientific dictionaries for defining technical words. See Anderson v. Int'l Eng'g & Mfg., Inc., 160 F.3d 1345, 1348-49, 48 U.S.P.Q.2D (BNA) 1631, 1634 (Fed. Cir. 1998) ("Dictionary definitions of ordinary words are rarely dispositive of their meanings in a technological context. A word describing patented technology takes its definition from the context in which it was used by the inventor."); Hoechst Celanese Corp. v. BP

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Chems., Ltd., 78 F.3d 1575, 1580, 38 U.S.P.Q.2D (BNA) 1126, 1130 (Fed. Cir. 1996) ("[A] general definition is secondary to the specific meaning of a technical term as it is used and understood in a particular technical field."). This case provides a good example of why definitions from general usage dictionaries may fail to provide satisfactory constructions of technical claim terms in dispute.

First, the dictionary definitions apparently adopted by the trial court erase the distinction set forth in the written description of the patent between "layer" and "interlayer." The written description clearly states that "interlayers" have different physical attributes than "layers," because, being relatively thin, they do not "substantially affect the optical properties" of the other layers. This statement in the written description, along with the remainder of the specification, provides the scientific and technical context for interpreting the meaning of the terms "layer" and "interlayer." A trial court, when construing a term of art, must define the term in a manner consistent with the scientific and technical context in which it is used in the patent. Only when the context is unclear, or it appears that the term is not being used in a technical manner, should the trial court rely upon a general purpose dictionary for construing the term. In the present case, the dictionary definition adopted for the term "interlayer" (i.e., a "layer placed between other layers") contradicts the meaning of the term "interlayer" as it is used in the technological context of the patent, as the dictionary definition does not account for the insignificant optical effect of the interlayers.

Second, the dictionary definitions adopted by the trial court are inconsistent with essentially undisputed testimony during the Markman hearing as to how persons of ordinary skill in the art would interpret the terms "layer" and "interlayer." As described above, AFG presented deposition testimony of Mr. O'Shaughnessy during the Markman hearing, who referred to a description of a Cardinal coating set forth in internal product literature. When asked whether the product also contained barrier layers in addition to the explicitly recited layers, O'Shaughnessy replied: "Absolutely. We can't run this product without barrier layers. I mean, it just goes whacko." He continued, stating that "because we can't run without [the barrier layer], we just always know it's there, so internally everybody just assumes the barrier is there." This testimony shows that a person of ordinary skill would understand that there is a substantive difference between "layers" and "interlayers" or "barrier layers," and that the claim construction in this case should reflect this distinction. This distinction is highlighted in other testimony elicited from O'Shaughnessy noted above.

Arguably, the brevity of the description of "interlayers" set forth in the patent may have created some ambiguity as to whether the construction of the term "layer" should reflect a distinction between "layers" and "interlayers." However, the testimony during the Markman hearing by persons of ordinary skill in the art, such as O'Shaughnessy, serves to clarify that this distinction is material, and that it should be reflected in the construction of the term "layer."

The facts of this case are essentially the inverse of those we discussed in Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 39 U.S.P.Q.2D (BNA) 1573 (Fed. Cir. 1996). In Vitronics, the district court construed the claim term "solder reflow temperature" to mean "liquidus temperature," based in part on testimony that persons of ordinary skill in the art would so define the claim term. On appeal, we determined that the patent specification established with reasonable clarity that the claim term "solder reflow temperature" should be defined to be the "peak reflow temperature" recited in the written description, rather than the "liquidus temperature." In light of our conclusion that the patent specification itself had sufficiently defined the term "solder reflow temperature," we ruled that the district court erred in relying upon expert testimony that contradicted the intrinsic evidence. Expert testimony, we stated, "may not be used to vary or contradict the claim language." Id. at 1584, 39 U.S.P.Q.2D (BNA) at 1577. Whereas in Vitronics, the expert testimony contradicted the meaning of "solder reflow temperature" set forth in the specification, in the present case, O'Shaughnessy's testimony explains, corroborates, and reinforces the distinction recited in the written description between "layer" and "interlayer."

As we explained in Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309, 51 U.S.P.Q.2D (BNA) 1161, 1168 (Fed. Cir. 1999), "it is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field." Moreover, we are reminded of the potential value of scientific testimony during claim construction hearings by the early statement of the Supreme Court that where the claims or specification "contain technical terms or terms of art the court may hear the testimony of scientific witnesses to aid the court in coming to a correct conclusion." Seymour v. Osborne, 78 U.S. 516, 546, 20 L. Ed. 33 (1870). The Court continued, stating that "the testimony of scientific witnesses is indispensable to a correct understanding" of the meaning of disputed claim terms, and that "it would undoubtedly be error in the court to reject the testimony." Id.

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This case presents a good example of how extrinsic evidence can and should be used to inform a court's claim construction, and how failure to take into account the testimony of persons of ordinary skill in the art may constitute reversible error. O'Shaughnessy's essentially undisputed testimony appears to represent "trustworthy" and "clearly expressed, plainly apposite" evidence that persons of ordinary skill in the art do distinguish between layers and interlayers. Pitney Bowes, 182 F.3d at 1309, 51 U.S.P.Q.2D (BNA) at 1168. This testimony reinforces the distinction drawn in the written description of the '532 patent between these two terms.

We conclude that the trial court erred by adopting a claim construction that does not distinguish between layers and interlayers. The primary error in the trial court's claim construction is that it eliminates the distinction between these terms that is set forth in the written description of the patent itself. It is also significant that the court's claim construction failed to take into account the testimony of O'Shaughnessy and other witnesses at the Markman hearing that further reinforced the distinction between "layers" and "interlayers." To the extent that the brief statement in the specification of the '532 patent may have been vague or ambiguous as to whether the claim term "layer" should be defined differently than "interlayers," the trial court should have considered the testimony presented in the Markman hearing and set forth a definition of "layer" that distinguishes between "layers" and "interlayers."

b. this court's construction of "layer" and "interlayer"

The parties' proposed definitions for the term "layer" are not much in disagreement. AFG asserts that a layer is "a thickness of a material of uniform chemical composition." Although Cardinal now seeks a simple affirmance of the trial court's construction, it originally proposed that a layer should be "a thickness of a material of uniform chemical composition bounded by a material of a different chemical composition." Under Cardinal's original approach, two adjacent deposits of the same material would consist of only one "layer."

Cardinal appears to have advocated applying this further limitation so that a prior art patent, U.S. Patent No. 4,943,484 to Goodman (that appears to disclose sequential deposits of zinc oxide/silver/zinc oxide/zinc oxide/silver/zinc oxide), would constitute a five layer coating and thus anticipate the asserted claim. However, the specification of the '532 patent nowhere limits the term "layer" to a deposit bounded by a material of a different chemical composition. We thus decline to include such a limitation in our construction of the term "layer."

The parties both suggest that to constitute a "layer," a deposit must have a "uniform" chemical composition. AFG suggests that because the titanium deposits in Cardinal's products appear to have incorporated silver and zinc oxide molecules from adjacent layers, that the titanium deposit cannot itself constitute a layer. However, focusing on the chemical uniformity of a deposit, rather than its optical properties, constitutes a departure from the disclosures and teachings of the patent. Nowhere does the patent refer to chemical "uniformity" as a characteristic of a layer or interlayer. While we do not doubt that a metallic deposit must be substantially uniform to constitute a "layer," we do not think that the incorporation of trace amounts of silver or zinc oxide into a titanium deposit would disqualify that deposit from constituting a layer. Accordingly, we hold that the chemical composition of a layer must only be "substantially uniform," rather than "uniform."

The definition of "layer," as discussed above, must also distinguish between "layers" and "interlayers." The written description of the '532 patent distinguishes between these two terms by stating that "interlayers" have "a thickness not to substantially affect the optical properties." Consistent with the specification, we conclude that "layer" should be interpreted as: "a thickness of material of substantially uniform chemical composition, but excluding interlayers having a thickness not to substantially affect the optical properties of the coating." When determining whether a deposit is optically significant, the focus should be on whether the thickness and composition of the material itself is optically significant, rather than whether the absence of that material would lead to oxidation and discoloration of adjacent layers. Moreover, we make no determination as to whether a chemical compound that has been deposited in multiple separate, sequential applications, without intervening layers or interlayers, constitutes a single "layer." This is a matter for the trial court to resolve in a manner consistent with our claim construction.

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"Lean body mass"

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The parties agree that the term "lean body mass," which appears in several claims from the '624 Patent, means "body mass excluding the mass of body fat." The Court agrees and construes the term accordingly.
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Linked	Physically and chemically joining DNA I and DNA II into the same piece of contiguous DNA prior to their insertion into the eucaryotic cell

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G. "Binding of Said Target Compound to … Capture Molecules Leads to a Catalytic Reduction of a Metal Present in Solution, and a Formation of a Metallic Precipitate"

* * *

Claim 16 of the '829 Patent explains that the diagnostic and/or quantification apparatus that the invention can be described as follows: "wherein bindingof said target compound to one or more of said multiple species of capture molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate in one or more of said discrete region(s)." '829 Patent, col. 12, II. 62-67. The parties offer similar proposed constructions, but dispute whether by stating that the binding of the target compound and capture molecules "leads to" a catalytic reduction of metal and formation of precipitate, the disputed claim term provides that the initial binding "is a necessary condition for" forming the precipitate, which is formed by the catalytic reduction, as Eppendorf asserts, or whether the initial binding "results in" the catalytic reduction and precipitate formation, as Nanosphere contends.

The "Summary of the Invention" section of the specification teaches that the initial binding of the target compound to the capture molecule(s) results in the formation of metallic precipitate:

> [t]he present invention is related to a method for identification and/or quantification of at least one target compound present in a biological sample by its binding upon a capture molecule fixed upon arrays of a solid support .. ., the binding of said target compound its corresponding capture molecule resulting in the formation of a metal precipitate at the location of said capture molecule.

Id. col. 2, II. 35 42 (emphasis added). This understanding is supported further by the common understanding of the verb "to lead" as "to tend toward or to have a result." Merriam- Webster Collegiate Dictionary 659 (10th ed. 1995). Accordingly, the Court has construed the disputed claim term to mean "binding of the target compound to one or more of the species of capture molecules results in a catalytic reduction of a metal present in solution and formation of a metallic precipitate in one or more of the discrete regions."
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B. The Meaning of "Lentiviral LTR-deleted (LLD) Vector"

The term "non-functional lentiviral 5' LTR promoter" appears only in the claims of the '123 patent. Sigma and Oxford contend that this term means "a lentiviral genetic sequence located at one end (called the 5' end) of the long terminal repeat that is not present or is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription)." Open contends that this term means "a lentiviral genetic sequence located at one end (called the 5' U3 region) of the long terminal repeat that is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription)."

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The parties disagree about two points. First, the parties disagree about whether this term is only limited generally to the "5' end" or specifically to the "5' U3 region." As discussed earlier, the "5' U3 region" is a more specific location within the 5' LTR. Claim 1 refers to the "5'" end and, by its own terms, is not limited to the "5' U3 region." The "U3 region" is an extraneous limitation that the Court will not read into the term.

The parties agree that the phrase "lentiviral LTR-deleted vector" (or "LLD vector") is a term coined by the inventors acting as their own lexicographers. The phrase did not have an ordinary meaning in the relevant art at the time the applications for the asserted patents were filed. The phrase appears in all claims of the '123 and '699 patents.

"LTR" is an abbreviation for "long terminal repeat," referring to the sections at either end of the viral genome. According to the specification, each LTR contains three distinct regions, known as the "U3," "R" and "U5" elements. See '123 patent, col. 6, ll. 41-46 ("The LTRs . . . are identical [nucleotide] sequences that can be divided into three elements, which are called U3, R and U5."). This is depicted in Figure 1 of the '123 patent. In lentiviruses such as HIV, the LTRs regulate the functions of reverse transcription, integration and transcription. See '123 patent, col. 6, ll. 31-37; Tr. at 67:12-19.

The parties agree generally that the term "lentiviral LTR-deleted vector" refers to a vector in which some portion of the LTRs has been deleted or modified, rather than one in which the LTRs have been deleted entirely. In other words, some nucleotide sequences found in the LTR of the original virus are no longer present in the claimed vector.

The parties dispute which portions of the LTR are deleted or modified. Open points to an embodiment that discloses substitution of the R region, and concludes that "lentiviral LTR-deleted vector" must be limited to a vector in which the entire R region has been substituted.

Sigma and Oxford contend that "lentiviral LTR-deleted vector" is not limited to this one embodiment, but instead to a vector in which "at least one such nucleotide sequence that is involved in transcription" is removed from or replaced in the LTR, while the other nucleotide sequences necessary for reverse transcription and integration are left intact. Sigma and Oxford contend that this definition encompasses all of the embodiments disclosed in the specification. The Court agrees with Sigma and Oxford.

The specification emphasizes that the vector must have three key characteristics to be safe and effective for gene therapy uses described throughout the specification:

1. The vector must have nucleotide sequences that make it capable of reverse transcription. This allows the RNA in the vector to be transcribed into beneficial DNA after it enters the host cell.

2. The vector must have nucleotide sequences that make it capable of integration. This allows the beneficial DNA to insert itself into the host cell's DNA after entering the nucleus. Once the beneficial DNA has been integrated, the cell can begin manufacturing proteins that serve a therapeutic purpose (such as by potentially making dopamine in brain cells for a patient who has Parkinson's disease).

3. The vector must not have at least one lentiviral LTR nucleotide sequence involved in transcription.

If a vector lacks either of the first two characteristics, it will be unable to deliver effective gene therapy. The third characteristic, deleting at least one lentiviral LTR nucleotide sequence involved in transcription, allows the vector to be safely used to deliver gene therapy. The specification teaches that these properties define a lentiviral vector that is "LTR-deleted" according to the invention.

The invention begins with the genome of a lentivirus, but creates a safer vector by either deleting or replacing various genetic sequences in the LTR. '123 patent, col. 9, ll. 4-8. This includes removing or replacing at least one original nucleotide sequence that is involved in transcription. See '123 patent, col. 7, ll 50-55, 63-65; col. 8, ll. 3-4; col. 9, ll. 45-53; col. 12, ll. 9-15; col. 14, ll. 15-31; Figs. 1-4 and 6. These deleted LTR sequences can be either "promoter" or "enhancer" sequences, both of which help to control transcription. '123 patent, col. 6, ll. 35-38, 48-49, 51-55.

At the same time, the specification teaches that the LTRs must not be modified to the extent that they are unable to engage

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in reverse transcription and integration. It teaches that these functions are necessary "in order to function as a vector":

As will be evident, in order to function as a vector, the lentiviral LTR-deleted vector according to the invention will need to have a reverse transcription system (compatible reverse transcriptase and primer binding sites) and an integration system (compatible integrase and integration sites) allowing conversion to the provirus and integration of the double-stranded DNA into the host cell genome.

'123 patent, col. 8, ll. 59-65 (emphasis added); see also id. at col. 8, ll. 6-8, 27-30, 37-39, 42-45, 47-51; col. 9, ll. 11-14; col. 13, l. 58-col. 14, l. 3; col. 14, ll. 11-12; Figs. 1-4 and 6. The specification defines a lentiviral LTR-deleted vector as a vector in which some nucleotide sequences from the LTRs have been substituted or removed while others have been retained. These changes must remove at least one lentiviral LTR nucleotide sequence involved in transcription, but still allow the vector to engage in reverse transcription and integration, which are essential "to function as a vector."

This interpretation is confirmed by the claims themselves and by the prosecution history. During prosecution, the inventors amended claim 1 of the '123 patent to clarify the role of the "lentiviral LTR deleted vector." The amended claim emphasizes the importance of allowing reverse transcription and integration while blocking replication. See Amendment and Response to Office Action dated Oct. 21, 2004 (Pls.' Ex. 13 7), at 4.

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7 Citations to "Pls.' Ex." are to the declaration and supplemental declaration of Paul M. Zagar, Docket Nos. 87 and 102. Citations to "Def.'s Ex." are to the declaration of Michael J. Hickey, Docket No. 96.

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The inventors further explained that this amendment was made to "correlate with the function of the LLD vector" as disclosed in the specification:

[T]he claims have been amended to recite language that correlates with the function of the LLD vector. For example, the vector sequences maintained in the LLD vector are only those sufficient for reverse transcription and integration of the virus. The claim amendments further clarify that the LLD vector is no longer capable of transcriptional control/virus replication because, upon transduction, the vector comprises a non-functional lentiviral 5' LTR promoter.

Amendment and Response to Office Action dated Oct. 21, 2004 (Pls.' Ex. 13) at 6 (emphasis added).

The inventors emphasized that the "lentiviral LTR-deleted vector" was not limited to any one embodiment depicted in the specification or figures, such as Figure 1. See id. Rather, this term should be construed broadly as including a vector with any modifications to the LTR, as long as "the sequences sufficient for the reverse transcription and integration of the lentivirus are maintained" and some other portions, i.e., those for transcription, "are not maintained." Id.

The specification discloses that HIV vectors in the prior art used HIV LTRs that were not active in the absence of a viral protein called Tat. See '123 patent, col. 2, ll. 10-12. HIV LTRs have a sequence in their R region called TAR. See id. at col. 2, ll. 19-22; col. 7, ll. 13-15; col. 7 l. 66-col. 8, l. 2. TAR by itself may weakly inhibit the HIV LTR promoter, but binding of the Tat protein to TAR causes transcription from the HIV LTR promoter to increase approximately one hundred-fold. Second Declaration of Dr. Bryan R. Cullen ("Second Cullen Decl.") [Doc. 101] at P 6; Tr. at 21:1-4, 68:19-21. Thus, efficient transcription from the HIV LTR promoter requires Tat. Second Cullen Decl. P 5. The problem with supplying Tat is that it complicates the system and may have cancer-causing properties. '123 patent, col. 2, ll. 39-43. The specification states that one aim of the invention is to modify the LTRs in such a way as to avoid the need for using Tat. '123 patent, col. 2, ll. 22-24.

The specification discloses at least three ways to make a lentiviral LTR-deleted vector. Each of these embodiments shows a modification to the LTRs that removes at least one lentiviral LTR nucleotide sequence involved in transcription and eliminates dependence on Tat, but still allows reverse transcription and integration:

1. Replace the R region. The specification discloses that the R regions of the LTRs can be replaced. See, e.g., '123 patent,

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col. 8, ll. 5-6. This embodiment overcomes the problems with supplying Tat by replacing the lentiviral R region where TAR is located. See, e.g., id., col. 7, l. 63-col. 8, l. 2. There is no need to supply Tat to the system because there is no TAR rendering the LTR promoter dependent on Tat.

2. Delete part of the U3 region. The specification also discloses that there are "alternative ways" of achieving the same result. It teaches that one way is to delete part of the U3 region from the 5' LTR to create a "self-inactivating" vector:

There are alternative ways of achieving a single transcription unit vector, however. The vector genome could be designed as a self-inactivating vector (Yu et al., 1986 PNAS 83, 3194) in which part of the 3' U3 sequences are deleted so that the transduced vector genome has a non-functional 5' LTR promoter.

'123 patent, col. 9, ll. 43-48 (emphasis added).

In this embodiment, the LTR promoter is removed and the vector instead relies on an internal promoter (located between the LTRs). See '123 patent, col. 9, ll. 49-54. There is no LTR promoter whose expression is dependent on the binding of Tat to TAR.

3. Replace the U3 region. The specification discloses a third embodiment that achieves the same results by replacing the U3 region (except for sequences necessary for integration) with a promoter from a cell or another virus. See, e.g., '123 patent, Figs. 1, 2, 6; col. 14, ll. 13-21; Tr. at 67:22-68:4. The non-lentiviral promoter is not dependent on Tat for efficient gene expression. See, e.g., '123 patent, col. 7, ll. 50-55. Thus, the need to provide Tat is removed.

These three disclosed embodiments for overcoming the Tat problem are not mutually exclusive. 8 Although any one embodiment by itself avoids Tat, embodiments can be combined for added safety. For example, the specification states that "a straightforward way to achieve the desired vector LTRs" includes both the R region replacement and U3 region replacement embodiments:

A straightforward way to achieve the desired vector LTRs is therefore to replace the lentiviral R regions and as far as possible the U3 region, but leaving essential lentiviral sequences present such as a short sequence of the U3 region necessary for integration.

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8 The specification also recognizes that these disclosures are merely "examples" that are "not intended to limit the invention to specific embodiments described." Id., col. 4, ll. 36-39. It further explains that the figures offer "generalized" illustrations that depict the "principle" of the invention. Id., col. 4, ll. 42-52; col. 5, ll. 12-14.

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Id., col. 8, ll. 4-8. Using this embodiment, both TAR (in the R region) and the lentiviral LTR promoter (in the U3 region) have been replaced. Open argues that this statement limits the invention to the R region replacement embodiment. It does not. Two other embodiments, i.e., "way[s] to achieve the desired vector LTRs," are disclosed. The R region replacement embodiment and the U3 region deletion embodiments can also be combined, as acknowledged by Open. Tr. at 103:16-19. Each one of these embodiments alone is an example of a way to make a vector "LTR deleted." Tr. at 20, 22, 27, 67-69.

Dr. Cullen testified that the 123 and 699 patents teach three separate ways to make an "LTR deleted" vector. See Tr. at 20-22, 27, 67-69. His testimony is consistent with the specification, and is contrary to Opens contention that the specification limits the claims to a single embodiment--even though three possible embodiments are disclosed. Open did not cross examine Dr. Cullen or offer contrary testimony, even though its own expert, Dr. Tal Kafri, was present at the hearing.

The specification teaches that "lentiviral LTR-deleted vector" is a lentiviral vector in which the LTRs have been modified from those of the original wild-type lentivirus. The modified LTRs must still function to allow reverse transcription and integration, which are essential for gene therapy, while simultaneously lacking at least one lentiviral LTR nucleotide sequence involved in transcription. This interpretation is supported by the prosecution history, the claims language and Dr. Cullens testimony. Sigma and Oxfords construction is therefore correct.

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Open contends that "lentiviral LTR-deleted vector" is limited to only the one embodiment above in which the R region is replaced. This would exclude the two other preferred embodiments disclosed in the specification (the "replace the U3 region" and the "delete the U3 region" embodiments), as well as any other alternatives for creating a lentiviral LTR-deleted vector. The Federal Circuit has emphasized that "[a] claim construction that excludes a preferred embodiment is rarely, if ever, correct." Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1374 (Fed. Cir. 2005) (quoting SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1285 (Fed. Cir. 2005)) (internal alterations omitted). Moreover, Opens definition contains no requirement that the lentiviral LTR-deleted vector be capable of reverse transcription or integration, which are essential "in order to function as a vector". 123 patent, col. 8, ll. 59-65.

Open offers three arguments in support of its proposed interpretation. First, Open argues that the specification contains "magic words" (i.e., "manifest words of exclusion") that limit the claim term to the single embodiment with a replaced R region. Tr. at 75:1-4, 84:10-14. Open contends that this language identifies the "replace the R region" embodiment as "the invention," to the exclusion of any other embodiments. Open argued at the claims construction hearing:

Lets look at Column 8, lines 9 through 10 . . . . "The invention is outlined in Fig. 1. The vector system is designated Lentiviral LTR-Deleted (LLD) vector." The magic words. "The invention is outlined in Fig. 1."

Tr. at 84:7-11.

The Court disagrees with Opens argument. Figure 1 discloses two embodiments: (1) R region replacement, and (2) U3 region replacement. Open also argued that Figures 2-4 and 6 limited the invention to the R region replacement embodiment. Tr. 87:20-90:8. This cannot be the case because these figures also show two embodiments.

The specification explains that there are "alternative ways" of creating a lentiviral LTR-deleted vector that do not involve changing the R region. Id., col. 9, ll. 43-45. The specification points to the "delete the U3" embodiment as one such "alternative way." Id., col. 9, ll. 45-48. The specification also discloses a third embodiment of replacing the U3 region. Each of these three embodiments meets the definition of a "lentiviral LTR-deleted vector" as it modifies the LTR in a way that allows reverse transcription and integration, but removes at least one lentiviral LTR nucleotide sequence involved with transcription. Id., col. 8, ll. 59-65.

Open also argues that the discussion concerning the "replace the R region" embodiment is found in a section entitled "detailed description of the invention," and contends that as a result this embodiment must represent the entire "invention." Opens argument is contradicted by language expressly stating that this section only provides "examples" that are "not intended to limit the invention," as well as by the disclosure of other embodiments in the same section, including the "delete the U3" and "replace the U3" embodiments. 123 patent, col. 4, ll. 36-40; see also id., col. 18, ll. 29-34 (reiterating that the specification only discloses "preferred embodiments," and noting that "many other variations thereof are possible" by a person of ordinary skill in the art). 9

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9 Open also relies on discussions of particular embodiments in other sections, such as one section entitled "examples." The specification likewise clarifies that this section only discloses "specific embodiments" that are "not intended to limit the invention." Id., col. 13, ll. 38-40.

Open further argues that the claims must be limited to embodiments that have particular "advantages" disclosed in the specification. See, e.g., 123 patent, col. 12, ll. 6-14 (discussing the "advantage of removing the HIV expression signals"). This is without merit. Just as claims are not limited to specific preferred embodiments, they are not limited to embodiments that feature particular "advantages." Such advantages may explain why some embodiments are preferred, but do not define the invention or the scope of the claims. See Phillips, 415 F.3d at 1327 ("Although deflecting projectiles is one of the advantages of the baffles of the [asserted] patent, the patent does not require that [the baffles] always be capable of performing that function." (emphasis added)); see also Ventana Med. Sys., Inc. v. Biogenex Labs., Inc., 473 F.3d 1173, 1181 (Fed. Cir. 2006) ("each claim does not necessarily cover every feature disclosed in the specification"); E-Pass Techs., Inc. v. 3COM Corp., 343 F.3d 1364, 1370 (Fed. Cir. 2003) ("An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them.").

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Opens argument is also refuted by the prosecution history, in which the inventors explained that there were many ways of creating a lentiviral LTR-deleted vector. See Amendment and Response to Office Action dated Oct. 21, 2004 (Pls. Ex. 13), at 6. The inventors specifically noted that "Figure 1 is exemplary, and in no way limits the scope of the claims." Id. In other words, the inventors anticipated and cautioned against Opens interpretation that "the invention" is confined to what is shown in Figure 1. In context, both the specification and file history make clear that the discussion of the "replace the R" embodiment is merely one preferred embodiment, rather than a limitation on the breadth of the claims.

There is no language that can be construed as "manifest words of exclusion or restriction" reflecting "a clear disavowal of claim scope" to restrict the meaning of lentiviral LTR-deleted vector. See Teleflex, 299 F.3d at 1327. Unlike the language of manifest exclusion that explains the claimed vectors must be replication defective, there is no suggestion here that "in any case" the claimed lentiviral LTR-deleted vector "will have" a replaced R region. Instead, the specification discloses the substitution of the R region as part of one "straightforward" way to create a lentiviral LTR-deleted vector, discloses "alternative ways" of creating a lentiviral LTR-deleted vector, and cautions that all of these are only "examples" that are "not intended to limit the invention."

Although the specification expressly discloses at least three different embodiments of the lentiviral LTR-deleted vector, Open proposes a construction that would exclude two of the embodiments. Even if the specification disclosed only a single embodiment, it would not be appropriate to confine the claims to that embodiment:

We do not import limitations into claims from examples or embodiments appearing only in a patents written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that "the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive."

JVW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005) (quoting Phillips, 415 F.3d at 1323); see also Ventana Med. Sys. v. Biogenex Labs., Inc., 473 F.3d 1173, 1181-82 (Fed. Cir. 2006) (rejecting argument that inventor had "implicitly defined" a claim term as being limited to a particular feature disclosed in each of the embodiments); Phillips, 415 F.3d at 1323 ("In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." (citations omitted)); Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1117 (Fed. Cir. 2004) ("even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction" (internal quotations omitted)).

Open relies on cases in which a broad term was interpreted narrowly because the specification disclosed only one embodiment, criticized prior art based on other embodiments, and unambiguously stated that the one embodiment defined the invention claimed in the patent. See, e.g., C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 860-61 (Fed. Cir. 2004) (interpreting the term "plug" narrowly where the specification "unequivocally" defined this term as meaning a "pleated plug" in the Summary of the Invention section, the specification did not disclose any other embodiments, and the inventors emphasized to the Patent Office that the claims were limited to a pleated plug to overcome prior art); 10 see also Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318-19 (Fed. Cir. 2006) (interpreting "fuel injection system component" narrowly where the specification repeatedly emphasized that the invention was limited to a "fuel filter," and the specification did not disclose any other types of fuel injection system components or suggest that the fuel filter was only a preferred embodiment); Astrazeneca, 384 F.3d at 1338-40 (interpreting term "solubilizer" narrowly where specification expressly states that the solubilizer must be a particular type of solubilizer and "clearly disavows" other types of solubilizers as unsuitable for the invention); Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1097-1102 (Fed. Cir. 2003) (interpreting term "chromosomally integrated" narrowly where the specification disclosed only one embodiment, and referred to that embodiment expressly as the invention in the Summary of the Invention); SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1342-44 (Fed. Cir. 2001) (interpreting term as limited to a particular configuration where the specification defined the term as such in the Abstract, criticized prior art that had different configurations, described this configuration in the Summary of the Invention as being the invention, and stated unequivocally that "all embodiments of the present invention contemplated and disclosed herein" are limited to this configuration).

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10 The court emphasized that disclaimers in sections such as the "Summary of the Invention" or the "Abstract" carry particular weight because they preface the entire specification. C.R. Bard, 388 F.3d at 864 ("Statements that describe the invention as a whole are more likely to be found in certain sections of the specification, such as the Summary of the Invention."). This rule does not apply to statements, like those relied on by Open here, found in the "Detailed Descriptions" of the invention or of the preferred embodiment.

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The type of limiting language described in the foregoing cases is not present in the patents here. As the Federal Circuit stated in Liebel-Flarsheim Co. v. Medrad, Inc., a narrow claim construction is appropriate in cases where "there were specific reasons dictating a narrow claim construction beyond the mere fact that the specification disclosed only a single embodiment or a particular structure." 358 F.3d 898, 907 (Fed. Cir. 2004). The Federal Circuit ruled that disputed claims should not be limited to particular embodiments absent a "clear disavowal of claim scope in either the written description or the prosecution history." Id. at 912; see also Phillips, 415 F.3d at 1323 (citing Liebel-Flarsheim with approval).

Unlike the cases cited by Open, the inventors here did not demonstrate any intent for the claims and embodiments "to be strictly coextensive," Phillips, 415 F.3d at 1323, or provide a "clear disavowal of claim scope." Liebel-Flarsheim, 358 F.3d at 912. The Court therefore declines to limit the claims to only one embodiment. See Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1332 (Fed. Cir. 2007) (refusing to limit claims to one embodiment absent "a clear intention to limit the claim scope"); Intamin, Ltd. v. Magnetar Techs., Corp., 483 F.3d 1328, 1335 (Fed. Cir. 2007) (refusing to limit terms to one embodiment where "the overall context of the patent . . . does not specifically disavow" alternative ways of practicing the invention); Phillips, 415 F.3d at 1324-28 (refusing to limit term "baffles" to a specific embodiment disclosed in the specification).

Second, Open argues that plaintiffs proposed construction of "lentiviral LTR-deleted vector" would render other language in the claims superfluous, because claim 1 of the 123 patent already states that the vector "comprises sequences sufficient for reverse transcription and integration." The Court disagrees.

One rule of claim construction provides that "a claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005). This is a useful rule of construction but "is not inflexible." Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1410 (Fed. Cir. 2004). "[W]here neither the plain meaning nor the patent itself commands a difference in scope between two terms, they may be construed identically." Id. (citing Pickholtz v. Rainbow Techs., Inc., 284 F.3d 1365, 1373 (Fed. Cir. 2002)) (emphasis added). Even if Opens argument is correct, however, such redundancy would not change the meaning of "LTR deleted" because the patents do not command a different result.

There is no such redundancy or conflict between the proper construction of lentiviral LTR-deleted vector and its use in the claims. Claim 1 of the 123 patent provides:

1. A lentiviral vector particle capable of transducing a non-dividing or slowly-dividing cell, said vector particle comprising a lentiviral LTR-deleted (LLD) vector, wherein the LLD vector comprises sequences sufficient for reverse transcription and integration, and wherein, upon transduction, the LLD vector comprises a non-functional lentiviral 5 LTR promoter.

(Emphasis added).

Through this language, the inventors merely reiterated what was already said in the specification and file history concerning the definition of lentiviral LTR-deleted vector. The specification says that the lentiviral LTR-deleted vector must be capable of reverse transcription and integration, and that is repeated for added clarity in the language of the claim. The inventors stated that their amendment was for consistency with the specification, even though they professed that it was not necessary. See Amendment and Response to Office Action dated Oct. 21, 2004 (Pls. Ex. 13), at 4, 6.

There is no conflict between the correct interpretation of this term and the claim scope. As in the Power Mosfet case, it is

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entirely proper to construe these terms coextensively where that interpretation is fully supported in the specification and file history. See 378 F.3d at 1410. It would be improper for the Court to adopt an interpretation that flies in the face of the specification and file history merely to avoid some overlap with the claim language. See also Nystrom v. TREX Co., 424 F.3d 1136, 1142 (Fed. Cir. 2005) (affirming construction of the term "board" to mean a "piece of elongated construction material made from wood cut from a log" even though it rendered "wooden decking board" in a dependent claim surplusage).

Further, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314. This language in claim 1 of the 123 patent further reiterates that this is an important part of how the term is defined. The repetition in this definition of "lentiviral LTR deleted vector" does not create superfluous language, but supports the definition advanced by Sigma and Oxford.

Opens proposed construction would lead to inconsistent results with claim 1 of the 699 patent. This claim provides that the vector comprises a lentiviral LTR-deleted vector, as defined in the specification and file history:

1. A lentiviral vector capable of transducing a non-dividing or slowly-dividing cell, said vector comprising a lentiviral LTR-deleted vector.

(Emphasis added). The examiner of this patent found this language to be straightforward by itself, and therefore did not request any further clarification. This claim does not have additional language about "reverse transcription" or "integration" because those requirements are already included in the definition of lentiviral LTR-deleted vector.

The specification teaches that reverse transcription and integration are essential "in order to function as a vector." 123 patent, col. 8, ll. 59-65. Under Opens construction of lentiviral LTR-deleted vector, there is no requirement that the vector must be capable of reverse transcription and integration. Under Opens construction there would be no requirement that the vectors in claim 1 of the 699 patent be capable of these essential functions. Such an interpretation is contrary to the unambiguous language in the specification, and cannot be correct. Sigma and Oxfords construction is consistent with the specification and with the claim language. .Even if this construction did render some claim language repetitious, such a construction is permissible. See Power Mosfet, 378 F.3d at 1410.

Third, Open argues that the definition of "lentiviral LTR-deleted vector" must be limited in view of an earlier patent issued to the Kingsmans, U.S. Patent No. 6,235,522 ("the 522 patent"). The 522 patent also relates generally to lentiviral vectors, but is not formally related to the two asserted patents. This patent uses the term "lentiviral LTR-deleted vector" once in its specification as a general description of a modified lentiviral vector, but never uses this term in the claims. See 522 patent, col. 6, ll. 32-33.

During prosecution, the examiner rejected certain claims of the pending 699 patent for double patenting as anticipated by the earlier 522 patent. The inventors filed a terminal disclaimer to overcome this rejection. Open takes this as an admission that the vectors in the two asserted patents must be limited to what is claimed in the 522 patent.

The Court disagrees. The filing of a terminal disclaimer is not an "admission" of any sort about the scope of a claim. See Ventana, 473 F.3d at 1184 n.4 (rejecting argument that terminal disclaimer "represents an admission by the inventors equating all claims of the [one] application to all claims of the [the other] Patent"); Quad Envtl. Techs. Corp. v. Union Sanitary Dist., 946 F.2d 870, 874 (Fed. Cir. 1991) ("the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection.").

Even if the '699 patent were anticipated by the '522 patent, this would not limit the claims of the '699 patent. To the contrary, the '699 patent could be anticipated but simultaneously be broader and claim additional subject matter (such as different embodiments of LTR-deleted vectors). Indeed, the '522 patent does not use the term "lentiviral LTR-deleted vector" in its claims, but rather uses entirely different terms to describe its claimed vectors. See Ventana, 473 F.3d at 1184 n.4 (noting that arguments concerning scope of other patent "are irrelevant" where the claims used different language). 11

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11 Moreover, the term "lentiviral LTR-deleted vector" is clearly defined in the specifications and file histories of the '123 and '699 patents themselves. The 522 patent has no familial relationship with the two asserted patents and therefore is not

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relevant for claim interpretation. See Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1167-68 (Fed. Cir. 2004) (holding that district court erred by interpreting patent based on unrelated patent to the same inventor, emphasizing the "distinct line between patents that have a familial relationship and those that do not."); Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1211 (Fed. Cir. 2002) (noting that prosecution history of unrelated patent "sheds no light" on proper interpretation of patent at issue). To the extent that the 522 patent uses the term differently from the two asserted patents, the two asserted patents must control. See Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc., 112 F. 3d 1137, 1143 (Fed. Cir. 1997) ("The specification that is relevant to claim construction is the specification of the patent in which the claims reside.").

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The Court construes "lentiviral LTR-deleted vector" or "LLD vector" as meaning "a replication-defective vector based on a lentivirus in which (a) one or more LTR nucleotide sequences from the lentivirus, including at least one such nucleotide sequence that is involved in transcription, are not present, and (b) lentiviral LTR nucleotide sequences necessary for reverse transcription and integration are present."
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A. The Meaning of "Lentiviral Vector"

The term "lentiviral vector" appears in independent claim 1 of the '699 patent, and is included within the phrase "lentiviral vector particle" in independent claim 1 of the '123 patent. The parties agree (1) that a "lentivirus" is any retrovirus of the genus or subfamily Lentivirinae, (2) that a "vector" is a vehicle or agent which is designed to carry selected genetic material (DNA or RNA) in order to introduce the selected genetic material into a cell, and (3) that a "lentiviral vector particle" means "a lentiviral vector in the form of a virus-like structure comprising viral components that enable the introduction of genetic material into a cell." Joint Claim Construction and Pre-hearing Statement [Doc. 40], at 2; Def.'s Stipulation Regarding Agreed Upon Construction Of Terms And Phrases Formerly In Dispute [Doc. 95], at 1.

The parties agree generally that the lentiviral vectors of this invention are lentiviruses that have been altered to carry genetic material into a cell. See, e.g., '123 patent, col. 9, ll. 8-11 ("[T]he vector according to the invention is based on a particular retrovirus, this may be a genetically or otherwise… altered version of the retrovirus."); id. at col. 1, ll. 61-63 (noting that invention relates generally to "the development of retroviral vector systems based on lentiviruses, a small subgroup of retroviruses"); id. at col. 9, ll. 4-7 ("That the vector particle according to the invention is 'based on' a retrovirus means that it is derived from that retrovirus."). 3

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3 While the parties agree on the definition of the general term "vector," the Court is mindful of the fact that in the claims the terms are "lentiviral vector" and "lentiviral LTR-deleted vector." It is the terms as actually used in the patent claims that are for the Court to construe.

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The parties disagree about whether the claimed "lentiviral vector" must be "replication defective," in other words, whether the virus must be neutered so that it can no longer make copies of itself and reproduce, such as after being administered to a patient for therapeutic purposes. Sigma and Oxford contend that the "lentiviral vector" claimed in the patents must be replication defective, so the term should be construed as "a replication-defective viral vector that comprises a sequence of RNA or DNA nucleotides derived from a lentivirus." Open urges a broader construction, that "lentiviral vector" means any type of "vector that is derived from a lentivirus," without a requirement that it be replication defective. 4

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4 Open had initially urged a narrower construction, that "lentiviral vector" be defined as "a vector that belongs to a group of retroviruses that cause 'slow disease' characterized by long incubation periods and chronic progressive phrases such as Human Immunodeficiency Virus (HIV)." Joint Claim Construction and Prehearing Statement [Doc. 40], at 3-4. It abandoned this position during claim construction briefing.

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The Court agrees with Sigma and Oxford. The specification makes clear that "in any case" the vectors claimed in these patents "will be replication defective":

The retroviral vector according to the invention may be constructed according to the methods known in the art. It is desirable that the retroviral vector genome does not encode any unnecessary polypeptides, that is any polypeptides that are not required for achieving the effect the vector is designed for. In any case, the retroviral vector will be replication defective.

'123 patent, col. 10, ll. 48-54 (emphasis added).

This passage contains language of "manifest exclusion" that represents "a clear disavowal of claim scope." Teleflex, 299 F.3d at 1327; see also Phillips, 415 F.3d at 1316 (noting that "the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor" which may be "regarded as dispositive" for interpreting a claim); Alloc, Inc. v. International Trade Comm'n, 342 F.3d 1361, 1370 (Fed. Cir. 2003) (interpreting claim term narrowly where "the specification makes clear at various points that the claimed invention is narrower than the claim language might imply").

The inventors expressly limited their invention by emphasizing that "in any case" the vector claimed in the patents "will be" replication defective. This passage unambiguously states that "any" embodiment of the claimed lentiviral vector must be replication defective. See Astrazeneca AB v. Mutual Pharm. Co., 384 F.3d 1333, 1338-39 (Fed. Cir. 2004) (holding that general term "solubilizer" in claims was limited where the specification unambiguously stated that the solubilizer must be a surfactant solubilizer). This statement in the specification is not discussing only a single embodiment among many, but is discussing every embodiment of the invention.

This is confirmed by the remainder of the specification. The specification discloses several different embodiments of vectors that are replication defective, but none are capable of replicating. See '123 patent at col. 5, ll. 51-54; col. 11, ll. 19-22, 30-36; col. 7, ll. 50-55, 63-65; col. 8, ll. 3-4; col. 9, ll. 45-53; col. 12, ll. 9-14; col. 14, ll. 15-31; Figs. 1-4 and 6. In every one of the disclosed embodiments, the vectors are replication defective.

This interpretation is also consistent with the stated purpose of the invention, which is to transform a potentially lethal lentivirus such as HIV into a beneficial lentiviral vector that can be used safely for gene therapy or research. If the vectors were allowed to replicate as the underlying viruses do in their natural state, they could cause serious harm to the patient, infect researchers or doctors, and spread disease to third parties. See '123 patent, col. 5, ll. 48-51 (noting that immunodeficiency viruses like HIV "inevitably bring with them safety considerations and prejudices").

Dr. Cullen testified that because of the risk of harm and disease, a vector that is replication defective is "absolutely essential" in a clinical setting. Deposition of Dr. Bryan R. Cullen ("Cullen Dep.") at 130:1-16. Dr. Cullen reiterated that non-replication-defective vectors "could not be used in any clinical setting because they would be dangerous." Transcript of Claim Construction Hearing ("Tr.") at 62:2-63:3. Dr. Susan Kingsman similarly explained in her deposition:

If [the vector] were not replication defective, it would be a virus, and you would not want to use a virus to modify cells or research for therapeutic purposes in the context of this invention. The whole art of making vectors is to convert viruses to replication defective entities.

Deposition of Dr. Susan M. Kingsman ("Kingsman Dep.") at 66:13-20.

Consistent with this goal, the specification emphasizes the importance of incorporating "safety aspects" into the vectors. '123 patent, col. 10, ll. 54-65. In particular, the vector should only have the "minimum retroviral material necessary to function." Id. These safety aspects are intended to prevent the "possible reconstruction of infectious virus particles," and thereby ensure that the vectors will remain replication defective. Id. 5

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5 This is further confirmed by the extrinsic evidence relied upon by Open. Although these references note that it is theoretically possible in other circumstances to use a lentiviral vector that is capable of replication, they emphasize that such vectors are highly disfavored. For example, one reference states "generally" that vectors "are engineered to be replication-

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defective" for safety reasons. Buchschacher, Lentiviral Vector Systems for Gene Transfer (2003) (Def.'s Ex. G). Another reference notes that vectors capable of replicating "have not been as popular as replication-incompetent vectors" because they are only suitable for use in "avian species" or "a tissue culture dish," and not for use in "mammals." Current Protocols In Molecular Biology, Vol. 2, Supp. 36 (Def.'s Ex. H) at 9.9.6.

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Open argues that the term "lentiviral vector" should be defined broadly as any "vector that is derived from a lentivirus." Open points to extrinsic evidence and asserts that the term "lentiviral vector" does not always mean a replication-defective vector in other circumstances "outside the context of these patents." Def.'s Br. at 16. While true, this is irrelevant because the claims must be interpreted within the context of these patents, not outside of them. See Phillips, 415 F.3d at 1319 (extrinsic evidence is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence").

The inventors acknowledged that in the prior art, other researchers had sometimes used vectors that were capable of replicating. The inventors expressly ruled out these types of vectors as part of their invention because such vectors were unsafe and therefore unsuitable for therapeutic purposes. The inventors emphasized that "in any case" the only vectors they claimed in these patents were replication defective. '123 patent, col. 10, ll. 48-54. In so doing, the inventors stated that they were not seeking to claim more than they were entitled to. They only claimed "replication-defective" lentiviral vectors.

Open also urges the Court to ignore the inventors' unambiguous disclaimer because it only appears in "one sentence." Defendant's Br. at 16; Tr. at 35:10-13. The Court is unaware of any authority requiring more than "one sentence" to create a disclaimer where that language is clear. To the contrary, the Federal Circuit has rejected the notion that "rigid formalism" is necessary for a disclaimer. Astrazeneca, 384 F.3d at 1339.

Open further argues that only some of the claims require lentiviral vectors that are replication defective. Some claims, such as claim 1 of the '123 patent, provide that the claimed lentiviral vector must have a "non-functional lentiviral 5' LTR promoter." Other claims, such as claim 1 of the '699 patent, do not have this limitation. Open contends that the vectors in these later claims do not need to be replication defective.

This argument is without merit. The specification teaches that "in any case" the lentiviral vectors "according to the invention," i.e., the vectors in these claims, "will be replication defective." The claim language Open points to is "non-functional 5' LTR promoter," not "replication defective." These terms are not synonymous. The patent specification explains that a non-functional lentiviral 5' LTR promoter is one way, but is not the only way, to make a lentiviral vector replication defective. The specification also discloses other ways to make lentiviral vectors that are replication defective, as explained below.

The claims reflect these different embodiments that are disclosed in the specification. In some claims, such as claim 1 of the '123 patent, the claimed vector must specifically have a "non-functional lentiviral 5' LTR promoter." This claim language only provides further guidance about a particular way to make the vector replication defective, not whether the vector is replication defective.

In other claims, such as claim 1 of the '699 patent, the language is broader and includes any type of lentiviral LTR-deleted vector that is replication defective. These claims are not limited to the "non-functional lentiviral 5' LTR promoter" embodiment, but can include vectors made replication defective through other methods. 6

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6 This interpretation is also consistent with the prosecution history. During prosecution, the inventors amended claim 1 of the '123 patent to add the limitation that it includes a "non-functional lentiviral 5' LTR promoter." Amendment and Response to Office Action dated Oct. 21, 2004 (Pls.' Ex. 13) at 4. The inventors explained that the purpose of the amendment was to "further clarify" that the vector "is no longer capable of . . . replication" because it includes this feature. Id. at 6. The inventors did not suggest, however, that this was the only way of making a vector that was replication defective, or that such a vector would be capable of replication unless it had this particular limitation.

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Accordingly, the Court construes "lentiviral vector" as used in these claims as meaning "a replication-defective viral vector that comprises a sequence of RNA or DNA nucleotides derived from a lentivirus."
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4. "less pronounced increase in gastrin levels" in "slow metabolisers"

The first term, "less pronounced increase in gastrin levels" appears in claim 3 and 15. The second, "slow metabolisers," appears in 3, 4, 15 and 16. Astra contends that "less pronounced increase in gastrin levels" should be construed as "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole." Astra further asserts that "slow metabolisers" means "the few individuals among a population that lack one or more drug metabolizing enzymes or express a mutant form of one or more drug metabolizing enzymes. In humans, the relevant drug metabolizing enzymes, include enzymes of the CYP1, CYP2 and CYP3 families and the 6 isoforms within these families. For purposes of the '192 patent, a "slow metabolizer" is individual which lacks the CYP2C19."

DRL argues that construction of the phrase "less pronounced increase in gastrin levels [in] slow metabolisers" is not required because it is not a limitation but rather the observed inherent result of the claimed method. In the event that the Court determines that construction is required, DRL proposes the following construction: "the observed inherent effect of the administration of a therapeutically effective amount of (-)-enantiomer of 5-methoxy-2[[(4- methoxy-3,5-dimethyl-2 pyridinyl)methyl]sulfinyl] -1H-benzimidazole that the average increase in gastrin levels for slow metabolizers treated with that compound is less than that for slow metabolizers treated with omeprazole, and that this distinction would support a claim of superiority that the FDA would allow in advertising and product literature." For the same reasons expressed earlier, the Court is not persuaded by DRL's argument that the term need not be construed and finds that construction of this phrase is appropriate. Because DRL's proposed construction merely embodies its argument, rejected by the Court, that the disputed claim terms simply state the inherent result or effect of the administration of the claimed compound and, therefore, do not require construction, and further, because DRL provides no support for its proposed language regarding "a claim of superiority that the FDA would allow," the Court rejects DRL's proposed construction.

In support of its proposed construction of "less pronounced increase in gastrin levels" as meaning "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole," Astra points to the prosecution history of the '192 patent, during which, in response to an office action during prosecution of the '504 patent, Astra submitted a response explaining the pronounced effect of administration of the (-)-enantiomer of omeprazole. Pl. Ex. '192-2. It explained that "[i]n addition as can be recognized from the data of Study B in the Declaration of Andersson, the (-)-omeprazole affords a longer time, 53% of the 24 hour period post dose, with gastric pH above 4 in reflux patients compared to 44% for racemic omeprazole (i.e., about two additional hours) which means a more pronounced acid inhibitory effect." Pl. Ex. '192-10 2/12/1997 Amendment and Response at 8. Astra also relies upon the dictionary definition of the term "pronounced," which is defined as "strongly marked." Pl. Ex. '192-11, Merriam-Webster's Dictionary, 10th Ed., 1993 at 934.

The Court finds that the plain language of the claim, as well as the intrinsic and extrinsic evidence relied upon by Astra, supports the conclusion that one skilled in the art would of ordinary skill would understand that the phrase "less pronounced" refers to a comparison to omeprazole. Consequently, the Court shall construe the phrase "less pronounced increase in gastrin levels" consistent with Plaintiff's proposed construction to mean "a smaller addition to the amount of any of the hormones secreted in the pyloricantral mucosa of the stomach that stimulate secretion of stomach acid by the parietal cells as compared to the addition produced by omeprazole."
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D. "Lipid-based component" (Claim 78)

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Plaintiff asserts that the term "lipid-based component" means an inner component having at least about 10% lipids by weight. Defendants contend that the phrase means a component having lipids as the fundamental part. 3

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3 Defendants further assert that Plaintiff expressly disclaimed any component that has an aqueous phase. Again, it is unclear whether Defendants seek to incorporate this assertion into their proposed construction of the claim term.

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In support of its argument, Plaintiff contends that: 1) the ordinary meaning of the term refers to an inner component with lipids as a fundamental part, and 2) the invention relates to using lipids in a sufficient amount to eliminate the need for moisture control agents while still providing a plurality of textures to increase palatability. See Jt. App., Exhibit A, col.3, lines 28-49. Based on its argument, Plaintiff concludes that the amount of lipids that comprises a "fundamental part" is the amount of lipids required to successfully practice the invention. According to Plaintiff, that amount, as provided in the specification, is greater than about 1.0%. See Jt. App., Exhibit A, col. 5, lines 64-65.

Based on this Court's reading of the specification, Plaintiff's argument is not well-taken. The claim language at issue uses general descriptive words, without specifying a numeric limitation, and the portion of the specification cited by Plaintiff merely states "it is preferable for the lipid content . . . [to] be greater than about 10% by weight. See Jt. App., Exhibit A, col.5, lines 64-65 (exmphasis added). The specification then goes on to state that higher weight percentages are still more advantageous. See Jt. App., Exhibit A, col. 5, lines 66-67 and col.6, lines 1-3. As such, the specification regarding lipid weight percentages appears to serve as more of a guideline, rather than a definitional limitation. Furthermore, the Federal Circuit has held that an element that is claimed using general, descriptive words is ordinarily not limited to numerical ranges recited in the specification or other claims. See Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

Defendants argue that "lipid-based" means a component having lipids as the fundamental part. Defendants further stated in oral argument that "fundamental" means "majority." Therefore, it would follow that Defendants propose a construction whereby lipids would necessarily constitute the majority ingredient of the component. However, there is nothing in the intrinsic evidence that supports this position.

The ordinary meaning of "base" is "a main ingredient; a supporting or carrying ingredient." Webster's Ninth New Collegiate Dictionary 133 (9th ed. 1990). Therefore, it would stand to reason that the ordinary meaning of the phrase "lipid-based component" is "a component in which lipids serve as the main, supporting or carrying ingredient." This definition, by itself, does not imply a quanitfiable amount of lipids. However, in the context of the patent, the amount of lipids necessary to be considered a main, supporting or carrying ingredient would be the amount of lipids necessary to make the subject matter (i.e., inner component) function in the way for which it was designed. According to the prosecution history, Plaintiff distinguished its invention from the Prior Art in response to the Examiner's rejection of Plaintiff's claims as being unpatentable over the Prior Art. With regard to the inner component, Plaintiff's main assertion was that the Prior Art taught away from Plaintiff's invention because the Prior Art (1) had to be thicker than a cream-like matrix, and (2) had to provide for the transport of water from the outer component to the inner component. In contrast, the transport of water was not possible in Plaintiff's invention since the "first component was formed from a lipid-based cream-like matrix with no aqueous phase and water will not migrate into a fat-based solution." Jt. App., Exhibit B, pg. 137 (emphasis added). Therefore, in order to for the inner component to successfully function as it was designed to function, the inner component of Plaintiff's invention must contain an amount of lipids sufficient to prevent the migration of water from the outer component into the inner component.

Reading the phrase in the context of the claim language and reviewing the intrinsic evidence, this Court finds that the meaning of "lipid-based" means "an inner component in which lipids constitute a sufficient portion to prevent the migration of water from the outer component into the inner component."
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A. The Meaning Of The Disputed Phrase "Lipophilic Phase Component"

Novartis contends that the phrase "lipophilic phase component" should be construed in accordance with its plain and ordinary meaning, namely "a material that is lipophilic, i.e., fat- or oil-loving, and serves as a carrier (i.e. solvent) for cyclosporin." (D.I. 129 at 12). According to Novartis, the specification of the '625 Patent supports this construction, as it fails to set forth any additional limitations. (D.I. 129 at 12-22).

Abbott agrees with Novartis' construction, but contends that a plain reading of the claim language and specification of the '625 Patent make clear that additional limitations exist. (D.I. 131 at 2-3). According to Abbott, the claim language and specification of the '625 Patent require that the phrase "lipophilic phase component" be construed to include at least one excipient meeting the following criteria: (1) a pharmaceutically acceptable lipophilic solvent in which cyclosporin is soluble, which is (2) immiscible with both water and the hydrophilic phase component(s) (in the absence of a surfactant), and which (3) lacks the amphiphilic function characteristic of a surfactant (i.e., it must not be a surfactant). (D.I. 131 at 13-25). In addition to the requirements of the claim language and specification, Abbott contends that the prosecution history of the '625 Patent supports its construction. (D.I. 131 at 25-29).

In construing the phrase "lipophilic phase component," the Court has considered the claim language, specification, and prosecution history of the '625 Patent. (See D.I. 129, Ex. A, '625 Patent, col. 33, Ins. 15-35, col. 8, ln. 58-col. 9, ln. 63, col. 12, lns. 42-48; D.I. 132 at A91, A110-111, A266, A496-501). Based on this review, the Court concludes that there is substantial support for Abbott's position. Specifically, the use of the term "comprising" in Claim 1 of the '625 Patent signifies that there must be at least one of the four components listed (i.e. a cyclosporin, hydrophilic phase component, lipophilic phase component, and surfactant). (D.I. 129, Ex. A, '625 Patent, col. 33, lns. 15-35). Additionally, the portion of the specification which addresses the "lipophilic phase component" provides:

Suitable components for use as the lipophilic phase include any pharmaceutically acceptable solvent which is non-miscible with the selected hydrophilic phase, e.g., as defined under (1.1) or (1.2). Such solvents will appropriately be devoid or substantially devoid of surfactant function.

(See D.I. 129, Ex. A, '625 Patent, col. 8, lns. 58-63). When read together, the Court is convinced that the claim language and specification require that the "lipophilic phase component" be devoid of the amphiphilic function characteristic of a surfactant, and immiscible with both water and the hydrophilic phase component in the absence of a surfactant. Moreover, the prosecution history further supports the requirements of the claim language and specification, as the applicant drew a clear distinction between lipophilic phase components and surfactants that are lipophilic in nature. (See D.I. 132 at A91, A110-111). Accordingly, the Court will construe the phrase "lipophilic phase component" to include at least one excipient meeting the following criteria: (1) a pharmaceutically acceptable lipophilic solvent in which cyclosporin is soluble, which is (2) immiscible with both water and the hydrophilic phase component(s) (in the absence of a surfactant), and which (3) lacks the amphiphilic function characteristic of a surfactant (i.e., it must not be a surfactant).
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Novartis claims that the district court erred by not giving the term "lipophilic component" the broadest meaning possible. More specifically, Novartis asserts the district court unnecessarily added limitations concerning whether the "lipophilic component" may include surfactants and whether the constituents of the lipophilic component must be immiscible.

A.

Novartis begins its analysis by observing that "lipophilic" has a well-defined meaning to those skilled in the art. As defined by Novartis' expert, lipophilic means "fat- or oil-loving, or water hating." Novartis then notes that the specification teaches that:

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The relative proportions will also vary, depending on the particular function of ingredients in the composition, for example, in the case of a surfactant component of a "microemulsion pre-concentrate", on whether this is employed as a surfactant only or both a surfactant and a co-solvent.

'840 patent, col. 16, ll. 36-41. Further, the specification teaches that:

When the surfactant comprises an effective solvent for the cyclosporin active ingredient, as in the case e.g. of surfactants or mixtures of surfactants under (3.1.1.) to (3.2.7.) above, it may be incorporated into compositions as defined under (A), not only as surfactant, but in excess as an additional carrier or co-solvent phase, i.e. as part of the hydrophilic or lipophilic phase.

Id., col. 12, ll. 44-49. Novartis claims that these teachings are inconsistent with the court's construction that a surfactant can form no part of the "lipophilic component." We agree with Novartis.

Claim 81 of the '840 patent recites a pharmaceutical composition that forms a microemulsion upon dilution by water. The composition comprises, in addition to the active ingredient, three other components. Namely, it contains (1) a hydrophilic component, (2) a "lipophilic component," and (3) a hydrophilic surfactant. Neither party cites any persuasive record evidence that the term "lipophilic component" (or "lipophilic phase component") had a well-defined meaning to those of ordinary skill in the art. Accordingly, the claim term requires that we turn to the intrinsic evidence, and if necessary, the extrinsic evidence, to elucidate the meaning that one skilled in the art would give the term. Johnson Worldwide, 175 F.3d at 990.

The passages of the specification quoted above indicate that a surfactant or a mixture of surfactants, provided it is an "effective solvent for the cyclosporin," may form, contrary to the district court's construction, a part of the lipophilic phase that dissolves the cyclosporin. Furthermore, the '840 patent discloses that if a surfactant forms a part of the lipophilic phase, it does so as a co-solvent. Col. 12, ll. 43-49, col. 16, ll. 36-41. A co-solvent is a "solvent that in conjunction with another solvent can dissolve a solute." Webster's Third New International Dictionary ("Webster's") 514 (1993) (emphasis added). Novartis' expert opines that the specification's disclosure indicates that a surfactant "could function alone" as the solvent in the lipophilic phase. (Emphasis added). By definition, however, a co-solvent operates with "another solvent" to dissolve a solute, such as cyclosporin. Novartis' expert testimony therefore directly contradicts the express teaching of the specification, and may not be used to give us appropriate guidance to reach the correct claim construction.

At oral argument, Novartis attempted to make a similar argument, asserting that the description of surfactants as making up only a "part" of the lipophilic phase, see '840 patent, col. 12, ll. 48-49, indicates that surfactants could constitute the whole lipophilic phase. "Part," however, means "something less than a whole." Webster's at 1645. Because Novartis supplies insufficient record evidence to validate its unconventional interpretations of "co-solvent" and "part," as those words are used in the specification, Novartis' reading of the specification must be rejected.

In an attempt to further support its view that surfactants may constitute the entire lipophilic phase, Novartis notes that Example 4.1 in the '840 patent describes a "regular emulsion pre-concentrate" in which only a surfactant is used to dissolve the cyclosporin. The composition defined by claim 81 is not a regular emulsion pre-concentrate, however, but rather a microemulsion pre-concentrate, and therefore the example does nothing to advance our understanding of what composes the "lipophilic component" in the claimed composition. n4

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N4 For the same reason, we must reject the assertion by Novartis' expert that the written description in the '840 patent at column 14, lines 39-44 provides further evidence that surfactants may form a part of the lipophilic component. The compositions as defined under (C) of the specification provide emulsion pre-concentrates and are directed to compositions "other than those as defined under (A) and (B)," (both of which are microemulsion pre-concentrates) to form "for example, solutions, suspensions, dispersion[,] regular emulsions and the like." '840 patent, col. 14, ll. 45-54.

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Because the specification teaches that "mixtures of surfactants," if used to dissolve the cyclosporin, form only a "part" of the

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lipophilic phase, '840 patent, col. 12, ll. 43-49 (emphasis added), the other solvent forming the rest of the lipophilic phase must not be another surfactant. Rather, according to the specification, the remainder of the solvent constituting the lipophilic phase is a pharmaceutically acceptable non-surfactant lipophilic excipient that is capable of dissolving cyclosporin, such as those described under section (2) of the specification. Id., col. 8, ll. 66-67; col. 9, ll. 5-46; col. 12, ll. 43-49. Accordingly, while we agree with Novartis that surfactants may form a part of the lipophilic component, the intrinsic record shows that this component cannot be composed entirely of surfactants, as urged by Novartis. Although Abbott initially argued in its opposition brief that the '840 patent "requires the lipophilic (phase) component to be comprised of an excipient other than a surfactant," Abbott later admitted in its cross-appeal brief and at oral argument that "a surfactant [may] contribute[] to the lipophilic phase so long as the lipophilic phase also contained at least one non-surfactant excipient." In view of the intrinsic evidence, the claimed "lipophilic component" must contain, at minimum, a pharmaceutically acceptable lipophilic substance capable of dissolving cyclosporin, and that is a non-surfactant excipient.

B.

Novartis also challenges the district court's inclusion of the requirement that the lipophilic component must be immiscible with the hydrophilic phase in the absence of surfactants. The specification states that "suitable components" for use in the lipophilic phase may include any pharmaceutically acceptable solvent that is non-miscible with the selected hydrophilic phase. '840 patent, col. 9, ll. 1-3 (emphasis added). The specification, contrary to the district court's reading, does not teach that the entire lipophilic phase must be immiscible with the hydrophilic phase, but rather only components, e.g., parts, of the phase, in one embodiment, should be immiscible. We find nothing within the intrinsic record that compels reading the immiscibility limitation into the "lipophilic component" term.
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Claim 81 of the '840 patent recites a composition comprising four components: cyclosporin A; a propylene glycol hydrophilic component; a hydrophilic surfactant; and a lipophilic component. The lipophilic component is described in the patent as an oil-loving substance that dissolves the cyclosporin so that when water is added to the composition an oil-in-water microemulsion is created.

It is not disputed that the accused Abbott composition contains the first three of the claimed components; only the presence of a lipophilic component is in dispute. Novartis argues that the Abbott composition has a lipophilic component in the form of Span 80, a lipophilic surfactant. Abbott argues that although Span 80 is lipophilic, it cannot serve as the lipophilic component of claim 81. The court today agrees with Abbott, based on statements in the specification of the '840 patent. Although the court acknowledges that a lipophilic surfactant such as Span 80 can serve as part of the claimed lipophilic component, it holds that the specification does not allow for a surfactant to serve as the entire lipophilic component. Accordingly, the court holds that because Span 80 is the only lipophilic component in Abbott's composition, the Abbott composition does not infringe, either literally or under the doctrine of equivalents.

Because it is undisputed that Span 80 is lipophilic and that cyclosporin dissolves in Span 80, Span 80 appears to qualify as a "lipophilic component" as that term is used in the '840 patent. Thus, Abbott can prevail on this claim construction issue only if the specification is read as requiring that the "lipophilic component" limitation be construed more narrowly. The court today concludes that the specification has that effect, but I do not agree.

In reaching its conclusion as to the proper construction of the term "lipophilic component," the court relies on a passage from the specification stating that a surfactant may be incorporated in a microemulsion composition of the invention not only as the surfactant, "but in excess as an additional carrier or co-solvent phase, i.e. as part of the hydrophilic or lipophilic phase." '840 patent, col. 12, ll. 47-49. See also id., col. 14, ll. 40- 42 (referring to a lipophilic surfactant serving "as a surfactant or as a co-solvent"); id., col. 16, ll. 39-41 (referring to a surfactant that is "employed as a surfactant only or both a surfactant and a co-solvent"). The court interprets that language, which recognizes that a surfactant can serve as part of the hydrophilic or lipophilic components of the claimed composition, as meaning that a surfactant may be a part of the lipophilic component but may not serve as the lipophilic component by itself.

I do not draw the same conclusion from the quoted language. The statement on which the court relies refers to the role performed by excess amounts of the substance that serves the role of the surfactant in the claimed composition. The quoted

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language indicates that the composition of the invention must have at least three components in addition to the cyclosporin, as required by claim 81. In addition, it contemplates that the substance that serves as the surfactant may also serve as part of either the hydrophilic or the lipophilic component. The quoted language therefore makes clear that the composition may not consist of only two components in addition to the cyclosporin, as would be the case if one ingredient served as both the surfactant and the lipophilic component in the composition. However, the quoted language does not address the case presented by Abbott's composition, which contains three components in addition to the cyclosporin, and in which a hydrophilic surfactant serves as the surfactant, while Span 80 serves the function of the lipophilic component (dissolving and carrying the cyclosporin). Thus, because in Abbott's composition Span 80 does not serve as the surfactant referred to in claim 81, the quoted language from the specification does not apply to Abbott's composition. For that reason, I agree with Novartis that, where another substance serves as the hydrophilic surfactant, the specification does not disclaim the use of a lipophilic surfactant such as Span 80 as the sole component of the lipophilic component of the claimed invention. I therefore do not find a disclaimer of subject matter in the specification. A fortiori, I do not find a specific exclusion of subject matter for purposes of the doctrine of equivalents.
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a. "liquid"

i. The Parties' Proposed Constructions

MiniMed proposes that I construe "liquid" to have its plain meaning. (D.I. 169 at 22.) MiniMed argues that although the specification teaches that "liquid" can be a medication, it is improper to limit it to a specific embodiment, (Id. at 22-23 (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001)).)

Smiths argues that liquid should be construed to mean "a dose of medication, such as insulin, measured in units." (D.I. 190 at 27.) Smiths argues that the terms "liquid" and "fluid," both used in Claim 1, should be construed differently. (d.) Moreover, it argues that "considering the claim language in context and definition of 'liquid' as used throughout the specification, one of ordinary skill in the art would understand that the applicants acted as their own lexicographer and redefined the term 'liquid' … ." (Id.) Specifically, Claims 4 and 5 also state that the "liquid to be infused is insulin." (Id. (citing '798 patent, col. 30:55-60).) As to the construction of the phrase "measured in units," Smiths points out that one of the preferred embodiments states that the insulin is delivered in units ('798 patent, col. 6:14-18) and that the amount delivered is usually delivered in terms on "units" (D.I. 192, Ex. 34 at 11).

ii. The Court's Construction

"Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

I agree with Smiths that the patentee has acted as his own lexicographer with respect to the term "liquid," but I do not agree that the term has the meaning Smiths suggests. In the specification, the patentee describes possible liquids as things such as "medication, chemicals, enzymes, antigens, hormones, vitamins or the like." ('798 patent, col. 6:13-17.) While some of these substances may be liquid in nature, others are not liquids but are rather dissolved in a liquid. Moreover, all of these substances have or can have an effect on the human body. The idea that the liquid is active in the human body is reinforced by dependent Claim 3, wherein the bolus estimator uses the patient sensitivity to the "liquid" to determine the proper amount of liquid to be infused. (Id., col. 30:51-54.) Further, Claim 9 states that the "liquid will remain active in the body." (Id., col. 31:4-7.) If "liquid" was not defined by the patentee to be a substance that is active in the human body, then the idea that a person would have a sensitivity to it or that it would remain active in the body is illogical. Consequently, I construe "liquid" to mean "a substance, such as insulin, that is active within the human body." 15

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15 I find no support in the specification or prosecution history for the assertion that "liquid" be limited to a medication

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measured in units. The fact that a substance is ordinarily measured in a certain way or is disclosed in the specification as being measured in a certain way does not limit the claim limitation. See Rexnord Corp. v. Laitram Corp., 274 F.3d at 1344 (holding that a court should not limit a claim term to a preferred embodiment).

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Clinical next argues that Claim 1's requirement for a "liquid-air interface," cannot read upon the accused device because the Koala has an air-filled balloon that acts as a barrier between the air and liquid. According to Claim 1, the liquid column must have a "liquid-air interface" with the second air-filled volume. An interface is defined as "a surface regarded as the common boundary of two bodies, spaces, or phases." Id. at 993. There is no dispute that this liquid-air interface occurs in the first chamber of the 161 device between the amniotic liquid and the air from the second chamber. Clinical argues that such an interface requires molecule-to-molecule contact between the amniotic liquid and the air for such an interface to exist. Utah Medical asserts that such an interface is simply an exchange between two different surfaces, arguing that nothing in Claim 1 requires a direct molecule-to-molecule interface, and that the interface can exist even if a membrane (such as the balloon in the Koala) acts as a barrier between the air and the liquid. The description of the liquid-air interface in the claim specifications describe an interface between the partially filled liquid and air chamber (161 patent at column 5, line 68 to column 6, line 2), as well as a maintenance of pressure ratios between the air and the amniotic liquid to prevent the liquid from entering the air-filled second chamber (161 patent at column 13, lines 20-28). Because Claim 1 describes this interface in conjunction with the requisite liquid column, the Court finds that Claim 1 contemplates direct contact between the air and the amniotic liquid. Accordingly, the Court interprets Claim 1 to require an actual interface--molecule-to-molecule--between the amniotic liquid and the air. Applying this claim interpretation to the accused device, the Court finds that the accused device does not involve such an air-liquid interface and therefore does not literally infringe on this aspect of the 161 patent. Whether the accused device infringes under the doctrine of equivalents is a question of fact.

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a. Claim Construction

Relying on the Lawson specification, P&G asserts that the term "liquid impermeable" means that the BLC will contain liquid and solid waste during wearing by retarding the movement of liquids through the BLC. Paragon counters that this term must be defined according to its ordinary or dictionary definition because the patent does not evidence that this claim limitation has a special meaning to one of ordinary skill in the art. Citing the dictionary definition of "impermeable," Paragon asserts that "liquid impermeable" means impossible for liquid to flow through.

The Court agrees with P&G that the inventor's definition of "liquid impermeable" is clear from reading the specification. The purpose of the Lawson BLC is to contain body exudates that are not immediately absorbed by the absorbent core in the central portion of the diaper. [PTX 1, at 2:17-31]. Regarding the use of a "liquid impermeable" material for the BLC, the Lawson specification provides:

> the barrier cuff may be rendered liquid impermeable so as to prevent the strikethrough of body exudates. A liquid impermeable barrier cuff retards the movement of liquid through the barrier cuff thereby making it more leakage resistant. The barrier cuff may be rendered liquid impermeable in any manner well known in the art such as selectively treating the barrier cuff, untreating the barrier cuff, or by securing a separate material to the barrier cuff.

Id. at 10:47-55 (emphasis added). 10

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10 The specification further provides that a particularly preferred material is manufactured by the Crown Zellerbach Company and known as Celestra. Id. at 9:10-12. Celestra is a hydrophobic, spunbonded, untreated polypropylene material.

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[Tr. 218, 221-222, 459-60].

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It is a well-settled tenet of patent law that a patentee may act as his own lexicographer. Vitrionics, 90 F.3d at 1582. Although the words used in a patent are generally interpreted according to their ordinary meaning, a court will construe terms used in a patent in accordance with a special meaning, provided that the special definition of this term is clearly stated in the specification. Id. It is clear from reading the Lawson specification that a BLC is "liquid impermeable" if it "retards the movement of liquid" from the central portion of the diaper above the absorbent core through the BLC to the edges of the diaper. There is nothing in the patent specification or the file history which contradicts this definition. Because this term is clearly defined in the patent specification, the Court may not resort to extrinsic evidence, such as the dictionary definition of "impermeable," to vary the definition provided in the specification. Accordingly, the Court construes the term "liquid impermeable," as it describes the BLC feature, to mean a material which is designed to prevent the strikethrough of body exudates by retarding the movement of liquid body exudates through the BLC to the outer portion of the diaper.
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A. Liquid Whole Egg and Liquid Whole Egg Product

The parties dispute the meaning of the terms "liquid whole egg" and "liquid whole egg product." 3 The key disagreement between the parties is whether "liquid whole egg product" and "liquid whole egg" may contain preservatives. Based on a review of the intrinsic evidence, the court concludes that both may contain preservatives.

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3 Michael Foods defines "liquid whole egg" as "Liquid whole egg includes Liquid Whole Egg or Liquid Whole Egg blends with less than 2% added non-egg ingredients. Such non-egg ingredients may include preservatives." (Kempf Aff., Ex. 27.) Sunny Fresh defines "liquid whole egg" as "only liquid egg yolk and the egg whites in the natural proportions occurring in unbroken eggs." (Kempf Aff., Ex. 26.) Michael Foods defines "liquid whole egg product" as follows:

Whole egg, fortified whole egg (whole egg with added yolk), salt whole egg (e.g. salt 10%), sugar whole egg (e.g. sugar 10%), blends of whole egg with syrup which syrups, dextrose and dextrims and/or other gums and thickening agents, blends of whole egg with less than 1% sugar and/or salf, scrambled egg mixes for example, a mix of about 51% egg solids, 30% skim mil solids, 15% vegetable oil and 1.5% salt, reduced cholesterol egg product, and blend thereof, custard blends, and the like, liquid whole egg and blends thereof (less than 2% added ingredients), liquid whole egg blends which are 24-38% egg solids and 12% or less of added non-egg ingredients." (Kempf Aff., Ex. 27.)

According to Sunny Fresh, "liquid whole egg product" means a product primarily of liquid whole egg which also may contain other ingredients to the extent specified and permitted by USDA regulations, but not shelf life extending additives. (Kempf Aff., Ex. 26.)

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Many claims in the '225 patent refer to "liquid whole egg products" and "liquid whole eggs." The claim language, however, does not define either term. The court therefore turns to the specification for clarification. See Vitronics, 90 F.3d at 1582.

The specification defines "liquid whole egg product" and "liquid whole egg" by stating that the terms in the patent have their "standard meaning in accordance with industry and regulatory usage." (Kempf Aff., Ex. 1, Col. 8, ll. 57-60.) Because the patent incorporates by reference regulatory usage, the court examines the regulations promulgated by the applicable regulatory agency, the USDA, at the relevant time. 7 C.F.R. § 59.5 (1985) defines liquid egg products as "… any … liquid eggs, with or without added ingredients…" 7 C.F.R. Part 59.411(d) (1985) states that "liquid whole eggs" can be blended to have different proportions than those directly from the shell. 4 These regulations do not exclude preservatives from their definition of "liquid whole egg product" or "liquid whole egg."

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4 It provides:

Liquid or frozen egg products identified as whole eggs and prepared other than in natural proportions, as so broken from the shell, shall have a total egg solids content of 24.70 per cent or greater. (Id.)

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The specification also gives examples of "liquid whole egg product." It provides:

Examples of whole egg products which can be pasteurized in liquid form by the method of the present invention include whole egg, fortified whole egg (whole egg with added yolk), salt whole egg (e.g. salt 10%), sugar whole egg (e.g. sugar 10%), blends of whole egg with syrup solids, syrups, dextrose and dextrins and/or gums and thickening agents, blends of whole eggs with less than 1% sugar and/or salt, scrambled egg mixes (for example, a mix of about 51% egg solids, 30% skim milk solids, 15% vegetable oil and 1.5% salt), reduced cholesterol egg products and blends thereof, custard blends, and the like. Products which are extremely sensitive to thermal processing and which are particularly suitable for ultrapasteurization by the present invention include, for example, liquid whole eggs and blends thereof (less than 2% nonegg ingredients), fortified whole egg and blends thereof (24-38% egg solids, 2-12% added nonegg ingredients), liquid salt whole egg, liquid sugar whole egg, and other liquid whole egg blend which are 24-38% egg solids and 12% or less of added nonegg ingredients.

(Kempf Aff., Ex. 1, Col. 8, ll. 39-58.) Within those examples, the specification explains liquid whole eggs and blends thereof as containing less than 2% non-egg ingredients. (Id. at ll. 53-54.) None of these examples exclude preservatives from the definition of "liquid whole egg product" or "liquid whole egg." Thus, because the court cannot import a limitation into the specification that does not exist in the claim, the specification illustrates that "liquid whole egg" and "liquid whole egg product" may contain preservatives.

The prosecution history also supports that conclusion. During the course of the prosecution, Michael Foods argued that Dunn could be distinguished from its inventions because some of the Dunn examples used preservatives. (Stewart Decl. Ex. 12 at 159.) The Board of Appeals rejected that position because it found that Michael Food's claim did not exclude preservatives. 5 The Board's holding emphasized that "liquid whole egg product" and "liquid whole egg" may include preservatives and that such an interpretation is consistent with agency regulations. (Kempf Aff., Ex. 20 at 13.)

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5 The Board held:

However, claim 20 does not exclude a liquid whole egg product which may contain preservatives or have some egg yolk removed…. Dunn's liquid whole egg complies with the definition of liquid whole egg set forth in the appellants' specification and the egg solid requirements found in 7 C.F.R. § 59.411(d).

(Kempf Aff., Ex. 20 at 13 (emphasis added).)

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Sunny Fresh argues that because the Board rejected Claim 20 for including preservatives, the definitions of "liquid whole egg product" and "liquid egg product" necessarily must exclude preservatives or else they are invalid based upon the Board's analysis. (Sunny Fresh's Resp. to Def.'s Initial Markman Br. at 14.) This argument fails however because the Board never found that only narrowed claims that excluded preservatives would be allowable over Dunn. In fact, the Board stated that claims with a shelf life of 8 weeks or more were patentable over Dunn. (Kempf Aff. Ex. 20 at 19-20.) If the Board believed that the exclusion of preservatives was the only possible basis for patentablilty, then the Board could not have reversed the rejection of, for example, claim 22, as claim 22 primarily differed from claim 20 by including a shelf life from about 8 weeks to about 36 weeks.

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Because intrinsic evidence unambiguously defines "liquid whole egg" and "liquid whole egg product," it is improper for the court to rely on extrinsic evidence in interpreting those disputed terms. See Vitronics, 90 F.3d at 1582; Interactive Gift Exp., Inc. v. Compuserve Inc., 256 F.3d 1323 (Fed. Cir. 2001); Bell & Howell Document Mgmt. Prod. Co. v. Altek Sys., 132 F.3d 701 (Fed. Cir. 1997). The court nevertheless notes that the extrinsic evidence supports the court's interpretation.

Sunny Foods' own 30(b)(6) witness agreed that "liquid whole egg product" may contain preservatives. In his deposition, Dr. Efstathiou reviewed the definition of egg product provided in the Section 59.5 of Code of Federal Regulations and testified that egg product could include preservatives:

Q: Do you understand that to be the definition of egg products given by the Code of Federal Regulations at about that time?

A: Yes

Q: Does that definition exclude preservatives, in your understanding?

A: It doesn't say so.

Q: And do you have any different understanding from your personal basis on whether it excludes it?

A: Preservatives, my understanding is, was, that they need to be allowed for use for specific products.

Q: So the preservatives had to be approved, but the final product using them would still be a liquid egg product?

A: Yes.

(Second Kempf Aff., Ex. 43, at 24, l. 25; Id. at 25 ll. 1-14.) Moreover, while the testimony of Dr. Woodward, another 30(b)(6) witness, was inconsistent, he admitted that preservatives could be included in the definition of "liquid whole egg product" in some circumstances. (Kempf Aff., Ex. 15 at 45, ll. 19-23.) Thus, even though the court does not rely on those two opinions, the opinions do suggest that "liquid whole egg product" may contain preservatives.

Accordingly, the court construes the disputed terms as follows:

Liquid Whole Egg: "Liquid whole egg" refers to liquid whole egg or liquid whole egg blends containing less than 2% added non-egg ingredients. Such non-egg ingredients may include preservatives.

Liquid Whole Egg Product: "Liquid whole egg product" refers to products which include liquid whole egg and may have more than 2% added non-egg ingredients. Such non-egg ingredients may include preservatives. 6 7

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6 The court also construes the term "liquid whole egg blend" to include blends of whole egg with less than 1% sugar and/or salt, liquid whole egg blends which 24-38% egg solids and 12% or less of added non-egg ingredients. (See Kempf Aff., Ex. 1, Col. 8, ll. 41-60.)

Two additional terms require interpretation: (1) "liquid whole egg product is liquid whole egg blend which is about 24.38% egg solids and about 12% or less of added non-egg ingredients" and (2) "wherein the liquid whole egg product contains not more than 12% of added non-egg ingredients." In particular, the parties dispute the meaning of non-egg ingredients. Based upon a review of the file, record, proceedings and relying upon the court's construction of the terms "liquid whole egg" and "liquid egg product," supra, the court construes the term non-egg ingredients to mean any ingredients not naturally found in the egg, including shelf life extending additives.

7 The court's definition of "liquid whole egg product" and "liquid whole egg" is consistent with the phrase "said liquid whole egg product is liquid whole egg" because liquid whole egg product is a category that includes the subcategory liquid whole eggs or blends thereof.

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III. "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)" 13

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13 As defined herein, the term "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)" is contained in claims 1-8 of the '499 patent and claims 1, 3, 4, 5, 25 and 28 of the '458 patent.

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Plaintiff's Proposed Construction	Defendants' Proposed Construction
An NSAID with a pharmacokinetic half-life of at least about 4-6 hours and preferably about 8-14 hours and a duration of action equal to or exceeding about 6-8 hours.	A non-steroidal anti-inflammatory drug with a pharmacokinetic half-life of at least about 4-6 hours and a duration of action equal to or exceeding about 6-8 hours.

The'499 and '458 patents contain the term "long-acting, non-steroidal, anti-inflammatory drug (LA-NSAID)." Pozen contends that the '499 and '458 patent specifications provide an express definition for the claim term and the claims and files histories do not contradict this definition. OPENING at 19. Defendants argue that Pozen is impermissibly reading a limitation from the specification into the claim terms. RESPONSE at 13-14 (citing relevant case law). Defendants particularly object to specification language in Pozen's proposed construction that reads "preferably about 8-14 hours" because the inclusion of the "preferably" limitation is "superfluous" and "creates confusion where none exists." RESPONSE at 13.

The Court does not read the additional language--"preferably about 8-14 hours"--to render the claim scope uncertain. Instead, the inventor's specific definition, should be honored in the meaning of the claim term. Defendants argue that this language constitutes a preferred embodiment that cannot be imported to alter the scope of the patentee's claims, but an examination of the '458 specification reveals a special definition, not a preferred embodiment. The Federal Circuit has extensivelydiscussed the fine distinction between the "twin axioms" regarding the role of the specification in claim construction: "On one hand, claims 'must be read in view of the specification, of which they are a part. On the other hand, it is improper to read a limitation from the specification into the claims." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed. Cir. 2004); Comark Commc'ns, 156 F.3d at 1187 ("[T]here is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.").

At the outset, the "preferably" clause in Pozen's proposed construction does not appear to narrow what is present in the claim terms. While this additional language does introduce the patentee's preferred time span for the drug's optimal effect, it is clear from the wording that the "at least about 4-6 hours" is the time span that is ultimately controlling. With the minimum of "at least about 4-6 hours" defining the metes and bounds of what is claimed, the patentee's "preference" does not introduce uncertainty because the scope of the claim is already defined. Put another way, the "at least" half-life language encompassesthe later half life language ("preferably about 8-14 hours ") to make the minimum half-life apparent to one of skill in the art. One of skill in the art would understand that the definition has a minimum, as well as a preferred range of action, for NSAIDs.

Therefore, the Court finds that the proper construction of the term "long-acting, nonsteroidal, anti-inflammatory drug (LA-NSAID)" is "an NSAID with a pharmacokinetic half-life of at least about 4-6 hours and preferably about 8-14 hours and a duration of action equal to or exceeding about 6-8 hours."
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3. Carbohydrate

Once again the parties disagree appreciably on the definition to be attributed to this word. 11 The term "carbohydrate" itself is not a controversial one; its definition specifies a "compound of carbon, hydrogen, and oxygen . . . in which the ratio of hydrogen to oxygen is the same as in water." Hawley's at 231 As used in the '793 patent, however, the term is restricted to a carbohydrate with a "low molecular weight," and the carbohydrate source is further specifically limited as being "selected from the group consisting of glucose, fructose, and higher saccharides based on glucose and/or fructose and mixtures thereof." 12 '793 Patent, col. 9, Ins. 47-67 - col. 12. The controversy in this instance centers around the source, including its purity and consistency, of the carbohydrate constituent.

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11 While the '793 patent specifies a low molecular weight carbohydrate, it is only the term "carbohydrate" that needs definition, since the claims themselves contain specific parameters addressing the permissible molecular weight range for the carbohydrate constituent. The likely sources of carbohydrates falling within those ranges must nonetheless be considered, however, when determining the intended degree of purity, or refinement of the carbohydrate source, to ascribe to the framers of the '793 patent claims.12 With a specified molecular weight range of between 180 and 1500, the carbohydrates referred to in the '793 patent can fall within a polymerization range of between hexoses or monosaccharides, of which glucose and fructose are common examples, up to nine, thus limiting the "higher saccharides" specified to a nonasaccharide. The largest molecule that falls within the more restrictive range of between 180 and 1000, which is specified in claims seven and eight, is a hexasaccharide, with a molecular weight of 990. See Nauman Second Decl. (Dkt. No. 183-2) P 12; see also Nauman First Decl. (Dkt. No. 174-16) P 16.

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While the term "carbohydrate" is readily definable, its use in the '793 patent must be considered in light of the limitations expressed, including the molecular weight range and the potential origins or sources of the designated carbohydrates. 13 The '793 patent stresses the importance of the requirement that the carbohydrates utilized be derived from sources with "consistent physical and chemical properties", '793 patent, col. 2, Ins. 28-29, and distinguishes prior art teaching de-icing agents derived from agricultural waste products with famously poor consistency. "'[A] claim term will not carry its ordinary meaning if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention.'" Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1370 (Fed. Cir. 2003) (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

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13 The '793 patent and its parent application cite several examples of the kind of sources of "low molecular weight carbohydrates" commonly available, including glucose, fructose, maltose, lactose, corn syrup DE44, corn syrup DE20, molasses, and maltodextrin.

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Consistent with this approach, the six specific embodiments set forth in the '793 patent utilize refined agricultural products with just such properties as a designated low molecular weight carbohydrate source. As the Federal Circuit has noted, "the written description of the preferred embodiments 'can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.'" Bell Atlantic Network Servs., Inc. v. Kovad Commc'ns Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001) (quoting SciMed, 242 F.3d at 1344).

From the terms of the '793 patent, including the specified embodiments, consideration of the potential sources of low molecular weight carbohydrates listed, and the prior art referenced, I concluded in Cargill that a person of ordinary skill in the art would construe the term "low molecular weight carbohydrate", as used in the '793 patent, as "a material which includes carbon, hydrogen, and oxygen where the ratio of hydrogen to oxygen is the same as in water, and which is obtained

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from a refined and consistent source." 14 Cargill, 334 F. Supp. 2d at 219. I have been presented with no new argument calling into question the court's construction, which was based upon the reality, as would have been well known to a person or ordinary skill in the art at the time of the invention, that under the specification and the prosecution history, in large part what distinguished the invention in question from prior art was the fact that the carbohydrate in question was derived from a consistent and refined source. Accordingly, I will adhere to my prior definition regarding this term.

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14 In Cargill, Sears' expert also proposed a requirement that the carbohydrate source has a recognized CAS registry -- a numerical identifier maintained under the auspices of the American Chemical Society. The CAS registry assigns a number to each new substance registered to describe such properties and information as molecular formula, structure diagram, systemic names, generic names, proprietary or trade names for registered substances. Because there was no intrinsic evidence in the record suggesting the additional requirement of a CAS number, I rejected this additional suggested definitional provision.

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* * *

ORDERED as follows:

1) The disputed terms of the '793 and '622 patents are hereby construed by the court as follows:

Terms	Construction
* * *	
"low molecular weight carbohydrate"	a material which includes carbon, hydrogen, and oxygen where the ratio of hydrogen to oxygen is the same as in water, and which is obtained from a refined and consistent source

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low molecular weight DADMAC

The Court modifies Defendants' proposed construction and construes the phrase as "a low molecular weight DADMAC having a molecular weight range of greater than about 50,000 and less than about 1,000,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." Plaintiffs argue that the phrase should be construed as "a low molecular weight DADMAC measures greater than about 20 cps at a concentration of about 20% in water and less than about 500 cps at a concentration of about 20% in water." Defendants argue that the phrase should be construed as "a low molecular weight DADMAC having a molecular weight range of greater than about 50,000 and less than about 1,000,000." Both Plaintiffs and Defendants re-urge the arguments set forth in support of their proposed constructions of the term "molecular weight." For the reasons discussed above with regard to "molecular weight," the Court rejects Plaintiffs' proposed construction and modifies Defendants' proposed construction to include various measurement techniques for determining molecular weight.

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low molecular weight epichlorohydrin di-methyl amine (Epi-DMA)

The Court modifies Defendants' proposed construction and construes the phrase as "a low molecular weight Epi-DMA having a molecular weight range of greater than about 20,000 and less than about 500,000 as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods."

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Plaintiffs argue that the phrase should be construed as "a low molecular weight Epi-DMA measures greater than about 20 cps at a concentration of about 50% in water and less than about 1,000 cps at a concentration of about 50% in water." Defendants argue that the phrase should be construed as "a low molecular weight Epi-DMA having a molecular weight range of greater than about 20,000 and less than about 500,000." Both Plaintiffs and Defendants re-urge the arguments set forth in support of their proposed constructions of the term "molecular weight." For the reasons discussed above with regard to "molecular weight," the Court rejects Plaintiffs' proposed construction and modifies Defendants' proposed construction to include various measurement techniques for determining molecular weight.
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(2) "C-max… are lower"

In Sandoz's view, a proper construction of claim 4 would assume that the C-max for the extended release formulation would necessarily be statistically significantly lower than the C-max for the immediate release formulation even though the term "statistically significantly" does not appear in the claim.

This Court will not reconstrue claim 4 to include the term "statistically significantly" to modify "lower". First, claims are to be given their ordinary and plain meaning. "Lower" simply means less than. "Statistically significantly" carries a much more precise meaning than "lower"; the result must be mathematically consistent to varying degrees of probability and not merely aberrational. Sandoz's expert, Dr. Harmut Derendorf, explains that an ordinary person skilled in the art of pharmacokinetics would treat the term "lower" as meaningless. Just because an ordinary person skilled in the art would denigrate a term or scoff at its inclusion does not automatically mean that such a person would not understand that term's meaning in the claim. The term has some meaning, even if it is less helpful than Dr. Derendorf would like to see. Although imprecise, "lower" excludes a C-max that is higher". Had Abbott intended for statistical significance to be a limitation in claim 4 it would have easily added such language, as it did in claim 1.
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B. Lowering or Maintaining Lowered Serum Parathyroid Hormone

Defendants contend that the phrase "lowering or maintaining lowered serum parathyroid hormone" is sufficiently straightforward, and need not be construed by the Court. Plaintiffs propose construing the phrase as "reducing elevated blood concentrations of parathyroid hormone (PTH) or maintaining blood concentrations of PTH at reduced levels." Plaintiffs' proposed claim construction does three things: (1) it replaces "lowering" and "lowered" with "reducing" and "reduced;" (2) it replaces "serum parathyroid hormone" with "blood concentrations of parathyroid hormone"; and (3) it adds that the reduction pertains to elevated concentrations of PTH.

With respect to Plaintiffs' first two proposals, the parties agree that Plaintiffs' substituted terms are synonyms for the claim terms (i.e., that "lower" and "reduce" are synonymous, and that "serum parathyroid hormone" and "blood concentrations of parathyroidhormone" are synonymous). They simply debate the usefulness of Plaintiffs' proposed substitutions.

The Court declines to construe the terms "lowering" and "lowered." The Federal Circuit has recognized that "district courts are not (and should not be) required to construe every limitation present in a patent's asserted claims." O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd., 521 F.3d 1351, 1362 (Fed. Cir. 2008); see also Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1349 (Fed. Cir. 2001) (finding no error in refusal to construe claim term); Mentor H/S, Inc. v. Med. Device Alliance, Inc., 244 F.3d 1365, 1380 (Fed. Cir. 2001) (finding no error in court's refusal to construe "irrigating" and "frictional heat"). The purpose of claim construction is to resolve "disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997). Where the construction of a claim term does nothing to clarify or explain the patentee's invention, the court is under no obligation toconstrue the claim. See id. (claim construction "is not an obligatory exercise in redundancy"). The Court recognizes that "[w]hen the parties present a fundamental dispute regarding the scope of a claim term," it has a "duty to resolve it." O2

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Micro Intern. Ltd., 521 F.3d at 1362. But here Plaintiffs do not contend that construing "lowering" and "lowered" as "reducing" and "reduced" affects the scope of the claim. As they are used in claim 7, the words lowering and lowered -- two commonplace terms -- are not ambiguous; their ordinary meaning applies. Therefore, the Court will not construe the terms lowering and lowered. See Biotec Biologische, 249 F.3d at 1349 (finding no error in court's refusal to construe "melting" where its "ordinary meaning" applied).

By contrast, the Court finds that the second component of Plaintiffs' proposed construction -- namely, the substitution of the phrase "serum parathyroid hormone" with the phrase "blood concentrations of parathyroid hormone" -- does help to clarify the patentee's claim. The ordinary meaning of the phrase "serum parathyroid hormone" is not immediately apparent to the Court. Plaintiffs' proposed construction -- the accuracy of whichDefendants do not challenge -- clarifies that "serum parathyroid hormone" refers to the concentration of parathyroid hormone in the blood. The construction of "serum parathyroid hormone" as "blood concentrations of parathyroid hormone" also is consistent with the '116 patent specification. See '116 patent, col. 4, lines 57-60 ("the present invention relates to therapeutic methods for lowering the excessively high blood levels of parathyroid hormone (PTH) which are secondary to end stage renal disease"). Therefore, the Court construes "serum parathyroid hormone" as "blood concentrations of parathyroid hormone."

Finally, the parties dispute whether claim 7 should be construed as stating a method for treating patients with "elevated" PTH levels or "substantially elevated" PTH levels. The specification appears to support each proposed construction, as it refers to both "elevated" and "excessively high levels of" PTH. See '116 patent, col. 5, ll. 1-7 ("In accordance with the invention, it has been found that when the analogs of formula (I) are administered to end stage renal disease patients with elevated serum parathyroid hormone, PTH concentration is lowered") (emphasis added); id., col.4, ll. 57-60 ("the present invention relates to therapeutic methods for lowering the excessively high blood levels of parathyroid hormone (PTH) which are secondary to end stage renal disease") (emphasis added).

Patent claims are not to be "read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Prima Tek II, L.L.C. v. Polypap, S.A.R.L., 412 F.3d 1284, 1289 (Fed. Cir. 2005) (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotations and citation omitted)). Here, the language of the specification evinces no clear intention to limit the scope of the claim to the treatment of patients with substantially elevated levels of PTH. Thus, the Court construes claim 7 as claiming a method for treating patients with "elevated" PTH levels.

In sum, the Court construes the phrase "lowering or maintaining lowered serum parathyroid hormone" as "lowering elevated blood concentrations of parathyroid hormone ("PTH") or maintaining lowered blood concentrations of PTH."
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(1) "Lubricant"

236. Bristol contends that the term "lubricant" must be limited to an excipient which, by itself, reduces the ejection forces during tableting of a particular pharmaceutical formulation, and which is present on the surface of the tableting mass during compression in the tablet press so that it can function in that capacity.

237. Teva asserts that one does not have to show that an excipient in a particular formulation accomplishes its lubricating function by itself.

238. While the patent does not explicitly define "lubricant," the specification defines its implicitly by its function. No additional requirement that a lubricant be able to lubricate in the absence of other lubricants is implied from the specification. (supra P 121).

239. The plain and ordinary meaning of "lubricant" does not exclude excipients that function as lubricants when in combination with other lubricants. (supra P 126).

240. The Court construes "lubricant" as follows: an excipient which, by itself or in combination with another excipient, reduces the ejection forces during tableting of a particular pharmaceutical formulation, and which is present on the surface

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of the tableting mass during compression in the tablet press so that it can function in that capacity.
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IV

Representative of the claims of the '890 patent, claim 1 is directed to "[a] lubricating oil composition suitable as a crankcase lubricant in internal combustion engines comprising" (1) a major amount of lubricating oil, (2) an ashless dispersant (i.e. one that neither contains nor is complexed with metal) in specified amounts of "about 1 to 10 wt. %", (3) from about 0.01 to 5.0 parts by weight of oil soluble ZDDP, (4) 5 to 500 parts per million by weight of added copper in the form of an oil soluable copper compound, and (5) magnesium or calcium detergent. n3

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n3 The full text of claim 1 is set forth in the appendix to this opinion. Claim 61 of the '890 patent is drawn to a lubricating oil concentrate composition suitable for use in preparing crankcase lubricants. That claim, like claim 1, has specific quantity limitations for the ingredients, including the ashless dispersant ingredient. However, claim 61 does not require a "major amount" of lubricating oil (it requires "a lubricating oil," without specific amount), and it requires 10 to 60 wt. of ashless dispersant. Both claims were submitted to the jury.

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The subject of claim interpretation was argued to the judge at the close of Exxon's case and was considered again in extensive argument at the close of all the evidence. At the conclusion of the arguments, the judge decided that Exxon was correct in its view of the claims' meaning. The parties did not contend that the claims of the '890 patent are process claims drawn to a specified manner of manufacture, and the claims as written could not have such meaning. Nor are the claims said to be, or could they be, product-by-process claims. The claims of the '890 patent are drawn to a particular composition: they are product claims. According to Exxon, its claims cover any product that is made by using the specific ingredients identified in the limitations of claim 1. n4 During the trial, Exxon's claims were thus said to be to a "recipe" for making the composition. Whether the specified ingredients could be found in the actual composition produced by mixing the ingredients is, according to Exxon, simply irrelevant to the meaning of the claims. To emphasize this point, Exxon's counsel stated -- both to the trial judge and this court -- that Exxon's claims will cover a composition that has the added copper regardless of whether any ashless dispersant can be found in the mixture. In short, in Exxon's view the claimed "recipe" for making the claimed product is the claimed product.

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n4 If the claim is defined solely by the starting ingredients, a product actually containing all the specified ingredients would seem to escape at least literal infringement if produced by the combination of different ingredients. Such is at odds with the doctrine that a product claim is infringed by any product containing every claim limitation, regardless of how the product is made. See Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535, 19 U.S.P.Q.2D (BNA) 1367, 1369 (Fed. Cir. 1991); see also 2 Donald S. Chisum, Patents § 8.05 at 8-79 (1994) (collecting cases). Under Exxon's view, its claims also would seem not to reach a product made with a nonashless dispersant starting ingredient that is somehow rendered ashless during manufacture, if such a rendering is chemically possible.

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The trial judge charged the jury accordingly:
I instruct you that Exxon's claims cover the ingredients which go into the composition. If you find that Exxon has proved that a Lubrizol product is made by using the starting ingredients in the amounts called for in one or more of Exxon's claims, then that product directly infringes.

The issue of claim interpretation had been raised first by Lubrizol in its motion for a directed verdict at the close of Exxon's case, which the judge denied. The issue was raised again by Lubrizol's motion for judgment as a matter of law at the close

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of all the evidence, also denied by the judge. The charge to the jury on claim interpretation was also challenged by Lubrizol, both before the case was submitted to the jury and by the post trial motion for judgment as a matter of law.

As noted above, Exxon's claims are drawn to a specific product which has particularly defined ingredients. Nothing in the claims, the specification, or the prosecution history suggests that Exxon's claims are not drawn to a product that contains particular ingredients. Indeed, to the contrary, the title to the '890 patent reads, with the emphasis added, "Lubricating Oil Compositions Containing Ashless Dispersant, [ZDDP], Metal Detergent and a Copper Compound". See Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 780, 227 U.S.P.Q. (BNA) 773, 777-78 (Fed. Cir. 1985) (referring to patent's title as interpretative aid). The language of claim 1 refers to "added" copper and to a detergent "additive." The specification demonstrates that those claim references aim at a chemical composition to which ingredients are being introduced. We must give meaning to all the words in Exxon's claims. In re Sabatino, 480 F.2d 911, 913, 178 U.S.P.Q. (BNA) 357, 358 (CCPA 1973) ("Claim limitations defining the subject matter of the invention are never disregarded.") In addition, the text of the '890 specification includes over twenty references to "containing" in reference to the ingredients claimed in the composition. Furthermore, during prosecution of the applications that resulted in the '890 patent, Exxon repeatedly emphasized that the genius of its invention lay "in the previously unknown synergism of this material [copper] with ZDDP in the presence of an ashless dispersant of the type described in the application . . . ."

In sum, a review of the claims, the specification, and the prosecution history all point to the conclusion that Exxon claims a product, not merely a recipe for making whatever product results from the use of the recipe ingredients. This conclusion respects that which is claimed, namely a chemical composition. The chemical composition exists at the moment the ingredients are mixed together. Before creation of the mixture, the ingredients exist independently. The particular proportions specified in the claims simply define the characteristics of the claimed composition.

Under Lubrizol's view of the claims, as asserted at trial and on appeal, the composition claimed by Exxon is limited to the final product made and ready for use in the engine environment. Lubrizol is correct that the claims read on a product, not simply a recipe, but Lubrizol errs in thinking that the claims read only on end product compositions. Lubrizol thus asserts a claim meaning that depends upon the time at which one views the composition claimed. The specification as a whole, and the claims in particular, contain no temporal limitation to the term "composition." Indeed, claim 61 reads on a concentrate for preparing lubricants, which is hardly a product ready for consumer end use. The composition of claim 1, once its ingredients are mixed, is a composition existing during manufacture that is being used to produce the end product. Consequently, as properly interpreted, Exxon's claims are to a composition that contains the specified ingredients at any time from the moment at which the ingredients are mixed together. This interpretation of Exxon's claims preserves their identity as product claims, and recognizes as a matter of chemistry that the composition exists from the moment created. Although Lubrizol is correct in taking Exxon's claims to read on a product, its interpretation of Exxon's claims is too narrow. Exxon is entitled to a broader scope that is not time-limited, one that reads on any product at any time that contains the claimed proportions of ingredients. The correct interpretation simply affords Exxon a wider range of product on which to assert infringement. Indeed, Exxon even took advantage of the correct interpretation during trial. When defending its case under Lubrizol's claim interpretation, Exxon did not introduce evidence that Lubrizol's final product infringed. Instead of offering evidence that analyzed the components of Lubrizol's final product, Exxon's witnesses testified to the reaction that occurs when the Lubrizol product is in the process of being made into the final product. According to Exxon's witnesses, that reaction did not result in complete elimination of ashless dispersant in the product. Exxon thus did not focus on Lubrizol's final product to prove infringement. Exxon adopted the broader view and described the infringing activity as occurring while the claimed ingredients were undergoing chemical reactions, necessarily a time before the final product, ready for sale, exists.

We thus hold that the judge erred as a matter of law in giving Exxon's preferred claim interpretation to the jury, and in using that interpretation in ruling on Lubrizol's post trial motion. Under the proper charge, the jury would not have been asked if Lubrizol used Exxon's starting ingredients. Instead, the jury would have been asked to find whether Exxon had proved by a preponderance of the evidence that Lubrizol's products at some time contained each of the claimed recipe ingredients in the amounts specifically claimed.

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CONCUR BY: PLAGER

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CONCUR: PLAGER, Circuit Judge, concurring.

I join in the reversal of the trial court's judgment of infringement, based on what I consider to be the correct claim interpretation as advanced by Judge Clevenger, and the consequences that flow therefrom.

There is testimony in the record that indicates that it is not known exactly how the chemical complexing, described in the opinion, actually works. If this is so, then Exxon's burden, to prove that the chemical ingredients exist at some point in the accused composition in the claimed proportions, may be impossible of accomplishment. That could be said to argue in favor of an alternative construction of the claims, that what was meant was a process or product-by-process claim. The difficulty with that argument is that the claims, as the opinion well demonstrates, are unquestionably composition of matter claims. In retrospect, it would appear that Exxon wishes it had product-by-process claims, and thus a "recipe." But we are not free to read the claims as they might have been drafted, even if as drafted they do not accomplish what the inventor may have intended.

Claim drafting is itself an art, an art on which the entire patent system today depends. The language through which claims are expressed is not a nose of wax to be pushed and shoved into a form that pleases and that produces a particular result a court may desire. The public generally, and in particular, the patentee's competitors, are entitled to clear and specific notice of what the inventor claims as his invention. That is not an easy assignment for those who draft claims, but the law requires it, and our duty demands that we enforce the requirement. There is no room in patent claim interpretation for the equivalent of the cy pres doctrine; that would leave the claiming process too indefinite to serve the purposes which lie at the heart of the patent system.
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DISSENT BY: NIES

DISSENT: NIES, Circuit Judge, dissenting.

Contrary to conventional wisdom in the art, Exxon discovered that small amounts of copper in automobile motor oil acts as an antioxidant, and it developed a highly successful commercial product using that discovery. The record discloses that Lubrizol learned of the presence of copper in Exxon's motor oil from Exxon's U.K. patent application and used the disclosure to prepare a competitive product. Both companies now use copper in the vast majority of their passenger car motor oil formulations. Following this phase of the litigation finding Lubrizol liable for infringement of Exxon's U.S. Patent No. 4,867,890, Exxon was awarded $ 48,000,000 in damages which were doubled for willfulness and $ 8,700,000 in interest plus $ 23,700,000 in attorney fees. n1

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n1 Appeal No. 94-1309 challenging the amount of damages is mooted by the majority decision.

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The issue of infringement essentially comes down to whether Exxon drafted a claim in its U.S. patent that covers its invention. The majority interprets the claims to require that each of the listed additives to a motor oil must retain its pre-mix identity, to the extent that each must be present in the claimed proportions at some point after mixing. Because Exxon failed to prove that the additives remained identifiable (in those proportions) in Lubrizol's product at some time during or after mixing, the majority reverses the judgment of infringement. I agree with the trial court that Lubrizol infringes. Lubrizol's motor oil contains the required additives in the required amounts. To hold that the final product does not "comprise" those ingredients because of their possible reaction with each other upon mixing seems to me nothing short of double speak. The claims can be interpreted as the majority does only by reading them in isolation from the context of the patent. Moreover, the majority's interpretation gratuitously provides grounds for invalidation of the patent under section 112, because the specification does not describe nor enable one skilled in the art to make a product containing the claimed ingredients in the claimed amounts except as starting ingredients, not mixed ingredients. n2

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n2 Paragraph 1 of 35 U.S.C. § 112 (1988) states, in relevant part: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same. . . ."

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The majority focuses principally on the claimed "ashless dispersant" which must remain in its view "ashless" in the required amount in the composition. I interpret "ashless dispersant" as simply the name or designation of an ingredient required as one of the additives. It does not mean the ingredient must remain inert.

As stated in Adams v. United States, 383 U.S. 39, 49, 148 U.S.P.Q. (BNA) 479, 482, 15 L. Ed. 2d 572, 86 S. Ct. 708 (1966), "it is fundamental that claims are to be construed in light of the specifications and both are to be read with a view to ascertaining the invention." Moreover, claims should be "construed, if possible, as to sustain their validity." North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1577, 28 U.S.P.Q.2D (BNA) 1333, 1337 (Fed. Cir. 1993).

Applying those precepts warrants an affirmance in this case. My concern is, however, not merely this case. The majority mandates technical rules for how chemical compositions must be claimed which I reject.

I.

Infringement here turns on interpreting claims 1 and 61. Claim 1 is directed to "a lubricating oil composition" comprising: (a) a major amount of lubricating oil; (b) a specified amount of dispersant (either about 1-10 wt. percent of an ashless dispersant n3 or about 0.3-10 wt. percent of a "polymeric viscosity index improver" n4); (c) about 0.01 to 5.0 parts by weight of zinc dihydrocarbyl dithiophosphate ("ZDDP"); (d) about 5 to about 500 parts per million by weight of added copper in the form of an oil soluble copper compound; and (e) a calcium or magnesium detergent. Claim 61 claims a "lubricating oil concentrate composition" comprising the same five ingredients in different, specified amounts.

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n3 "Ashless" denotes an absence of combined or complexed metal. Lubrizol's Dr. Salomon testified that "it is easier from a manufacturing point of view to manufacture it in the ashless form." She added that "as a formulator, I don't care [if it is ashless or non-ashless in the product] where I have some surprising discovery that affects performance. But it doesn't matter to me. . . . Typically, most dispersants are made ashless from a manufacturing point of view."

n4 The polymeric viscosity index improver ("PVII") is not at issue here, inasmuch as the challenged Lubrizol products are alleged to use the ashless dispersant, not the PVII. Henceforth, this opinion will not mention PVII.

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The trial judge interpreted those claims for the jury, instructing them as follows:
I instruct you that Exxon's claims cover the ingredients which go into the composition. If you find that a Lubrizol product is made by using the starting ingredients in the amounts called for in one or more of Exxon's claims, then that product directly infringes.

Lubrizol argues that that instruction is wrong. It maintains that, regardless of what ingredients are mixed together, there is infringement only if the final lubricant composition contains the five claimed ingredients, in the claimed amounts. Thus, although it is essentially uncontested that Lubrizol adds ashless dispersant and the other claimed ingredients in the claimed amounts to its motor oil, Lubrizol argues that there is no infringement because it was not proved that "ashless" dispersant, in the claimed amount, was present in its final products. Specifically, it urges, the ashless dispersant that it uses in admixture with the other ingredients specified in the claims complexes with metal moieties from those ingredients so that the dispersant in the final product can no longer be considered "ashless."

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Exxon, on the other hand, urges that the trial judge's instruction reflects the proper claim interpretation that ashless dispersant identifies a starting ingredient, and under that interpretation, it does not matter what complex forms between metal and the dispersant.

The majority opinion interprets the claims somewhere between the interpretations of Exxon and Lubrizol, as covering any mixed product--final or otherwise--in which the five ingredients specified in the claims exist in the claimed amounts. The majority accepts Lubrizol's proof that at least some ashless dispersant is converted to nonashless dispersant during production of Lubrizol's products, and because of that, proving that the required amounts of the five ingredients were mixed is not enough to prove infringement. Consequently, to show infringement, the majority believes that it was Exxon's burden to prove that, at some point during production of Lubrizol's products, the mixing pot contained the claimed amounts of "ashless dispersant" and the other four claimed ingredients. And, the majority concludes, Exxon has not introduced enough evidence in the record to meet that burden.

I agree with the trial judge's interpretation of the claims that one skilled in the art, upon reviewing the patent specification, claims, prosecution history, and testimony, would interpret claims 1 and 61 as covering a lubricating oil composition comprising the product resulting from a combination of the required five ingredients, in the claimed amounts, regardless of any unknown reactions, or metal complexes formed between those ingredients that occurs upon mixing. With that interpretation, literal infringement is admitted.

A. Claim Interpretation In General

To determine the meaning of claims, we must examine the patent specification, other claims, and the prosecution history. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995) (in banc). Resort to testimony of those knowledgeable in the art might also be helpful to the court inasmuch as claims are interpreted from the perspective of one of ordinary skill in the art. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 882, 8 U.S.P.Q.2D (BNA) 1468, 1471 (Fed. Cir. 1988).

B. The Specification and Claims

The patent specification discusses the invention in terms of an additive for motor oil which does not interfere with the function of other additives. The particular focus is on addition of the copper compound as an antioxidant and the amount of it that is employed. Moreover, the amounts specified in the working examples and other parts of the specification are identified as the amount of the additives, not the amounts in the final product after mixing. There is no analysis anywhere in the specification of the identity of intermediate or final "complexation" products produced by combining the ingredients specified in the claims, or of their amounts. In light of those omissions, to say that one of ordinary skill in the art would nevertheless conclude that the proportions must be measured in the pot is divorced from reality.

The interpretation that the claims list starting ingredients is bolstered by comparing the many nonborated, ashless dispersants disclosed at columns 6-8 of the patent, and expressly included in the claims, with the one type of dispersant--the borated version of certain ashless dispersants--that the parties agree does not complex with the metal moieties from the other ingredients specified in the claims. Because the nonborated, ashless dispersants do not remain completely ashless when mixed with the other ingredients specified in the claims, under the majority's interpretation the claims would not cover use of such dispersants if a sufficient amount thereof complexed with metal to form nonashless dispersants. Yet, it is those nonborated dispersants to which the specification and claims are primarily directed. n5 Consequently, the majority interpretation limits coverage to far fewer dispersants than indicated by the specification and claims.

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N5 Borated ashless dispersants are discussed at column 8, lines 43-50 of the '890 specification and are used in the four working examples. Of the 83 claims in '890, claims 7, 14-24, 30, 37-60, 65, and 72-82 specifically mention the borated, as well as other, dispersants.

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Moreover, the '890 specification does not describe nor teach the invention contemplated by the majority's claim

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interpretation, i.e., it does not teach the types of dispersant, the amounts thereof, or the conditions needed to attain a composition containing--after complexation--the amounts of ingredients specified in the claims. Although, under the majority's interpretation, the specification would be enabling for the claimed borated dispersants (because they do not complex), those dispersants constitute only a small portion of the disclosed and claimed dispersants. Hence, formulating the composition as interpreted by the majority, even if within ordinary skill in the art, would require extensive experimentation not even suggested in the patent, thereby rendering the claims invalid. n6

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n6 See generally Genentech, Inc. v. The Wellcome Foundation Ltd., 29 F.3d 1555, 1564-65, 31 U.S.P.Q.2D (BNA) 1161, 1168 (Fed. Cir. 1994) (rejecting a claim interpretation that covers many inoperative permutations); Atlas Powder Co. v. E.I. duPont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 U.S.P.Q. (BNA) 409, 414 (Fed. Cir. 1984) ("if the number of inoperative combinations becomes significant, and in effect, forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid"); Raytheon Co. v. Roper Corp., 724 F.2d 951, 956, 220 U.S.P.Q. (BNA) 592, 596 (Fed. Cir. 1983) ("Because it is for the invention as claimed that enablement must exist, and because the impossible cannot be enabled, a claim containing a limitation impossible to meet may be held invalid under § 112."), cert. denied, 469 U.S. 835, 83 L. Ed. 2d 69, 105 S. Ct. 127 (1984).

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C. Prosecution History

As does the specification, the prosecution history focuses on the additives as starting ingredients, not on any reaction products (and the amounts in a final or intermediate product). As an example, the Examiner's Answer prepared with respect to appeal of the examiner's rejection of the claims in Application Ser. No. 362,114 (which was the grandparent of Application Ser. No. 49,712, the application resulting in the '890 patent), states:

The claims are believed to be directed to the composition comprising known additives, combined at conventional levels of additions for their combined attendant functions.

And in the Reply Brief to that Examiner's Answer, the applicants state:

The question should be whether the specific combination of additives claimed by Appellants is novel, and gives it unobvious results. The answer is the combination is novel and the combination does give unexpected results.

And elsewhere during prosecution of that application, and of SN 049,712, the examiner refers to "the various additives of the claims (dispersants . . . dithiophosphates . . .)."

Exxon's interpretation is also supported by the following episode. SN 362,114 included both claim 37, which referred to a "copper compound," and claim 38, which was to a "composition according to claim 37, said copper compound being oil soluble." Claim 38 was rejected because it duplicated claim 37. n7 The examiner took the position that the copper compound must be oil soluble--hence, "copper compound" and "oil soluble copper compound" are the same. The applicants, however, argued that "one can have a solution of a dispersant complexed with an oil insoluble copper compound, or can have an oil soluble [copper] compound" (emphasis added). Similar debate transpired during prosecution of Application SN 177, 367, the parent of SN 362,114. The Board agreed with applicants. n8

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n7 Paragraph 2 of 35 U.S.C. § 112 (1988), states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

n8 The Board noted that the examiner had not yet raised an "insufficient disclosure" rejection (under 35 U.S.C. § 112, P 1). That rejection was subsequently raised, in the context of rejecting claims 15-17 of SN 049,712 on the specific ground of insufficient support in the specification for an oil insoluble copper compound. Those claims were eventually dropped by applicants.

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The argument made during prosecution that some of the claims read on embodiments wherein the copper complexes with the ashless dispersant is probative of Exxon's claim interpretation as well as that of the examiner. Specifically, it shows the claim is directed to a product with "ashless" dispersant as a starting ingredient, inasmuch as some of the claims covered formation of a complex between that dispersant and metal, a formation that would render the dispersant "non-ashless". Significantly, the examiner found no flaw in claiming a motor oil product with additives as set out in Exxon's claim here (and I note in its foreign applications as well).

D. Other Considerations

The record includes testimony by Exxon witnesses that it is not known how copper serves as an antioxidant in the environment of the claimed composition, that certain reactions are not predictable in that environment, even though they might be predictable in a model, that it is uncertain whether zinc or phosphorus of ZDDP undergoes interaction, and in general, that no one was certain of the exact identity of the final composition or what was happening in the pot. Despite that, the majority holds applicants responsible for knowing about the formation of a complex between the five ingredients required by the claims. In effect, therefore, the majority opinion penalizes applicants for not knowing or caring about exactly how their invention works.

But, "it is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests." Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570, 219 U.S.P.Q. (BNA) 1137, 1140 (Fed. Cir. 1983); accord In re Isaacs, 52 C.C.P.A. 1791, 347 F.2d 887, 892, 146 U.S.P.Q. (BNA) 193, 197 (CCPA 1965). As stated in Diamond Rubber Co. v. Consolidated Rubber Tire Co., 220 U.S. 428, 435-36, 55 L. Ed. 527, 31 S. Ct. 444 (1911):

And how can it take from his merit that he may not know all of the forces which he has brought into operation? It is certainly not necessary that he understand or be able to state the scientific principles underlying his invention, and it is immaterial whether he can stand a successful examination as to the speculative items involved. [Citations omitted.]

In that respect, Frank Johmann, who helped prosecute the relevant applications for Exxon, stated:
[When looking at an invention like this with a number of components, to determine infringement] . . . you look at what is combined to make the product. The reason for that is that the patent law doesn't require that you understand what happens to that final product. All that is necessary is how you obtain the result. And it is sort of like baking a cake. You mix them together. And what happens chemically in the oven, you are not concerned with. With these compositions, what happens in the engine no one really knows and it is not a consideration.

Mr. Johmann stated that he has "seen probably literally thousands of lubricant patents over the years, and this is like a standard format for a composition." Id. Thus, claiming the composition in terms of amounts of additives is "a typical way it is done in connection with motor oil additives." Id. Though Mr. Johmann was a patent practitioner, as opposed to a scientist skilled in the art, he adds to the record the perspective of one who has seen many patents in this field, and by shedding some light on how claims have been written in the field, he helps illuminate how one skilled in the art would read the '890 claims.

Furthermore, when Lubrizol asked its own employee, Mr. Pindar, in 1988 to determine whether certain of its products infringed the European counterpart of '890, he performed the analysis by comparing the starting ingredients, not the final or intermediate products. n9 Mr. Pindar, who was a scientific advisor to Lubrizol, read the claims as a person of skill in the art would read the claims. Moreover, Dr. Salomon, a lubricant formulator working for Lubrizol, testified (although not in the specific context of interpreting claim language) that her concern as a formulator is "what goes in the pot."

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n9 Mr. Pindar's claim infringement charts were made of record and analyzed by witnesses.

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Lubrizol argues that Exxon's omission of the word "mixture" from the '890 claims precludes interpretation of the claims as a

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list of starting ingredients. This is indeed a slender reed on which to lean. "Mixture" is implied in the composition claims at issue, because by listing five "additives," the claim implies that coverage is for a mixture of those. Thus, Exxon is claiming a "composition of matter," which:

". . . is an instrument formed by the intermixture of two or more ingredients, and possessing properties which belong to none of these ingredients in their separate state. . . . The intermixture of ingredients in a composition of matter may be produced by mechanical or chemical operations, and its result may be a compound substance resolvable into its constituent elements by mechanical processes, or a new substance which can be destroyed only by chemical analysis." [Footnote omitted.]

Walker notes that "this class is a very broad one and embraces chemical compounds, mechanical or physical mixtures, alloys and a great variety of things." [Footnote omitted.]

1 Chisum, PATENTS, § 1.02[2] at 1-10 (1995) (quoting from W. Robinson, The Law of Patents for Useful Inventions 278-79 (1890)).

E. Conclusion

Lubrizol added to its motor oil the ingredients taught by the specification, and articulated in the claims, of Exxon's '890 patent. Lubrizol then sought to avoid infringement by arguing at trial that the claims are not literally infringed because metal ions from some of the ingredients complex with the ashless dispersant specified in the claims, converting "ashless dispersant" to nonashless dispersant. That argument was unsuccessful under the district court's claim interpretation, but it has succeeded on appeal under the majority's claim interpretation.

The majority and concurring opinions seem to be of the view that, if Exxon wanted to claim a lubricating oil composition formed by combining the five ingredients specified in the claims, it made a technical error in writing the claims. The majority would require a product by process claim to cover a product comprising a formula of starting ingredients even though the claim requires no particular method of mixing or particular process steps. It is not a "recipe" with specific directions for making the product. Certainly the examiner found nothing technically wrong with the claim as a list of additives for motor oil. In the view of an experienced claim drafter, Mr. Johmann, this is a standard form for such a product. I am of the view that, to one of ordinary skill in the art, the claims as written cover a product, not a method. n10 Consequently, I disagree with the majority and would affirm the district court's judgment of liability.

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n10 The majority, in its footnote 3, questions whether the claims as so interpreted would be literally infringed if one of the "starting ingredients" is made in situ. That issue is not before us, but it appears to me that there would be literal infringement in such a circumstance because the product formed "in situ" itself can be considered a "starting ingredient".

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b. "the luminal portion of the tunica mucosa"

ACell argues that the district court erred in construing the term "the luminal portion of the tunica mucosa." ACell asserts that this term was defined by the patentee through the '389 patent's incorporation by reference of the procedure for preparing intestinal submucosa as detailed in U.S. Patent No. 4,902,508 (the "'508 patent"). According to ACell, the '508 patent specification defines "the luminal portion of the tunica mucosa" as "layer G" which includes the lamina epithelialis mucosa (or the epithelium layer) and its lamina propria. Thus, ACell asserts that the term "the luminal portion of the tunica mucosa" in the '389 patent should be given the same meaning, i.e., the epithelium layer and the tunica propria 5 layer.

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5 The parties and patents at issue refer to this layer as the tunica or lamina propria and either reference is understood to refer

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to the same tissue layer.

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Appellees argue in response that the phrase "at least the luminal portion of the tunica mucosa" does not require a special definition and accuse ACell of "fishing" for a special definition. Further, appellees assert that there is no basis for importing a definition, even assuming the term is defined as ACell alleges, of the term from the '508 patent into the '389 patent because the '508 patent is directed to SIS whereas the '389 patent is directed to UBS. Appellees assert that the district court's construction of the term as "the epithelial cells" should be affirmed.

The phrase "urinary bladder submucosa" is present in all three claims at issue. Based on our construction of that term as meaning "urinary bladder submucosa delaminated from . . . at least the luminal portion of the tunica mucosa," our construction of "the luminal portion of the tunica mucosa" applies to all three claims with equal force. We begin with the representative claim language from claim 1 of the '389 patent, which states:

1. A composition comprising urinary bladder submucosa delaminated from both the abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of a urinary bladder of a warm blooded vertebrate.

'389 patent, col. 5, ll. 20-23 (emphases added). The '389 patent specification informs our inquiry into the meaning of the claims. The "BACKGROUND AND SUMMARY OF THE INVENTION" section discloses that "[t]he wall of the urinary bladder is composed of the following layers: the tunica mucosa (including a transitional epithelium layer and the tunica propria), a submucosa layer, up to three layers of muscle and the adventitia (a loose connective tissue layer)--listed in thickness crossection from luminal to abluminal sides." Id. at col. 1, ll. 49-55. The "DETAILED DESCRIPTION OF THE INVENTION" section sheds considerable light on the issue before us. It states:

The preparation of UBS from a segment of urinary bladder is similar to the procedure for preparing intestinal submucosa detailed in U.S. Patent No. 4,902,508, the disclosure of which is expressly incorporated herein by reference. A segment of urinary bladder tissue is first subjected to abrasion using a longitudinal wiping motion to remove both the outer layers (particularly the abluminal smooth muscle layers) and the luminal portions of the tunica mucosa layers--the epithelial layers). The resulting submucosa tissue has a thickness of about 80 micrometers, and consists primarily (greater than 98%) of a cellular, eosinophilic staining (H&E stain) extracellular matrix material.

Id. at col. 2, ll. 17-28 (emphasis added). That paragraph makes clear that "the luminal portions of the tunica mucosa layers" 6 were defined by the patentee as the "epithelial layers" and that "the procedure for preparing intestinal submucosa" as detailed in the '508 patent is expressly incorporated by reference into the '389 patent specification.

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6 While we recognize that the phrase in the specification refers to the luminal portions and the claim language refers to the luminal portion, this section of the specification sheds the most light on how the patentee chose to define the claim term.

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The term "epithelial layers" may arguably be subject to two interpretations. On the one hand, it refers to "layers" which appears to reflect that it was meant to encompass more than just the transitional epithelium layer, i.e., the transitional epithelium layer and the tunica propria layer, the only other layer that the '389 patent teaches is part of the tunica mucosa. See id. at col. 1, ll. 51-52. On the other hand, as recognized by the district court, the epithelium in the urinary bladder is made up of multiple layers of epithelial cells. Markman Order, slip op. at 10. Even accepting that the disclosure in the '389 patent specification itself is less than clear as to which interpretation is correct, the second important disclosure of the '389 specification is dispositive. As noted, the '389 patent specification expressly incorporates by reference the procedure for preparing intestinal submucosa from the '508 patent.

"Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) (citations omitted). "To incorporate material by reference, the host document must identify with detailed particularity what

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specific material it incorporates and clearly indicate where that material is found in the various documents." Id. (citations omitted). Whether and to what extent material has been incorporated by reference into a host document is a question of law. Id.

The relevant portions of the '508 patent specification are as follows:

Layers E, F, and G collectively represent the so-called tunica mucosa. Layer E is a layer of smooth muscle cells known as the lamina muscularis mucosa. Layer F, the stratum compactum, consists of a cellular collagen and elastin fibers. Layer G consists of the lamina epithelialis mucosa and its lamina propria, which together and arranged in villous processes, a series of finger-like outgrowths of the mucous membrane.

. . . .

The tissue graft material of this invention is prepared by abrading intestinal tissue to remove the outer layers including both the tunica serosa and the tunica muscularis (layers B and C in FIG. 1) and the inner layers including at least the luminal portion (layer G) of the tunica mucosa (layers E through G in FIG. 1).

'508 patent, col. 3, ll. 13-20, 53-58 (emphases added).

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Id. at fig. 1.

As this disclosure makes clear: (1) "the luminal portion of the tunica mucosa" is represented by "layer G" in Figure 1 of the '508 patent, and (2) layer G in that figure corresponds to the lamina epithelialis mucosa and its lamina propria. Id. Even acknowledging appellees' argument that the layers of the wall of the intestine are somewhat structurally different than the layers of the wall of the bladder, neither party disputes that the basement membrane of the transitional epithelium is located between the epithelialis mucosa layer and its lamina propria layer in both organs. Thus, because the basement membrane is located between the two tissue layers explicitly identified, "the luminal portion of the tunica mucosa" must also refer to the basement membrane. Therefore, "the luminal portion of the tunica mucosa" means the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria.

The '389 patent's incorporation by reference of the '508 patent's procedure for preparing intestinal submucosa, in combination with the '508 patent's disclosure pertaining to which tissue layers are removed by that procedure, leads to the conclusion that the patentee's definition of the claim term as reflected in the '389 patent as the epithelial layers and in the '508 patent as the lamina epithelialis mucosa and its lamina propria was intended to refer to the same structures, i.e., the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria.

The district court's reasoning is contradicted by its own analysis. Relying on a medical dictionary, the district court recognized that the tunica mucosa comprises the epithelium, basement membrane, lamina propria mucosae, and lamina muscularis mucosae. Markman Order, slip op. at 10-11. The court then rejected ACell's proposed construction that "the luminal portion of the tunica musoca" means the epithelial cells (i.e., the transitional epithelium), the basement membrane, and the lamina propria because the term "would not require the entire tunica mucosa including the basement membrane, tunica propria and all epithelial cells to be removed as ACell contends." Id., slip op. at 11.

That statement by the district court reflects that it believed ACell's proposed construction of that term encompassed the entire tunica mucosa, rather than just "the luminal portion" as the claim requires. The district court's reasoning, however, overlooks the fact that ACell's construction permits the retention of the lamina muscularis mucosae layer of the tunica mucosa. This construction is consistent with both the medical dictionary's list of layers that comprise the tunica mucosa, and the teachings of the '508 patent, which specifically refer to that layer as "layer E" of the tunica mucosa. '508 patent, col. 3, ll. 14-15. As this discussion indicates, ACell's proposed construction does not require removal of the entire tunica mucosa as the district court's opinion suggests, but rather removal of only a portion of the tunica mucosa. 7 Therefore, we construe "the luminal portion of the tunica mucosa" to mean "the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria."

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7 The district court also relied upon extrinsic evidence in the form of testimony from a Dr. Harbin who convinced the court that there was no compelling reason on the part of Cook to remove the basement membrane, lamina propria, or any other non-cellular component of the bladder wall layers. Markman Order, slip op. at 11. In light of the discussion above, however, such extrinsic evidence cannot override the patentee's definition of the term contained in the intrinsic evidence of the '389 and '508 patent disclosures.

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1. "Lutein"

The parties disagree as to what "Lutein" means for the purposes of measuring lutein purity. Plaintiffs contend that "Lutein" includes all isomers of lutein. As explained by Plaintiffs, "Lutein is lutein." (Doc. # 161 at 15). Defendants, on the other hand, assert that "Lutein" means only "trans-lutein" also known as "e-lutein." In support of this proposition, Defendants note that the inventor defines "lutein" as "trans-lutein" or "e-lutein."

While the '714 patent states at one point, "Unless specified lutein refers to all -E (all-trans) isomer" ('714 patent, Column 1, Lines 40-41), the patent later uses the term "lutein" to refer to all isomers of lutein. ('714 patent, Column 6, Lines 44-45; Column 7, Lines 26-42). 4

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4 The '714 patent has been filed with the Court and is located at Doc. # 163-2.

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Furthermore, the Court realizes that the language of claim 1 uses a depiction of a lutein isomer that happens to be trans-lutein. However, all isomers of lutein bear the same formula. As explained in the report of Steven J. Schwartz, Ph.D., "The '714 patent refers to a formula for lutein that includes all geometrical isomers. An organic chemist of ordinary skill would understand the formula for lutein to include all cis and trans isomeric forms." (Dr. Schwartz Report, Doc. # 164 at 6). The purity calculation should be based on the percentage of lutein and not based only on the percentage of trans-lutein.

The Court adopts Plaintiffs' position on this point. All lutein isomers have the exact chemical formula as claimed in claim 1 of the '714 patent; they differ only in the way those chemical elements are arranged in three-dimensional space. (Doc. # 161 at 15). Thus, "Lutein" as used in claim 1 is all isomers of lutein, and not just "trans-lutein."

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5. "lysis of a chemical bond"

* * *

TheCourt construes "lysis of a chemical bond" to be "breaking a chemical bond." Plaintiff argues the term "lysis" as used in the claim would be understood by one of ordinary skill in the art to mean "breaking." For support, Plaintiff cites a dictionary definition. See Churchill's Medical Dictionary 1087 (1989) (defining "lysis" as "[a]ny form of dissolution, particularly the breaking of membrane-bound structures such as cells"). Defendants argue that the term "lysis" means "hydrolysis." Defendants state that the only structure disclosed in the specification for the treating material is hydrolysis of a chemical bond, and Defendants argue that the inventor merely used "lysis" as shorthand for "hydrolysis" in claim 3.

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The Court agrees with Plaintiff. Aside from claim 3, there is no mention of the word "lysis" in the intrinsic record. Therefore, the Court will consider extrinsic evidence to determine how one of ordinary skill in the art would understand the term "lysis." Plaintiff's dictionary definition supports a construction of the term "lysis" as "breaking." The Court is unconvinced of Defendants' argument that the inventor used "lysis" as shorthand for "hydrolysis" in claim 3. Rather,the inventor used the term "hydrolysis" many times in the specification, and the inventor never used "lysis" as shorthand for "hydrolysis" in the specification. See, e.g., 10:14; 14:61; 15:2. This further shows the inventor knew how to use the word "hydrolysis," so the fact that the inventor did not use the word "hydrolysis" in claim 3 demonstrates the inventor did not mean "hydrolysis" in claim 3. Hence, the Court construes "lysis of a chemical bond" as "breaking a chemical bond."
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3. "macromolecules" (claims 1, 4, 8, 15, and 16)

Plaintiff argues that "macromolecules" should be construed as "molecules having a molecular weight of at least 500." Defendant argues that the term should be construed as "molecules larger than about 500 molecular weight." The specification states that the "cardinal feature" of the patent is its ability to restrain macromolecules. See 7:39-41. The specification further states that "the precise size of the molecules that the minimally-porous sheet can restrain is not important, for the purposes of this invention, the pores should be small enough to restrain molecules greater than around 500 Daltons." 8: 3-6. In light of the intrinsic record, the court defines "macromolecules" as "molecules with a molecular weight of at least approximately 500 Daltons."
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c. "Magnetic or magnetizable"

The parties next dispute the construction of the term "magnetic or magnetizable" in claim 1 of the '196 patent. Ideal asserts that no construction of this unambiguous term is required, even as an alternative to Rivard's proposed construction. Therefore, the chart that follows shows only the claim term and Rivard's proposed construction.

THE '196 PATENT

	Claim Term	Rivard's Proposed Definition
c.	Magnetic or magnetizable	The needle or needle piece has been magnetized to be a permanent magnet that produces a magnetic field, or has been magnetized in a magnetic field to maintain a residual magnetism that produces its own magnetic field that persists when the magnetic field is removed, prior to use of a detector. The term does not refer to stainless steel which is merely attractable to a permanent magnet.

i. Arguments of the parties. Rivard argues that claim 1 refers to stainless steel that is "magnetic or magnetizable," then thereafter refers to the "magnetism" of the needle. Rivard argues that, to be grammatically and substantively consistent, the term "magnetism" must relate back to and be produced by the stated "magnetic or magnetizable" feature of the needle cannula, and that the term "magnetism" does not refer to the mere capacity to be magnetized, but to something that actually operates as a magnet. Rivard also argues that the specification repeatedly refers to a magnetic needle or one that is magnetized before detection and to "magnetic stainless steel." From this language, Rivard apparently infers that "magnetic or magnetizable" means already made a magnet, not merely capable of becoming a magnet. Similarly, Rivard argues that the prosecution history shows (1) that the invention requires the needle to be magnetized not just to have the capability to be magnetized, and (2) that the patentee distinguished prior art that was merely capable of being magnetized and not actually magnetized because non-magnetized prior art needles did not provide increased detectability. Rivard's arguments in its rebuttal brief concerning the "magnetism" terms of the two patents, which were discussed in reference to construction of the "magnetism" terms of the '668 patent, are also asserted as to the "magnetic or magnetizable" terms of the '196 patent. Ideal,

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however, argues that "magnetic or magnetizable" is unambiguous and that the prosecution history reveals no intent to disavow any scope to the term.

ii.Analysis. Beginning with the words of the claim, Nystrom, 424 F.3d at 1142 (courts must "begin [their] claim construction analysis with the words of the claim"), it is apparent that "magnetic or magnetizable" refers to two possible, and different, conditions. See Merck & Co., 395 F.3d at 1372 (the court must construe claims so that no term becomes "superfluous," and "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). The first problem with Rivard's construction, in the court's view, is that it improperly conflates the two stated conditions into a single condition, "magnetic."

The second problem with Rivard's construction of this phrase, in the court's view, is that "magnetic" and "magnetizable" do not have the same ordinary meaning, and nothing in the patent suggests that a specialized meaning conflating the latter term into the former one is appropriate. See Free Motion Fitness, Inc., 423 F.3d at 1348 (recognizing such use of a dictionary as appropriate, citing Phillips, 415 F.3d at 1320); Phillips, 415 F.3d at 1324 ("[A] judge who encounters a claim term while reading a patent might consult a general purpose or specialized dictionary to begin to understand the meaning of the term, before reviewing the remainder of the patent to determine how the patentee has used the term."). More specifically, as to ordinary meaning, in the sense appropriate here from the intrinsic evidence of the patent, see Free Motion Fitness, Inc., 423 F.3d at 1348 ("The court must ensure that any reliance on dictionaries accords with the intrinsic evidence."), "magnetic" means "magnetized or capable of being magnetized," and "magnetize" means "to induce magnetic properties in." See MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 700 (10th ed. 1995). Thus, "magnetic" means having been induced with magnetic properties, see OXFORD ENGLISH DICTIONARY (on-line ed. at dictionary.oed.com) ("magnetic" means, inter alia, "having the properties of a magnet"), and "magnetizable" means "capable of being magnetized." See OXFORD ENGLISH DICTIONARY (on-line ed. at dictionary.oed.com). While the definitions of "magnetic" and "magnetizable" overlap at the broadest definition of "magnetic" as "capable of being magnetized," Rivard argues that the appropriate meaning for both "magnetic" and "magnetizable" is the narrowest meaning of "magnetic" as "magnetized," which is a meaning that the term "magnetizable" simply will not bear. Moreover, in a context where both terms are used in succession, it is appropriate to read them to have different meanings. See Merck & Co., 395 F.3d at 1372 (the court must construe claims so that no term becomes "superfluous," and "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). Thus, applying ordinary meanings, "magnetic" means "magnetized" or "induced with magnetic properties," and "magnetizable" means "capable of being magnetized" or "capable of being induced with magnetic properties."

Returning to intrinsic evidence, the court is unpersuaded by Rivard's argument that the subsequent references to "magnetism" in claim 1 mean that "magnetic or magnetizable" must refer to something that actually operates as a magnet, not to something that merely has the capacity to be magnetized. It is true that claim 1 does not include any limitation requiring that the "magnetic or magnetizable" needle actually be magnetized, even though it later refers to the "magnetism" of the needle. See the '196 patent, claim 1. 16 The subsequent references to "magnetism" in claim 1 are in an extended "so that" clause, which "simply expresses the intended result of a process step positively recited"; consequently, that clause is not given weight and does not state a material limitation in the method claim. Cf. Hoffer v. Microsoft Corp., 405 F.3d 1326, 1329 (Fed. Cir. 2005) (explaining that a "whereby" clause is given "no weight" when it "simply expresses the intended result of a process step positively recited" in a method claim, but "when the 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention"). Here, the method claim is "a method of injecting an animal health product into flesh of a living food animal." The '196 patent, claim 1, Col. 8, ll. 58-60. The "process" step is "providing an injection means comprising a needle assembly . . . wherein the needle cannula is made of stainless steel which is magnetic or magnetizable . . ." Id., Col. 8, ll. 61-67. The intended result is "so that . . . the magnetism . . . enables detection of the magnetism of the needle cannula or piece thereof in the flesh of the animal upon slaughter and processing into a food if the needle cannula or piece thereof were to break off in the flesh of the living animal during the injection." Id., Col. 9, ll. 4-12. The fact that this intended result may not actually follow if a "magnetizable" needle is not also claimed to be "rendered magnetic" is beside the point; the references to "magnetism" in the "so that" clause cannot alter the meaning of the limitation actually claimed, that "the needle cannula is made of stainless steel which is magnetic or magnetizable." Id., Col. 8, ll. 66-67 (emphasis added). Moreover, the Summary of the Invention repeatedly refers to a "magnetic or magnetizable" needle, not merely one that "is magnetic" or "is magnetized." Consequently, it cannot be said that a "magnetic" needle is the fundamental invention to the exclusion of a "magnetizable" needle, such that the references to "magnetism" in the "so that" clause limit the claimed method in claim 1. Compare Hoffer, 405 F.3d at 1330 (the condition stated in the "whereby" clause was part of the "fundamental invention," based on the specification, and did

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limit the method claimed). 17

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16 On the other hand, independent claim 8 does not include a "magnetic or magnetizable" limitation, but nevertheless expressly claims an invention "wherein the needle cannula or piece thereof is magnetized . . . ." The '196 patent, Claim 8, ll. 13-5 (emphasis added). Similarly, claims 1, 7, 13, and 15 of the '668 patent expressly claim that the needle is "rendered magnetic" or "is magnetized," even though they do not include a "magnetic or magnetizable" limitation.17 The court will return to the question of the weight to be given a "so that," "such that," or "whereby" clause in more detail infra, beginning at page 132.

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The specification also supports distinguishing between the meanings of the two words "magnetic" and "magnetizable." See Aquatex, 419 F.3d at 1380 ("Where . . . the disputed claim term is technical or a term of art, '[t]he best source for understanding [it] is the specification from which it arose, informed, as needed, by the prosecution history.'") (quoting Phillips, 415 F.3d at 1315); Phillips, 415 F.3d at 1314 (the specification is not only "highly relevant" to claim construction, "[u]sually, it is dispositive," and "is the single best guide to the meaning of a disputed term"). The Summary of the Invention repeatedly refers to a needle that is "magnetizable or magnetic," see the '196 patent, Col. ll. 10, 29, 43, and Col. 4, l. 2, thereby reinforcing the notion that the two terms have different meanings and that both conditions that the terms describe are intended to be fundamental to the invention.

The court turns, next, to the question of what is meant by "magnetic or magnetizable," in the context of the patent. Again, as with other "magnetism" terms in the '668 patent, it is clear from the intrinsic evidence that "magnetic" or "magnetizable" would be understood by one of ordinary skill in the art reading the patent to mean that the needle is or is capable of becoming a permanent magnet or a residual magnet, that is, a magnet that retains its magnetic field for a period of time. For example, the Detailed Description identifies a preferred embodiment as one in which the "stainless steel alloy is an alloy that is permanently magnetic or magnetizable before detection," but also notes that, "[a]lternatively, the needle cannula of the present invention can comprise a stainless steel alloy that is not a permanent magnetic [sic] but is capable of being magnetized in a magnetic field to maintain a residual magnetism." See the '196 patent, Col. 5, ll. 50-63.

Rivard contends, as it did with other "magnetism" terms of the '668 patent, that the construction of this phrase must state that it "does not refer to stainless steel which is merely attractable to a permanent magnet." The court finds, however, that such a construction, while accurate, is superfluous, where the claim term unambiguously requires that the needle be or be capable of being made magnetic, not merely that it be attracted or attractable to a magnet.

Also as with the "magnetism" terms of the '668 patent, Rivard argued at the Markman hearing that the court's tentative construction of "residual magnet" in the '196 patent should be modified to add that a residual magnet is a magnet that retains its magnetic field for a period of time "when removed from the magnetizing field" and that the court should add to its tentative construction "that [the magnetism] makes it possible for the magnetism to be detected in a metal detector and magnetic detector." Ideal contended that the first proposed addition improperly requires the magnetization of the needle and withdrawal of the magnetizing field before the needle enters the metal detector, a matter of timing of the magnetization of the needle addressed above. Again, the court finds it unnecessary to add that a "residual magnet" is one that retains its magnetism for a period of time "when removed from a magnetic field," as Rivard proposes, and potentially improper to do so, because the court has found nothing in the record that disavows a construction that permits the needle to be rendered a residual magnet as it is detected, i.e., a circumstance in which the residual magnetism of the needle is detected before the needle is removed from the magnetizing field. The court finds it improper to add to the construction of "magnetic or magnetizable" that "[the magnetism] makes it possible for the magnetism to be detected in a metal detector and magnetic detector," because enabling detection is not a limitation in claim 1, but only language appearing in a "such that" clause, as explained more fully below, beginning on page 132.

iii. The court's construction. In summary, the court concludes that "magnetic or magnetizable" in claim 1 of the '196 patent must be construed as follows: "Is or is capable of becoming a permanent magnet or a residual magnet, that is, a magnet that retains its magnetic field for a period of time."
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IV.

TorPharm advances several claim constructions that, if resolved in its favor, would provide an adequate and independent basis to affirm the summary judgment of non-infringement. Because these issues involve questions of law, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995) (in banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577 (1996), over which we exercise plenary review, see Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 46 U.S.P.Q.2D (BNA) 1169, 1171 (Fed. Cir. 1998) (in banc), and that were adequately developed before the district court, we will consider them, see Fireman's Fund, 909 F.2d at 499.

Claim 1 of the '431 patent recites "Form 2 ranitidine hydrochloride characterized by an infra-red spectrum as a mull in mineral oil showing the following main peaks: [table listing 29 frequencies]." (emphasis added). TorPharm argues that when "showing" and "main" are properly interpreted, there is no infringement. TorPharm contends that the word "main" should be interpreted to mean "chief in size, extent, or importance; principal; leading," quoting a dictionary definition. According to TorPharm, this definition is not only supported by the plain language but is also supported by the prosecution history. TorPharm argues that because the peaks of the Form 2 component of the accused product are overwhelmed by the predominant peaks of the Form 1 component in the overall spectrum, the 29 peaks of Form 2, even if present, could not be "main peaks." The problem with TorPharm's argument is that it fails to recognize that "main" is a relative term. In order to be "chief in size," the peaks must be measured relative to something. We think it is clear from the intrinsic record, including the prosecution history, that all the word "main" requires is that the peaks be "chief in size" relative to the baseline of the pure Form 2 compound. TorPharm's definition would require us to define "main" relative to the overall compound, which is not the subject of the claim.
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Stern claims to be a co-inventor of the Patent's independent claim one and dependent claims three, five, and nine through twelve. The parties' only dispute is the meaning of the phrase "to maintain reduced intraocular pressure" in claim 1. Stern contends the phrase should be read to mean reduction of intraocular pressure between periodic applications. Pltf. Claim Construction Brief at 6. Defendants assert the phrase should be interpreted as "maintenance of reduced intraocular pressure throughout the course of treatment without development of tachyphylaxis, i.e., throughout the period of time that the claimed method is being used to treat glaucoma." Def. Reply Claim Construction Brief at 3.

Stern contends Defendants' definition requires the insertion of two distinct phrases -- "through the course of treatment" and "without the development of tachyphylaxis" -- without support of the specification. Stern also argues that Defendants' construction of the phrase is unduly limiting because "any drug otherwise falling under the '353 Patent which demonstrated any tolerance over time would fall outside the scope of the patent." Pltf. Claim Construction Brief at 6. The phrase was added by an amendment purportedly in effort to distinguish the claimed invention from the 1977 rabbit experiments that showed prostaglandins could reduce intraocular pressure. Plaintiff submits that Defendants tried to distinguish the patented invention from the rabbit experiments by arguing the earlier experiments produced an initial increase, followed by a decrease, followed by another increase in intraocular pressure.'353 Patent File History at C0005299-5300, at Niles Decl. Tab 3. The '353 Patent, on the other hand, "provides a decrease which is sustained by periodic administration of prostaglandins." Id. C0005300. Plaintiff contends the plain meaning of the claims and Defendants' argument to the PTO supports the conclusion that reduction in intraocular pressure need only be maintained between periodic applications.

Defendants submit that Plaintiff's view that the avoidance of tachyphylaxis and the maintenance of intraocular pressure are distinct goals is incorrect because if tachyphylaxis occurs the drug loses its effectiveness and the reduction of intraocular pressure is lost. Further, they point to three instances in the specification in which the phrase "to maintain reduced intraocular pressure" is defined to include the avoidance of tachyphylaxis. See'353 Patent, col. 2, ll.56-58 ("Repeated application, preferably daily, provides long-term reduction of intraocular pressure, without development of tachyphylaxis."); id. col. 3, ll. 4-10 ("Periodic application of eicosanoids reduces elevated intraocular pressure levels to normal values which continues during the course of treatment without development of tachyphylaxis."); id. col. 12, ll. 3-6 ("The main focus of

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this experiment was the demonstration that P[gs] can be used to maintain lower intraocular pressure over a prolonged period of time without the development of tachyphylaxis or tolerance.").

The Court finds the plain meaning of the disputed phrase and the intrinsic evidence support the Defendants' proposed construction. The phrase at issue was the basis for the PTO's eventual issuance of the Patent. Before the PTO approved the Patent, Columbia had to insert the following italicized language into the claim: "A method for treating hypertension or glaucoma in a primate subject's eye comprising periodically contacting the surface of the eye with an amount of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure in the eye without any substantial initial increase in said pressure and to maintain reduced intraocular pressure." Accordingly, the Court finds that the maintenance of reduced intraocular pressure and the corresponding prevention of tachyphylaxis through periodic application of prostaglandins is integral to the '353 Patent. Plaintiff's suggestion that the phrase should be interpreted as maintaining lowered intraocular pressure and avoiding tachyphylaxis only between each dosage does not make sense and is not supported by the Patent itself. See, e.g.,'353 Patent, col. 2, ll.56-58 ("Repeated application, preferably daily, provides long-term reduction of intraocular pressure, without development of tachyphylaxis."). Accordingly, since Defendants' proposed construction of the phrase in claim one is supported by the Patent itself and encompasses the terms' ordinary meaning, the Court adopts Defendants' proposed construction.
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4. "maintaining"

Claims 1, 7, 13, and 19 of the '600 patent contain the phrase "maintaining said plant cell under conditions suitable to allow replication." Monsanto claims that when the plant cell into which the synthetic gene is inserted produces its first daughter cells, the step is over. Mycogen claims that the claim covers the entire process of keeping the cell in a cell culture or under conditions that allow the plant cells to divide and multiply.

The patent specification offers some context for the claim:
Once plant cells expressing a synthetic insecticidal structural gene under control of a plant expressible promoter are obtained, plant tissues and whole plants can be regenerated therefrom using methods and techniques well-known in the art. The regenerated plants are then reproduced by conventional means and the introduced genes can be transferred to other strains and cultivated by conventional plant breeding techniques.

Col. 14, lines 18-22.

The maintaining step describes the method of taking the newly-created plant cell and preserving it so that it can divide and grow, and eventually form into a full plant. This is the whole point of the invention. Monsanto's proposed construction ignores the plain meaning and intent of the claim. Thus the court finds that "maintaining" means keeping the plant cell in tissue or as part of a plant, so long as conditions continue that allow the plant cell to divide and multiply.
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Maintaining a therapeutic level of AAKG in the patient's circulatory system

The Court agrees with MRI that this term does not require construction. BSN argues that the term should be construed as "maintaining at least 25 ng/mL of [AAKG] in the patient's circulatory system and in a sufficient level that is sufficient to treat the disease in the patient taking the formulation." As previously discussed, the Court has construed "therapeutic level" and "patient." The remaining words in the phrase--"maintaining" and "circulatory system"--do not require construction.
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At the center of the parties' dispute is the meaning of the phrase "melting point of said microcapsules" as it appears in the "maintaining" step found in both claims 1 and 21. The language of the "maintaining" step is shown below as it appears in claim 21: 4

maintaining said compressible layer at a temperature below the melting point of said microcapsules for a time sufficient to cause said elastomeric material to vulcanize to a degree sufficient to substantially fix the positions of said microcapsules within said compressible layer,

' '928 patent, col. 10, ll. 13-18.

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4 The "maintaining" step in claims 1 and 21 are identical, but for one exception. The "compressible layer" in claim 21 is referred to as an "intermediate compressible layer" in claim 1. This difference, however, is irrelevant for purposes of the claim construction in this dispute.

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In both claims, the phrase "melting point of said microcapsules" appears without any explicit qualifications in terms of specific temperature ranges. Day argues that "melting point of said microcapsules" has a plain and clear meaning to one of ordinary skill in the art, rendering any reference to the written description unnecessary. While it is true that, as a general rule, the words of a patent claim are to be given their plain, ordinary and accustomed meaning to one of ordinary skill in the relevant art, Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 U.S.P.Q.2D (BNA) 1065, 1067 (Fed. Cir. 1999), a court must nevertheless examine the remaining intrinsic evidence to determine whether the patentee has set forth an explicit definition of a term contrary to its ordinary meaning, has disclaimed subject matter, or has otherwise limited the scope of the claims. See SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc., 242 F.3d 1337, 1344, 58 U.S.P.Q.2D (BNA) 1059, 1065 (Fed. Cir. 2001); BiodexCorp. v. Loredan Biomedical, Inc., 946 F.2d 850, 862-63, 20 U.S.P.Q.2D (BNA) 1252, 1262 (Fed. Cir. 1991).

In this case, the magistrate judge found that arguments made by the patentee during the prosecution of the '928 patent limited the scope of the invention to processes which involve an initial curing at "low temperatures," namely at 110-170 degrees F. Day Int'l, slip op. at 19. The judge identified several passages in the prosecution history which led the court to conclude that the patentee "intentionally specified a curing step at a low temperature to differentiate its process from prior art." Id. The relevant passages from the prosecution history relate mainly to two prior art references, U.S. Patent No. 3,700,541 issued to R. H. Shrimpton, et al., on October 24, 1972 ("Shrimpton") and U.S. Patent No. 4,042,743 issued to Charles E. Larson, et al., on August 16, 1977 ("Larson").

Like the '928 patent, Shrimpton discloses a printing blanket containing a compressible layer with voids formed by incorporating hollow thermoplastic microspheres (i.e., microcapsules) into the polymer prior to curing. Shrimpton, col. 1, ll. 38-45. However, unlike the '928 invention, the curing of the compressible layer in Shrimpton does not take place at "low temperatures," but at a conventional curing temperature, 284 degrees F. Day Int'l, slip op. at 20. In distinguishing Shrimpton, the patentee stated that the invention solved a problem not addressed by Shrimpton (i.e., the agglomeration of voids) by subjecting the compressible layer "to a lower temperature, namely 110 degrees F to 170 degrees F." (emphasis in original). Furthermore, the patentee argued that Shrimpton disclosed "complete curing or vulcanization, rather than a reduced temperature cure below the melting point of the microcapsules." (emphasis added). In a statement revealing what it regarded as the melting point of the microcapsules, the patentee stated that Shrimpton's conventional curing temperature of 284 degrees F was "well above the melting point of the microcapsules, and therefore completely opposite of the claimed feature of claim 1." The above statements indicate that the microcapsules the patentee contemplated were those that would melt at conventional curing temperatures, and that the initial curing step in the '928 invention would take place at temperatures below conventional curing temperatures, namely 110 degrees F to 170 degrees F.

Like Shrimpton, the Larson reference also discloses a printing blanket in which the compressible layer is vulcanized at conventional vulcanization temperatures, rather than at lower temperatures. Day Int'l, slip op. at 20. More importantly, Larson also teaches the importance of using microballoons (i.e., microcapsules) that do not soften or melt during

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vulcanization. Larson, col. 4, ll. 7-12. In light of these two specific teachings, the patentee's explicit statements that Larson does not relate "to a low temperature vulcanization step" indicates that the initial curing contemplated by the '928 invention uses temperatures lower than those used in conventional vulcanization procedures.

In addition to the above, the patentee's representations to the patent examiner that it had "discovered that the standard curing temperatures used in prior art procedures such as those practiced by Shrimpton and Larson caused the microcapsules to melt," and its numerous references to a "low temperature cure" or "low temperature vulcanization" throughout the prosecution of the '928 patent all support the finding that the patentee had disavowed curing done at the higher conventional curing temperatures. Therefore, we conclude that the magistrate judge did not err, in light of the prosecution history, when it construed the "maintaining" step in claims 1 and 21 to require microcapsules that melted at conventional curing temperatures and when it concluded that the claims require an initial curing step that took place at temperatures below conventional curing temperatures.

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B. The Meaning Of The Disputed Term "Stabilizer" And The Disputed Phrase "Which Maintains The Size Distribution Of [Cyclosporin] Particles"

Novartis contends that the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles" should be construed to mean "a substance which inhibits an increase in the size of the solid particles of cyclosporin." (D.I. 298 at 2, 9).

Eon contends that the term "stabilizer" should be construed to mean: a) an excipient which forms a "protective colloid" about solid particles of cyclosporin, i.e., completely surrounds the solid particles of cyclosporin; b) an excipient in which cyclosporin is not soluble; and c) a gelatin. (D.I. 302 at 4). Under this construction, Eon further contends that the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles" should be construed to mean: a) the stabilizer keeps the size distribution of the solid particles constant, i.e., the stabilizer prevents the solid particles of cyclosporin from increasing or decreasing in size; and b) the stabilizer maintains the size distribution of the particles for at least several hours after the hydrosol is formed. (D.I. 302 at 4).

In construing the term "stabilizer" and the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles," the Court has considered the claim language, specification, and prosecution history of the '382 Patent. (See D.I. 303, '382 Patent, at A4, col. 4, lns. 35-40, 49-53, at A6, col. 7, lns. 29-39, at A5, col. 6, lns. 12-17; D.I. 303, at A66, pgs. 2, 4, at A345, PP113, 114). Based upon this review, the Court concludes that there is support for Eon's position. Specifically, the specification provides that:

One difference from the prior art process is that the . . . hydrosol particles are bound-when a water soluble colloid stabilizer is used-to exchangeable colloid molecules . . . .

(D.I. 303 at A5, '382 Patent, col. 6, lns. 12-17). Additionally, the prosecution history indicates:

To avoid coagulation and crystallization, a protective colloid must be present during the formation of the drug compound colloid particles.

(D.I. 303 at A66). In view of this language, the Court is persuaded that a protective colloid must be present in the disclosed stabilizer, and, in order to "avoid coagulation and crystallization," such a colloid must not be soluble in the target "drug compound", i.e., cyclosporin. (See D.I. 303 at A345, PP113, 114). As for whether the term "stabilizer" includes a gelatinous component, the Court concludes that the specification discloses such a vehicle only as a preferred embodiment, and therefore does not require such a form. (See D.I. 303 at A4, '382 Patent, col. 4, lns. 49-53, 65-68).

Turning to the disputed phrase "which maintains the size distribution of [cyclosporin] particles," the '382 Patent specification describes the function of the disclosed stabilizer as follows:

In order to inhibit an increase in the size of the particles of active agent in water, e.g. to prevent an increase in the size of the

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larger particles at the expense of the smaller particles, a stabilizer is preferably added, which maintains the size distribution of the active hydrosol particles in the dispersion constant.

(D.I. 303 at A4, '382 Patent, col. 4, lns. 35-40) (emphasis added). The Court is persuaded that this language contemplates a stabilizer which, in addition to inhibiting particle growth, also "maintains" and keeps "constant" the size distribution of the hydrosol particles. The Court concludes that a person of ordinary skill in the art would understand that pharmaceutical preparations, including the invention disclosed in the '382 Patent, must remain stable for at least six hours so as to ensure their pharmacological integrity. (See D.I. 303 at A605-606, P6).

For all of the above reasons, the Court construes the term "stabilizer" to mean: a) an excipient which forms a "protective colloid" about solid particles of cyclosporin, i.e., completely surrounds the solid particles of cyclosporin; and b) an excipient in which cyclosporin is not soluble. In addition, the Court construes the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles" to mean: a) the stabilizer keeps the size distribution of the solid particles constant, i.e., the stabilizer prevents the solid particles of cyclosporin from increasing or decreasing in size; and b) the stabilizer maintains the size distribution of the particles for at least six hours after the hydrosol is formed.
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2. "Mammalian"

Hoodlums defines "mammalian" as "[t]he class of mammals or animals which suckle their young including but not limited to a human, dog and gorilla as shown in Figures 5 through 9 of the '972 patent." (Doc. 37, Ex. B at 3.) Redtail defines 'mammalian" as "[f]urred, warm-blooded animals with a backbone that nourish their young with milk secreted by mammary glands." (Id.) Both definitions are based on dictionary definitions.

The term "mammalian" is only found in claim 2, in reference to "mammalian facial features." (Doc. 44, Ex. B at 8.) In the specification, the summary notes that the "invention is a welding helmet . . . molded in to the shape of a mammalian head. Particular implementation includes a human skull, a bulldog, and a gorilla." (Id. at 7.) Figures 5, 6, and 7, show the respective implementations. (Id. at 4.) Under Federal Circuit law, any construction should include these preferred embodiments. See On-Line Techs., Inc., 386 F.3d at 1138. Only the plaintiff's definition includes a reference to these embodiments. In addition, the defendant's definition includes a requirement that the mammal be furred. Because humans are generally considered to have hair, and not fur, this definition does not capture the ordinary and customary meaning of mammalian. E.g., Nicholas Wade, Why Humans and Their Fur Parted Ways, N.Y. Times, August 19, 2003, at F1. Instead, the court finds "the class of mammals or animals which suckle their young," more accurately captures the ordinary and customary meaning of mammal. See New Webster's Dictionary and Thesaurus, 234.

Looking to the claims, the specification, Federal Circuit law, and the dictionary, the court defines mammalian as "the class of mammals or animals which suckle their young, including, but not limited to, a human, dog, and gorilla, as shown in Figures 5 through 9 of the '972 patent."
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TKT asserts, in addition to the exogenous/endogenous distinction discussed above, that the district court misconstrued the terms "non-naturally occurring," "vertebrate cells," and "mammalian cells" -- which appear in many of the asserted claims -- to include human cells. Reviving the same argument the district court rejected below, TKT contends Amgen expressly disavowed the use of human cells to make human EPO.

The district court found that the definition of the term "non-naturally occurring" can be discerned through the doctrine of claim differentiation. Specifically, the court concluded that TKT's proffered construction must fail in light of '933 patent claim 3, discussed previously, which claims a "non-naturally occurring glycoprotein product of the expression in a

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mammalian host cell of an exogenous DNA sequence encoding human erythropoietin . . . ." By its terms, then, this claim would cover the expression of human DNA in a cat host cell, for example, because a cat is a mammal. The court thus concluded that the phrase "non-naturally occurring" would be redundant in claim 3 if the phrase had the meaning TKT sought to ascribe to it. Further, because the patent specification compares the biological activity of synthetic products to "EPO isolates from natural sources" or "natural EPO isolates," the court concluded that non-naturally occurring simply means "not occurring in nature." Amgen, 126 F. Supp. 2d at 90-91, 57 USPQ2d at 1462-63.

Similarly, finding that the term vertebrate is widely known and understood to cover anything with "a segmented bony or cartilaginous spinal cord [which obviously includes humans]," id. at 85, 57 USPQ2d at 1457-58, the court adopted Amgen's proposed construction. The court also adopted Amgen's proposed construction of the term "mammalian cells" appearing in '422 patent claim 1 and '698 patent claim 9 under a similar rationale. Id. at 84-86, 57 USPQ2d at 1458.

We indulge a heavy presumption that a claim term carries its ordinary and customary meaning. CCS Fitness, 288 F.3d at 1366, 62 USPQ2d at 1662; see also Gart v. Logitech, Inc., 254 F.3d 1334, 1341, 59 USPQ2d 1290, 1295 (Fed. Cir. 2001). Although TKT is correct that the prosecution history is always relevant to claim construction, it is also true that the prosecution history may not be used to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage, such as an amendment to overcome a rejection. See York Prods., Inc. v. Central Tractor & Farm Fam. Ctr., 99 F.3d 1568, 1575, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996). No such clear disavowal occurred here.

We agree with Amgen that the specification expressly describes humans as a subset of mammals, and mammals, in turn, as a subset of vertebrates. See '933 patent, col. 4, lines 47-48; col. 10, line 21. Moreover, the specification can fairly be read to, if not expressly, disclose the use of human DNA in human host cells in culture:

Conspicuously comprehended are expression systems involving vectors of homogeneous origins applied to a variety of bacterial, yeast, and mammalian cells in culture as well as to expression systems not involving vectors . . . . In this regard, it will be understood that expression of, e.g., monkey origin DNA in monkey host cells in culture and human host cells in culture, actually constitute instances of 'exogenous' DNA expression inasmuch as the EPO DNA whose high level expression is sought would not have its origins in the genome of the host.

'933 patent, col. 37, lines 33-43 (emphasis added). The astute reader will observe what appears to be a breakdown in the parallelism of the sentence emphasized in the block quote above. Specifically, the reference to the expression of "monkey origin DNA in monkey host cells in culture and human host cells in culture" seems a bit nonsensical because the expression of monkey origin DNA in human host cells is perforce the expression of exogenous DNA. The original 1983 application from which all the patents in suit claim priority, by contrast, contained language that upholds the parallelism of the sentence and logically makes sense. It read, in pertinent part: "It will be understood that expression of, e.g., monkey origin DNA in monkey host cells in culture and human DNA in human host cells in culture constitute instances of 'exogenous' DNA expression." J.A. at 2862 (emphasis added).

TKT boldly asserts that the variance between the original application and the patents in suit bespeaks some volitional act by Amgen to narrow the scope of the asserted claims in light of certain experimental data. In particular, TKT advances a theory whereby Amgen intentionally removed the language from subsequent applications (allegedly) because test results using human cells were not good, and later admitted (during an opposition proceeding against the European counterpart patent) that the omission was not inadvertent. But the record contains a more benign explanation as to what happened. According to the testimony of Dr. Lin, he was unaware of, and therefore did not authorize, the change. Further, the prosecuting attorney testified in his deposition that to the best of his knowledge the error was a typographical error.

But even assuming that the error was intentional, the district court's claim construction would not be foreclosed: our precedent is clear that claims are not perforce limited to the embodiments disclosed in the specification. E.g., Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344, 60 USPQ2d 1851, 1856 (Fed. Cir. 2001) ("An applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). Here, the patent plainly discloses the use of human host cells in culture, and our review of the record indicates no "clear disavowal" sufficient to undercut the express disclosure in the specification.

As a result, we are satisfied that the terms "non-naturally occurring," "vertebrate," and "mammalian" should be construed as they were by the district court, in a manner consistent with their plain meaning. Accordingly, we reject TKT's attempt to

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limit the scope of the asserted claims under an unduly constricted reading of the specification.
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Mammalian Cell	Any cell of mammalian origin, including both a wild-type and a mutant cell

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B. Mammalian Cells

The term "mammalian cells" is contained in Claim 1 of the '422 patent and dependent Claim 9 of the '698 patent. Consistent with its approach to vertebrate cells, TKT proffered a construction of the term "mammalian cells" that excluded human cells. Specifically, TKT contended that "mammalian cells" are "cells from warm-blooded non-human vertebrate animals whose young are fed by milk secreted from the mammary glands." Defs.' Markman Hr'g Demonstrative Ex. 1. Again, with an eye toward literal infringement, Amgen opposed this construction and instead argued that "mammalian cells" are "cells from a warm-blooded animal that has a backbone and whose young are fed by milk secreted from mammary glands." Pl.'s Markman Hr'g (Mar. 27, 2000) Demonstrative Ex. 14. For the same reasons explained above, the Court could not remain faithful to the widely known and specific meaning of the word "mammalian" if it were to add the non-human limitation. Simply put, the claim term was not reasonably susceptible to TKT's construction. As a result, the Court determined that "mammalian cells" are "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands." Tr. of Markman Hr'g, Vol. I at 67:9-11.
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6. "Marker for a Haplotype"

GTG proposes the construction "indicator for a haplotype," and Applera proposes "a haplotypic pattern which uniquely identifies a haplotype."

The court adopts GTG's proposed construction. For the reasons stated previously, the patent and the prosecution history do not require that the haplotypic pattern "uniquely" identify the haplotype in question. The term "marker for a haplotype" is construed as: indicator for a haplotype.
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1. Claim Construction

Claim construction begins with the intrinsic evidence of record. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). In construing patent claims, there is a heavy presumption that the terms carry their ordinary and customary meanings as would be understood by one of ordinary skill in the art. Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996); CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). Where a claim term has no ordinary and customary meaning, a court must resort to the remaining intrinsic evidence--the written description and the prosecution history--to obtain the meaning of that term. See Lear Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 888-89 (Fed. Cir. 1984). Extrinsic evidence, although not part of the intrinsic evidence, may be used to aid a court in construing claim terms as they would be understood in the relevant art, but may not be used to vary the meaning disclosed by the patent itself. Markman, 52 F.3d at 980-81.

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The district court construed "intracellular marker substance" to mean "an antigen existing within a body cell." 2 Claim Construction Opinion at 10. Immunomedics challenges this construction by arguing that, in the absence of an ordinary meaning, the written description must be controlling. Immunomedics explains that neither claim 1 nor the written description require a marker substance to be an entire antigen or that the marker substance be wholly within a cell. To the contrary, Immunomedics continues, the intrinsic evidence actually precludes that interpretation by permitting sub-units of antigens to qualify as marker substances. Immunomedics urges us to construe "intracellular marker substance" to mean "an antigen or a portion thereof that is located inside a cell." Appellants' Br. at 27 (emphasis added). Under this interpretation, if the epitope for the specific antibody is located within the cell, the claim limitation is satisfied.

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2 We note that, although "intracellular marker substance" appears in the preamble of claim 1, it provides an antecedent basis for "said marker substance" appearing in the body of the claim, thus "indicating a reliance on both the preamble and claim body to define the claimed invention." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002).

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We disagree with the construction urged by Immunomedics. The parties agree that the term "marker substance" has no accepted meaning to one of ordinary skill in the art, and we find no reason to disagree with their conclusion. Accordingly, we construe it only as broadly as is provided for by the patent itself. See Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999); J.T. Eaton & Co., Inc. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1570 (Fed. Cir. 1997) ("In this case, the dispositive claim limitation is a term unknown to those of ordinary skill in the art at the time the patent application was filed. It thus fell to the applicants, as a duty, to provide a precise definition for the . . . limitation."); Lear Siegler, 733 F.2d at 888-89 (Fed. Cir. 1984). The '559 patent discloses twenty-six different antigens that are described as "suitable . . . marker substances." '559 patent, col. 2, l. 57 to col. 3, l. 8. At a minimum, therefore, the '559 patent clearly regards "antigens" as falling within the scope of "marker substances." In addition to antigens, both claim 1 and the written description refer specifically to the "beta sub-unit" of human chorionic gonadotropin (HCG) antigen.

Immunomedics broadly construes "sub-units" as encompassing any portion of an antigen, including epitopes. As Cytogen points out, however, HCG is a dimeric antigen, which means that it is composed of two individual protein sub-units held loosely together by ionic and hydrophobic forces. Each sub-unit is itself a whole protein molecule. The alpha sub-unit is common to several hormones, but the beta sub-unit is unique to HCG. See Dorland's Illustrated Medical Dictionary 763 (29th ed. 2000). Due to its uniqueness, antibodies targeting the beta sub-unit will only localize concentrations of HCG, while those antibodies targeting the alpha sub-unit may errantly identify concentrations of an entirely different hormone. Thus, contrary to Immunomedics' argument, the reference to the beta sub-unit of HCG is not a reference to "portions" of antigens generally, but is instead a reference to a very specific and well-known molecule in the field of immunology: the beta sub-unit in the dimeric antigen HCG. The inclusion of the sub-unit in the claims and the written description, therefore, does not support a reading of the claims as broadly as Immunomedics requests. J.T. Eaton & Co., 106 F.3d at 1570.

The prosecution history further reveals the inventor's understanding of the term "marker substance" as synonymous with "antigen." For example, Goldenberg explained: "The method and compositions claimed in the present application relate to antibodies to intracellular tumor-associated antigens." Response to Office Action Dated March 24, 1981, at 2 (emphasis omitted). 3 Nowhere does the prosecution history suggest that a "marker substance" includes epitopes as Immunomedics would now have us construe the term. Accordingly, we will not read the claim scope that broadly. See J.T. Eaton & Co., 106 F.3d at 1568. Nor does Immunomedics argue that PSMA is characteristically similar to the dimeric HCG antigen. Because neither the patent specification nor the prosecution history supports the breadth of construction that Immunomedics desires, we affirm the district court's claim construction of "marker substance" as an antigen, but clarify that molecular sub-units, such as those present in the HCG antigen, qualify as antigens under this construction.

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3 While this is only one example, the applicant used the terms interchangeably throughout the prosecution history. See, e.g., Response to Office Action Dated March 24, 1981, at 3 ("The present invention is directed to methods and compositions useful for tumor localization and/or therapy using radiolabeled antibodies to intracellular tumor-associated antigens."

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(emphasis omitted)); id. at 5 ("There is no suggestion that antigens which are not located on the surface of the tumor cell may be used in a similar manner."); Response to Office Action Dated October 29, 1981, at 5 ("Applicant was the first to envision the use of antibodies to intracellular antigens . . . .").

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We also agree with the district court that the marker substance must be wholly internal to the cell. Cytogen argues, and Immunomedics does not dispute, that none of the twenty-six example antigens provided in the '559 patent associates in any way with the membrane of the cells in which they are found. The written description further describes intracellular marker substances as those which are produced by tumor cells or accumulate "in the cytoplasm, the nucleus or in various organelles or sub-cellular structures" of tumor cells. '559 patent, col. 2, ll. 36-40. Each of the listed structures is completely internal to the cell. The prosecution history further supports this understanding, specifically explaining that HCG is a "cytoplasmic antigen." Response to Office Action Dated October 29, 1981, at 5 (emphasis added). Finally, the ordinary meaning of "intracellular," as reflected by its dictionary definition, lends additional support to the interpretation adopted by the district court. See Dorland's Illustrated Medical Dictionary 912 (defining "intracellular" as "within a cell"). Combining the terms, an "intracellular marker substance" must be an antigen existing within a cell. This is the construction adopted by the district court, which we now affirm.

In addition to the intrinsic evidence, the district court permitted expert testimony at the summary judgment hearing. Immunomedics criticizes the district court's use of expert testimony as impermissible, citing this court's prohibition on using extrinsic evidence to vary the meaning of claim terms from that apparent in the intrinsic evidence. Immunomedics is correct that "although expert testimony and declarations are useful to confirm that the construed meaning is consistent with the denotation ascribed by those in the field of the art, such extrinsic evidence cannot be used to vary the plain language of the patent document." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1332 (Fed. Cir. 2003) (citations omitted). However, the interpretation of the claims reached by the district court was consistent with that required by the intrinsic evidence, and the district court's use of expert testimony therefore falls within the permissible first clause of the above-quoted language rather than the impermissible second clause. Contrary to Immunomedics' apparent belief, there is no prohibition on a district court's ability to hear expert testimony. Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998).
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PROST, Circuit Judge, concurring-in-part, dissenting-in-part.

While I concur with the majority's decision to remand this case to the district court to evaluate infringement under the doctrine of equivalents, I respectfully dissent with regard to the affirmance of the claim construction and grant of summary judgment of no literal infringement.

With respect to claim construction, I remain unpersuaded by the majority's view that "intracellular marker substance" does not encompass portions of an antigen located inside a cell. The majority concludes that "marker substance" is an equivalent term for "antigen," when in view of the intrinsic record, I believe "marker substance" bears a broader meaning. First, the claims expressly recognize that the "marker substance" may correspond to only a fragment, i.e., sub-unit, of an antigen. See '559 patent, claim 1 ("when said antibody is an antibody specific to human chlorionic [sic] gonadotropin or its beta-subunit, said radioisotope is other than Tc-99m"); claim 17 (narrowing the scope of "marker substance," recited in claim 1, to exclude a specific sub-unit of an antigen). Further, the specification expressly acknowledges that a "sub-unit of a tumor-associated marker" may be "advantageously used to raise antibodies having higher tumor specificity." Id., col. 2, ll. 51-53. Moreover, the specification states that "such marker substances" that are "useful in the present invention include, but are not limited to, alphafetoprotein (AFP), human chorionic gonadotropin (HCG) and/or its beta-subunit (HCG-beta)." Id., col. 2, ll. 57-61 (emphases added). The specification and the claims clearly signal that part of an antigen, i.e., the epitope, may correspond to the "marker substance." My understanding of "marker substance," as derived from the intrinsic record is consistent with testimony by Goldenberg's expert, Dr. Primus, who testified that "any substance that has in this case an epitope, a marker, which an antibody sees that occurs within the cytoplasm of the cell, is an intracellular marker substance."

The appellees submit and the majority agrees that the beta sub-unit of HCG does not correspond to a portion of an antigen, but rather is an antigen itself. The specification acknowledges that HCG is an antigen made up of smaller constituents,

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namely, an alpha and beta sub-unit. Id. The majority rejects, in my opinion, the seemingly inescapable conclusion that the beta sub-unit, identified by the specification to be a "marker substance," composes a portion of the HCG antigen. The majority cites no intrinsic evidence, much less the extrinsic evidence of any expert, to support its position that the beta sub-unit, which undeniably forms only a part of the HCG antigen, is recognized by those skilled in the relevant art to qualify as an antigen.

The prosecution history, which the majority discusses, ante at 11, is of little help to its proposed claim construction. The patentee had attempted to overcome a double patenting rejection by arguing that the method and compositions claimed by the '261 application (the predecessor to the application that became the '559 patent) are distinguishable from the '262 application (the predecessor to the '744 patent application) on the basis that the '261 application relates to "antibodies to intracellular tumor associated antigens" whereas the '262 application relates to "cell surface antigens" that are "located on the surface of the tumor cell." (Emphases in original). In other words, the pertinent novelty and difference between the '261 application and the '262 application and prior art lay in the site of tumor localization. As explained by the patent applicant, "before the work of the present inventor, the art did not know that antibodies to . . . intracellular [tumor associated] antigens, e.g., human chorionic gonadotropic (HCG) and alpha-fetoprotein (AFP) could be used successfully for tumor localization and therapy." The specification further informs us that in addition to HCG and AFP, other "marker substances to which specific antibodies may be raised which are useful in the present invention include, but are not limited to . . . [the beta-subunit of HCG]." '559 patent, col. 2, ll. 57-61. "Occasionally, a sub-unit of a tumor associated marker is advantageously used to raise antibodies having higher tumor-specificity." Id., col. 2, ll. 51-54 (emphasis added). The distinguishing statement relied on by the majority in the prosecution history can hardly be characterized as definitional of the term "marker substance, " and cannot be used, in my view, as a basis to conclude that "marker substance" corresponds to an antigen, and not portions thereof.

"Where, as here, the written description and prosecution history fail to express a manifest exclusion or restriction limiting the claim term, and where the written description otherwise supports the broader interpretation, we are constrained to follow the language of the claims, and to give the claim term its full breadth of ordinary meaning as understood by persons skilled in the relevant art." Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc., 334 F.3d 1294, 1301-02 (Fed. Cir. 2003) (internal quotations and citation omitted); see also ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1091 (Fed. Cir. 2003); Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1328 (Fed. Cir. 2002). From my review of the intrinsic evidence, the "marker substance," as described by the specification and set forth in the claims, plainly embraces portions of an antigen, provided that they are inside the cell. Because transmembrane antigens generally have an element that extends into the intracellular region, I would submit that the intracellular portion of such an antigen plainly falls within the scope of "intracellular marker substance."

Notably, the patentee clearly knew of and knew how to use the word "antigen," as shown by its use of the term throughout the applications that led to the '559 and '744 patents. Evidently, however, the patentee chose not to use that term in the claims, instead choosing "marker substance." Although the majority correctly observes that the patentee indicated that an antigen may be a marker substance, it cites to nothing in the intrinsic record that negates the indication by the specification and claims that "marker substance" may also correspond to only a portion of an antigen.

Appellees contend that even if appellants' claim construction is correct, they do not literally infringe because no portion of the antigen to which their antibody responds, is located inside the cell. This question of infringement, either literal or under the doctrine of equivalents, is a disputed factual matter that should be left to the district court to resolve in the first instance. Given my view of the term "intracellular marker substance," I would reverse the claim construction, vacate the summary judgment entirely, and remand for further findings as to infringement literally and, if necessary, under the doctrine of equivalents. Accordingly, I respectfully dissent-in-part and concur-in-part with the majority's opinion.
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In this case, we have already completed the first step of the analysis by construing three elements of claim 4 of the '514 patent:

"Material for finishing" This claim element means a material that makes more durable the underlying surface of the floor, and is applied for that purpose.

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4. "layer having material release means for release of an at least one treating material in a directional manner" 2 (claim 1)

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2 The court elected to construe the recited function and the corresponding structure for these limitations. The portion of the claim language that recites "when said layer is placed adjacent to damaged tissue" needs no construction by the court.

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Both parties agree that this limitation is a means-plus-function limitation. Plaintiff argues that the recited function is "to release a drug preferentially toward the damaged tissue when the layer is placed adjacent to damaged tissue" and that the corresponding structure(s) in the specification is/are "various structures performing the claimed function, including chemical bonds and linkages such as a hydrophobic layer and a hydrophobic drug."

The defendant argues that the recited function is "the release of an at least one treating material in a directional manner from the first major surface when said first major surface of the layer has been placed facing the damaged tissue" and that the recited structure(s) in the specification is/are "the previously described layer (which as manufactured, has pores smaller than an at least one treating material such that the layer is impermeable to that treating material), wherein that treating material is initially affixed to the first major surface."

The court will first address the recited function. The parties disagree about the meaning of "directional." The specification supports construing "directional" to mean toward the damaged tissue. In the Background of the Invention, the patentee states that "the invention can be modified such that a treating material, when affixed to a major surface of the minimally-porous sheet, can be directed preferentially to the site of the injury." 1:24-27. Further, at col. 9, the patent states that "healing macromolecules can be contained at the site of the injury, and medicine can be applied directly and preferentially to an injured wall to promote healing." 9:20-23. Additionally, the patent supports "administering antibiotics in a directional manner . . .at the site that they are needed most." 9:36-37; see generally 9:33-44.

Defining "directional" to mean "toward the damaged tissue" renders the term synonymous with "unidirectional," a term used in claims 8 and 15 when the sole direction is toward the damaged tissue. The prosecution history, however, supports this view. The patentee overcame the Scott reference by telling the examiner that the invention disclosed in the '760 patent was "directional" delivery, whereas Scott disclosed 'multidirectional' delivery. See 9/15/96 amendment at 5. In doing this, the patentee thus disclaimed "multidirectional" delivery in the application process.

Turning to the question of structure, the plaintiff argues that the corresponding structure includes chemical bonds or linkages. In support, the plaintiff correctly notes that the specification supports this argument. See e.g., 15:6-20, 22:4-17, and 14:58-15:5. For example, chemical bonds are clearly linked to the recited function in the specification at col. 15, ll. 6-20:

This device can be manufactured with several different medicines, each with their own particular release bond. Remarkably, one can implant the device of this invention such that one medicine is released by enzymes from Neutrophils (the first inflammatory cells to arrive), a second medicine released by enzymes from fibroblasts (cells that arrive later), and a third medicine which can be released only by osteoblasts (cells arriving even later). Although I have disclosed the implementation of multiple medicines in my application for the Malleable Fracture Stabilization Device with Micropores, the surprising specificity of medicine release provided by the chemical bond is entirely new and unexpected. The above-described feature of specific drug release is impossible using the prior art, and it represents a major advance in fracture treatment.

15:6-20

Elsewhere, the description states:

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The rate of healing can be further accelerated by the attachment of a treating material, either mechanically or by chemical bond, to the inner surface of the device. The method of medicine release by chemical bond is also a method of highly significant improvement over the prior art. Prior art references all rely on the efflux of treating materials from micropores to deliver medicine. The ability to release medicine according to a rate constant, rather than relying on random efflux of molecules from various sized micropores, provide a surprising consistency to drug delivery not before seen in the art. Moreover, the chemical coupling of medicine and device provides for unprecedented specificity of release. The unexpected ability to be able to link medicine release with the specific enzymatic activity of healing cells is a highly significant improvement over the prior art.

22:4-17

Accordingly, the court construes the recited function as "releasing a treating material toward the damaged tissue." Because the patentee used a means-plus-function limitation, the patentee is limited to the structure clearly linked or associated with the claimed function. The court identifies the corresponding structure in the specification that is clearly linked to the claimed function to be chemical bonds and linkages. The court rejects the defendant's proposed structure because, inter alia, it recites limitations found elsewhere in the claim.
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3. One Subcoating May Contain One "Material"

Cheminor asserts that under claim 1 of both the '505 and the '230 patents, the subcoating must be made up of two or more materials and that any subcoating consisting of only one material does not come within the scope of the claims. The court notes that this construction, like others adopted by Cheminor, is newly proposed. Cheminor conceded in a letter written two months after trial began that this was a new claim construction. (See Letter from Cheminor to court of 2/6/02; Trial Tr. 4037:16-4038:5.) Cheminor did not come forward with it until a month after Astra's last witness with respect to infringement, Dr. Lovgren, left the stand on January 4, 2002. The prejudice to Astra from this decidedly late claim construction argument is plain. Astra did not have a reasonable opportunity to present documentary evidence or to have its experts testify concerning this new construction. The court, therefore, sustains Astra's objection to Cheminor's change in position and precludes Cheminor from asserting noninfringement on the basis of this argument. Nevertheless, for purposes of completeness, the court addresses this argument, which is at best superfluous and at worst specious. Before February of 2002, Cheminor apparently never noticed this new construction, and it can hardly be deemed the way one of ordinary skill in the art would construe the claims.

Turning to the claim language itself, the pertinent language is not merely "materials," but rather claim 1 of the '505 patent, which requires "one or more layers of materials," (P1, col. 16:50-51), and claim 1 of the '230 patent, which requires "one or more layers comprising materials." (P2A, col. 13:12-13). When construing this claim language, the court must remain cognizant of the rules of grammar and syntax. In re Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983). The court finds that even though the term "materials" in claims 1 of the '505 and '230 patents was clearly intended to include the singular, the plural form was used to comply with grammatical correctness. See Huntington Dry Pulverizer Co. v. Whittaker Cement Co., 89 F. 323, 326 (D.N.J. 1898) (construing the claim, which included the terms "rollers" and "shafts," to include a roller and a shaft; explaining that "the use of the plural included the singular, if the singular could do the work marked out by the plural"). The phrases "one or more layers of materials" and "one or more layers comprising materials" require at least one material when there is one layer, and at least two materials when there is more than one layer. This is the only construction that makes sense for either the '505 or the '230 patent when one considers the substance of the inventions. There is no support in either patent for the exclusion of subcoatings made of only one material. Several examples listed in the patent use only one material in their subcoats: Examples 3 and 4 use only polyvinylpyrrolidone ("PVP") in the subcoating (P1, col. 8:58, 9:27); and Examples 2, 5, 7, and 8 use only HPMC (P1, col. 8:10, 10:10, 11:23-24). Any construction of the claims that excludes 6 of the first 8 examples included in the patent cannot be the proper construction, absent some express intent or reason to exclude them, and Cheminor relies solely on attorney argument in support of this contention and has presented no testimony on the issue. Therefore, the court rejects Cheminor's attempt to limit the claims of the '505 and '230 patent to cover only those formulations containing more than one "material" in the subcoating.
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C. Mature Erythropoietin Amino Acid Sequence of Fig. 6

This phrase is contained in Claims 4 and 6 of the '698 patent and Claims 2 and 3 of the '080 patent. Although the phrase sits in different contexts -- and thus modifies different subjects -- the parties agree that the phrase should have the same meaning in both settings. Focusing on the ordinary meaning of the term "mature," Amgen contended that the phrase means "the fully processed form of the protein secreted by a cell . . . when it transcribes and translates the DNA in Figure 6." Id. at 70:24 to 71:4. In contrast, relying on a portion of the specification that explains that "Fig. 6 thus serves to identify the primary structural conformation (amino acid sequence) of mature human EPO as including 166 specified amino acid residues," Trial Ex. 1 at 21:3-5, 12 TKT contended that the phrase means "the 166 amino acid sequence of human EPO shown in Fig. 6," 13 see Tr. of Markman Hr'g, Vol. I at 90:9 to 102:15. The dispute focused on the amino acid located in the 166th position, arginine. Unknown to Dr. Lin at the time of the invention, arginine is cleaved off at some point during protein synthesis prior to secretion from the cell. Thus, the protein that is actually secreted from the cell contains only 165 amino acids. Figure 6, however, depicts the arginine.

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12 Although the Court did not receive evidence during the Markman hearing, for the sake of unity throughout this decision, citations to the patent are made to what was eventually identified as Trial Exhibit 1.

13 TKT's early submissions to the Court regarding claim construction attempted to limit the DNA that encodes the mature erythropoietin amino acid sequence of Figure 6 to "cloned exogenous" human EPO DNA that encodes such sequence. Defs.' Claim Construction Submission (Sept. 20, 1999) at 19. Had TKT continued to press such a construction, the Court would have rejected it for the reasons previously explained. Simply put, no word or words in this disputed claim term are reasonably susceptible of this construction.

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By proffering the language "fully processed," Amgen hoped to obtain an interpretation encompassing the secreted version of the protein, regardless of the specific number of amino acids. Meanwhile, TKT, whose process produces secreted proteins containing only 165 amino acids, sought an interpretation of Figure 6 that specifically required 166 amino acids.

The Court agreed that the term "mature" implied the fully processed form of EPO secreted by the cell, but whether "mature" included the 165 amino acid sequence as well as the 166 amino acid sequence was ambiguous. The patent specification used "mature" to describe an EPO polypeptide that has been secreted by a cell:

> the first residue designated for the amino acid sequence of the mature protein is indicative of the likelihood that EPO is initially expressed in the cytoplasm in a precursor form including a 27 amino acid "leader" region which is excised prior to entry of mature EPO into circulation.

Trial Ex. 1 at 19:36-41. By identifying the EPO that enters circulation as "mature," Dr. Lin essentially defined the term "mature" to mean "the fully processed form of the protein that is secreted by the cell." Consequently, on the one hand, the Court agreed with Amgen's contention that "fully processed" or "fully realized" ought be incorporated into the Court's construction of the phrase "mature erythropoietin amino acid sequence of Fig. 6." On the other hand, the Court was not further persuaded by Amgen that reference to Figure 6 did not limit the meaning of the claim terms to the 166 amino acid sequence disclosed in that figure. Yet neither was TKT able to persuade the Court at the Markman hearing that the term was necessarily limited to a 166 amino acid construction. Consequently, the Court chose to abstain for the time being from deciding the "165-166 dispute" and concluded only that the phrase "the mature erythropoietin amino acid sequence of Figure 6" means "the fully realized form of amino acid sequence of Figure 6." Tr. of Markman Hr'g, Vol. II at 23:14-18.
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None of the following elements are disputed and each term is assigned its plain and ordinary meaning as understood by a skilled artisan. The term "pharmaceutical composition" means an aggregated product formed from two or more substances for use as a drug in medical treatment. The term "gastrointestinal environment" means the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus. The term "mean fluctuation index" means the average degree of fluctuation ((Cmax-Cmin)/Cavg) over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma.
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BACKGROUND

The Particle Size Patents are U.S. Patents No. 6,066,861 (the '861 patent); No. 6,277,301 (the '301 patent); No. 6,613,247 (the '247 patent); No. 6,245,259 (the '259 patent); and No. 6,592,780 (the '780 patent). The patents are directed to compositions, methods, and uses wherein luminous pigment powders contain phosphors that produce a spectral shift in the light emitted by electroluminescent components such as LEDs. The phosphors absorb wavelengths in the ultraviolet, blue, or green ranges, and convert some of the radiation to a higher wavelength, particularly in the yellow spectral range, whereby the ensuing combination of complementary wavelengths appears white to observers.

Light-emitting diodes are described as lasting longer than and using less energy than traditional light sources, and the patented subject matter is described as overcoming several disadvantages of prior products. The aspect of the claims relevant to this suit is the grain size 2 of the pigment powders, claimed as having a maximum size of 20 micrometers and a mean grain diameter of no more than 5 micrometers ([mu]m) 3 . The meaning and the measurement of this limitation are determinative of infringement. Claim 1 of the '861 patent is representative, with the term at issue shown in boldface:

1. A wavelength-converting casting composition, for converting a wavelength of ultraviolet, blue or green light emitted by an electroluminescent component, comprising:

a transparent epoxy casting resin;

an inorganic luminous substance pigment powder dispersed in said transparent epoxy resin, said pigment powder comprising luminous substance pigments from a phosphorus [sic: phosphor] group having the general formula A[3]B[5]X[1]2:M, where A is an element selected from the group consisting of Y, Ca, Sr; B is an element selected from the group consisting of Al, Ga, Si; X is an element selected from the group consisting of O and S; M is an element selected from the group consisting of Ce and Tb;

said luminous substance pigments having grain sizes </= 20 [mu]m and a mean grain diameter d[50] </= 5 [mu]m.

Dominant conceded that its imported powders meet all of the claim limitations except for the "mean grain diameter d[50] </= 5 [mu]m." Whether that limitation is met depends on how the grain diameter is measured.

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2 The terms "particle size" and "grain size" are used interchangeably by the parties and in this opinion. 3 "[mu]m" stands for micron or micrometer, denoting a millionth of a meter.

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In the first Initial Determination, the ALJ observed that the claims use the word "mean," but with the symbol d[50] whose conventional meaning is "median." Mean and median do not always produce the same result, for "mean" is the average diameter, while "median" is the diameter at which 50% of the particles are smaller and 50% of the particles are larger. On this ground the ALJ held all of the claims invalid for indefiniteness. The full Commission did not accept this ruling, and

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held that the claims can reasonably be construed by application of the general rule that words prevail over symbols and that the patentee can be its own lexicographer. The Commission explained that d[50] is "a variable defined by the words 'mean grain diameter' directly preceding it," and that the word "mean" is used throughout the specifications and claims, whereas "median" does not appear in the patents. Thus the full Commission concluded that "mean grain diameter d[50]" means the mathematical average diameter of the grains, and rejected the ALJ's holding of invalidity on the ground of indefiniteness.

The full Commission also deemed it unclear whether the mean grain diameter is measured as the average diameter based on the number of grains, or the average diameter based on the volume of the grains. This aspect of the claim construction had evolved during the trial, as it became apparent that its resolution could be dispositive of infringement. The Commission observed that the patent specifications did not state how the mean diameter is determined, and selected the volume-based method; this is a principal focus of this appeal. On this construction, the Commission remanded to the ALJ for application to the products at issue. Applying the volume-based method, the ALJ found that Dominant's "Fine Series LED" phosphors are within the claim limitation of having a mean diameter of </= 5[mu]m, but that Dominant's "Normal Series LED" phosphors have a volume-based mean diameter higher than 5[mu]m. Thus the ALJ found that the Fine Series products infringe the patents, but the Normal Series do not.

The ALJ also determined that OSRAM's own products of the domestic industry are outside this claim limitation when measured by the volume-based method. The ALJ concluded that OSRAM did not meet the "technical prong" of the domestic industry requirement of Section 337, 19 U.S.C. §1337(a)(2). On this ground the ALJ ruled that Section 337 was not violated as to any of the imported products. The full Commission affirmed, and this appeal followed.

DISCUSSION

Rulings of the International Trade Commission are reviewed on the standard of the Administrative Procedure Act, 5 U.S.C. § 706(2)(E). 19 U.S.C. § 1337(c). Rulings of law by the ITC are reviewed for correctness, and findings of fact are reviewed to ascertain whether they were supported by substantial evidence on the record as a whole. See Jazz Photo Corp. v. International Trade Comm'n, 264 F.3d 1094, 1099 (Fed. Cir. 2001). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolidated Edison Co. v. N.L.R.B., 305 U.S. 197, 217, 59 S. Ct. 206, 83 L. Ed. 126 (1938). Claim construction is reviewed as a matter of law. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc).

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No appeal is taken from the Commission's determinations that the claims are not invalid for indefiniteness, or that the "mean grain diameter d[50]" is the arithmetic average diameter. The issues on appeal flow from the ruling that the average or mean grain diameter of the phosphor grains is based on the volume, not the number, of grains. OSRAM states that the mean or average diameter of the grains as set forth in the patents would be readily understood by persons of experience in this field as the number-based average, and that the Commission erred in choosing the volume-based average.

The number-based average is calculated as the sum of the diameters of all the grains, divided by the number of grains. The volume-based average is calculated by multiplying the diameter of each grain by its volume, summing the products thereof, and dividing that sum by the sum of the volumes of the grains. These methods can produce divergent results; OSRAM gives the example that by the number method the mean diameter of a 1 [mu]m grain and a 10 [mu]m grain is 5.5 [mu]m, whereas the mean diameter calculated by the volume method is 9.99 [mu]m 4 .

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4 Calculated by volume: ((1x1<3>)+(10x10<3>))/(1<3>+10<3>) = 9.99.

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The Commission states that its choice of the volume method was "art-specific", and thereby distinguished from the "general understanding" of how to describe the average diameter of particles. The Commission cited two technical treatises: the Phosphor Handbook and Perry's Chemical Engineers Handbook. The Phosphor Handbook discusses the number-based method as generally used for phosphors, stating that the number-based method "is easy to use, but both 'area-based'

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(volume-based) and weight-based methods are frequently adopted to express the characteristics of actual powders." Perry's Chemical Engineers Handbook states, in a general section for particle size designation, that "[i]t is common to use a weight basis for percentage of frequency but surface or number may, in some cases, be more relevant." The Commission placed primary reliance on these sources, plus the evidence that it is common for manufacturers of phosphors to report phosphor size for sale to customers by volume. The Commission held that a person of ordinary skill in this field would understand "mean grain diameter" to be based on the volume method of measurement.

OSRAM states that this construction was incorrect, and contrary to the great weight of evidence. The experts for both sides were in full and emphatic agreement that the ordinary meaning of the average diameter of these particles is the number-based average--until Dominant's expert changed his position. OSRAM'S three expert witnesses testified that average diameter of phosphors is generally measured by the number-based method, and that the patents would be so understood by persons of ordinary skill in this field. This testimony was not disputed. Dominant's expert testified unequivocally in his deposition that "[t]o one skilled in the art, the term 'mean grain diameter d[50]' means that one determines the mean or average grain diameter, which is defined as 'the integral (or sum) of the diameter times the grain (particle) size distribution divided by the total number of grains (particles);'" the witness later changed his position when it became apparent that this question could determine liability. In addition, Dominant in its motion for summary judgment had stated:

Here, the "mean grain diameter d[50]" refers to the average grain or particle diameter, where "mean" is defined by its standard, well-known and accepted meaning--namely, the sum of the diameters of the grains or particles times the grain size distribution divided by the total number of grains.

OSRAM's witness distinguished the way powders are sold from the way they are characterized by scientists working on LED development, stating that "the R&D guy [measures phosphor size] on a number basis only."

The descriptive text in the patents is in accordance with the number-based measurement, as both Dominant and OSRAM had presented it. The patent specification is the primary resource for determining how an invention would be understood by persons experienced in the field. See Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998). The patent specifications are in accordance with a number-based mean, for the invention stresses the homogeneity of size, not volume, of the phosphor particles. It is not disputed that homogeneity of size is better reflected in a number average than a volume average, for a few large particles have a greater effect on the volume-based calculation. Expert witness Dr. Zachau explained that "if you really said you want to do it on a volume basis, large particles would be heavily overemphasized." Dr. Zachau explained that such distortion arises because volume is calculated as the cube of the diameter, 5 and the cube of a larger particle, for example a particle having a diameter of 10 [mu]m, is a thousand times the cube of a particle with a diameter of 1 [mu]m. He explained that this cubing effect of the volume-method obscures the information that particle size measurement is intended to convey, that is, the average size of the particles.

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5 Volume = 4/3 [pi]r<3>, where r = diameter/2

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As applied to the products at issue, OSRAM presents the example that for a powder hypothetically containing 6,250 1-[mu]m particles, 50 5-[mu]m particles, and 1 20-[mu]m particle, the mean grain diameter calculated by the number-based method is 1.03 [mu]m. In contrast, the mean diameter calculated by the volume-based method is 9.6 [mu]m. Dr Zachau testified that to achieve optimum homogenous light output, the number-based method provides the more useful information:

For this context, [persons in this field] do it on a number basis only. . . . The number distribution best measures--is more appropriate for this application, and for this device application. . . . Large particles, if they are very large, the core doesn't even contribute because the light doesn't get fully in. . . . [T]he small particles of the phosphor are very, very important, as we have seen before, for the scattering . . . . So the small particles do have the most important function here in the device. It's those we want to count. It's not the large ones.

This testimony was not disputed by the witnesses for either side, although Dominant's witness later amended his statement after it became clear that Dominant's position was affected; the ALJ questioned the witness on this point, and it is noted that

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the ALJ did not adopt the volume-based method in the Initial Determination.

We agree that the number-average measurement is better supported by the specification, and that it provides the better description of a product whose purpose is homogeneous distribution. See '861 patent, col.3, lines 21-25 ("[t]he luminous substance pigments, with the above-indicated particle size, can advantageously . . . be dispersed homogeneously in the epoxy casting resin."). When there is more than one method of measurement and the patent does not explicitly discuss the methods, persons experienced in the field are reasonably deemed to select the method that better measures the parameters relevant to the invention. See Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd., 401 F.3d 1367, 1372 (Fed. Cir. 2005) (when a person of ordinary skill would recognize which measurement is appropriate to the invention, that is the measurement that applies). All of the experts agreed that the volume-based measure is more sensitive to large particles, which do not function in the invention, and that the number-based measure is more sensitive to the size and distribution of the particles that perform the inventive function. There was no contrary evidence. Two commercial product specification sheets that describe phosphor particles by mean volume and mean weight had been submitted by OSRAM in the Patent and Trademark Office with its disclosure documents, but not referred to by either OSRAM or the examiner during prosecution. It is rare that references that were submitted with a disclosure document, but not even cited by the examiner, are probative of an intent to depart from the plain technical meaning of terms used in the specification and claims. See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (references considered for other purposes during prosecution do not establish that the patentee renounced the ordinary meaning of a term as used in the specification and claims).

OSRAM states that the volume-based statement of particle size gives a less accurate measure of the function of the LED, whereas the average diameter by number better informs a person of ordinary skill whether the LED will operate well. Although the Commission argues that the volume-based method, since more sensitive to "boulders," can indicate whether boulders are present, OSRAM correctly states that the purpose of the claim limitation is to state the parameters of the products that work in the desired way, not those that may not. See Howmedica, 401 F.3d at 1372. The Commission erred in construing the claims as requiring the volume-based method, contrary to the ordinary meaning of the term as reflected in the specification and the testimony, and at odds with the purposes of the invention. See Phillips, 415 F.3d at 1314 (claim terms are given the meaning with which they are used in the patent specification); the court may consider extrinsic evidence such as the testimony of experts in the field of the invention.

This conclusion is reinforced by the undisputed fact that the volume-based measure would exclude the OSRAM products that the patents were designed to cover. Cf. Hoechst Celanese Corp. v. BP Chemicals, 78 F.3d 1575, 1581 (Fed. Cir. 1996) (a claim construction that excludes the preferred embodiment is rarely, if ever, correct); Modine Mfg. Co. v. United States International Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996) ("a claim interpretation that would exclude the inventor's device is rarely the correct interpretation").

We conclude that the Commission erred in construing "mean grain diameter" as the volumetric mean, not the number-based mean. This ruling is reversed.
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C. "Measuring the HIV RNA copy number"

Roche seeks to define this term as "techniques available in May 1992 to quantify HIV RNA copy number using PCR, specifically the assay in the 1991 JID article as set forth in the specifications." Stanford, on the other hand, argues that no construction is necessary because the plain meaning suffices to guide the jury in its fact-finding.

Roche argues that Stanford's patents enable no more than the five-step end point PCR assay set forth in the 1991 JID paper and that "[t]he scope of the claims must be less than or equal to the scope of the enablement. " Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). Although the foregoing is true, the same confuses invalidity with claim construction. Questions as to whether the disclosure is sufficient to enable a person skilled in the art to practice the invention are best reserved for arguments alleging invalidity. As the Federal Circuit has stated, unambiguous claim terms "can be construed without the need to consider whether one possible construction would render the claim invalid while the other would not. " Phillips, 415 F.3d at 1328. The ordinary and customary meaning of "measuring the HIV

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RNA copy number" is unambiguous and allows for any measuring technique. Since the claim terms are unambiguous, the invalidity analysis is premature.

Roche also seeks to limit the measuring steps used to determine the HIV RNA copy number to the techniques available in May 1992 because after-developed technologies such as real-time PCR and internal standards were not taught by the patents and unknown when Stanford applied for the patents. Specifically, Roche claims that what one of skill in the art today would understand by a method using PCR is different than it would have been in May 1992. That argument is not related to the definition of "measuring the HIV RNA copy number" because the copy number is measured using the product of the PCR. Roche is again confusing claim construction issues with infringement issues. Roche may well argue, at the summary judgment stage or later, that its product does not infringe upon Stanford's patents based upon the claim limitations, but it may not inject the end point PCR limitation into the definition of "measuring the HIV RNA copy number." It is settled patent law that the claims of a patent must not be construed as being limited to the embodiment if the patent describes only one embodiment. Phillips, 415 F.3d at 1323. In fact, it is improper to read limitations from the specifications into the claim term because the same can "restrict[] the claims to coverage of a single embodiment." Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 1368 (Fed. Cir. 2005).

Nevertheless, the claims that state "about 30 cycles" must be limited to end-point PCR. The court can, as part of claim construction, construe the scope of "about 30 cycles." The claims' specific reference to the number of cycles of PCR must limit those claims to end-point PCR as a specific number of cycles is only germane within the context of end-point PCR. The fact that the number of cycles is irrelevant in real-time PCR further buttresses this finding.

Some of the patent claims, however, do not limit themselves to "30 cycles of PCR," but use the more generic term "PCR. " See '041 patent, Claims 1-3, 5-8. This categorical term is distinguishable from the categorical anti-retroviral agents because there is no evidence in the record that, as of 1992, one of ordinary skill in the art knew of real-time PCR or of its conceptual framework. Thus, based on SuperGuide, the term "PCR " cannot include real-time PCR. Mass. Inst. of Tech. v. Abacus Software, 462 F.3d 1344, 1353 (Fed. Cir. 2006), is also instructive. Abacus held that at the time of the patent application, a person of ordinary skill in the art would have known of two general types of scanners, drum scanners and flatbed scanners. Since both those scanners required close proximity between the color original and the scanner, the court defined the term scanner by what was known in the art at the time and included a requirement of close proximity. Id. Similarly, in 1992, a person of ordinary skill in the art did not know of real-time PCR. Defining PCR by what was known in the art at the time requires that real-time PCR be excluded.

In sum, the court holds that no construction is necessary for "measuring the HIV RNA copy number," but limits the claims stating "about 30 cycles" to end-point PCR and excludes real-time PCR from the scope of the term "PCR."
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8. "medicament"

This term appears in claims 12-19. Astra asserts that the Court should construe "medicament" as "medicine." DRL does not propose a construction for this individual term, but rather argues once again that the phrases in which this term appears in claims 12-19 do not require construction because they are not limitations. Although it rejects DRL's argument, the Court nevertheless shall not construe the term "medicament." Astra provides no basis for its construction, and the Court finds no ambiguity as to the meaning of the term "medicament" to one of ordinary skill. Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe the term "medicament" as it is used in claims 12-19 the '192 patent. The term's ordinary meaning as understood by those of ordinary skill in the art shall apply.
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DISCUSSION

The '259 and '933 patents are both directed to a medium and method for detecting target bacteria in an environmental

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sample using a chemical "nutrient-indicator." '259 patent, col. 1, ll. 17-18; '933 patent, col. 1, ll. 15-17. The nutrient-indicator, which cannot be consumed by non-target microbes in the sample, acts as both the primary nutrient for the targeted bacteria and, once metabolized, releases a moiety that alters a characteristic of the sample, such as its color. '259 patent, col. 1, ll. 18-24; '933 patent, col. 1, ll. 17-23. The medium, in addition to the nutrient-indicator, also contains varying amounts of amino acids, vitamins, and other ingredients.

Claim 9 of the '259 patent and claim 10 of the '933 patent are the only independent claims at issue in this appeal. Claim 9 reads as follows:

9. A method for detecting the presence or absence of a target microbe in an environmental or biological liquid sample, said method comprising the steps of:

a) mixing the liquid sample with a medium which includes an effective amount of vitamin, amino acid, element and salt ingredients operable to allow viability and log phase reproduction of said target microbe in the presence of a nutrient-indicator and to aid the target microbe through lag phase and into log phase of growth in the medium/sample mixture; and an effective amount of a nutrient-indicator which is provided in an amount sufficient to support log phase growth of said target microbe until a detectable characteristic signal is produced from said nutrient-indicator in the medium/sample mixture during said log phase growth; said nutrient-indicator being incapable of supporting continued logarithmic growth of any viable non-target microbes in the sample to produce a detectable characteristic signal; and said nutrient-indicator being operable to alter a detectable characteristic of the medium/sample mixture when metabolized by the target microbe so as to confirm the presence or absence of the target microbe in the sample; wherein said medium lacks a gelling agent so that when said medium is mixed with a liquefied sample a liquid is formed, and wherein said ingredients and said nutrient-indicator are chosen such that growth of non-target microbes do not interfere with growth of said target microbe: and

b) thereafter evaluating the medium/sample mixture to determine whether said detectable characteristic has been altered, wherein the presence of said detectable characteristic indicates the presence of said target microbe in said sample and the absence of said detectable characteristic indicates the absence of said target microbe.

'259 patent, col. 8, l. 36 to col. 9, l. 3 (emphases added). Claim 10 is similar to claim 9 in all respects relevant to this appeal, '933 patent, col. 9, ll. 24-60, and thus we will focus our analysis on the language of claim 9.

Edberg sued CPI in the district court, alleging that CPI's Colitag TM testing medium infringed the '259 and '933 patents, as well as U.S. Patent 4,925,789, a related patent that is not at issue in the present appeal. Edberg v. CPI-The Alternative Supplier, Inc., 156 F. Supp. 2d 190, 192 (D. Conn. 2001). After holding a "Markman hearing," the district court interpreted the claims of the '789 patent to require that the medium used to detect target bacteria be a "specific medium," i.e., a medium that is capable of supporting log-phase, reproductive growth of only the target microbes. Id. at 197. The court also determined that limitation to be present in the relevant claims of both the '259 and '933 patents based on the specifications and prosecution histories of those patents, despite the fact that the word "specific" is not found in any of those claims. Id. at 199-200. Based on that claim construction, the court granted CPI's motion for summary judgment of noninfringement of all three patents because it determined that no reasonable juror could find that CPI's Colitag TM product is a specific medium that permits substantial, log-phase growth of only target microbes. Id. at 202.

Edberg thereafter filed a motion for reconsideration, requesting that the district court either: (1) restrict the scope of its decision to the '789 patent; or (2) modify that decision so as to indicate that genuine issues of material fact preclude the entry of summary judgment as to claim 9 of the '259 patent. Edberg II at 1. The district court denied that motion, repeating its earlier conclusion that the intrinsic evidence of all three patents demonstrates that the "specific medium" limitation is "the essence of the 'invention'" and thus is present in every claim at issue. Id. at 2. The court reconciled the absence of the term "specific" in claim 9 of the '259 patent by recognizing the lack of inconsistency between the minor growth of non-target microbes during the initial lag phase, which claim 9 contemplates, and the log-phase, reproductive growth of those non-target microbes, which the specification and prosecution history of the '259 patent expressly forbid. Id. at 4. Edberg appeals from the district court's grant of summary judgment that CPI's Colitag TM product does not infringe the '259 and '933 patents as a matter of law. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to

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a judgment as a matter of law." Fed. R. Civ. P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). We review a district court's grant of a motion for summary judgment de novo. Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 149 F.3d 1309, 1315, 47 U.S.P.Q.2D (BNA) 1272, 1275 (Fed. Cir. 1998).

A determination of infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted . . . and then the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, 46 U.S.P.Q.2D (BNA) 1169, 1172 (Fed. Cir. 1998) (en banc) (citations omitted). Claim construction is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71, 34 U.S.P.Q.2D (BNA) 1321, 1322 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), that we review de novo, Cybor, 138 F.3d at 1456, 46 U.S.P.Q.2D (BNA) at 1172. Determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1125, 227 U.S.P.Q. (BNA) 577, 589 (Fed. Cir. 1985) (en banc).

Edberg argues that the district court erred in its claim construction, and that the claims at issue are properly construed to cover media that permit log-phase growth of non-target microbes, but only to the extent that such growth does not interfere with the log-phase growth of target microbes. Edberg contends that the district court improperly read the "specific medium" limitation into the claims at issue because the term "specific" is not found in any of those claims, and that the court ignored the ordinary meaning of the word "medium," which includes both general and specific media. Edberg further argues that because claim 9 explicitly requires that only the "nutrient-indicator," which constitutes only a portion of the claimed "medium," be incapable of supporting logarithmic growth of non-target microbes, the district court's interpretation renders that language superfluous. Edberg also contends that because claim 9 expressly refers to "growth of non-target microbes," and because all microbial growth is by definition logarithmic in nature, that claim must be construed to permit log-phase growth of non-target microbes. Finally, Edberg argues that it distinguished its invention from the prior art cited by the examiner during prosecution only on the basis that one chemical in the medium is used as both a nutrient and an indicator, and that it never stated that growth of non-target microbes is impermissible.

CPI responds that the district court correctly interpreted the term "medium" to mean a specific medium, as the written descriptions of both patents define that term as such. CPI further contends that the "growth" of non-target microbes referred to in claim 9 of the '259 patent is not log-phase growth, but rather is the lag-phase growth caused by the addition of a growth accelerant. CPI also argues that the prosecution histories of the '259 and '933 patents make clear that Edberg disclaimed any interpretation of the term "medium" that permits log-phase growth of any non-target microbes.

We conclude that the district court did not err in interpreting the claims at issue and in granting summary judgment that CPI does not infringe either the '259 or the '933 patent as a matter of law. The term "medium," while perhaps amenable to a broader interpretation under ordinary circumstances, was defined by the inventor of the patents at issue to be a specific medium, i.e., one that supports log-phase, reproductive growth of only the target microbes. The written descriptions of both patents are replete with statements indicating that the claimed medium is a specific medium. In summarizing the invention, the written descriptions state that "the medium is thus a 'specific medium' in that it will support growth in log phase of only the target microbes, rather than a general medium which will also support growth in log phase of microbes other than the target microbes." '259 patent, col. 1, ll. 24-28; '933 patent, col. 1, ll. 23-27 (emphases added). The written description of the '259 patent goes on to state:

> As previously noted, there is very little, or no, competition for food or nutrients among the microbes in the medium because the only nutrient present in the medium which can be metabolized to any significant extent can be metabolized solely by the target microbes. . . . Thus, only the presence of the target microbes in the specimen can result in sufficient metabolism of the nutrient to cause the color, or other characteristic change, in the sample. This is the crux of the invention.

'259 patent, col. 3, ll. 20-28 (emphases added).

Edberg argues that construing the term "medium" to mean a specific medium renders superfluous the language "said nutrient-indicator being incapable of supporting continued logarithmic growth of any viable non-target microbes in the sample to produce a detectable characteristic signal" in claim 9 of the '259 patent because there is no need to state that the nutrient-indicator is incapable of supporting log-phase growth of non-target microbes if none of the other ingredients in the medium has that capability. That argument, however, is belied by the following passage found in the written description of

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the '259 patent:

The specific nutrient is the only ingredient in the medium which will allow substantial growth, i.e., growth which will allow microbial reproduction at logarithmic rates (log phase) of any microbes in the sample. Thus, the medium will only support reproductive growth of the target microbes. For this reason the population of non-target microbes in the sample will not substantially increase, and will actually begin to decline during the log phase.

Id. at col. 7, ll. 21-29 (emphases added); see also '933 patent, col. 7, ll. 33-41. Therefore, although claim 9 indicates only that the nutrient-indicator is incapable of supporting logarithmic growth of non-target microbes, the written description makes clear that no other ingredients in the medium can support such growth, and Edberg has not pointed to any teaching in either written description to the contrary.

Furthermore, Edberg's argument regarding the phrase "growth of non-target microbes" in claim 9 is similarly unavailing. First, Edberg's contention that all growth is logarithmic in nature is belied by the reference to lag-phase microbial growth in the written descriptions of the '259 and '933 patents. See '259 patent, col. 2, ll. 48-50 ("In the lag phase, none of the microbes will significantly multiply and grow until they adjust to the new environment."); '933 patent, col. 2, ll. 51-53 (same). Second, the written descriptions provide an explanation for the presence of the phrase "growth of non-target microbes" in the claims at issue that is consistent with the repeated teaching in both patents that the medium cannot support log-phase growth of non-target microbes: "The testing medium also includes a minor amount of a growth accelerant which will boost the target microbes and all of the other viable microbes in the sample through lag phase towards log phase of growth in the testing procedure." '259 patent, col. 2, ll. 39-42; '933 patent, col. 2, ll. 41-45 (emphases added). That statement, when read in conjunction with the other portions of the written descriptions cited above, makes clear that the growth accelerant causes all microbes, both target and non-target, to engage in lag-phase growth for a period of time before the log phase is reached, at which time only the target microbes can grow. Consequently, the "growth of non-target microbes" language is properly interpreted to refer to the lag-phase growth of non-target microbes resulting from the nutrients present in the growth accelerant.

That interpretation is supported by statements made by Edberg during prosecution of the '259 patent. In an attempt to avoid a double patenting rejection over the '789 patent that ultimately resulted in the filing of a terminal disclaimer, Edberg explained that

the difference between the subject matter of the claims of the '789 patent and the claims of this application is that the latter include the "accelerant," or the step of "accelerating," to speed the growth of the target microbes through the lag phase of growth and into the log phase of growth. . . . In view of this fact, the inventions claimed in the two cases are not "the same."

Edberg does not dispute that the "medium" of the '789 patent is a specific medium that permits logarithmic growth of only target microbes, and therefore the addition of a minor amount of growth accelerant that affects only lag-phase microbial growth does not alter the definition of that term for purposes of the '259 and '933 patents. We therefore reject Edberg's argument that the language of the claims at issue requires that the term "medium" be interpreted to allow log-phase growth of non-target microbes.

Moreover, other excerpts from the prosecution histories of the '259 and '933 patents clearly demonstrate that Edberg disclaimed coverage of a medium that is not specific to the target microbes. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) (citations omitted). During prosecution of an earlier application that eventually led to both the '259 and '933 patents, Edberg stated that "the Damare et al article thus describes a general bacteriological growth medium that will support reproductive growth of target and non-target microbes, and therefore is not specific to any particular microbes, contrary to the subject matter claimed in this application." (Second emphasis added.) Although Edberg also attempted to distinguish its invention from the prior art on the basis that one chemical in the medium is used as both a nutrient and an indicator, those statements are unrelated to Edberg's clear disclaimer of media that permit logarithmic growth of non-target microbes. Accordingly, we conclude that the district court did not err in interpreting the term "medium" in the claims at issue to mean a specific medium that is capable of supporting log-phase growth of only the target microbes.

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"Melting"

The defendants state that the district court "failed to discharge its duty under Markman" when the court declined to construe 'melting.'" They state that the correct construction of "melting" would avoid infringement. Biotec states that the defendants did not object to the jury instruction on the ground that it did not construe "melting"; the defendants respond that indeed they objected, but the district court rejected their position. Despite this debate, the meaning of "melting" does not appear to have required "construction," or to depart from its ordinary meaning. The issue in dispute was the application of the melting step in the accused process, a factual question of infringement.
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Claim 10 describes Form A as having "a melting point of about 123-125 [degree]," '759 Patent, col. 18, ll. 15-16, and the parties dispute how to construe this term.

1. The Parties' Contentions

GSK avers that the specification, although not providing a definition of "melting point," indicates that the term should be construed with reference to the pharmaceutical field, because the invention relates to pharmaceuticals. (GSK Opening 21.) GSK contends that the United States Pharmacopeia (USP) is "the authoritative pharmaceutical reference relied upon by both parties' experts." (GSK Resp. 7.)According to GSK, the USP confirms that the melting point is the temperature at which a test substance fully becomes liquid, thereby supporting GSK's construction. (GSK Resp. 7-8.) GSK argues that Apotex's construction draws support from "generalized organic chemistry" publications, rather than from pharmaceutical texts. (GSK Resp. 9-10.)

As for the word "about" in the disputed claim term, GSK argues that case law has construed the word to mean "approximately," without requiring additional specificity or details. (GSK Resp. 14-16.) GSK contends that Apotex itself previously proposed the same definition, and that the prosecution history indicates that the inventors intended for the term to account for the practical variation associated with measuring the melting point. (GSK Resp. 14-16.) GSK continues that there is no intrinsic evidence supporting Apotex's assertion that experimental variation is up to a degree, and that Apotex, in essence, seeks to have the Court weigh in on a contested infringement issue regarding how to define the range of "about 123 to 125 degrees." (GSK Resp. 16-19.)

Apotex, however, contends that several prior art references, including a text authored by one ofGSK's experts, define melting point as the temperature when a compound is in equilibrium between its liquid and solid phases or forms, and that a person of ordinary skill in the art would not understand the melting point to be when a compound has finished melting. (Apotex Opening 15-16; Apotex Resp. 16-17.) According to Apotex, "melting point" relates to thermal properties and should be measured using a capillary apparatus. (Apotex Opening 16.)

As for the temperature range described in the disputed claim term, Apotex avers that Federal Circuit cases have clarified that "about" is "notorious" for its vagueness and is dependent upon the factual situation presented. (Apotex Resp. 16.) Apotex continues that here, "about" refers to the range of experimental error associated with determining the melting point using a capillary apparatus, and that a person with ordinary skill in the art would understand that each analytical technique has its own degree of precision. (Apotex Resp. 17.)

2. Analysis

First of all, "melting point" should be construed in the context of pharmaceutical products, because the specification indicates that the invention covered by the '759 Patent "relates to novel compounds,to processes for preparing them and to their use in treating medical disorders, id. col. 6, ll. 9-11, and is used in various "pharmaceutical compositions," id. col. 7, ll. 1-42. In construing "melting point," the primary issues disputed by the parties are as follows: (1) whether the "melting

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point" is the "end of melting" or the temperature at which the substance is at an "equilibrium between the liquid and solid states"; (2) whether the method of measuring the melting point, such as use of a "capillary melting point apparatus," needs to be specified; (3) whether "about" means "approximately" or needs to also account for "experimental error"; and (4) whether the temperature range needs to be specified with a variation of give or take a degree.

Turning first to the proper construction of "melting point," neither party points to any intrinsic evidence shedding light on the inventors' understanding of the term, nor has the Court found any. The Court, therefore, will look to extrinsic evidence to define "melting point," which may "shed useful light on the relevant art." Phillips, 415 F.3d at 1317. Merriam-Webster's Collegiate Dictionary defines "melting point" as "the temperature at whicha solid melts." Merriam-Webster's Collegiate Dictionary 723 (10th ed. 1995). The USP, upon which GSK relies and which the parties' experts accept as a standard pharmaceutical text, 8 explains that "the melting range or temperature of a solid is defined as those points of temperature within which, or at the point which, the solid coalesces and is completely melted," and that "the temperature at which the test substance becomes liquid throughout is defined as the end of melting or the 'melting point.'" The United States Pharmacopeia, The National Formulary 1805 (1995).

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8 (See GSK Opening, Ex. 3A (Byrn Rep.), at PP 40-41; GSK Opening, Ex. 3B (Byrn Opp. Rep.), at P 26; GSK Opening, Ex. 14, at PP 63-64 (Mislow Rep.).)

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The USP's definition is supported by the European Pharmacopoeia, the European counterpart to the USP, which defines the "melting point determined by the capillary method [a]s the temperature at which the last solid particle . . . passes into the liquid phase." European Pharmacopoeia 23 (3d ed. Council of Europe 1996). Dr. Kurt Mislow, one of Apotex's experts, also noted in his thesis that the melting point "is readily determined at the disappearance of the last crystal. (GSKOpening Ex. 24, at 55.) Thus, learned pharmaceutical texts understand melting point to be the temperature at which a solid becomes a liquid. The Court, however, will not adopt GSK's proposed "end of melting" language, because this adds confusion by suggesting that "melting point" is a temporal measure, rather than a temperature point.

Apotex seeks to have melting point construed in terms of the temperature at which an equilibrium exists between the solid and liquid states, and cites to several texts so defining the term. 9 The Court declines to adopt a similar construction. Most of the sources relied upon by Apotex are organic chemistry texts, rather than treatises specific to the pharmaceutical sciences, which is the relevant context for purposes of the '759 Patent, as this Court has already explained. More importantly, the Court finds Apotex's proposed construction to be unnecessarily detailed and confusing. As the texts cited by Apotex demonstrate, defining "melting point" in terms of equilibrium focuses on the intermolecular forces and thermal energy between the particles, and the energy needed to bring about the transformation of the solid into the liquid. 10 These definitionsin no way contradict the USP's definition and instead describe melting point on a molecular and chemical level. In fact, one of the organic chemistry texts relied upon by Apotex expressly confirms that the two sets of definitions are not incongruous by first defining melting point in terms of being an equilibrium, and then stating that "[t]he temperature at which a crystalline solid changes to a liquid or melts, is called the melting point." Solomons, supra note 8, at 425 (emphasis removed). Apotex's construction also lacks intrinsic support, because Claim 10 of the '759 Patent only uses the disputed melting point term in order to describe the analytical characteristics embodied by Form A, rather than detailing what happens at the chemical and molecular level when Form A melts. The Court, therefore, has determined that the appropriate definition of melting point for purposes of the present invention is the temperature at which a solid becomes a liquid. The Court finds that this definition will be understandable and helpful to the trier of fact.

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9 See Solomons, Organic Chemistry 76 ("The melting point of a substance is the temperature at which an equilibrium exists between the well-orderedcrystalline state and the more random liquid state."); Joel Bernstein, Polymorphism in Molecular Crystals 40 (Oxford Univ. Press 2002) ("The melting point is defined as the temperature at which the liquid is in equilibrium with the solid . . . ."); Douglas C. Neckers & Michael P. Doyle, Organic Chemistry 11 (John Wiley & Sons 1977) ("The melting point of any substance is the temperature at which the solid and liquid phases of that substance exist in equilibrium." (emphasis removed); C. David Gutsche & Daniel J. Pasto, Fundamentals of Organic Chemistry 135 (Prentice-

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Hall, Inc. 1975) ("The melting point . . . is the temperature at which the solid and liquid phase are in equilibrium.").

10 See Solomons, supra note 8, at 76 ("A large amount of thermal energy is required to break up the orderly structure of the crystal into the disorderly open structure of a liquid."); Bernstein, supra note 8, at 40 ("The melting point is defined as tthe temperature at which the liquid is in equilibrium with the solid so that the difference in Gibbs free energy between the two phases is zero); Neckers & Doyle, supra note 8, at 11 ("When melting occurs the regular arrangement in the crystalline lattice becomesthe random array of particles of the liquid. Such a transformation requires the addition of sufficient kinetic energy, usually in the form of heat, to break down the crystal lattice."); C. Gutsche & Pasto, supra note 8, at 135 ("The melting point . . . of a substance can be defined as the temperature at which the thermal energy of the particles driving them apart from each other is equal to the intermoleular forces holding them together in the solid state.)

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Regarding whether to include in the construction the "capillary . . . apparatus," the Court has not found, nor has Apotex identified, anything in the intrinsic evidence indicating the appropriate method for measuring the melting point. Because the Federal Circuit clarified that "a court, under the rubric of claim construction, may [not] give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," PPG Indus., 156 F.3d at 1355, this Court will not include language respecting "capillary . . . apparatus" in its construction of the melting point claim term.

As for the word "about," numerous Courts have construed "about" to mean "approximately" in cases inwhich the intrinsic evidence did not demonstrate that the inventor intended for the word to have a specific meaning, 11 For example, in Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed. Cir. 2005), the parties disputed how to construe "about" in relation to a claim term respecting dosage. The Federal Circuit held that the inventor "did not clearly set out its own definition of 'about' with reasonable clarity, deliberateness, and precision, and thus failed to act as its own lexicographer." Id. at 1371 (internal quotation marks omitted). The Merck court then concluded that because "the specification . . . suggest[ed] the patentee contemplated a range of dosages," "the term 'about' should be given its ordinary and accepted meaning of 'approximately.'" Id. at 1372. The same is true in this case. The language of Claim 10 demonstrates that the inventors contemplated a range of temperatures, from 123 degrees to 125 degrees Celsius. No other definition of "about" is set out in the specification or any other part of the intrinsic record. The Court, therefore, sees no reason to depart from the ordinary meaning of the word "about." 12

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11 See, e.g., Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1367-72 (Fed. Cir. 2005);ACCO Brands USA LLC v. Secucomputer, Inc., No. 03-1820, 2008 U.S. Dist. LEXIS 49032, 2008 WL 2566863, at *3 (N.D. Ill. June 25, 2008); Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care, No. 07-0753, 2009 U.S. Dist. LEXIS 84423, 2009 WL 2973165, at *9 (D. Del. Sept. 15, 2009); Biopolymer Eng'g, Inc. v. Immunocorp., No. 05-0536, 2007 U.S. Dist. LEXIS 94207, 2007 WL 4562592, at *11-12 (D. Minn. Dec. 21, 2007); Kim v. Dawn Food Prods., No. 01-1906, 2004 U.S. Dist. LEXIS 20837, 2004 WL 2658068, at *4-5 (N.D. Ill. Oct. 13, 2004); Cellnet Data Sys., Inc. v. Itron, Inc., 17 F. Supp. 2d 1100, 1114 (N.D. Cal. 1998).

12 A contrary result is not warranted by BJ Services v. Halliburton Energy Services, Inc., 338 F.3d 1368, 1372-73 (Fed. Cir. 2003), in which the patentee "argue[d] that the term "about" [wa]s intended to encompass the range of experimental error that occurs in any measurement." BJ Services did not focus on claim construction, and instead examined whether the claim term met the definiteness requirement. See id. BJ Services, therefore, is inapposite.

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Turning finally to the temperature range, nothing in the intrinsic record appears to support Apotex's assertion that temperature measurements vary up to a degree, and Apotex's briefing are noticeably silent as to the reasons for adopting such a construction. Not only is this Court reluctant to adopt a construction that imports "additional precision or specificity" not present in the patent itself, PPG Indus., 156 F.3d at 1355, but also, the Federal Circuit does not require "mathematical precision" in a patentee's definition of his invention. Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1340-41 (Fed. Cir. 2003). As with the "capillary . . . apparatus" language Apotex seeks to read into the construction, the Court has determined

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that it is not necessary to include the range of purported temperature measurement variation in construing "melting point." In accordance with the reasons detailed above, the Court construes "a melting point of about 123-125 [degree]," to be "the temperature at which the solid becomes a liquid, of approximately 123-125 [degree]."

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B. "having a melting point of 41 - 42 [degrees] C"

The only phrase that the parties present for construction in this case is "having a melting point of 41 - 42 [degrees] C." JM proposes dividing the phrase and construing "having a melting point" and "41 - 42 [degrees] C" separately, while the defendants propose construing the phrase as a whole. For brevity, the court will define the phrase as a whole. Shire and Noven generally agree on their proposed construction, with the exception that Shire wishes to further limit the testing apparatus for determining melting point to "a capillary melting point apparatus."

Claim Phrase	JM's Proposed Construction
"having a melting point of 41 - 42 [degrees] C"	melting point: "Temperatures at which melting activity is taking place, ranging from the temperature at which the first sign of liquification appears to the temperature at which the material is completely liquefied."
	41-42 [degrees] C: "41-42 [degrees] C and such variation above and below as one of ordinary skill in the art would deem appropriate based on the lack of decimal points and the known variability of melting point data to enable identification of solid methylphenidate free base of the invention."

Claim Phrase	Noven's Proposed Construction
"having a melting point of 41 - 42 [degrees] C"	"The solid begins to liquefy at a temperature between 40.5 [degrees] C and 41.4 [degrees] C and becomes liquid throughout at a temperature between 41.5 [degrees] C and 42.4 [degrees] C"

Claim Phrase	Shire's Proposed Construction
"having a melting point point of 41 - 42[degrees] C"	"when the solid substance is melted in a capillary melting apparatus, some liquid is first present at 40.5-41.4 [degrees] C and the solid becomes liquid throughout at 41.5-42.4 [degrees] C"

Notwithstanding the differences between the parties' proposed constructions, there are a few points of agreement regarding the issues involved in the present claim construction. First, there is no dispute that the compound "methyl [alpha]-phenyl-2-

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piperdine acetate free base" in claim 1 discloses methylphenidate free base, and that the further limitation, "in solid form," requries methylphenidate free base in solid physical form. See JM's Brief at 1; Noven's Brief at 3; Shire's Brief at 2-3. Regarding the melting point limitation, the parties agree on the significance of the patent's disclosure of a melting point using two significant figures without a decimal point. Specifically, the parties agree that a person of ordinary skill in the art would regard such disclosure as incorporating generally accepted principles of rounding, such that numbers ranging from 40.5 to 41.4 would be rounded to 41, and numbers ranging from 41.5 to 42.4 would be rounded to 42 when comparing a measured melting point value to the asserted claims. See JM's Opening Brief at 7; Noven's Brief at 3; Shire's Brief at 8. Additionally, there is consensus among the parties and their respective experts that a number of variables intrinsic to distinct samples of methylphenidate free base in solid form and individual experimental designs will result in varying melting points. For example, JM contends that heating rate, amount of material tested, state of subdivision of the sample, purity, operator error, and instrument variation and calibration can lead to slightly different melting point measurements. See JM's Brief at 8. Similarly, Noven asserts that purity, heating rate, calibration, size, and physical forms will affect melting points. See Noven Brief at 7-8; Ex. V to JM's Brief at p. 101, l. 16 - p. 102, l. 8, p. 105, ll. 5-22. Finally, Shire suggests that impurities (water, residual solvents, dust, etc.), the stereoisometric composition of a mixture, and workup parameters (drying time, temperature, and variation of solvents) would likewise result in varying melting point measurements. See Shire's Brief at 3; Ex. O to JM's Brief at p. 82, l. 20 - p. 83, l. 19, p. 232, l. 4 - p. 233, l. 4. Finally, the parties generally agree that a melting point range, as in these claims, describes the range from the temperature at which the first sign of liquification appears to the temperature at which the material is completely liquefied. See JM's Brief at 18; Noven's Brief at 17; Shire's Brief at 7.

The essential point of contention among the parties regarding the disputed phrase, setting aside Shire's proposed instrument limitation, concerns the amount of allowable variation incorporated into the claim limitation and the range of values allowable to affirmatively conclude that the melting point limitation of the '760 patent reads on a measured melting point of an accused product.

JM seeks to define this range as "variation above and below as one of ordinary skill in the art would deem appropriate based on the lack of decimal points and the known variability of melting point data to enable identification of solid methylphenidate free base of the invention." Fundamentally, JM argues that this definition would satisfy the first prong of an infringement analysis (claim construction), allowing the fact-finder to answer the second prong. JM contends that the jury will determine, after hearing testimony from the various experts, the relevant and applicable variables in evaluating whether the accused product meets the claim limitation.

In support of its proposed construction, JM points to the prosecution history and a number of extrinsic sources. First, JM points to previous published papers of the defendants' experts. In its briefing, JM lists various melting point variations that have been previously accepted by both Noven and Shire's experts in both statements made during deposition and contained within previous scientific publications. See Ex. U at 1708; Ex. V at p. 175, ll. 12-25 & p. 177, ll. 8-12; Ex. W; Ex. X at 1206-07; Ex. Y at 557; Ex. Z at 6117-18; and Ex. AA at 1190 to JM's Brief. JM provides these examples to demonstrate the broad range of historically accepted variations by one of ordinary skill in the art. JM also relies on the variability of the tested melting points of the accused product--JM cites to various documents purporting to show the accepted variability among lots of Daytrana TM by Noven. Turning to the prosecution history, JM asserts that the patentee viewed the melting point amendment as "unnecessary for claim 1 to be patentable" and as a way of merely highlighting the uniqueness of the present invention and the erroneous information in the Merck Index. It urges that the examiner's silence regarding the addendum and focus on the discrediting of the Merck Index further supports the assertion that the melting point limitation played no role in patentability. JM also notes that at no time during the prosecution of the '760 patent did the patentee or the examiner discuss limiting the invention to any particular subset of solid methylphenidate free base based on a purity level, crystalline structure, or any other particular property. Accordingly, JM suggests that the function of the melting point limitation is merely a means for identifying and confirming the identity of an unknown compound, and not to "exclud[e] certain batches of the same compound." See JM's Brief at 19-20.

After evaluating the intrinsic and extrinsic evidence, as well as the arguments of the parties, the court is not persuaded by JM's argument. JM's argument, at its core, would have the court ignore the claim language and its inclusion of the melting point limitation. 2

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2 As a threshold matter, the parties dispute whether the boundaries of the melting point observation--i.e., the observations of liquid for the first time and complete liquification--must occur at a defined range around 41 [degrees] and 42 [degrees] C, respectively. Noven and Shire assert that the evidence suggests that the inclusion of two significant factors and the exemplary instrument indicate that the compound must begin to liquefy at 41 [degrees] C (40.5 [degrees] C if rounding) and will be completely liquefied at 42 [degrees] C (42.4 [degrees] C if rounding). JM, to the contrary, would only require some melting activity to occur at any point within that range. As a matter of claim scope, the court concludes that the onset of melting activity and complete liquification of the compound must occur at a range within 41 [degrees] and 42 [degrees] C in order to satisfy the claim limitation. Thus, for example, a product which begins to liquefy at 41.5 [degrees] C and is completely liquefied at 42 [degrees] C falls within the scope of the claim. See THE UNITED STATES PHARMACOPEIA, THE NATIONAL FORMULARY 1805 (1995).

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The Federal Circuit has addressed the importance of numerical claim ranges in claim language. In Talbert Fuel Sys. Patents Co. v. Unocal Corp., the court adopted a literal interpretation of a numerical range. 347 F.3d 1355, 1357 (Fed. Cir. 2003). The limitation in question required a "gasoline having a boiling point range of 121 [degrees] F - 345 [degrees] F at 1 atmosphere pressure." Id. The court rejected the plaintiff's reading of the limitation, suggesting that the limitation was only included as a mere method of identification, i.e., "only to confirm the gasoline's predominant composition." Id. The court also relied on the patentee's inclusion of the limitation during prosecution for support that the patentee intended a literal interpretation of the claim limitation. 3 Again, in Jeneric/Pentron, Inc. v. Dillon Company, Inc., the court adopted a literal interpretation of a numerical range, stating "the claim language indicates that the invention's chemical components should be limited to the precise ranges set forth therein." 205 F.3d 1377, 1381 (Fed. Cir. 2000) (internal quotes omitted). The court noted that other numerical limitations in the patent contained broadening words like "about," whereas, "the precise weight ranges of claim 1 do not avoid a strict numerical boundary to the specified parameter." Id. (internal quotes omitted) ("This construction, assigning numerical precision to composition ranges, is particularly appropriate when other variables in the same claims explicitly use qualifying language."); see also Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007) (stating, "[t]his leads to a conclusion that one of ordinary skill in the art would understand the inventors intended a range when they claimed one and something more precise when they did not."). Much like in Talbert, the Jeneric court also relied on limiting amendments and statements made during prosecution. Id.

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3 The court is not persuaded by JM's argument distinguishing Talbert from the present case. In Talbert, in support of its analysis, the Federal Circuit acknowledged that the examiner required the precise numerical range limitation for patentability. While such explicit recognition of the limitation was not addressed by the examiner in this case, JM must live within the confines of the language of its asserted claims. See Ethicon-Endo Surgery, 93 F.3d at 1583 (noting that, even where the patentee "need not have included [a] limitation in its claim[,] [h]aving done so, it must live with the language it chose.").

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Notwithstanding JM's assertion to the contrary, the claiming of "melting point of 41 - 42 [degrees] C" is an implicit recognition of the form and purity sought, and it is not simply an indicator of identity. 4 This is supported by the prosecution history. Prior to the amendment, the patent claimed methylphenidate free base in solid form. The appending of "melting point of 41 - 42 [degrees] C" to claim 1 reflects an additional distinguishing characteristic of the claimed invention. In addition, the variables cited by the parties, particularly JM, can all be controlled to a certain extent. Indeed, the cited references suggest that those variables and testing parameters should be properly controlled, and instruments should be properly calibrated so as to minimize error.

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4 In fact, as indicated above, the parties do not dispute the chemical identity at issue in this case.

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Additionally, much like in Jeneric, the use of a strict numerical boundary in claims 1 and 2 and the inclusion of broadening words in claims 9 and 10 support a literal interpretation of the numerical range. Claims 9 and 10 of the '760 patent read as follows:

9. A process for preparing methyl [alpha]-phenyl-2-piperidine acetate (free base), which process comprises the steps of:

(i) stirring methyl [alpha]-phenyl-2-piperidine acetate hydrochloride in a suitable organic solvent and aqueous base;

(ii) evaporating the organic layer to leave an oil which solidifies on standing; and

(iii) dissolving the crude solid in an organic solvent, cooling to less than 10 [degrees] C and seeding with crude solid whilst continuing stirring.

10. A process according to claim 9, which process comprises:

(i) stirring methyl [alpha]-phenyl-2-piperidine acetate hydrochloride in heptane and an aqueous inorganic base, such as an alkali or alkaline earth metal hydroxide or carbonate;

(ii) evaporating the solvent from the organic layer to leave an oil that solidifies on standing; and, optionally,

(iii) dissolving the crude solid in 2,2,4-trimethylpentane, and seeding with crude solid at below 10 [degrees] C with stirring. (emphasis added).

Likewise, the specification also contains a reference to an approximation of temperature:

A preferred temperature range for the recrystallisation step (iii) is from about 3 [degrees] to about 8 [degrees] C. More preferably, the solution is seeded at from about 8 [degrees] C to about 10 [degrees] C and the temperature reduced further to from about 2 [degrees] to about 5 [degrees] C during stirring. '760 Patent, col. 2, ll. 32 - 36 (emphasis added); see also id. at col. 3, ll. 47-50 (describing precise temperatures).

The patentee's inclusion of words of approximation or variance in some claims and exclusion of them in others, coupled with the patentee's discussion of approximations in the specification, demonstrates the inventor's intention to limit "melting point of 41 - 42 [degrees] C" to its literal range. Consequently, the claim language, specification, prosecution history, and precedent suggest that the court must give literal effect to the melting point limitation. 5

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5 In view of this holding, the court need not address the defendants' argument that JM's construction renders the claims indefinite.

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C. Instrument Limitation

Shire argues that the court should limit the disputed claim term to require measurement of the melting point using a capillary melting point apparatus. Shire argues that one of ordinary skill in the art would read the claim limitation and understand that any measurement of a melting point range would require such an apparatus. Shire argues, "unlike other instruments routinely employed to study solid-liquid phase changes, a capillary melting point apparatus allows one to observe two temperatures. . . ." Shire's Brief at 7-8. Shire points to the specification, various extrinsic sources, and the inventor's testimony for support of its instrument limitation. 6 JM argues that the court should not read the capillary melting point apparatus limitation into the claims.

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6 The U.S. Pharmacopeia regards the capillary method as the standard technique for melting point determination, as does

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Vogel's Textbook of Practical Organic Chemistry. See THE UNITED STATES PHARMACOPEIA, THE NATIONAL FORMULARY 1805 (1995); B.S. Furniss, et al., VOGEL'S TEXTBOOK OF PRACTICAL ORGANIC CHEMISTRY INCLUDING QUALITATIVE ORGANIC ANALYSIS (Longman Scientific & Technical 4th ed. 1987).

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The specification's only discussion of melting point discloses as follows:

The combined solids were dried at room temperature in the vacuum over for 15 hours giving methyla-phenyl-2-piperidine acetate (free base) as white solid and their melting point (measured on a Thomas Hoover Capillary Melting Point Apparatus) was found to be 41 [degrees] - 42 [degrees] C. '760 Patent, col. 3, ll. 58-63 (emphasis added).

Although the issue is close, the case law supports Shire's argument. In Honeywell Intern., Inc. v. Int'l Trade Comm'n, the Federal Circuit considered the construction of the term, "melting point elevation." 341 F.3d 1332, 1339-40 (Fed. Cir. 2003). The dispute focused on whether the claims required any particular sample preparation method when determining the melting point elevation ("MPE"). Unlike the present case, however, "neither the claims, the written description, nor the prosecution history reference any of the four sample preparation methods that can be used to measure the MPE." Id. at 1339. Accordingly, the Federal Circuit, acknowledging that different sample preparation methods yielded different MPE results, held the claims indefinite as insolubly ambiguous. Id. at 1340 ("[T]he claims, the written description, and the prosecution history fail to give us, as the interpreter of the claim term, any guidance as to what one of ordinary skill in the art would interpret the claim to require. Moreover, because the sample preparation method is critical to discerning whether a PET yarn has been produced by the claimed process, knowing the proper sample preparation method is necessary to practice the invention.").

In ReedHycalog UK, Ltd. v. United Diamond Drilling Servs., Inc., Judge Davis applied Honeywell and concluded a claim was definite. 2009 U.S. Dist. LEXIS 32959, 2009 WL 1011730 (E.D. Tex. 2009). The claim at issue in ReedHycalog required "a thermal characteristic such that a 950 degrees C. temperature at the working surface results in a temperature of less than 750 degrees C. at the depth." ReedHycalog, 2009 U.S. Dist. LEXIS 32959, 2009 WL 1011730 at *8. The defendants argued that the claim language was indefinite for failing to "disclose the conditions, tests, or methods to measure the claimed 'thermal characteristics.'" Id. The court rejected the defendants' argument. The court concluded that they failed to "show that skilled artisans were aware of multiple methods to measure the claimed thermal characteristics and that the methods produced significantly varied results such that the thermal characteristics cannot be calculated or measured." Id. (citing Honeywell, 341 F.3d at 1340-41).

Unlike in Honeywell and ReedHycalog, the '760 patent discloses a specific method to test melting point--a capillary melting point apparatus. Furthermore, in its briefing, Shire suggests that two of the relevant testing methods, capillary melting point apparatus and differential scanning calorimeter ("DSC"), yield different results, and the failure of the court to require an instrument method might render the claims indefinite as DSC and capillary instruments yield different melting points. See Honeywell, 341 F.3d at 1340; ReedHycalog, 2009 U.S. Dist. LEXIS 32959, 2009 WL 1011730 at *8.

Under Honeywell, Shire's argument is persuasive. The claim's disclosure of a melting point range, coupled with the specification's suggestion of a measuring instrument, support Shire's argument. When the court adds to those facts the understanding that the industry standard instrument for measuring melting point range is a capillary melting point apparatus, the court concludes that Shire's argument has merit.

For all of the foregoing reasons, the court defines "having a melting point of 41 - 42 [degrees] C" as follows: "the solid begins to liquefy and becomes liquid throughout at a temperature range between 40.5 [degrees] C and 42.4 [degrees] C, as measured by a capillary melting point apparatus."

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(J) "melting temperature"

Peak of the melting endotherm as reflected by a DSC trace.

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1. "Immunosorbing Member" and "Liquid Absorbing Member"

The crux of this claim dispute is whether "immunosorbing member" should be construed identically with "immunosorbing zone" and whether "liquid absorbing member" should be construed identically to "liquid absorbing zone." First, the Court confronts the immunosorbing terminology. Dade Behring explains that while the "immunosorbing zone" is where the mips are bound, the "immunosorbing member" may be identical in scope or may subsume within it the "immunosorbing zone," as the "immunosorbing member" acts as a support for the "immunosorbing zone." Biosite, on the other hand, argues that the "immunosorbing member" and "immunosorbing zone" should be construed in the same manner, as they refer to the same aspect of the '241 invention.

The Court is persuaded that the "immunosorbing member" and the "immunosorbing zone" should be construed in the exact same manner. Claim 1 contains an "immunosorbing zone" whose definition is adequately set out in the definitions portion of the specification, while the "immunosorbing member" of Claim 25 is not defined in the specification. In fact, the latter term is not even mentioned in the specification or the prosecution history. It appears that there was no need to refer to the "immunosorbing member" separately in the specification or the prosecution history because it had no separate meaning from "immunosorbing zone," which had already been explicitly defined in the specification. Importantly, neither the specification drawings nor the prosecution history make reference to a separate immunosorbing member which supports the immunosorbing zone. Further, the "immunosorbing member," like the "immunosorbing zone" is comprised of mip, non-diffusively bound to at least a portion of a bibulous support. See Col. 1, lines 33-35 (Claim 1); Col. 1, line 66 through Col. 2, line 2 (Claim 25).

Recognizing it is well settled that claims are not to be interpreted so as to render claim language meaningless, see Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed.Cir.1991), the Court attributes the use of the word "member" rather than the use of the word "zone" to the fact that Claim 1 is a method claim, while Claim 25 is a device claim. Whereas "zone" is defined as "one of the sections or divisions of an area created for a particular purpose," see Webster's Dictionary at 2660, "member" is defined as "an essential part of a device." Id. at 1408 (emphasis added). The "zone" language terminology illustrates that the immunoassay method requires an area to be set aside for immunosorbing purposes. The "member" terminology, on the other hand, explicitly recognizes that the immunosorbing attribute has been assigned to an essential part of a device.

For analogous reasons, the Court is persuaded that the "liquid absorbing member" and the "liquid absorbing zone" have the same meaning. In fact, the "liquid absorbing member," is in a "liquid receiving relationship" with the "immunosorbing member," just as the "liquid absorbing zone" is in a "liquid receiving relationship" with the "immunosorbing zone." See Col. 1, lines 36-38 (Claim 1); Col 2, lines 3-6 (Claim 25). Additionally, the Court notes that counsel for Dade Behring was unable during oral argument to explain to the Court how an immunoassay, consistent with the '241 invention, could have both a "liquid absorbing member" and a separate and distinct "liquid absorbing zone." See D.I. 138 at 109-110.

Accordingly, the Court finds the "immunosorbing zone" of Claim 1 and the "immunosorbing member" of Claim 25 have the same meaning. The Court also construes "liquid absorbing zone" and a "liquid absorbing member" in an identical manner.

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A. "Menthol"

Wrigley seeks to construe menthol as "menthol in its pure or separated form." Cadbury objects to that phrasing because it insists that Wrigley is improperly adding qualifiers/modifiers to a term that is self-explanatory. According to Cadbury, use of the term menthol should refer to the plain and ordinary meaning of menthol as the molecule defined by the molecular formula C[10]H[20]O, regardless of whether that molecule is separate or part of another substance. While Cadbury's reading is a permissible lexical reading of the patent, based on the intrinsic evidence, I believe Wrigley's interpretation is

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true to the meaning in the patent. Although mint oils are an acceptable source of menthol, the patent specification consistently lists menthol and mint oils separately, and when it refers to menthol, it does so in many instances in which there is no peppermint oil present.

It is apparent from the language of the '233 Patent that, in nearly all of the situations in which the patent refers to menthol, it is not referring to any menthol that may exist in the formula as a result of the inclusion of any mint oils. Therefore, in the context of the '233 Patent, I am construing "menthol" as "menthol, as a distinct and separate substance, as distinguished from being present in mint oils." This construction does not impose any restriction or requirement on the actual source of the menthol, it only acknowledges the fact that when the patent mentions menthol, it is not talking about any menthol already present as a result of mint oils. There is ample evidence suggesting that a person of ordinary skill in the art would not assume that the menthol indicated in the formula could be the same menthol contained in any added mint oils.

Claim 34 itself does not give any indication of whether it requires the menthol to be separate and distinct from any other substance, but the other claims offer further insight. Claim 1 refers to a "cooling flavor composition which . . . does not impart a peppermint flavor . . . comprising: about 40% to about 80% by weight menthol . . . ." ('233 Patent, 54:39-43). Specifically stating that the composition does not impart a peppermint flavor means that, even if peppermint oil (rather than some artificial means) was the original source of the menthol, that menthol is now a separate substance.

This same distinction is drawn again in several other claims in the patent. Indeed, it is drawn in nearly every other claim in which menthol is mentioned. Claim 12 is a dependent claim, adding a flavored coating chosen from a group including, "spearmint, peppermint, eucalyptus, fruity-mint, menthol, wintergreen, and combinations thereof." 2 ('233 Patent, 55:23-25). Similar groupings are repeated in claims 17 and 23 as well. Lastly, Claim 36 refers to a flavoring agent which "is substantially free of menthol and other mint oil components." Menthol being mentioned completely independent of mint oils shows that the inventors considered the menthol as a separate substance. The '233 Patent even specifically states in the specification that the menthol used in a particular embodiment was"used in their separated, or pure, form, as distinguished from being present in peppermint oil." ('233 Patent, 11:66-12:1). By using menthol in such a way, it would prevent adding a peppermint flavor.

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2 Admittedly, the use of the word menthol in this circumstance (referring to a flavor, rather than a chemical compound) is not identical to its use in the disputed claim, but it is still instructive in showing that Cadbury's proposed construction does not fit.

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E. The Term "Metabolism"

Claim 1 of the '765 patent calls for the recipient strain to be mutated so that "metabolism" of the selected amino acid is partly blocked. (D.I. 240, Ex. A, col. 12, lines 10-14) ADM argues that the term "metabolism" should be interpreted to mean the "breaking down and synthesis of molecules" and cites two scientific treatises for support. n12 (D.I. 240 at 13) Ajinomoto has argued that the term "metabolism" should be interpreted to mean only the breaking down of molecules and that the synthesis of complex molecules, such as proteins from amino acids, should not be included in the term "metabolism." (D.I. 221 at 180-182)

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n12 ADM relies on: Albert L. Lehninger, Principles of Biochemistry 975 (1982) and William T. Keeton, Biological Science, A10 (3rd ed. 1980). (D.I. 240, Ex. C and F)

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The '765 patent specification does not define the term "metabolism." The language of the '765 patent claims, however,

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makes a distinction between the term "synthesis" and the term "metabolism." For example, in claim 1 the recipient bacterial strains are described as having a "mutation blocking the synthesis of the selected" amino acid and a "mutation partly blocking the related step of metabolism of said" amino acid. (D.I. 240, Ex. A, col. 12, lines 10-14) (emphasis added). In claims 3 and 4, the recipient bacterial strain VL334 is described as having a mutation blocking the synthesis of L-threonine and a mutation partly blocking the synthesis of L-isoleucine. (D.I. 240, Ex. A, col. 12, lines 35-37 and 62-65) The distinction between the term "synthesis" and the term "metabolism" is also supported by the patent specification. (D.I. 240, Ex. A, col. 5, lines 1-65) Since the patent applicants chose to make distinctions between the terms "synthesis" and "metabolism" in the patent claims and specification, it appears that they intended the term "metabolism" to mean only the breaking down of molecules. Consequently, although the treatises cited by ADM define "metabolism" to mean the breaking down and synthesis of molecules, the court construes the term "metabolism" in the '765 patent to mean only the breaking down of molecules.

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C. "A Method For Eliminating The Troughs And Peaks Of Drug Concentration In A Patient's Blood Plasma"

The phrase "[a] method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" appears as the preamble to claims 21, 24, and 25 of the '171 patent and claims 2, 5, and 6 of the '958 patent. Each of these asserted claims recite a method of orally administering an encapsulated extended release formulation that provides a single peak blood plasma level in about four to about eight hours after administration, thereby eliminating the troughs and peaks of drug concentration in a patient's blood plasma.

Impax contends that the disputed phrase means that "the peak(s) and trough(s) due to the 'therapeutic metabolism' of any second or third dose given in a single day is eliminated by dosing only once in 24 hours." Wyeth contends that Impax's definition does not correctly grasp the claims, because eliminating the peaks and troughs of a second or third dose of venlafaxine hydrochloride, but not the sharp peak and trough of the first dose, is not the same as having a profile of one peak and one trough extended over a twenty-four hour period. Thus, Wyeth proposes a more detailed construction that explains how the troughs and peaks are eliminated:

A method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus time.

Reviewing the claim language in light of the specification 2, the Court concludes that Wyeth's proposed construction is correct. The specification explains that this invention provides a method for obtaining a "flatted drug plasma concentration to time profile" compared to what could be achieved with multiple daily dosing. Ex. 1, col. 2, ll. 22-24. According to the Brief Description, this effect is possible because immediate release tablets give peak blood plasma levels in two to four hours followed by a gradual decline, while extended release formulations allow the blood plasma levels to rise for "between about five to about eight hours (optimally about six hours) and then begin to fall through a protected, substantially linear decrease from the peak plasma level for the remainder of the twenty four hour period, maintaining at least a threshold therapeutic level of the drug during the entire twenty-four hour period." Id. at col. 2, ll. 29-38. Stated another way, the claimed extended release formulations provide a method of eliminating the sharp, multiple peaks and troughs associated with multiple daily dosing of the immediate release formulation and replacing those sharp, multiple peaks and troughs with a more controlled flattened blood plasma drug concentration to time profile which includes a peak followed by a gradual and protracted decline.

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2 The prosecution histories of the patents do not illuminate the meaning of this term, and therefore, the Court limits its discussion to the specification and claim language.

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Impax's proposed construction requires the peaks and troughs of the second and third doses to be eliminated, but maintains the plasma concentration to time profile of immediate release formulations, which is at odds with the specification. Thus, the Court adopts Wyeth's position that the claimed method is a way to flatten the plasma concentration to time profile into a single peak and trough, and not merely to eliminate multiple peaks and troughs. Accordingly, the Court adopts Wyeth's construction, and construes "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" to mean:

A method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide, during the course of treatment, relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus time.

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A. The Preamble: A Method for Treating Induced Contact Dermatitis

Plaintiffs take the position that the preamble represents an affirmative limitation on claim 1 while defendants take the position the preamble does not limit claim 1 because it merely recites the intended use and purpose of the claimed invention. This is an inversion of the usual positions of the inventor and the putative infringer: the inventor looks for a broad interpretation so that the claim can capture a wide range of alleged infringing products while the putative infringer looks for a narrow interpretation to escape the scope of the claim.

This difference between the parties needs no extended discussion. The examiner initially rejected a claim drawn to "methods for treating contact dermatitis" stating "only claims reciting methods for treating urushiol induced contact dermatitis were acceptable." See Px 7 - File History - at p. 20866-67 (Office Action mailed July 14, 2004). 3 As filed, the preamble reads "a method for treating contact dermatitis." Following a rejection by the examiner, the preamble was amended to read "a method for treating urushiol induced contact dermatitis." As argued by plaintiffs in their opening Markman Brief:

Reading the claim of the '963 patent to indiscriminately cover treatment of all types of contact dermatitis would impermissibly ignore the Patent Office's rejection and Yarborough's deliberate decision to amend his claim in response.

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3 Px represents the exhibits in the Appendix in Support of Plaintiffs' Opening Markman Brief.

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While the significance of the parties' differences on the preamble escapes the Court, the preamble breathes life, meaning and vitality into the claim by making clear the purpose of the invention. See Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333 (2003) ("The preamble . . . is a statement of the intentioned purpose for which the method must be performed."). Bristol-Meyers Squibb Co. v. BenVenue Laboratories, Inc., et al., 246 F.3d 1368 (2001), cited by defendants' post-argument, does not persuade the Court otherwise. It may well be that plaintiffs' infringement argument or defendants' defense to infringement may require reconsideration of this issue.

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A. Claim Construction

Bristol argues that the district court erred by not giving effect to the preamble "for reducing hematologic toxicity" and the expression "an antineoplastically effective amount" in the '803 claims. In particular, Bristol asserts that "an

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antineoplastically effective amount" is limiting because it was added by amendment to distinguish over Kris, who observed no antitumor efficacy. Similarly, Bristol argues that the court improperly read out the phrase "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" from claims 5, 6, 8, and 9 of the '537 patent, asserting that this expression is the only difference between claims 1 and 5 and therefore must be given effect under the doctrine of claim differentiation. Finally, Bristol argues that these expressions are limitations because they distinguish the new use of the process over the prior art, which did not show usefulness for treating cancer in three-hour paclitaxel infusions.

The defendants respond that the expressions "reduced hematologic toxicity" and "antineoplastically effective amount" in the '803 patent claims merely state the intended result of those claims and are non-limiting. Furthermore, the defendants point out that "antineoplastically effective amount" was not required by the examiner to distinguish over the prior art because Bristol voluntarily added the phrase to the claims after the examiner had found them allowable. The defendants also assert that the preamble language of the '537 claims, "to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity," only states an intended result of that claimed method. Moreover, the defendants assert that the doctrine of claim differentiation does not apply to distinguish the scope of claim 5, which recites that expression, from claim 1, which does not, because both claims are independent. The defendants also argue that Bristol's claim construction arguments violate the rule of consistency, which requires courts to construe claims consistently for both validity and infringement. Finally, the defendants respond to Bristol's argument that the asserted claim limitations are necessary to distinguish over the prior art on the basis of the discovery of the new "usefulness" of three-hour paclitaxel infusions, arguing that the prior art was directed to that same use -- treating cancer -- and that Bristol's sole contribution was in recognizing a new result of that same use, i.e., that it worked to treat cancer.

We first address the preamble language of the claims in the '803 patent, "for reducing hematologic toxicity." We discern no error in the district court's interpretation of that language as non-limiting, and merely expressing a purpose of reducing hematologic toxicity relative to the toxicity experienced by a patient undergoing a twenty-four-hour infusion. The steps of the three-hour infusion method are performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim. See, e.g., In re Hirao, 535 F.2d 67, 70, 190 U.S.P.Q. (BNA) 15, 16-17 (CCPA 1976) (holding that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim). Furthermore, this is not a case in which a new use of a process should be considered to be a limitation because that new use distinguishes the process over the prior art, as we will discuss infra. We therefore affirm the district court's construction of this expression as non-limiting.

We reach the same conclusion with respect to the expression "an antineoplastically effective amount," also in the '803 claims. That expression of intended result essentially duplicates the dosage amounts recited in the claims that are also described in the specification as "antineoplastically effective." '803 patent, col. 5, ll. 40-44 ("It has also been surprisingly discovered that lower taxol dosages, such as about 135 mg/m2 can be administered via infusions lasting about 3-hours to about 28-hours, and still be antineoplastically effective."). The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim.

We also agree with the defendants that the amendment adding "antineoplastically effective amount" was voluntarily made after the examiner had already indicated to Bristol that the claims were allowable. See Supplemental Response for Application No. 08/544,594 (Jan. 10, 1997). These unsolicited assertions of patentability made during prosecution do not create a material claim limitation where we have determined that the language does not create one. Indeed, for purposes of infringement, Bristol apparently does not see this expression as requiring efficacy; Bristol stated its view in response to requests for admission that the claims of each patent would be infringed without a showing of an objective response in every patient. Bristol cannot have an expression be limiting in this context and non-limiting in another. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 842 F.2d 1275, 1279, 6 U.S.P.Q.2D (BNA) 1277, 1280-81 (Fed. Cir. 1988) ("Having construed the claims one way for determining their validity, it is axiomatic that the claims must be construed in the same way for infringement."). We therefore affirm the district court's interpretation of "antineoplastically effective amount" as non-limiting.

We next construe the expression "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" in the preambles of claims 5 and 8 of the '537 patent. Again, we agree with the defendants that this language is only a statement of purpose and intended result. The expression does not

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result in a manipulative difference in the steps of the claim. Moreover, Bristol would have us construe the claims as limited to those instances of practicing the claimed method that achieve the stated result for purposes of validity, but as encompassing all instances of carrying out the physical steps for purposes of infringement. Again, Bristol cannot have it both ways. W.L. Gore, 842 F.2d at 1279, 6 U.S.P.Q.2D (BNA) at 1280-81.

We are also unpersuaded by Bristol's argument that this expression must be given effect under the doctrine of claim differentiation to distinguish between claims 1 and 5 and claims 2 and 8. The doctrine only creates a presumption that each claim in a patent has a different scope; it is not a "hard and fast" rule of construction. Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186, 48 U.S.P.Q.2D (BNA) 1001, 1005 (Fed. Cir. 1998). We decline to blindly apply the doctrine in this case to supplant other canons of claim construction that compel our conclusion that independent claims 1 and 5 have identical scope and that independent claims 2 and 8 have identical scope. We therefore affirm the district court's interpretation of claims 5 and 8 as limited only to the actual steps of those claims, without regard to the result of performing the claimed steps.

Finally, we address Bristol's argument that new uses of old processes are patentable, that we should treat the expressions of efficacy as limitations because they distinguish the new use of the process over the prior art, and that claims should be read to preserve their validity. Bristol is correct that new uses of known processes may be patentable. See 35 U.S.C. § 101 (1994) ("Whoever invents or discovers any new and useful process . . . may obtain a patent therefor."); 35 U.S.C. § 100(b) (1994) ("The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."). However, the claimed process here is not directed to a new use; it is the same use, and it consists of the same steps as described by Kris. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. In re May, 574 F.2d 1082, 1090, 197 U.S.P.Q. (BNA) 601, 607 (CCPA 1978); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 633, 2 U.S.P.Q.2D (BNA) 1051, 1054 (Fed. Cir. 1987) (holding claimed process for making fertilizer anticipated by a disclosure of the same process for making fertilizer even though prior art did not disclose the "inventive concept"); cf. Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366, 52 U.S.P.Q.2D (BNA) 1303, 1306-1307 (Fed. Cir. 1999) (finding anticipation of a method of hair depilation by an article teaching a method of skin treatment but recognizing the disruption of hair follicles).

In May, one of our predecessor courts held that claims to the method of effecting analgesic activity without producing physical dependency by administering a genus of non-addictive analgesic compounds were anticipated by a disclosure of a species of that genus that was used as an analgesic. In re May, 574 F.2d at 1090, 197 U.S.P.Q. (BNA) at 607. Although the prior disclosure was silent as to the addictiveness of the prior art compound, May's appealed claims merely recited a newly discovered result -- non-addictiveness -- of a known method directed to the same use, i.e., treating pain with an analgesic. Id. The court therefore held that those claims were anticipated by the prior disclosure. Id. Similarly, Bristol has done no more than claim a result (efficacy) of three-hour paclitaxel infusions in cancer patients. As in May, the purpose -- treating cancer -- is no different from the purpose disclosed by Kris. Although in suitable cases we will construe claims so as to preserve their validity, Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1383, 53 U.S.P.Q.2D (BNA) 1161, 1165 (Fed. Cir. 1999), the expressions "reduced hematologic toxicity," "antineoplastically effective amount," and "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" do not impart patentability to Bristol's claims because, as we hold here, they do not distinguish those claims over the prior art. We therefore affirm the district court's conclusion that these expressions of intended efficacy and reduced toxicity are non-limiting.

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A. Identification and Detection of Nucleic Acids In A Multi-Nucleic Acid Mixture

The parties argue at length over the meaning of the disputed language of the preamble to Claim 1, "a method of identification and detection of nucleic acids in a multi-nucleic acid mixture." The central dispute is whether this language means that the '648 patent claims encompass DNA sequencing.

Perkin-Elmer argues that the disputed language must be construed to mean, "a process in which detectably different labels are used to identify and detect nucleic acids while in a mixture of different, pre-existing nucleic acids. This method does not cover DNA sequencing." Perkin-Elmer advances several lines of analysis to support this position. The first is that the

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detection step in DNA sequencing does not occur in a mixture but, rather, after the nucleic acid fragments in the mixture are separated into individual components through the step of electrophoresis. Therefore, Perkin-Elmer argues, Amersham's interpretation ignores the language "in a multi-nucleic acid mixture." Perkin-Elmer draws upon the restriction requirement issued in the parent '924 application for support that the Examiner excluded DNA sequencing from the scope of the '648 patent claims. Perkin-Elmer then argues that the claim language actually refers only to probing techniques, which allow nucleic acid to be detected while in a mixture.

Perkin-Elmer next contends that DNA sequencing normally involves the sequencing of one nucleic acid of interest, the template DNA, and does not involve the use of "a multi-nucleic acid mixture" at all. Perkin-Elmer presents its expert, Dr. Roberts, who testifies that one of skill in the art would not understand "multi-nucleic acid mixture" to refer to primer extension products, as these nucleic acids are composed of varying lengths of the same sequence and are therefore not a "mixture." Perkin-Elmer also argues that no "multi-nucleic acid mixture" exists when the fluorescent labels are covalently bonded to the nucleic acids to be detected, again offering Or. Roberts' testimony. 15

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15 The Court will address this particular argument in analyzing the "covalently bonding" claim term, infra, at Section IV-B.

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Amersham contends that a "multi-nucleic acid mixture" means "a mixture of nucleic acids that contain two or more non-identical nucleic acids." The disputed language as a whole means, "the different nucleic acids in a multi-nucleic acid mixture that are labeled with different fluorescent labels can be distinguished by irradiating the labels and measuring the fluorescence they emit." Amersham's position is that the claim preamble does not require that the "detection" step take place "in the multi-nucleic acid mixture," but rather only that detection occurs by means of irradiating followed by detection, as the "comprising" language allows for any necessary additional method steps. Parkin-Elmer's construction would exclude the preferred embodiment, DNA sequencing, disclosed in the specification. Perkin-Elmer's contention that no "multi-nucleic acid mixture" is involved in DNA sequencing ignores the science. The imperfect separation achieved during DNA sequencing results in a "multi-nucleic mixture" composed of both unlabeled and labeled fragments. As for the prosecution history, Perkin-Elmer's reliance on the restriction requirement in the '924 application is unavailing to limit the scope of the '648 claims. Moreover, it is inconsistent with the Examiner's actions with respect to the '648 patent which supports the construction that DNA sequencing is allowed by the claims.
1. The Importance of the Preamble Language

While generally the preamble does not limit the scope of a claim, the preamble may be read to shed light on the meaning of the claim and to define the invention. In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994); DeGeorge v. Bernier, 768 F.2d 1318, 1322, n.3 (Fed. Cir. 1985). "[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). "No litmus test can be given with respect to when the introductory words of a claim, the preamble, constitute a statement of purpose for a device or are, in themselves, additional structural limitations of a claim….the effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works v. Sumitomo Elec. USA Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality to the claim, then the claim preamble should be construed as if in the balance of the claim. Pitney Bowes, 182 F.3d 1298, 1305.

Perkin-Elmer argues that the preamble is necessary to give meaning to the claims and properly define the invention. Perkin-Elmer contends that the phrase "identification and detection of nucleic acids in a multi-nucleic acid mixture" mandates detection while multiple acids are in a mixture and is, therefore, a limitation that should be read into the claims. From there, Perkin-Elmer argues that the claim excludes the use of the subject energy transfer coupled dyes in DNA sequencing processes, because DNA sequencing requires separation of the nucleic acids from a mixture prior to "identification and detection."

Amersham first contends that the preamble is not required in order to construe the claims and may be ignored by the Court. That being said, Amersham then argues that "a method of identification and detection of nucleic acids in a multi-nucleic

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acid mixture" must be read so that "in" modifies "nucleic acids," not "identification and detection." The claim language means that the method (of identification and detection) is applied to the nucleic acids found in a (multi-nucleic acid) mixture, Amersham insists the language is not restricted so that an "identification and detection step" must take place while nucleic acids are in a multi-nucleic acid mixture. In addition, Perkin-Elmer's interpretation would ignore the preferred embodiments and substitute a method not disclosed in either the specification or prosecution history.

In this case, the preamble, properly construed, gives meaning to the claims and helps to properly define the invention. Pitney Bowes, 182 F.3d at 1305. However, the preamble language itself is not without certain ambiguity. "In" is among the most ubiquitous words in the English language, freely used as a preposition, adverb, adjective or noun. See Webster's Ninth New Collegiate Dictionary (1984) at 607. The Court cannot say which of the proposed constructions is the correct one without reference to the specification.
2. The Patent Specification Indicates DNA Sequencing Is a Preferred Embodiment of the '648 Claims

Claim 1 requires "detecting each of said labeled nucleic acids by irradiating…and detecting the fluorescence of each of said labels." It does not require that the detection take place in the multi-nucleic acid mixture. The use of the term "comprising" allows additional method steps to occur within the process contemplated by the claim. 16 Thus, this claim does not exclude a separation step prior to the detection step, as occurs in DNA sequencing when the nucleic acid extensions are subjected to electrophoresis before any attempt is made to "detect" them. Nor does the claim require that the labeled nucleic acids continue to be part of a multi-nucleic acid mixture throughout the subsequent detecting process.

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16 "A comprising type claim by definition does not exclude the presence of other steps, elements or materials. Reese v. Hurst, 661 F.2d 1222, 1229 (C.C.P.A. 1981). "Comprising" does not exclude additional unrecited elements, or steps [in the case of a method claim]." Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271 (Fed. Cir. 1986).

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"Methods of identification and detection" includes DNA sequencing, which requires the identification and detection of nucleic acid strands of a specific length to determine the DNA sequence. Both the '648 patent specification and prosecution history clearly describe DNA sequencing. In the specification the inventors directly addressed DNA sequencing (Patent, Col.1:15-63; 2:14-19; 4:37-39; 5:23-32; 5:48-67; 39-50; 8:16-42; 9:36-62; 10:1-4; TR 18:13-25; 19:1-25; 20:1-6), clearly assuming that the detection may take place following separation, as the use of electrophoresis makes clear. See Patent, Col.5:62-67; Figures 2, 4-7. At Example III (figure 7), entitled "Preparation of DNA Sequencing Fragments with FAM-3-ROX and FAM-10-FAM" (Patent, Col.9:36-55; 10:1-4), the inventors describe the separation of DNA sequencing fragments and their subsequent detection using laser irradiation, looking at two bases, adenine and thymine. TR 20:1-6 (Dr Chamberlin). In contrast, the inventors do not discuss applications where the labeled fragments are detected without undergoing a separation step in the specification.

The inventors were interested in improving existing automated DNA sequencing processes through the use of their labels, as they state at the beginning of the '648 patent specification. Patent, Col.1:14-63. The specification is quite clear that application of the energy transfer coupled dye labels in DNA sequencing is the preferred embodiment of the invention. See id., Col.2:14-19 ("The subject invention finds particular application in sequencing, where the fluorophores may be attached to universal or other primers in different fluorophore combinations used for different dideoxynucleosides.") (emphasis added). Because Perkin-Elmer's construction would exclude the best mode of the invention described in the patent, that construction is erroneous. 17

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17 Burke, Inc. v. Bruno Independent Living Aids, Inc., 183 F.3d 1334, 1341 (Fed. Cir. 1999)(reversing claim interpretation that would exclude the preferred embodiment described in the specification); Enercon GmbH v. International Trade Commission, 151 F.3d 1376, 1384 (Fed.Cir. 1998)((claims are not limited to the preferred embodiments); Vitronics, 90 F.3d 1576, 1584 (court's reliance on extrinsic evidence to contradict the specification is reversible error); Howes v. Medical Components, Inc., 814 F.2d 638, 643-44 (Fed. Cir. 1987)(claim interpretation which is inconsistent with the specification is erroneous).

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The parties expend much effort debating how one or more multi-nucleic acid mixtures figure in DNA sequencing. The premise of all DNA sequencing is that an investigator can "detect and identify" the sequence of bases within a nucleic acid "mixture" (DNA or other genetic fragment) by labeling certain base nucleotides. As previously described, a primer catalyst is used to precipitate a reaction with the subject nucleic acid -- the primer extension reaction-- to generate the DNA fragments which make sequencing possible. Ex. 210; TR 24:13-25. Sequencing practices may be distinguished by such features as the manner of labeling or marking nucleotides for purposes of detection and identification, by primers used, by whether the primer or the terminator nucleotides are labeled, or by now the DNA strands created by primer extension are separated. 18 Sequencing processes, where a label is covalently bonded to the nucleic acid, are distinguishable from a probing assay, where a labeled probe is non-covalently attached or "hybridized" to DNA. Ex. 63, at 2:19-21; 184:1-185:13.

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18 See, e.g., Patent, Col.1:25-39; Ex. 63, at 2:5-18; TR 13:12-25; 14:1-25; 15:1-22; 171:3-13; 182:7-183:8. For example, radioactive end-labeling of one or both DNA strands may be employed, followed by either cleavage or extension of labeled strands to produce end-labeled fragments. 12 McGraw-Hill Encyclopedia of Science & Technology, at 214.

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Perkin-Elmer argues that nucleic acids formed by primer extension are not a mixture because they are merely different length extension products complementary to the template DNA. To "mix" is to "bring into close association," and "mixture" by definition includes "a portion of matter consisting of two or more components in varying proportions that retain their own properties" or "a combination of several different kinds." Webster's Ninth New Collegiate Dictionary (1984) at 761. Whatever their genesis, the extension fragments meet this common usage criteria.

Perkin-Elmer would interpret the claim language so as to exclude DNA sequencing from the invention's scope, by artificially forcing the invention into one stage (the subject mixture) and ignoring the progression of stages (primer extension reaction, attaching labels, electrophoresis, laser activation of the labels) needed to ascertain the sequence of the bases. Available extrinsic evidence shows that one skilled in the art understands that sequencing is accomplished in stages and would read the specification and claims with this understanding. Dr. Chamberlin testified credibly that one of skill in the art would understand that the examples of multi-nucleic mixtures described in the specification would include the nucleic acid mixture produced during DNA sequencing. See, e.g., Ex. 63, at 3:16-23; 9:11-27; TR 23:17-24:3. The Court also finds Professor Glazer's testimony to the same effect credible and internally consistent. TR 117:12-122:5. Dr. Roberts' testimony is not to the contrary. TR 168:16-169:3; 182:24-183:8; Roberts Dep. (10/11/99) 61:12-17. See Pitney Bowes, 182 F.3d 1298, 1309 ("[E]xtrinsic evidence is particularly appropriate to ensure that [the trial court's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art.").
3. The '648 Patent Prosecution History Shows that the Patent Claims Encompass DNA Sequencing

The Examiner considered DNA sequencing art in deciding whether to issue the '648 claims. The applicants submitted seventeen scientific references and patents that the inventors believed were relevant to the prosecution of these claims during the prosecution of the '890 application. Ex. 205. Nine references are to publications about DNA sequencing and specifically describe methods for DNA sequencing. Id.; Ex. 63, at 5:6-28. Eight articles explicitly refer to DNA sequencing in their titles. The nine art references concerning DNA sequencing were included in the '648 specification. See TR 20:11-24.

Two references discussing the use of labeled primers to identify and detect nucleic acids were cited by the Examiner as a basis for rejecting the pending claims. TR 21:1-22:7; Ex. 61, at 48-49. The article by McKeown el at. in 17 BioTechniques. pp. 901-907, entitled "Generation of Mini-Satellite Variant Repeat Codes on an Automated DNA Sequencer Using Fluorescent Dye-Labeled Primers," discloses the use of the polymerase chain reaction in which a fluorescently labeled primer is covalently bonded to the nucleic acid which is then detected. Ex. 74. Dr. Chamberlin testified that this reference is part of the DNA sequencing art because it uses the same primer extension process used in DNA sequencing. Ex. 63, at 6:7-14; TR 21:20-22:7. The Examiner's statements in the Office Action of June 24, 1996, indicate that she considered the McKeown reference to be part of DNA sequencing art. Ex. 61, at 49. She cited the reference because it related to the use of primers which were fluorescently labeled with a single fluorescent dye, like the primers used in DNA sequencing:

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"McKeown et.al. disclosed methods for identification and detection of target nucleic acids in a mixture of nucleic acids using fluorescently labeled oligonucleotides as primers [sic] amplification by PCR." Id. The use of labeled primers is at the heart of DNA sequencing.

The Examiner also considered an article by Fregeau and Fourney, entitled "DNA Typing with Fluorescently Tagged Short Tandem Repeats: A Sensitive and Accurate Approach to Human Identification," 15 BioTechniques, at pp. 100-119 (1993), which discloses the use of fluorescently labeled primers which may be used in DNA sequencing. Ex. 75; TR 21:9-14; 183:9-15. The Examiner wrote that, "Fregeau and Fourney disclosed methods for identification and detection of target nucleic acids in a mixture of nucleic acids using fluorescently labeled oligonucleotides as primers for hybridization and amplification by PCR and detecting labeled components by irradiating with light of appropriate wavelength." Ex. 61, at 40. The prosecution history of the '648 patent and the related '804 patent demonstrate that the Examiner treated the '648 claims as encompassing DNA sequencing. The Examiner's use of the McKeown et al and Fregeau and Fourney publications, which discuss "methods for identification and detection of target nucleic acids in mixture of nucleic acids" (id. at 40), to reject the '648 claims indicate that the Examiner understood that claims directed to "methods of identification and detection of nucleic acids in a multi-nucleic acid mixture" include sequencing. See TR 21:1-22:7; 97:8-99:4.

During the prosecution of the related '804 patent claims, the same Examiner reviewed the patentability of other claims directed to methods of identification and detection. Original claim 4 of the '804 patent parallels claim 1 of the '648 Patent as a "method of identification and detection":

"A method of identification and detection of components in a multi-component mixture employing different fluorescent labels to detect at least two components of interest, wherein said labels are characterized by… ."

Ex. 62, at 24 (emphasis added). The Examiner repeatedly referred to polynucleotide (i.e., DNA) sequencing when discussing these claims, for example when discussing why this claim was patentable over the prior art:

"The advantage of such labels is that the same excitation wavelength can be used to excite all the labels simultaneously to produce different signals, such as is needed for polynucleotide sequencing.…"

Id. at 102-103 (emphasis added). And in the Examiner's Notice of Allowance:

"The labels are used in methods of detecting at least two different components in a multicomponent mixture, wherein the multicomponent mixture is not limited to nucleic acid mixtures. The labels are also employed as sequencing primers and exhibit the advantage that different sequencing reaction can be detected using the same excitation wavelength."

Id. at 112 (emphasis added).

Perkin-Elmer contends that, because these comments were made in the context of the '808 patent application, concerning the claims 11-16 that contain a limitation to DNA sequencing, they have no relevance to understanding the broader claims of the '648 patent which are not so limited. This assumption is unwarranted. The '890 and '804 applications were prosecuted before the same Examiner, and it is reasonable to consider the Examiner's view of that portion of the claim language that the two patents have in common.

Perkin-Elmer also suggests that the '804 patent claims, which include an express limitation to DNA sequencing, should preclude the '648 claims from also covering methods for DNA sequencing. The '804 claims are not the subject of this proceeding and the Court will not draw inferences as to the meaning of the '804 patent claims to construe the '648 claims against the claim language, the preferred embodiment in the specification, and the prosecution history as discussed above.

Extrinsic evidence is helpful in understanding how the prosecution history defeats Perkin-Elmer's contention. Mr. Bjorge testified that it is very common that a patent, such as the '648 patent, may have claims which are broader than those of a related patent, such as the '804 patent. Ex. 1008, P37. Mr. Bjorge explained how the double patenting rejections in the '890 and '808 applications operated. See Ex. 1008, PP2-4; TR 84:20-89:5; Ex. 61, at 45-47, 65, 70, 77; Ex. 62, at 74, 93, 104-107. During the prosecution of the '808 application, the Examiner made a provisional double patenting rejection of claims 1-6 as directed to the same inventions as claims 1-6 of the '890 application. Ex. 62, at 74, 100. In response, the applicants canceled claims 1-3 of the '808 application and filed a terminal disclaimer limiting the term of any patent granted on the

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'890 application. Id. at 9.3. The Examiner's record for February 5, 1997, stated that the terminal disclaimer "will be reconsidered in light of amendments to claims submitted in 08/574,890 that may obviate statutory double patenting." Id. at 105. The applicants argued that the only type of double patenting remaining after the amendment was obviousness-type double patenting, which was overcome by the terminal disclaimer (id. at 104-107), and the Examiner then allowed the claims. Ex. 62A.

In the '890 application, the Examiner issued a provisional double patenting rejection of claims 1-6, as being directed to the same inventions as claims 1-6 of the '808 application. TR: 86:19-89:5; Ex. 61, at 45-46. The Examiner also objected to claims 4-6 "as being substantial duplicates of claims 1-3." Id. at 47. The applicants then cancelled claims 4-6, thereby eliminating same invention-type double patenting. Id. at 65, 70, 77. They eliminated obviousness-type double patenting by means of a terminal disclaimer. Id. The Examiner then issued the Notice of Allowance. Ex. 61, at 81-82; Ex.1008, P3.

Mr. Bjorge testified that interpretation of claims 1-3 of the '804 patent as being directed to DNA sequencing, as Perkin-Elmer urges, is consistent with the restriction requirement in the prosecution of the '924 application leading to the '419 patent. Ex. 1008, P4; TR 82:23-86:18; 88:6-89:5. The Examiner's Amendment in the '808 application indicates that the '804 patent claims, including claims 1-3, are directed to sequencing. The '804 patent addressed the use of the labels as a sequencing primer. Ex. 62-A, at 3; TR 85:13-86:18. Claims 1-3 of the '648 patent are directed to a variation of the same invention as issued claims 1-3 of the '804 patent. See Ex. 1008, P4; TR 86:19-89:5. This aspect of the prosecution history indicates that the '648 patent claims encompass DNA sequencing.
4. The Restriction Requirement Is Irrelevant To The Claim Construction

Perkin-Elmer argued that the restriction requirement imposed by the Examiner during the initial stages of the prosecution of the parent '924 application should be used to exclude DNA sequencing from the scope of the '648 patent. A restriction requirement is not a rejection and it cannot be used to controvert the plain language of the claim. R2 Medical Systems, Inc. v. Katecho, Inc., 931 F.Supp. 1397, 1438 (N.D. Ill. 1996). Here, the restriction requirement is far too ambiguous to subvert the claim language as approved by the Patent Office, when taken with the unambiguous statements in the specification about sequencing and also taken with the prosecution history of the divisional '890 application.

The Examiner separated the original 21 claims of the '924 application into four different categories: (1) methods of identification detection, (2) methods of separating components, (3) sequencing methods, and (4) kit claims. Ex. 206 at 57. Dr. Chamberlin opined that this restriction requirement would not cause one skilled in the art to understand that the claims directed to methods of identification and detection would not cover DNA sequencing. Ex. 63, 8:13-18. The restriction requirement in itself does not compel the conclusion that the '648 patent claims, which are broader than claims limited specifically to DNA sequencing methods, do not also cover DNA sequencing processes.

Few decisions have examined the importance of a restriction requirement in interpreting claims. In R. Medical Systems, 931 F.Supp. 1397, 1438, cited by Amersham, the court refused to use an Examiner's restriction requirement to limit the scope of a patent claim. Because a restriction requirement is administrative and does not constitute a "rejection" by the patent examiner, it should not be used to limit the scope of a claim for the purpose of determining infringement. Id. at 1438-39. The court wrote, "[T]here is some question whether an applicant's response to a restriction has the same preclusive effect as a response to a rejection. In fact, the court has not identified any precedent using prosecution history of the election of a species in order to restrict or otherwise interpret the scope of a patent claim." Id. The district court reviewed the claim, the patent specification and the restriction requirement and ultimately refused to limit the scope of the claims because the claims and the patent specification were not limited. Id. Signtech U.S.A., Ltd. v. Vutek, Inc., 174 F.3d 1352, 1357-58 (Fed. Cir. 1999), cited by Perkin-Elmer, is inapposite. In Signtech, the patentee attempted to use a restriction requirement in the prosecution history to "redeem its choice of claim language." 174 F.3d at 1357. The petitioner was unsucessful because the court would not use the prosecution history to contravene the language choices in the claims and specification, and was compelled by statute, 35 U.S.C. §112, P6, to limit the scope of the means-plus-function claims to the embodiments disclosed in the specification. 174 F.3d 1358. The Federal Circuit's recent decision in Merck & Co., Inc. v. Mylan Pharmaceuticals, Inc., 190 F.3d 1335, 1999 WL 689731 (Fed. Cir. 1999), also cited by Amersham, is consistent with R. Medical. In Merck, the applicant was faced with both a restriction requirement and an obviousness rejection. The court restricted the claim to the elected species because the applicant made the amendment principally to avoid the obviousness rejection.

Here, in contrast, the election was purely administrative and offers little insight into construction of the '648 claims. For the

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purpose of case management and to control filing and search fees, a patent examiner may require the applicant "to divide his or her claims among distinct, though related, patent applications." R. Medical, at 1438. Mr. Bjorge testified that, as a matter of patent office practice during 1994, when the restriction issued, this administrative tool would likely be employed early in the prosecution, at the discretion of the Examiner, to control the Examiner's time (TR 78:1-23), and prior to determining the scope or boundaries of any the claims. Ex. 1007, at 10:25-26.

In Pitney Bowes, 182 F.3d 1298, the Federal Circuit held that complying with an administrative requirement, such as amending the patent title, should not be regarded as having the same or similar effect as an amendment of the claims by the applicant. "[I]f we do not read limitations into the claims from the specification that are not found in the claims themselves, then we certainly will not read limitations into the claims from the patent title." Id. at 1312. In this case, the applicants' compliance with an administrative requirement (i.e., the restriction requirement), over their objection by a traversal, in the parent application, is entitled to little weight as against the applicants' claims as amended, and the Examiner's allowance of those claims, in the issued '648 patent. As a matter of practice, as Mr. Borge explained, in working with a restriction requirement, the applicant and the examiner are not disputing what subject matter is included in the invention versus the public domain, or whether the application uses language that is sufficient to satisfy the requirements of 35 U.S.C. §112. Ex.1007, at 11:2-5. In the case of the '924 application restriction, the Examiner and the applicants ignored the restriction in the subsequent prosecution of both the '648 and '804 patents. Ex. 1008, P1; TR 82:14-84:4. 19 The first Examiner's attempt to organize the '924 application's 21 claims into a more manageable format by means of the restriction requirement, while understandable, is not particularly illuminating for purposes of this proceeding.

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19 In Mr. Borge's experience, an examiner may have a minimal understanding of the claims and the invention at an early stage of the proceedings. TR 89:25-90:5; Ex. 1007, at 10:33-27. Here, for example, the Examiner's decision to issue a restriction requirement in the '924 application among claims classified in the same class and subclass was highly unusual (TR 80:3-14), and the applicants objected by filing a traversal. TR 81:6-15; 93:14-22. Claims 1-6 of the '924 application were directed to "methods of identification and detection." The Examiner issued the restriction requirement for "Claims 1-6, drawn to methods of identifying cells, classified in Class 435, subclass 6 . . . ," although none of these claims referred to "cells." Ex. 206, at 57. The reference to cells is confusing and renders the restriction ambiguous. TR 22:12-23:7 (testimony of Dr. Chamberlin); TR 80:15-81:5 (Borge testimony).

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Having considered the claim language, the specification, the prosecution history, and the extrinsic evidence, the Court finds that the language "a multi-nucleic acid mixture" refers to a mixture of nucleic acids that contain two or more non-identical nucleic acids, such as the mixture of acids produced during DNA sequencing. "Method of identification and detection of nucleic acids in a multi-nucleic in acid mixture" means that different nucleic acids in a multi-nucleic acid mixture that arc labeled with different fluorescent labels can be distinguished by irradiating the labels and measuring the fluorescence they emit.
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Method of Treating Atherosclerosis

Because this term appears in the preamble of claim 10, the Court must first determine whether this term is limiting. The Court agrees with BSN that it is. The Patent Examiner suggested that the patentee include the amount of AAKG and excipient into claim 10 to place the application in condition for allowance. Instead, the patentee amended claim 10 by inserting "atherosclerosis in" after the phrase "method of treating."

MRI argues that "atherosclerosis" is only a reference point such that any administration of the formulation sufficient to treat atherosclerosis is within the method, regardless of whether there is any intent to treat atherosclerosis. The Court rejects MRI's argument because it effectively reads "atherosclerosis" out of the claim contrary to the presumption that there is a "substantial reason relating to patentability for including the limiting element added by amendment." Schoenhaus, 440 F.3d at 1359; see also Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1557 (Fed. Cir. 1995)("[W]e must give

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meaning to all the words in [the] claim."). Therefore, the term limits claim 10 to a method that is intended to treat atherosclerosis.

The Court agrees with MRI and construes the term "treating" according to the '707 patent definition of "treatment" as

> obtaining a desired pharmacological and physiological effect. The effect may be prophylactic in terms of preventing or partially preventing a disease, symptom or condition thereof and/or may be therapeutic in terms of a partial or complete cure of a disease, condition, symptom or adverse effect attributed to the disease.

'707 Patent co1.5:6-12; see also Phillips, 415 F.3d at 1316. BSN argues that "treating" in the term-at-issue is limited to treating an actual disease because the patentee distinguished between treating diseases from treating symptoms in the specification and therefore only claimed treatment as to a disease by using a disease term in the claim. This argument is unpersuasive because the '707 patent defines "treatment" of a disease to include preventative measures before any diagnosis is made. The specification examples of treating "symptoms" or "adverse effects" are just that, examples of treatments within the broad range of potential treatment. See '707 Patent col.7:44-47; col.5:8-11.

The Court construes atherosclerosis as "a disease, symptom, or condition characterized by a progressive narrowing and hardening of the arteries." The patent does not define atherosclerosis, but extrinsic evidence supports the Court's construction. See WEBSTER'S NEW WORLD MED. DICTIONARY 29, 33 (2d ed. 2006); Phillips, 415 F.3d at 1318. BSN's proposed construction of atherosclerosis as "a disease, involving abnormal fatty deposits in a[] fibrosis of the inner lining of arteries" is too narrow. BSN relies on a dictionary definition that does not support its contention that fatty deposits are necessary; the definition states that "[a]therosclerosis is a multistage process set in motion when cells lining the arteries are damaged ... high density lipoproteins accumulate at the site of arterial damage," making clear that fatty deposits occur after arterial linings are damaged. STEDMAN'S MED. DICTIONARY 162 (26th ed. 1995). Furthermore, BSN's interpretation includes terms that would also require construction (e.g., fatty deposits, fibrosis). To the extent that atherosclerosis involves accumulating arterial deposits, these symptoms are reflected in the Court's construction (i.e., "a progressive narrowing and hardening of the arteries").
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II. Claim Construction

Preliminarily, the Court addresses a claim construction dispute that has arisen in the context of these motions. Both parties agree that the Court should neither add nor disregard language in claim 1 of both TYERS I and II -- the broadest of the claims at issue -- but defendant argues, in essence, that these claims should be read as limitless, encompassing all nausea induced by whichever source and mediated by whichever pathway. Plaintiffs counter that no skilled artisan would read the claims as such.

Again, the relevant claims are as follows:

> A method of treatment for the relief of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for treatment for the relief of nausea and vomiting of [ondansetron] or a physiologically acceptable salt or solvate thereof[; and]
>
> A method of treatment of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for the treatment of nausea and vomiting of [ondansetron].

'789 patent, claim 1; '628 patent, claim 1.

The Court accords the claim terms their plain and ordinary meaning, as understood by those skilled in the art, and presumes that these "mean what they say." Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). Consequently, as the plain language of these claims places no limitation on the types of nausea combated by ondansetron, and plaintiffs concede that these claims apply to any effective administration of ondansetron so long as the subject is suffering (or will suffer) from nausea (see Tr. of Proceedings of 7/11/05, at 32, 40-42), the Court will not read any such

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limitation into the claims.

By the same token, however, the Court does not construe these claims to create a panacea, as it were, for the general condition of nausea and vomiting. To do so would be to interpret the claims in a manner no person skilled in the art would deem tenable. TYERS I and II claim "a method of treatment" whereby ondansetron is administered in "an effective amount" to relieve nausea and vomiting. '789 patent, claim 1; '628 patent, claim 1. By their terms, therefore, the claims are directed to a successful course of treatment for relieving nausea with certain dosages of a certain compound. See Kao Corp. v. Unilever United States, Inc., 334 F. Supp. 2d 527, 546 (D. Del. 2004) (construing "amount effective" to mean, in part, conferring a "benefit"). That compound, ondansetron, is described in the patent's specification as a "potent and selective antagonist[]" of the 5-HT[3] receptor. '789 patent, col. 2:5-10. Thus, in light of the context of the patents' claim language, as further illuminated by the specification, the Court will not construe TYERS I and II as claiming a cure-all for all human and animal forms of nausea, as no skilled artisan would interpret these as such. 2 See Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) (rejecting litigant's attempt to interpret claims without context of how the invention works as described in the specification); V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (stating that the specification is usually the best source for discerning claim context as understood by those skilled in the art).

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2 Indeed, defendant's own experts testified, in essence, that they interpret -- or that a skilled artisan in 1985 would have interpreted -- these claims as directed only to those forms of nausea potentially mediated by the 5-HT[3] receptor. (See Hain Dep. at 213:18-214:14; Davis Dep. at 217:22-219:12.) Dr. Davis in particular stated: "If I take myself back to [1985] and I was apprised of this information, my prediction if it was potent and selective up to 5-HTM, that, by definition, it would not also be active at the D2 receptors." (Davis Dep. at 219:4-8 (emphasis added).)

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In sum, the Court holds that the relevant claim language -- namely, "a method of treatment for the relief of nausea and vomiting which comprises administering to a human or animal subject in need thereof an effective amount for treatment for the relief of nausea and vomiting of [ondansetron]" - means what it says. The claims reach administration of ondansetron for the treatment of nausea, however induced, but only those manifestations of nausea against which ondansetron, a 5-HT[3] antagonist, is effective. Put another way, TYERS I and II are directed to any use of ondansetron that may work to treat a patient's nausea, but these patents do not claim a method of treatment for the relief of those forms of nausea, such as apomorphine-induced nausea, against which it would be obvious to skilled artisans that a 5-HT[3] antagonist is ineffective.
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II. "Method For The Treatment Of A Mammal, Including Man, Suffering From Or Susceptible To Infection By HIV"

GSK's Proposed Construction	Teva's Proposed Construction
Method for managing human immunodeficiency virus infection in a person suffering from or susceptible to that disease.	Method for the treatment of a mammal which is infected with HIV or which is susceptible to becoming infected with HIV.

GSK contends, first, that the word "treating" should be defined as "managing" and, second, that this limitation, in spite of its plain language, refers only to the treatment of humans. (See D.I. 32 at 13-15.) The Court will not adopt GSK's construction.

With respect to whether "treating" should be defined as "managing," GSK's position appears to be, in effect, an attempt to limit the claims to "long term" treatment of HIV infection. Indeed, GSK argues, for instance, that "the prior art patents considered by the examiner and listed on the face of the '021 patent confirm that a person of ordinary skill in the art would understand that treatment of HIV means long-term management." (D.I. 32 at 14 (emphasis added).) Thus, in support of its construction, GSK points to, for example, passages in the specification suggesting that HIV requires long-term treatment. ('021 patent at 1:20-23 ("However, HIV infection of cells results in integration of the virus genome into the host

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chromosome, and so it has been necessary to continue AZT treatment for long periods of time.").) In addition, GSK cites a declaration in the prosecution history from a GSK researcher who carried out a 52-week study on the effectiveness of the claimed invention. (D.I. 32, Exh. D.) Apparently, GSK contends that the 52-week study length confirms that the claims are limited to long-term management. (See, e.g., D.I. 44 at 57:13-17 (GSK argues at the Markman hearing that the declaration included a chart that "itself represents the inhibition of HIV over the course of 52 weeks" and urges the Court to note that "it didn't stop at zero," "it didn't stop at a single dose" and that "[i]t kept going").) GSK further maintains that because the specification never suggests the possibility of a one-time treatment or that the claimed invention will cure HIV, the claims must be referring to long-term treatment. (See D.I. 32 at 13.)

However, "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004)(quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)). The Court has reviewed all of GSK's arguments and evidence that "treatment" should be redefined as "management" so that the claims are then limited to "long-term" care of HIV infection. On so doing, the Court concludes that GSK's evidence falls well short of warranting this limitation.

As to GSK's position that the claims should be limited to the treatment of only people, the Court notes that this limitation refers generally to "mammals" and lists "man" as an exemplary "mammal." Furthermore, the specification explains that the amount of drug to be used will be "at the discretion of the attendant physician or veterinarian." ('021 patent at 4:26-32 (emphasis added).) Thus, the claims and specification exhibit a definitive intent for the invention to cover more than just the treatment of humans. In these circumstances, the Court requires compelling evidence to adopt GSK's proposed construction. GSK points out only that "HIV" means "human immunodeficiency virus" and that the "specification and prosecution history clearly focuses on the treatment of humans." (See D.I. 35 at 10.) In the Court's view, this evidence is not sufficient to effect the drastic alteration of the claim language that GSK seeks.

GSK attacks Teva's proposed construction as bearing too much similarity to the raw claim language. (See D.I. 35 at 9.) However, having concluded that the claims should not be limited in the manner suggested by GSK, the Court agrees with Teva that this is a case where the "claim language is simple enough . . . such that it does not require further 'construction' . . . ." (D.I. 36 at 14.)

Accordingly, the Court concludes that this term requires no further construction.
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Methotrexate	A folate analog that is lethal to cells

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3. The Term "Micro-environment"

The term "micro-environment" introduces a limitation relative to claims 1 concerning the core region. (See, e.g., P1, col. 16:67; P2A, col. 14:7.) Claim 5 requires that the core "comprises omeprazole" and a "pH-buffering alkaline compound" that renders to the "microenvironment" of omeprazole a pH of 7 to 12. The term "microenvironment" is construed to refer to the regions immediately around or in close proximity to the omeprazole particles. (See Langer Tr. 318:16-23, 588:16-589:11; Auslander Tr. 2691:3-7; Seth Tr. 2057:12-15.) This definition is supported by the patent specifications, which state that the alkaline reacting compound should create a "micro-pH" around the omeprazole" when water is adsorbed to the particles . . . or when water is added in small amounts to the mixture." (P1, col. 3:43-46.) The exact size of the microenvironment depends on the way the core is formulated, including the substances in it. (See Davies Tr. 1173:4-1177:2.) Defendant Genpharm argues that the term "microenvironment" is unclear and renders the claim invalid under 35 U.S.C. § 112. The court will address that argument in the section of this opinion devoted to invalidity defenses.

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Ciba's case for infringement of the '766 patent turns on the meaning of "microbead," a limitation that is present in all of the claims of that patent. Claim 1 of the '766 patent, from which all the other claims depend, reads:

A method of making paper which comprises adding to an aqueous paper furnish from about 0.05 to about 20 lbs/ton, based on the dry weight of paper furnish solids, of an ionic, organic, cross-linked polymeric microbead, the microbead having an unswollen particle diameter of less than about 750 nanometers and an ionicity of at least 1%, but at least 5%, if anionic and used alone.

('766 patent, 29:39-46 (emphasis added).)

a. The Parties' Proposed Constructions

Ciba and Hercules agree that a microbead, as claimed by the '766 patent, is a product formed by the polymerization of monomers. (D.I. 275 at 28; D.I. 286 at 33.) The dispute centers on whether or not an additional limitation applies. Hercules contends that a "microbead" is limited by the following definition: "The microbead must be an integral unit which can be separated from any emulsifier n5 present." (D.I. 286 at 33-35.) That construction is based on statements made during the '766 patent prosecution in response to an examiner's rejection.

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n5 An "emulsifier" is "an agent used to make an emulsion of a fixed oil." Am. Heritage Stedman's Medical Dictionary (2002). In turn, an "emulsion" is "a suspension of small globules of one liquid in a second liquid with which the first will not mix." Id.

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By contrast, Ciba contends that the statements in the prosecution history were made in the context of a discussion about the requirement that the microbead be "ionic," and so the statements should not be read as a general description of the microbead. (D.I. 325 at 16-17.) Ciba further contends that the claims were not amended in response to that particular rejection, and that the statements merely describe the prior art. (Id. at 18.) Thus, according to Ciba, those statements do not limit the scope of the term "microbead" as claimed.

b. The Court's Construction

I conclude that the statements made during the '766 patent prosecution are descriptions of the patentee's invention, and that those statements do limit the scope of the claimed "microbead." Therefore, "microbead" will be construed as: "A product formed by the polymerization of monomers. The microbead must be an integral unit which can be separated from any emulsifier present."

During the examination of the application that issued as the '766 patent, U.S. Application 07/540,667, the patent examiner rejected several claims, including the claim that issued as claim 1, as obvious over U.S. Patent No. 4,659,431 (issued Apr. 21, 1987) (the "Probst reference," D.I. 316, Ex. 11). (D.I. 316, Ex. 6 at HERC0076011.) The Probst reference discloses a "Cationic Sizing Agent for Paper, and a Process for its Preparation." (D.I. 316, Ex. 11 at CIBA 000218.) In response, the applicants made the following argument:
Applicants' claims require that the organic, polymeric microbeads be ionic! Probst employs ionic group containing emulsifiers in order to create dispersion stability in the solution. The ionic groups remain part of the emulsifier and are not chemically bonded to the hydrophobic copolymers. The Probst product, therefore, is a nonionic hydrophobic polymer mixture stabilized by cationic surfactants.

Applicants' invention resides in the use of the polymer microbead having an ionic charge covalently bonded to the polymer, whereas, in Probst, the only ionic charge present is on a different molecule i.e. a surfactant which can dissolve out of and/or

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migrate from the polymer microbeads. Applicants' microbead does not require the use of an emulsifier. It is an integral unit which can be separated from any emulsifier present if made in emulsion form.

(D.I. 316, Ex. 6 at HERC0076020 (emphasis in original).) The examiner maintained the rejection, arguing that the backbone of the microbead disclosed by the Probst reference was ionic. (Id. at HERC0076028.) The applicants responded that the chemical referred to by the examiner was part of the emulsifier, and that by contrast, "Applicants' microbead has an ionic charge covalently bonded thereto and is an integral unit which can be separated as such." (Id. at HERC0076038.) According to the applicants, "it is only the emulsifier which is ionic in the Probst composition." (Id.) One week later, the claims were allowed. (Id. at HERC0076046.)

Ciba contends that the prosecution history should not limit the scope of "microbead" in this case. First, Ciba argues that the statements are only relevant to the construction of "ionic," a term whose meaning is not disputed in this case. (D.I. 325 at 17.) I disagree. The examiner argued that the invention was obvious in light of the Probst reference, and the applicant responded that the only part of the Probst composition that was ionic was the emulsifier. To overcome the rejection, the applicants argued, in two separate responses, that its microbead was an integral unit that could be separated from any emulsifier in the composition. (D.I. 316, Ex. 6 at HERC0076020, HERC0076038.) The applicants further argued that their "microbead does not require the use of an emulsifier." (Id. at HERC0076020.) While those arguments were used to support a position about the ionicity of the Probst composition, they are not limited to ionicity. The applicants described, in unambiguous terms, features of the claimed microbead.

Second, Ciba argues that the statements in the '766 prosecution history are simply a discussion of the prior art. (Id. at 18 (citing Gemstar-TV Guide Int'l, Inc. v. ITC, 383 F.3d 1352, 1375 (Fed. Cir. 2004)).) Again, the applicants' statements are not so limited. The applicants describe the "invention." (D.I. 316, Ex. 6 at HERC0076020.) According to the applicants, the invention requires that the microbead be "an integral unit which can be separated from any emulsifier present if made in emulsion form." (Id.) That unambiguous statement limits the claimed invention.

Therefore, Hercules's proposed construction is correct. A "microbead" is defined as: "A product formed by the polymerization of monomers. The microbead must be an integral unit which can be separated from any emulsifier present."
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A. "microporous film"

One of the two films of Claim 1 is an "uncoated microporous film." The proposed Claim 1 recited a "a microporous or nonwoven film" which was amended by agreement to "microporous film." n1 The patent examiner noted in his interview summary that Mr. Cox, counsel for the applicant inventors, "agreed to the deletion of the phrase 'or nonwoven' within the claims as it was being used with respect to a film, which is recognized within the art as a single sheet structure, which may or may not be laminated, but is definitely not of a structure incompassing [sic] woven or nonwoven properties, which are indicative of a web, batt, mat, mesh, or pad, for example, but not a film."

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n1 The Examiner's Interview Summary and the Examiner's Amendment both indicate that "or nonwoven" was to be deleted from Claims 1, 2, 3, 5, 6, 9, and 10. Claim 1 is the only independent claim of the '942 patent. The '942 patent issued without the deletion of "or nonwoven" from Claim 10. The court assumes that this was a typographical error.

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The defendant, Multisorb Technologies, Inc., contends that the deletion of the phrase "or nonwoven" constituted a disclaimer of all woven and nonwoven materials from Claim 1's "film." We do not find Multisorb's argument for the narrowing of "film" availing.

Claim 1 does not define "film." We find, however, that when read together, the specification and prosecution history support the conclusion that there was no narrowing of the scope of "film" by amendment. In order to find a narrowing of the claim,

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there must be evidence of a clear and unambiguous disavowal of claim scope. Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347 (Fed. Cir. 2005). We do not find such evidence in this case.

The inventors agreed to the deletion of the phrase "or nonwoven" on the basis that "film" is not a structure encompassing woven or nonwoven properties. The statement of reasoning offered by the patent examiner does not evidence Multisorb'c contention that "nonwoven film," as a subset of "film" was excluded from the definition of the term "film" in order to obtain allowance of the claim. Rather the examiner indicated that "woven" and "nonwoven" were not properties of film and therefore "nonwoven" was not to be used with respect to "film." The examiner's notation concerning the agreement indicates that, in his view, woven or nonwoven properties indicate or are descriptive of a web, batt, mat, mesh, or pad, but not a film. The agreement of the inventors was not acquiescence to a narrowing of the scope of films in issue, however. There was no discussion of a prior art preclusion to be overcome by the proposed amendment. Rather, the examiner's focus was on the descriptive terminology employed relative to "film," concluding that woven and nonwoven properties are not indicative of a film. This is not the same, however, as disclaiming nonwoven materials from Claim 1, as urged by Multisorb. Rather, the claim as amended recites "microporous film," which is to be given its common and ordinary meaning. There is no dispute concerning the ordinary definitions of "microporous" and "film." We leave for another day the question of whether any given material is a "microporous film" of Claim 1. We conclude only that the examiner's amendment did not narrow the scope of the term.

The court's reading of the prosecution history is in harmony with the Background of the Invention in the '942 patent in which the inventors described desiccant containers in the prior art as generally "comprised of a water or water vapor permeable packaging material formed from fibrous or film products." Additionally, reference is made therein to two prior art patents to Inoue which recite "nonwoven cloth laminated onto several layers of a plastic film," and "nonwoven fabric or microporous film laminated to various plastic films." The inventors' description of the art within which they were inventing suggests that the property of wovenness was not associated with films. Indeed, the' 175 patent to Inoue recited "nonwoven" with respect to fabric and "microporous" with respect to film. n2

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n2 This reference to prior art is illustrative only. The comment is not to be construed as determining the applicability of "nonwoven" in any other context than with respect to the conclusion that "film" did not have properties of wovenness, in the patent examiner's view. As noted herein, we leave to another day whether any given material is a "microporous film" of Claim 1 of the '942 patent.

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Because of the patent examiner's comment that in the art, "film" did not encompass the property of wovenness, the court cannot find a clear and unmistakable disclaimer. Therefore, we conclude that the claim as amended recites a "microporous film" not narrowed in scope by the amendment deleting "or nonwoven."

The Preferred Embodiment states that the microporous film "comprises a film having a plurality of fine openings, which film is gas permeable, but water impermeable when there is no difference between the air pressure outside of the film and inside of the film." It states that it may constitute a single layer or may comprise a laminate of separate microporous film layers, and may be prepared by any conventional film forming process.
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B. "minimum antibiotic serum concentration"

Plaintiffs propose that the term "minimum antibiotic serum concentration" means "the lowest concentration known to exert a significant antibiotic effect based on steady-state pharmacokinetics." (D.I. 53 at 27) Mylan proposes that the term instead means "the lowest concentration known to significantly inhibit the growth of microorganisms, e.g., bacteria." (D.I. 55 at 22) 1 largely agree with Mylan.

Plaintiffs misapprehend that the minimum antibiotic serum concentration refers to a number calculated from the

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concentration of a given compound in a subject's blood measured over long term administration. Instead, as Mylan explains, the minimum antibiotic serum concentration is the lowest concentration of a given compound known to exert a significant antibiotic effect. (Tr. at 98-99) In other words, the minimum antibiotic serum concentration is not a measure of the serum antibiotic level (i.e., the antibiotic level in the blood), but is instead a characteristic of the tetracycline compound. It is a constant; and it is measured in a laboratory, not in a patient's body. The concept of steady-state pharmacokinetics (and with it the dispute as to the time at which one measures the serum concentration in a human's blood) is not relevant to construction of this disputed claim term.

The patent specification provides a definition, stating: "The minimum antibiotic serum concentration is the lowest concentration known to exert a significant antibiotic effect." ('267 patent, col. 6 lines 14-16) Thus, I recommend that the Court construe "minimum antibiotic serum concentration" as "the lowest concentration known to exert a significant antibiotic effect." This language is slightly different from that proposed by Mylan.
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6. Mixed Prior To

The construction of the phrase "mixed prior to" is in dispute. It appears in the following context: "said concentrated detergent solution is mixed prior to being directed onto said fabric." ('370 patent, claims 2, 9, 16.)

Whirlpool seeks the following construction: "This claim element means that detergent and water are combined to form the concentrated detergent solution before the resulting solution is sprayed onto the fabric. There is no limitation or restriction as to the location where the mixing occurs, i.e., the mixing is not required to occur in a mixing tank or a zone separate from the fabric and the wash chamber."

LG seeks the following construction: "The concentrated detergent solution having a fixed concentration level in the range of 0.5 to 12% by weight is mixed in a zone separate from the fabric and the wash chamber prior to being directed onto the fabric in the wash chamber."

The dispute turns on whether the claim limits not only when the mixing occurs, but where. The plain, ordinary meaning of the claim language supports Whirlpool's position. The claim speaks of mixing the detergent solution prior to directing it onto the fabric; it says nothing about where the mixing must occur, whether it be inside the wash chamber or in a mixing tank or other separate location. Moreover, neither the ordinary meaning nor any dictionary definitions of "mix" embrace a locational requirement.

In spite of the unambiguous meaning of the terms, LG argues that the patent specification discloses a requirement for the mixing to occur in a mixing tank. The Court rejects this argument for several reasons. First, although one embodiment discloses a mixing tank, that is not the only embodiment. ('370 patent, col. 3, lines 31-34 ("A mixing tank 80, as shown in FIG. 3, forms a zone for receiving and storing a concentrated solution of detergent during a wash cycle, and is used in some embodiments of the invention.") (emphasis added)) Second, the mixing tank embodiment is not the preferred embodiment. ('370 patent, col. 6, lines 35-36 ("In the preferred embodiment of the invention a mixing tank is not utilized.")) The fact that the word "mix" is used to describe events both inside and outside of a mixing tank shows that "mixing" can happen in both places.

Accordingly, the Court adopts Whirlpool's construction that the claim does not require mixing to occur in any particular location such as a separate mixing tank.
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B. "Mixing" and "Compression mixture"

Claim 5 recites the method of:

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c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a compression mixture; then d) pressing the compression mixture to form a solid oral dosage form.

(Emphasis added.) Plaintiffs define "mixing" as "combining two or more ingredients into one mass," and "compression mixture" as "one mass containing two or more ingredients that are compressed into a tablet." Plaintiffs' construction of these terms is sufficiently broad to encompass both one-layer and two-layer coated granule tablets. Defendants propose the following alternative construction of "mixing" and "compression mixture": "Effecting a uniform dispersion of liquid, semi-solid or solid ingredients of a mixture by means of a mechanical agitation." (Emphasis added.) Defendants' construction would purportedly encompass only a one-layer tablet because the famotidine and antacids would not be "uniformly dispersed" if they are separated into two layers.

This Court must "determine the ordinary and customary meaning, if any, that would be attributed to the terms by those skilled in the art." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1346 (Fed. Cir. 2003). None of the parties have submitted a proposal for the qualifications and experience required of a person skilled in the art. Nevertheless, this Court concludes that one of skill in the art would have a Ph.D in chemistry, organic chemistry, pharmaceutics or pharmaceutical microbiology, or a B.S. or M.S. with several years of work experience in pharmaceutics or pharmaceutical microbiology, or an M.D. with several years of clinical experience in administering H2 blockers or antacids. See, e.g., Astrazeneca Pharms., LP v. Mayne Pharma (USA) Inc., 352 F. Supp. 2d 403, 411-12 (S.D.N.Y. 2004); Bayer AG v. Carlsbad Tech., Inc., No. 01 Civ. 867 (LSP), 2001 U.S. Dist. LEXIS 24487, 2001 WL 34125673, at *3 (S.D. Cal. Oct. 24, 2001).

1. Specification

This Court must examine the specification to determine a construction that is consistent with the spirit of the claimed invention. Phillips, 415 F.3d at 1315-17. The specification favors Plaintiffs' broad construction of "mix" and "compression mixture" in two ways. First, Examples II and III each contemplate a dual-layer coated granule tablet. ('340 Patent col. 10, ln. 63 - col. 12, ln. 51.) Example II requires that the "famotidine [be] layered on top of [the] antacid blend" and compressed into a bilayer tablet. ('340 Patent col. 11, ln. 39.) Likewise, Example III expressly involves a "bilayer tablet." ('340 Patent col. 11, ln. 58.) "[I]t is . . . well established that a claim construction that excludes a preferred embodiment is 'rarely, if ever, correct.'" Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1378 (Fed. Cir. 2001) (quoting Vitronics, 90 F.3d at 1583); see also Burke, Inc. v. Bruno Ind. Living Aids, Inc., 183 F.3d 1334, 1341 (Fed. Cir. 1999) (holding that a claim interpretation excluding the preferred embodiment was improper). This is because "it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way." Hoechst Celanese Corp., 78 F.3d at 1581.

Second, Example II describes a two-layer tablet comprised of "coated famotidine granules admixed with granules of an antacid and formed into a solid oral dosage form." ('340 Patent col. 10, ll. 63-66 (emphasis added).) Defendants concede that the term "admixed" means "to mix with." (Kiel Decl. Ex. 11 PP 64-65.) Thus, Example II implicitly defines "mix" to include a dual-layer embodiment. Phillips, 415 F.3d at 1321 (the specification "acts as a dictionary when it . . . defines terms by implication").

Perrigo responds by contending that portions of Example II were copied from McNeil's United States Patent 5,679,376 (the "'376 patent"), which claims a single-layer tablet comprised of loperamide and simethicone. (Defendants' Claim Construction Exhibit ("Defs. Cl. Constr. Ex." H: '376 Patent col. 10, ln. 40 - col. 11, ln. 55.) According to Defendants, the word "admixed" was mistakenly used in Example II because of this copying error, and for that reason should not be considered in connection with the two-layer embodiment. This Court disagrees. Extrinsic evidence such as the '376 patent cannot be used to contradict the unambiguous intrinsic evidence. See Vitronics Corp., 90 F.3d at 1584. Moreover, the relevant language of the '376 patent is different from its alleged counterpart in the '340 patent. Defendants offer no testimonial or documentary evidence demonstrating that the latter is derived from the former. Finally, Plaintiffs' proposed constructions of "mixing" and "compression mixture" broadly cover both a one-layer and a two-layer coated granule embodiment. (Tr. at 49, 88.) These constructions are entirely consistent with Plaintiff's use of the term "admixed" to describe a one-layer embodiment in the '376 patent and, later, a two-layer embodiment in the '340 patent.

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2. Prosecution History

The prosecution history also supports Plaintiffs' construction. A court must consider the prosecution history of the patent "to determine whether the applicant clearly and unambiguously 'disclaimed or disavowed [any interpretation] during prosecution in order to obtain a claim allowance.'" Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002) (quoting Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985)) (alteration in original). Disclaimer during prosecution of the patent may include instances where "the patentee distinguished [a] term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366-67 (Fed. Cir. 2002). Prosecution disclaimer must be narrowly tailored, however, to exclude only claim scope that has been "clearly and unmistakably" disclaimed. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324-26 (Fed. Cir. 2003) ("For prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable."); accord Sunrace Roots Enter., Co. v. SRAM Corp., 336 F.3d 1298, 1306-07 (Fed. Cir. 2003). "Where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of surrender." Omega Eng'g, 334 F.3d at 1324; accord Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310 (Fed. Cir. 2003).

Significantly, Perrrigo identifies no statement made by McNeil disclaiming the dual-layer coated granule embodiment. Perrigo instead asserts that the scope of claims allowed on the basis of unexpected results cannot exceed the parameters of those results, and therefore, the '340 claims must be limited to the single-layer tablets tested by Roche. It is true that a patent applicant using unexpected results to show non-obviousness must provide data commensurate in scope with the claims which the evidence is offered to support. See In re Grasselli, 713 F.2d 731, 743 (Fed. Cir. 1983); In re Tiffin, 58 C.C.P.A. 1420, 448 F.2d 791, 792 (C.C.P.A. 1971). However, that does not mean that courts mechanically import limitations from the test results into the claims. See, e.g., In re Cescon, 474 F.2d 1331, 1334 (C.C.P.A. 1973) (allowing "broadly drawn" claims even though "not all compounds encompassed by the claims [were] tested"). Moreover, the Federal Circuit has held that claims allowed based on "surprising results" may be construed more broadly that the results themselves. Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1135-37 (Fed. Cir. 2006).In Purdue Pharma, Plaintiff Purdue Pharma ("Purdue") alleged that Defendant Endo Pharmaceuticals Inc. ("Endo") infringed various Purdue patents by filing an ANDA for a generic version of Purdue's OxyContin, a pain relief tablet comprised of a controlled release oxycodone product. After the examiner rejected the OxyContin patents as obvious, Purdue distinguished the prior art using "surprising results" allegedly observed in a specific dosage range of oxycodone. Purdue Pharma, 438 F.3d at 1130. Thereafter, Purdue relied on these "surprising results" as a "prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of the claims." Purdue Pharma, 438 F.3d at 1130 (internal quotations omitted). Construing the term "controlled release," the district court found a prosecution disclaimer of claims to oxycodone outside the range detailed in the extraordinary results.

Sitting en banc, the Federal Circuit reversed the district court's construction of the claim. Purdue Pharma, 438 F.3d at 1135-37. The panel:

agreed with Purdue that it made no such disclaimer or disavowal . . . While it is true that Purdue relied on its 'discovery' of the . . . dosage range to distinguish its claimed oxycodone formulations from other prior art . . ., Purdue's statements do not amount to a clear disavowal of claim scope.

438 F.3d at 1136. By restricting the claims in accord with the alleged test results, "the trial court [had] impermissibly imported a limitation [from the prosecution history] into the claims." Purdue Pharma, 438 F.3d at 1136-37. Perrigo urges this Court to make precisely the same error of law. See also Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1220 (Fed. Cir. 1996) (refusing to import limitations from the prosecution history into the claims). The submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims.

Absent evidence of a clear disavowal in the prosecution history, this Court will not deviate from the claim meanings compelled by the remainder of the intrinsic evidence. See, e.g., Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 908 (Fed. Cir. 2005); Cordis Corp. v. Medtronic Ave, Inc., 339 F.3d 1352, 1359-62 (Fed. Cir. 2003). Here, there is no incontrovertible evidence that McNeil disavowed the two-layer embodiment during the prosecution of the '340 patent. McNeil's initial claims were rejected by the Patent Office. Following the submission of the Roche declaration, the examiner

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found McNeil's claims "persuasive as to unexpected results . . . over the prior art for the dosage form tested therein, i.e. coated granule solid dosage form." The Patent Office accepted application claims 9, 10 and 27, each of which was sufficiently broad to encompass a dual-layer coated granule embodiment.

Again, there is no record evidence of an express disclaimer of the dual-layer coated granule embodiment. Purdue Pharma, 438 F.3d at 1135-37. Perrigo focuses on statements made by the examiner following the submission of the Roche declaration. As an initial matter, "unilateral statements by an examiner do not give rise to a clear disavowal of claim scope by an applicant." Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347-48 (Fed. Cir. 2005). To the extent the examiner's statements are relevant, they are, at most, ambiguous. After McNeil submitted the Roche declaration, the examiner noted that the unexpected results were sufficient to allow the "dosage form tested therein." (Kiel Decl. Ex 2: Paper No. 33, at 2.) Perrigo asserts that the singular "form" refers only to the single-layer embodiment tested by Roche. Yet the examiner explained that the phrase "dosage form tested therein" broadly referred to the "coated granule solid dosage form." (Kiel. Decl. Ex. 2: Paper No. 33, at 2.) Having failed to distinguish between one-layer and two-layer embodiments, the examiner apparently was persuaded as to all coated granule embodiments. This interpretation of the examiner's statement is consistent with the specification's description of the preferred embodiment, in which the singular "form" expressly refers to both one-layer and two-layer tablets. ('340 Patent col. 9, ll. 12-14.)

Likewise, in explaining her reasons for allowing claims 9, 10 and 27, the examiner expressed her approval of claims that "limited allowed claims to coated granules. Other barrier means, e.g., the barrier sandwich, have not been allowed." (Kiel Decl., Ex. 2: Paper No. 36.) Defendants contend that the dual-layer coated granule embodiment is one of the "other barrier means" that, in addition to the barrier sandwich, was disallowed. Yet the quoted passage does not distinguish between one-layer and two-layer coated granule embodiments in describing the allowed application claims. The better reading of the passage is that both one-layer and two-layer coated granule embodiments were allowed, and the remaining embodiments--the barrier sandwich and the core embodiments--were rejected. At the very least, the examiner's statement is open to more than one reasonable interpretation, meaning there has been no demonstration of a "clear and unmistakable" disclaimer. Sandisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1287 (Fed. Cir. 2005); Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed. Cir. 2004).

Perrigo's contentions are further weakened by the nature of the unexpected results. Perrigo asserts that its proposed constructions are necessary because the 25-70% degradation Roche observed in uncoated famotidine can be achieved only by mixing the ingredients into a single layer coated granule tablet. But Perrigo offers no evidence demonstrating that the same results would not be achieved using a two-layer tablet. Perrigo admits that the examiner did not review the results of a test exploring the degradation in a two-layer embodiment. (Tr. at 65.) Nor can Perrigo identify any such test that was completed prior to the allowance of the '340 patent. (Tr. at 66.) Regardless, there is no record evidence showing that either the examiner or McNeil viewed the unexpected results as narrowly as the Defendants submit.

Perrigo also notes that the examiner rejected application claim 24. (Kiel Decl. Ex. 2: Paper No. 36.) That claim, as amended February 27, 1998, recites:
An oral dosage form . . . comprising: a first portion containing a therapeutically effective amount of famotidine granules; a second portion containing a therapeutically effective amount of [antacid]; and barrier means between said first and second portions for separating the [antacid] from the famotidine, wherein the barrier means is a coating disposed on the famotidine granules which prevents the famotidine from degrading more than an additional 1% by weight of the famotidine as compared to an identically formulated dosage form not containing an antacid . . .

(Kiel Decl. Ex. 2: Paper No. 34, at 3.) Defendants contend that this claim was rejected because it encompassed a two-layer coated granule embodiment. However, the examiner explained her rejection of this claim as follows: "Claim 24 is indefinite as to how the absence of 'an antacid' broadly . . . would be relevant to the construction of the dosage form." (Kiel Decl. Ex. 2: Paper No. 36, at 1.) This explanation has nothing to do with the inclusion of a two-layer embodiment in the claim. Application claim 24 also contains the quoted "1% by weight" language which is irrelevant to the number of layers in the tablet and which references the data the examiner had found to be insufficient on several occasions during the prosecution history. n4 (Kiel Decl. Ex. 2: Paper Nos. 16, at 6; 20, at 3; 29, at 4.) No clear disavowal arose from the rejection of application claim 24.

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n4 The inclusion of the "1% by weight" language in application claim 32 would explain why the examiner rejected that claim as well.

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3. Other Evidence

As a final matter, this Court may consult dictionaries, encyclopedias and treatises to develop an understanding of the disputed terms. Phillips, 415 F.3d at 1324. Here, the dictionary definitions of the word "mix" are inconclusive. Webster's Third New International Dictionary, at 448 (3d ed. 1986), provides a variety of definitions. One is "to stir, shake, or otherwise bring together (different substances) with a loss of separateness of identity" and to "cause to be scattered or diffused throughout." This definition supports Defendants' proposed construction. However, Webster's also defines "mix" to mean: (1) to "combine . . . in one mass," (2) to "put as an ingredient," (3) to "bring together in . . . close association," and (4) to "combine with or introduce into a mass already formed." These constructions are sufficiently broad to encompass a two-layer tablet.

Technical dictionaries can also assist claim construction by showing how persons skilled in the art define a particular term. Dow Chem., 257 F.3d at 1375. Defendants cite the portion of Hawley's Condensed Chemical Dictionary that defines "mixing" as "[e]ffecting a uniform dispersion of liquid, semi-solid or solid ingredients of a mixture by means of a mechanical agitation. " However, an alternative definition in Hawley's also supports Plaintiff's construction: "A heterogeneous association of substances which cannot be represented by a chemical formula. Its components may or may not be uniformly dispersed . . ." These conflicting dictionary definitions do not aid this Court's construction of the claims.

Based on the intrinsic evidence, this Court adopts McNeil's proposed definitions and construes "mixing" to mean "combining two or more ingredients into one mass," and "compression mixture" to mean "one mass containing two or more ingredients that are compressed into a tablet."
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Forthe identified "mixing" and "introducing" terms, the Court need only construe "mixing" and "introducing." The remainder of the identified phrases does not require construction because the Court is construing the constituent terms.

The parties propose wildly different constructions for "mixing," neither of which can be correct. US Foam proposes a definition that allows mixing to take place but does not require the step. Defendants argue that US Foam's use of "allowing" writes the step out of the claim. Defendants offer proposals, on the other hand, with an eye toward their invalidity case as their definitions incorporate pinpoint cites to unrelated prior art patents. The Court cannot adopt a construction that lacks intrinsic support and also invalidates the claims. See Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc) ("[W]e have limited the maxim [of construing a claim to preserve its validity] to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'" (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004))).

The Court sees from comparing the proposals that theparties agree that "mixing said nitrogen" means, at least in part, "combining nitrogen." As terms should be given the same meaning across different claims in a patent, see Paragon Solutions, LLC v. Timex Corp., 566 F.3d 1075, 1087 (Fed. Cir. 2007) (quoting PODS, Inc. v. Porta Stor, Inc., 484 F.3d 1359, 1366 (Fed. Cir. 2007)). The Court construes "mixing" to mean "combining." Likewise, the parties agree, at least in part, that "introducing" means "adding." The Court construes "introducing" to mean "adding" and "introduce" means "add."
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II. Construction Of The Disputed Phrases

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The parties dispute the construction of four phrases: "substantially powdered form," "mixing the drug and the carbohydrate material," "solid integral mass," and "drug-containing matrix." The four disputed phrases appear in independent Claims 1, 6, 18, and 37 of the '737 patent. Claims 1 and 18 are method claims and Claims 6 and 37 are article of manufacture claims. The language of Claims 1 and 6 are representative of the disputed phrases. In full, Claim 1 provides (emphasis added):

1. A method for producing a drug-containing lollipop for use in transmucosal delivery of the drug to a patient, the method comprising the steps of:

(a) obtaining a pharmacologically effective dose of the drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus;

(b) obtaining a soluble carbohydrate material capable of forming a compressible confectionary matrix and capable of dissolving in the mouth of the patient;

(c) mixing the drug and the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material to form a drug-containing matrix such that the drug is dispersed substantially throughout the matrix, the drug-containing matrix being capable of releasing the drug for absorption through the mucosal tissues upon dissolution of the matrix in the mouth of the patient;

(d) compressing the drug-containing matrix in a mold to form an integral mass such that, when the integral mass dissolves in the mouth of the patient, the drug is released for absorption through the mucosal tissues; and

(e) incorporating a holder as part of the integral mass in order to form the drug-containing lollipop.

('737 patent, col. 26, 11. 35-60).

In full, Claim 6 provides (emphasis added):

6. A drug-containing lollipop for use in transmucosal delivery of the drug to a patient comprising:

a soluble, compressible carbohydrate material;

a pharmacologically effective dose of a drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus and being dispersed substantially uniformly throughout the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material and compressed with the carbohydrate material into a solid integral mass which is capable of dissolving in the mouth of the patient so that the drug is released for absorption through mucosal tissues of the mouth, pharynx, and esophagus upon dissolution of the integral mass in the mouth of the patient;

holder means secured to the integral mass so as to form a drug-containing lollipop, the holder means being configured so as to permit convenient insertion and removal of the drug-containing integral mass into and out of the mouth of a patient.

('737 patent, col. 27, 11. 12-33).

The essence of the dispute with regard to all four disputed phrases is whether they should be construed to require the absence of "free liquid." "Free liquid" is defined by Barr as "any liquid that is not incorporated chemically into the fine particles, beyond that which may be sorbed naturally." (D.I. 41 at 15 n.8.) Cephalon takes no position with regard to whether Barr's definition of "free liquid" is correct. (D.I. 50 at 7 n.17.) The Court construes "free liquid" in accordance with Barr's definition.

Cephalon contends that the disputed claim phrases should not be limited by requiring the absence of free liquid, first, because the plain and ordinary meaning of the phrases does not require it, and second, because neither the specification nor the prosecution history shows any clear disclaimer of the use or presence of free liquid. In response, Barr contends that statements in the specification that describe the "present invention" limit the scope of the claims to preclude free liquid. Barr further contends that the prosecution history shows an effective disclaimer of the use of free liquid in the methods and

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articles of manufacture claimed by the '737 patent.

The Federal Circuit's recent decision in Phillips v. AWH Corp. clarified the approach that a court should take in construing disputed terms of a patent claim. 415 F.3d 1303 (Fed. Cir. 2005) . Rather than beginning with a broad, dictionary definition and then limiting it in accordance with the specification and the prosecution history, the preferred approach is to focus "at the outset on how the patentee used the claim term in the claims, specification, and prosecution history . . . ." Id. at 1321. Here, both the specification and the prosecution history demonstrate that the inventions actually described and claimed by the '737 patent are a method of producing drug-containing lollipops using the compression of dry, powdered ingredients, and the products resulting from the use of that method. Nowhere in the claims, the specification, or the prosecution history do the inventors ever discuss the possibility of using a liquid as part of their invention. In addition, and more significant, many of their statements indicate that the inventors viewed their invention as enveloping only the dry mixing and compression of powders to form the drug-containing lollipops.

The following are illustrative examples. In the Summary of the Invention section, the '737 patent states that "the present invention teaches the combination of dry powdered ingredients by geometric dilution," ('737 patent, col. 5, 11. 43-45); and "flavorings, drugs, and other components (which may be insoluble in liquid form) are easily mixed when they exist as a dry powder," (Id. at col. 6, 11. 6-8). In the General Discussion of the Preferred Embodiments section, the '737 patent states that "the present invention teaches the mixing of solid powders at room temperature, as opposed to liquid components at elevated temperatures," (Id. at col. 7, 11. 62-65); and "because solid powders are combined together, constituents which may be chemically incompatible when in a heated solution or suspension can be mixed," (Id. at col. 8, 11. 3-6). In the Methods of Manufacture of the Preferred Embodiments section, the '737 patent states that "each of the components is mixed with the other components in dry form to produce the compositions of the present invention." (Id. at col. 11, 11. 47-49).

Cephalon argues that these examples do not amount to a clear disclaimer of the use of liquid in the claimed manufacturing method (D.I. 50 at 12-13), but that argument is misplaced. Whether or not there was an explicit disclaimer, the consistent use of a claim term by the inventor in the specification may serve to limit the scope of a claim. Nystrom v. Trex Co., 424 F.3d 1136, 2005 U.S. App. LEXIS 19748, 2005 WL 2218632, 6-7 (Fed. Cir. 2005).

"What Phillips now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to . . . those of ordinary skill in the art . . . that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."

Id. 2005 U.S. App. LEXIS 19748, at 7 (citing Phillips, 415 F.3d at 1321). Here, the inventors consistently referred to the "present invention" as teaching the formation of drug-containing lollipops through the compression of "dry" or "solid" powders. There is nothing in the written description or the prosecution history to suggest that they intended the disputed phrases to cover methods or articles using free liquid. Therefore, it would be improper for this Court to broaden the inventors' use of the disputed phrases and construe them to encompass the use of free liquid.

This result is not, as Cephalon argues (D.I. 50 at 12-13), the improper importation of limitations from the specification into a claim. This is a case where "the specification read as a whole suggests that the very character of the invention requires the limitations to be a part of every embodiment." Alloc, Inc. v. ITC, 342 F.3d 1361, 1369 (Fed. Cir. 2003).

For the reasons discussed above, the Court construes the disputed claim phrases as follows:

A. "Substantially powdered form" means "largely in the form of fine particles absent the presence of free liquid."

B. "Mixing the drug and the carbohydrate material" means "combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids."

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The Volume of Binder

The '489 patent is directed to a method for the manufacture of an abrasive article by first making a soft and flexible preform 2 from a mixture containing a liquid binder, powdered matrix material, and abrasive particles, and then sintering the preform. Claim 1, the broadest claim in suit, follows:

1. In a method for making an abrasive article wherein a plurality of abrasive particles and a quantity of powdered sinterable matrix material are combined together and sintered to form the article, the improvement comprising forming a soft, easily deformable and flexible preform from a mixture of said quantity of powdered sinterable matrix material and a liquid binder composition, including a plurality of abrasive particles at least partially in said preform and then sintering said preform to form said abrasive article.

Kinik states that claim 1, correctly construed, is limited to preform mixtures that contain a larger volume of liquid binder composition than powdered matrix material, for that is the invention described in the specification. Kinik states that the patentee made clear that this was the invention intended to be claimed, and disclaimed mixtures other than those with an excess of liquid binder over powder. Kinik states, and the Commission found, that in the process practiced in Taiwan the volume of liquid binder is significantly less than the volume of matrix powder. However, the Commission construed the '489 claims as not limited to any ratio of liquid binder to powder.

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2 "Preform" is defined as a composition that can be shaped and holds its shape to the extent needed for subsequent processing.

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In the '489 specification the applicant states that in the preform mixture the volume of the liquid binder "substantially exceeds" the volume of the matrix powder. The specification does not permit a contrary construction. The Summary of the Invention states:

To form an SEDF [soft easily deformable] preform, a slurry or paste is formed of the powdered composition and the binder composition. The concentration of powdered composition and abrasive particles (if included) in the slurry or paste is low, and the volume of the binder composition is high. In fact, the volume of the binder composition or binder phase in the mixture substantially exceeds the volume of the powdered composition and the abrasive particles.

Col. 3, lines 7-15. The ratio is quantified in the Detailed Description of the Embodiments:

By volume, the percentage of the powder within the binder-powder mixture is usually from 1 to 5%, but it can be extended to a range of 0.3 to 10%.

Col. 3, lines 29-32. During prosecution the applicant added text to the application "to more accurately define applicant's invention" and in connection with that definition stressed that the volume of the binder composition "substantially exceeds" the volume of the metal powder, relying on this distinction to overcome cited references. Response to Office Action, at 20 (June 3, 1996) (Preliminary Amendment). The applicant stated:

Further [the invention] is the mixture of the powdered sinterable matrix material and the liquid binder composition used to form the SEDF preform where the volume of the binder composition substantially exceeds the volume of the matrix material and in which the weight of the binder composition is usually from 3 to 20% by weight of the mixture.

Id.

3M stated that during prosecution it was arguing patentability in the context of the preferred embodiment, but that the invention should not be limited to use of excess binder in the preform because such limitation is not included in the claims. The Commission agreed, citing Federal Circuit precedent that limitations from the specification should not be read into the claims. The Commission cited decisions such as Sjolund v. Musland, 847 F.2d 1573, 1581 (Fed. Cir. 1988), wherein the

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court explained that while claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims. Similarly in Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986), the court "cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."

This precedent is sound. However, precedent does not hold that the claims are not limited by what is described and enabled. Patent claims are directed to the invention that is set forth in the specification. See 35 U.S.C. § 112 (the claims "particularly point out and distinctly claim" what the applicant views as the invention); see also Slimfold Mfg. Co. v. Kinkead Indus., Inc., 810 F.2d 1113, 1116 (Fed. Cir. 1987) (claims are understood in light of the specification, of which they are a part).

3M is correct in that when the specification describes the invention in broad terms, accompanied by specific examples or embodiments, the claims are generally not restricted to the specific examples or the preferred embodiments unless that scope was limited during prosecution. See Dow Chem. Co. v. United States, 226 F.3d 1334, 1342 (Fed. Cir. 2000) (as a general rule claims of a patent are not limited to the preferred embodiment); Intel Corp. v. United States Int'l Trade Comm'n, 946 F.2d 821, 836 (Fed. Cir. 1991) ("Where a specification does not require a limitation, that limitation should not be read from the specification into the claims.").

In the '489 patent the invention was described with specificity in the specification, and this specificity was illustrated in the examples. During prosecution the same specificity -- the excess volume of liquid binder over matrix powder in the preform mixture -- was emphasized as a material distinction from the prior art. The specification states that prior art preforms having low binder volume are hard, stiff, and brittle, for example at col. 1, lines 18-43, and col. 2, lines 15-19. The inventor's discussion of the disadvantages of the low binder prior art sheds light on the scope of the invention. See Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) (arguments contained in the prosecution history which purport to distinguish an invention from the prior art may affect the scope of the patent ultimately granted). Claims cannot be construed as encompassing the prior art that was distinguished in the specification and disclaimed during prosecution. See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 (Fed. Cir. 2001).

Even the broadest descriptive text in the '489 specification describes only mixtures where binder volume exceeds matrix powder volume. During prosecution the applicant disavowed the breadth whereby the volume of matrix powder exceeds binder volume, for a preform having low binder content was in the prior art. We have noted 3M's argument that the '489 specification states a range of weight percentages as well as relative volumes, and that the lowest weight percentage of binder mentioned (3% of the weight of the mixture) would not produce an excess volume of binder. However, that calculation, if accurate, contradicts the applicant's repeated statements that the invention is directed to mixtures having high volumes of binder. If anything, it contributes to imprecision or invalidity, not increased claim breadth.

The Commission, however, declined to review the ALJ's ruling that since the ordinary dictionary meaning of "mixture" is not limited by the proportion of the components of the mixture, the claims should not be so limited. The ALJ pointed to Federal Circuit precedent that encourages recourse to dictionaries, as in Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1372 (Fed. Cir. 2001), and Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The issue, however, is not one of dictionary definition of a common word, but the meaning of "mixture" as used in the patent documents. Dow Chem., 257 F.3d at 1378 (scope is limited to the meaning set forth in the patent documents). The words of patent claims have the meaning and scope with which they are used in the specification and the prosecution history. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998) ("The best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history.").

The invention that was submitted for examination, and that was patented, explicitly requires an excess of liquid binder over powdered matrix. The word "mixture" in the claims has the scope given it in the specification, for it is clear that no broader scope was contemplated or intended. We conclude that the '489 claims require that the preform process employs a volume of liquid binder that exceeds the volume of powdered matrix. It is not disputed that Kinik's preform process uses a volume of liquid binder that is significantly lower than the volume of matrix powder. There was no contrary evidence on this aspect. On the correct claim construction, the judgment of violation of 19 U.S.C. § 1337(a)(1)(B)(ii) is not supported by substantial evidence, and is reversed.

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Disputed Claim Language	ASM's construction	Genus's construction
exposing the substrate to a mixture of hydrogen halide vapor and either water vapor or a vapor of a hydroxyl-containing replacement for water vapor to etch native oxides from a surface of the substrate	mixing a precursor consisting of hydrogen halide vapor and a precursor consisting of either water vapor or ethyl alcohol, methyl alcohol or isopropryl alcohol and passing the combined vapors through the reaction chamber to the substrate	"vapor of a hydroxyl-containing replacement for water vapor" is the gas phase of a compound, other than water, containing a hydroxyl (OH) group

Here, the parties agree that hydrogen halide vapor is "the gas phase of a compound consisting of a hydrogen atom and a halogen atom (i.e., HF, HCl, HI, HBr, or HAt)." They disagree about the meaning of a "hydroxyl-containing replacement for water vapor," and whether the mixture of the vapors must occur prior to entering the reaction chamber. The parties also disagreed initially about whether the water vapor used in the process must be introduced from outside the chamber or whether the process can use only the water vapor that is produced in the chamber as a result of the reaction. Genus concedes in its reply brief, however, that some water vapor must be introduced from outside the chamber.

"Mixture"

Nothing in the claim language itself requires the mixture of "hydrogen halide vapor and either water vapor or a vapor of a hydroxyl-containing replacement for water vapor" to occur outside the reaction chamber. The claim language simply requires that the substrate be exposed to such a mixture, which could, under the plain meaning of the claim language, occur by adding the substances separately to the reaction chamber so that they mix in the reaction chamber itself.

ASM's expert, Martin L. Hammond, states in his expert report, however, that the person of ordinary skill in the art would understand that the vapors are mixed together outside the reaction chamber, and then the mixture is subsequently passed through the reaction chamber to the substrate. (Brown Decl., Ex. F, Hammond expert report 6:3-8, 7:7-9.) Genus' expert, Oldham, correctly points out that Hammond relies on language describing preferred embodiments, which are not limitations on the claim language. (Brown Decl., Ex. E, Oldham Rebuttal Expert Report at 8.)

For example, the specification states that "in accordance with a principal embodiment of the present invention, the hydrogen halide is either hydrogen fluoride or hydrogen fluoride and hydrogen chloride each derived from a separate aqueous solution or derived from a common aqueous solution[.]" (Id. 2:55-59.) In another description of a preferred embodiment, "a hydrogen halide vapor such as HF vapor and water vapor or HF vapor, HCl vapor and water vapor in an inert carrier gas such as nitrogen is passed through the reactor chamber for exposing the oxides on the substrate[.]" (Id. 4:6-9.) Figure 2, which describes a preferred embodiment, also shows the vapors being mixed outside the chamber. (Id., Fig. 2, and 5:13-44.) The specification also contains other language describing preferred embodiments in which the vapors are mixed before being introduced into the reaction chamber, as Hammond cites in his expert report. Nothing in the specification, however, even suggests that the mixture must occur outside the reaction chamber. "In the course of construing the disputed claim terms, a court should not ordinarily rely on the preferred embodiments alone as representing the entire scope of the claimed invention." CCS, 288 F.3d at 1370.

It is also true that claims 2 through 7, and 9 through 17, each claim a method using various hydrogen halides in water. (Id. 7:65-8:14, 8:27-46.) Dependent claims, by definition, though, place no limitations on the independent claim upon which they depend. 35 U.S.C. § 112 P 4 ("a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.") It is black letter law that each claim sets forth a distinct and

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separately patentable invention. 35 U.S.C. § 112 P 2. Thus, the fact that a limitation exists in one claim does not require that the same limitation appear in any other claim.

It is undisputed that HF vapor reacts with silicon dioxide wafers to create water as a by-product. The parties originally disputed whether the process claimed by the '568 patent could use that water by-product as the only water vapor in the reaction, or whether the claims required that the water vapor be introduced from outside the chamber. Genus concedes in its reply brief, however, that "during prosecution the '568 applicants limited the claim language 'exposing the substrate to hydrogen halide vapor and water vapor' so as to exclude water that was generated as a by-product of the etching reaction." (Reply brief at 15; see also Brown Decl., Ex. H (Prosecution History) at '568 FH0066-67.)

The Court rejects Genus' claim that only claim 1 excludes water that was generated as a by-product of the etching reaction, however. Genus contends that claim 8 is not so limited because it does not require water vapor at all. The relevant language of claim 1 requires "exposing the substrate to a mixture of hydrogen halide vapor and water vapor to etch native oxide," while the relevant language of claim 8 requires "exposing the substrate to a mixture of hydrogen halide vapor and either water vapor or a vapor of a hydroxyl-containing replacement for water vapor to etch native oxides[.]" Although claim 8 does not require the use of water vapor, it does provide for the use of water vapor as one alternative. The Court does not see how claim 8 can be construed to permit the use of water vapor that is created as a by-product of the reaction just because the claim also permits the use of a substitute for water vapor. Claim 8 claims the use of water vapor, just as does Claim 1. To the extent the process of Claim 8 uses water vapor, it is subject to precisely the same limitations as claim 1.

Accordingly, the Court finds that the "mixture" contemplated by the claim language need not occur outside the reaction chamber. Each of the ingredients of the mixture, i.e., the "hydrogen halide vapor and either water vapor or a vapor of a hydroxyl-containing replacement for water vapor," must come from outside the reaction chamber, however. In particular, water vapor must be introduced to the reaction chamber from outside the chamber, and cannot exist in the chamber solely as a by-product of reactions occurring inside the chamber.
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Scope of the Term "Mixture" in Claim 4

In interpreting the meaning and scope of the claims of the '046 patent, the Court must now consider what is meant by the term "mixture" in dependant Claims 4 and 5. Of these two claims, Plaintiffs have only asserted infringement of Claim 4, which encompasses:

> The composition of claim 1 consisting essentially of a mixture of (1) said particulate glass having a particle size in the range of from about 90 to about 350 [mu]m, (2) said particulate glass having a particle size in the range of from about 355 to about 500 [mu]m, and (3) said particulate glass having a particle size in the range of from about 500 to about 710 [mu]m.

United States Patent No. 4,851,046, column 12, lines 18-24.

Defendants have argued Claim 4 dictates, that in order for a product containing smaller sized particles to be infringing, it must have been created by "mixing" three separate compositions of glass, each of the three said compositions consisting only of particles in each of the three ranges cited. With regard to the language in dependant Claim 4, which claims a composition that consists 'essentially of a mixture,' Defendants state that the term "mixture" in that claim "must be interpreted to require the preparation and subsequent combination of the three compositions. 11 (Doc. 93, p.16 n. 12). To construe it otherwise say the Defendants, would be to resurrect the scope of application Claim 1 which was held unpatentable by the Board of Appeals, and such a construction would effectually broaden, rather than narrow the scope of independent Claim 1, all in violation of 35 U.S.C. § 112. Defendants state that "'the dependant claim tail cannot wag the independent claim dog.'" (Doc. 93, p.16 n.12) (quoting North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993)).

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11 According to Defendants, Claims 5 and 6 require that the claimed composition be

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"a 'mixture' of three compositions, each having a different range of particle sizes. Thus one composition [with] a particle size range of from about 90 to 350 [mu]m, a second composition [with] a particle size range of from about 355 to 500 [mu]m, and the third composition [with] a particle size range of from about 500 to 710 [mu]m."

(Doc. 93, p.15 n.11).

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The Court cannot accept Defendants' interpretation of the term 'mixture' for several reasons. First, the plain meaning of the term 'mixture' is that which consists of different elements; it is a noun which refers to what is contained in a composition, not how a composition is created. Specifically, a mixture has been defined as "a portion of matter consisting of two or more components that do not bear a fixed proportion to one another and that however thoroughly commingled are regarded as retaining a separate existence." WEBSTER'S THIRD NEW INTERNATIONAL UNABRIDGED DICTIONARY 1149 (1968). Thus, one would be able to identify the components of a mixture because each component would retain its own composition.

In this case, the resultant embodiment of the patented claims is a powder consisting of bioactive and biocompatible glass particles. If three compositions of glass particles, i.e. three powders, each falling within the three respective size ranges cited in Claim 4, were to be combined with one another, they would no longer remain recognizable in any of the three separate composition forms which they embodied prior to being mixed together, rather they would form a new powder which would only be identifiable as having particles somewhere within each of the three cited ranges. The individual glass particles would retain their original characteristics, but if three powder compositions consisting of particles within three separate ranges were mixed, those three separate powder compositions would no longer be distinguishable. 12 For example, if Powder-A, containing only particles in the range of 90 to 350 [mu]m, were combined with Powder-B containing particles in the range of 355 to 500 [mu]m, it would not be possible to identify Powder-A within the new Powder-AB, much less to distinguish Powder-AB from another composition powder that was simply created directly from particles in the size range of 90 to 500 [mu]m. Consistent with the above-referenced definition of a mixture, if particles are mixed together to form a resultant powder by any process, each particle will retain its own size characteristics within the mixture, thus, it matters not how the resultant powder composition is formed. The relevant inquiry regarding the "mixture" cited in Claim 4, is whether the resultant mixture contains particles in each of the three cited ranges, not whether three separate compositions of glass particles were mixed to form one.

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12 This is inconsistent with Defendants' proffered interpretation of the term 'mixture' as meaning a process of combining three separate compositions together to form the resultant product.

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The Court concludes that the term 'mixture' as used in dependant Claim 4 of the '046 patent means a composition of particulate glass which contains a mixture of glass particles, said particles having sizes within each of the three size ranges cited in Claim 4, and that the term does not mean a mixture comprised of three separately composed compositions of glass particles mixed with one another to form a compound composition as argued by Defendants. The Court's interpretation of the term 'mixture' as used in the context of Claim 4 of the '046 patent is consistent with the definition cited above. As construed, Claim 4 deals with a mixture of glass particles of various sizes, which particles would each retain their own identity within the mixture; it does not deal with a mixture of three separately composed compositions of particles, which compositions' individual identities would be lost in, or subsumed by, the resultant mixture comprised thereof.

Citing to the '046 patent specification at column 4, lines 48-57, Defendants contend that the specification refers to a process of blending three different particle size range components to obtain the 'mixture' referred to in Claim 4. (Doc. 106, pp. 9-10). However, the reference in the specification is an explanation of the patentee's hypothesis that a composition of glass particles with a broader range of particle sizes, i.e. within each of the three cited ranges, yields the most effective osseous defect repair mechanism. The reference is included as support for the proposition that powders containing glass particles over a wider range of particle sizes would improve the cohesiveness and workability of the resultant product. The Court

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must reject Defendants interpretation of the term 'mixture' on these grounds because it is legally improper to read from the specification and into the patent, a process limitation which is simply not there. Additionally, a patent claim cannot be limited by the examples listed within the patent specification. See Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir.), cert. denied, 518 U.S. 1005, 116 S. Ct. 2523, 135 L. Ed. 2d 1048 (1996) (citing Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)).

Defendants' argument that construction of the term mixture to mean anything other than the process of mixing three separate compositions would improperly resurrect the application claim rejected by the Board of Appeals and impermissibly broaden, rather than limit the scope of independent Claim 1, is also wrong. Defendants mistakenly assume that if the term mixture is construed to mean the resultant particulate glass composition, regardless of how it is formed, that such a construction would transform Claim 4 into the equivalent of application Claim 1 which cited a range of particles sizes from about 90 to 710 [mu]m. Application Claim 1 was refused because it was too broad and could be construed to encompass a composition containing glass particles only in the size range below 355 [mu]m, without a requirement that larger particles be present as well. Claim 4, by construing the term 'mixture' to mean the resultant composition, regardless of the process by which it was formed, encompasses those compositions in which the smaller particles co-exist with particles in the 355 to 500 [mu]m range and with particles in the 500 to 710 [mu]m range. Thus, the scope of the '046 patent Claim 4 is substantially different than application Claim 1. The Court must also reject Defendants' argument that this interpretation of Claim 4 broadens rather than narrows the scope of independent Claim 1, in violation of 35 U.S.C. § 112. Claim 1 involves a composition containing glass particles within the size range of 355 to 710 [mu]m. Claim 4 further restricts this claim by also requiring the additional presence of particles within the range of about 90 to 350 [mu]m, thus narrowing the scope of Claim 1.

Having considered the patent claims themselves and the specification provided therefor, the Court concludes that the proper interpretation of the scope of the '046 patent, and specifically Claim 1, is that it not only allows for, but anticipates via Claims 4 and 5, the presence of glass particles with sizes smaller than 355 [mu]m, however, it excludes from Claim 1 the presence of those smaller particles when they occur in a number sufficient to affect the performance in such a manner that they also alter the basic characteristics of the claimed invention. Additionally, the presence of smaller particles allowable under Claim 1 remains subject to the further limitations of dependant Claims 4 and 5, which narrow the scope of Claim 1 by allowing the additional presence of up to one-third of the particles in the size range of 90 to 355 [mu]m. Thus, where a composition contains substantially more than one-third of its particles in the smaller range (e.g. two-thirds or more), it will not be within the scope of Claim 1.

ii. The Prosecution History

The prosecution history of the patent is also relevant to the proper construction of the claims therein. As will be discussed below, the prosecution history of the '046 patent also reveals that it encompasses not only those compositions of particulate glass which consist only of particles sized within the range of from 355 to 710 [mu]m, but that it also encompasses compositions with particles in the range of 355 to 710 [mu]m that also include particles sized smaller than 355 [mu]m.

Claim 1, which originally cited a particle size range of from about 90 to about 710 [mu]m, was rejected by the Patent Examiner under 35 U.S.C. § 103 as unpatentable over prior art, the Gross et al. Patent No. 4,239,113 ("Gross patent"). The examiner concluded that Claim 1 was too broad and could theoretically encompass the prior art Gross patent which required the presence of much smaller particles (those in the range of 10 to 200 [mu]m). On appeal of the examiner's rejection of Claim 1, the Patent Office Board of Patent Appeals and Interferences ("Board of Appeals") held that any of the claims which could be construed as requiring only smaller particles were not patentable, but it noted that those claims which required the presence of larger particles were indeed patentable. The original Claim 5, which was re-numbered as Claim 4 in the '046 patent, was found to be patentable by the Board of Appeals because it cited and required the presence of particles within size ranges substantially larger than anything disclosed in the Gross patent. See Opinion on Appeal, No. 88-0461 at p.13 (Doc. 88, Exh. 10 at OVIT 00368).

Defendants have argued under their fourth defense, that the additional subject matter of Claim 4, i.e. the range of particles from 90 to 350 [mu]m, was "ceded" to the public domain when the Patent Examiner rejected the original broad Claim 1 in favor of the more restrictive Claim 1 that cited particle sizes in the range of about 355 to 710 [mu]m. See Transcript of Feb. 6, 1998 hearing (Doc. 125, p.27, lines 2-5); see also (Doc. 106, p.4). Defendants argue that "the purported scope of claim 1, as now advanced by [Plaintiffs], was 'disclaimed during prosecution,' and, cannot be adopted now." Id. (quoting Southwall

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Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)). However, Southwall and the other cases cited by Defendants, deal with situations where the patentee construed a term one way in order to obtain its allowance in the patent, and then sought to construe it the opposite way against accused infringers. See Southwall, 54 F.3d at 1576. In this case, what was originally claimed was a range of particle sizes which could be construed to include only smaller particles to the exclusion of larger ones, thus violating a prior art patent regarding the smaller particles. What is now claimed is a composition which includes particles within the lower range of particle sizes, but only where the co-presence of larger particles is explicitly required as well. This construction is not inconsistent with the position previously taken by Plaintiffs, and all that was ceded to the public domain, or that was "disclaimed" during the prosecution of the original patent application, that can now limit the interpretation of dependant Claim 4, was any claim which permitted the presence of only the smaller particles to the exclusion of any larger particles. No portion of the original Claim 5, re-numbered as Claim 4, was ever disclaimed or rejected by the Board of Appeals such that Plaintiffs are now forbidden from advancing an interpretation of its current patent claims consistent therewith. Thus Defendants' fourth defense of prosecution history estoppel must fail.

Plaintiffs had wanted to patent the original broader range because their testing indicated that those compositions with the broadest range, i.e. with particles in the range of from 90 to 710 [mu]m, created the most adhesive and manipulable resultant product; this was a clear advantage over the prior art Gross patent material, and this advantage served as the impetus for the original application to patent the range of 90 to 710 [mu]m. See '046 Patent, col. 4, lines 23-68 (Doc. 106, Exh. 1). However, since the originally requested open range was denied because it was so open and broad as to potentially encompass the Gross patent, Claim 1 was cut back to provide Plaintiffs with an open range from 355 to 710 [mu]m. Claims 2 and 3 concern two separate ranges within the broader initial range of Claim 1, and Claims 4 and 5 allow Plaintiffs to claim rights to a composition consisting of a mixture which is subject to Claim 1 and which also contains particles in the lower range. This allowed the Plaintiffs to have a patent over a composition with particles in the most desirable range of 90 to 710 [mu]m, but only so long as the composition consists of a mixture of glass particles across the entire range of particle sizes, so as to avoid the problem of the original claim 1 which would have overlapped the Gross patent. 13 The revised versions of the '046 patent claims allowed the Plaintiffs to take as full advantage as possible of the benefits which flow from the use of the broadest range of particle sizes, and to prevent potential infringers from duplicating or mimicking the composition of PerioGlas TM only to avoid an infringement claim by simply adding in some smaller sized particles.

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13 The only way the Gross patent ever falls within the '046 patent is in compositions under Claim 4, but even then, the '046 patent is distinct because it requires the co-presence of particles from two separate size ranges larger than those cited in the Gross patent.

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In this case, the prosecution history only serves to bolster this Court's conclusion that the '046 patent claims do not exclude the presence of smaller particles, and it is consistent with this Court's determination that the claims of the '046 patent, while requiring the presence of particles within the size range of from 355 to 710 [mu]m, do not exclude the possible presence of particles with sizes smaller than 355 [mu]m.

Thus, having considered the patent claims themselves, the patent specification, and the prosecution history thereof, this Court concludes that as a matter of law, the '046 patent, and more specifically, Claim 1, is not restricted to an interpretation that all particles be between 355 and 710 [mu]m, as suggested by Defendants. It is sufficient for a finding of infringement of the '046 patent claims, that a composition contain either particles solely within the range cited in Claim 1, from about 355 to 710 [mu]m, or that the composition contain additional smaller particles in such quantities that do not affect the basic characteristic of the claimed composition or which occur in a manner consistent with the additional limitations of dependant Claims 4 and 5. However, while infringement of Claim 1 cannot be avoided by the mere additional presence of particles smaller than 355 [mu]m when those smaller particles either do not affect the material characteristics of the composition, or appear in a manner consistent with Claims 4 and 5, a composition which contains a substantially greater number of its particles in the smaller range than is explicitly referred to in Claim 5, can only be found infringing in the unlikely event that Plaintiffs can show that the basic characteristics of the claimed invention are not altered by the presence of so great a number of smaller particles.

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2. Independent Claims 17-19

Although written in slightly different language, claims 17-19 provide the same limitation as claims 13-15. The claims describe a "mixture" of bupropion hydrochloride and "means for releasing" bupropion hydrochloride over the course of an hour, "said means comprising [HPMC]." (Id., Ex. A.) As with claims 13-15, these claims as originally written did not contain the HPMC limitation. The examiner rejected these claims and did not approve the claims until the HPMC limitation was added. Thus, under the same reasoning applicable to claims 3, 6, 7, and 13-15, supra III.A.1., the court concludes that claims 17-19 describe a specific polymer, HPMC, that is blended with bupropion hydrochloride to form an admixture. The addition of HPMC serves to retard the release of bupropion hydrochloride into the bloodstream. n10

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n10 Although claims 17-19 describe a "mixture" of bupropion hydrochloride and claims 13-15 claim an "admixture" of these compounds, for the purposes of the '798 patent, these terms are synonymous. This conclusion is confirmed by the fact that the specification uses these terms interchangeably. (e.g., Specification 2:40-60.)
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II. "heterogeneous mixture of labeled unique sequence nucleic acid fragments"

The phrase "heterogeneous mixture of labeled unique sequence nucleic acid fragments" appears only in claim 1 of the '479 patent: "1. A method of staining target interphase chromosomal DNA . . ., the method comprising: (a) providing a heterogeneous mixture of labeled unique sequence nucleic acid fragments which are substantially complementary to nucleic acid segments within the interphase chromosomal DNA for which detection is desired . . ." '479 patent at 16:6-13 (emphasis added).

Abbott argues that the phrase should be construed to mean "labeled nucleic acid fragments that include unique sequences." Dako argues that the phrase should be construed to mean "fragments of labeled DNA or RNA that contain only unique sequences." The parties' constructions differ in only one respect: whether the mixture must consist entirely of unique sequences, or whether the mixture may also contain repetitive sequences.

The language of claim 1, standing alone, is ambiguous. The claim phrase recites a "mixture of" labeled unique sequence nucleic acid fragments, not a "mixture comprising" or a "mixture consisting of." Although the Federal Circuit has construed the similar phrase "composed of" narrowly, the word "of" does not have an established meaning as open or closed ended. See AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1245 (Fed. Cir. 2001) (finding that "'composed of' in this case should be interpreted in the same manner as 'consisting essentially of' . . . [which excludes] ingredients that would materially affect the basic and novel characteristics of the claimed composition," but noting that transition phrases without established meaning "must be interpreted in light of the specification to determine whether open or closed claim language is intended.") The court must therefore look to the remainder of claim 1, the other claims of the '479 patent and the remainder of the intrinsic record for guidance.

The remainder of claim 1 provides some support for Dako's proposed construction. Element (a) indicates that the fragments are "designed to allow detection" of various characteristics of interest, such as "an extra or missing portion or portions of a chromosome." '479 patent at 16:13-14. Element (b) recites "employing the heterogeneous mixture [i.e., the mixture referenced in element (a)] . . . to permit detection of labeled nucleic acid fragments which are hybridized to interphase chromosomal DNA." Id. at 16:17-20. Finally, element (c) recites "detecting the labeled nucleic acid fragments which are hybridized to the interphase chromosomal DNA [i.e., the fragments recited in element (b)] to determine whether an extra or missing chromosome . . . is present in the target interphase chromosomal DNA." Id. at 16:24-29. As Dako correctly points out, if the heterogenous mixture includes a substantial number of repeat sequences, unless some form of blocking (not recited in claim 1) is employed, the fragments cannot be used to reliably detect the presence or absence of particular

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chromosomes. According to Dako, the fact that the claim as construed by Abbott encompasses inoperative matter makes Abbott's proposed construction implausible.

It is true that "[c]laims which include a substantial measure of inoperatives . . . are fairly rejected under 35 U.S.C. § 112." In re Corkill, 771 F.2d 1496, 1501 (Fed. Cir. 1985); see also Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 336 U.S. 271, 277, 69 S. Ct. 535, 93 L. Ed. 672, 1949 Dec. Comm'r Pat. 527 (1949), aff'd on reh'g, 339 U.S. 605, 70 S. Ct. 854, 94 L. Ed. 1097, 1950 Dec. Comm'r Pat. 597 (1950) ("it is clear that [claims] fail equally to perform their function as a measure of the grant when they overclaim the invention."). The canon of construing claims to avoid invalidity, however, only applies when the record is otherwise in equipoise. See Phillips, 415 F.3d at 1327 ("we have limited the maxim [that claims should be construed to preserve their validity] to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.'").

Here, dependent claim 12 unambiguously indicates that the word "of" in claim 1 was intended to be open ended. Claim 12 recites "[t]he method of claim 1, wherein the heterogeneous mixture further comprises repetitive sequences." '479 patent at 16:57-58. Claim 13 adds to claim 12 "the step of disabling the hybridization capacity of repetitive sequences in the heterogeneous mixture." In order for claims 12 and 13 to be valid, claim 1 must allow for repetitive sequences in the heterogeneous mixture, and must further allow for them to be disabled through blocking. The parties do not dispute that claim 1 permits the addition of a blocking step, as a result of the express use of the word "comprising" between the preamble and the recited method steps. Claim 12 suggests that the word "of" should be read as "comprising" with respect to the contents of the heterogeneous mixture as well.

Dako also argues that the narrow claim language stands in contrast to broader language in the specification, which uses the phrase "heterogeneous mixture of labeled nucleic acid fragments" without the "unique sequence" modifier. See Spec. at 4:2-9. The heterogeneous mixture described in the specification includes fragments with unique sequences as well as fragments with repetitive sequences. See id. at 4:20-23 ("preferably the heterogeneous mixtures are substantially free from so-called repetitive sequences, both the tandem variety and the interspersed variety"). As this passage makes clear, the mixture must include unique sequences (which bond to the region of interest) and may include repetitive sequences, but is preferably "substantially" free of repetitive sequences. Abbott's proposed construction for the claim language, which encompasses both unique and repetitive segments, is apparently coextensive with the broader phrase used in the Specification. Although the court is troubled by assigning the same meaning to different phrases, the unambiguous guidance provided by claim 12 is clearer than any inference which might be drawn from the inconsistent use of language.

Finally, Dako argues that the patentee gave up repetitive sequences during prosecuting. In responding to a rejection, the applicant stated that "'[u]nique sequence nucleic acid fragments are in contrast with, and free of, 'repetitive sequence' nucleic acid." Hoffman Dec., Exh. J at 7. The quoted statement is perfectly consistent with Abbott's proposed construction, which does not interpret "unique sequence . . . fragments" to include repetitive fragments, but rather depends on the word "of" for inclusion of repetitive sequence fragments in addition to the unique sequence fragments which are expressly recited in the claim.

The court therefore construes "heterogeneous mixture of labeled unique sequence nucleic acid fragments" to mean "a heterogeneous mixture of labeled nucleic acid fragments that includes unique sequence fragments."
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D. The Court's May 20, 1998 Claim Construction Hearing

1. Overview of Claim Construction Issues

On May 20, 1998, the court held its claim construction hearing. The parties submitted pre- and post-hearing briefs. At the hearing, the court heard further argument from the parties, as well as the testimony of three experts, Dr. Nam-Hai Chua, Dr. Julia Bailey-Serres, and Dr. Joseph Falkinham, III.

The parties dispute the meaning of only one phrase of the claims at issue. Specifically, Claims 7, 8, 9 and 12 of the '365 patent all refer to a "modified chimeric gene." There are two methods for altering gene sequences to make a modified

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chimeric gene. The first method, known as site-directed mutagenesis, is the process of designing a gene by substituting one or more nucleotides at predetermined sites in a natural gene. The second method, known as chemical synthesis, is the process of creating synthetic DNA by chemically linking nucleotides in the proper sequence to produce the desired DNA sequence. The synthetic DNA is then incorporated into the native gene to alter the sequence.

Defendants argue that a "modified chimeric gene" includes only genes made by site-directed mutagenesis. Monsanto argues that a "modified chimeric gene" is a gene made by either method. At the conclusion of the claim construction hearing, the court determined that a "modified chimeric gene," as used in the '365 patent, includes a gene designed by either site-directed mutagenesis or chemical synthesis. The court explains its reasoning below.

2. Hearing Testimony of Expert Witnesses

Dr. Nam-Hai Chua, a professor at Rockefeller University and the head of its plant molecular biology laboratory, testified for Monsanto. According to Chua, site-directed mutagenesis is a method for altering DNA sequences at specific locations on a gene. He testified that one would use site-directed mutagenesis to make changes in discrete areas in a gene. According to Chua, chemical synthesis is a process where pieces of synthetic DNA are made and then incorporated into the native gene to alter the DNA sequence. Chua testified that one would use chemical synthesis to make changes in a large number of areas in the gene.

Chua testified that there is no difference between genes designed by site-directed mutagenesis and those designed by chemical synthesis, so long as the sequences changed by the different methods are identical. He further testified that the subject matter of the '365 patent concerns increasing Bt expression in plants, and that nothing in the patent is process-specific. According to Chua, the word "modified" in the '365 patent means "changes in the DNA sequence that are different from the native Bt sequence."

Dr. Julia Bailey-Serres, an associate professor of genetics specializing in plant gene expression at the University of California at Riverside, testified for Novartis. According to Bailey-Serres, site-directed mutagenesis involves synthesizing a short DNA sequence that differs from the native gene sequence in only a few nucleotides. The synthetic DNA is then hybridized, or bound, with native DNA, then enzymatically copied to produce a DNA sequence which is altered in a small, discrete region. She testified that chemical synthesis involves the insertion of a large piece of synthetic DNA into the native gene. This procedure alters large sections of the DNA sequence. Bailey-Serres testified that the '365 patent claims an invention in which specific gene sequences are altered by site-directed mutagenesis.

Dr. Joseph Falkinham, III, a professor of microbiology and genetics at Virginia Polytechnic Institute, testified for Mycogen. He agreed with Bailey-Serres's testimony about the differences between the two methods. Falkinham testified that the term "modified chimeric gene" refers to a gene designed by site-directed mutagenesis.

3. The Prosecution History Of The '365 Patent

On February 24, 1989, Monsanto filed U.S. Patent Application Serial No. 315,355 ("the '355 application") with the Patent and Trademark Office ("PTO"), naming David A. Fischhoff and Frederick J. Perlak as the inventors. This application, entitled "Synthetic Plant Genes And Method For Preparation," disclosed several different Bt genes, including genes with changes in a specific region referred to as the "240 region" or "B region."

The so-called 240 region of a native Bt gene is a region of 36 nucleotides beginning at the positions indicated below:

TTAATTAACCAAAGAATAGAAGAATTCGCTAGGAAC

1 5 10 15 20 25 30 35

Monsanto scientists learned that while Bt genes consist of approximately 62% A and T nucleotides, most plant and other bacterial genes consist of only 45% to 55% A and T nucleotides. Thus, Monsanto scientists discovered that by replacing certain A and T nucleotides with G and C nucleotides, the Bt gene became more plant-like. Throughout the prosecution history of the '355 application, Monsanto often referred to ATTTA sequences and polyadenylation sequences, which include sequences such as AATAAA, AATAAT, AACCAA, ATATAA, AATCAA and others.

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On February 12, 1990, Monsanto filed an addendum to the '355 application, known as a continuation in part ("CIP"). The CIP added information and examples relating to the 240 region. The CIP also included the first use of the word "modified" in the claims. For example, Claim 30 claimed:

A chimeric plant gene which comprises a structural coding sequence encoding an insecticidal protein of [Bt], said structural coding sequence being modified to reduce the number of putative polyadenylation signals within said structural coding sequence.

A chimeric gene is an engineered gene produced by combining DNA sequences from more than one organism. See, e.g, In re Vaeck, 947 F.2d 488, 490 (Fed. Cir. 1991) (defining chimeric as a "[(]hybrid) gene comprising (1) a gene derived from a bacterium of the Bacillus genus whose product is an insecticidal protein, united with (2) a DNA promoter effective for expressing the Bacillus gene in a host cyanobacterium, so as to produce the desired insecticidal protein"). At the Markman hearing, Monsanto argued that in the CIP, the word "modified" is used "to reduce the number of putative polyadenylation signals, which means one could reduce either one or all of them," and that "modified" was not used to impose a limitation on the way in which this reduction occurs.

After reviewing the '355 application, the PTO classified its claims as falling into two categories: either claims (1) "drawn to a method for improving a transformed gene in plants," known as method claims, or (2) "drawn to a modified Bt toxin structural gene, DNA per se, and transformed plant cells," known as gene claims. On October 1, 1991, the PTO asked Monsanto to restrict its claims to either method claims or gene claims pursuant to 35 U.S.C. § 121. This law provides that "if two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. § 121 (1998). On October 29, 1991, Monsanto elected to restrict the claims to the second category, the modified Bt gene claims. Monsanto argued that choosing to restrict the claims to "modified Bt genes" demonstrates that the '355 application was not claiming "the way that the gene is to be manufactured."

On February 3, 1992, the PTO rejected all claims either under § 112 for lack of adequate written description and lack of enablement, or under § 103 for obviousness.

In response, on April 22, 1992, Monsanto filed an amendment to the claims. Monsanto made several changes to the claims including adding the word "modified" before "structural gene" in certain claims. For example, Claim 13, as amended, read:

A modified structural gene which encodes an insecticidal protein of Bacillus thuringiensis, wherein a naturally occurring structural gene of Bacillus thuringiensis has been modified to remove a sufficient number of polyadenylation signals and ATTTA sequences so as to increase expression of said protein in a plant cell.

In response to the PTO's § 112 objection, Monsanto argued that "the application enables anyone of ordinary skill in the art to modify any DNA sequence from any Bt strain from its naturally occurring sequence so as to remove polyadenylation signals and ATTTA sequences." Monsanto also argued that the "present claims are reasonably crafted to include the subject matter to which applicants regard as their invention and to which they are entitled, which is a modified structural gene and a plant containing the claimed modified structural gene."

In response to the PTO's § 103 objection, Monsanto distinguished its invention from the prior art by stating that "none of the references relied upon by the examiner suggests or discloses ATTTA sequences and none of the references provides any suggestion or disclosure of replacing ATTTA or polyadenylation sequences in a structural gene to increase expression of a gene or that these sequences have any effect on the expression of a gene in any cell."

On July 13, 1992, the PTO rejected all claims. The PTO rejected some of the amended claims under 35 U.S.C. § 132 because the amended claims added new matter into the specification. The PTO rejected the remaining claims under either § 112 or § 103.

On October 9, 1992, Monsanto filed a continuation application, U.S. Application Serial No. 959,506, from which the '365 patent eventually issued. In the continuation application, Monsanto argued that "the claims have been amended so as to only encompass modified chimeric genes and not encompass naturally occurring structural coding sequences in which the

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claimed modifications have not been made."

In the continuation application, Monsanto argued that it had developed "a method for modifying the structural coding sequence which codes for the proteins from Bt to increase the expression of a chimeric gene containing that structural coding sequence in plant cells." Monsanto further argued that the "application enables anyone of ordinary skill in the art to modify any DNA sequence from any Bt strain from its naturally occurring sequence so as to remove polyadenylation signals and ATTTA sequences." At the claim construction hearing, Monsanto argued that this clarification of the claims shows that the word "modified" has no particular significance related to the method of how the gene is made.

In the continuation application, Monsanto also argued that "the claimed invention is not rendering the structural coding sequences 'plant preferred.' Indeed, some of these changes can result in changing to a less preferred codon for a particular amino acid." At the hearing, defendants argued that this statement shows that Monsanto "surrendered during the prosecution the subject matter of the synthetic gene made by plant preferred codons."

On June 1, 1993, the PTO again rejected the claims under either § 112 or § 103.

On October 4, 1993, Monsanto filed an amendment to clarify the term "modified." Monsanto noted:

The issue discussed in the earlier Office Action and discussed in the interview was that the claims may encompass Bt toxin proteins that may naturally not have to be modified (i.e., may not meet any of the criteria set forth in the claims where change would be required). The claims have been amended so as to only encompass modified chimeric genes and not encompass naturally occurring structural coding sequences in which the claimed modifications have not been made.

In the amendment, Monsanto also stated that "in the invention as claimed, only [the] structural coding sequence is modified to increase the expression of the chimeric gene." Additionally, "the claimed invention is directed to changes in the structural coding sequence and not in non-coding regions." Monsanto wrote that the claimed invention uses "a method which involves modifying some, but not all, ATTTA sequences and polyadenylation sequences."

On January 25, 1994, the PTO again rejected all claims.

On May 25, 1994, Monsanto again amended the claims to "rewrite the claims to be in product format, rather than product-by-process format," and to clarify the language in the claims. In particular, Monsanto amended Claim 43, which became Claim 1 of the '365 patent, to state that the Bt gene structural coding sequence has "a DNA sequence which differs from the naturally occurring DNA sequence encoding said Bacillus thuringiensis protein."

On September 9, 1994, the PTO announced the allowability of some of Monsanto's claims, and finally rejected the remaining claims. The PTO explained:

Again, the claims, as written, read upon almost any (silent) alteration to the coding sequence of the gene, either recombinant or chemical, etc. The claims are not within the enablement of the specification, as they do not provide one of ordinary skill in the art with a mode of 'modification' of the gene. There is no basis given for one of ordinary skill in the art to determine what amount would constitute as an 'increase' in expression.

Furthermore, the PTO concluded that "the claims are not even limited to the recombinant replacement of the target sites in the genes." On October 12, 1994, Monsanto canceled the rejected claims.

On November 1, 1994, the PTO suspended prosecution of the pending claims for six months, explaining that "[a] reference relevant to the examination of [Monsanto's] application may soon become available." This reference was U.S. Patent No. 5,380,831 ("the '831 patent"), which the PTO issued to Mycogen's predecessor on January 10, 1995. The '831 patent named Michael J. Adang as one of the inventors. The '831 patent discloses a method for creating "synthetic [Bt] toxin genes designed to be expressed in plants at a level higher than naturally-occurring Bt genes are provided." A synthetic Bt gene is a gene created by chemical synthesis.

On March 7, 1995, the PTO withdrew its previous allowance of the claims pending in the '355 application, and rejected all claims "in view of the newly discovered prior art to Adang et al., US Patent 5,380,831." The PTO wrote that "the references

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teach several points regarding the problems of expression in plants due to the A+T sequence-rich regions causing polyadenylation and/or splicing in the codon regions, and Adang et al. ('831) provide a successful and demonstrated means to solve the problem." Furthermore, the PTO stated that the prior art "provided one of ordinary skill in the art with the necessary information to delete and/or replace codons that were detrimental to the heterologous Bt gene expression in plants."

On April 26, 1995, Monsanto filed another continuation application. Monsanto distinguished its invention from the '831 patent by emphasizing that Monsanto's invention focused on making changes in the 240 region. Monsanto argued that its invention was "directed to the discovery that when one eliminates certain sequences and when one increases plant preferred codons, that some changes are more important than others and that certain locations in the Bt gene are more important to change to achieve Bt gene expression than other locations." Monsanto compared this to the '831 patent which "does not distinguish any region of the Bt gene from any other region of the Bt gene."

Additionally, Monsanto noted that specific claims "are directed to the discovery by application of a result effective region of Bt genes that when modified to remove the occurrence of certain sequences, can improve the expression of the Bt gene in plant cells dramatically." Monsanto also argued that "while Claims 43, 44 and 51 are open to changes in other regions, they require changes in the [240] region, which has been shown to be more result effective than any other region." Claim 43 became Claim 1 of the '365 patent.

On October 4, 1995, the PTO finally rejected all claims under § 112 and § 103, explaining that "the combination of teachings of the prior art, either generally or specifically, set forth the ideas of the instant invention." Additionally, the PTO noted that "the instantly disclosed '[240] region,' as well as others, are encompassed by the teachings of the prior art," and the "fact that some regions in the sequence respond better than others is still regarded as encompassed by the teachings of the prior art."

On October 24, 1995, Monsanto filed an amendment to the '355 application. Monsanto stated that "the pending claims are limited to that subset of modified Bt genes that at least have modifications in a particular region, which has been referred to in the previous response as the 'B region' or '240 region' and plant cells that contain a modified Bt gene that has modifications in the 'B region' or in the '240 region.'"

In the amendment, Monsanto emphasized the differences between its claimed invention and the prior art. Monsanto argued that "none of the cited art, other than [the '831 patent], discusses modifying the structural coding sequences of Bt genes for the purpose of improving the expression of those structural coding sequences in plant cells." Additionally, while not agreeing with the PTO's characterization of the '831 patent as prior art, Monsanto
Enhanced Coverage Linking noted that the '831 patent "only generally describes modifications and does not render obvious the claimed invention." Comparing its invention with the prior art, Monsanto stated that its "claimed invention . . . requires that those Bt genes that contain the 'B' or '240' region must have certain modifications in at least that region."

Monsanto described the claimed invention as "directed to a chimeric gene modified in a particular region." Monsanto noted:

> None of the cited art provides an example of a Bt gene containing a modified "B" [240] region. None identifies the "B" [240] region for any purpose. None of the cited art discloses that one skilled in the art should modify any region or that modifications in one region are more result effective than any other region. None of the cited art discloses modifying a Bt gene to remove the occurrence of sequences that occur in the "B" region, i.e., AATTAA or AACCAA sequences.

Co-inventor Fischhoff filed a declaration with the amendment, in which he declared that the '831 patent "has only one example of a synthetic Bt gene, a Btt gene shown in Figure 1. This gene does not contain a 'B' or '240' region." Btt refers to Bacillus thuringiensis var. tenebrionis.

On November 14, 1995, the PTO announced that the claims in the '355 application were ready for allowance. On December 13, 1995, a Monsanto attorney filed a request for early issuance on the basis that the "claims are being infringed upon."

4. The '365 Patent

The PTO issued the '365 patent on March 19, 1996. The patent, entitled "Synthetic Plant Genes," discloses a "method for

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modifying structural gene sequences to enhance the expression of the protein product" and "novel structural genes which encode insecticidal [Bt] proteins." The '365 patent discloses a method to increase production of Bt toxin by replacing Bt gene sequences believed to reduce Bt expression in plants with sequences believed to enhance Bt expression in plants. The invention results in insect-resistant plants.

The "Statement of the Invention," found at column 7, lines 32-35 of the patent's specification, reads: "the present invention provides a method for preparing synthetic plant genes which genes express their protein product at levels significantly higher than the wild-type genes." At column 10, lines 1-13, the patent's specification describes the invention:

In its most rigorous application, the method of the present invention involves the modification of an existing structural coding sequence ("structural gene") which codes for a particular protein by removal of ATTTA sequences and putative polyadenylation signals by site-directed mutagenesis of the DNA comprising the structural gene. It is most preferred that substantially all the polyadenylation signals and ATTTA sequences are removed although enhanced expression levels are observed with only partial removal of either of the above identified sequences. Alternately if a synthetic gene is prepared which codes for the expression of the subject protein, codons are selected to avoid the ATTTA sequence and putative polyadenylation signals.

The patent's specification, describing a figure accompanying the text, notes that "another embodiment of the present invention, represented in the flow diagram of Figure 1, employs a method for the modification of an existing structural gene or alternately the de novo synthesis of a structural gene which method is somewhat less rigorous than the method first described above." See column 10, lines 22-27.

At column 12, lines 30-34, the specification states that it should be clear to those skilled in the art that "while the above description [of regions with 'many consecutive A+T bases or G+C bases'] is directed toward the modification of the DNA sequences of wild-type genes, the present method can be used to construct a completely synthetic gene for a given amino acid sequence." Additionally, the patent's specification states that the DNA construct of the invention contains "a modified or fully-synthetic structural coding sequence which has been changed to enhance the performance of the gene in plants. In a particular embodiment of the present invention the enhancement method has been applied to design modified and fully synthetic genes, encoding the crystal toxin protein of [Bt]." Column 13, lines 49-55.

The '365 patent consists of twelve claims. Claims 7, 8, 9 and 12 are the four asserted claims at issue in this case. Claim 7 is independent and reads:

A modified chimeric gene comprising a promoter which functions in plant cells operably linked to a structural coding sequence and a 3' non-translated region comprising a polyadenylation signal which functions in plants to cause the addition of polyadenylate nucleotides to the 3' end of the RNA, wherein said structural coding sequence encodes a toxin protein derived from a Bacillus thuringiensis protein, wherein said structural coding sequence comprises a DNA sequence which differs from the naturally occurring DNA sequence encoding said Bacillus thuringiensis protein and comprises the following characteristics:

said naturally occurring DNA sequence comprises a region having the following sequence:

TTAATTAACCAAAGAATAGAAGAATTCGCTAGGAAC

1 5 10 15 20 25 30 35

and where said structural coding sequence comprises modifications so that at least said region contains at least one fewer sequence selected from the group consisting of an AACCAA and an AATTAA sequence.

Claim 8 depends from Claim 7 and claims "the modified chimeric gene of claim 7 wherein said modifications increase the number of plant preferred codons in said structural coding sequence." Claim 9 also depends from Claim 7 and claims "the modified chimeric gene of Claim 7 wherein said Bacillus thuringiensis is Bacillus thuringiensis var. kurstaki."

Claim 12 is independent and reads:

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A transformed plant cell comprising a modified chimeric gene which comprises a promoter which functions in plant cells operably linked to a structural coding sequence and a 3' non-translated region comprising a polyadenylation signal which functions in plants to cause the addition of polyadenylate nucleotides to the 3' end of the RNA, wherein said structural coding sequence encodes a toxin protein derived from a Bacillus thuringiensis protein, wherein said structural coding sequence comprises a DNA sequence which differs from the naturally occurring DNA sequence encoding said Bacillus thuringiensis protein and has characteristics comprising the following:

said naturally occurring DNA sequence comprises a region having the following sequence:

TTAATTAACCAAAGAATAGAAGAATTCGCTAGGAAC

1 5 10 15 20 25 30 35

and wherein said structural coding sequence comprises modifications so that at least said region contains at least one fewer sequence selected from the group consisting of an AACCAA and an AATTAA sequence.

5. What is the Legal Standard for the Court's Claim Construction?

The court construes claims according to their "ordinary and accustomed meaning," see Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998), and from the vantage point of a person of ordinary skill in the art at the time of the invention. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). In construing a claim, a court looks first to the intrinsic evidence of record, namely, the language of the claim, the specification, and the prosecution history. Insituform Tech. Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1105 (Fed. Cir. 1996), cert. denied, 520 U.S. 1198, 137 L. Ed. 2d 703, 117 S. Ct. 1555 (1997).

The claim language itself defines the scope of the claim. However, the court may interpret a term in a patent claim to have a meaning other than the one a person of ordinary skill in the art would give it if it is apparent from the patent and the prosecution history that the inventor intended a different meaning. See Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1579 (Fed. Cir.), cert. denied, 519 U.S. 911, 136 L. Ed. 2d 198, 117 S. Ct. 275 (1996).

The court may consider expert testimony if needed to assist it in understanding the meaning or scope of technical terms in a claim. See Hoechst, 78 F.3d at 1579. However, the court should not rely on any extrinsic evidence where the claims, specification, and file history unambiguously define the scope of the claim. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996); see also Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1999 U.S. App. LEXIS 13781, 1999 WL 415392, *9 (Fed. Cir. 1999).

Although the Court of Appeals for the Federal Circuit has held that claims should be read in light of the specification, Vitronics Corp. at 1582, the court has repeatedly cautioned against limiting the scope of a claim to the preferred embodiment or specific examples disclosed in the specification. See e.g., Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997); Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (explaining that it is "improper" to read an extraneous limitation from the specification into the claim).
6. How Does the Court Construe the Term at Issue, "Modified"?

Claims 7, 8, 9 and 12 all refer to a "modified chimeric gene." Monsanto argues that "modified" (as well as variations of the word, including "modify" and "modification") means changes to the naturally occurring gene sequence, whether by site-directed mutagenesis or by chemical synthesis. Defendants argue that "modified" only includes changes by site-directed mutagenesis. The patent does not specifically define the method by which structural gene sequences are modified.

The specification discusses genes designed by chemical synthesis. For example, at column 6, lines 30 to 33, the patent's specification explains that "it is an object of the present invention to provide a method for preparing synthetic plant genes which express their respective proteins at relatively high levels when compared to wild-type genes."

The specification also discusses genes designed by site-directed mutagenesis. For example, at column 10, lines 1-6, the specification states that "in its most rigorous application, the method of the present invention involves the modification of

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an existing structural coding sequence ('structural gene') which codes for a particular protein by removal of ATTTA sequences and putative polyadenylation signals by site-directed mutagenesis of the DNA comprising the structural gene."

The specification discusses both site-directed mutagenesis and chemical synthesis. For example, an entire section of the specification, entitled "Synthetic Oligonucleotides For Mutagenesis," discusses how the "oligonucleotides used in the mutagenesis are designed to maintain the proper amino acid sequence" in the "modified gene." This section concludes by explaining that "it is evident to those skilled in the art that while the above description is directed toward the modification of the DNA sequences of wild-type genes, the present method can be used to construct a completely synthetic gene for a given amino acid sequence." Column 12, lines 30 to 34.

Similarly, Table III of the specification "lists the synthetic oligonucleotides designed and synthesized for the site-directed mutagenesis of [a specific Bt] gene." And the specification discusses "hybrid genes, part wild-type, part synthetic, [which] were generated to determine the effects of synthetic gene segments on the levels of B.t.k. expression." Column 18, lines 62 to 67.

These portions of the specification demonstrate that a synthetic gene can be designed by chemical synthesis, or a synthetic gene sequence can be designed and inserted into predetermined sites in a native gene by site-directed mutagenesis. As explained throughout the specification, the '365 patent encompasses genes that are partially synthetic in a specific region and genes that are synthetic throughout the entire gene. Thus, from reading the specification, the court determines that "modified" refers to genes with changes by either site-directed mutagenesis or by chemical synthesis.

The court finds that the prosecution history of the '365 patent provides further support for this determination.

From the beginning of the prosecution of the '355 application, Monsanto focused on making changes to the 240 region of the gene. For example, responding to the PTO's request that Monsanto restrict its claims to either method claims or gene claims, Monsanto decided not to claim the process for designing the genes, whether by site-directed mutagenesis or by chemical synthesis. Rather, Monsanto claimed genes with changes in the 240 region, regardless of the process involved in designing the genes.

As the prosecution history demonstrates, Monsanto continually distinguished its claimed invention from the prior art on the grounds that its invention identified the 240 region as the "result effective" or key region. Notably, Monsanto did not distinguish its invention on the grounds that the prior art claimed genes designed by chemical synthesis, as opposed to genes designed by site-directed mutagenesis.

For example, after the PTO suspended prosecution of the '355 application when it issued the '831 patent, Monsanto filed a declaration from Fischhoff. In this declaration, Fischhoff distinguished the invention from the '831 patent on the basis that the '831 patent did not specify the 240 region, not on the basis of whether the gene was created by site-directed mutagenesis or chemical synthesis.

The PTO recognized that Monsanto was not focusing on the specific process for making changes to the 240 region. For example, on September 9, 1994, the PTO noted that the "claims are directed to a gene, and not a method of increasing expression or a host organism, etc." Similarly, the PTO remarked that "again, the claims, as written, read upon almost any (silent) alteration to the coding sequence of the gene, either recombinant or chemical, etc." The PTO further stated that "the claims are not even limited to the recombinant replacement of the target sites in the genes."

Thus, as both the specification and the prosecution history demonstrate, the '365 patent does not impose any limitation on the process by which a gene is designed to enhance Bt expression. Rather, the '365 patent encompasses genes designed by both methods: site-directed mutagenesis and chemical synthesis. Furthermore, the '365 patent and the prosecution history demonstrate that the only limitation imposed by the claimed invention is that the native Bt gene is changed, regardless of the manner in which the change occurs.

Claims 7 and 12 of the '365 patent refer to a "modified chimeric gene" with a structural coding sequence which "comprises a DNA sequence which differs from the naturally occurring DNA sequence." Additionally, the claims refer to the 240 region as the "naturally occurring DNA sequence" in which "modifications" are made so that "at least said region contains at least one fewer sequence selected from the group consisting of an AACCAA and an AATTAA sequence." Thus, it appears from

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"the ordinary and accustomed meaning of claim terms" that the word "modified" is used to draw a distinction between a gene that has alterations to the 240 region and a gene that is naturally occurring. See, e.g., Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 1999 WL 243570, *3 (Fed. Cir. 1999) ("[A] court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms.").

Additionally, throughout the prosecution history, Monsanto explained that the claimed invention "enables one of ordinary skill in the art to modify any DNA sequence from any Bt strain from its naturally occurring sequence so as to remove polyadenylation signals and ATTTA sequences." Monsanto did not use language that would limit these modifications to only those made by site-directed mutagenesis.

Accordingly, the court concludes that the word "modified," and variations of the word, including "modify" and "modification," means altered or changed from the naturally occurring gene sequence, irrespective of the manner in which the changes are made. Thus, a "modified chimeric gene," as used in the '365 patent, includes a gene designed by either site-directed mutagenesis or a gene designed by chemical synthesis, with changes in the 240 region.
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A. "Moisturizing Composition"

Plaintiffs' Construction	Defendants' Construction
A composition that adds moisture to the skin.	A composition for use on human skin that contains an antimicrobial agent, an emollient and an absorption enhancer.

Defendants contend that the term "moisturizing composition" must include (1) an antimicrobial agent, (2) an emollient, and (3) an absorption enhancer. Though Defendants' proposed construction includes three components, Defendants place the greatest emphasis on the absorption enhancer, arguing that "[t]he need for an absorption enhancer - Ms. Mansouri's 'secret ingredient' - is made particularly clear" in the specification. (D.I. 145 at 15.) Whether the term "moisturizing composition" requires the presence of an absorption enhancer appears to be the essence of the parties' dispute over this claim term.

In support of their proposed construction, Defendants point to passages in the specification that state such things as "[c]ompositions for cleaning and moisturizing the skin according to the invention comprise an antimicrobial agent, an emollient, and an absorption enhancer . . . ." ('516 patent at 4:19-22.) As another example, Defendants note that the specification states that "[i]n particular, skin care products of the instant invention comprise an absorption enhancing material." (Id. at 2:20-21; see also D.I. 145 at 15-16 (Defendants point to other portions of the specification that refer to an "absorption enhancer").) In relying on such passages in the specification, Defendants place particular weight on the presence of the word "comprising." For instance, at the Markman hearing, Defendants argued as follows:

We also want to direct the Court's attention to their use of the term "comprise." We know you've come across that term many times, Your Honor. "Comprise" is a term of art in patent law.

And underneath you see we've provided a definition from a Federal Circuit case. "Comprising" is a term of art used in claim language, which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claims.

So our position, Your Honor, is if you're going to use "comprise," either in the claims or elsewhere in the spec, you are alerting a person reading your patent, one of skill in the art, that the list of components after the term comprise are mandatory, but does not exclude the addition of further components.

(D.I. 191 48:16-49:10; see also D.I. 174 at 7 (in referring to the specification, Defendants argue that "the term 'comprise' means the listed ingredients are required").) According to Defendants, any definition of "moisturizing composition" that

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fails to include the three components listed in their proposed construction has the additional shortcoming of excluding the preferred embodiment from the scope of the claims. (See D.I. 145 at 16-17.)

In response, Plaintiffs argue first and foremost that the claims simply do not include an explicit "absorption enhancer" limitation. Defendants' proposed construction, Plaintiffs contend, is nothing more than an improper attempt to import a limitation from the specification into the claims. (See D.I. 175 at 4-5.) Though rapid penetration of the skin through the use of an absorption enhancer is one feature of the invention, Plaintiffs contend that there are other benefits of the invention that are independent of an absorption enhancer, such as providing reduced risk of skin infections. (See id. at 9.) Plaintiffs urge that the claims need not contain each and every advantage set forth in the specification. Plaintiffs further note that the specification discloses an embodiment that merely requires an absorption enhancer concentration of "up to 5% w/w." Plaintiffs contend that by failing to set a floor on the absorption enhancer concentration, this example allows for an absorption enhancer concentration of 0%. (Id. at 10.) With the patent disclosing such an embodiment, Plaintiffs maintain that it makes little sense to construe the claims to always require an absorption enhancer. (Id. at 10.) With respect to the prosecution history, Plaintiffs note that the application that issued as the '516 patent originally contained claims that specifically required an absorption enhancer. All such claims, however, were removed in favor of claims that lacked an "absorption enhancer" limitation. (Id. at 10-11.) Having conscientiously removed a particular limitation from the claims, Plaintiffs contend that the claims should not now be construed to require that particular limitation.

The Court agrees with Plaintiffs that the term "moisturizing composition" should not be construed to require, among other things, an absorption enhancer. Instructive is the Federal Circuit's decision in Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327 (Fed. Cir. 2004). In Golight, the patent at issue was directed to a wireless, remote-controlled, portable search light. Golight, 355 F.3d at 1329. The defendant in Golight argued that the asserted claims required the claimed search light to be capable of rotation through 360 degrees. In support of this position, the defendant argued that the specification disclosed nothing other than search lights having this feature. Id. at 1331. The Golight defendant placed particular reliance on a passage in the specification stating that "[a] searchlight apparatus in accordance with the present invention includes a lamp unit mounted in a housing which has a motor-driven vertical drive mechanism for tilting the lamp unit in a vertical direction and a motor-driven horizontal drive mechanism for rotating the lamp unit in a horizontal direction through at least 360 degrees." Id. In holding that the claims did not require 360 degree rotation, the Federal Circuit explained that the specification did not contain a clear definition or disavowal of claim scope and that, although rotation through 360 degrees was a feature of the invention, it was only one such feature. There was no requirement, the Federal Circuit explained, that the patentee include every such feature of the invention in each claim. Id. at 1331.

Here, as in Golight, the Defendants, in an attempt to limit the claims, point to passages from the specification characterizing features of the invention. In particular, the Defendants draw their proposed construction for "moisturizing composition" from a portion of the specification stating that "[c]ompositions for cleansing and moisturizing the skin according to the invention comprise an antimicrobial agent, an emollient and an absorption enhancer in combinations as described below." ('516 patent at 4:19-22; D.I. 145 at 15.) Like the passage in Golight, this passage characterizes the "invention" as including a set of particular features. Furthermore, like the defendant in Golight, the Defendants in this case further argue that "every example enumerated in the specification (including the preferred embodiment) contains an absorption enhancer." (D.I. 145 at 2.)

However, just as in Golight, these facts do not compel the conclusion that the claims require an absorption enhancer. Indeed, the Court sees nothing in the specification constituting a clear disavowal of claim scope. In addition, like the specification in Golight, the specification of the '516 patent sets forth multiple features of the invention. Specifically, in addition to rapid skin penetration through the use of an absorption enhancer, the '516 patent describes the prevention of skin infections, the prevention of excess drying of the skin, and compatibility with latex gloves. ('516 patent at 1:21-26, 3:1-18.) Though some of these benefits may be heightened through the use of an absorption enhancer, it is clear from the specification that an absorption enhancer is not required to achieve them. For instance, the specification describes the absorption enhancer as a separate and distinct component from both the "Antimicrobial Component," which prevents infections, and the "Emollient," which moisturizes the skin. (See id. 4:23-45 (specification's description of the "Antimicrobial Component"; id. at 4:46-6:14 (specification's description of the "Absorption Carrier"); 7:16-8:3 (specification's description of the "Emollient")). As the Federal Circuit explained in Golight, the patentee need not claim each of these components in every claim.

Notably, the claims themselves suggest an intent to claim such features in variable combinations. For instance, Claim 1 of

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the '516 patent, though lacking an "absorption enhancer" limitation, includes distinct limitations directed to "(a) an amount of triclosan effective to kill microorganisms" (i.e., an antimicrobial component) and "(b) an emollient." Construing the term "moisturizing composition," which appears in the preamble, to include these components would, as Plaintiffs note, render these explicitly distinct claim limitations vestigial. (D.I. 175 at 6.) The Court will not adopt such a construction.

The prosecution history provides further support for Plaintiffs' proposed construction. As Plaintiffs note, during prosecution of the '516 patent, the patentee intentionally replaced all claims that included an explicit absorption enhancer limitation with claims that lacked such a limitation. (Compare D.I. 175, Exh. 2 at 30 with '516 patent at Claim 1.) In the Court's view, this is a "strong indication" that the claims as issued do not require an absorption enhancer. See Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 (Fed. Cir. 2004) ("The omission of reference to a pressure jacket in many of the claims of the applications that matured into the '669 and '261 patents is a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets.").

The portions of the specification relied upon by Defendants provide an insufficient basis upon which to limit the scope of the claims. It is true that the specification is littered with statements characterizing the "invention" as including an absorption enhancer. The trouble with these statements is that they also characterize the "invention" as including a number of other components, none of which any party could reasonably contend is a requirement of the claims. For instance, in support of their position that the claims require an "absorption enhancer," Defendants point to the following passage:

In particular, the invention is concerned with formulations for cleansing and moisturizing the skin which are antimicrobial, alcohol-free, contain no animal- or petroleum-based products, have a water base, and comprise an absorption enhancer to promote rapid uptake of the formulation by the skin.

('516 patent at 1:27-32.) Notably, in their briefing, Defendants use an ellipsis to omit the portion of this passage referring to the absence of alcohol and animal- or petroleum-based products and the presence of a water base. (See D.I. 174 at 7.) Thus, though Defendants contend that this passage supports the notion that the claims require an absorption enhancer, they apparently do not contend that the other things mentioned in this passage are also required by the claims.

A similar situation exists with regard to passages in the specification that use the word "comprising," which, as explained above, is a word that Defendants contend means that "the listed ingredients are required," even when the word appears only in the specification. 1 For instance, the specification unambiguously states that "[t]he composition according to the invention also comprises a cosmetically and physiologically acceptable preparation obtained from the Aloe vera plant." ('516 patent at 9:20-22.) Likewise, the specification explains that "[t]he composition according to the invention also comprises one or more natural scents" and that "[t]he compositions according to the invention also comprise one or more natural herbal extracts." (Id. at 9:34-35, 9:46-47.) Yet, in spite of the word "comprise," no party contends that the claims require aloe vera, natural scents, and/or herbal extracts. Interestingly, with regard to an "emollient," a component that Defendants contend is required by the claims, the specification explains that "[c]ompositions under the invention may optionally comprise one or more emollients . . . ." ('516 patent at 7:18-19 (emphasis added).) Thus, in the Court's view, the specification - including its passages that use the word "comprise" - simply does not provide a clear and consistent basis upon which to limit the claims.

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1 The Court is aware of no cases, and Defendants do not cite any, standing for the proposition that the term "comprising," when used in the specification, means "the listed ingredients are required." (D.I. 174 at 7.)

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As to Defendants' argument that Plaintiffs' construction would exclude the preferred embodiment, the Court finds that Defendants are misapplying the doctrine that claims should rarely be construed to exclude the preferred embodiment. Indeed, Defendants' proposed construction, if adopted, would have the effect of limiting the claims to the preferred embodiment, which, for the reasons set forth above, is not appropriate in this case.

Having concluded that the claims should not be limited as Defendants contend, the Court further concludes that this term requires no additional construction. In the Court's view, Plaintiffs' proposed construction adds no additional insight as to the

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meaning of this claim term to one of skill in the art. 2

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2 During the claim construction process, in particular at the Markman hearing, Defendants further argued that the claims would be invalid as anticipated and for lack of enablement unless construed to require an "absorption enhancer." (See, e.g., D.I. 145 at 16 n.7; D.I. 192 at 46:20-47:1.) In response, Plaintiffs explained that they "appreciate the Defendants' wanting to construe [their] claims to preserve their validity, but with all due respect, [they'll] take care of [their] own validity arguments." (D.I. 192 at 70:22-71:1.) On the current record, the Court is unable to conclude that failing to construe the claims to require an "absorption enhancer" would clearly lead to the invalidity of the claims. Nevertheless, to be clear, the Court understands Plaintiffs as having waived any argument that the claims should be construed to require an "absorption enhancer."

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7. "molasses feed solution"

Finally, the parties dispute the term "molasses feed solution." (Joint Stmt. p. 7). This dispute involves the same issue as above, the inclusion of numerical limitations in the construction of the term. As previously discussed, numerical limitations should not generally be read into a claim from which it is absent. Specialty Composites, 845 F.2d at 987. This is true even if the specification may describe a numerical range in its discussion of the disputed term. Id. Thus, the court interprets the term "molasses feed solution" without the numerical limitation as prescribed in Defendants' proposed instruction. The term "molasses feed solution" means "beet molasses which is diluted with water." (Joint Stmt. p. 7).
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The '502 patent claims a method for extracting desired proteins from refractile bodies and separating these proteins from high molecular weight contaminants by use of a molecular sieve or high speed centrifugation. ('502 patent, Col. 4, 11. 31-37.) The key contested term in the claims construction is the term "molecular sieve," as used in paragraph (c).

Genentech contends that the term "molecular sieve" is "a general term used to describe various techniques for separation based on size," including a filter, gel electrophoresis or gel permeation chromatography (also known as gel filtration). BM contends that the term "molecular sieve" refers only to a gel permeation chromatography or gel filtration, and does not include BM's use of "dead-end filtration."

1. Intrinsic Evidence

BM relies primarily on intrinsic evidence to support its argument. In a section headed "Detailed Description of the Invention," the specification of the '502 patent states:

(A) Definitions: . . . . There are abbreviations and descriptions conventionally used with regard to particular techniques that are used in this invention, and for convenience these will be described briefly here:

Gel permeation chromatography or gel filtration is a commonly used purification technique which discriminates between molecules according to their size. This is also frequently referred to as a "molecular sieve." By suitable selection of the gel, almost any range can be selected for. Molecules which are large enough to be excluded from the gel pores are passed untreated through a column containing the gel; smaller molecules are fractionated by the column.

(Col. 6, ll. 8-10; Col. 8, ll. 30-38.) (emphasis added).

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In the "Definitions" section, defined terms generally appear in quotation marks. The specification later states:
In carrying out the removal of high molecular weight impurities through gel filtration, a column containing a molecular sieve, such as, for example, Sephacryl S-300 is equilibrated in a suitable buffer and the solution containing the heterologous protein passed through the column.

(Col. 14, ll. 1-14.) and again:
Use of gel permeation chromatography as a first chromatographic step in a commercial purification process for protein, i.e. carrying out gel permeation prior to, for example, ion exchange chromatography, is unusual.

(Col. 14, ll. 19-25.) Finally, the specification refers to the separation of high weight contaminants as the "gel filtration step," (Col. 21, l. 13.) and describes an "optimal subsequent purification regime which has, as a primary step, gel filtration or high speed centrifugation." (Col. 22, ll. 4-7.)

The prosecution history also refers to a "gel filtration step" and a "size-discriminating gel permeation molecular sieve." (Prosecution History, at pp. 25-6, 40.)

Genentech argues that in 1982, several different types of molecular sieves were known and in common use by protein biochemists and chemical engineers. There are two extrinsic sources of evidence. First, court-appointed expert, Dr. Cepko, testified that the term "molecular sieve" meant, to one skilled in the art at the relevant time in 1982, any technique that separates molecules based on size, including filters. (Tr. 3-35 - 3-37.) Second, Genetech introduced into evidence contemporaneous bioprocessing literature to support its argument that molecular sieve means a size-based separator and that ultra filtration membranes and depth filters have been described as molecular sieves in the relevant time period. (See, e.g., Pl. Ex. 28, 31.) The defendants read into evidence a portion of the book by Robert Scopes, Protein Purification Principles and Practice, which states, for the relevant time period, under the heading "gel filtration":
"Several other names for this method have been put forward, including 'gel permeation, and 'molecular sieving.' However, the use of the term 'gel filtration' is now so widespread and generally recognized that it will be used here. This name is unfortunate, since the procedure does not depend on the material used being a true gel, and it is not really filtration."

(Tr. 3-41; Defendants' Exhibit U, at p. 368.)

Although the meaning of "molecular sieve" to those skilled in the art encompassed more than gel filtration in 1982, Genentech cannot use extrinsic evidence to vary an unambiguous, defined term in quotations in the patent. Patent applications must disclose their inventions adequately. See North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1576 (Fed. Cir. 1993) ("A patent application cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent."), cert. denied, 511 U.S. 1069, 128 L. Ed. 2d 365, 114 S. Ct. 1645 (1994). Genentech claims that gel filtration or gel permeation is provided only as an example or preferred embodiment of a molecular sieve. Although references to a preferred embodiment are not claim limitations, a court may look to a preferred embodiment in a specification for assistance in construing its claim. See Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1575 (Fed. Cir. 1997).

Nothing in the patent specification or prosecution history supports Genentech's claim that the inventors, or the PTO, envisioned the term "molecular sieve" to mean anything other than gel permeation or gel filtration. Cf. Wellcome, 29 F.3d at 1564 ("An appropriate method for resolving the issue [when the specification contains diverse definitions of a given term] is to avoid those definitions upon which the PTO could not reasonable have relied when it issued the patent."); cf. Novo, 108 F.3d at 1366 ("It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.").

2. Claim Construction

The term "molecular sieve" as used in the '502 patent is construed to mean gel permeation or gel filtration techniques which separate molecules based on size.
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K. Molecular species being characterized by a triple helix conformation

The term "molecular species being characterized by a triple helix conformation" appears in claim 8 of the '643 Patent, which claims: "An underivatized, aqueous soluble [beta] (1-3)-glucan consisting essentially of a molecular species which migrates as a single peak when analyzed by gel permeation chromatography, the molecular species being characterized by a triple helix conformation." The proposed constructions are similar to those offered in connection with "triple helix conformation." The Court declines to read the process to produce a triple helix conformation into the term. The Court concludes that the term has a readily understood meaning such that no construction is necessary.
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L. Molecular species migrates as a single peak

The term "a molecular species which migrates as a single peak when analyzed by gel permeation chromatography" appears in claim 8 of the '643 Patent, quoted above. Plaintiffs propose this construction: "A molecular species characterized by a triple helix is identified through gel permeation chromatography as a single peak." Immunocorp and Biotec offer: "Molecular species which migrates as a single peak and does not migrate as multiple peaks when analyzed by gel permeation chromatography." The Court concludes that this term needs no construction.
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molecular weight

The Court modifies Defendants' proposed construction and construes the term as "the sum of the atomic weights of all the atoms in a molecule as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods." Plaintiffs argue that the term "molecular weight" should be construed as "molecular weight, as used in the context of quaternized ammonium polymers, is defined within a polymer of repeating unit moiety, as a relationship between viscosity and activity of said quaternized ammonium polymer in water."

Plaintiffs argue that the '690 patent provides a clear description of the correlation between a polymer's molecular weight and its viscosity at a measured concentration in water. Plaintiffs contend that when the term "molecular weight" is used, the patent is referring to the molecular weight as determined by a particular viscosity in a solution as opposed to the "molecular weight" of the polymer as determined by any other method. In support of its proposed construction, Plaintiffs point to statements such as the one found in the abstract of the '690 patent that states "a molecular weight of greater than approximately 1,000,000 and [having] a viscosity greater than about 1,000 cps at a concentration of approximately 20% in water." Plaintiffs also point to other similar references in both the summary and description of the patent. See Col. 3:1-4; Col. 3:46-50; Col. 6:37-48. Plaintiffs contend that the patentee gave the term "molecular weight" a limited and special definition by using this language in the specification. Plaintiffs further argue that those of ordinary skill in the art define and measure molecular weight using viscosity. Finally, Plaintiffs argue that the prosecution history of the '690 patent reveals that the applicant intended to limit the patent such that molecular weight was only defined in terms of viscosity. Plaintiffs point to an excerpt from an office action, which states:
Attached at Tab C is a document which shows the correlation of molecular weight to viscosity and activity (% of solid) for Epi-DMA as summarized below:
. High molecular weight Epi-DMA has a molecular weight of 500,000 to 3,000,000 defined as follows:

500,000 -- less than 1,000,000 as measured by having a viscosity of 2,000 -- 9,000 cps at a concentration of approximately 50% in water.

Response to Office Action, mailed Apr. 2, 1999 at 10. Plaintiffs contend that the use of the word "defined" is strong

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evidence in support of their construction. Additionally, Plaintiffs point to a Clearvalue presentation in the file history of the '690 patent that contains statements such as, "This polyamine is normally of very low molecular weight (50,000 to 150,000 MW defined as 50 to 150 cps at a 50% activity in water)" in support of their argument. Clearvalue Presentation, Clarification of Water & Wastewater, filed Dec. 13, 1999.

The claim language of the '690 patent does not support Plaintiffs' proposed construction. The claims do not describe the viscosity of the polymers used in the invention but rather indicate that the high molecular weight DADMACs claimed have a molecular weight range between 1,000,000 and 3,000,000. The original claims, in the application from which the '690 patent claims priority, defined the polymer in terms of both its molecular weight and its viscosity at a certain concentration in water. When an inventor uses different terms in the claims, it is presumed that the terms have different meanings. See Applied Med. Res. Corp. v. U.S. Surgical Corp., 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006). The original application claimed both the molecular weight and the viscosity of the polymer, therefore, it is presumed that they have different meanings. Having defined both the molecular weight and the viscosity of the polymer in the original application, the applicant clearly could have claimed the polymer only in terms of its viscosity if that was his intention. Furthermore, dependent claim 7 is the only claim that mentions viscosity, stating, "wherein said aluminum sulfate is used with said di-allyl di-methyl ammonium chloride that is 10% active at viscosities of 150 to 250 cps." However, claim 7 merely describes another characteristic of the DADMAC polymer described in claim 1 with a molecular weight of at least approximately 1,000,000 to approximately 3,000,000 when an aluminum sulfate is used in place of an aluminum salt.

Like the claim language, the specification of the '690 patent does not support Plaintiffs' proposed construction of the term "molecular weight." The specification contains no definition for molecular weight, nor does it identify a particular method that should be used to determined molecular weight. The specification contains multiple instances where the molecular weight of a polymer is given without any reference to viscosity. See Cols. 4:14-22, 6:53-65, 7:9-15. Although the specification does contain instances where the molecular weight of a polymer is given and then followed by its viscosity, the specification never merely states the viscosity of a polymer without also indicating the polymer's molecular weight. The specification does not describe viscosity as the method for determining the molecular weight, but as a characteristic of the "high molecular quaternized polymer." See Col. 3:1-4 ("The quaternized polymer has a molecular weight of greater than approximately 1,000,000 and has a viscosity greater than about 1,000 cps at a concentration of approximately 20% in water."). Plaintiffs' argument that molecular weight should be defined in terms of viscosity contradicts the patentee's description of the quaternized polymer in terms of both its molecular weight and viscosity. Furthermore, in one instance, the specification discusses viscosity as a characteristic of raw water containing the polymer as opposed to viscosity as a measurement of the polymer in clean water. n3 Col. 3:46-50. This use of viscosity to describe the properties of raw water containing the polymer, rather than solely as a measurement technique, shows that it was understood that viscosity could be used as an indicator of parameters other than molecular weight. Accordingly, the specification of the '690 patent does not consistently use viscosity as a measure of the molecular weight of a polymer in pure water.

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n3 Raw water refers to the water being subjected to the clarification process.

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The specification does teach that there is a correlation between the molecular weight of a polymer and its viscosity at a particular concentration in water. See Col. 6:37-42. However, a correlation does not support the argument that viscosity is the same as molecular weight. Instead, such a correlation suggests to one of skill in the art that viscosity and molecular weight are distinct but related concepts.

The prosecution history of the '690 patent also fails to support Plaintiffs' proposed construction of the term "molecular weight." Although the prosecution history can be informative in construing a claim term, the claims themselves and the specification are often more useful for purposes of claim construction. See Phillips, 415 F.3d at 1317. The prosecution history represents an ongoing negotiation between the applicant and the Patent and Trademark Office ("PTO") and, therefore, often lacks the clarity of the specification. Id.

In the prosecution history of the '690 patent, the applicant continuously refers to the molecular weight of the polymers without reference to viscosity when distinguishing the invention from the prior art and in generally describing the invention

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in correspondence with the PTO. The references in the prosecution history that Plaintiffs contend "define" molecular weight in terms of viscosity are not indications by the applicant that molecular weight should only be measured in terms of viscosity. During the prosecution of the application that resulted in the '690 patent, the applicant distinguished the present invention from the prior art by demonstrating that polymers falling within the recited claims provided unexpected results. The tests that supported the applicant's unexpected results did not provide the molecular weight of the polymers as recited in the claims but instead provided the polymer's viscosities at a certain concentration. The applicant argued out of necessity that there was a correlation between these viscosities and the claimed molecular weights. Accordingly, statements that certain polymers were "defined as" ranges of viscosities at stated concentrations were not intended to imply that viscosity was the only indicator or the definition of molecular weight as compared to some other measurement. Rather, such examples were meant to demonstrate that the polymers used in the test submissions had the molecular weights specified in the claims.

It is improper for the Court to read limitations from a particular embodiment into the claims, unless it is clear that the embodiment is coextensive with the invention. JVW Enters., Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005). This rule equally applies to statements made in the prosecution history as it does to the description in the specification. See Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). Moreover, any disclaimer in the prosecution history must be made with reasonable clarity and deliberateness. Superguide Corp. v. DirectTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004). There is no indication in the prosecution history that the applicant intended to limit the claim scope such that viscosity must always be used to determine the molecular weight of the polymers for the entire invention. Instead, the prosecution history demonstrates that the applicant used viscosity as a method for determining molecular weight in specific embodiments that were then used to distinguish the patented invention from the prior art.

The claim language, specification, and prosecution history of the '690 patent at most identify that there is a correlation between molecular weight and viscosity. This correlation is not disputed. However, the patent does not claim a polymer of a particular viscosity. The patent claims the use of a polymer of a particular molecular weight. Furthermore, the specification and prosecution history do not indicate that the patentee intended to limit molecular weight such that it could only be defined in terms of viscosity. Instead, the specification and prosecution history identify viscosity as a measurement that correlates to a polymer's molecular weight. However, neither indicates that the patentee intended for the term "molecular weight," as used in the claims, to be limited to measurements of molecular weight in terms of viscosity. Accordingly, the Court rejects Plaintiffs' proposed construction of the term.

Defendants contend that the term "molecular weight" should be construed as "the sum of the atomic weights of all the atoms in a molecule." Defendants rely on the definition of "molecular weight" in Hawley's Condensed Chemical Dictionary as the basis for their proposed construction. Defendants argue that "it is undisputed that this is an authoritative standard reference source for the scientific definition of 'molecular weight.'" In Phillips, the court stated, "We have especially noted the help technical dictionaries may provide to a court 'to better understand the underlying technology' and the way in which one of skill in the art might use the claim terms." 415 at 1318. The court further stated that technical dictionaries "have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." Id. Here, it is helpful to reference a technical dictionary to determine the general meaning of "molecular weight" as it would be understood by one skilled in the art. Although Defendants' proposed construction provides a starting point for the construction of the term, one skilled in the art would likely understand that the molecular weight of a polymer must be determined using one of several available measurement techniques.

The parties do not dispute that molecular weight must be determined by using one of the various available measurement techniques. It is also undisputed that viscosity is one of the methods used to determine the molecular weight of the types of polymers claimed in the '690 patent. However, other methods are also available. For example, Defendants indicate that they use a method called gel permeation to measure the molecular weight during the production of polymers. Several of the prior art patents referenced in the '690 patent also refer to gel permeation as a method for measuring molecular weight. Additionally, the Court is aware of at least four other methods for measuring molecular weight, which include osmotic pressure, light scattering, chromatography, and ultracentrifugation. Other similar accepted methods may be available as well. Accordingly, the Court construes "molecular weight" as "the sum of the atomic weights of all the atoms in a molecule as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods."
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molecular weight of at least approximately 1,000,000 to approximately 3,000,000

The Court modifies Defendants' proposed construction and construes the phrase as "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having a molecular weight range of about 1,000,000 to approximately 3,000,000." Plaintiffs argue that the term should be construed as "a high molecular weight DADMAC measuring about 1,000 cps to about 3,000 cps at about a concentration of about 20% in water." Defendants argue that the term should be construed as "a high molecular weight DADMAC measuring about 1,000 cps or greater at a concentration of about 20% in water and having an average molecular weight range of about 1,000,000 to approximately 3,000,000." Both Plaintiffs and Defendants re-urge the arguments they set forth in support of their proposed constructions of the term "molecular weight." For the same reasons discussed above with regard to "high molecular weight quaternized ammonium polymer," the Court includes a molecular weight range and excludes the term "average" from its construction of the phrase.
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B. The '141 Patent and the '483 Patent

Cleanox owns two patents for inventions developed by R. Vigneri for the remediation of certain groundwater contamination. See Amended Complaint at 3, P 12. The '141 Patent was filed 12 February 1993 and was issued 15 February 1994. See '141 Patent. The '483 Patent was filed 10 February 1994 and was issued 28 May 1996. See '483 Patent.

Both patents describe their processes as "a method for remediating a hydrocarbon-contaminated region of a subterranean body of groundwater to destroy or reduce the initial levels of hydrocarbon contaminants." '141 Patent at col. 8, lines 23-26; '483 Patent at col. 9, lines 33-35. The two patents rely upon the interaction of hydrogen peroxide and the hydrocarbon contaminants to alleviate the harm caused by groundwater contaminants.

Claim One of the '141 Patent provides as follows:

1. A method for remediating a hydrocarbon-contaminated region of a subterranean body of groundwater to destroy or reduce the initial concentration levels of hydrocarbon contaminants, comprising the steps of:

(a) providing a plurality of mutually spaced wells intersecting said groundwater region ("Step A of the '141 Patent");

(b) determining the existence of acceptable continuity and well interflow paths for the said region by generating a test flow of a solution of hydrogen peroxide from one of said wells and monitoring pH changes at each other of said wells as a function of time to detect a pH drop of at least 0.2 ("Step B of the '141 Patent"); and

(c) subsequent to detecting said pH drop, providing a treating flow of said hydrogen peroxide solution from one or more of said wells ("Step C of the '141 Patent").

Claim One of the '141 Patent (emphasis added).

Claim One of the '483 Patent provides as follows:

1. A method for remediating a hydrocarbon-contaminated region of a subterranean body of groundwater to destroy or reduce the initial concentration levels of hydrocarbon contaminants, comprising the steps of:

(a) providing a plurality of mutually spaced wells intersecting said groundwater region ("Step A of the '483 Patent");

(b) providing a treating flow of acetic acid from one or more of said wells into said groundwater region, to establish

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acidic conditions therein ("Step B of the '483 Patent");

(c) introducing a turbulent flow of an aqueous solution of ferrous ion into said groundwater region, for mixing with said acidified groundwater, thereby providing a catalyst for disassociation of hydrogen peroxide ("Step C of the '483 Patent"); and

(d) providing a treating flow of hydrogen peroxide solution from one or more of said wells into said groundwater region, said hydrogen peroxide undergoing a Fenton-like reaction in the presence of said acidic conditions and said ferrous ion to generate hydroxyl free radicals for oxidizing said contaminants ("Step D of the '483 Patent").

Claim One of the '483 Patent (emphasis added).

LEGAL STANDARD

A. Patent Infringement Generally

In a patent infringement action, a two-step analysis must be conducted. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, (Fed.Cir. 1998) (in banc); CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1152 (Fed.Cir. 1997), cert. denied, U.S. , 140 L. Ed. 2d 105, 118 S. Ct. 1039 (1998); Cole v. Kimberly-Clark Corp., 102 F.3d 524, 528 (Fed.Cir. 1996)), cert. denied, U.S. , 139 L. Ed. 2d 20, 118 S. Ct. 56 (1997); Markman, 52 F.3d at 976 (citing Read Corp. v. Portec, Inc., 970 F.2d 816, 821 (Fed.Cir. 1992)); Phillips Elec. North Am. Corp. v. Universal Elec. Corp., 930 F. Supp. 986, 997 (D.Del. 1996). First, the meaning and scope of the patent claims asserted to be infringed must be determined. See Markman v. Westview Instruments, 517 U.S. 370, 384, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996); Cybor Corp., 138 F.3d at 1454; CVI/Beta Ventures, 112 F.3d at 1152; Cole, 102 F.3d at 528; Markman, 52 F.3d at 976. This step is commonly referred to as "claim construction" or "claim interpretation." 8 Markman, 52 F.3d at 976. Second, the properly construed claims must be compared to the device or method that is accused of infringing. See Cybor Corp., 138 F.3d at 1454; Markman, 52 F.3d at 976.

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8 For purposes of consistency, the term "claim construction" will be used throughout this opinion when referring to the first step in an infringement analysis.

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As mentioned, the only issue sub judice is the question of the construction of Claim One of the '141 Patent and Claim One of the '483 Patent. Accordingly, only step one of the infringement analysis, i.e., claim construction, is discussed in this, the Supplemented Opinion.

B. Claim Construction

A patent is a fully integrated document; it must set out a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains" to practice the invention. 35 U.S.C. § 112. "It has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he [or she] is entitled, [and] to apprise the public of what is still open to them." Markman, 517 U.S. at 373.

The interpretation and construction of a patent claim are "exclusively within the province of the court." Markman, 517 U.S. at 391; see Cybor Corp., 138 F.3d at 1454; CVI/Beta Ventures, 112 F.3d at 1152. A court therefore has "the power and obligation to construe as a matter of law the meaning of language used in the patent claim." Markman, 52 F.3d at 979; see Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1556 (Fed.Cir. 1995), cert. denied, 518 U.S. 1020, 135 L. Ed. 2d 1073, 116 S. Ct. 2554 (1996); CVI/Beta Ventures, 112 F.3d at 1152. When performing such an analysis, various sources may be consulted, including those that are intrinsic and extrinsic to the patent claims. See Cybor Corp., 138 F.3d at 1454; Lubrizol, 64 F.3d at 1556; Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed.Cir. 1996); CVI/Beta Ventures, 112 F.3d at 1152; Markman, 52 F.3d at 979-80.

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There is a hierarchy of evidence which must be considered with the emphasis given first to the words of the claims, then to the specification of the patent, then to the prosecution history of the patent and finally to extrinsic evidence. Vitronics, 90 F.3d at 1582; see Cybor Corp., 138 F.3d at 1454 (majority opinion) and Cybor Corp., 138 F.3d at 1462 (Plager, J. concurring); Lubrizol, 64 F.3d at 1556. Despite this hierarchy, a court nevertheless may properly decide to hear all proffered evidence prior to construing the claims, provided it does not accord any weight to extrinsic evidence that is inconsistent with the intrinsic evidence. Vitronics, 90 F.3d at 1584; see also Cybor Corp., 138 F.3d at 1454 (majority opinion) and Cybor Corp., 138 F.3d at 1475 (Rader, J. dissenting).

1. Intrinsic Evidence

The intrinsic evidence of the public record must first be examined when construing the meaning of a patent claim. See Vitronics, 90 F.3d at 1582. Such evidence is "the most significant source of the legally operative meaning of disputed claim language." Id. Reliance on intrinsic evidence enables individuals to review the public record, apply the established rules of claim construction, ascertain the scope of the claimed invention and, then, design around the claimed invention.

Intrinsic evidence includes (1) the claims of the patent, (2) the specifications of the patent and (3) the prosecution history of the patent. See Cybor Corp., 138 F.3d at 1466-67 (Mayer, C.J. concurring); Vitronics, 90 F.3d at 1582; see also Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1580 (Fed.Cir. 1995), cert. denied, 517 U.S. 1167, 134 L. Ed. 2d 666, 116 S. Ct. 1567 (1996); Markman, 53 F.3d at 979. In most instances, an analysis of the intrinsic evidence alone will resolve any asserted ambiguity in a disputed claim term. Markman, 517 U.S. at 389; Vitronics, 90 F.3d at 1583.

a. The Claims

Section 112 of Title 35 of the United States Code requires a patent specification "conclude with one or more claims 9 particularly pointing out and distinctly claiming the subject matter which the applicant regards as his [or her] invention." 35 U.S.C. § 112. The claims of the patent define "the precise scope of the patent." Lucas Aerospace, Ltd. v. Unison Indus., L.P., 890 F. Supp. 329, 332 (D.Del. 1995) (citing Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 395 (Fed.Cir. 1967)).

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9 A patent claim typically has three parts: the preamble, the transition, and the body. See Donald S. Chisum, Patents § 806(1)(b) (1997). The preamble is an introductory phrase summarizing the invention, its relation to the prior art, or its intended use or properties. The transition is a phrase connecting the preamble to the body of the claim. The body consists of a recitation of the elements and limitations that "define the product or process to be encompassed within the patent." Id.

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When interpreting a claim, the words of the claim itself are first considered "to define the scope of the patented invention." Vitronics, 90 F.3d at 1582 (citing Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir. 1995)). The words are interpreted in accordance with their ordinary meaning, as understood by a person reasonably skilled in the art. See Quantum, 65 F.3d at 1580; Vitronics, 90 F.3d at 1582; Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387 (Fed.Cir. 1992); Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir. 1984); Phillips Elec. North Am. Corp. v. Universal Elec. Corp., 930 F. Supp. 986, 997 (D.Del. 1996) (citing Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 867 (Fed.Cir. 1989)).

Technical terms should be construed from the perspective of a person experienced in the field of the invention. 10 See CVI/Beta Ventures, 112 F.3d at 1153 (quoting Hoechst Celanese Corp. v. BP Chems., Ltd., 78 F.3d 1575, 1578 (Fed.Cir. 1996)). A claim should not be construed in a manner that renders the claim language "meaningless or superfluous." Lucas Aerospace, 890 F. Supp. at 332 (citing Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed.Cir. 1993)).

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10 The case law is unclear whether non-technical terms should be interpreted in accordance with their common meanings or

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whether such terms should instead be interpreted in accordance with their meanings as understood by a person reasonably skilled in the art. The better rule is the former; non-technical terms should be given their common meaning absent evidence that they should be interpreted differently. The issue remains, however, as to whether a particular term is a "technical term."

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If the inventor has used a term in a manner other than its ordinary meaning, that meaning should be given effect because the inventor is free to be his or her own lexicographer. See Vitronics, 90 F.3d at 1582 (citing Hoechst Celanese Corp. v. BP Chems., Ltd., 78 F.3d 1575, 1578 (Fed.Cir. 1996)); see also Markman, 52 F.3d at 980; accord Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (1990); ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1580 (Fed.Cir. 1988). Any term given a special meaning, however, must be so defined in the specification or its definition must be clear by implication. See Markman, 52 F.3d at 980; accord Vitronics, 90 F.3d at 1582.

b. The Specification

The patent claims "must be read in view of the specification, of which they are a part." Markman, 52 F.3d at 979 (citing Autogiro, 384 F.2d at 397)); see also SRI Intern. v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed.Cir. 1985). Section 112 of Title 35 of the United States Code provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. The specification is "highly relevant to the claim construction analysis" because it contains a written description of the invention that must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Vitronics, 90 F.3d at 1582.

The specification must be reviewed "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Vitronics, 90 F.3d at 1582; CBI/Beta Ventures, 112 F.3d at 1153. In this regard, the specification "may act as a sort of dictionary, which explains the invention and may define terms used in the claims." Markman, 52 F.3d at 979. It acts as a dictionary when it "expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582.

The specification "does not delimit the right to exclude. That is the function and purpose of the claims." Markman, 52 F.3d at 980. In addition, "references in the specification to a preferred embodiment, or an illustrative example, do not limit the scope of the patent claim." Lucas Aerospace, 890 F. Supp. at 332.

c. The Prosecution History

When construing the language of a claim, the prosecution history of the patent also should be considered, provided that it is in evidence. Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.), cert. denied, 516 U.S. 987, 133 L. Ed. 2d 424, 116 S. Ct. 515 (1995); Markman, 52 F.3d at 980; Vitronics, 90 F.3d at 1582 (citing Graham v. John Deere, 383 U.S. 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)); CBI/Beta Ventures, 112 F.3d at 1155. The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Vitronics, 90 F.3d at 1582. It is "often of critical significance in determining the meaning of the claims." Id.

The prosecution history "limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall, 54 F.3d at 1576; see CBI/Beta Ventures, 112 F.3d at 1155. However, the prosecution histories "cannot 'enlarge, diminish, or 'vary' the limitations in the claims." Markman, 52 F.3d at 980 (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149 (1880)).

In the instant action, the parties agree there is no relevant prosecution history that would be instructive in interpreting the disputed claims because the United States Patent and Trademark Office accepted all the claims without objection or

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amendment. See Brief - Cleanox at 3, 5; Markman Hearing Transcript at 62:10-12.

2. Extrinsic Evidence

Extrinsic evidence is "all evidence external to the patent, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 979, 980; see Hormone Research Found., 904 F.2d at 1562. This type of evidence may be consulted during construction of a claim to assist with the understanding of "scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history." Markman, 52 F.3d at 980; see Vitronics, 90 F.3d at 1584. In addition, extrinsic evidence may be received to aid in "'coming to a correct conclusion' as to the true meaning of the language employed' in the patent." Markman, 52 F.3d at 979 (citations omitted). Moreover, if, after consideration of all available intrinsic evidence, there still is some genuine ambiguity in the claims, extrinsic evidence may be consulted to interpret the meaning of the language used in the claim. See Vitronics, 90 F.3d at 1584. Extrinsic evidence cannot be used, however, for the purpose of varying or contradicting the terms of the claims. See id.

ANALYSIS

A. Claim Construction of Claim One of the '141 Patent and Claim One of the '483 Patent

The preambles of Claim One of the '141 Patent and Claim One of the '483 Patents are identical. See '141 Patent at col. 8, lines 23-26; '483 Patent at col. 9, lines 33-36. In addition, sub-part (a) of Claim One of the '141 Patent and sub-part (a) of Claim One of the '483 Patent are identical. See '141 Patent at col. 8, lines 28-29; '483 Patent at col. 9, lines 37-38. The parties appear to agree on the interpretation of the preambles, which reads from the beginning of the claim up to the colon. See Brief - Cleanox at 3; Brief - Defendants at 6. The parties also appear to agree that the words in sub-part (a) of Claim One of each patent, "providing a plurality of mutually spaced wells intersecting said groundwater," must be construed to mean physically providing at least two wells. See Brief - Defendants at 6; Markman Hearing Transcript at 65:3-9.

As mentioned, however, the following issues are disputed by the parties: (1) the meaning of the term "well" in Claim One of the '141 Patent and Claim One of the '483 Patent, (2) whether Step B of Claim One of the '141 Patent requires that pH be monitored for a particular purpose, (3) whether the term "treating flow" in Step C of Claim One of the '141 patent requires a "pressure limitation" and permits "bioremediation," and (4) whether Claim One of the '483 Patent requires that each of its steps be performed separately and sequentiality in order to practice the invention. See Brief - Cleanox at 3 n.1; Brief - Defendants at 6 n.1 and Exhibits C and D thereto; 18 December 1997 Letter.

After briefs were requested and received, reply briefs were sought from the parties. In their briefs and at the Markman Hearing, the parties advised that extrinsic evidence need not be considered to properly construe the meaning of Claim One of the '141 Patent and Claim One of the '483 Patent. See Brief - Cleanox at 3; Brief - Defendants at 8-10. Nevertheless, the parties cited extrinsic evidence in their briefs. When offered a hearing on the construction issues, the parties stated that they did not believe one was necessary but welcomed the opportunity to address these issues. See supra, note 3. Accordingly, each party was permitted to present testimony and arguments at the Markman Hearing.

* * *

2. Construction of Step B of '141 Patent

The parties dispute whether Step B of the '141 Patent requires that pH be monitored for a particular purpose.

a. The Cleanox Argument

Cleanox argues that Step B of '141 Patent "does not require that the practitioner have any specific purpose or intent in monitoring pH." Reply Brief - Cleanox at 4 (emphasis in original). The practitioner's intent during monitoring, Cleanox argues, is irrelevant to an infringement analysis if the practitioner practices what Step B of '141 Patent teaches. See id. (citing Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1519 (Fed.Cir. 1995), rev'd on other grounds, 520 U.S. 17, 137 L. Ed. 2d 146, 117 S. Ct. 1040 (1997)). Cleanox contends, therefore, that any monitoring of pH by a practitioner infringes Step B of the '141 Patent. See id.

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b. The Defense Argument

Defendants argue Step B of '141 Patent expressly requires "the pH be monitored for the particular purpose of determining the existence of acceptable continuity and well interflow paths." Reply Brief - Defendants at 3. They argue the reliance by Cleanox on the testimony of Dr. Piotrowski to interpret the meaning of Step B of the '141 Patent is misplaced because, among other things, it is extrinsic evidence. See id. at 4. Finally, in an effort to avoid jury confusion, Defendants seek a ruling that Step B of the '141 Patent requires all of the following:

1) generating a test flow of a solution of hydrogen peroxide from one of the wells provided in the step of subpart(a);

2) monitoring the other wells provided in the step of subpart (a) to detect a pH drop of at least 0.2; and

3) using the detected pH drop of at least 0.2 for the express purpose of determining that continuity and well overflow paths are acceptable to receive the treating flow.

See id. at 4 n. 1; see also Brief - Defendants at 11.

c. Judicial Construction

The express language of Step B of the '141 Patent requires that the pH be monitored to "determine the existence of acceptable continuity and well interflow paths." Step B of the '141 Patent. The reliance by Cleanox on extrinsic evidence, such as the testimony of Dr. Piotrowski, to construe the meaning of Step B of the '141 Patent is unnecessary for the reasons previously discussed in this Supplemented Opinion. Although Cleanox correctly states that the intent of a practitioner while practicing the invention is not a proper element of patent infringement, here the intent of the practitioner is not analyzed. Rather, the patent claim itself is construed to determine whether it discloses a purpose for the pH monitoring. As mentioned, the language of Step B of the '141 Patent expressly teaches the purpose of such monitoring is to "determine the existence of acceptable continuity and well interflow paths." Step B of the '141 Patent. Finally, Step B of the '141 Patent should be read to require all of the following:

1) generating a test flow of a solution of hydrogen peroxide from one of the wells provided in the step of subpart(a);

2) monitoring the other wells provided in the step of subpart(a) to detect a pH drop of at least 0.2; and

3) using the detected pH drop of at least 0.2 for the express purpose of determining that continuity and well overflow paths are acceptable to receive the treating flow.

* * *

Conclusion

For the reasons stated, the claim construction of the disputed terms is as follows: (1) the term "well" in Claim One of the '141 Patent and Claim One of the '483 Patent means "a structure used for both monitoring and injecting the groundwater," (2) Step B of the '141 Patent is read to require that pH be monitored for the particular purpose of determining the existence of acceptable continuity and well interflow paths, (3) the term "treating flow" in Step C of the '141 Patent is read to have no pressure limitation associated with it and to be limited to "chemical remediation", and (4) Claim One of the '483 Patent is read to require the performance of Steps A-D both separately and sequentially to practice the invention.
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A. "Monoclonal Antibody"

The term "monoclonal antibody" appears in all of the patent claims. Claim 1 is representative:
A monoclonal antibody that binds to a human breast cancer antigen that is also bound by monoclonal antibody 454 C11 which is produced by the hybridoma deposited with the American Type Culture Collection having Accession No. HB 8484.

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'561 Patent, Claim 1.

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n3 The American Type Culture Collection ("ATCC") is a bank of tissues and cell lines. Thus, persons skilled in the art can obtain hybridoma No. HB 8484 on file with the ATCC and make the 454 C11 monoclonal antibody referred to in the claim. Using that antibody, the person can identify the breast cancer antigen described in the claim.

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Chiron and Genentech vigorously dispute the meaning of the term "monoclonal antibody." Genentech argues that "monoclonal antibody" refers to a homogenous population of antibodies having a structure that can be made by a murine hybridoma. n4 Chiron agrees that the term refers to a homogeneous population of antibodies, but contends that the term is not limited in any way by the type of antibodies making up the population.

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n4 Genentech's proposed construction of this term has changed over the course of this litigation. Initially, Genentech proposed that a monoclonal antibody referred to "a uniform population of antibodies produced from a hybridoma." (Genentech Claim Construction Statement, at 2:5-6.) Magistrate Judge Hollows rejected this construction because, among other things, it improperly attempted to limit a product by the process in which it was made. (See F & R's at 24-27)("It is well established that if the 'patent is upon a product, and if the product complained of is the patented article substantially as described, it makes no difference by what path or process, new or old, inferior or improved, the infringing product is manufactured.")(quoting Amgen Inc. v. Chugai Pharm. Co., 706 F. Supp. 94, 103-104 (D. Mass. 1989)). Genentech's new proposed construction of "monoclonal antibody" defines the antibody in terms of its structural characteristics, rather than as a product of a particular process. Genentech has also shifted its focus away from the patent itself toward the prosecution history of the patent. Because Genentech has refocused its arguments, the court's analysis will not track the analysis set forth in Magistrate Judge Hollows' findings and recommendations. However, many of the substantive issues remain the same.

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1. Claim Language n5

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n5 Genentech's objections to the findings and recommendations do not discuss the term "monoclonal antibody" as it is used in the '561 patent. Rather, Genentech refers to the prosecution history, and argues that it is dispositive of the meaning of "monoclonal antibody." Although the prosecution history is relevant to claim construction, it is never the starting point of the analysis. The court looks first to the patent itself.

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Looking at the claim language itself, only one structural limitation can be inferred from the way "monoclonal antibody" is used: the antibody must have a structure that enables it to bind to the referenced human breast cancer antigen. The language of the claims, standing alone, does not support Genentech's more limited construction.

2. Specification

The specification also supports a broad construction of the term. The specification expressly defines "monoclonal antibody" as follows:
As used herein, the term "monoclonal antibody" refers to an antibody composition having a homogeneous antibody population. The term is not limited regarding the species or source of the antibody, nor is it intended to be limited by the manner in which is is made. The term encompasses whole immunoglobulins.
'561 Patent, 8:40-45 (emphasis added).

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It is a well established rule of claim construction that "an inventor may be his own lexicographer." Kopykake, 264 F.3d, at 1383. Thus "when the meaning of a term is sufficiently clear in the patent specification, that meaning shall apply," even if common understandings of the term are different. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473 at 1477-78 (Fed. Cir. 1998).

In light of the above quoted definition, one skilled in the field of microbiology and immunology in 1984 and 1985 would interpret the term "monoclonal antibody" to encompass any antibody, from any source or species (murine or otherwise), produced by any method (known at the time or not), so long as the population of antibodies is homogenous. Therefore, the term "monoclonal antibody" as defined in the specification is broad enough to include homogenous populations of humanized antibodies. Genentech's more limited construction is inconsistent with this definition.

Genentech argues that other language in the specification suggests that the term "monoclonal antibody" does not include chimeric, hybrid, or humanized antibodies. First, Genentech points to the definition of "antibody":
The term "antibody" encompasses polyclonal [non-homogeneous] and monoclonal antibody preparations, as well as preparations including hybrid antibodies, altered antibodies, chimeric antibodies and, humanized antibodies. n6
'561 Patent, 8:36-39.

Genentech contends that the use of "as well as" indicates that monoclonal antibody preparations are separate and distinct from preparations including hybrid, chimeric, and humanized antibodies. As Genentech puts it, "saying that 'a balanced diet consists of meats, fruits and vegetables, as well as bread and dairy products' does not connote that bread and dairy products are subsets of meats or fruits or vegetables." (Genentech Objections to F & R's, at 5.)

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n6 In discussing this language, Magistrate Judge Hollows referred to chimeric, hybrid, and humanized antibodies as "distinct" subsets of antibodies. (See F & R's at 23:6-7.) Chiron objects to the characterization of these subsets of antibodies as "distinct," and argues that they are overlapping. (Chiron Objections at 7.) How these subsets are characterized, however, is irrelevant to the construction of the term "monoclonal antibody." Accordingly, the court will not decide this issue at this time.

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However, "as well as" does not always differentiate between mutually exclusive categories. See In re Hyatt, 708 F.2d 712, 714 (Fed. Cir. 1983)(stating that patent claims "must be read in accordance with precepts of English grammar.") For example, one might say, "Our city is very diverse. It has a large African American and Asian population, as well as people from many different religious backgrounds, such as Muslims, Buddhists, and Jews." No one would interpret this phrase to mean that African Americans cannot also be Muslims. Likewise, it is not necessary to interpret monoclonal and humanized antibodies to be mutually exclusive. An equally plausible interpretation of the quoted language from the patent is that it describes two separate attributes of antibodies: their composition (monoclonal or polyclonal), and their structure (hybrid, chimeric, and humanized). Under this interpretation, an antibody can be both monoclonal and humanized.

The specification supports the latter interpretation. For example, it discusses humanized antibodies, and refers to non-hybridoma derived molecules as embodiments of the claimed monoclonal antibodies. See '561 Patent, 11: 12-12:26 (discussing humanized antibodies); 5:40-46 ("In various related embodiments, nucleic acid molecules are provided including ... molecules which combine murine CDRs with supporting human FRs ...."); see Bell Atlantic Network Serv. v. Covad Communs. Group, Inc., 262 F.3d 1258, 1269 (Fed. Cir. 2001)("The written description of the preferred embodiments ... guides our interpretation of the claim language, as claims must be read in light of the specification.") n7

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n7 Genentech argues that this interpretation renders the categories of antibodies discussed in the patent "demonstrably incomplete" because the mentioned structures do not include the hybridoma-derived antibodies that are referenced throughout the patent. (Genentech Objections to F & R's at 7.) The definition of "antibody," however does not purport to be all-inclusive.

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Next, Genentech contends that language in the "background" section of the specification "makes ... clear" that homogeneity is merely one of several attributes of a monoclonal antibody. Specifically, Genentech points to the following sentence:
A monoclonal antibody belongs to a group of antibodies whose population is substantially homogeneous, i.e. the individual molecules of the antibody population are identical except for naturally occurring mutations.
'561 Patent, 1: 50-54

This sentence certainly suggests that homogeneity is an attribute of a monoclonal antibody, but it has nothing to say one way or another about whether homogeneity is one of many relevant attributes, or the only relevant attribute of a monoclonal antibody. The definition in the specification does; it makes clear that a monoclonal antibody is an antibody that comes from a homogeneous antibody population, without any other limitations.

Finally, Genentech argues that because the humanized antibodies described in the patent are not referred to as "monoclonal antibodies," the patentees must have intended to carve out humanized antibodies from the classification of monoclonal antibodies. Given the express definition of the patent, this interpretation is implausible. The extrinsic evidence helps to clarify this point. At the Markman Hearing, experts for both parties testified that humanized antibodies would not be useful if they were not homogeneous. (Mar. 7 Markman Tr. at 57:6-15)(testimony of Genentech expert Dr. Unkeless that those in the field understand that a humanized antibody is homogeneous "otherwise, why would you have it.") Thus, one skilled in the art would have understood humanized antibodies as that term is used in the '561 patent to refer to homogeneous populations of antibodies. Because homogeneity would have been assumed, using the term "monoclonal antibody" when referring to humanized antibodies would have been unnecessary.

Therefore, looking at the claim language and the specification, one skilled in the art in 1984 and 1985 would broadly construe the term "monoclonal antibody" to mean any homogeneous antibody population. There is no support in the issued patent for reading an additional structural limitation into the claims.

3. Prosecution History

The analysis does not end, however, with a review of the claims and the specification. The prosecution history, or the back-and-forth between the patentee and the Patent and Trademark Office ("PTO") prior to the issuance of the patent, can shed light on the meaning of terms in the claims, and even limit claim terms. See Biovail Corp. Int'l v. Andrx Pharmaceuticals, Inc., 239 F.3d 1297, 1301 (Fed. Cir. 2001)("Claim language ... must be read consistently with the totality of the patent's applicable prosecution history."). For example, "the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during the prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995). The prosecution history may also "show a particular meaning attached to the terms, or a position taken by the applicant to ensure that the patent would issue." Markman, 52 F.3d at 991. "Although the prosecution history can and should be used to understand the language used in the claims, it ... cannot 'enlarge, diminish, or vary the limitations in the claims.'" Markman, 52 F.3d at 979 (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880)).

The prosecution history of the '561 patent is long and complicated. In February of 1984, Chiron's predecessor, Cetus, filed an application for a patent for monoclonal antibodies. In 1985, and then again in 1995, Chiron filed continuation applications. n8

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n8 A "continuation" of an earlier parent application claims the same invention as the parent application, with some variation in scope. For example, a continuation might add new claims, or it might disclose newly discovered embodiments of the existing claims. To the extent that continuations add "new matter" that is not supported by the disclosures in the earlier applications, they are not entitled to the filing dates of the earlier applications; otherwise, continuations date back to the parent application. See Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551 (Fed. Cir. 1994). Thus, "patent claims may ... be amended to cover a competitor's product discovered subsequent to the filing of the original application, so long as the amendments are supported by the disclosure in the original application." Laitram Corp. v. Morehouse Indus.,

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Inc., 1197 U.S. Dist. LEXIS 23026, No. Civ. S-94-0452 WBS/GGH at *37-38 (E.D. Cal. Apr. 24, 1997).

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The 1985 application, though similar in many relevant respects to the 1984 application, offered an explicit definition of "monoclonal antibody" that did not appear in the 1984 application. That definition is almost identical to the definition found in the '561 patent. The 1985 application eventually became U.S. Patent No. 4,753,894 (the '894 patent), which is the subject of related litigation between Chiron and Genentech. SeeChiron v. Genentech, CIV-S-01-503 WBS/GGH.

The 1995 application was much longer than the 1984 and 1985 applications, and is the first application in the chain to discuss recombinant and humanized antibodies. The 1995 application initially contained claims to nucleic acid molecules encoding single chain polypeptides capable of binding to human breast cancer antigens. These claims were rejected by the PTO on the basis that they were not supported by the priority applications, and were obvious in light of intervening prior art. Chiron then withdrew the rejected claims and added claims to "monoclonal antibodies," which the PTO allowed.

After the claims were allowed, but before the patent was issued, Chiron sought two "post allowance" amendments pursuant to 37 C.F.R. § 1.312(a). The first amendment revised the definition of monoclonal antibody to "encompass[] only subject matter that was encompassed by the term 'monoclonal antibody' in the priority applications." (Chiron Markman Exhibit 175, Tab 156). The second amendment sought to add claims to (1) monoclonal antibodies prepared by a hybridoma process; (2) a hybridoma capable of producing monoclonal antibodies; (3) monoclonal antibodies prepared by a cell line process; (4) a cell line capable of producing monoclonal antibodies. (Chiron Markman Exhibit 175, Tab 157). The patent examiner allowed only the hybridoma claims, finding that the cell line claims did not find support in the priority applications. On April 25, 2000, the '561 patent issued.

a. The 1984 and 1985 Priority Applications

Genentech argues that given the prosecution history of the patent, the meaning of the term "monoclonal antibody" as used in the 1984 and 1985 priority applications controls the construction of the term as it is used in the '561 patent. Further, Genentech argues that the 1984 and 1985 applications use the term "monoclonal antibody" in the limited sense of an antibody having a structure derived from a murine hybridoma.

The court accepts Genentech's argument that the meaning of "monoclonal antibody" in the '561 patent must be consistent with the way the term was used in the priority applications. During prosecution of the '561 patent, Chiron disclaimed an interpretation of "monoclonal antibody" broader than the 1984 and 1985 applications. To escape the examiner's prior art rejection of the 1995 patent, Chiron withdrew the originally submitted claims and added claims to monoclonal antibodies, stating that "no new matter has been added by way of these amendments, and the entry thereof is respectfully requested." (Chiron Markman Ex. 175, Tab 146.) Thus, Chiron represented to the PTO that the monoclonal antibody claims were equivalent in scope to the parent applications. See York Prods., Inc. v. Cent. Tractor Farm & Family Cent., 99 F.3d 1568, 1575 (Fed. Cir. 1996)(holding that an applicant can limit claims during prosecution by altering claim language to escape an examiner rejection or by clearly disavowing claim coverage). In addition, in its first post-allowance amendment, Chiron amended its definition of "monoclonal antibody" to "encompass[] only subject matter that was encompassed by the term 'monoclonal antibody' in the priority applications." (Chiron Markman Exhibit 175, Tab 156). n9

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n9 Genentech offers a number of other reasons why the court should look to the priority applications. For example, Genentech points out that the priority applications are incorporated by reference into the '561 patent, and that Chiron submitted a terminal disclaimer during the prosecution of the '561 patent. Because Chiron's statements during the prosecution history regarding the meaning of "monoclonal antibody" are sufficient to disclaim a meaning of the term broader than the 1984 and 1985 applications, the court expresses no opinion regarding the merits of these additional arguments.

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Accordingly, the court turns to the 1984 and 1985 applications. n10

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n10 Chiron argues that interpreting the '561 patent in light of the priority applications impermissibly blurs issues of validity and priority with the question of claim construction. See Vandor Corp. v. Wilson,149 F. Supp. 2d 633, 2001 WL 747281 (S.D. Ind. Jul. 3, 2001) (holding that a partially formed validity argument cannot force a claim construction that is contrary to the plain meaning of the claim language read in light of the specification). It is not clear to the court, however, that these issues can be separated. Whether or not there was new matter added to the '561 patent, and regardless of the possibility that new matter in the '561 patent might have been invalidated by intervening prior art, Chiron represented to the PTO that the term "monoclonal antibody" was no broader than the scope of the 1984/1985 applications. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1356 (Fed. Cir. 1998) (a patentee can disclaim a particular interpretation even if the examiner was incorrect in making the rejection). As a matter of claim construction (not validity or priority), the court is compelled to consider those applications.

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i. The 1984 Application

Like the '561 patent, the 1984 application concerns monoclonal antibodies capable of binding to human breast cancer antigens. Although the application discusses primarily murine monoclonal antibodies, it is not necessarily so limited. For example, while Claim 1 of the 1984 application claims "a murine monoclonal antibody that ... binds selectively to human breast cancer cells," Claim 2 is not expressly limited to murine monoclonal antibodies. (See 1984 Application, at 28:1-18.) Rather, it is directed toward "a monoclonal antibody selected from the group consisting of [various antibodies including] 454 C 11 and monoclonal antibodies that are functionally equivalent to a member of said group." (1984 Application, at 28:7-18.)

A more difficult question is how the term "monoclonal antibody" should be construed in light of the 1984 specification. The 1984 application lacks the expansive definition of "monoclonal antibody" found in the '561 patent; indeed, the term is not defined at all in the 1984 application.

In some respects, the 1984 specification supports a narrow construction of the term. For example, the specification repeatedly refers to the invention as a "murine monoclonal antibody," see 1984 Application, 1:5-9 ("This invention ... concerns murine monoclonal anti-human breast cancer antibodies, [and] hybridomas that produce those antibodies ...."); id. at 2: 7-17 (describing the 454 C11 antibody and its functional equivalents as preferred embodiments of murine monoclonal antibodies that bind selectively to human breast cancer cells), and the only preferred embodiment disclosed in the specification is a murine, hybridoma-derived monoclonal antibody.

On the other hand, in describing the "important characteristics" of the invention, the 1984 specification does not refer to its murine hybridoma-derived structure:
The important characteristics of the monoclonal antibodies are (1) their immunoglobulin class, (2) their selectivity for human breast cancer cells and the range of human breast cancer cells to which they bind and (3) their usefulness in making effective anti-human breast cancer immunotoxins.
1984 Application, at 5: 1-7.

In fact, it is evident from the application's discussion of prior art that murine monoclonal antibodies derived from hybridomas had already been discovered, and that the novel aspect of the invention concerned monoclonal antibodies capable of binding to specific breast cancer antigens. See 1984 Application at 1:11-2:5 (describing "background art" regarding murine monoclonal antibodies); id. at 10:24-11 (describing how, in order to make the invention, the inventors prepared somatic cell hybrids using existing hybridoma methods). Moreover, before setting forth the best mode for making the invention, the 1984 specification emphasizes that the monoclonal antibodies are not intended to be limited by the manner in which they are made:
The following examples provide a detailed description of the preparation, characterization, and use of representative monoclonal antibodies of this invention. These examples are not intended to limit the invention in any manner.
Id. at 10: 1-5 (emphasis added).

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Nevertheless, Genentech argues that because only one preferred embodiment is described in the specification, the invention claim in the 1984 application is limited to that embodiment.

ii. 1985 Application

Genentech makes the same argument with respect to the 1985 application. Like the 1984 application, the only preferred embodiment disclosed in the 1985 specification is a monoclonal antibody derived from a hybridoma. However, the 1985 application expressly defines "monoclonal antibody" for the first time:
As used herein, the term "monoclonal antibody" means an antibody composition having a homogeneous antibody population. It is not intended to be limited as regards the source of the antibody or the manner in which it is made.
1985 Application, at 3:19-23.

This definition is virtually identical to the broad definition of "monoclonal antibody" found in the '561 patent. n11

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n11 The definition in the '561 patent adds that the invention is not limited regarding the species from which the antibody is derived. Genentech argues that the addition of the word "species" means that "monoclonal antibody" has a broader meaning in the '561 patent. However, the PTO allowed the definition in the '561 patent with the reference to "species" on the understanding that it had the same scope as the definition in the 1985 application. In addition, both the issued patent and the 1985 application define "monoclonal antibody" as a homogeneous population of antibodies, with no other structural limitations. Given ordinary understandings of the phrase "not limited by the manner in which it is made," it would not matter for either the 1985 application or the '561 patent whether hybridoma or recombinant techniques were used. The court, like Magistrate Judge Hollows, rejects Genentech's "strained conjecture" that the "manner" in which the monoclonal antibody was created refers to in vivo or in vitro creation and the "source" of the antibody refers to culture media or body fluids. (See F & R's at 22.) The only support for this argument comes from a phrase that is in a completely different part of the application from the definition, and makes no reference to the terms used in the definition. See 1985 Application, 5:7-13.

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The question for the court is whether, under these circumstances, the monoclonal antibodies claimed in the priority applications are limited to the preferred embodiment described therein.

iii. Preferred Embodiment As Limitation

The Patent Act, 35 U.S.C. § 112, requires the patent to include a written description of the invention, including the manner and method of its making and the best mode (or preferred embodiment) for carrying it out, so that others skilled in the art can use it. See Brookhill-Wilk 1, L.L.C. v. Intuitive Surgical, Inc., 178 F. Supp. 2d 356, 363 (S.D.N.Y. 2001) (citing Wang, 197 F.3d at 1383). A claim is ordinarily not limited to the preferred embodiment described in the specification. See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1582 n.7 (Fed. Cir. 1996). "However, in a given case, the scope of the right to exclude may be limited by a narrow disclosure." Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998). For example, "there are times when an enumerated 'best mode' or 'preferred embodiment' of an invention is, in fact, nothing more than the invention itself." Brookhill-Wilk 1, L.L.C. v. Intuitive Surgical, Inc., 178 F. Supp. 2d 356, 363 (S.D.N.Y. 2001)(citing Wang Lab. Inc. v. Am. Online, Inc., 197 F.3d 1377 at 1383 (Fed. Cir. 1999)).

As the Federal Circuit has recognized, there is sometimes a "fine line" between reading a claim in light of the specification, which is permissible, and reading a limitation into the claims from the specification, which is not. See Comark Communications v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998). Although no hard and fast rules exist for drawing this "fine line," some general principles can be gleaned from the case law. Courts have limited the claims to the preferred embodiments disclosed in the specification in certain narrow circumstances where (1) it is clear from the specification that the embodiment is essential to the invention, or (2) the disclosure expressly distinguishes other embodiments that the patentee later argues are encompassed by the invention. n12

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n12 Genentech appears to advocate a bright-line rule that would limit an invention to the preferred embodiment if only one embodiment is disclosed in the specification. Such a categorical rule is contrary to the principle that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." Rexnord, 274 F.3d at 1344. The case law suggests that a more nuanced approach is required. See Gentry Gallery, 134 F.3d 1473 (patent for L shaped sofas with side-by-side recliner seats did not encompass sofas with controls for the recliners located on arms of sofa, where the embodiment described the invention as having a console between the seats, and the only discernable purpose for the console was to house the controls); Brookhill-Wilk, 178 F. Supp. 2d 356 (patent for surgery system that permits a surgeon to operate from "a remote location beyond a range of direct manual control" did not encompass virtual surgery systems used within the operating room, given distinctions over prior art on the basis that the invention allowed surgeons to operate from outside the hospital, as well as repeated emphasis in specification that the patent would facilitate surgery around the world and reduce the cost of surgery by eliminating the need to travel to a qualified surgeon); Modine, 75 F.3d 1545 (patent limited to particular embodiment because of an unambiguous amendment that narrowed the range of the claim term); Bell Atlantic, 262 F.3d 1258 (Fed. Cir. 2001)(rate of data transfer was not included in the "plurality of different modes" claimed in the invention, because the specification repeatedly referred to "rate" and "mode" as distinct concepts); Laitram Corp. v. Morehouse Indus., Inc., 143 F.3d 1456 (Fed. Cir. 1998)(limited because patentee argued the embodiment distinguished over prior art).

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For example, in Watts v. XL Sys., Inc., 232 F.3d 877 (Fed. Cir. 2000), the Federal Circuit held that a patent for joints and couplings in oil well pipes was limited to the preferred embodiment disclosed in the specification, which was a pipe joint having a varying tapered angle feature. The specification expressly stated that "the present invention utilizes" a varying tapered angle feature, thereby equating the invention with the preferred embodiment. In addition, the patentee had referred to the tapered angle feature in distinguishing prior art.

Similarly, in Wang Labs, 197 F.3d at 1383-84, a patent claiming a system providing computer users with "frames" of textual and graphic information via a telephone network was limited to the character-based "frames" disclosed in the patent. The patent described only a character-based system, and language describing the embodiment as a "preferred" embodiment that those skilled in the art "may" make was insufficient to suggest that other systems were contemplated. In addition, the inventors had distinguished over prior art by focusing on the character-based aspect of the invention.

This case bears some similarity to Watts and Wang Labs in that the invention is described in the priority applications as if it were the preferred embodiment. See 1984 Application (see 1984 Application, 1:5-9 ("This invention ... concerns murine monoclonal anti-human breast cancer antibodies, [and] hybridomas that produce those antibodies ...."). However, unlike the inventors in Watts and Wang Labs, the inventors here did not focus on the murine-hybridoma structure to distinguish prior art. More importantly, unlike the patents at issue in Watts and Wang Labs, the 1984 and 1985 applications expressly contemplate other embodiments of the claimed invention. Both the 1984 and 1985 applications refer to the preferred embodiment as an "example" of the invention, and emphasize that "these examples are not intended to limit the invention in any manner." Id. at 10: 1-5. The 1985 application, which contains the broad definition of "monoclonal antibody" adopted by the '561 patent, is even more explicit on this point. n13

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n13 Genentech argues that the definition in the 1985 application expands the scope of "monoclonal antibody" beyond the meaning of the term as it was used in the 1984 application. However, the prosecution history reveals that both Chiron and the PTO understood the definition in the 1985 application to be consistent with the scope of the 1984 application. When Chiron proposed to define "monoclonal antibody" in the '561 patent to encompass the same subject matter as encompassed in the priority applications, it specifically cited the examiner to the 1985 application. (See Chiron Markman Ex. 175 at tab 156.) Thus, Chiron represented to the PTO that all priority applications, including the 1984 application, fell within the definition of "monoclonal antibody" in the 1985 application. As Magistrate Judge Hollows correctly concluded, this "renders the statement to the Examiner less than and 'clear disavowal' of its presently asserted interpretation." (F & R's at 28.)

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In Rexnord Corp. v. Laitram Corp., 274 F.3d 1336 (Fed. Cir. 2001), the Federal Circuit refused to limit the invention to the preferred embodiment where the patent contained similar non-limiting language:

The written description explicitly states that aside from the preferred embodiment, "the invention is capable of other embodiments and of being practiced and carried out in different ways." ... These phrases reflect the inventor's teaching that his invention could be embodied "in various ways." Finally, the inventor explicitly qualified his detailed "Description of a Preferred Embodiment" by stating that "it is to be understood that the invention is not limited in its application to the details of construction and the arrangements of components or illustrated drawings." Id. at 1345 (internal citations to patent omitted).

Similarly, the text of the 1984 and 1985 applications teaches that the claimed antibodies are not limited to the disclosed embodiment. Contrast N. Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1576 (Fed. Cir. 1993)(limiting the invention to one type of linkage because the specification taught that other linkages were "unlikely" or "not significant"); O.I. Corp. v. Tekmar Corp., 115 F.3d 1576 (Fed. Cir. 1997)(finding that the term "passage" in a patent for an apparatus for removing water vapor from a sample did not include smooth-walled passages, where the specification stated "although a threaded configuration is shown, other non-smooth geometries may be used to remove water vapor," and therefore only contemplated non-smooth geometries); Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998)(holding that the invention was limited to the conical prosthetic hip sockets described in the specification, where the specification "[did] not attempt to identify other, equally functional shapes or talk in terms of a range of shapes.").

Moreover, it is clear from those applications that the importance of the invention is not its murine hybridoma-derived structure, but its ability to selectively bind to human breast cancer cells, and its usefulness as an effective therapeutic against cancer. See 1984 Application, at 5: 1-7 (listing the "important characteristics of the monoclonal antibodies," without any mention of their hybridoma-derived structure).

Genentech therefore cannot successfully argue that the murine hydridoma-derived structure was essential to the invention. The priority applications do not support reading such a limitation into the broad language of the claims in the issued patent.

b. Rejections by the PTO

Genentech argues that not to limit the definition of "monoclonal antibody" gives Chiron a claim scope that was repeatedly rejected by the PTO during the application process. This argument misrepresents much of what occurred during the prosecution history, and fails to acknowledge Chiron's non-acquiescence with these rejections.

i. Functional Equivalent Claims

The 1984 and 1985 applications, as well as a subsequent continuation in part application filed in 1986, attempted to claim monoclonal antibodies and their "functional equivalents." The "functional equivalent" claims were rejected each time by the PTO on the grounds that the term was indefinite and not enabled by the disclosure in the specification. According to Genentech, this history indicates that the PTO believed the claims were limited in scope to murine hybridoma derived monoclonal antibodies. However, in setting forth the reasons for the rejection, the Examiner never explained why the functional equivalent claims were not enabled, and never stated that the priority applications were limited to antibodies with murine hydbridoma derived structures. See Rexnord, 274 F.3d at 1345 ("It is significant that the examiner made no explicit reference to [the disputed claim scope] in rejecting the claim.") Rather, the Examiner focused on the indefinite nature of the claims:

Claim 2 is indefinite as to the scope of the term "functionally equivalent." Which functions need to be equivalent to be included in this claim. [sic.] For example, which of the following are functionally equivalent: monoclonal/antibody able to (1) fix compliment, (2) bind to a human cell, (3) specifically bind to any human carcinoma, (4) binds only to breast carcinoma, (5) binds to the same antigen on or in the cell, (6) binds to the same site on the same antigen, or (7) the same isotype binding to the same eptiope? (Chiron Markman Ex. 175 tabs 7, 26.)

Thus, contrary to Genentech's assertions, the Examiner's rejection of the functionally equivalent claims tells us little about the proper scope of the priority applications and the issued patent. Moreover, Chiron never acquiesced in the rejection or "clearly disavowed" a claim scope that would cover functional equivalents. See York Products, 99 F.3d at 1575. In fact,

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Chiron withdrew the claims to functional equivalents stating that it was doing so "without prejudicing applicant's rights to antibodies having equivalent properties." (Chiron Markman Ex. 175, at Tab 55.) Ultimately, Chiron was issued both the '774 patent and '561 patent without the adjective "murine" in claims to monoclonal antibodies. (See Chiron Markman Ex., at Tab 101.)

ii. Single Chain Antibody Claims

Genentech next points out that during the prosecution of the 1995 application, the PTO rejected claims to nucleic acid molecules "encoding a humanized, single chain antibody" on the basis that they were preempted by prior art. (Chiron Markman Ex. 175 at Tab 140, p. 4.) The patent examiner explained that these claims "only have a priority date, 06/07/1995 because the claimed invention is not disclosed in the parent cases." (Id. at p. 6.)

The examiner obviously did not believe that single chain humanized antibodies were supported by the priority applications. The examiner was silent, however, about whether humanized antibodies having the usual four-chain antibody structure were encompassed by the priority applications. n14 "Drawing inferences of the meaning of claim terms from an examiner's silence is not a proper basis on which to construe a patent claim." De Marini Sports, Inc. v. Worth, Inc., 239 F.3d 1314 at 1326 (Fed. Cir. 2001). Therefore, the rejection of claims to single chain humanized antibodies does not justify limiting the term "monoclonal antibody" to exclude four-chain humanized antibodies.

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n14 The prior art cited by the patent examiner discusses single chain humanized antibodies as distinct from humanized antibodies with four chains. (See Chiron Markman Ex. 175 at Tab 140) (citing Ladner, et. al., U.S. Patent No. 4,946,778, August 7, 1990). The Ladner patent, for example, describes the advantages of single chain antibodies over recombinantly manufactured multiple chain antibodies: "Antibodies are three-dimensional aggregates of two heavy and two light chains ... In order to produce such complex materials by recombinant DNA technology ..., it becomes necessary to clone and express a gene coding for each one of the different kinds of polypeptide chains ... The approach ... necessitates expression of multiple genes, and as indicated, in some cases, multiple and different hosts. These approaches have proven to be inefficient ... [Therefore], it would indeed be greatly advantageous to be able to produce, by genetic engineering, single polypeptide chain binding proteins having the characteristics and binding ability of multi-chain variable regions of antibody molecules."

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iii. Cell Line Claims

Finally, Genentech relies on Chiron's failed attempt to add claims to cell lines. After the monoclonal antibody claims had been allowed, but before the patent issued, Chiron sought to add new claims for hybridoma processes, as well as a claim for a monoclonal antibody "prepared by a process [involving] a cell line capable of producing the monoclonal antibody" and a claim for the cell line itself. (See Chiron Markman Ex. 175, Tab 157.) The patent examiner rejected the cell line claims on the basis that they did "not find support in the specification as well as in the priority specification," and asked Chiron to "resubmit ... with claims only to the hybridomas and the antibodies produced by hybridomas." (Id., Tab 162.) Chiron resubmitted the proposed amendment with only claims to hybridomas, which were allowed. (Id., Tab 159.)

The term "cell line" is broader than "hybridoma" and could include recombinant, genetically engineered cell lines such as those used to produce a humanized antibody. Accordingly, Genentech argues that the rejection of the cell-line claims indicates that the patent examiner did not consider humanized antibodies to be within the scope of the patent.

Genentech's argument would have more force if it were not for the timing of the rejection. Before rejecting the cell line claims, the examiner had already allowed the claims to monoclonal antibodies on the understanding that they had the same scope as the priority applications, and without taking any limiting action with respect to the broad definition of monoclonal antibody found in the 1995 application. As discussed above, both this definition and the priority applications suggest that a monoclonal antibody is nothing more or less than a homogeneous population of antibodies.

The proposed claims to cell lines were narrower, dependent claims containing additional "process" limitations on the

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product (monoclonal antibody) that had already been accepted by the PTO. n15 Because the proposed cell line claims imposed additional "process" limitations on the invention, any rejection of those claims has little bearing on the scope of the broader, allowed claims. It would be improper for the court to read a limitation into the broad monoclonal antibody claims because narrower claims to cell lines were rejected. See Ethicon Endo-Surgery v. United States Surgical Corp., 93 F.3d 1572, 1582 n.7 (Fed. Cir. 1996) (finding that the examiner's rejection of a narrow claim because it was not supported by the disclosure could not be used to limit a broad claim to the disclosed embodiment.); n16 Markman, 52 F.3d at 979 ("Although the prosecution history can and should be used to understand the language used in the claims, it ... cannot 'enlarge, diminish, or vary the limitations in the claims.'")(quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880)).

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n15 There are three ways an inventor may seek protection for his invention under the patent laws: product claims, process claims, and product by process claims. A "product" claim is defined in terms of its physical and structural characteristics, and is not limited by the process in which it is made. A "process" claim is directed toward the method of manufacture used to make a given product. The hybrid "product by process" claim is one in which a product is claimed in terms of the process by which it is made. See Amgen Inc. v. Chugai Pharm. Co., 706 F. Supp. 94, 103-104 (D. Mass. 1989) aff'd in part and rev'd in part on other grounds, 927 F.2d 1200 (Fed. Cir. 1991) (describing the difference between product and process claims). These three types of claims are not mutually exclusive, and it is not uncommon for a patentee to seek all three types of claims to maximize protection for his invention.

n16 "The district court confused a claim supported by the specification, which is not allowable, with a broad claim, which is. Claim 1 was properly rejected because it recited an element not supported by [the] disclosure, i.e. a lockout 'on the stapler.' It does not follow, however, that [the] disclosure could not support claims sufficiently broad to read on a lockout off of the cartridge ... If Fox did not consider the precise location of the lockout to be an element of his invention, he was free to draft claim 24 broadly (within the limits imposed by the prior art) to exclude the lockout's exact location as a limitation of the claimed invention ... Such a claim would not be unsupported by the specification even though it would be literally infringed by undisclosed embodiments. The district court should not have imposed on claim 24 an additional limitation which it does not contain." Ethicon, 93 F.3d at 1582 n.7 (internal citations omitted)(emphasis added). Though somewhat counter-intuitive, the Federal Circuit's reasoning is that a broad claim encompasses even subject matter that cannot be specifically claimed. Thus, a rejection of a narrow claim because it is not supported by the disclosure cannot be used to limit issued claims that are written broadly.

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Plant Genetic Sys. N.V. & Biogen, Inc. v. Dekalb Genetics Corp., 175 F. Supp. 2d 246 (D. Conn. 2001), cited by Genentech, is inapposite. In that case, the court held that "plant" was limited to dicotyledonous plants, because during prosecution the examiner expressed his view that the specification did not enable the invention as to monocotyledonous plants. Id. at 268. Not only did this happen before the patent examiner allowed the claims to "plants," the discussion that took place directly referenced the claims in dispute. Id. ("there can be little question from the exchanges between the examiner and the applicants that the issue of whether the plant ... claims would cover both dicots and monocots arose on several occassions").

Here, the exchange between the patent examiner and Chiron took place after the claims to monoclonal antibodies had been allowed, and without reference to the meaning or scope of "monoclonal antibody." The relevance of the examiner's rejection to the already allowed monoclonal antibody claims is ambiguous at best. Absent a more detailed explanation of the reasons for rejection, the court will not guess at what was in the mind of the patent examiner. See Rexnord, 274 F.3d 1348 (refusing to deviate from broad interpretation of claim terms where prosecution history was "inconclusive"); Markman v. Westview Instruments, Inc., 52 F.3d 967, 985 ("Of course the views of the [PTO] are generally not obtainable, except as reflected in the prosecution history.")

Moreover, nothing about Chiron's response to the rejection of the second proposed amendment can be considered a "clear disavowal" or "disclaimer" of claim scope by Chiron. Entry of a post-allowance amendment is completely discretionary. If the amendment is rejected, the applicant has no right to appeal and is not entitled to a detailed explanation of the reasons for the rejection. See Ex parte Stone, 1902 Dec. Comm'r Pat 434 (Comm'r Pat. 1902); Ex parte la Bore, 145 U.S.P.Q. 494 (Bd. App. 1964); 3 Lester Horowitz, Patent Office Rules and Practice § 312a[4] at 31-8 (2001). Because Chiron could not appeal

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the rejection of the proposed amendments, it cannot be said to have acquiesced in the patent examiner's rejection.

Therefore, the court adopts Magistrate Judge Hollows' finding that rejected amendments went to 'process' and 'product by process' claims "that did not affect the pure 'product' claims at issue in this litigation." (F & Rs at 29). The court agrees with Magistrate Judge Hollows' conclusion that the patent examiner thus "left intact the product claims ... as well as the examiner's prior analysis for allowance which did not limit the claims to hybridoma (murine) based antibodies." (Id. at 29-30). Thus, both the '561 patent and the priority applications define "monoclonal antibody" broadly to encompass non-hybridoma derived, non-murine antibody structures.

c. Schering/Kopykake

Genentech contends that if the court interprets the 1984 and 1985 applications to encompass humanized antibodies, it will in effect allow Chiron to claim an invention it did not make. Citing two recent federal circuit decisions, Schering Corp. v. Biogen, Inc., 222 F.3d 1347 (Fed. Cir. 2000), and Kopykake Enterprises, Inc. v. The Lucks Co., 264 F.3d 1377, 1383 (Fed. Cir. 2001), Genentech argues that the phrase "monoclonal antibody" cannot encompass humanized antibodies because humanized antibodies had not been discovered in 1984. n17 However, neither case cited by Genentech is on point.

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n17 Antibodies produced through recombinant technology were first discussed in 1984. A humanized antibody was developed in the late 1980s.

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Schering involved a patent for recombinant DNA molecules encoding what was originally described in the patent application as a "leucocyte interferon." A leucocyte is a white blood cell. Leucocytes produce interferons, which are molecules that help the body fight viral infections and tumors by immunizing healthy cells. At the time of the invention, scientists thought that leukocytes produced only one interferon having a specific amino-acid sequence. That interferon, along with its amino-acid sequence, was the subject of the claims in the initial application. Subsequently, it was discovered that leucocytes produce numerous interferons. Scientists therefore revised the nomenclature so that "leucocyte interferon" referred to the source of the interferon, while "IFN-alpha" was used to refer to a category of interferons produced by leucocytes. Due to these changes, the inventor amended the patent to substitute the term "leucocyte interferons" with the term "polypeptide of the IFN-alpha type."

Later, the owner of the patent tried to argue that the patent claimed all interferons falling within the IFN-alpha category. The court rejected this contention because "the patentee expressly limited the term 'IFN-alpha' to define the leucocyte interferon described in the initial application." Id. at 1353. The interferon described in the initial application was a single, specific polypeptide; therefore, the court reasoned, persons skilled in the art would not interpret the invention to claim the later-discovered interferons, which had different amino-acid sequences. "Because, at the time of the '901 application neither [the inventor] nor others skilled in the art knew of the existence of, let alone the identity of, the specific polypeptides now identified as subtypes of IFN-alpha, those subtypes cannot be within the scope of the claims." Id. at 1353. Thus, the term "did not and could not enlarge the scope of the patent to embrace technology arising after its filing." Id. The court concluded that "to grant broader coverage "would reward [the inventor] for inventions he did not make." Id. at 1354.

The similarities between this case and Schering are superficial. Like the inventor in Schering, Chiron defined the disputed term with reference to the way that term was initially used. However, as discussed at length above, in this case, neither the priority applications nor the PTO placed any express limitations on the meaning of the term. Unlike the claims in Schering, the claimed monoclonal antibodies of the priority applications are not directed toward molecules described by specific amino acid sequences. Rather, they are expressly defined by (1) their homogeneity, and (2) their ability to bind to specific human breast cancer antigens. These characteristics do not depend on whether the antigen is humanized or murine in structure (although at a molecular level murine and humanized antibodies are undoubtedly different in structure to a degree). Whereas the inventors in Schering were attempting to claim a completely different invention than what was claimed in the initial application, Chiron is claiming the same invention described in the priority applications: a homogenous preparation of antibodies capable of binding to human breast cancer antigens.

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The full relevance of Schering to this case cannot be appreciated without reference to the extrinsic evidence in the record. This evidence reveals that, unlike the meaning of "leucocyte interferon," the meaning of "monoclonal antibody" has not changed since 1984/1985. Chiron's expert, Dr. Lanier, testified that the understanding of "monoclonal antibody" to those skilled in the art is consistent with the definition in the '561 patent, and has been so since 1984/1985. Genentech's expert, Dr. Unkeless, agreed that the meaning of "monoclonal antibody" had not changed, but testified at the hearing that humanized and chimeric antibodies are not understood to be the same thing as monoclonal antibodies. This testimony was substantially impeached on cross examination by numerous references in the literature (including some of Genentech's own publications) in which humanized and chimeric antibodies were referred to as monoclonal antibodies. n18 In light of these references, Dr. Unkeless began to refer to his conclusions as his "personal view," rather than the objective understanding of one skilled in the art. Like Magistrate Judge Hollows, this court is persuaded by Dr. Lanier's testimony that one skilled in the art would consider any homogeneous population of antibodies to be monoclonal. (See F & R's at 35.) Thus, Chiron is not claiming a different invention than that disclosed in the priority applications; Chiron is merely claiming a later-developed embodiment of the same invention. n19 See Amgen Inc. v. Chugai Pharm. Co., 706 F. Supp. 94, 103-104 ("Although the development of recombinant technology provides the scientific and commercial communities with innovative techniques for manufacturing certain products and compositions, the patent protection of product claims has not changed."); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991)(upholding district court's finding that claims to purified blood clotting factor, Factor VIII: C, encompassed "any Factor VIII: C preparation, regardless of how produced, having the same material and functional characteristics as the plasma-derived preparation.").

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n18 Patents and publications referring to genetically engineered humanized antibodies as "monoclonal" date from the 1990s. Genentech suggests that therefore these publications have no bearing on the meaning of "monoclonal antibody" to one skilled on the art in 1984 and 1985. To the contrary, given the testimony of both experts that the meaning of "monoclonal antibody" has not changed, its use in 1990 must be consistent with its use in 1984 and 1985. Therefore, the term must have been understood broadly in 1984 and 1985 to mean nothing less than a homogeneous population of antibodies. Moreover, in 1984 and 1985, methods other than hybridoma methods were being used to produce monoclonal antibodies. (See Markman Tr. at 31:20- 32:3, testimony of Dr. Lanier regarding four ways of making monoclonal antibodies known in the art in 1984). By November of 1984, scientists had published articles about chimeric antibodies. (See Chiron Markman Ex. 5, Morrison article discussing chimeric antibodies). Thus, one skilled in the art in 1984 and 1985 would have understood a "homogenous population of antibodies" to include not just murine, hybridoma derived antibodies.

n19 It is true, as Genentech points out, that Dr. Lanier testified at the Markman hearing that the named inventors of the '561 patent did not invent humanized antibodies. (See Mar. 6, 2002 Markman Tr., at 77:3-10.) However, Dr. Lanier was not testifying as an expert in patent law, and the court will not impute a legal conclusion into his testimony.

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As Chiron points out, the Schering court did not state that it overruled a long history of Federal Circuit decisions holding that an applicant is not required to do the impossible and "describe in the specification every conceivable and possible future embodiment of his invention." See Rexnord, 274 F.3d at 1344; SRI Int'l v. Matsushita Elec. Corp., 775 F.3d 1107 at 1121 (Fed. Cir. 1985). Rather, Schering appears to carve out an exception to this rule in cases where the inventor has expressly limited the claims to particular embodiments known at the time of the invention.

For similar reasons, Kopykake, 264 F.3d 1377, is also inapposite. Kopykake involved a patent that claimed a method for "screen printing" decorations onto food stuffs. At issue was whether the term "screen printing" was broad enough to include ink jet printing. The court began its analysis by looking to the specification, which defined "screen printing" to include "any other conventional methods" of printing pictorial images onto food. Because it was not "conventional" at the time of the invention to use ink jet printing to print images on food, the court held that "screen printing" did not encompass ink jet printing. Id. at 1383-84. Thus, the court stated that "when a claim term understood to have a narrow meaning when the application is filed later acquires a broader definition, the literal scope of the term is limited to what it was understood to mean at the time of filing."Id.

In Kopykake, the fact that the specification was expressly limited by its terms to "conventional printing processes" carried dispositive weight. Because what is "conventional" necessarily changes over time, and because patents must be construed at

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the time of their filing, the Kopykake patent could only be understood by reference to conventional methods at the time of the patent's filing. In contrast, the priority applications in this case have no similar teaching that their claims are limited to what was "conventional" at the time. Moreover, as discussed above, the meaning of "monoclonal antibody" has not changed since those applications were filed. n20 Therefore, the 1984 and 1985 applications do not limit the broad definition of monoclonal antibody found in the '561 patent to homogeneous populations of antibodies having structures that can be made by murine hybridomas.

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n20 Magistrate Judge Hollows distinguished Kopykake on the grounds that it involved a process patent, while this case involves a product patent. The court is not convinced that Kopykake is distinguishable on these grounds, since its sister case, Schering, was a product case.

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Accordingly, the court adopts the definition of monoclonal antibody proposed by Magistrate Judge Hollows:
The term "monoclonal antibody" means an antibody composition having a homogeneous (essentially identical) antibody population. The term is not limited regarding the species or source of the antibody, nor is it limited by the manner in which it is made. For example, the term includes monoclonal antibodies produced by a methodology other than hybridoma which results in monoclonal antibodies no matter how subcategorized, e.g., hybrid, altered, chimeric, or humanized. The term includes variants that naturally arise during the production of monoclonal antibodies. The term includes whole immunoglobulins.
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One limitation that appears in all of the claims in the '561 patent is that the antibody must be a "monoclonal antibody." The court has construed the term "monoclonal antibody" to mean:

An antibody composition having a homogeneous (essentially identical) antibody population. The term is not limited regarding the species or source of the antibody, nor is it limited by the manner in which it is made. For example, the term includes monoclonal antibodies produced by a methodology other than hybridoma which results in monoclonal antibodies no matter how subcategorized, e.g., hybrid, altered, chimeric, or humanized. The term includes variants that naturally arise during the production of monoclonal antibodies. The term includes whole immunoglobulins.

(April 22, 2002 Order, at 38) (emphasis added).
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III. "Monomer"

Plaintiff argues that the term "monomer" should be construed to mean small repeating units found within an already formed polymer. 29 At the hearing, Plaintiff clarified that it is arguing that it has acted as its own lexicographer in this instance, giving the term a meaning with which it is not normally associated. To support this argument, Plaintiff points to various sources of intrinsic evidence. First, a claim limitation in claim 24 of patent '450 states that "B is a . . . polymer including . . . monomers" and "weights of . . . monomers comprise about 50 weight percent of . . . polymer B." 30 Second, a claim limitation in claim 41 of '450 states that "B is a . . . polymer comprising a plurality of monomers." 31 Third, the definition of "polymerization" in the '450 patent states that it is a process whereby monomers are connected to form a polymer. 32 Fourth, the specification in the '450 patent, which contains Figures 6a through 6d, illustrates what are called by Plaintiff monomers, only in reacted form, as they exist within a polymer. 33 Fifth, a narrative statement in the '450 patent states, with respect to a polymer used in all of Plaintiff's products, that the "polymer . . . is made up of . . . monomers." 34

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29 Docket No. 355, at 11.30 Id.31 Id. at 11-12.32 Id. at 12.33 Id. at 13-14.34 Id. at 15.

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Defendants argue that the proper construction of the term "monomers" is "small molecules capable of reacting with like or unlike molecules to form a polymer." 35 Defendants point to two sources of intrinsic evidence to support their proposed construction. First, like Plaintiff, Defendants point to the '450 patent specification which states that "monomers are connected in a chain-like fashion to form a polymer." 36 Second, during the prosecution history of the '450 patent, the USPTO patent examiner stated that Plaintiff-defined monomers were not actually monomers in the sense that that term should be used. 37 Defendants also point to one source of extrinsic evidence, the Standard Terminology Relating to Rubber, to support their claimed construction. 38

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35 Docket No. 356, at 10.36 Id.37 Id. at 10-11.38 Id. at 10.

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The Court believes that Plaintiff's intrinsic evidence, as well as Defendants' evidence from the prosecution history, support that Plaintiff acted as its own lexicographer with respect to this term. Collectively, the above mentioned limitations and specifications clearly state that Plaintiff referred to monomers as they existed within an already formed polymer, and not as unreacted molecules. This conclusion is supported by the fact that the USPTO, during the prosecution of the patent by Plaintiff, noted that the Plaintiff was using a rather unorthodox definition of the term. Additionally, the Court views Plaintiff's construction as correct because an adoption of Defendants' proposed definition, as it relates to this patent, would obviate Plaintiff's invention. 39

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39 See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996), overruled on other grounds by Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558 (Fed. Cir. 2000)("Indeed, a claim interpretation that would exclude the inventor's device is rarely the correct interpretation.").

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2. "Monomer"

The plaintiff proposes "a molecule that is capable of being chemically reacted with other molecules to form a larger molecule, such as a polymer." The defendants propose "a molecule that is capable of combining with like or unlike molecules to form a polymer. It is a repeating structure or unit within a polymer."

The Court construes "monomer" to mean "a molecule capable of being combined with other molecules to form a polymer."
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2. "more highly expressed"

The preamble to claims 1, 7, 13, and 19 claim a "method of designing a synthetic [Bt] gene to be more highly expressed in plants." Mycogen claims that this requires that the synthetic Bt gene created must produce a greater amount of messenger RNA, the material that translates the DNA coding sequence, than the native Bt gene. Monsanto, on the other hand, argues that this phrase refers to the amount of protein produced by the gene, not the amount of messenger RNA.

The specification of the '600 patent makes several references to the degree of expression. It offers a specific definition for

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the disputed phrase:

The term, designed to be highly expressed as used herein refers to a level of expression of a designed gene wherein the amount of its specific mRNA transcripts produced is sufficient to be quantified in Northern blots and, thus, represents a level of specific mRNA expressed corresponding to greater than or equal to approximately 0.001% of the poly(A)+mRNA. To date, natural Bt genes are transcribed at a level wherein the amount of specific mRNA produced is insufficient to be estimated using the Northern blot technique. However, in the present invention, transcription of a synthetic Bt gene designed to be highly expressed not only allows quantification of the specific mRNA transcripts produced but also results in enhanced expression of the translation product which is measured in insecticidal bioassays.

Col. 7, line 58 - col. 8, line 14. The specification goes on to explain that the invention is based on a desire to "increase[] expression of stabilized mRNA transcripts." Col. 8, lines 33-42.

Monsanto points to another portion of the specification, however, that explains that "expression refers to the transcription and translation of a structural gene to yield the encoded protein. " Col. 5, lines 1-2.

Dr. Messing states in his report that defining the phrase as referring to the amount of messenger RNA is "scientifically flawed." (Docket Item ("D.I.") 133, p.7). He claims that those skilled in the art would measure expression as the level of protein rather than the level of messenger RNA.

The Federal Circuit has held that "the specification acts as a dictionary when it expressly defines terms used in the claims." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). While claims are ordinarily given their "ordinary and customary meaning," there is an exception where "a special definition is clearly stated in the specification." Id.

The specification clearly offers a definition for the disputed phrase. The portion of the specification offered by Monsanto only provides a definition for the word "expressed." Thus, the court finds that the phrase "more highly expressed" refers to the level of messenger RNA produced by the synthetic gene.
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a. "morphologically identifiable chromosome or cell nucleus"

i. Claim Construction

The parties agree that "morphologically identifiable chromosome" refers to a chromosome that has consolidated in metaphase, and not a chromosome that is distributed throughout the nucleus during interphase. The parties also agree that the accused kit does not make use of morphologically identifiable chromosomes. The dispute centers on the meaning of "morphologically identifiable cell nucleus." Dako proposes that "morphologically identifiable . . . cell nucleus" should be construed to mean an "intact" nucleus-one that retains its entire complement of chromosomal DNA. Plaintiffs contend that "morphologically identifiable . . . cell nucleus" should be construed to mean "capable of being identified by its form and structure." Plaintiffs' proposed construction, unlike Dako's, does not require that the nucleus contain the full set of DNA.

In Regents of the University of California v. Oncor. 44 U.S.P.Q.2d 1321 (N.D. Cal. 1997) (Walker, J.), this court already construed the phrase in claim 1 of the 841 patent that is at issue here. The parties in Oncor disputed whether the phrase "a morphologically identifiable chromosome or cell nucleus" referred narrowly to a single target nucleus or chromosome, or more broadly to multiple target nuclei or chromosomes. 44 U.S.P.Q.2d at 1324. UC Regents, the plaintiff in Oncor, argued that the claimed process was limited to operation on a single nucleus because, among other reasons, the principal advantage of the invention was the ability to "detect unique DNA sequences on a single chromosome or cell nucleus." Id. The defendant in Oncor argued that the disputed phrase "merely clarifies that the target chromosomal DNA are present in intact chromosomes or cell nuclei, but does not limit the number of these structures." Id. After a review of the meaning of the word "a," the court reviewed the intrinsic record and concluded that the claim phrase was ambiguous. In light of the ambiguity, the court construed the phrase narrowly-against the drafter-to refer to a single chromosome or cell nucleus. Id. at 1326. n3

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n3 Dako also points to language earlier in the Oncor opinion, which explains the invention: "this process is known as in situ hybridization when it occurs on intact, or morphologically identifiable, chromosomes or cell nuclei." Id. at 1323. As plaintiffs point out, the quoted passage is not part of the court's claim construction. The quoted language suggests, at most, that the Oncor court assumed that "morphologically identifiable" meant "intact," without expressly so deciding.

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The doctrine of construing ambiguity "against" the drafter actually benefitted UC Regents considerably, as the court's narrow construction provided the basis for granting summary adjudication that the claimed invention was not anticipated or rendered obvious by prior art. The prior art processes in question, like the process described in the 841 patent, used unlabeled repetitive sequences to prevent labeled probes from binding to the repetitive sites on the target chromosomes. Id. at 1327. The prior art process, however, relied upon "frequency distribution tables revealing the sites where the hybridizations were most likely to occur" because the binding was not reliable enough to permit detection in a single cell. Id. As the prior art process did not "permit detection of target chromosomal DNA on a single chromosome or cell nucleus" as required by the court's construction of the claim language, the court concluded as a matter of law that the cited prior art did not invalidate the patent under 35 U.S.C. sections 102 or 103. Id. at 1328.

Plaintiffs' claim not to contest the court's construction in Oncor, but argue that the "single cell nucleus" required by the 841 patent need not be completely intact. n4 In support of their argument, plaintiffs rely on a portion of the specification, which states that optimum practice of the invention requires preparing the nucleus in a way that promotes easy hybridization, but "does not cause unacceptable loss of morphological detail." 841 patent at 11:66-67. According to plaintiffs, this language suggests that the nucleus need not be completely intact, but must only retain enough of its structure to remain recognizable. However, the portion of the specification cited by plaintiffs is not helpful in resolving the issue in this case, which is whether the nucleus must retain its full set of genetic material.

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n4 Nor could plaintiffs reasonably do so. Regardless of general concerns of uniformity in construction of the same claim terms in different lawsuits, see Markman, 517 U.S. at 391, plaintiffs would likely be judicially estopped from advocating a different construction in this case. The Oncor court accepted UC Regents' construction, and the narrow construction was necessary to the court's grant of summary adjudication of lack of anticipation and obviousness. See generally New Hampshire v. Maine, 532 U.S. 742, 750, 121 S. Ct. 1808, 149 L. Ed. 2d 968 (2001).

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The court's ruling in Oncor, on closer inspection, strongly favors Dako's proposed construction. According to the Oncor court, the claimed process must be able to "[detect] hybridized labeled nucleic acid containing unique segments" in a single "morphologically identifiable . . . cell nucleus." Id. at 17:20-22. For the claimed process to operate successfully on a single nucleus, that single nucleus must, at a minimum, contain the full set of chromosomal DNA. If the single cell does not contain the full set of DNA, there is some chance that the portion of the DNA containing the target region is not present. A failure to detect the target in a single incomplete set of DNA is therefore inconclusive.

Thus, combining the court's express construction of the overall claim phrase in Oncor with the implicit additional requirement that the cell nucleus contain the full complement of chromosomal DNA, the court construes the phrase "morphologically identifiable . . . cell nucleus" to refer to a single cell nucleus that contains the full complement of chromosomal DNA.

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3. Meaning of "moxifloxacin" to person of ordinary skill in the art

The court first addresses Teva's redefinition argument. Teva maintains that Alcon has redefined the "moxifloxacin" of claim

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1 of the '830 patent to represent the compound depicted in the specification. Indeed, it is well settled that "inventor's lexicography governs" when the specification reveals a special definition for a claim term that "differs from the meaning it would otherwise possess." Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc). Teva contends that, because the specification of the '830 patent provides an alternate meaning for the claim term "moxifloxacin" in the form of the depiction of a structurally different compound, the ordinary meaning of moxifloxacin has been displaced. (D.I. 108 at 2) Teva marshals support for its proffered meaning by pointing to a specific reference in the specification to a "new class of antibiotics." (PTX 5 at col. 1, ll. 18-19) Quinolones, Teva argues, were not a new class of antibiotics; therefore, the subject matter of the '830 patent must be directed to a different family of compounds. 22 (D.I. 108 at 4)

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22 Teva seeks, in the alternative, to distinguish its generic moxifloxacin product on grounds of stereochemistry. (D.I. 108 at 1) Specifically, Teva points to the absence of graphical indicia of stereochemistry in the '830 patent, and asserts that Alcon has claimed a racemic mixture, or a 50/50 mixture of enantiomers, instead of just the S,S enantiomer, which is the active ingredient in both VIGAMOX(R) and Teva's generic product.

This is unpersuasive. That a molecule has a known stereochemistry does not require the graphical depiction of such. As discussed previously, the names of certain compounds will themselves convey such information. Moxifloxacin is one of these names. Furthermore, even the failure to graphically indicate the stereochemistry of a molecule without known stereochemistry does not mandate an interpretation that it is a racemic mixture. Indeed, scientists have indicated racemic mixtures by including, next to the structures, conventions such as RAC, (racemic), DL or RS. (D.I. 100 at 87)

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The court rejects Teva's proposed construction. In order for a patentee to act as his own lexicographer, any redefinition must "appear with reasonable clarity, deliberateness, and precision before it can affect the claim." Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1355 (Fed. Cir. 2003) (internal quotation marks omitted); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998). The record before the court is replete with instances in which Teva's proposed construction is at odds with the specification of the '830 patent so as to cause an absence of the requisite clarity, deliberateness and precision. See id.

First, it is clear that the "new class of antibiotics" refers to the class of compounds depicted in the specification by formula (I). 23 Formula (I) depicts the general structure of quinolone compounds. (PTX 5 at col. 2, ll. 50-60) The specification further provides that "moxifloxacin is [the] most preferred" within the formula's class of compounds. (PTX 5 at col. 3, l. 36) Here, Teva's construction is precluded because formula (I) would not encompass a compound containing a 3-position methyl group 24 or, in the alternative, lacking a 3-position carboxylic acid. 25

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23 "The compositions and methods of the invention are based on the use of a new class of antibiotics." (PTX 5, at col. 1, ll. 18-19); "The antibiotics used in the compositions and methods of the present invention have the following formula: (I)." (Id. at col. 2, ll. 48-50); "Compositions of the present invention will contain one or more compounds of formula (I)." (Id. at col. 5, ll. 55-58)

24 Teva argues that the line at the 3-position of "moxifloxacin" in the '830 patent represents a methyl group. (D.I. 108 at 13) While one convention for drawing organic molecules includes the use of lines to indicate methyl groups, using "Me" to indicate such groups is another popular practice. (D.I. 100 at 70) Generally, conventions are consistent throughout the structure. (Id. at 70-71) Teva has declined to comment on the presence of both conventions in the '830 patent's depiction of moxifloxacin. This, of course, militates toward the finding that a typographical error in the form of an omission, and not a methyl group, exists at the 3-position of "moxifloxacin" in the '830 patent.

25 The 3-position may also exist as an ester, which is a pro-drug form of the active carboxylic fuctionality. (PTX 5 at col. 2, l. 48 - col. 3, l. 35)

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A conflict is also readily apparent between the portion of the specification immediately below the structure and the alleged alternative meaning of moxifloxacin. The '830 patent explains, "[f]urther details regarding the structure, preparation, and physical properties of [m]oxifloxacin and other compounds of formula (I) are provided in U.S. Pat. No. 5,607,942." (Id. at col. 3, ll. 49-50) As stated, supra, the '942 patent is directed to the disclosure of numerous quinolone compounds and specifically claims the structure which would later receive the INN moxifloxacin. The '942 patent offers absolutely no guidance regarding a structure with a 3-position methyl group. Thus, the incorporation by reference to the '942 patent buttresses the conclusion that the inventors of the '830 patent did not define a novel compound that did not belong to the quinolone class.

The specification, when viewed as a whole, does not clearly, deliberately or precisely indicate that the inventors have acted upon their lexicographic license to change the meaning of moxifloxacin. See Abbott Labs., 334 F.3d at 1355. The court, therefore, finds that the inventors of the '830 patent did not redefine moxifloxacin; rather, a typographical error exists at the 3-position of the structure.

This conclusion is supported by an examination of the prosecution history and all relevant extrinsic evidence. See Phillips, 415 F.3d at 1314. The file history of the '830 patent reveals a mutual understanding between the PTO and the inventors that moxifloxacin was a compound well known in the art. (PTX 6 at BA001-002828) Indeed, the examiner initially rejected the claims of the '797 application as anticipated by the '942 patent. (Id.) In traversing the rejection, Alcon explained that, while moxifloxacin was disclosed in the '942 patent, ophthalmic compositions containing moxifloxacin were not. (Id. at 2839) This comports with the testimony of Dr. Stroman, who explained that the patentees were claiming a novel ophthalmic composition containing the previously known moxifloxacin and not "the use of a brand new compound in an ophthalmic composition." (D.I. 102 at 618-19)

The international naming conventions of the WHO would likewise assist in conveying the ordinary and accustomed meaning of moxifloxacin. A person of ordinary skill in the art would understand from the nomenclature alone, specifically the suffix "-oxacin," that moxifloxacin belonged to the class of quinolone antibacterial compounds. (D.I. 100 at 61; id. at 77) A person of ordinary skill would also understand that, because the WHO had already proposed the name "moxifloxacin" as of the priority date, moxifloxacin designated a specific structure and stereochemistry. (Id. at 120-21)

In view of the specification, the claims, the prosecution history and all relevant extrinsic evidence, the court concludes that a person of ordinary skill in the art would understand "moxifloxacin," as used in claim 1 of the '830 patent, to indicate the quinolone compound of the same name, whose structure, stereochemistry and other properties were well known as of the priority date.

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V. "a multilayer pharmaceutical tablet" 21

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21 The term "a multilayer pharmaceutical tablet" is contained in claims 1-20 of the '183 patent.

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Plaintiff's Proposed Construction	Defendants' Proposed Construction
A pharmaceutical tablet with multiple distinct areas.	A pharmaceutical tablet with at least two separate, distinct layers; it does not include: tablets that are admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing

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multiple drug release pellets or
microparticles.

The'183 patent contains the term "a multilayer pharmaceutical tablet." The parties primarily dispute the meaning of the term "layer," and therefore the Court will focus its discussion on this claim term. Pozen acknowledges that the relevant claims are necessarily limited to a very specific tablet architecture. OPENING at 25. As recognized by both parties, the patentee disclaimed "admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles." OPENING, EXH. 10 at 6, EXAMINER AMENDMENT AND RESPONSE (April 5, 2007)). Despite this disclaimer, Pozen contends that a tablet "with multiple distinct areas" was not disclaimed and is supported by the specification. OPENING at 26. This proposed construction includes multiple layers and does not limit "a multilayer pharmaceutical tablet" to just two layers. Pozen points to the prosecution history where the examiner used the term "areas" when allowing the claim and argues that the examiner's usage supports a construction where "layer" need not have any specific geometric shape and can be describedas an "area." REPLY at 9; OPENING, EXH, 12 at 4, NOTICE OF ALLOWABILITY (Nov. 20, 2007).

Defendants argue that the plain language of the '183 patent clearly requires a tablet with two distinct layers of triptan and NSAID. Defendants point to language in the claims, the '183 patent specification, and the prosecution history to contend that the disclosed tablet architecture is geometrically limited. See RESPONSE at 23-25.

Given that Pozen does not appear to dispute the disclaimed tablet architectures identified in the second part of Defendants' proposed construction, the Court adopts these limitations but declines to include this language in its construction for the claim term. Thus, in light of the Patent Office's 35 U.S.C. § 103 rejection, the claimed tablet architecture does not encompass the following dosage forms: "admixtures; any dosage forms other than tablets; tablets in which one drug is in a core and surrounded by a layer or coating containing the second drug; and tablets containing multiple drug release pellets or microparticles." Pozen will be held to the patent applicants' description of the claimed invention as detailed in the specification language and prosecution history.See Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed. Cir. 2003) ("[T]he notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent.").

The relevant claim language makes clear that triptan is located in a "first layer" of the tablet and naproxen is located in a "second, separate layer." See '183 patent at 18:30-38 (claim 1). Importantly, there is no mention of "areas." The claims themselves repeatedly discuss "layers" and they appear to use the term in a manner that is consistent with the understanding that it refers to a physical structure rather than to an amount of a particular material. 22 A plain meaning interpretation is further supported by the '183 patent specification. For example, the '183 patent specification recites, "[t]he main characteristics of the dosage forms are that they are in the form of tablets in which the triptan and NSAID are maintained in separate distinct layers. . ." '183 patent at 3:47-49. Figure 1 in the specification further depicts the claimed invention as having a geometric layers without any depiction of "areas." Id. at 3:32-40, Fig. 1.

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22 The'183 patent claims consistently relate to the geometric relationship of additional structures termed "layers." For example, claim 6 defines a particular symmetrical juxtaposition of the two layers. '183 patent at 18:48-53 (claim 6). Claim 7 refers to a planar surface contact between the two layers. Id. at 54-56 (claim 7). Claim 8 refers to at least one additional layer separating a first and second. Id. at 61-63 (claim 10).

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Based on these intrinsic representations, the Court interprets "layer" to imply a variable geometric structure corresponding to one of the tablet's two therapeutic agents. Pozen's proposal appears to broaden the term in a manner that would not require any geometric boundaries. Having reviewed the patentee's exchange with the Examiner in response to the § 103 rejection, the Court concludes that the claims were eventually allowed after Pozen limited its tablet structure to at least two layers. To give effect to Pozen's proposed construction (i.e. "distinct areas") risks impermissible ambiguity, especially if Pozen accuses a tablet with a coating of one drug and a core of another. Even with Pozen's suggestion that the claims require a "side-by side-arrangement," thereis uncertainty as to whether the coated tablet type arrangement could be considered "distinct areas." 23 Therefore, in order to provide a construction that is most clearly supported by the intrinsic evidence, the

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Court finds that the proper construction of the term "a multilayer pharmaceutical tablet" is "a pharmaceutical tablet with at least two separate, distinct layers."

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23 Pozen's definition of "layer" potentially encompasses Panel B of Figure 1 of the '183 patent, a coated tablet type arrangement, which was explicitly disclaimed during prosecution. In the disavowed tablet structure, Pozen made clear that the '183 patent does not encompass a tablet in which one drug is in a core and surrounded by a layer or coating containing the second drug. See Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys. Inc., 242 F.3d 1337, 1340-42 (Fed. Cir. 2001).

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Multiplicity Multiple

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CLAIM LANGUAGE	CIEA'S PROPOSED CONSTRUCTION CONSTRUCTION	JACKSON'S PROPOSED
* * *		
"murine embryonic stem cell"	A mouse embryonic stem cell that is a stand-alone product and is purchased or licensed as a stand-alone product separate and apart from a mouse.	A mouse embryonic stem cell.
* * *		

2. "Murine Embryonic Stem Cell"

Both parties agree that the term "murine embryonic stem cell" refers to a mouse embryonic stem cell. As discussed above, the '173 Patent describes a process for creating a mouse with an IL-2R γ deficiency, which involves inserting transgenic mouse embryonic stem cells into a mass of normal embryonic stem cells and then implanting this mass into a female foster mouse. '173 Patent 4:47-49. CIEA explained in its briefs and at the claim construction hearing that with respect to thisterm, it does not seek a limitation that excludes all in vivo cells. CIEA seeks a construction that includes embryonic stem cells after they have been implanted in a mouse so long as they have not yet undergone cell differentiation. CIEA's Opp'n for the '173 Patent at 2 n.2. In other words, CIEA seeks to exclude in vivo cells only after they have undergone cell differentiation.

Once an embryonic stem cell has undergone cell differentiation, it becomes a specialized cell and is no longer referred to as an embryonic stem cell. Thus, by definition, an embryonic stem cell is a non-differentiated cell, and Jackson's proposed construction satisfies the limitation CIEA seeks (to exclude differentiated cells). To make this clear, the court adopts Jackson's construction but adds the clarification that all embryonic stem cells are non-differentiated cells.

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C. "N-ethyl-p-menthane-3-carboxamide"

Similarly to the prior term, the constructions proposed by the parties for this term do not differ significantly. Cadbury offers "a species of molecule from the genus of N-substituted-p-menthane carboxamides known by the trade name WS-3."

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Wrigley proposes "an N-substituted-p-menthane carboxamide commonly known as WS-3." I construe the term as "an N-substituted-p-menthane carboxamide known by the trade name WS-3."
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B. "N-substituted-p-menthane carboxamide"

Cadbury suggests that the term "N-substituted-p-menthane carboxamide." be construed as "a class of molecules with physiological cooling properties with the chemical formulas set forth in Claims 1 and 12 of the '893 Patent." Wrigley contends that I construe it as "a compound of the formula at column 4, lines 39-63; and which is at least 30% by weight of the combination with menthol." These two constructions are not much different. For reasons I will explain later, I decline to add the 30% limitation offered by Wrigley. In addition, I believe Cadbury's construction adds some unnecessary language. I construe "N-substituted-p-menthane carboxamide" to mean "a class of molecules with the chemical formulas set forth in Claims 1 and 12 of the '893 Patent."
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1. "NOD/Shi Mouse" and "NOD/Shi-scid Mouse"

The parties' proposed constructions are as follows:

CLAIM LANGUAGE	CIEA'S PROPOSED CONSTRUCTION	JACKSON'S PROPOSED CONSTRUCTION
"NOD/Shi mouse"	A NOD mouse, i.e. a mouse with a NOD strain background.	A non-obese diabetic mouse from the original NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories, or a mouse separated from that colony by less than 20 generations. NOD/Shi mice are commercially available from CLEA JAPAN, INC.
"mouse A" and "NOD/Shi-scid mouse"	A NOD/scid mouse, i.e. a mouse with a NOD/scid strain background.	A mouse strain produced by multiple backcross generations of a C.B.-17 scid mouse with a non-obese diabetic mouse from the original NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories, or with a mouse separated from that colony by less than 20 generations. NOD/Shi-scid mice are commercially available from CLEA JAPAN, INC.

The parties agree that "mouse A" refers to a "NOD/Shi-scid mouse" and thus the two terms should be construed identically. The parties also agree on the following: (1) "NOD" refers to non-obese diabetic mice;(2) "Shi" is a laboratory code for the Shionogi Research Laboratory in Japan; and (3) "scid" refers to the mouse's severe combined immunodeficiency background. What the parties dispute is the meaning and significance of "Shi" as used in "NOD/Shi mouse" and "NOD/Shi-scid mouse."

CIEA contends that the "Shi" in "NOD/Shi mouse" and "NOD/Shi-scid mouse" merely refers to the fact that the mouse can be traced back to the NOD/Shi colony (the NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories), regardless of the number of generations the mouse has been separated from that colony. Since all NOD mice

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can be traced back to the NOD/Shi colony, CIEA seeks a construction that equates "NOD/Shi mouse" with "NOD mouse" and equates "NOD/Shi-scid mouse" with "NOD-scid mouse." Jackson, on the other hand, argues that the "Shi" in "NOD/Shi mouse" and "NOD/Shi-scid mouse" refers to a specific mouse strain, including only mice that have not been separated from the NOD/Shi colony or have been separated from that colony by less than twenty generations. Under Jackson's proposed construction, NOD/Shi mice are a subset of NOD mice and are not the same. Likewise, NOD/Shi-scid mice areonly a subset of NOD-scid mice and are not identical.

Claim terms are generally construed to mean what a person of ordinary skill in the art at the time of the invention would have understood the terms to mean. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). When the meaning of a claim term, as understood by persons of ordinary skill in the art, is not immediately apparent, courts are to look to sources available to the public to determine what the disputed claim language means. Id. at 1314. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The court thus begins by looking at the words of the claims themselves. Vitronics Corp. v. Conceptronic, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The claims use the term "NOD/Shi mouse" rather than "NOD mouse." As explained above, adopting CIEA's proposed construction and interpreting "NOD/Shi mouse" to include any mouse that can be tracedback to the NOD/Shi colony would equate "NOD/Shi mouse" with "NOD mouse" and read "Shi" out of the claims. Because a "claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so," Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005), the claim language supports Jackson's contention that "NOD/Shi mouse" is not the same as "NOD mouse." See also Phillips, 415 F.3d at 1314 (claim language "steel baffles" "strongly implies that the term 'baffles' does not inherently mean objects made of steel").

The specification provides further evidence that "NOD/Shi mouse" does not include all NOD mice (and that "NOD/Shi-scid mouse" does not include all NOD-scid mice). Claims are read in light of the specification, which is the "single best guide to the meaning of the disputed term." Phillips, 415 F.3d at 1315. At times, the applicant uses the clearly generic term "NOD-scid" in the patent rather than "NOD/Shi-scid." See, e.g., '055 Patent Fig. 1; '055 Patent 9:4-7 ("Fig. 4 shows . . . a comparative test between the NOG mouse and a β 2 microglobulin deficient NOD-SCID mouse (NOD/LtSz-scid, β 2 m null mouse).") (emphasisadded). The fact that the patent uses both the term "NOD/Shi-scid" and the term "NOD-scid" suggests that the two phrases do not refer to the same mouse. Moreover, since the patent contains the clearly generic term "NOD-scid," the inventor clearly was aware of this generic term and could have chosen to use "NOD-scid" rather than "NOD/Shi-scid" when drafting the claims.

In addition, the specification states: "Above all, an NOD/Shi-scid mouse and an NOD/LtSz-scid mouse which exhibit multifunctional immunodeficiency . . . are the most noteworthy laboratory animals suitable for engraftment of heterologous cells." '055 Patent 1:32-38. By referring separately to NOD/Shi-scid mice and NOD/LtSz-scid mice, this statement acknowledges a difference between the two and provides further evidence that "NOD/Shi-scid" is not the same as "NOD-scid." After all, if "NOD/Shi-scid mouse" were construed to mean NOD-scid mouse, any reference to NOD/Shi-scid mice would include NOD/LtSz-scid mice. Under this construction, it would be redundant to say both NOD/Shi-scid mice and NOD/LtSz-scid mice are "the most noteworthy laboratory animals" since NOD/LtSz-scid mice would already be included as a subset of NOD/Shi-scid.1

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1 To illustrate this point, consider the following sentence: "Apples and oranges are the tastiest foods available." This sentence makes sense because apples and oranges are two distinct types of food. One would not say, "Fruit and oranges are the tastiest foods available" because the fact that oranges are a subset of fruit makes the phrase "and oranges" redundant.

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The language in the prosecution history upon which CIEA relies demonstrates that the patentee recognized (and that a person of ordinary skill in the art would have recognized) that the term "NOD/Shi-scid mouse" did not include all NOD-scid mice. For example, the patentee wrote:

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As shown in Figure 1 and the description[] in the section "Similarity of multiple immunological impairments between NOD-Shi-scid and Nod/LtSz-scid mice,["] the immunological properties of these two mice were the same. It was known that the NOD-LtSz-scid mice were a sub-strain[] of NOD-Shi-scid mice. It can, therefore, be said that the NOD-LtSz-scid mice are substantially the same strain [as] the NOD-Shi-scid mice.

Decl. of Ronald M. Daignault in support of CIEA's Opening Cl. Construction Br. ("Daignault Decl.") Ex. 2 (CIEA-0003199). Though this passagestresses the similarities in the immunological properties of NOD/Shi-scid mice and NOD/LtSz-scid mice, by comparing the two, it implicitly acknowledges that the terms "NOD/Shi-scid" and "NOD/LtSz-scid" refer to distinct types of mice. After all, if "NOD/Shi-scid mouse" were construed to include all NOD-scid mice, this passage would be nonsensical. One cannot compare the immunological properties between NOD-scid mice and NOD/LtSz-scid mice because NOD/LtSz-scid mice are a subset of NOD-scid mice. Nor does it make any sense to say that NOD/LtSz-scid mice are substantially the same strain as NOD-scid mice. 2 As discussed above, the language of the claims themselves, the specification, and the prosecution history make clear that "NOD/Shi mouse" does not include all NOD mice (and that "NOD/Shi-scid mouse" does not include all NOD-scid mouse). Unfortunately, these sources do not provide the court with much information as to what mice are included within the meaning of the disputed terms. However, the patent cites and incorporates various scientific publications which shed some light on the meaning of the disputed terms. Prior art cited in the patent constitute intrinsic evidence to be consideredduring claim construction. Arthur A. Collins, Inc. v. Northern Telecom Ltd., 216 F.3d 1042, 1045 (Fed Cir. 2000). "When prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning." Id.

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2 To continue the earlier fruit example, this would be like saying oranges are substantially the same as fruit.

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The scientific publications cited in the '055 Patent provide additional confirmation that "NOD/Shi mouse" is not equivalent to "NOD mouse" (and that "NOD/Shi-scid mouse" is not equivalent to "NOD-scid mouse") and provide insight as to what mice are included within the scope of the disputed terms. For example, the patent cites "NOD/SCID/γ c<null> mouse: an excellent recipient mouse model for engraftment of human cells," an article in BLOOD that was authored by six of the inventors. This article uses the term "NOD" (not "NOD/Shi") when referring to all NOD mice and compares NOD/Shi-scid mice to NOD/LtSz-scid mice. Decl. of Chelsea A. Loughran in support ofJackson's Responsive Cl. Construction Br. for the '055 Patent ("Loughran Decl.") Ex. G. It also states: "NOD/Shi with different genetic backgrounds used for the generation of NOD/Shi-scid mouse is an original strain maintained by Dr. Makino." Id. (emphasis added). This indicates not only that a person of ordinary skill in the art would understand that "NOD/Shi mouse" refers to mice from the original NOD mouse colony created by Dr. Susumu Makino (and does not refer to all substrains of mice that descended from this colony), but also that the patentee intended to adopt this meaning. Arthur A. Collins, Inc., 216 F.3d at 1045.

Though courts are to look first to intrinsic evidence, they may also rely on expert testimony when it establishes that a term has a particular meaning in the pertinent field, so long as it does not contradict the claim language itself, the specification, and the prosecution history. Phillips, 415 F.3d at 1318. Extrinsic evidence, such as expert testimony, is generally less reliable than intrinsic evidence. Nonetheless, "because extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinaryskill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence." Id. at 1319. The court therefore considers the expert testimony of Dr. Janan T. Eppig in determining what a person of ordinary skill in the art would understand the disputed claim terms to mean.

Dr. Eppig, the chairperson of the International Committee on Standardized Genetic Nomenclature in Mice, testified regarding inbred mouse strains, mouse substrains, and rules for mouse nomenclature. In order to reliably reproduce experiments involving mice, researchers strive to maintain populations of mice with a homogenous genetic makeup. Decl. of Dr. Janan T. Eppig in support of Jackson's Proposed Claim Construction ("Eppig Decl.") P 27. To create a mice colony with a homogenous genetic makeup, researchers breed mice with siblings for twenty or more consecutive generations, creating what is known as an inbred mouse strain. Id. at PP 28-29. If mice from the inbred colony are reproductively separated from the colony for more than twenty generations, it is likely that there will be genetic drift, meaning that the

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genetic makeup of the mice inthe new colony will no longer be the same as the genetic makeup of mice in the original inbred colony. Id. at P 30. The mice in the new colony constitute a new mouse substrain, and the rules for mouse nomenclature require re-designating the new colony as such. Id.

In light of the rules of mouse nomenclature, a person of ordinary skill in the art would understand "NOD/Shi mouse" to refer to a mouse that had not been reproductively separated from the inbred NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories or had been separated by twenty or fewer generations. Once mice have been reproductively separated from this inbred colony for more than twenty generations, they would constitute a new mouse substrain with a distinct name, such as the NOD/LtSz substrain. Id. at P 31.

Extrinsic evidence, such as expert testimony, cannot be used to contradict intrinsic evidence, including the specification. Vitronics, 90 F.3d at 1584. The specification clearly states that a NOD/Shi mouse is "commercially available from CLEA JAPAN, INC." '055 Patent 4:29-30. Consequently, the court may not construe the disputed terms using extrinsic evidence about the rules of mouse nomenclatureif these rules contradict the specification's express declaration that NOD/Shi mice are commercially available from CLEA JAPAN, INC. Because CLEA JAPAN, INC. ("CLEA") is the commercial arm of CIEA, CIEA possesses information regarding what kinds of mice were commercially available from CLEA at the time of the invention. However, CIEA has failed to come forth with any evidence that NOD/Shi mice (construed according to the rules of mouse nomenclature) were not commercially available from CLEA at the time of the invention.

If "NOD/Shi mouse" were construed according to the rules of mouse nomenclature, there are three possible scenarios under which NOD/Shi mice could have been commercially available from CLEA at the time of the invention: (1) the entire colony of NOD/Shi mice had been moved from the Shionogi Laboratory to CLEA; (2) the CLEA colony was periodically repopulated with NOD/Shi mice from Shionogi Laboratory; or (3) at the time of the invention, there had not yet been more than twenty generations of reproductive separation between the NOD/Shi mice that were moved to CLEA and the colony of NOD/Shi mice at Shionogi Laboratory. In the absence of any evidence to the contrary, anyof these scenarios are possible, though only the second scenario seems particularly plausible. Jackson presented evidence that CIEA has, in the past, entered into at least one license agreement that required replenishing of its mice colony once every ten generations. 3 Thus, Jackson has shown how NOD/Shi mice (construed according to the rules of mouse nomenclature) could have been commercially available from CLEA, as required by the patent specification, and CIEA has failed to provide any evidence to the contrary. Therefore, the court finds no basis for excluding Dr. Eppig's testimony regarding the rules for mouse nomenclature from its consideration when construing the disputed terms.

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3 CIEA objected to the admission of this license agreement because Jackson had not produced it before the hearing. Jackson represented that it just recently obtained the document. Based upon that representation and the fact that it is a CIEA agreement, the court has considered it.

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The issues faced in construing "NOD/Shi mouse" and "NOD/Shi-scid mouse" are similar to those addressed in Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339 (Fed. Cir. 2003). In Boehringer, the FederalCircuit considered a patent that was directed to a process for growing and isolating a pig virus known as PRRS. 320 F.3d at 1343. The Boehringer scientists who invented the method had deposited a sample of the virus with the American Type Culture Collection (ATCC), which had assigned it deposit number VR-2332. Id. The patent claimed "[a] method of growing and isolating swine infertility and respiratory syndrome virus, ATCC-VR2332." Id. at 1344. The district court rejected Boehringer's argument that "ATCC-VR2332" should be construed as a generic term for all PRRS viruses and held that it was limited to the specific strain of PRRS deposited with the ATCC. Id. at 1347-48. The Federal Circuit upheld the district court's claim construction because:

Boehringer chose to claim its virus using the term "ATCC-VR2332," a term on its face referring to a particular ATCC deposit. Boehringer did not use the broader term "PRRS virus," nor did Boehringer attempt to claim the virus in terms of the more general functional and structural properties disclosed by the specification. Boehringer did not choose to define the term "ATCC-VR2332" in the specification, nor did Boehringer state that ATCC-VR2332 wasa "generic" or "prototype" virus, nor did Boehringer assert that viruses related to but not identical to the isolated strain were within the scope of the

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invention. These choices must be held against it.

Id. at 1348. Similarly, the inventors in this case chose to draft claims using the term "NOD/Shi mouse" and "NOD/Shi-scid mouse," rather than using the broader terms "NOD mouse" and "NOD-scid mouse." Though CIEA now points to similarities in the genetic background and immunological properties of NOD/Shi-scid mice and NOD/LtSz-scid mice, the inventors did not claim the mouse in terms of more general genetic or immunological properties. The inventors did not choose to define the disputed terms in the specification, nor did they state that "NOD/Shi mouse" and "NOD/Shi-scid mouse" were generic terms referring to NOD mice and NOD-scid mice, nor did they assert that mice related to but not identical to the identified mouse substrain were within the scope of the invention. Accordingly, these choices must be held against the inventors.

The court therefore construes "NOD/Shi mouse" to mean a non-obese diabetic mouse that: (1) has not been reproductively separated from the NOD mouse colony createdby Dr. Susumu Makino at Shionogi Research Laboratories or (2) has been reproductively separated from that colony by 20 or fewer generations. 4 The court declines to include the statement that "NOD/Shi mice are commercially available from CLEA JAPAN, INC." in the construction because the court finds that including such a statement would likely be more confusing than clarifying. Though the specification states that NOD/Shi mice are commercially available from CLEA, this does not mean that NOD/Shi mice must still be commercially available from CLEA today; rather it only requires that NOD/Shi mice were commercially available from CLEA at the time of the invention.

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4 Though Jackson's proposed construction uses "less than 20 generations" of separation, Dr. Eppig's expert testimony regarding the rules of mouse nomenclature establishes that substrain designation occurs when there is more than 20 generations of separation. Eppig Decl. P 30. For this reason, the court adopts a construction based on 20 or fewer generations of separation, rather than less than 20 generations of separation.

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1. A nanophase diamond film

The plaintiffs contend that "nanophase diamond film" should be construed to mean "a film having some of the physical characteristics of diamond." The defendant urges, however, that nanophase diamond film is "a non-columnar diamond-like carbon film having at least 75% sp<3> bonded carbon." The term "nanophase diamond" is expressly defined in the specification of the '797 patent. "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Accordingly, the court construes "nanophase diamond film" to mean "a film having nanometer-scale nodules of diamond-bonded carbon displaying characteristics similar to that of diamond." See '797 patent, col. 7, ll. 19-22.

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* * *

The '499 and '458 patents contain the term "said LA-NSAID is naproxen." The parties' primary dispute as to this term is whether the term "naproxen" should be construed to include all pharmaceutically acceptable forms of the active agent, including its free acid forms, isoforms, and salt forms. As noted in the above chart, Pozen proposes alternate constructions for "naproxen" based on where the claim term appears. The discussion herein will focuson contexts where Pozen argues for the broadest possible construction. 18 See OPENING at 20-22.

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18 For Term Number 81, Pozen proposes "(S)-6-methoxy- [alpha] -methyl-2- naphthaleneacetic acid in any pharmaceutically acceptable form," but its briefing as to this term focuses on a proposed construction that includes "any pharmaceutically acceptable salt form of the active moiety naproxen, including the free acid form of naproxen and naproxen sodium." OPENING at 20 (emphasis added).

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Pozen contends that "naproxen" would be understood to be a generic designation for (S)-6-methoxy- [alpha] -methyl-2- naphthaleneacetic acid and its pharmaceutically acceptable forms because it was known at the time of the invention that naproxen and naproxen sodium contain the same active moiety. Id. at 20-22 (citing '458 patent at 8:62-66).

Defendants contend that the plain language of the claims supports a construction of "naproxen" that interprets naproxen and its salts to be distinct chemical entities with different properties. Defendants point out that the specification and claim language successfully distinguishes between naproxen and its sodium salt, thus inferring that the general use of "naproxen" excludesits salt forms. RESPONSE at 17-18. For example, Defendants identify distinguishing specification language discussing different "cautionary guideline[s]" concerning different maximum dosages of naproxen and naproxen sodium. Id. at 18 (citing '499 patent at 9:30-41 and '458 patent at 9:24-26). Similarly, under a theory of claim differentiation, Defendants point out that in claim 13 of the '499 patent, Pozen specifically claimed "naproxen sodium" (i.e. the pharmaceutically acceptable salt form) as a separate alternative to the acid form disclosed in claims 15 of the '499 patent and claims 12, 26, and 29 of the '458 patent. RESPONSE at 16.

A review of the claims, especially in light of the specification, suggests that there is ambiguity as to whether "naproxen" was intended to encompass other forms of the active moiety. The structure of some of the claims seems to support the premise that naproxen was used in a generic sense to include any pharmaceutically acceptable form, but other claims and language in the specifications can be read to identify distinct forms of naproxen acid and naproxen salt. Defendants' claim differentiation arguments are not determinative because despite the apparentinconsistency in the claims, Pozen offers an alternative understanding of the claims that supports its position. Pozen explains the inconsistent use of "naproxen" by arguing that the scope of the claim term is premised on whether it is an independent or dependent claim. As illustrated in the briefing, independent claim 23 of the '458 patent recites: "[t]he method or composition of claim 22, wherein said LA-NSAID is naproxen." '458 patent at 14:4-5 (emphasis added). As stated, claim 23 presumably refers to "naproxen" in a generic sense, but claim 24-- which is dependent on claim 23-- specifically refers to "said naproxen" in a salt form. Applying principles requiring that a dependent claim incorporate by reference all the limitations of the claim to which it refers, Pozen counters that claim 24 should be given the broader scope present in claim 23. OPENING at 20-21 (citing 35 U.S.C. § 112 P 4 (2008) ("A Claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.")). Therefore, weighing the claim interpretation principles presented by both parties, the Court finds that the claims fail to convey a clear meaning of the term.

Turningnext to the specification, the controlling inquiry is what one skilled in the art of these patents would understand the chemical composition of "naproxen" to be in light of the claims and specification around the time of the invention. Phillips, 415 F.3d at 1313 (citing Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998)). A review of the specification again makes clear that "naproxen" is used both in a generic sense and as a distinct salt form depending on which claim is being described and whether the specification is describing the preferred embodiment. 19 The patentee's failure to choose a consistent meaning dictates that "naproxen" should be accorded the ordinary meaning ascertainable to one of ordinary skill in the art. See Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1990). At the hearing, both parties acknowledged that such a generally accepted meaning for "naproxen" is (S)-6-methoxy- [alpha] -methyl-2- naphthaleneacetic acid, as it is identified in the 1989 edition of the Merck Index. 20 Where, as here, there is some ambiguity that could result from intrinsic review, technical dictionary definitions can be usefulguideposts and indicative as to how one skilled in the art would understand a technical term. Phillips, 415 F.3d at 1322-24; Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("Extrinsic evidence may also be considered, if needed, to assist in determining the meaning or scope of technical terms in the claims.").

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19 For example, all of the '499 and '458 patent examples are directed to a composition comprising sumatriptan succinate and naproxen sodium- the salt form of naproxen. E.g., '458 patent at 10:3-15.

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20 The Merck Index is a reference for chemists that is akin to a dictionary encyclopedia of chemical compounds. This technical dictionary contains a list of almost all known chemicals and their physical properties. See The Merck Index, 11th ed. at 1014 (1989).

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Importantly, the Merck Index has a definition for "naproxen" that lists the chemistry of the acid, but is also lists two salts (including the sodium salt) under the same entry. This extrinsic evidence, which would be available to one of ordinary skill at the time of the invention, supports Pozen's position that the term "naproxen" should be understood to include pharmaceutically acceptable salt forms. Afair reading of the Merck Index, however, does not include "all pharmaceutically acceptable forms of the active moiety naproxen." Therefore, this extrinsic definition, coupled with the lack of a broadened definition in the specification, supports that the acid and its salts are both correctly referred to as "naproxen," but the present record does not support extending the meaning of the claim term to include every possible derivative of the acid. Accordingly, the Court finds that the proper construction of the term "said LA-NSAID is naproxen," is "said LA-NSAID is (S)-6-methoxy- [alpha] -methyl-2- naphthaleneacetic acid or a pharmaceutically acceptable salt thereof."
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Nebulized and nebulizing

Claim 16 of the '990 patent refers to an apparatus for adding a mass flow of nebulized water to a gas turbine and a means for nebulizing water. Nebulize is a common term, the definition of which may be found by reference to dictionaries. 4 Grant & Hackh's Chemical Dictionary (X-14) defines nebulization as "the transformation of a liquid into a fine spray." Webster's Collegiate Dictionary (X-16) defines "nebulize" as "to reduce to a fine spray." At the hearing, Plaintiff agreed that the spray obtained by nebulizing water could have a wide range of water droplet sizes. Accordingly, pursuant to the parties' stipulation, the Court adopts the following definition of nebulize:

To reduce a liquid to a fine spray having a wide range of particle sizes.
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E. "Human in Need of Such Treatment"

Novartis proposes the following construction of the term "human in need of such treatment" as used in Claim 15:

A human prone to develop PHN and for whom there is a recognized need for the prophylactic treatment of PHN.

(Novartis's Resp. Br., at 5.) Roxane, on the other hand, defines "human in need of such treatment" as used in Claim15 to mean:

A human diagnosed with PHN.

(Id.) The only difference between these proposed constructions and those in the previous section is that Claim 15 is limited to prophylactic treatment, which this Court has interpreted, in the context of the '581 patent, to mean treatment involving preventative measures administered before PHN manifests itself. Thus, because a diagnosis is not possible before PHN manifests itself, this term in Claim 15 cannot reasonably include humans diagnosed with PHN as proposed by Roxane. Therefore, for this reason and those discussed in the previous section, the Court construes the term "human in need of such treatment" in Claim 15 to mean: A human with acute herpes zoster who is at high risk of developing PHN, for example, the elderly.
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D. "Mammal in Need of Such Treatment"

Novartis proposes the following construction of the term "mammal in need of such treatment" as used in Claim 1:

A mammal prone to develop PHN and for whom there is a recognized need for the treatment of PHN.

(Novartis's Resp. Br., at 4.) Roxane, on the other hand, defines "mammal in need of such treatment" as used in Claim 1 to mean:

A mammal diagnosed with PHN.

(Id.) Roxane argues that the "need for treatment of PHN can only be deemed necessary when a medical professional has diagnosed the subject as having PHN." (Roxane's Br., at 21.) It is undisputed that PHN cannot be diagnosedduring acute herpes zoster since PHN, as defined above, only occurs if pain persists or occurs after healing. Dr. Gilden, Roxane's expert, agreed. (Gilden Dep. Tr. 67:11-13.) Additionally, Claims 2 and 3 of the '581 patent describe methods "wherein the treatment is within 72 [and 48] hours of [herpes zoster] rash onset," respectively. (581 patent, Col. 15:28-31.) In the summary of the invention section, the specification also states that "[i]t has now been discovered that the above compounds are particularly effective in reducing the duration of PHN when given to the patient during the acute infection." (Id. at 2:8-10 (emphasis added).) Indeed, the specification states that "[t]he treatment is preferably carried out as soon as possible after symptoms appear usually within 72 hours, preferably within 48 hours of rash onset." (Id. at 3:45-47.) Thus, if "in need of such treatment" is construed as proposed by Roxane, the construction would exclude two claims and the preferred method of treatment identified in the specification. Such a construction is presumptively incorrect. See OSRAM GmbH v. ITC, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

Roxane argues that "the Examiner plainly understoodthat the independent claims require 'the administration of famciclovir or penciclovir . . . after healing of the zoster legion." (Roxane's Responsive Claim Constr. Br. [hereinafter "Roxane's resp. Br."], at 9 n.3.) This redacted quote is misleading. The Examiner stated, in full, that "Gheeraert does not teach or suggest the administration of famciclovir or penciclovir in methods for the treatment of postherpetic neuralgia after healing of the zoster lesion or for the prophylactic treatment of postherpetic neuralgia." (Gilden Decl., Ex. 16, at ROX00050348.) The Examiner did not say that the administration of the drug was after healing. Additionally, the Examiner noted that the prior art did not include prophylactic treatment of PHN, which occurs prior to manifestation of the disease. Dr. Gilden, Roxane's expert, also testified that "Claim 1 doesn't require a diagnosis of postherpetic neuralgia like in the ordinary sense." (Gilden Dep. Tr. 120:10-20.)

Additionally, neither case relied on by Roxane, Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (Fed. Cir. 2003), or Schering Corp. v. Glenmark Pharm. Inc., No. 07-1334, 2008 U.S. Dist. LEXIS 69880, 2008 WL 4307189 (D.N.J. Sept. 16, 2008), supports Roxane's construction.First, regardless of the construction given to a term in other cases, the term in this case must be evaluated in the context of the patent at issue here. Second, neither case stands for the proposition that the term "in need of" requires a diagnosis. These cases construed "in need of" to require only that the need be "recognized and appreciated," Jansen, 342 F.3d at 1334, or that there be "an appreciation for the purpose of the drug," Schering, 2008 U.S. Dist. LEXIS 69880, 2008 WL 4307189, at *9. Thus, the Court does not find that the interpretations in these cases supports Roxane's proposed construction.

Roxane also argues that its construction comports with good medical practice because "a physician cannot prescribe a drug for a particular condition unless he or she first makes a diagnosis that the patient actually has the condition." (Roxane's Resp. Br., at 10.) At the June 10 hearing, the Court pressed Roxane's counsel on this point, and its counsel would not concede that it was appropriate to prescribe a medication where a patient did not presently have the actual condition sought to be addressed by the treatment—i.e., the patient had not been diagnosed with the condition. (See Hearing Tr. 93:25-99:25.) Asidefrom the fact that the basis for its construction centers on extrinsic evidence considered without reference to the patent, the Court finds this argument to be contrary to common sense. For example, if a person is bitten by a wild raccoon, and the animal is not caught, doctors may give rabies shots to the person even though the person does not presently have rabies because that person would be considered at risk of developing rabies. Finally, while the Court understands Roxane's

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argument that the '581 patent must be differentiated from prior art, it disagrees that a definition may be adopted that is directly contrary to the intrinsic evidence. For these reasons, the Court rejects Roxane's proposed construction. This does not mean, however, that the Court agrees that Novartis's construction as proposed is appropriate.

Novartis agrees that the need for treatment must be recognized and appreciated. It argues that its definition, which requires that the mammal be one who is "prone to develop PHN and for whom there is a recognized need for the treatment," adequately limits Claim 1 to those mammals with a recognized need for treatment for PHN, as treatment has been defined above. Roxane,on the other hand, argues that the "prone to develop" limitation was "fashioned from whole cloth" and is inappropriately indefinite. (Roxane's Resp. Br., at 11-12.) Novartis argues that the term prone is not indefinite. Novartis argues that, if a patient "fall[s] into at least one high-risk group, a [person of ordinary skill in the art] would consider [the] patient[] prone to develop PHN and would recognize [him] as 'in need' of treatment for PHN." (Novartis's Resp. Br., 27.) In response, Roxane points out that the only risk factor addressed in the specification is age. The Court agrees that age is mentioned numerous times in the specification as a risk factor for developing PHN. (See, e.g., 581 Patent, Col. 1:65-67 ("Although rare in patients under 50 years of age, the frequency of PHN rises steeply with increasing age."); id. at 10:9-11 ("those patients most at risk of developing postherpetic neuralgia (eg, elderly)").) But, it disagrees that a claim must be narrowed in scope to only those factors explicitly identified in the specification. See Silicon Graphics, Inc. v. ATI Techs., Inc, 607 F.3d 784, 792 (Fed. Cir. 2010) (A construing court's reliance on the specification must notgo so far as to import limitations into claims from examples or embodiments appearing only in a patent's written description . . . unless the specification makes clear that the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.") (internal quotations omitted); Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("[E]ven where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.").

Given that the term "in need of" was included in Claim 1 and that the specification precludes a finding that a diagnosis is always required, the Court finds that the intrinsic evidence implies that there must be some way, other than diagnosis, for the need to be recognized. The specification does discuss risk factors, albeit focusing on age. The Court agrees with Novartis that the presence of high risk factors in a mammal with acute herpes zoster sufficiently limits Claim 1 to those mammals with a recognized and appreciated need, and that this constructionis consistent with the intrinsic evidence. A person of skill in the art in 1993 could recognize high risk factors for PHN. (See, e.g., Whitley Decl., Ex. B, at ROX00050270 (identifying age and extensive rash as risk factors) & Ex. D, at 748 (identifying age and severe initial neuralgia as risk factors).2) In other words, Novartis argues, and this Court agrees, that a mammal at high risk objectively could be considered at high risk to develop PHN and, thus, could be recognized by a person of skill in the art as being in need of treatment for PHN. This construction also is consistent with, but sufficiently differentiated from, dependent claims 5, 6, and 7 in the '581 patent, which address only age.

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2 Roxane argues that some of these extrinsic materials cannot be used to support Novartis's construction because the authors used a different temporal definition of PHN than the one used by Novartis. (See Roxane's Resp. Br., at 12 n.5.) But, someone at risk of developing PHN four weeks after rash healing is still at risk for developing PHN using Novartis's definition. Thus, the Court finds Roxane's argument unpersuasive. Factors other than age were identified as risk factors for developing PHNprior to 1993.

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But, the Court also finds that Novartis's proposed construction is more limited than appropriate, given the intrinsic evidence, in that Novartis's proposed definition requires proneness. Although the patent focuses on treatment methods administered during an acute herpes zoster outbreak, as noted above, Claim 1 is not limited to such treatments. It is possible, under a reasonable interpretation of Claim 1, that treatment could occur after PHN has manifested itself. In fact, Claim 15 is limited to prophylactic treatment, implying that Claim 1 is not of such a limited scope. Therefore, the Court construes the term "mammal in need of such treatment" in Claim 1 to mean: A mammal with acute herpes zoster who is at high risk of developing PHN, for example, the elderly, or a mammal who has been diagnosed with PHN.

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IV.

The parties agree that the term "no substantial increase in said internal core temperature" in claim 7 of the '299 Patent requires construction. Dkt. # 56. The Court hereby construes thisclaim as follows:

1. The term "no substantial increase in said internal core temperature" in claim 7 of the '299 Patent 4 is construed as: "an increase in internal core temperature of no more than 1[degrees] F." The parties agreed upon this construction. Dkt. # 56.

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4 The parties did not seek construction of the term "substantially no increase in said internal core temperature" claims 21 and 32 of the '448 Patent. Dkt. # 56.

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3. "No Traces of Toxic Chemicals"

In the jointly submitted claim construction stipulation, the parties set forth their differing positions regarding "no traces of toxic chemicals" as follows:

OmniActive's position: "No traces of toxic chemicals" means no detectable amounts of any toxic chemicals as measured by methods known to persons of ordinary skill in the art at the time the patent application was filed in 1994.

Kemin's position: "No traces of toxic chemicals" means no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994 by a person of ordinary skill in the art who was preparing a product suitable for human consumption.

(Doc. # 244 at 2).

The parties have come a long way toward reaching an agreement concerning what "no traces of toxic chemicals" means. Originally, Defendants asserted that "no traces of toxic chemicals" meant exactly that - no traces of any toxic chemicals using a state-of-the-art method of detection available in 2008. At this point in the litigation, Defendants have retreated from this argument.

The parties appear to agree that the level of detection for toxic chemicals, including hexane, should be measured by the science that was available to a person of ordinary skill in the art in 1994. 6 The Court agrees with the parties on this point.

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6 The parties take varying positions throughout their filings concerning whether the applicable year is 1993 or, rather, 1994. For instance, in Plaintiffs' claim construction brief filed on February 17, 2009, Plaintiffs focus on 1993. (Doc. # 181 at 19). In the parties' stipulation on claim construction, the parties agree that 1994 is the relevant year. (Doc. # 244 at 2). The Court determines that 1994 is the applicable year because that is the year that the parties agreed to in the most recent, stipulated filing. (Doc. # 244).

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The Federal Circuit explained in SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1338 (Fed. Cir. 2005) (en

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banc), "The court [must] place the claim language in its proper technological and temporal context." It is not appropriate to apply a level of detection threshold considered to be state of the art in 2009, to an invention formed in 1994. San Huan New Materials High Tech, Inc. v. U.S. Int'l Trade Comm'n, 161 F.3d 1347 (Fed. Cir. 1998). See also Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) ("We have made clear . . . that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application").

However, the Court must delve deeper into the analysis. Looking closely at the parties' respective positions, the Court determines that there are three issues within the term "no traces of toxic chemicals" that the parties continue to dispute: (1) whether the Court must take into consideration what is "suitable for human consumption," (2) whether an ordinary person would either "use" or "know" of the method of detection for toxic chemicals, and (3) what method of detection applies.

i. Suitable for Human Consumption

Defendants argue that what is "suitable for human consumption" does not factor into the determination of what "no traces of toxic chemicals" means.

In Plaintiffs' initial brief and reply brief on claim construction (Doc. # 161, 181), Plaintiffs never once requested that "suitable for human consumption" be added into the definition of "no traces of toxic chemicals." Instead, Plaintiffs argued in their initial and reply claim construction briefs "the term 'no traces of toxic chemicals' means 'no traces of toxic chemicals taking into account the limits of detection for a method that would have likely been relied upon by an organic chemist for that product in 1993.'" (Doc. # 161 at 20; Doc. # 181 at 19).

As far as this Court can ascertain, Plaintiffs inserted "suitable for human consumption" on the eve of the Markman hearing in the parties claim construction stipulation. (Doc. # 244 at 2). During the Markman hearing, Plaintiffs pointed to many references in the '714 patent that discuss the necessity for creating lutein that is suitable for human consumption: "To date, pure lutein suitable for human use has not been commercially available for use as a chemopreventive agent in clinical trials. Pure lutein, free from chemical contaminants and suitable for human consumption, is needed to design and conduct proper human intervention studies." ('714 patent Column 2, Lines 5-10) (emphasis added). "Another objective of the present invention is to provide purified lutein in crystalline form such that it is acceptable for human consumption and use in cancer prevention trials and treatments without causing toxic side effects due to residual impurities." ('714 patent Column 3, Lines 17-21) (emphasis added).

Nevertheless, the Federal Circuit expressly stated in the PIVEG case that it was "error" for the district court to include the "suitable for human consumption" language in its construction of claim 1 of the '714 patent. Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro, S.A., 93 F. App'x 225, 232 (Fed. Cir. Mar. 17, 2004). The district court, in PIVEG, modified its claim construction by deleting "suitable for human consumption" and the Federal Circuit affirmed. 357 F.Supp.2d 1105, 1122 (S.D. Iowa 2005), aff'd in relevant part, 464 F.3d 1339 (Fed. Cir. 2006).

Since the beginning of this case, Plaintiffs have argued that this Court should follow the PIVEG claim construction. This Court is not inclined to insert "suitable for human consumption" into the definition of "no traces of toxic chemicals" in derogation of the Federal Circuit's clear instructions.

ii. "Known" or "Used"

In the context of determining how persons of ordinary skill in the art would go about detecting toxic chemicals, such as hexane, the parties disagree as to whether the chemicals are detected by "methods known to persons of ordinary skill in the art" or whether such chemicals are detected by "a method that would have been used" by a person of ordinary skill in the art. (Doc. # 244 at 2) (emphasis added).

As posited by Plaintiffs, "the dispute boils down to a choice between the theoretically best available method as opposed to the method actually used by persons of ordinary skill in the art at the time of the invention." (Doc. # 239 at 3) (emphasis in original). In support of the argument that "no traces of toxic chemicals" means "no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994 by a person of ordinary skill in the art . . .," Plaintiffs persuasively contend that "a person of ordinary skill in making purified lutein under this patent would use a

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readily available testing method that was sufficient to make sure the product was suitable for its stated goals. She or he would not research endlessly to determine if some better technology existed somewhere in the world that, with unlimited time and resources, she or he might be able to access." (Doc. # 239 at 5).

The Court is persuaded by Plaintiffs' common sense approach to this issue. Defendants' arguments on this point -- that toxic chemicals should be measured by a method "known" -- are nebulous and could lead to confusion in this already complex case. Defendants will have an opportunity to argue to the jury that their proffered method of detecting toxic chemicals would have been "used" by a person of ordinary skill in the art in 1994. 7

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7 Without determining which method of detecting toxic chemicals applies, the Court determines that persons of ordinary skill in the art would likely "know" of several methods for detecting toxic chemicals, ranging from the most simple (such as using the human senses of sight, touch, smell, and taste) to the most complex (likely some variation of gas chromatography mass spectrometry (GC-MS) coupled with flame ionization detection (GC-FID)). As stated by Dr. Schwarz, "Many methods have been developed to measure residual solvent concentrations, and therefore, methods with varying sensitivities have been published in the scientific literature." (Dr. Schwartz Report, Doc. # 164 at 25). A person of ordinary skill in the art would likely not use the most advanced, expensive, or cutting-edge method of detection in every situation. For instance, Dr. Khachik used nuclear magnetic resonance (NMR) to test for hexane. Dr. Khachik's "educated guess is that this method had a limit of detection of 30-40 parts per million. The jury must determine what method a person of ordinary skill in the art would use to detect toxic chemicals in 1994, when making purified lutein.

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iii. Method of Detection

The last point of contention regarding the definition of "no traces of toxic chemicals" concerns how a person of ordinary skill in the art would go about detecting toxic chemicals, namely hexane. Although the parties have fully briefed the issue, the Court declines to address it at this juncture. A jury, rather than this Court, should decide what method would have been used in 1994, by the person of ordinary skill in the art who was preparing a purified lutein product. 8 After the jury makes this factual determination, the Court will be able to answer the question of "how much hexane must be present to take a lutein product outside the scope of the '714 patent." (Doc. # 239 at 2).

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8 Plaintiffs agree that this issue should be left to the jury, and Plaintiffs argue "OmniActive appears to want this Court to decide fact questions under the guise of claim construction." (Doc. # 181 at 2). The Court will not invade the province of the jury by deciding factual issues.

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Accordingly, the Court clarifies the term "no traces of toxic chemicals" to mean no detectable amounts of any toxic chemicals as measured by a method that would have been used in 1994, by a person of ordinary skill in the art.
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2. Nodules of carbon bonded predominately in three dimensional sp<3> bonds

The plaintiffs argue that this disputed phrase should be construed to mean "crystal-like clusters of carbon atoms wherein the most common bonds between the carbon atoms in each cluster are three dimensional sp<3> bonds." The defendant proposes that the disputed phrase means "non-columnar rounded clusters of 95% or more sp<3> bonded carbon." Primarily at issue here is the meaning of the term "predominantly."

The plaintiffs urge that "predominantly" should be given its ordinary meaning. The dictionary defines "predominantly" as

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"for the most part: MAINLY" and defines "predominant" as "being most frequent or common." Ninth New Collegiate Dictionary (1988). On the other hand, the defendant argues that in the context of the '797 patent, "predominately" means that the nodules have at least 95% sp<3> bonding. According to the defendant, the plaintiffs are contending that the patent discloses nodules that are only 50% sp<3> bonded, which position is not supported by the specification.

The defendant's argument is persuasive. To understand what is disclosed in the '797 patent, it is necessary to refer to the specification, particularly the Summary of the Invention. The patentees have disclosed the results of scientific testing which show that "estimates supported by measurements of mass densities and soft x-ray (ka) emission spectra suggest that the sp<2> content within the nodules is less than 5% and perhaps even as low as 2% indicating a 'diamond-like' material. Between the nodules is found an amorphous mixture of carbons and void." '797 patent, col. 4, ll. 37-43. In addition, the specification incorporates by reference an article authored by the plaintiffs and others titled "The Bonding of Protective Films of Amorphic Diamond to Titanium." '797 patent, col. 2, ll. 18-21. "When a document is 'incorporated by reference' into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein." Telemac Cellular Corp. v. Topp Telecom., Inc., 247 F.3d 1316, 1329 (Fed. Cir. 2001). This article explains that "the sp<2> content within the nodules is less than 5% and perhaps even as low as 2%." C.B. Collins, et al., The Bonding of Protective Films of Amorphic Diamond to Titanium, 71 J. App. Phys. 3260 (1992). Thus, one ordinarily skilled in the art reading the specification would understand that the nodules are comprised of at least 95% sp<3> bonded carbon.

The specification of the '797 patent also incorporates by reference an article titled "Low Pressure, Metastable Growth of Diamond and 'Diamondlike' Phases." This article underscores that one ordinarily skilled in the art would understand that "[t]he key to understanding the structure and properties of the diamondlike carbons . . . is the ratio of sp<3> to sp<2> sites." John C. Angus & Cliff C. Hayman, Low Pressure, Metastable Growth of Diamond and "Diamondlike" Phases, 241 Science 914, 920 (1988). The patentees, having incorporated the article by reference, disclosed to the public that the ratio of sp<3> to sp<2> sites is an important aspect of their invention because the percentage of sp<3> bonded carbon in the nodules is what gives the film its diamond-like characteristics. See '797 patent, col. 1, ll. 58-63. Likewise, in the Summary of the Invention, the patentees stated that "the basic unit of construction of the nanophase diamond of the present invention is the sp<3>-bonded nodule." '797 patent, col. 4, ll. 27-29.

A second issue is whether "nodules" must be rounded and non-columnar in shape. The plaintiffs contend that the defendant's proposed construction is not supported by the intrinsic record. The defendant, however, relies on the specification of the '797 patent and the ordinary meaning of the term "nodules" to support its construction. A picture is worth a thousand words. Figure 6 of the '797 patent is such a picture, and it depicts "nodules," many of which are clearly rounded in shape and others that are irregular in shape. The court therefore construes "nodules of carbon bonded predominately in three dimensional sp<3> bonds" to mean "clusters of carbon atoms of rounded or irregular shape wherein approximately 95% or more of the bonds between the carbon atoms in each cluster are three dimensional sp<3> bonds."

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VIII. "a nominal addition amount of the catalyst (having a nominal weight)" '236 patent, col. 16, ll. 15-16.

The parties agree that "nominal" means "approximate or assumed (but not necessarily actual)" and "nominal weight" means "an approximate or assumed (but not necessarily actual) weight." 73 Plaintiff construes the entire phrase to mean "an assumed or approximate addition amount of the catalyst additive (having an assumed or approximate weight)." 74 Defendants define it as "an amount of catalyst that is injected into the FCC unit and is assumed to be the same weight as that of the 'addition amount' determined in Step II." 75

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73 (Joint Claim Construction Br. at 1-2.)

74 (Pl.'s Claim Construction Br. at 33.)

75 (Defs.' Opening Claim Construction Br. at 27.)

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A. "addition amount"

With respect to "addition amount," the Court has previously defined this phrase to mean "the amount of catalyst added to raise the concentration of the catalyst from the desired lower concentration boundary to the desired upper concentration boundary." See supra Analysis Part VI.B. Because this phrase is used consistently throughout the claim, the Court gives it the same construction here. See Phonometrics, Inc., 133 F.3d at 1465.
B. "nominal addition amount"

With respect to the "nominal addition amount," the Court agrees with Defendants that this phrase refers to "an approximate or assumed amount of catalyst that corresponds to the 'addition amount' previously determined." 76 As seen from the claim's context, the term "nominal" modifies "addition amount" and there is no indication that this "addition amount" is anything other than the "addition amount" determined in the "entering the data" step. For example, the claim states that one will "enter[] the data concerning the FCC unit into a programmed computer in order to determine . . . (4) an addition amount of the catalyst. . . ." '236 patent, col. 15, l. 62-col. 16, l. 3 (emphasis added). Later, the claim states that one will "place[] the FCC unit under control of a computerized control device and thereby . . . (2) introduce a nominal addition amount of the catalyst (having a nominal weight) into the FCC unit." Id., col. 16, ll. 11-16.

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76 (Id.)

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C. Summary

Accordingly, the Court concludes that the phrase "a nominal addition amount of the catalyst (having a nominal weight)" means "an approximate or assumed amount of catalyst added to raise the concentration of the catalyst from the previously established lower concentration boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) to the previously established upper concentration boundary (but not necessarily the minimum boundary) of a range of catalyst concentrations (which may be expressed as a weight percentage) (having an approximate or assumed but not necessarily actual weight)."
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3. "Non-aluminum modified." Consistent with the plain meaning and intrinsic evidence, the term "non-aluminum modified" shall mean silica particles that have "not been surface modified with aluminum."
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1. Defendant's Initial Challenge Based upon the Term "Non-agueous"

Defendant argues that it has not literally infringed claims 1, 5, 6, 8, 9, 16-18, 21, or 22 in the '782 patent, as each of those claims requires that the composition of the plaintiff's dentifrice has either essentially no water or only a trace amount of water. Defendant first points out that it cannot be disputed that its products contain water, and thus the products are not literally "water free" or without water. In addition, defendant points out that its products, at the very least, contain water in a greater quantity than that which could reasonably be considered to be a "trace amount of water." Specifically, defendant has submitted evidence which indicates that each of its accused products contain more than one percent "by weight" of water. Referring to the scientific definition of "trace element," defendant explains that because a measurement of one percent water is more than one hundred times greater (in scientific measurement) than "a trace amount of water," there can be no literal

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infringement. (Def.'s Br. in Supp. at 8-9.)

Defendant's claim construction argument with respect to its alleged literal infringement of the claims asserted in the '782 patent is centered around its construction of a term found in claims 1, 5, 6, 8, 9 and 21 of the '782 patent. 4 Specifically, defendant has focused its attention upon the word "non-aqueous." The term "non-aqueous" is found in claims 1, 5, 6, 9, and 21 of the '782 patent, where the claims require "a non-aqueous toothpaste or gel" and a "non-aqueous vehicle." Our claims construction analysis will begin with those claims.

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4 While the term "non-aqueous" is not used in claims 16 through 18 and 22 of the '782 patent, defendant argues nevertheless that those claims also require "compositions that have no more than a trace amount of water." (Def.'s Br. in Supp. at 12.) Specifically, defendant notes that each of the claims requires "bicarbonate salt" in an amount effective to provide a neutral or basic pH when the composition is contacted with water. From that observation, defendant argues that "by defining the amount of bicarbonate salt in terms of its reaction when the composition is brought into contact with water, it is clear that water is not part of the claimed composition." (Id. at 12-13.) Defendant also argues that because the claims require peroxide and peroxide stabilizer "in amounts effective to inhibit decomposition of [the] peroxide during storage," the claims require the compound to be non-aqueous, i.e., not having more than a trace amount of water. This is because plaintiff's specification states that the composition reacts, i.e., decomposes, when exposed to water. We will address the validity of defendant's construction of those claims not containing the term "non-aqueous" infra at Section A.2.

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a. Claims 1, 5, 6, 8, 9, and 21

The parties appear to agree that Claim 1 of the '782 patent is representative of the use of the term "non-aqueous" in Claims 5, 6, 8, 9 & 21. 5 Therefore, in the interest of brevity, our analysis will focus upon the use of that term in claim 1 of the '782 patent. Claim 1 states:

1. A non-aqueous tooth paste or gel composition comprising a peroxide selected from one or more members of the group consisting of urea peroxide, hydrogen peroxide, magnesium peroxide, calcium peroxide, lithium peroxide, sodium percarbonate, and ammonium persulfate; a bicarbonate salt; a peroxide stabilizer; and a hydrophilic, non-aqueous vehicle which is water dispersible, water emulsifiable or water soluble; wherein said bicarbonate is present in an amount effective to provide a neutral or basic pH when the composition is contacted with water; said peroxide stabilizer comprising a material selected from one or more members of the group consisting of a dessicating agent, a sequestering agent, colloidal particles, free radical preventatives, inorganic hardness salts, acidulating agents, and a coating on at least one of said peroxide and said bicarbonate salt that either readily dissolves, disperses or emulsities in water; and wherein said peroxide, stabilizer and vehicle are present in amounts effective so as to inhibit decomposition of said peroxide during storage of said composition in a closed container, but so as to allow release of sufficient oxygen when the composition is contacted with water in the mouth to inhibit the motility of oral bacteria.

(Miskewitz Aff., Ex. C: '782 Patent.) The parties' positions diverge on the meaning of the term "non-aqueous" as it is used in the preamble 6 (which describes the "composition" covered) and in connection with the element of the claim which requires a "non-aqueous vehicle." (See Miskewitz Aff., Ex. C.)

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5 The Court notes that claims 5, 6, 8, and 9 are dependent claims based upon claim 1. A dependent claim refers back to one earlier claim and is considered to include all of its own limitations as well as those of the referenced claim. Fed. Jud. Center, Patent Law and Practice at 12 (2d ed. 1995). Defendant has raised an additional argument concerning another limitation found in claims 9, 16 and 17, separate and apart from its argument regarding the proper meaning of the "non-aqueous" limitation. (Def.'s Br. in Supp. at 17.) Specifically with respect to claims 9, 16, and 17, defendant argues that it has not infringed those claims by the manufacture or sale of the following C&D products: PEROXICARE, AHDC EXTRA WHITENING, reformulated PEROXICARE and reformulated TC PEROXICARE. We will consider those arguments infra

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at Section A.3.6 "The preamble [portion of a claim] sets the stage for the recitations which follow, either by summarizing the invention expressed by the claims and/ or placing it in the perspective of the prior art." Schering Corp. v. Amgen, 18 F. Supp. 2d 372, 383 n.18 (D. Del. 1998) (citing Peter Rosenberg, Patent Law Fundamentals § 14.05 at 14-21)). The "transitional phrase" of the claim is the introductory clause between the preamble and the limitations of a claim, and materially affects the scope of protection afforded by the claim. Id. The "body" of the claim, which is all the language coming after the transitional phrase, states, as a series of phrases, the structural elements which make up and form the nucleus of the invention.

The Federal Circuit has recently reaffirmed the principle that under certain circumstances, language found in the preamble takes on increased significance:

[A] claim preamble has the import that the claim as a whole suggests for it. If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning and vitality to the claim, then the claim preamble should be construed as if in the balance of the claim. Indeed, when discussing the "claim" in such a circumstance, there is no meaningful distinction to be drawn between the claim preamble and the rest of the claim, for only together do they comprise the "claim." If however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Pitney-Bowes, 182 F.3d 1298, 1999 WL 415392, at *6 (citations and quotation marks omitted). Here, the preamble which commences with the statement "A non-aqueous toothpaste or gel composition" is "necessary to give life, meaning and vitality" to claim 1 and the dependent claims. Id. at 6-7. Indeed, the body of claim 1 refers to the "composition" three times without defining its meaning. An understanding of that term can only be gleaned from the preamble which states that the composition is "a non-aqueous toothpaste or gel." See id. (finding that the preamble statement was part of the claimed invention where it contained terms not elsewhere defined). Thus we must "construe the preamble and the remainder of the claim as one unified and internally consistent recitation of the claimed invention." Id. at 7. What this means with respect to claims 1, 5, 6, 8 and 9 is that the preamble containing the phrase "a non-aqueous tooth paste or gel composition" must be considered a limitation. Of course, because claim 21 does not contain this phrase as part of its preamble, it may not be so considered. However, claim 21 does include its own limitation which requires a "non-aqueous" vehicle, and thus our construction of the term "non-aqueous" is pertinent to the construction of that claim.

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Defendant's argument is rather straightforward: it argues that the term "non-aqueous" should be accorded its ordinary meaning. Pointing to Webster's Third International Dictionary and McGraw-Hill Dictionary of Scientific and Technical Terms, defendant observes that the "ordinary meaning of the term 'non-aqueous' is without water." Its products contain water; therefore there is no literal infringement. In addition, defendant recognizes that the term "non-aqueous" could also be construed to mean that the composition contains only "a trace of water." Defendant argues that even this construction demonstrates that its products do not infringe the '782 patent. This is because the accused products contain at minimum one percent water, which is an amount greater than a "trace" of water as that term is defined scientifically. Thus under either construction, defendant argues, it is entitled to summary judgment of non-infringement. (Def.'s Br. in Supp. at 7.)

Anticipating plaintiff's reply, defendant next contends that any argument by plaintiff that the term "non-aqueous" is not so limited, and that the composition described in claim 1 can have any amount of water present so long as the peroxide and bicarbonate remain stable, is not supported by the intrinsic evidence in this case. Defendant maintains that its construction of non-aqueous as "water free" or containing only "traces of water" is consistent with the following intrinsic evidence in the record: (1) in describing the invention, the applicants explained that the presence of water in a toothpaste containing sodium bicarbonate and peroxide has a destabilizing effect, (id. (citing '782 patent, col. 1, line 61-col. 2, line 4); (2) the specification does not support a special meaning for the term "non-aqueous" because it stated that "preferably, the compositions of the invention include either no water or traces of water," and the term "trace element" is defined as "less than 100 micrograms per gram," (id. at 8 (citing '782 Patent, col. 2, lines 58-65 and discussing the scientific dictionary meaning of the phrase "traces of water")); (3) defendant's construction of the term "non-aqueous" is supported by reference to the examples relied upon by the applicants in prosecuting the patent; and (4) the prosecution history of the '782 patent demonstrates that the claimed invention is limited to dentifrices containing no more than a trace amount of water because the applicants

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repeatedly distinguished their alleged invention over the prior art based on, inter alia, the prior art containing water.

In contrast, the construction which plaintiff proposes is that the use of the term "non-aqueous" was not meant to indicate that each element of the claims at issue in the '782 patent would contain no water whatsoever. Instead, plaintiff urges a construction of the term "non-aqueous" which would indicate that it meant that water should not be included in the overall composition, or specifically in the element of the "non-aqueous" vehicle, in such an amount that it would adversely affect the peroxide stability of the composition. Specifically, plaintiff relies on the following language found in the specification of the continuation-in-part application submitted to the Patent and Trademark Office ("PTO") on April 9, 1985:

As noted above, the compositions of the invention are preferably non-aqueous. By non-aqueous, we mean that the compositions do not include water in such an amount that it will adversely affect the peroxide stability provided by the composition of the intention, e.g., the components of the compositions of the invention consist essentially of water free materials. Preferably, the compositions of the invention include either no water or only traces of water.

(Miskewitz Aff., Ex. C: '782 Patent, col. 2 lines 57-65.) Plaintiff also points to various extrinsic evidence in support of its interpretation of the meaning of "non-aqueous." (See Pl.'s Br. in Opp'n at 10-17.)

"It is well established that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1998). Indeed "such intrinsic evidence is the most significant source of the legally operative meaning of the disputed claim language." Id.

The Court has reviewed the claims of the patent at issue, the language in the specification upon which plaintiff relies, 7 and the relevant prosecution history in connection with the applicants' attempts to obtain the '782 patent. Notably, defendant's interpretation begins by referring to the dictionary definition of the term "non-aqueous." Such an approach is plainly inappropriate in this case, as it is clear that the patent specification in connection with the continuation-in-part application filed in the PTO in 1985 provides the operative definition of the term "non-aqueous." "Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Id. at 1582.

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7 Defendant has asserted that the relevant language in the specification portion of the April 9, 1985 continuation-in-part application should be disregarded as "new matter" pursuant to the principles explained and followed in Schering Corp. v. Amgen, Inc., 18 F. Supp. 2d 372, 389, reconsideration denied, 25 F. Supp. 293 (D. Del. 1998). In particular, defendant states that because plaintiff is attempting to rely upon the original filing date of its application, here September 14, 1983, in connection with its argument concerning defendant's motion as to the invalidity issue, the information pertinent to the meaning of the term "non-aqueous," which is included in the specification of the continuation-in-part application, should be considered by the Court to be "new matter." "New matter" is considered to be outside the scope of evidence which we may consider in construing the meaning of the claims at issue.

At oral argument, counsel for plaintiff explained that the April 9, 1985 application was a continuation-in-part application. Indeed, as plaintiff's counsel points out, there is no mention of the term "non-aqueous" either in the claims or specification submitted in support of the parent application. (See Howard Aff., Ex. B at CD002884.) Plaintiff argues that because the 1985 application qualifies as a continuation-in-part application, the additional information found in the specification in that application is not "new matter" as that term is understood in patent terminology. Plaintiff's counsel then explained that under certain circumstances, the applicants who file a continuation-in-part application are entitled to the benefit of the parent application's filing date. Of course, the filing date of the patent application becomes important in determining the scope of the prior art, which is an inquiry relevant to the issue of validity raised in this case.

The Court has considered the parties' arguments in this regard. We conclude that both parties are correct to some extent. We have reviewed the following explanation which is helpful in this regard:

A continuation-in-part application is an application that has some subject matter in common with the parent but also has

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new subject matter. A continuation-in-part is entitled to the parent's filing date as to any subject matter in common, but only to its own filing date as to the new matter. A continuation-in-part might be filed if the applicant had to add limitations to the parent claims to distinguish a reference or references, but the added limitations were not supported by the specification of the parent and the examiner would not allow supporting material to be added to the specification because it introduced new matter. The applicant could file a continuation-in-part to include the new matter ….

Federal Judicial Center, Patent Law & Practice at 20-21 (2d ed. 1995). As this passage conveys,.a continuation-in-part application is entitled to the parent's filing date as to any subject matter in common, but only to its own filing date as to any new matter. Thus defendant is correct that plaintiff cannot have "its cake and eat it too," i.e., gain the benefit of the filing date of the parent application, yet ask the Court to consider newly included claim limitations and specifications pertaining thereto in the continuation-in-part application not found in the parent application. However, as this passage makes equally clear, the Court may consider the information in the specification of the continuation-in-part application in determining the intended meaning of the term "non-aqueous." The effect of this ruling on the issues of validity raised by defendant will be discussed infra at Part B.

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Here, we need go no further than the specification of the 1985 continuation-in-part application. There it states in the first section of the "Description of the Patent" that by using the term "non-aqueous," the applicants meant

that the compositions do not include water in such an amount that it will adversely affect the peroxide stability provided by the compositions of the invention, e.g., the components of the compositions of the invention consist essentially of water free materials. Preferably, the compositions of the invention include either no water or traces of water.

(Howard Aff., Ex. C at CD002931.) Put simply, this passage in the specification renders meaningless defendant's reliance upon the dictionary definition of the term "non-aqueous" as "pertaining to a liquid solution that is not water." (Def.'s Br. in Supp. at 7.)

Similarly, we have uncovered certain statements contained in the prosecution history of the '782 patent which confirm the meaning which we ascribe to the term "non-aqueous." For example, in the amendment submitted in response to the PTO Office Action dated June 14, 1985 rejecting plaintiff's continuation-in-part application filed April 9, 1985, the applicants further explain their use of the term "non-aqueous." The response states that "where a vehicle is present, as in the toothpaste or gel, the vehicle is non-aqueous, as is indeed the entire composition, in order to assure that none of the species are in an active form, such as the bicarbonate." (Howard Aff., Ex. C at CD003015.) The same explanation of the term "non-aqueous" is found in the Appeal Brief submitted by the applicants after the PTO's Final Office Action of October 20, 1986. In describing the nature of the claimed invention, the appeal brief highlights the fact that the applicants' invention was distinguishable from the prior art because it is comprised of a single stable composition including both peroxide and bicarbonate together. It next states that in the form of a toothpaste or gel, stabilization is achieved by the use of a peroxide stabilizer. In addition, the brief explains that "where a vehicle is present, as in the toothpaste or gel, the vehicle is non-aqueous, as is indeed the entire composition, in order to assure that none of the species are in a reactive form, such as the bicarbonate." (Id. at CD003090.)

We hold that the term "non-aqueous" as it is used in the relevant portions of claim 1 should be afforded the following construction. First, the "composition" at issue in claims 1, 5, 6, 8 and 9 of the '782 patent is "non-aqueous" in the sense that the composition does not include water in such an amount that will adversely affect the peroxide stability provided by the overall structure of the invention. Second, with respect to the limitation of a "non-aqueous vehicle" which is found in claims 1, 5, 6, 8, 9 and 21 of the '782 patent, the term "non-aqueous" means that the vehicle itself must not include water in such an amount that will adversely affect the peroxide stability of the overall composition at issue.

We note that the construction afforded in view of the specification and those portions of the prosecution history referred to above is not contradicted by those aspects of the prosecution history upon which defendant relies for its argument that "non-aqueous" is equivalent to "water free." First, we note that much of defendant's argument is premised upon its secondary analysis of the term "trace" which is used in that aspect of plaintiff's specification which we deemed instructive. Defendant states that the term "trace element" is defined in a scientific reference as "less than 100 micrograms per gram." (Def.'s Br. in Supp. at 9; Howard Aff., Ex. H.) From its premise that the phrase "trace of water" is equivalent to "non-aqueous" in this

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context, defendant maintains that a composition is thus "non-aqueous" if it has no more than .01 percent "by weight" of water. (Def.'s Br. in Supp. at 8-9.) Defendant's calculation in that connection is favorable to it because its accused products, by comparison, contain at least (i.e., at a minimum) one percent water, which is by definition much greater than .01 percent water.

We reject the proposition that the phrase "trace of water" as it is used in this portion of the specification contradicts plaintiff's definition of "non-aqueous" found in the specification. We agree with plaintiff that the construction of the sentence in which the phrase "trace of water" is placed is significant: here the phrase "trace of water" is found in a sentence beginning with the adverb "preferably." That particular sentence follows the more explicit description of the meaning of the term "non-aqueous." Understood in this context, we do not agree that this language, found in the specification, can be construed as a limitation to the effect that the term "non-aqueous" can only mean a "trace of water."

We will briefly explain our rationale for our construction of the description found in the specification. When claim construction is required, claims are construable in light of the specification. See United States v. Adams, 383 U.S. 39, 49, 15 L. Ed. 2d 572, 86 S. Ct. 708, 174 Ct. Cl. 1293 (1966). However, "that claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims." SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1987). The court in SRI explained the applicable principle as follows:

> If everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Id. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment. Nor would a basis remain for the statutory necessity that an applicant conclude his specification with "claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112; It is the claims that measure the invention …. Infringement, literal or by equivalence, is determined by comparing an accused product not with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed claims in suit …. The law does not require the impossible. Hence, it does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention. The law recognizes that patent specifications are written for those skilled in the art, and requires only that the inventor describe the "best mode" known at the time of making and using the invention. 35 U.S.C. § 112.

Id. Here, limiting the term "non-aqueous" to the description of a "trace of water" which is found in the last sentence of the relevant aspect of the specification runs afoul of these principles.

We also note that plaintiff's use of examples 1, 2, and 11 as descriptive of its asserted claims does not support defendant's proposed claim construction. That those examples describe the composition as "non-aqueous" and "water-free" does not change the import of the clear description in the specification. Similarly, the applicants' statements in distinguishing their embodiments over the prior art lend no support to defendant's construction, as it is clear that the prior art contained, in the applicants' own words, "large amounts of water." (Howard Aff., Ex. C at CD003019.) That the applicants' embodiments were arguably distinguishable from the prior art in the sense that they did not contain "large amounts of water" does not lead to the conclusion that by so arguing, the applicants meant to imply that their invention contained no water at all or only trace amounts which could be interpreted as less than 1 percent water.

For each of these reasons, the Court finds that the construction asserted by plaintiff is correct. The Court thus rejects defendant's construction of "non-aqueous" as erroneous as a matter of law.

After construing the meaning of the term "non-aqueous," our next step in a literal infringement action is to address the issue of infringement. Defendant's motion for summary judgment of non-infringement addresses that issue; however, it is clear that its argument in that connection is premised upon its asserted construction of the term "non-aqueous." Specifically, the argument is that because the evidence demonstrates that defendant's products contain no less than one percent of water, and one percent of water cannot amount to a "trace" of water as that term is used in the specification language quoted above, the accused products cannot be said to infringe upon plaintiff's '782 patent. However, because we have found plaintiff's construction correct, defendant's arguments concerning infringement which are predicated upon its construction of the term "non-aqueous" are not persuasive. Moreover, our review of the record demonstrates that plaintiff has provided evidence which demonstrates a genuine issue of material fact on this issue. (See, e.g., Stabille Aff. 4-10; 30.) Accordingly, the Court will deny defendant's motion for summary judgment of non-infringement based upon its argument concerning the

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construction of the term "non-aqueous." 8

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8 Plaintiff also appears to assert infringement based upon the doctrine of equivalents. Generally speaking, the question of equivalence is one of fact. See Texas Instr. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1172 (Fed. Cir. 1993); Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics, 976 F.2d 1559, 1570 (Fed. Cir. 1992). On the basis of the record presented to us in connection with this motion, the Court finds there are genuine issues of material fact which preclude judgment as a matter of law on this theory of infringement at this juncture.

We note parenthetically that we have considered and rejected defendant's argument that the doctrine of prosecution history estoppel precludes plaintiff from pursuing an infringement claim under the doctrine of equivalents at trial. We disagree with defendant's interpretation of the import of the applicants' amendments to the parent application, as well as the applicants' words used in distinguishing its claims from prior art. Put simply, we find nothing in the prosecution history of this patent application which would indicate that the plaintiff surrendered a construction of the meaning of the term "non-aqueous" which is anything broader than defendant's proposed construction of that term, that being that non-aqueous means "water free" or containing only a "trace of water." Thus, to the extent that defendant seeks summary judgment of non-infringement under this theory, we will deny that motion.

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IV. Claim Construction of "Non-Chloride Sodium Salt"

Finally, Lonza also argues that the district court misconstrued the claim term "non-chloride sodium salt," as used in the '281 patent, by allowing that term to encompass sodium hydroxide (NaOH). We review assertions that the district court legally erred in construing a claim term de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

Because the district court's claim construction comports with the intrinsic and extrinsic evidence of record in this case, we affirm. First, although the '281 patent specification does not discuss NaOH, the prosecution history explicitly states that NaOH is a non-chloride sodium salt, J.A. at 4329--a clear indication that the applicant used the term "non-chloride sodium salt" in a manner broad enough to encompass NaOH. Moreover, Martek presented extrinsic evidence to support its position. Specifically, Martek produced two treatises, each of which teaches that NaOH can be considered a salt. See Charles W. Keenan & Jesse H. Wood, General College Chemistry 121-22 (4th ed. 1971); Wesley E. Lingren, Inorganic Nomenclature: A Programmed Approach 114 (1980). In contrast, Lonza cites no evidence that NaOH cannot be considered a salt. Although Lonza argues in its opening brief that NaOH cannot be considered a salt because it is a base, Appellant's Br. at 44, Lonza concedes in its reply brief that we need not decide whether NaOH is technically a salt. Specifically, Lonza states:

> Whether NaOH is . . . technically a 'salt' and whether the reaction product of sodium and water can be considered a reaction of a sodium base and a non-chloride acid are difficult scientific questions that need not be considered, because the intrinsic record clearly excludes NaOH from the scope of the claims. . . . [T]he critical issue is that the prosecution history demonstrates that NaOH was excluded from the claims.

Appellant's Reply Br. at 23-24.

Thus, Lonza's primary argument on appeal is that Martek disclaimed coverage of NaOH during prosecution of the application that issued as the '281 patent. That argument fails. To support its assertion, Lonza cites selected statements spanning two pages of the prosecution history. Although the selected statements arguably support Lonza's assertion, those statements are undercut considerably by additional statements recited in the same two pages of prosecution history relied upon by Lonza: (1) the applicant's explicit statement that NaOH is a non-chloride sodium salt, and (2) the applicant's statements distinguishing the prior art at issue from the claimed invention on alternative grounds unrelated to the way NaOH was used in the prior art reference. Thus, under this court's precedent, Martek committed no clear and unmistakable disavowal of claim scope. See, e.g., Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) ("[F]or

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prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable."); Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1252 (Fed. Cir. 2000) ("In determining whether there has been a clear and unmistakable surrender of subject matter, the prosecution history must be examined as a whole.").

For these reasons, we uphold the district court's claim construction.
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1. "Non-Coding Region Sequence"

GTG proposes the definition "any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci." Applera proposes "all non-exon sequences, including sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci." The parties agree that the definitions' examples of untranslated DNA sequences are accurate, but dispute whether the term "untranslated DNA sequences" or "non-exon sequences" better describes the regions at issue.

In the prosecution of the '179 patent, the applicant conceded that the term "non-coding region sequence" should be substituted for the term "intron" throughout the claims, because the applicant was using the term "intron" in a broader sense than its then-accepted definition at the time. GTG Exh. E at 58227 (Sept. 23, 1992 Preliminary Amendment). Thus, the specification states:

As used herein, the term "intron" refers to untranslated DNA sequences between exons, together with 5' and 3' untranslated regions associated with a genetic locus. In addition, the term is used to refer to the spacing sequences between genetic loci (intergenic spacing sequences) which are not associated with a coding region and are colloquially referred to as "junk." While the art traditionally uses the term "intron" to refer only to untranslated sequences between exons, this expanded definition was necessitated by the lack of any art recognized term which encompasses all non-exon sequences.

'179 patent col. 5:40-50.

GTG argues that its definition is more accurate than Applera's, because at the time the patent issued, the 5' and 3' UTRs were considered exons, see, e.g., GTG Exhs. U, V (biology texts defining 5' and 3' sections as exons), and it would thus be inconsistent to define the term "non-exon sequences" as including an exon sequence. 2 Texas Digital, 308 F.3d at 1202-03 (dictionaries in use at the time of the patent's issuance may be relied upon in construing a claim). The court agrees with GTG. The term is thus construed as: any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci.

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2 The analogy provided at the hearing was that it would be inconsistent to proffer a definition such as "non-shoe objects, including trucks, cars, and stilettos," since stilettos are a type of shoe and it would be inconsistent to define a shoe as a "non-shoe object."

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A. Non-Diffusively Bound and Non-Diffusively Immobilized

Abbott argues that the jury's finding of noninfringement based on the failure to satisfy the claim terms "non-diffusively bound" and "non-diffusively immobilized" is not sustainable because of error in the jury instruction.

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All of the asserted claims require a reactant that is either "non-diffusively bound" or "non-diffusively immobilized." The parties agree that these recitations as properly construed have the same meaning. The district court adopted, and instructed the jury using the following definition of "non-diffusively bound":

Nondiffusively bound means a reactant immobilized in the reaction zone so as to provide a detectable signal indicating the presence or absence of analyte in the solution, and the reactant is not capable of detaching from the medium, spreading out, and moving along the test strip . . . . [A] reactant is nondiffusively bound only if it is found in such a manner that a sufficient and reproducible amount of reactant remains bound in the reactive zone or zones to conduct both quantitative and qualitative assays.

(Tr. at X-132.) Abbott objected to the district court's construction, urging instead that the disputed recitations "require only that the reactant be immobilized sufficiently to permit detection of the analyte in the reaction zone." (Appellant's Br. at 25.).

On appeal Abbott urges that the adoption of an instruction including the underscored language was error because it interpreted the claim to require quantitative analysis. Syntron urges that the inclusion of the "quantitative" language in the jury instruction was proper.

The first step in the analysis is to determine the ordinary meaning of the claim terms. Tex. Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1817 (Fed. Cir. 2002); see also Inverness Med. Switz. GmbH v. Warner Lambert Co., 309 F.3d 1373, 1378, 64 USPQ2d 1933, 1936 (Fed. Cir. 2002); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). Dictionary definitions provide evidence of a claim term's "ordinary meaning." Inverness, 309 F.3d at 1378, 64 USPQ2d at 1936. The parties have conceded that the recitations "non-diffusively bound" and "non-diffusively immobilized" are to be construed consistently. Starting with the words themselves, "non-diffusively" is an adverb defining the verbs "immobilized" and "bound." Webster's defines "bound" as "held in chemical or physical combination: COMBINED." Webster's Third International Dictionary 260 (1968) ("Webster's"). Webster's defines "immobilize" as "to make immobile: fix in place or position: render incapable of movement." Id. at 1130. The plain meaning of "immobilized" requires that the reactant not move relative to the medium, and the recitation "bound" further defines how that immobilization is provided, by requiring that the reactant be chemically or physically combined with the medium so as to be immobilized.

"Diffusively" defines the degree or character of the recitations "bound" and "immobilized." "Diffusive", the adverb form of which is "diffusively", means "having the quality of diffusing: tending to diffuse: characterized by diffusion." Id. at 631. Webster's defines diffusion as "the process whereby particles (as molecules and ions) of liquids, gases, or solids intermingle as the result of their spontaneous movement caused by thermal agitation and in dissolved substances move from a region of higher concentration to one of lower concentration." Id. at 631 (emphasis added). Thus, a dissolved substance that moves diffusively moves from a region of high concentration to one of lower concentration within the liquid, i.e., disperses within the liquid.

Taking the words together, the plain meaning of "non-diffusively bound" and "non-diffusively immobilized" is - a chemical or physical combination of the reagent and the medium, such that the reagent does not dissolve and move within the liquid from a region of high concentration to a region of low concentration. This definition closely mirrors the first portion of the construction adopted by the district court - the reactant is not capable of detaching from the medium, spreading out, and moving along the test strip - but bears no resemblance to the underscored portion of the instruction. None of the pertinent dictionary definitions supports the underscored portion. The plain meaning of the claim recitation, therefore, does not support the district court's narrowing construction.

The usage of the disputed claim terms in the context of the claims as a whole also informs the proper construction of the terms. See RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1263-64, 66 USPQ2d 1593, 1598 (Fed. Cir. 2003). Here, the language of the asserted claims suggests that quantitative analysis should not be read as a requirement of the recitations "non-diffusively bound" or "non-diffusively immobilized." In claim 22 of the '484 patent, for example, element (c) requires "detecting the presence of analyte." Similar language is found in each of the asserted claims. This language is broad enough to encompass both qualitative and quantitative analysis, and therefore, militates against the narrow definition used to instruct the jury. Syntron appears not to argue to the contrary on appeal. Rather, Syntron urges that the underscored language, in fact, broadens rather than narrows the construction of "non-diffusively bound." (Appellee's Br. at 20.) According to Syntron, the jury instruction did not require "quantitative analysis," but rather defined the quality of binding

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between the reactant and the test strip. We cannot agree, as the language "sufficient and reproducible amount of reactant remains . . . to conduct both quantitative and qualitative assays" is an additional requirement beyond the ordinary meaning of the claim language. 2

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2 Syntron also cites the description of the disclosed invention in the specification as using "covalent bonding" between the reactant and the test strip as somehow supporting the district court's adopted jury instruction. (Appellee's Br. at 21-22.) The description in the specification of a particular embodiment does not require that the claims be limited to that embodiment.See Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 2003 U.S. App. LEXIS 13861, No. 02-1145, slip op. at 12 (Fed. Cir. June 27, 2003).

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Thus, the construction adopted by the district court and used to instruct the jury was erroneous insofar as it included the underscored language requiring a sufficient amount to conduct quantitative assays. Because we have found that the jury was improperly instructed, and Syntron does not argue that the instruction was harmless error, we cannot affirm the judgment of noninfringement on the basis of the accused products' not incorporating a "non-diffusively bound" and "non-diffusively immobilized" reactant. Abbott urges that we enter JMOL in its favor instead of ordering a new trial. However, we think the issue of whether JMOL or a new trial should be granted is an issue best addressed in the first instance by the district court. Moreover, we must determine whether the judgment of noninfringement as to any of the claims can be sustained on other grounds.
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(F) "A non-fibrillating fluorocarbon particulate polymer"

Any fluorocarbon polymer which remains in particulate form and does not fibrillate under typical processing conditions.
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D. The Meaning of "Non-functional Lentiviral 5' LTR Promoter"

The term "non-functional lentiviral 5' LTR promoter" appears only in the claims of the '123 patent. Sigma and Oxford contend that this term means "a lentiviral genetic sequence located at one end (called the 5' end) of the long terminal repeat that is not present or is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription)." Open contends that this term means "a lentiviral genetic sequence located at one end (called the 5' U3 region) of the long terminal repeat that is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription)."

The parties disagree about two points. First, the parties disagree about whether this term is only limited generally to the "5' end" or specifically to the "5' U3 region." As discussed earlier, the "5' U3 region" is a more specific location within the 5' LTR. Claim 1 refers to the "5'" end and, by its own terms, is not limited to the "5' U3 region." The "U3 region" is an extraneous limitation that the Court will not read into the term.

Second, the parties disagree about whether the "non-functional" description means that the sequence is simply "no longer able to perform its normal function," or whether it also includes a sequence that is "not present."

The term "non-functional lentiviral 5' LTR promoter" was added to claim 1 through an amendment during the prosecution history. See Amendment and Response to Office Action dated Oct. 21, 2004 (Pls.' Ex. 13), at 4-6. To support this amendment, the inventors cited the specification as follows: "part of the 3' U3 sequences are deleted so that the transduced vector genome has a non-functional 5' LTR promoter." Id.

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According to Dr. Cullen, the promoter in the 3' U3 region becomes the 5' LTR promoter upon transduction. Cullen Decl. at P 160. The specification and prosecution history therefore show that deletion of the 5' LTR promoter, i.e., making it "not present," is one means of rendering it non-functional. Thus, in the context of the patent, "non-functional" includes "not present." Moreover, there is no disclaimer or disavowal that would prohibit deleting all of the promoter sequences, as opposed to deleting only some portion of the promoter sequences. See, e.g., '123 patent, col. 8, ll. 5-8 (deleting all of U3 except short sequence necessary for integration).

The Court agrees with Sigma and Oxford that "non-functional lentiviral 5' LTR promoter" is properly construed as "a lentiviral genetic sequence located at one end (called the 5' end) of the long terminal repeat that is not present or is no longer able to perform its normal function of initiating creation of RNA from DNA (transcription)."
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D. Non-human DNA Sequences That Control Transcription and Transcription Control DNA Sequences

As background, transcription is the process whereby RNA polymerase copies genetic information contained in a DNA nucleotide sequence into a complementary RNA sequence. As the patent explains, "the programming function of DNA is generally effected through a process wherein specific DNA nucleotide sequences (genes) are 'transcribed' into relatively unstable messenger RNA (mRNA) polymers." Trial Ex. 1 at 1:52-55. Transcription is a critical step in the expression of proteins like erythropoietin and is itself controlled by its own DNA sequences. These "transcription control DNA sequences" "precede a selected gene (or series of genes) in a functional DNA polymer [and] cooperate to determine whether the transcription (and eventual expression) of a gene will occur." Id. at 2:10-13. According to the patent, "transcription control sequences" is the collective term for DNA sequences that not only "provide a site for initiation of transcription into mRNA," but also are capable of binding proteins that determine "the frequency (or rate) of transcriptional initiation." Id. at 2:3-12. Claims referring to these transcription control sequences were the subject of the following disputes between the parties.

The phrase "non-human DNA sequences that control transcription" is contained in Claim 1 of the '349 patent. Amgen contended that this phrase means "non-human DNA sequences that are able to initiate or regulate RNA synthesis from EPO DNA." Pl.'s Markman Hr'g (Mar. 27, 2000) Demonstrative Ex. 69. In contrast, TKT argued that the phrase means "DNA sequences which did not originate in the human genome, which initiate and regulate RNA synthesis of adjacent DNA, and which replace the human EPO transcription control sequences." Defs.' Markman Hr'g (Mar. 27-28, 2000) Demonstrative Ex. 1. The dispute centered around a few crucial terms.

First, TKT contended that in order to "control" transcription, the DNA sequences must both initiate and regulate the transcription of a gene. Amgen objected to the use of "and," preferring a construction that required DNA sequences either to initiate or regulate transcription.

Second, the parties disputed the importance of location. By including the term "adjacent DNA" in its construction, TKT sought to require the DNA sequences that control transcription to be located in a position adjacent to the gene segment intended to be expressed.

Third, the parties disagreed as to the meaning of "non-human." Amgen argued that "non-human" means "not part of the human genome," whereas TKT contended that it means "not originating in the human genome." Because it is scientifically arguable that viral DNA originates in the human genome, the viral promoter DNA that TKT employs thus might not fall within the meaning of the claim.

The Court first determined that "non-human" DNA sequences are DNA sequences that are "not part of the human genome." Tr. of Markman Hr'g, Vol. II at 56:25 to 57:1. The Court rejected TKT's construction, ruling that Amgen meant simply to exclude the human DNA sequences that control transcription from the reach of its claim, sequences which, of course, are part of the human genome. By construing the term "non-human" to mean "not part of the human genome," then, the Court settled on a construction that best effectuated Amgen's intent.

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Second, the Court rejected TKT's "adjacent" language because no claim term could reasonably be construed to be limiting the transcription control DNA sequences by their location. Consequently, the Court adopted a construction that was in no way limited by the location of the transcription control sequences relative to the gene to be expressed.

Third, the Court held that "DNA sequences that control transcription are DNA sequences that initiate and may regulate the processes of transcription." Id. at 57:1-4. When it announced its construction of this phrase, the Court used the term "may," which signifies that while the DNA sequence must initiate transcription, it need not regulate transcription.

The Court then considered the phrase "transcription control DNA sequences," which is contained in Claim 4 of the '349 patent. Borrowing extensively from the patent specification, the Court explained that "transcription control sequences" are "collectively promoter DNA sequences that provide a site that is capable of initiating transcription . . . and regulator DNA sequences that are capable of binding proteins that determine the frequency or rate . . . of transcription initiation." Id. at 57:16-23. At the time, the Court did not recognize the inconsistency between these two constructions. Although "DNA sequences that control transcription" and "transcription control DNA sequences" should have the same meaning, the Court's constructions permitted regulator functions in one instance and required them in the other instance. As will be explained in the infringement portion of the decision, however, the parties tried the case with the latter construction in mind and thus no harm to the parties resulted.
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TKT asserts, in addition to the exogenous/endogenous distinction discussed above, that the district court misconstrued the terms "non-naturally occurring," "vertebrate cells," and "mammalian cells" -- which appear in many of the asserted claims -- to include human cells. Reviving the same argument the district court rejected below, TKT contends Amgen expressly disavowed the use of human cells to make human EPO.

The district court found that the definition of the term "non-naturally occurring" can be discerned through the doctrine of claim differentiation. Specifically, the court concluded that TKT's proffered construction must fail in light of '933 patent claim 3, discussed previously, which claims a "non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence encoding human erythropoietin . . . ." By its terms, then, this claim would cover the expression of human DNA in a cat host cell, for example, because a cat is a mammal. The court thus concluded that the phrase "non-naturally occurring" would be redundant in claim 3 if the phrase had the meaning TKT sought to ascribe to it. Further, because the patent specification compares the biological activity of synthetic products to "EPO isolates from natural sources" or "natural EPO isolates," the court concluded that non-naturally occurring simply means "not occurring in nature." Amgen, 126 F. Supp. 2d at 90-91, 57 USPQ2d at 1462-63.

Similarly, finding that the term vertebrate is widely known and understood to cover anything with "a segmented bony or cartilaginous spinal cord [which obviously includes humans]," id. at 85, 57 USPQ2d at 1457-58, the court adopted Amgen's proposed construction. The court also adopted Amgen's proposed construction of the term "mammalian cells" appearing in '422 patent claim 1 and '698 patent claim 9 under a similar rationale. Id. at 84-86, 57 USPQ2d at 1458.

We indulge a heavy presumption that a claim term carries its ordinary and customary meaning. CCS Fitness, 288 F.3d at 1366, 62 USPQ2d at 1662; see also Gart v. Logitech, Inc., 254 F.3d 1334, 1341, 59 USPQ2d 1290, 1295 (Fed. Cir. 2001). Although TKT is correct that the prosecution history is always relevant to claim construction, it is also true that the prosecution history may not be used to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage, such as an amendment to overcome a rejection. See York Prods., Inc. v. Central Tractor & Farm Fam. Ctr., 99 F.3d 1568, 1575, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996). No such clear disavowal occurred here.

We agree with Amgen that the specification expressly describes humans as a subset of mammals, and mammals, in turn, as a subset of vertebrates. See '933 patent, col. 4, lines 47-48; col. 10, line 21. Moreover, the specification can fairly be read to, if not expressly, disclose the use of human DNA in human host cells in culture:

Conspicuously comprehended are expression systems involving vectors of homogeneous origins applied to a variety of

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bacterial, yeast, and mammalian cells in culture as well as to expression systems not involving vectors . . . . In this regard, it will be understood that expression of, e.g., monkey origin DNA in monkey host cells in culture and human host cells in culture, actually constitute instances of 'exogenous' DNA expression inasmuch as the EPO DNA whose high level expression is sought would not have its origins in the genome of the host.

'933 patent, col. 37, lines 33-43 (emphasis added). The astute reader will observe what appears to be a breakdown in the parallelism of the sentence emphasized in the block quote above. Specifically, the reference to the expression of "monkey origin DNA in monkey host cells in culture and human host cells in culture" seems a bit nonsensical because the expression of monkey origin DNA in human host cells is perforce the expression of exogenous DNA. The original 1983 application from which all the patents in suit claim priority, by contrast, contained language that upholds the parallelism of the sentence and logically makes sense. It read, in pertinent part: "It will be understood that expression of, e.g., monkey origin DNA in monkey host cells in culture and human DNA in human host cells in culture constitute instances of 'exogenous' DNA expression." J.A. at 2862 (emphasis added).

TKT boldly asserts that the variance between the original application and the patents in suit bespeaks some volitional act by Amgen to narrow the scope of the asserted claims in light of certain experimental data. In particular, TKT advances a theory whereby Amgen intentionally removed the language from subsequent applications (allegedly) because test results using human cells were not good, and later admitted (during an opposition proceeding against the European counterpart patent) that the omission was not inadvertent. But the record contains a more benign explanation as to what happened. According to the testimony of Dr. Lin, he was unaware of, and therefore did not authorize, the change. Further, the prosecuting attorney testified in his deposition that to the best of his knowledge the error was a typographical error.

But even assuming that the error was intentional, the district court's claim construction would not be foreclosed: our precedent is clear that claims are not perforce limited to the embodiments disclosed in the specification. E.g., Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344, 60 USPQ2d 1851, 1856 (Fed. Cir. 2001) ("An applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). Here, the patent plainly discloses the use of human host cells in culture, and our review of the record indicates no "clear disavowal" sufficient to undercut the express disclosure in the specification.

As a result, we are satisfied that the terms "non-naturally occurring," "vertebrate," and "mammalian" should be construed as they were by the district court, in a manner consistent with their plain meaning. Accordingly, we reject TKT's attempt to limit the scope of the asserted claims under an unduly constricted reading of the specification.
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9. "a non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin" ('933 claims 3,7-9,11-12 and 14).

Amgen	Roche/Hoffmann	Federal Circuit
A glycoprotein product not occurring in nature that is expressed in a mammalian cell from a DNA sequence that does not originate in the genome of the host and comprises a DNA sequence encoding human erythropoietin	A protein that is the expression product of the mammalian host cell having the amino acid sequence of human erythropoietin which is glycosylated naturally by the host cell at specific amino acids	"Non-naturally occurring" means not occurring in nature. Amgen, 314 F.3d at 1329

The main difference between the parties constructions for this claim is that Roche/Hoffeman's construction defines the recited "non-naturally occurring" glycoprotein product as "having": (a) the amino acid sequence of human EPO and glycosylation (b) added by the host cell, (c) only at specified amino acid residues. Amgen's construction, on the other hand,

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refers only to the first one of these three limitations. Tr. 40:16-62:25.

From reading the actual specification the Court is aware that while the claim includes the limitation that the glycoprotein incorporates a DNA encoding human EPO, it does not expressly state such glycoprotein product must be glycosylated or that glycosylation must occur at a specified amino acid residue.

The Court is bound to read the terms of a claim giving them their ordinary and customary meaning as understood by "a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13. In Phillips, the Federal Circuit not only explained how a court must give more weight to intrinsic, rather than to extrinsic evidence but also cautioned against improper importation of unintended limitations from the written description into the claims. Id.

At oral argument, the parties argued extensively over the meaning of "product of expression," its distinction from secretion, and its implications. Tr. 40:16-62:25. At the moment, however, the Court need not discuss matters implicating prior art or infringement arguments. The Court only must rely heavily in the written description in order to give the terms their ordinary meaning at the time of the invention. Phillips, 415 F.3d.at 1323. Accordingly, the Court now adopts the following construction:

"a non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin": a glycoprotein (not occurring in nature) that is the product of the expression 3 in a mammalian host cell of a DNA sequence that does not originate in the genome of the host, and which contains the genetic instructions (or a DNA sequence) encoding human erythropoietin.

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3 Wherein expression means that the glycoprotein was produced in a cell and recovered from the cell culture. Tr. 60: 17-19.

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2. "non-polar unsaponifiable fraction"

Plaintiff's proposed construction of "non-polar unsaponifiable fraction" is: "the relatively water insoluble fatty alcohols that result from saponification of jojoba oil." Defendant's proposed construction is: "water insoluble fatty alcohols that result from saponification."1

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1 After the claim construction briefing and hearings concluded,the parties provided a joint list of the disputed claim terms with proposed definitions. The joint list provided slightly different (though not materially different) proposed constructions for "non-polar unsaponifiable fraction" than the parties had previously proposed and argued for in their briefs and at the hearings. The Court will consider the versions set forth in the parties' briefs and argued for at the hearing, which are set forth above.

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The dispute turns on the inclusion of the word "relatively." Defendant argues Plaintiff's patent requires the fraction to simply be water insoluble, not relatively water insoluble, because it states: "The post saponification products may be either hydrophilic (water soluble) or hydrophobic (water insoluble)." Defendant also points to the fact that Plaintiff provided a specific definition for "unsaponifiable" in the specification: "Herein we use the term 'unsaponifiable' to mean those materials that, after saponification is completed, remain water insoluble." (Doc. 32-1 at 18). Plaintiff argues that a person of ordinary skill in the art would understand water insoluble to mean "relatively insoluble," not "absolutely" insoluble. At the hearing,Plaintiff stated that in chemistry, if applying the right energy and conditions, "just about anything" can be made soluble. (Doc. 42 at 21). Plaintiff argues a chemist would understand "water insoluble" in the context of the Patent to mean

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relatively, not absolutely, insoluble. Defendant does not dispute that almost anything can be made soluble, and presents no evidence that a chemist or other person skilled in the art would understand the term "water insoluble" to mean "absolutely water insoluble." Plaintiff's proposed construction will be adopted.
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A. Claims 1, 12, 18: "Non-Radioactive Moiety"

Claim 1 of the Brakel patent claims "an oligo- or polynucleotide having at least one non-radioactive moiety directly or indirectly attached to each of the 5' and 3' end nucleotides thereof." '830 Pat. 13:63-65. Claim 12 is more specific to a "non-radioactive moiety . . . attached to the 5' and 3' terminal nucleotides external to a target hybridization region. . . ." Id. at 14:29-33. Claim 18 of the patent claims:

A method for detecting target nucleic acid sequence in a sample comprising:

rendering the nucleic acid in said sample in single-stranded form

contacting said single-stranded nucleic acid under hybridizing conditions with (i) an oligo- or polynucleotide probe having at least one nonradioactive moiety directly or indirectly attached to each of the 5' and 3' end nucleotides thereof, said probe being capable of hybridizing to said target nucleic acid sequence, and (ii) a preformed detectable molecular complex; and

detecting any hybridized complexes, thereby detecting the target nucleic acid sequence

Id. at 14:53-66 (emphasis added).

Both parties agree that the literal meaning of "non-radioactive moiety" is too broad, and not intended by the inventors, but they disagree on how to appropriately narrow the construction of that term. Plaintiffs' interpretation would allow the independent claims of the patent to cover direct detection methods, while defendants assert that the patent should be construed to cover only indirect detection. Specifically, plaintiffs construe the phrase "non-radioactive moiety" to mean "non-radioactive detection moiety," i.e., interchangeable with the terms "non-radioactive label" and "detection moiety" as used in the patent summary and specifications. They argue that because the dependent claims, specifically Claims 14 and 15, teach "a nucleic acid hybridization assay composition comprising an oligoor polynucleotide of claims 1 or 12, and a preformed detectable molecular complex," '830 Pat. 14:37-40, which relates to indirect detection, the independent Claims 1 and 12 cannot permissibly be read to contain such a limitation.

Defendants interpret "non-radioactive moiety" to mean "a moiety capable of being detected indirectly through use of a 'preformed detectable molecular complex.'" They argue based on the method in Claim 18 that the non-radioactive moiety must be different from the directly-detectable moiety, because otherwise, step (ii) of the hybridizing method would be superfluous. They also point out that the preferred embodiment of the invention uses biotin as the non-radioactive moiety and avidin/strepavidin as the detectable molecule, illustrating that the non-radioactive moiety is a separate entity from the detectable molecule.

In this situation, the admonition against reading limitations from dependent claims into independent claims conflicts with the recognition that claim terms "are normally used consistently throughout the patent" such that "the usage of a term in one claim can often illuminate the meaning of the same term in other claims," Phillips 415 F.3d at 1314, because Claims 1 and 12 (which, when read together with their dependent claims, claim the non-radioactive moiety itself for detection) appear to use the term differently than Claim 18 (which claims use of the non-radioactive moiety plus a preformed detectable molecular complex for detection).

In such a situation, the Court relies on the fundamental principle that "claims 'must be read in view of the specification, of which they are a part.'" Id. at 1315 (citing Markman, 52 F.3d at 979); see also On Demand Machine Corp. v. Ingram Indus., Inc., 442 F.3d 1331, 1337-38 (Fed. Cir. 2006) (". . . the court in Phillips, resolving conflict, stressed the dominance of the specification in understanding the scope and defining the limits of the terms used in the claim."). The specification of the

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patent provides as follows. First, it defines "analyte specific moiety," the preferred embodiment of which is a nucleic acid hybridization probe. '830 Pat. 3:14-16. Then, it provides that the "analyte specific moiety" is attached "with other moieties such as biotin or biotin analogues." Id. at 3:25. Third,

Detection of the analyte specific moiety when attached to the analyte can be accomplished by a variety of means employing detectable molecules. Detectable molecules refer to enzymes, fluorochromes, chromogen and the like which can be coupled to the analyte specific moiety either directly or indirectly. As an example, biotin attached to the analyte specific moiety can be detected with a preformed detectable molecule comprising avidin or streptavidin and a biotinylated enzyme. The enzyme of the resultant complex formed between the detectable molecule and the analyte specific moiety can thus serve as the signal reporting moiety of the assay composition.

'830 Pat. 3:41-53.

In context, the specification's reference to "enzymes, fluorochromes, chromagen and the like," refers to indirect detection, where such molecules are utilized to detect the "biotin or biotin analogues" attached to the probe. Furthermore, unlike the Ward patents, the four examples provided in the Brakel specification all relate to use of a biotin-avidin (or equivalent) complex, which constitutes indirect detection.

Based on the specification, therefore, the Court concludes that the "non-radioactive moiety" claimed in Claims 1, 12 and 18 must be defined as a moiety that is utilized in indirect detection, i.e., a moiety that can be detected with a preformed detectable molecular complex.
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II. The '830 Patent

Thedistrict court construed the term "non-radioactive moiety" in the '830 patent to mean "a moiety that is utilized in indirect detection, i.e., a moiety that can be detected with a preformed detectable molecular complex." Claim Construction, 2006 U.S. Dist. LEXIS 74570, 2006 WL 2927500, at Enzo would like the term construed simply to mean "a non-radioactive detection moiety." Thus, under Enzo's proposed construction, the moiety could be utilized in either indirect detection (wherein the preformed detectable molecular complex is the thing that generates a detectable signal) or direct detection (wherein the non-radioactive moiety is itself the thing that generates a detectable signal). We agree with the district court's construction.

Claims 1, 12, and 18 are independent claims. Claim 14 is a multiple dependent claim that refers back to claims 1 and 12. The claims recite, with key term emphasized:

1. An oligo- or polynucleotide having at least one non-radioactive moiety directly or indirectly attached to each of the 5' and 3' end nucleotides thereof.

12. An oligo- or polynucleotide having at least one non-radioactive moiety directly or indirectly attached to each of the 5' and 3' terminal nucleotides external to a targethybridization region of said oligo- or polynucleotide.

14. A nucleic acid hybridization assay composition comprising an oligo- or polynucleotide of claims 1 or 12, and a preformed detectable molecular complex.

18. A method for detecting a target nucleic acid sequence in a sample comprising:

rendering the nucleic acid in said sample in single-stranded form;

contacting said single-stranded nucleic acid under hybridizing conditions with (i) an oligo- or polynucleotide probe having at least one non-radioactive moiety directly or indirectly attached to each of the 5' and 3' end nucleotides thereof, said probe being capable of hybridizing to said target nucleic acid sequence, and (ii) a preformed detectable molecular complex; and

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detecting any hybridized complexes, thereby detecting the target nucleic acid sequence.

Enzo concedes that the term "non-radioactive moiety" cannot be given its literal meaning (i.e., a molecular substructure not labeled with a radioisotope), since the claims would then encompass any piece of natural DNA, rendering the claims invalid on their face. The district court therefore looked to the specification, which contains no disclosure of direct detection but instead refersto an "analyte-specific moiety" detected using "detectable molecules." '830 patent col.3 ll.41-53. Because all detectable molecules mentioned in the specification are those relating to detection via a "preformed detectable molecular complex," the district court concluded that a "non-radioactive moiety" must be detected via a signal generated from the preformed detectable molecular complex rather than from the moiety itself. On appeal, Enzo faults the district court for equating "non-radioactive moiety" with "analyte-specific moiety," and argues that the specification instead equates "non-radioactive moiety" simply with "labeling" of nucleic acids using "labeling moieties." Id. col.1 ll.8-11. But even if a non-radioactive moiety is simply a "label," as Enzo suggests, this still leaves open the question whether the non-radioactive moiety is itself capable of generating a detectable signal or whether the preformed detectable molecular complex is what generates the signal.

The claim language strongly suggests that the non-radioactive moiety serves simply as a binding site for a preformed detectable molecular complex, and that the signal is generated by the complex, not the moiety. Independentclaim 18 is unambiguously limited to indirect detection via "a preformed detectable molecular complex." Id. col.14 ll.63-64. If the non-radioactive moiety were itself the thing that generated a detectable signal, then there would be no reason to contact it with the preformed detectable molecular complex, as required in part (ii) of the "contacting" step of claim 18. Moreover, in the last step of this claim, what is detected is "any hybridized complexes," not the moiety. Id. col.14 l.65 (emphasis added). Thus, at least with regard to claim 18, the "non-radioactive moiety" is a moiety that can be detected with a preformed detectable molecular complex. Enzo has not argued that the "non-radioactive moiety" should have a different meaning in independent claim 18 than in independent claims 1 and 12. Indeed, we have recognized that "claim terms are normally used consistently throughout the patent." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc).

Referring to the claim language, Enzo argues that the district court's construction of "non-radioactive moiety" violates the doctrine of claim differentiation. Under this doctrine, "the presence of a dependent claim that addsa particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1315. Because dependent claim 14 adds "a preformed detectable molecular complex" to claim 1, Enzo asserts that the district court's construction of "non-radioactive moiety"--which refers to detection with "a preformed detectable molecular complex"--renders the two claims coextensive. But the district court's construction imposes no requirement that a preformed detectable molecular complex is actually present in claim 1; rather, it simply requires the "non-radioactive moiety" to be capable of performing a function: "can be detected with a preformed detectable molecular complex." Claim Construction, 2006 U.S. Dist. LEXIS 74570, 2006 WL 2927500, at *11 (emphasis added). Claim 1, unlike claim 14, is infringed even in the absence of a preformed detectable molecular complex. See Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1370 (Fed. Cir. 2009) (holding that a component of an accused device meets "capable of engaging" limitation even though device is not designed or sold with component in engaging configuration). Because claim 1 is broader than claim 14 under the districtcourt's construction, this case simply does not implicate the doctrine of claim differentiation.

The specification lends no support to Enzo's proposed construction because it contains no disclosure whatsoever of direct detection. This fact alone is not dispositive, of course, because "it is improper to read limitations from a preferred embodiment described in the specification--even if it is the only embodiment--into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 913 (Fed. Cir. 2004). But, as already discussed, the claim language strongly suggests that the non-radioactive moiety must have the capability of being indirectly detected with a detectable molecular complex.

The prosecution history is not to the contrary. Enzo overcame an obviousness rejection by stating:

Prior to the instantly claimed invention, no mention or suggestion was ever made regarding the attachment (directly or indirectly) of at least one non-radioactive moiety, e.g., biotin or a biotin analogue, to each of the 5' and 3' end nucleotides of an oligo- or polynucleotide. Furthermore, no prior artreference ever taught or suggested the possibility of a nucleic acid hybridization assay composition comprising such a labelled oligo- or polynucleotide and a preformed detectable complex, e.g., a preformed avidin or streptavidin detectable molecular complex, as defined by the present claims.

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J.A. 307 (emphasis added). On appeal, Enzo argues that this statement supports its proposed construction because it equates a "non-radioactive moiety" with a "labeled oligo- or polynucleotide," which in turn suggests that the moiety is simply a "label." But again, the question is how this "label" is detected. The very same sentence that refers to the claimed compound as a "labelled oligo- or polynucleotide" also refers to a "preformed detectable complex," suggesting that detection is accomplished by the latter. Indeed, the unique binding of a biotin moiety with an avidin complex, referenced in this passage, is an example of indirect detection. Moreover, these prosecution statements were made with regard to all rejected claims standing or falling together, and were not directed to any dependent claim reciting a detectable molecular complex as an express limitation of the claim. All of this suggeststhat the non-radioactive moiety must be capable of indirect detection with a preformed detectable molecular complex. The prosecution history thus tends to undercut, rather than support, Enzo's proposed construction.

For the foregoing reasons, we affirm the district court's construction of "non-radioactive moiety." Because Enzo stipulated that it cannot prove infringement under this construction, we affirm the judgment of noninfringement of the '830 patent.
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a. "Non-specific and charge-dependent"

Caliper urges the Court to interpret the term "differential association" to require "non-specific and charge-dependent" binding. Caliper proposes that the term "non-specific and charge-dependent" be construed to mean that "the polyionic polymer has an affinity for either the first reagent of the fluorescently labeled product that does not require the presence of a specific recognition site (binding instead to a charged portion of the first reagent or fluorescently labeled product), and that the binding of the polyionic polymer to the first reagent or the fluorescently labeled product is at least partially driven by charge."

MDC urges that the Court adopt the further explanatory language for the term binding indicating that it is the charge difference, not any structural differences, that is the basis for the differential association.

The patent expressly addresses the term "non-specific interaction" and states that "it will be appreciated that the polyions used in accordance with the present invention do not require the presence of a specific recognition site in the product (or substrate)." ('774 Patent at 8:34-37.) Accordingly, the Court adopts the construction of a "non-specific" interaction to mean that an interaction that does not require the presence of a specific recognition site.

Charge-dependent is not expressly defined in the patent. However, "the terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." Texas Digital, 308 F.3d at 1202 (citations omitted). During the Markman Hearing, Caliper conceded that its proposed verbiage "at least partially driven by charge" is not the most precise construction and instead offered the language "charge is necessary to the interaction." (Markman Hearing 23:15.) This construction encapsulates the ordinary meaning of the term. Accordingly, the Court adopts the construction of "charge-dependent" to mean that charge is necessary to the interaction. Thus, a "non-specific and charge-dependent" interaction is construed to mean an interaction that does not require the presence of a specific recognition site and in which charge is necessary to the interaction. 1

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1 This construction of "non-specific and charge-dependent" applies throughout all the remaining disputed terms that include this terminology.

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A. Language of the Claim

As detailed above, Claim 1 claims "a non-toxic liquid antifreeze" contained in the cavity of the ball which "moves freely" over the interior surface of the ball. (SJ Ex. 1, 906 Patent, col. 4, ll. 1-2, 7). No description of the chemical composition of the non-toxic liquid antifreeze is given. Franklin conceded in oral argument that the plain and ordinary meaning of such language to one skilled in the art does not exclude the calcium chloride solution used in its ball. Since the language of the claim itself does not support Franklin's defense, we therefore turn to the specification and the prosecution history.

B. Language of the Specification

The specification describes the liquid in the following manner: "the preferred liquid is a nontoxic antifreeze. Such antifreeze is available for use in RVs (recreational vehicles)." (SJ Ex. 1, 906 Patent, col. 2, ll. 13-15). The specification provides a description of the general benefits of non-toxic antifreeze, to wit: "non-toxic antifreeze . . . lowers the ball's center of gravity, increases control, and reduces bounce. The antifreeze is particularly useful for this application since its viscosity is relatively low and varies little with temperature so that, whether the ball is used in winter or summer, the ball's improved performance is substantially unaffected." (Id. at ll. 59-65). No further description of the antifreeze is provided, nor are any further details given concerning the types of antifreeze which might be used by RVs.

C. Language of the Prosecution History

"Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d at 1576 (citing Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562 (Fed. Cir. 1991)). A patentee may "relinquish[] a potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." 3 Id. Franklin contends that Gentile relinquished a broad construction of "non-toxic liquid antifreeze" by his representations to the PTO during the prosecution of the patent. However, after examination, this court finds that the prosecution history does not reveal the relinquishment of claims to the extent urged by the defendant. The pertinent history is given in some detail below, as the exchange between the patent examiner and Gentile forms the basis for the present dispute between the parties.

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3 The prosecution history must be in evidence to be considered by court in construing claims in a motion for summary judgment. See Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001). The defendant submitted the entire prosecution history to the court following oral argument on this motion.

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On March 21, 1994, Gentile filed Patent Application No. 08/215,892 for a "Hockey ball containing fluid." (Patent and Trademark Office File History submitted by the defendant ("PTO History") at Ex. 1). The invention was of a ball with a "hard, sturdy, bounce resistant shell which contains a freely moving weight," preferably a liquid. (Id. at p. 3 (Summary)). The description states that the "preferred liquid is a nontoxic antifreeze. Such antifreeze is available for use in RVs (recreational vehicles)." (Id. at p. 4). The application included over 20 claims. The most detailed description in the claims of the liquid was "a nontoxic antifreeze." (Id. at pp. 7-8). On September 2, 1994, all the claims were rejected. (PTO History at Ex. 2). Among the reasons given was that claims were anticipated by the "Brewster" patent and "Goldfarb" patent. (Id. at pp. 2-3). The Brewster patent was for a ball containing a viscous, friction, fluid, i.e. oil, and the Goldfarb patent was for a ball containing a ball which caused erratic movement. (PTO History at Ex. 4, pp. 3-4).

Gentile filed an "Amendment and Response" on January 6, 1995, adding a new Claim 5 for a ball with a "freely moving liquid" inside. (Id., Ex. 4 at p. 2). Gentile distinguished the viscosity of oil, syrup and a nontoxic antifreeze, specifically "UNIGARD-50 Freeze Proof, Propylene Glycol Based." (Id. at p. 4). It was Gentile's position that the viscous fluid would not work for a hockey puck as it becomes very thick, especially when cold. On the other hand, "nontoxic antifreeze is very non-viscous, and its viscosity varies little with temperature. Since street hockey is played in hot summer weather and cold late fall weather, sometimes below freezing, a ball consistently simulating a hockey puck is necessary." (Id. at p. 3, P 4).

On March 10, 1995, all pending claims, as amended, were again rejected, partially for being anticipated by "McNeill," a

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sports ball with a void "which contains loose internal material which can be water." (PTO History at Ex. 5, pp. 1-3). The examiner also noted that while Gentile had made comparisons between oil, syrup and antifreeze, "none of these materials is being claimed." (Id. at p. 3.)

On or about July 10, 1995, Gentile submitted an Amendment and Response specifically adding Claim 25 for the liquid to comprise "a nontoxic antifreeze." (PTO History at Ex. 6, claim 25 and p. 4). No further description of the liquid is included. On August 22, 1995, the examiner rejected the claims, citing the Townsend patent as anticipating Gentile's application by disclosing a ball that could be partially filled with liquid. (PTO History at Ex. 7, p. 3). The examiner noted, however, that Claim 25 would be allowable if rewritten in an independent form. (Id.).

Shortly thereafter, in or about September 1995, Gentile filed a petition under 37 C.F.R. § 1.102(d) to have his application advanced out of turn due to the entry into the market of Sun Hockey's Zero Ball which he believed infringed on his claims. (PTO History at Ex. 8). The petition was granted on December 14, 1995. (PTO History at Exs. 9, 10). Gentile then filed a "Preliminary Amendment to Continuation Application" which amended Claim 25 to be for a ball for hockey which contained "freely moving non-toxic antifreeze." (PTO History at Ex. 13 at p. 3). 4 The accompanying specification explained that "the preferred embodiment of the invention employs non-toxic antifreeze as the liquid which lowers the ball's center of gravity, increases control, and reduces bounce. The antifreeze is particularly useful for this application since its viscosity is relatively low and varies little with temperature so that, whether the ball is used in winter or summer, the ball's improved performance is substantially unaffected." (Id. at p. 2). In accompanying remarks, Gentile stated that the "invention transcends the type of liquid contained" in the ball, and requested a broad reading of his application's claims since "knock-offs" selling a "less preferred embodiment using a different liquid" (i.e., a liquid other than nontoxic antifreeze) were enjoying the benefits of his invention even though not exactly duplicating his invention's preferred embodiment. (Id. at p. 6.)

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4 The application was now being reviewed by a different patent agent. (PTO History at Ex. 13, p. 4).

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On May 23, 1996, the claims were again rejected. (PTO History at Ex. 15, p. 4). In rejecting the claims, the examiner introduced the concept of "salt" which has been pivotal in the instant case, but which had never been mentioned before. (Id. at p. 2). As the examiner wrote in relevant part:

> It is not clear what features are critical in this case. Base claim 25 is too broad, obviously, and indefinite, due to the relative terms "freely moving" and "non-toxic" and "antifreeze" found within any relatively small, relatively hard spherical object. For example, a small quantity of "salt" is an "antifreeze" material inherently and doubtless can be found in a spherical shaker container, which structure would correspond to claim 25. Numerous other examples can be found by the examiner, if necessary.

(Id. at pp. 2-3) (emphasis added). In addition, in rejecting the claims as being anticipated by, or as obvious over Brewster, the examiner wrote:

> In regard to applicant's remarks and comparative data regarding oil, syrup, and antifreeze, filed January 6, 1995, such are directed to a propylene glycol based antifreeze solution, rather than to the antifreeze materials defined so broadly by the claims. Since claims 24-29 define no certain materials for the ball's hard outer shell, Brewster's ball shell is inherently as much a ball for use in street hockey as is the applicant's game ball.

(Id. at p. 4) (emphasis added). Thus, at least as of May 23, 1996, it was clear that Gentile was not limiting his claim either to an antifreeze used in RVs or, even more limiting, to a propylene glycol antifreeze. 5

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5 The examiner stated briefly that the claims were also anticipated by the later-filed "Aiello" patent, and assumed that the original application date of March 21, 1994 could not be used "due to new matter being claimed" in the continued

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application. (PTO History at Ex. 15, p. 4.) Gentile disputed the examiner's contention that the continuing claim could not relate back to the original filing date, as the amended claims were contained in the original conception of the invention. (PTO History at Ex. 16, p. 14.)

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Gentile submitted another amendment to Claim 25 on or about July 16, 1996, describing the liquid as a "freely moving, non-toxic liquid antifreeze solution." (PTO History at Ex. 16, p. 12). In addition, he proposed a new dependent Claim 29 that specified the antifreeze as a "non-toxic propylene glycol based antifreeze solution." (Id.) The claims were rejected on September 18, 1996. (PTO History at Ex. 17). With respect to Claim 25, the examiner objected because "it is not clear whether it is the liquid antifreeze 'solution' that occupies less than half the void, or whether it is the antifreeze component of a liquid solution that occupies less than half of the void." (Id. at p. 3). With respect to the other claims, the examiner contended that the liquid claimed could be simply water "to which another component such as TEPOL is added." (Id. at p. 4).

In a response dated November 5, 1996, Gentile amended Claim 25 again, to return to the more general description of a shell "containing freely moving, non-toxic, liquid antifreeze, and the non-toxic, liquid antifreeze occupying less than half of the void." (PTO History at Ex. 18, revised claim 25 at claims p. 5). He also removed the reference to the "propylene glycol based antifreeze solution" in Claim 29. (Id.) In his remarks, Gentile again stressed the advantage of a "liquid antifreeze" as settling quickly so that the ball maintains a low center of gravity for more control, and exhibits substantially the same characteristics, regardless of the temperature. (Id. at Ex. 18, p. 3). All claims were again rejected on March 7, 1997, with the examiner again concluding that water alone or water with TEPOL could be the antifreeze. (PTO History at Ex. 19, p. 3). As the examiner wrote, "it is well known that citrus growers in Florida commonly spray water on their citrus trees to prevent the fruit from freezing during cold spells, hence, said water, itself is a 'non-toxic' (claim 29) 'antifreeze' inherently since it can be used for that purpose." (Id.)

Gentile then requested, and received, a personal interview with the examiner. Gentile's counsel, Thomas O'Connell, also attended the meeting on May 14, 1997. (PTO History at Ex. 20). The examiner's notes of the meeting indicated that an agreement was not reached, and that the Townsend patent had been discussed as prior art. The examiner further noted:

> Only one base claim 26 will be presented [and] will include "consisting" [and] "non-toxic" limitations. Remarks will include label of non-toxic antifreeze used in RVs.

(Id.)

On May 23, 1997, Gentile filed an Amendment After Final Rejection, which included an interview summary as required by the Manual of Patent Examining Procedure § 713.04. (PTO History at Ex. 21). The revised claim 26 now read:

> A ball for use in street hockey, the street hockey ball consisting of a hard, hollow sphere of material and a freely moving, non-toxic liquid antifreeze contained within an inner volume of the sphere . . . , and the non-toxic liquid antifreeze occupying less than one-half of the volume of the sphere whereby the street hockey ball's center of gravity is lowered below the geometric center of the ball.

(Id. at p. 1) (emphasis in the original).

In describing the substance of the interview, Gentile's counsel wrote:

> The inventor gave a brief summary of his invention for a street hockey ball including the need left by prior art balls and his attempted solutions thereto. The inventor noted that mercury functioned exceedingly well as a liquid contained in the street hockey ball but that mercury was unusable due to its toxicity. The inventor stated that he found non-toxic antifreeze of the type used in recreational vehicles (RVs) to be ideal. The inventor remarked that he discovered that non-toxic antifreeze worked equally as well as mercury while avoiding safety concerns regarding poisoning. It prevented freezing, did not "cling" to the inner surface of street hockey balls, and settled quickly even after being struck with a hockey stick.
>
> The participants then discussed the meaning of "non-toxic" and "antifreeze." The applicant and his attorney emphasized

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that the originally-filed specification indicated that "non-toxic liquid antifreeze" meant the type used in recreational vehicles. The Examiner was presented with a label from a bottle of such an antifreeze. A copy of the label is included herewith as Appendix A. The inventor's attorney noted that the specification's term comported with that found in Random House Webster's School and Office Dictionary which unequivocally defines "antifreeze" as "a liquid used in the radiator of an internal-combustion engine to lower the freezing point of the cooling medium."

The participants discussed the Townsend patent including whether it disclosed a viscous liquid alone within a ball and whether it disclosed a salt water solution in a ball. The examiner cited a concern regarding whether the term "non-toxic antifreeze" could include salt water, and the inventor pointed out that salt water is toxic and would not be within the scope of his claims. The inventor noted that too much salt water can poison and kill a person.

(Id., Ex. 21 at p. 2) (emphasis added). The attached "Appendix A" contained a label for "Easy Going," "a non-toxic" "RV & Marine Antifreeze" which was "odorless," "tasteless" and "contains propylene glycol." (Id.)

In the "Remarks" section of the submission, Gentile (through counsel) stated that by changing the preamble to "consisting of" from "comprising," the claim was now for "a spherical shell that contains only 'non-toxic liquid antifreeze.'" (Id. at Ex. 21, p. 4). As he wrote in addition:

Further still, the claim is clearly limited by the term "antifreeze" which further defines the single base claim over the prior art. On this note, Applicant respectfully submits that the Office's assertion in its Detailed Action that "liquid antifreeze" includes such liquids as water is contrary to both the commonly accepted definition of antifreeze and to Applicant's intended meaning for the claim limitation. Random House Webster's School and Office Dictionary unequivocally defines "antifreeze" as "a liquid used in the radiator of an internal-combustion engine to lower the freezing point of the cooling medium." As the originally filed specification makes clear, this is essentially the definition Applicant intended to be attached to his use of the term "antifreeze." On page 5, lines 4 and 5, the originally-filed specification makes the term's meaning still more clear by stating that the "liquid antifreeze" used and claimed is of the type "available for use in RVs (recreational vehicles)." To make the Applicant's intended meaning of "liquid antifreeze" clearer still, Applicant submits herewith a label from a bottle of the antifreeze "available for use in RVs" as Appendix A of this paper.

With the foregoing in mind, Applicant submits that the definition of "liquid antifreeze" as used in Applicant's application is clear, and water can not be said to comport with such a definition because it would not lower the medium's freezing point. Indeed, water is normally the medium whose freezing point is sought to be lowered. The Office's assertion that water is used as an antifreeze by Florida citrus growers is not accurate. As the memo that is included as Appendix B herewith from Tropicana Products, Inc. indicates, citrus growers often use water as a jacket of insulation, not as antifreeze. The water does not function as an antifreeze for the citrus products any more than does fiberglass act as antifreeze for a home.

Even beyond the previously-described claim limitations, which Applicant submits adequately distinguish over the prior art, the sole base claim further specifies that the "liquid antifreeze" is "non-toxic." As we discussed during Applicant's interview with the Office and even ignoring all other claim limitations, "non-toxic" would exclude a multitude of liquids including salt dissolved in water. As the inventor of the street hockey ball noted during the interview and as he writes in his declaration on Appendix C, salt water properly may be considered toxic. One need only look to stories of sailors lost in a sea of salt water who have died for lack of potable drinking water.

. . . .

Through experimentation during his development of the invention, the inventor discovered that for a multiplicity of reasons antifreeze was uniquely useful as the liquid to be included within the street hockey ball. Among the advantages of antifreeze are its low viscosity and low affinity for the inner surface of the ball. Together, these characteristics permit the liquid antifreeze to settle to the bottom of the ball quickly after the ball's being struck such that the ball maintains a low center of gravity even during the spirited play of street hockey. A further advantage of the liquid antifreeze is the consistency of its performance over a wide range of temperatures. Unlike other, less-preferred liquids, such as water, balls containing antifreeze exhibit substantially identical handling characteristics whether used in the heat of summer or the dead of winter. With the unique advantages of non-toxic liquid antifreeze in mind, it becomes clear that presently-pending claims 24 and 26 are patently distinct over the prior art references.

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(Id. at pp. 4-5) (emphasis added).

On June 5, 1997, the examiner himself amended, and allowed as amended, a new claim (now numbered 1). As allowed by the examiner, the claim is for:

A game ball in the shape of a sphere for use in playing street hockey, the game ball consisting of a hard, rigid spherical shell enclosing a cavity, and a non-toxic liquid antifreeze contained in said cavity, the spherical shell having a smooth unobstructed spherical inner surface, and the non-toxic liquid antifreeze occupying less than one-half of the volume of said cavity whereby the center of gravity of said game ball is below the geometric center of said game ball and the non-toxic liquid antifreeze moves freely over the spherical inner surface of said game ball during movement of the game ball over a playing surface.

(PTO History at Ex. 23, p. 2) (emphasis added).

IV. ANALYSIS OF PATENT INFRINGEMENT CLAIM

A. The Alleged "Salt Water" Exclusion

"Although claims are construed objectively and without reference to the accused device, only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d at 803. As detailed above, Franklin contends that the 906 Patent excludes coverage of salt water solutions and that Franklin's ball, which contains "the salt calcium chloride dissolved in water," cannot, therefore, infringe. It is well established that claims are to be interpreted to exclude an interpretation which had been "'disclaimed or disavowed during prosecution in order to obtain claim allowance.'" KX Indus., LP v. Pur Water Purification Prods., 18 Fed. Appx. 871, 2001 U.S. App. LEXIS 18155, at *8, No. 00-1543 (Fed. Cir. Aug. 21, 2001) (internal citation omitted). Thus, if a patentee disclaims a particular interpretation of a claim term, the term's ordinary meaning is modified according to such disclaimers. See Hockerson-Halberstadt v. Avia Group Int'l, 222 F.3d 951, 956 (Fed. Cir. 2000). "But any limitation of the meaning attributed to the claim language based on such disclaimer must be shown in the intrinsic record with reasonable clarity and deliberateness." KX Indus., LP v. Pur Water Purification Prods., 18 Fed. Appx. 871, 2001 U.S. App. LEXIS 18155, at *10.

Here, neither the claim nor the specifications make any reference to salt water. The references in the prosecution history to salt water are not broad enough to exclude the non-toxic salt calcium chloride contained in Franklin's ball. "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998), and cases cited. Here, it would not be reasonable to interpret the history as excluding the multitude of potential salt compounds which exist.

"Salt" appears in the patent's prosecution two times: when the examiner inquired whether salt in a round salt shaker would be claimed by Gentile's patent; and when the inventor disclaimed "salt water" as a "toxic" liquid because "too much salt water can poison and kill a person," giving as an example sailors dying despite being surrounded by a "sea of salt water." As an initial matter, the plain meaning of the first statement refers to table salt, and the second to seawater. There is not any attempt to address the large number of salt compounds which exist. More importantly, any alleged disclaimer by Gentile is to a toxic liquid -- it is impossible to separate the reference to salt water from its toxic effect. However, Franklin admits that its ball contains a non-toxic salt solution. 6 No competitor reading the 906 Patent history could reasonably conclude that a non-toxic salt solution is excluded. Since the alleged exclusion of all saltwater solutions is not shown "with reasonable clarity and deliberateness," Franklin's argument must fail.

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6 While recognizing that Gentile argued that "salt water" was excluded from his patent due to its toxicity, Franklin simply ignores the fact that its ball contains a non-toxic salt solution. Franklin seems to be implying that Gentile should be bound by an erroneous conclusion that all "salt water" solutions are toxic and are therefore excluded from the patent. This argument is not only illogical, it goes much too far. Gentile did not purport to exclude all salts, nor did he contend that all salts are toxic. Franklin's contention that all "saltwaters" are excluded from the patent is without merit.

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Franklin argues that Gentile excluded "salt water" to distinguish it from the Townsend patent. However, the Townsend patent does not specifically claim a salt water solution. See SJ Ex. 3. Moreover, according to his counsel's summary of their interview, Gentile and the examiner discussed "whether [Townsend] disclosed a viscous liquid alone within a ball and whether it disclosed a salt water solution in a ball" -- no resolution was apparently reached. (PTO History at Ex. 21, p. 2). In any event, Gentile stressed that toxic salt water solutions would be excluded from his patent. (Id.) The fact that this assertion was made in the context of distinguishing the Townsend patent adds nothing. Finally, and perhaps most importantly, in order to distinguish the Townsend patent, the claim was amended to consistently refer to "non-toxic liquid antifreeze." (Id. at p. 3). It was not amended to otherwise exclude salt water solutions. It is not appropriate to read a limitation into the claim which is not apparent from its ordinary meaning. See Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d at 989 ("a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of the claim terms").

B. The Alleged Limitation to RV Anti-Freeze

Franklin also argues in passing that "Gentile's patent covers only recreational vehicle antifreeze," and that it is therefore entitled to a judgment of non-infringement as a matter of law. See Def.'s Mem. at 8. 7 This argument, however, is not clearly articulated and required extensive analysis by the court. For example, Franklin implies, but does not expressly assert, that the limitation to RV antifreeze is also properly limited to propylene glycol solutions. However, while I find that the claim is properly interpreted to incorporate the dictionary definition of antifreeze specifically identified by the inventor, it is not limited to antifreeze containing propylene glycol.

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7 Franklin's principal argument is that salt water solutions are excluded from Gentile's patent, a claim I have rejected.

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The claim itself makes no reference to any limitation on the type of non-toxic liquid antifreeze which might be used. The specification states only that the "preferred liquid" is a "non-toxic antifreeze" and that such antifreeze is "available for use in RVs." However, the "general rule, of course, is that the claims of a patent are not limited to the preferred embodiment, unless by their own language." Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 973 (Fed. Cir. 1999), and cases cited. The "court consistently declines to construe claim terms according to the preferred embodiment." N. Telecom Ltd. v. Samsung Elecs. Co., Ltd., 215 F.3d 1281, 1293 (Fed. Cir. 2000), and cases cited. Therefore, "preferred embodiments, without more, do not limit claim terms." Id. and cases cited. In the present case, the passing reference to RVs as part of a preferred embodiment in the specification does not limit the claim to non-toxic liquid antifreeze used in recreational vehicles.

The patent history does establish some limitations on the definition of "antifreeze," but it is not nearly as limited as Franklin suggests. Thus, the antifreeze is not limited to propylene glycol, nor is it limited to antifreeze used in RVs. Gentile did, however, adopt a specific dictionary definition of antifreeze which does control his claim.

In 1995, when Gentile provided information about the viscosity of oil, syrup and a propylene glycol-based antifreeze, the examiner expressly noted that "none of these materials is being claimed." (PTO History at Ex. 5, p. 3). This was again confirmed by the examiner in a rejection dated May 23, 1996. (PTO History at Ex. 15, p. 4). When in an effort to satisfy the examiner Gentile proposed in July 1996 that the antifreeze claimed be limited to a "non-toxic propylene glycol based antifreeze solution," the examiner still rejected the claim and the proposed limitation was then removed from all subsequent versions of the claims. (See PTO History at Ex. 16, p. 12; Ex. 17, pp. 3-4; Ex. 18, claims p. 5). Where, as here, a limitation is expressly removed from a claim during the application process, a reader of the record could only conclude that the proposed amendment did not constrain the meaning of the claim terms. See Bailey v. Dart Container Corp., 980 F. Supp. 560, 579 (D. Mass. 1996) (excluding limitation from claim construction where patentee added and then, prior to patent approval, removed limitation from claim).

The balance of the interactions between Gentile and the examiner similarly compels the conclusion that antifreeze is not limited to propylene glycol or to an antifreeze for RVs. Although Gentile provided a label from an RV and Marine anti-

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freeze which contained propylene glycol, the label was provided only as an example of the type of antifreeze which would be covered by the patent. (PTO History at Ex. 21). This conclusion is supported by the fact that although the claim subsequently was amended both by Gentile and then by the examiner, there were no limitations made to the "non-toxic liquid antifreeze" description contained in the claim. In addition, there is no precise chemical composition of the antifreeze provided either in the label or in the viscosity comparison made by Gentile. 8 It makes no sense to limit the definition of "antifreeze" to an undefined product. "Given the examiner's obligation to confer the broadest reasonable interpretation on [a claim term], if the examiner wanted to hinge patentability upon [a particular interpretation of the term], he would have said so, and required a specific amendment to reflect [that interpretation.]" Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 2001 U.S. App. LEXIS 24810, at *25 (Fed. Cir. 2001) (reversing district court's claim construction as unnecessarily limiting the meaning of the disputed term). Since the examiner did not limit the claim to propylene glycol or to an antifreeze used in RVs, the court should not do so either.

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8 Not only are the ingredients of the product not defined in the label with any specificity, but the label provided is for a different product than the one Gentile used to compare viscosity. (Compare PTO History Exs. 4 and 21). Presumably the composition of the products differ to some extent.

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I do find, however, that Gentile did limit his definition of anti-freeze to the Random House Dictionary definition of "a liquid used in a radiator of an internal combustion engine to lower the freezing point of the cooling medium." During the interview with the examiner, and in the subsequently filed summary and remarks, Gentile and his attorney stressed that this was the definition Gentile intended. (See PTO History at Ex. 21, pp. 2, 4). A standard dictionary definition can be used to define the ordinary meaning for the purpose of claim construction. See MSM Invs. Co., LLC v. Carolwood Corp., 259 F.3d 1335, 1339 (Fed. Cir. 2001) (citing Webster's Dictionary to define term "feeding"); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996) (judges are "free to consult" dictionaries "at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents"). Thus, one reading the patent history could assume that this definition applied, even though the examiner declined to amend the claim to expressly limit the type of antifreeze involved. Such an interpretation, limiting the claim to the dictionary definition given by the inventor, properly balances the well established principles of claim construction -- namely, that "while terms used in a patent generally should be construed to have the ordinary meaning they had at the time of the patent application, a patentee is still entitled to 'choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.' . . .In those circumstances where the patentee's meaning is clear, the court must adopt the special definition of the term." Bailey v. Dart Container Corp., 157 F. Supp. 2d 110, 114 (D. Mass. 2001) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d at 1578). Here, the inventor selected the "ordinary meaning" to be given to the term "antifreeze" and his choice should be honored.

Admittedly, there are other dictionary definitions which are broader, and which the plaintiff now urges. For example, Merriam-Webster's Collegiate Dictionary has defined antifreeze since 1924 as "a substance added to a liquid (as the water in an automobile engine) to lower its freezing point." Other definitions are more specific. For example, "Dictionary.com" defines antifreeze as a "substance, often a liquid such as ethylene glycol or alcohol, mixed with another liquid to lower its freezing point," with the source of the definition being The American Heritage Dictionary of the English Language (Fourth Ed. 2000). There are a myriad of dictionary definitions which can be used to define "antifreeze." The inventor chose The Random House Dictionary definition to define his claim. 9

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9 Although the precise edition of the dictionary used by the plaintiff has not been cited, the court found this definition in The Random House Dictionary of the English Language (Second Edition) at p. 91 (1987).

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Gentile argues that the references to the definition of antifreeze were intended only to distinguish plain water as being an

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antifreeze. (See Pl.'s Mem at 11). As an initial matter, it does not appear that the repeated statements as to what the inventor meant by "antifreeze" were intended to be so limited in purpose. More importantly, "whether the limiting assertions made were necessary for allowance of the claims is not dispositive as to whether a patentee has disclaimed a certain subject matter . . . . Rather, what is determinative is whether the patentee has defined a claim term as excluding a broader interpretation with reasonable clarity and deliberateness." KX Indus., L.P. v. Pur Water Purification Corp., 18 Fed. Appx. 871, 2001 U.S. App. LEXIS 18155, at *11 (internal citations omitted).

Gentile further argues that he should not be bound by his attorney's summary of the meeting with the examiner, relying on Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050 (Fed. Cir. 1989). In that case, an attorney, in the "Remarks" section of an amendment, "made the unqualified and now admittedly untrue statement that 'the claims are restricted to a single vaccination scheme.'" Id. at 1054. The court concluded that the examiner had not relied on the statement and that the language of the claim, as opposed to the erroneous remark of the attorney in the course of prosecution of the application would control. Id. However, the present case differs significantly from Intervet. There is no conspicuous error, and no one reading the history would have any "reason to believe that a mistake was made or that the inventor meant anything other than what he said." See Hockerson-Halberstadt, Inc. v. Am. Sporting Goods Corp., 222 F.3d at 957. Here, Gentile "clearly 'intended his statements to be relied on' by the patent examiner, and 'the courts and the public may rely on them as well.'" Les Traitments des Eaux Poseidon, Inc. v. KWI, Inc., 135 F. Supp. 2d 126, 137 (D. Mass. 2001) (quoting Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997)).
C. Summary of Claim Construction

Based on the foregoing, I construe the phrase "non-toxic liquid antifreeze" in the 906 Patent as not excluding non-toxic salt solutions and as limiting the "antifreeze" to "a liquid used in the radiator of an internal combustion engine to lower the freezing point of the cooling medium."
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Before me is Magistrate Judge Dein's Report and Recommendation on Cross-Motions For Summary Judgment, dated February 15, 2002 ("Report"). I hereby adopt the findings and conclusions of Judge Dein detailed in her Report. Defendant Franklin Sports, Inc.'s ("Franklin") motion for summary judgment [docket entry # 30] is DENIED in its entirety. Plaintiff Robert Gentile's ("Gentile") cross-motion for summary judgment [docket entry # 33] is GRANTED with regard to Count I, patent infringement, and DENIED with regard to Count V, false marking. I write further simply to address an argument advanced by Franklin based on the Supreme Court's recent decision in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 152 L. Ed. 2d 944, 122 S. Ct. 1831 (May 28, 2002), which was handed down after Judge Dein issued her Report. The issue raised by the parties is -- which party bears the burden of proving that a patent claim has been narrowed by representations made in the prosecution history?

In her Report, Judge Dein correctly noted that when faced with a patent infringement claim, a court must first construe the meaning of the claim as a matter of law, in order to "define the scope of the patentee's rights under the patent." Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). As a part of this claim construction analysis, Franklin argued, based on Festo, that the burden is on the patentee to show that statements made by him during the prosecution of his patent do not limit a more expansive construction of his claim that would otherwise spring from the plain, ordinary meaning of the language of the claim.

In Festo, the Supreme Court addressed the relation between two patent law concepts -- the doctrine of equivalents and the rule of prosecution history estoppel. It held that where the patentee is seeking to broaden the scope of the literal terms of his patent through the doctrine of equivalents, he bears the burden of showing that amendments made to his claim during the prosecution history did not relinquish the particular equivalent he argues has been infringed, at least where he made the amendment for a substantial reason relating to patentability. Festo, 122 S. Ct. at 1841-42.

While it is true that under the doctrine of prosecution history estoppel, the burden is on the patentee to prove that he did not surrender the particular equivalent in question with an amendment to his claim, the analysis is different when a court is construing the language of a claim in the first instance. The Federal Circuit has made "a clear distinction between following the statements in the prosecution history in defining a claim term, and the doctrine of prosecution history estoppel." Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995). It has defined the relevant difference

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as follows:

Claim interpretation in view of the prosecution is a preliminary step in determining literal infringement, while prosecution history estoppel applies as a limitation on the range of equivalents if, after the claims have been properly interpreted, no literal infringement has been found. The limit on the range of equivalents that may be accorded a claim due to prosecution history estoppel is simply irrelevant to the interpretation of those claims.

Id. (emphasis added) (internal citation omitted).

In her Report, Judge Dein correctly noted that when a court construes claim language, there is a "'heavy presumption' in favor of the ordinary meaning of the claim language as understood by one of ordinary skill in the art." Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). However, this presumption may be overcome if the intrinsic evidence, including the prosecution history, "clearly redefine[s] a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term." Id. In other words, when engaging in claim construction, a court begins with the ordinary meaning of the claim language as understood by one of ordinary skill in the art. If there is then clear evidence in the prosecution history that the patentee redefined the claim term to a narrower construction in order to overcome an objection by the examiner, a court construing the claim must accept this narrower construction. Thus, in claim construction, there is a presumption that favors an interpretation adopting the ordinary meaning of the claim language, which may be overcome by evidence that the patentee effectively narrowed his claim during the patent application process.

The different settings -- claim construction, on the one hand, and the doctrine of equivalents, on the other -- determine the nature of the burdens. Under Festo, the patentee seeking to expand the scope of his claim beyond literal infringement through the doctrine of equivalents bears the burden of demonstrating that an amendment to his claim during the prosecution history should not estop him from claiming a particular equivalent. However, a defendant seeking to narrow the claim by arguing that the patentee has relinquished a potential claim construction based on the plain, ordinary meaning of the language of the claim bears the burden of overcoming a heavy presumption in the patentee's favor. He must prove that the patentee made clear representations during the prosecution history which limit the scope of his claim.

This allocation of the burden of proof makes sense because it places the burden on the party seeking to change the scope of patent protection from what the ordinary, plain meaning of the claim language would otherwise grant. In the claim construction context, where a party seeks to limit the reach of the otherwise plain meaning of the claim language, the burden is on him to prove that the prosecution history limits the claim language. Similarly, in the doctrine of equivalents context, where a patentee seeks to broaden the scope of the patent's protection beyond that which would be otherwise granted by the plain meaning of the claim language, the burden is on him to prove that an amendment made during the patent's prosecution should not limit the scope of the patent's protection.

In the case at bar, Franklin has failed to demonstrate that during the prosecution of the patent, Gentile limited the plain, ordinary meaning of the phrase "non-toxic liquid antifreeze" by excluding any solution of salt dissolved in water or by confining this phrase to propylene-based antifreeze used in recreational vehicles. As detailed by Judge Dein in her Report, the statements and amendments made by the patentee in his patent prosecution do not show that he relinquished an interpretation of his claim that included non-toxic saltwater solutions or antifreeze solutions beyond those used in recreational vehicles.

For the foregoing reasons, I adopt the findings and conclusions contained in Judge Dein's Report. Franklin's motion for summary judgment [docket entry # 30] is DENIED in its entirety. Gentile's cross-motion for summary judgment [docket entry # 33] is GRANTED with regard to Count I, patent infringement, and DENIED with regard to Count V, false marking.
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(2) Containing a nonnative DNA construct . . . The Court concludes that the prokaryotic or eukaryotic cell referred to in the first element must contain a DNA construct. This DNA construct must be comprised of a small DNA fragment or segment containing the promoter, the terminator and the genetic sequence in between as more fully described in elements (4)-(7). In addition, the Court construes the term "nonnative" to mean that the DNA construct must not occur naturally in the cell, but

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instead must be introduced into the cell from an outside source.
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2. Normal Quantity

The term "normal quantity" appears in Claim 2. Metametrix argues that normal quantity is an indefinite and undefined term and advocates that the court adopt the definition of "normal" level from the specification as meaning "the mean of a given marker compound...determined from the analysis of...samples from a statistically significant sampling of non-autistic individuals." Metametrix raises three objections: 1) Dr. Shaw expressly defined normal in the specification; 2) plaintiffs' proposed definition of quantity conflicts with plaintiffs' own definition of quantity; and 3) using "normal quantity" is tautological as it includes "normal individuals" in the definition. Plaintiffs argue that "normal quantity" means "about the average measured of the particular compound in question in normal individuals."

Based on the claim language and the specification, the court adopts defendant's definition. The inventor did include a definition of "normal" level but prefaced it as an example and described it for only urine samples. At the same time, this definition includes language that is valuable in determining the meaning of "normal quantity." First, while using slightly different language, both parties agree that the mean or average of a particular compound or marker compound should be determined. The relevant language is best taken from the specification as "the mean of a given marker compound." (Col. 2, lines 7-8). Plaintiffs' use of "about" in their proposed definition injects ambiguity. Next, the specification uses "statistically significant" in describing the sample to be collected. Again, this was used in the example of urine, but the principle appears to be based on good scientific practice that the inventor advocated in the specification.

The court will also address Metametrix's remaining objections. First, the court finds that plaintiffs' did not contradict their proposed definition. Metametrix does not elaborate on this argument in its opening brief. Next, the court is in agreement with Metametrix that using the term "normal individuals" may lead to ambiguity, particularly where it is clear that normal will be determined based on the sampling of non-autistic individuals. The more specific and less ambiguous definition, as found in the specification, is preferred under these circumstances.

Thus, the court adopts Metametrix's definition. Normal quantity means "the mean of a given marker compound determined from an analysis of samples of a statistically significant sampling of non-autistic individuals." This definition incorporates the substantive aspects of the cited example in the specification without importing its limitations. It also avoids the ambiguity injected in repeating the use of the word "normal" in describing the individuals sampled.
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This, however, does not completely define the key phrase in question: "exhibits resistance to normally toxic levels of glyphosate." In addition to an interpretation of what "resistance" means, it is also necessary to construe the second part of this phrase, specifically what levels of glyphosate would be "normally toxic".

When construing patent claims, the Court does not presume any of the words of the claim to be superfluous. See Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000). Therefore, the words "toxic" and the word "normally" must both be given a meaning. Both parties agree that "normally toxic" should be interpreted broadly as a differential and not a specific level or amount of glyphosate. n33 However, the question remains as to whether "normally toxic" requires that the non-transgenic corn plant is killed or merely harmed by the application of the glyphosate.

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n33 The parties disagree regarding what the differential should be: DeKalb arguing that it should be the amount that would effectively kill a plant (Hr'g Tr. 54, Aug. 31, 2000), and RPA arguing it should be the amount that would harm a plant (Hr'g Tr. 55, Aug. 31, 2000.)

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The plain meaning of "toxic" suggests something less is required than the plant actually being killed. Rather, the word "toxic" is generally equated with the word "poison". See Webster's New Universal Unabridged Dictionary 2003 (defining "toxic" as "acting as or having the effect of a poison; poisonous"). "Poison", however, is defined in the following manner, "a substance with an inherent property that tends to destroy life or impair health." Id. at 1495. Thus, the word "toxic" likely covers both harm to the plant, as well as death to the plant.

This definition of "toxic" is supported by the patent specification as well. In column 12 the specification uses the word "toxic" in a way that suggests that something can be "toxic" at varying levels. ('798 Patent, col.12, II.7-25.) For example, the specification discusses exposure to a toxic agent first at a "relatively low toxic agent concentration" which should result in "about a 5-40% level of growth inhibition . . ." ('798 Patent, col. 12, II.11-18.) It then discusses exposure of a toxic agent at a higher concentration to "kill essentially all untransformed cells" and resulting in a "30 to 100% growth inhibition." ('798 Patent, col. 12, II.23-29.) Thus, although not referring directly to the process described in claim 1, the specification clearly uses the word toxic to mean harming as well as killing the subject of the application. Applied to the application of glyphosate to non-transgenic corn, as described in claim 1, toxic would refer to an amount of glyphosate that would harm or make sick the non-transgenic corn plant. n34

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n34 The patent examiner, however, makes a comment in the patent history on May 24, 1996, that is contrary to this construction. (Pros. Hist. '798 Patent at 804)(stating that the invention had been reduced to practice based in part on the ability to obtain resistance or partial resistance at "levels that would normally kill corn")(emphasis added). However, because the patent history is not to be used to "enlarge, diminish, or vary the limitations in the claims," the patent examiner's comments are not instructive. Markman, 52 F.3d at 980 (citations omitted).

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In this case "normally" refers to the amount of the glyphosate that would cause this harm, but it likely does not mean any amount of glyphosate conceivable. Rather "normally" in this sense logically correlates to the amount of glyphosate that would, if applied, at least make the non-transgenic corn plants sick or have some other adverse affect. Thus, the term "normally" should be construed as the amount of glyphosate that, under similar circumstances, is usually enough to adversely affect or harm a non-transgenic corn plant. This construction addresses DeKalb's concerns that the amount of glyphosate that is normally applied varies depending on the geographic location of the plants, the stage of growth at which the glyphosate is applied, and other factors that may affect the amount that would harm a plant.
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D. "Resistance to normally toxic levels of glyphosate"

The next claim term for this Court to construe is "resistance to normally toxic levels of glyphosate." This phrase can be broken down into two distinct terms, "resistance" and "normally toxic levels of glyphosate." DeKalb argues that resistance means any level of resistance above that observed in a non-transformed plant, and normally toxic levels of glyphosate means any level of glyphosate which will damage a normal plant. Syngenta proposes that the phrase means "that as a result of the expression of the DNA construct, the corn plant will not be significantly injured when glyphosate is applied to it at a rate that will typically kill a non-transgenic corn plant of the same variety growing under similar conditions." Syngenta's Opening Claim Construction Br., 26-27. The Court notes that it is necessary to address the terms of this phase independently, as the phrase itself is not found in the patent specification. 16

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16 This is where DeKalb petitions the Court to rely upon the North Carolina decision, which defined the term as partial resistance to low levels of glyphosate. However, as the Court discussed above, the Court is not bound by that opinion, and will therefore conduct it's own analysis.

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The Court first looks at the available intrinsic evidence in determining the meaning of resistance to normally toxic levels of glyphosate. See Phillips, 415 F.3d at 1315. The applicable language of Claim 1, for the purposes of construing these terms states, "wherein said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a Zea mays plant not containing said DNA construct. . ." This claim language is significant because it compares resistance between the fertile transgenic plant and the non-transgenic plant. The claim language expresses a comparison of resistance, not an exact result or absolute value. DeKalb's definition of "resistance" presents a comparative definition. There is no absolute value described in the claims, in the Specification, or in the Prosecution History.

The Court looks next to the specification. As correctly noted by Syngenta, the specification does not reference "resistance to normally toxic levels of glyphosate." The specification does address the purpose of the patent in general, which is to enhance beneficial features in corn, through the use of the process outlined in the patent. The specification states that "[t]he transgenic plants produced herein are expected to be useful for a variety of commercial and research purposes." United States Patent 5,554,798, column 14, lines 11-12. The specification then spends the next four paragraphs describing potential uses of the invention, almost entirely discussing commercial applications. Id. at column 14, lines 13-49. The reference to research is expounded in the fourth paragraph of the section entitled "Uses of Transgenic Plants," and states as follows:

The transgenic plants may have many uses in research or breeding, including creation of new mutant plants through insertional mutagenesis, in order to identify beneficial mutants that might later be created by traditional mutation and selection. The methods of the invention may also be used to create plants having unique "signature sequences" or other marker sequences which can be used to identify proprietary lines or varieties.

United States Patent, 5,554,798, column 14, lines 42-49. DeKalb argues that this reference to research value allows a less stringent interpretation of resistance, as any level of resistance would be beneficial for research purposes. However, the portions of the patent which reference research, as quoted above, anticipate research beyond the original enhanced trait, in this case glyphosate resistance. These portions of the specification do not support DeKalb's argument, as they do not suggest that the invention is useful for providing a basis for future research that might produce corn with the desired enhanced trait. However, this conclusion does not conclusively support Syngenta's position either, as this portion of the specification does not specifically address the level of resistance necessary to fall within the scope of the invention.

Looking to how the inventors view their invention, under Example 1, set forth in the specification, the patent describes an experiment performed with hygromycin. The experiment tested the resistance to hygromycin in plant shoots, not full grown plants. The specification states that, following the application of either 0 or 100 mg/l 17 hygromycin, each plate contained duplicate sections of each shoot, and was incubated in the dark for 18 hours.

They were then incubated in a light regimen of 14 hrs light 10 hrs dark at 26 [degrees] C. for 48 hrs, and rated on a scale of from [sic] 0 (all brown) to 6 (all green) for the percent of green color in the leaf tissue. Shoots were classified as untransformed (hygromycin sensitive) if they had a rating of zero and classified as transformed (hygromycin resistant) if they had a rating of 3 or greater.

United States Patent 5,554,798, column 21, lines 6-12. While it is correct that this section does not reference glyphosate resistance, it does reference resistance in general and therefore is instructive on the meaning of that term. The intention of the inventors was to create resistance to glyphosate, the inventors stated that they had created resistance in an experiment where there was some resistance. While the Court finds this evidence strongly supportive of DeKalb's position, it is not conclusive. The experiment was in the context of small portions of plant roots, not the plant themselves, and involved hygromycin, not glyphosate.

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17 Milligrams per liter.

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Syngenta argues that exposure to toxic levels of glyphosate means that the non-transgenic plant would be killed. DeKalb complains that Syngenta relies on the extrinsic evidence of Dr. Ward who disregards the first stage of the selection process in the specification to refer to the second stage of that process. The Court is not relying on the extrinsic evidence of Dr. Ward, but notes from reading the specification on page 12 at columns 22-24, the inventors say that "once the few individual transformed cells have grown sufficiently, the same may be shifted to media containing a higher concentration of the toxic agent to kill essentially all untransformed cells." Referring to the first stage, the specification language states, "[p]referably, the concentration of the agent is initially such that about a 5 to 40 percent level of growth inhibition will occur." This passage talks about harm to plants, not killing, and its talking about the effect caused by a toxic agent. Reference to resistance to toxic levels of glyphosate includes both harming and killing the non-transformed plant.

DeKalb's definition of resistance is further supported by the patent prosecution history. In an amendment filed by DeKalb in the prosecution of the '798 patent, it states that "the DNA construct is expressed so that the transgenic plant exhibits tolerance or resistance to glyphosate at levels that render it identifiable over the corresponding untransformed corn plant which does not comprise the heterologous DNA." Pros. Hist. United States Patent 5,554,798, 748-749. Furthermore, the patent officer, in the course of prosecution, stated that:

The specification does not clearly evidence the effects of the expression of EPSP synthase in transgenic corn plants in the absence of Spencer declaration, the original filed in parent application 07/508,045, of the instant continuation application. Applicants' attorney submitted said declaration for review in this interview. The declaration clearly evidences that a person of ordinary skill in the art, employing the methods disclosed in the specification, would have obtained a transgenic corn plant expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at levels that would normally kill corn.

United States Patent 5,554,798, Pros. Hist. Joint Submission, 6372 (emphasis added). These statements made during the prosecution of the '798 patent, taken in conjunction with the specification, lead the Court to conclude that "resistance" means any level of resistance above that observed in a non-transformed plant.

However, this does not conclude the Court's analysis, as it is also necessary to define "normally toxic levels of glyphosate." 18 The specification does not define the term normally toxic levels of glyphosate, and therefore the Court again turns to the prosecution history. The portion of the prosecution history cited above will again be restated with emphasis supplied by this Court to different language in the Examiner's conclusions. The Patent examiner states in the parties joint stipulation:

The specification does not clearly evidence the effects of the expression of EPSP synthase in transgenic corn plants in the absence of the Spencer declaration, the original filed in parent application 07/508,045, of the instant continuation application. Applicants attorney submitted said declaration for review in this interview. The declaration clearly evidences that a person of ordinary skill in the art, employing the methods discussed in the specification, would have obtained a transgenic corn plant expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at levels that would normally kill corn. . ..

United States Patent 5,554,798, Pros. Hist. Joint Submission, 6372 (emphasis added). This language supports Syngenta's proposed construction. DeKalb attorneys represented to the patent examiner that a fertile transgenic corn plant with the EPSP gene would obtain resistance or partial resistance to glyphosate at levels that would normally kill corn.

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18 The North Carolina Court reached the same conclusion regarding the definition of resistance, however, the North Carolina Court reached a different conclusion regarding the definition of "normally toxic levels of glyphosate." However, this Court notes that the North Carolina Court relied on Webster's dictionary definition of the term toxic. Pl. DeKalb's Opening Claim Construction Brief, Ex. 3, 49. Using such definitions is cautioned against by the Federal Circuit in Phillips. 415 F.3d at 1321 ("The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.").

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The Court emphasizes that the purpose of the patent, as articulated in the introduction of the specification, is to create

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transgenic corn, which can then be bred with existing corn lines, to create a desired characteristic, in this case resistance to glyphosate. The Court notes that while even partial resistance would be beneficial, such resistance would not be beneficial if the levels at which the glyphosate were applied were so low that the glyphosate would not effectively kill the weeds, without killing the corn, as glyphosate's function is as a weed-killer. This Court does not find, and nor does Syngenta argue, that the words, "normally toxic levels of glyphosate " must be at a commercial level, because the Federal Circuit cautions against trial judges making claim construction determinations on the basis of the commercial embodiment of the invention. ACS Hosp. Systems Inc. v. Montefiore Hosp., 732 F.2d 1572, 1578 (Fed. Cir. 1984) (Finding error by the District Court in comparing the accused device with the commercial embodiment of the patent, rather than to the claims of the patent); see also Unique Functional Products, Inc. v. Mastercraft Boat Co., Inc., 82 Fed.Appx. 683, 689 (Fed. Cir. 2003) ("It is of no consequence that those extraneous features are present in [Plaintiff's] commercial embodiment."). However, the court believes that the language in the specification supports Syngenta's argument and the Court's conclusion, that the level of glypohsate applied must be at levels sufficient to kill non- transformed corn.

Syngenta further submits extrinsic evidence, in the form of expert testimony on the ordinary meaning of "normally toxic levels of glyphosate," however, it is unnecessary for the Court to look to extrinsic evidence. The intrinsic evidence, which includes the prosecution history, supports Syngenta's proposed construction. Contrary to DeKalb's argument, the definition of resistance, as including partial resistance, does not necessitate that the term "normally toxic levels of glyphosate " be defined as something less than a lethal dose.
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B. Claim Construction

Scantibodies argues that the district court erred by construing the phrase "not detecting an interfering non-(1-84) parathyroid hormone fragment" to mean having no detectable binding to an interfering non-(1-84) parathyroid hormone fragment. According to Scantibodies, the phrase should instead be construed to mean that the level of detection of such fragments must be below that which would interfere with providing a clinically meaningful assay for whole PTH and that adequately differentiates whole PTH from an interfering non-(1-84) PTH fragment.

We begin our analysis with the plain language of the claim. See Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.'") (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (en banc)). Here, the plain meaning of "not detecting" is fully consistent with the district court's construction requiring "no detectable binding." None of Scantibodies' arguments to the contrary are convincing.

First, Scantibodies argues that the district court erred because the complete absence of cross-reactivity is not necessary for a clinical immunoassay to meet the stated goals and purpose of the invention. Scantibodies contends that a person having ordinary skill in the art would not use such an impossibly stringent definition of "not detecting" because such a definition would exclude all antibodies, including its preferred embodiment. However, the district court's definition of "not detecting" was not as strict as Scantibodies alleges. The district court indicated that its construction of "not detecting" was based on its construction of another limitation, "does not specifically bind to an interfering non-(1-84) parathyroid hormone fragment," which Scantibodies does not dispute. The court construed the non-binding limitation to mean having no measurable affinity for and no detectable binding to an interfering non-(1-84) parathyroid hormone fragment, and further explained that no measurable affinity meant having an association constant of less than 10^5 liter/mole. While this level is less than what is clinically significant, it is not "no binding whatsoever."

Second, Scantibodies argues that its own construction of "not detecting an interfering non-(1-84) parathyroid hormone fragment" is consistent with Scantibodies' clinical use and product literature. One inventor of the '566 patent, Thomas L. Cantor, explained in a declaration that the chemistry of immunoassays is complex and measurements of whole PTH in blood serum are not absolutes because immunoassay science has not evolved to the point where PTH can be determined with absolute precision. Cantor further noted that none of the invention described in the patent, or Scantibodies' whole PTH assays, absolutely detect PTH without any detectable cross-reactivity, but that any such degree of cross-reactivity was not significant. Such detection was described in Scantibodies' product literature as having "no cross-reactivity."

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We cannot give Cantor's self-serving testimony much weight because it is, at best, relatively weak extrinsic evidence. The use of language in marketing materials often means something quite different from the language used in a patent. Moreover, the inventors of the '566 patent chose to draft the claims with the narrow term "not detecting" when there were alternatives that were less confining. If the inventors wanted "not detecting" to have a different meaning based on the clinical or marketing context, they could have drafted the claims differently. For example, the inventors could have chosen a term with a broader meaning or have assigned "not detecting" a unique definition different than its ordinary meaning by clearly expressing that intent in the written description. See Phillips, 415 F.3d at 1313. Here, the inventors elected to do neither. Because of this choice, a competitor reading the '566 patent would not know that "not detecting" means something other than its ordinary meaning and would not be forewarned that it might infringe.

In addition, Scantibodies' claim that no PTH assay can absolutely detect PTH without detectable cross-reactivity is contradicted by the 2001 Gao et al. article that lists among its authors both inventors of the '566 patent. The Gao article disclosed an N-terminal PTH antibody that would only bind to PTH if the first amino acid was present, and further, did not detect fragments of (7-84) PTH at concentrations of 10,000 pg/ml, far beyond any clinically relevant level. The antibody could specifically bind to whole PTH while not specifically binding to the interfering (7-84) PTH fragment, illustrating that it would have been possible to meet the district court's construction using then-existing technology.

Thus, we hold that the district court correctly construed "not detecting an interfering non-(1-84) parathyroid hormone fragment" to mean having no detectable binding to an interfering non-(1-84) parathyroid hormone fragment.
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C. '928 Patent, '824 Patent, '955 Patent, Claim 1: "Said Linkage Group Not Interfering Substantially With" / '767 Patent, Claim 1: "Linkage Group That Does Not Substantially Interfere With"

All four of the Ward patents claim a linkage group "not interfering substantially with" or "that does not substantially interfere with" detection of A. The linkage group at issue is between A and B, where A is defined above and B is defined in all three patents as either purine, 7-deazapurine or pyrimidine that attaches to a nucleotide.

Plaintiffs construe this language to mean that the linkage group "cannot substantially interfere with the characteristic ability of the compound or [nucleic acid] sequence to hybridize with a nucleic acid and cannot substantially interfere with formation of the signalling moiety or detection of the detectable signal. This means that the linkage group may interfere with both hybridization and detection so long as the interference is not substantial. . ." Sinden Report at 29 (emphasis added).

Defendants argue that the term "substantially" means that "the ability of A (when attached to B via said linkage group) to form a detectable complex is essentially identical to the ability of A to form a detectable complex when directly attached to B." Def. Claim Constr. Br. [Doc. # 91] at 22-23. They draw this language from a description of the invention, which states that the modified polynucleotides claimed are capable of denaturation and renaturation at melting point temperatures "essentially identical to that of the control, biotin-free DNAs." '824 Pat. 18:66. Plaintiffs' expert, Dr. Sinden, testified that melting point is related to interference with hybridization. Sinden Dep. at 136. However, he never adopted the "essentially identical" definition. Instead, he stated that the definition of "substantial" is "difficult to answer" and "probably in the hands of the experimenter. Clearly if it didn't work at all, it wouldn't work. If it worked 50 percent and you were able to get your signal and publish a paper, you may go with it." Id. at 139. Defendants offered no expert testimony commenting on this term or rebutting plaintiffs' expert testimony, and the language from the specification concerning melting points appears to be taken out of context and not relevant to the claims in question.

The more likely, and more persuasive, root for the claim term "not interfering substantially" is the explanation in the detailed description that the detection uses a "linker arm" between A and B to allow for hybridization:

> [T]he detection system should be capable of interacting with probe substituents incorporated into both single-stranded and double-stranded polynucleotides in order to be compatible with nucleic acid hybridization methodologies. To satisfy this criterion, it is preferable that the probe moiety be attached to the purine or pyrimidine through a chemical linkage or "linker arm" so that it can readily interact with antibodies, other detector proteins, or chemical reagents.

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'824 Pat. 6:55-63.

Thus, the claim language should be construed to account for the function of the linker arm. As plaintiffs request, the terms "not interfering substantially with" and "that does not substantially interfere with" detection of A will be construed to mean that "the linkage group neither substantially interferes with the ability of the compound to hybridize with the nucleic acid nor substantially interferes with the ability of A to be detected." Nothing in the specification or preferred embodiments supports the narrower construction urged by defendants.
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As stated above, plaintiff has asserted claims 1 and 5 of the '955 patent.

Claim 1 provides:
A nucleotide or oligo- or polynucleotide sequence comprising at least one of a moiety having the structure -BA: n5

wherein B represents a 7-deazapurine or pyrimidine moiety;

wherein A represents a moiety selected from the group consisting of biotin and iminobiotin;

provided that if B is a 7-deazapurine, A is attached to the 7-position of the deazapurine, and if B is a pyrimidine, A is attached to the 5-position of the pyrimidine, A being attached to B directly or through a linkage group, said linkage group not interfering substantially with the characteristic ability of A to form a detectable complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin.

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n5 Throughout this litigation, all parties have proceeded as if the term "--BA" in fact appears at the end of the preamble to claim 1 of the '955 patent. The preamble appearing in Plaintiff's Exhibit 1, a copy of which was provided to the Court, however, reads as follows: "A nucleotide or oligo- or polynucleotide sequence comprising at least one moiety having the structure:." Based on the assumptions made by the parties, and on the fact that no sense can be made of claim 1 without the inclusion of the term "--BA," this Court will assume that the omission was inadvertent and will proceed as if the term appeared in the preamble.

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Although all parties agree that a naturally-occurring nucleotide is comprised of a phosphate group, a pentose sugar, n6 and a nitrogenous base, see Hr'g Tr. at 385, 643, 786, plaintiff contends that claim 1 of the '955 patent does not require the presence of a pentose sugar (or for that matter a phosphate group) because the claim does not specifically call for the presence of those structures and because the patent as a whole is directed not to naturally-occurring nucleotides but rather to "modified nucleotides" or "nucleotide analogs," Pl.'s Proposed Order at 9.

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n6 A pentose sugar is a sugar molecule composed of five carbon atoms in a ring structure.

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This Court cannot agree. Although the patent is concerned with modified nucleotides, when read as a whole it is clear that the modification contemplated is the addition of the "A" group, which serves as a label or probe, n7 to the base of the nucleotide. See, e.g., Hr'g Tr. at 169-70, 752. This is made abundantly clear by the "Detailed Description of the Invention." That segment of the patent lists several "essential criteria [that] must be satisfied in order for a modified nucleotide to be generally suitable as a substitute for a radioactively-labeled form of a naturally occurring nucleotide." '955 patent col. 6, 11.

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36-39. Each of those criteria concern "the probe," including its positioning, qualities, and characteristics. Id. at col. 6, 11. 39-68, col. 7, 11. 1-17. There is simply no support in the patent for any modifications other than the contemplated addition of a label to the base.

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n7 As discussed infra, because the polynucleotide sequences at issue are far too small to be visible, see, e.g., Hr'g Tr. at 516, the addition of a label to the nucleotide is necessary in order to determine if hybridization with its complementary nucleic acid sequence has occurred.

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Similarly, plaintiff's contention that the claim does not specifically call for a pentose sugar is unpersuasive. The claim is directed to a "nucleotide or oligo- or polynucleotide sequence," which is a structure that, absent clear indication otherwise, requires phosphate groups and pentose sugars. Although patentees can define terms in their patents as they wish, see Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996), this patent offers no definitions that would supplant the ordinary meanings of these terms as understood by a person of ordinary skill in this field at the time of the invention. See, e.g., Hr'g Tr. at 391-92. n8 Therefore, this claim requires that the "nucleotide or oligo- or polynucleotide sequence" at issue be comprised of otherwise naturally-occurring nucleotides which have been modified solely by the addition of at least one label "A" to a nitrogenous base "B." n9

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n8 In addition, defendants point out that plaintiff, in prosecuting a patent with the same specification as the '955 patent and a claim similar to claim 1, told the Patent and Trademark Office that "[a]n oligo- or polynucleotide by definition has a defined sugar ring structure. Depiction of a ring structure in claim 190, it is respectfully submitted, is unnecessary and would be redundant." Defs.' Ex. 58, Tab 17, at 14. According to the Federal Circuit, these statements are relevant to the construction of the claim at issue, see Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349-50 (Fed. Cir. 2004), and they further support this Court's construction.

n9 Plaintiff argues that this construction is foreclosed by the principle of claim differentiation, because, according to plaintiff, claim 5 of the '955 patent is identical to the Court's construction of claim 1. Claim 5, however, contains a series of elements, "X," "Y," and "Z" which must be attached to the pentose sugar moiety and which are not discussed in claim 1. As such, the pentose sugar moiety present in claim 1 need not contain these elements and therefore plaintiff's argument is unpersuasive.

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The second disputed term in claim 1 of the '955 patent is its restriction that the linkage group which can be used to link "A" to "B" "not interfer[e] substantially with the characteristic ability of A to form a detectable complex." Although the parties have argued extensively over the proper interpretation of this term, it is clear to the Court that the claim language contemplates that the linkage group can cause some interference, but that it cannot completely prevent the formation of a detectable complex or cause other considerable levels of interference. Having thoroughly considered the claim language in the context of the entire patent, the Court concludes that the only reasonable interpretation of the term is that the use of linkage groups which make it more likely than not that "a complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin" will not form, or that, once formed, such a complex will not be "detectable" are not covered by the language of this claim. n10

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n10 Avidin and streptavidin are polypeptides that form tight bonds with biotin and iminobiotin.

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The only disputed language in claim 5, n11 that "said linkage group not interfering substantially with the characteristic

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ability of A to form a detectable complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin," is identical to the language in claim 1 and therefore is construed in the same fashion.

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E. Not Known To Bind.

Citing to portions of the patent specifications and the prosecution histories, Scriptgen claims that the term "not known to bind" means "neither known, suspected, nor suggested to bind." For example, the specifications of both the '277 patent and the '582 patent explain that individuals who employed some of the previous screening methods were "frequently forced to chose novel chemical compounds based on some prior knowledge suggesting [that] the compounds are likely to be effective." In addition, in the prosecution histories of both of the patents, the inventors explained that the claimed "method involves a repetitive screening procedure by which compounds not previously known or suspected to bind to a target protein can be identified . . . ." (emphasis omitted).

In response, 3-DP points out that the claim language expressly states "not known to bind." It does not read "neither known, suspected, nor suggested to bind." For this reason, 3-DP argues that these additional limitations should not be read into the claims. Instead, 3-DP contends, the plain meaning of "known" should control, especially since the term is not defined in the specification. In other words, according to 3-DP, the court should interpret the term "not known to bind" as meaning "not known with certainty to bind" or, more specifically, "not known with scientific certainty to bind."

The court agrees. Although the inventors could have easily used a different term, such as "neither known nor suspected to bind," in their claims, they chose to use the term "not known to bind." Because this term is not defined in the specification, its ordinary meaning should control. See, e.g., Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 951 (Fed. Cir. 1993) (citing ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579 (Fed. Cir. 1988)). In the context of these patents, that meaning would appear to be "to apprehend with certitude as true, factual, sure, or valid" or to "perceive . . . with clarity and the perception of certainty." See Webster's Third New Intn'l Dictionary 1252. Even though the inventors may have intended a different meaning and expressed these intentions during the prosecution histories of both patents, they failed to include this express definition in either their patent claims or their specifications. For this reason, the court will not now afford a different interpretation to the term "not known to bind" in order to correct a problem which has resulted from imprecise drafting. See Hoganas, 9 F.3d at 951. Consequently, the court will give the term "not known to bind" its plain or ordinary meaning--namely, a meaning "not know with scientific certainty to bind." 2

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2 If it is any consolation to Scriptgen, the court notes that the terms "not known with scientific certainty to bind" and "neither known, nor suspected, nor suggested to bind" are not necessarily mutually exclusive. For example, a compound which is "not known to bind" may also be "not suspected" or "not suggested" to bind. Likewise, a compound which is "suggested" or "suspected" to bind would still be "not known to bind" if there was less than scientific certainty about its binding properties.

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D. "nucleic acid binding agent"

In their claim construction briefs, Applera argued that it was unnecessary to construe this term, whereas Stratagene defined it as "a fluorescent dye or other chromophore, enzyme, or agent capable of producing a signal, directly or indirectly, when bound to double-stranded DNA, that is distinguishable from the signal produced when that same agent is in solution or

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bound to a single stranded nucleic acid."

Applera persuasively argues that Stratagene's proposed construction is too narrow because it limits the term to specific examples mentioned in the specification. Elsewhere in the specification, the inventor states that "any DNA binding agent is suitable." (Col. 6, ln. 60.) I therefore reject Stratagene's proposed construction as unduly narrow.

Although the specification provides that any DNA binding agent is suitable, it goes on to state, "so long as in the presence of that agent a net increase in the amount of double-stranded DNA present is reflected in a change [in] signal intensity that is detectable directly or indirectly." (Col. 6, lns. 60-64.) Therefore, it is appropriate to construe the disputed term as "any DNA binding agent so long as in the presence of that agent a net increase in the amount of double-stranded DNA present is reflected in a change in signal intensity that is detectable directly or indirectly."
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As stated above, plaintiff has asserted claims 1 and 5 of the '955 patent.

Claim 1 provides:
A nucleotide or oligo- or polynucleotide sequence comprising at least one of a moiety having the structure -BA: n5

wherein B represents a 7-deazapurine or pyrimidine moiety;

wherein A represents a moiety selected from the group consisting of biotin and iminobiotin;

provided that if B is a 7-deazapurine, A is attached to the 7-position of the deazapurine, and if B is a pyrimidine, A is attached to the 5-position of the pyrimidine, A being attached to B directly or through a linkage group, said linkage group not interfering substantially with the characteristic ability of A to form a detectable complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin.

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n5 Throughout this litigation, all parties have proceeded as if the term "--BA" in fact appears at the end of the preamble to claim 1 of the '955 patent. The preamble appearing in Plaintiff's Exhibit 1, a copy of which was provided to the Court, however, reads as follows: "A nucleotide or oligo- or polynucleotide sequence comprising at least one moiety having the structure:." Based on the assumptions made by the parties, and on the fact that no sense can be made of claim 1 without the inclusion of the term "--BA," this Court will assume that the omission was inadvertent and will proceed as if the term appeared in the preamble.

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Although all parties agree that a naturally-occurring nucleotide is comprised of a phosphate group, a pentose sugar, n6 and a nitrogenous base, see Hr'g Tr. at 385, 643, 786, plaintiff contends that claim 1 of the '955 patent does not require the presence of a pentose sugar (or for that matter a phosphate group) because the claim does not specifically call for the presence of those structures and because the patent as a whole is directed not to naturally-occurring nucleotides but rather to "modified nucleotides" or "nucleotide analogs," Pl.'s Proposed Order at 9.

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n6 A pentose sugar is a sugar molecule composed of five carbon atoms in a ring structure.

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This Court cannot agree. Although the patent is concerned with modified nucleotides, when read as a whole it is clear that the modification contemplated is the addition of the "A" group, which serves as a label or probe, n7 to the base of the nucleotide. See, e.g., Hr'g Tr. at 169-70, 752. This is made abundantly clear by the "Detailed Description of the Invention."

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That segment of the patent lists several "essential criteria [that] must be satisfied in order for a modified nucleotide to be generally suitable as a substitute for a radioactively-labeled form of a naturally occurring nucleotide." '955 patent col. 6, 11. 36-39. Each of those criteria concern "the probe," including its positioning, qualities, and characteristics. Id. at col. 6, 11. 39-68, col. 7, 11. 1-17. There is simply no support in the patent for any modifications other than the contemplated addition of a label to the base.

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n7 As discussed infra, because the polynucleotide sequences at issue are far too small to be visible, see, e.g., Hr'g Tr. at 516, the addition of a label to the nucleotide is necessary in order to determine if hybridization with its complementary nucleic acid sequence has occurred.

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Similarly, plaintiff's contention that the claim does not specifically call for a pentose sugar is unpersuasive. The claim is directed to a "nucleotide or oligo- or polynucleotide sequence," which is a structure that, absent clear indication otherwise, requires phosphate groups and pentose sugars. Although patentees can define terms in their patents as they wish, see Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996), this patent offers no definitions that would supplant the ordinary meanings of these terms as understood by a person of ordinary skill in this field at the time of the invention. See, e.g., Hr'g Tr. at 391-92. n8 Therefore, this claim requires that the "nucleotide or oligo- or polynucleotide sequence" at issue be comprised of otherwise naturally-occurring nucleotides which have been modified solely by the addition of at least one label "A" to a nitrogenous base "B." n9

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n8 In addition, defendants point out that plaintiff, in prosecuting a patent with the same specification as the '955 patent and a claim similar to claim 1, told the Patent and Trademark Office that "[a]n oligo- or polynucleotide by definition has a defined sugar ring structure. Depiction of a ring structure in claim 190, it is respectfully submitted, is unnecessary and would be redundant." Defs.' Ex. 58, Tab 17, at 14. According to the Federal Circuit, these statements are relevant to the construction of the claim at issue, see Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349-50 (Fed. Cir. 2004), and they further support this Court's construction.

n9 Plaintiff argues that this construction is foreclosed by the principle of claim differentiation, because, according to plaintiff, claim 5 of the '955 patent is identical to the Court's construction of claim 1. Claim 5, however, contains a series of elements, "X," "Y," and "Z" which must be attached to the pentose sugar moiety and which are not discussed in claim 1. As such, the pentose sugar moiety present in claim 1 need not contain these elements and therefore plaintiff's argument is unpersuasive.

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E. Numerical Limitations for Molecular Weight Ranges, the Polydispersity Range, and the Degree of Estenfication Range

Aventis and Teva request construction of various numerical limitations within the patent and particularly claims 1, 28, 31, and 32. Aventis argues that the court should construe numerical limitations strictly Teva argues these numerical limitations should be construed to include values stated to one or more decimal places that can be rounded to that same whole number. n3

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n3 For example, Teva proposes that the limitation "from 9% to 20% of polysacchande chains having a molecular weight less than 2000 daltons" should be construed to include products having between 8 6% and 20 4% of the polysacchande chains with a molecular weight less than 2000 daltons.

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Aventis cites Jenenc/Pentron, Inc v Dillon Co, 205 F.3d 1377, 1381 (Fed Cir 2000) to support its position. In Jenenc, the Federal Circuit held that claim terms not modified by a term of approximation should be strictly construed. Id. "Assigning numerical precision to composition ranges [] is particularly appropriate when other variables in the same claims explicitly use qualifying language." Id. Aventis points out that the 618 patent, like Jeneric, uses qualifying language in other parts of 618's claims. For example, claim 1 recites an "average molecular weight of between approximately 3,500 and 5,500 daltons" 618 patent, 10 24-25. Claim 28 recites "an anti-Xa activity of about 100 IU" 618 patent, 11 50-51.

In addition, like Jenenc, the 618 patent uses ranges and degrees Aventis argues that these ranges and degrees reinforce the use of precise values because the patentee repeatedly emphasized the cnticahty of the claimed ranges to overcome prior art rejections. n4 Thus, Aventis concludes that the intrinsic evidence supports strict interpretation of the numerical limitations.

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n4 For example, Lopez, a prior art reference, claimed 4 3% of its polysacchandes greater than 8000 daltons. In contrast, the 618 patent claimed 5% to 20% of its polysacchandes greater than 8000 daltons.

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Teva cites two cases to support its position that 618's numerical limitations should be construed to include values stated to one or more decimal places that can be rounded to that same whole number. The court finds that neither of these cases undermines the applicability of Jenenc. The first, San Huan New Matenals High Tech v ITC, 161 F 3d 1347 (Fed Cir 1998), is incongruous because it implemented rounding with respect to the factual inquiry of infringement, not claim construction. The second, Viskase Corp v Amencan Nat'l Can Co, 261 F 3d 1316, is less on point than Jenenc because it recognized that rounding is "a standard scientific convention when a number has not been carried to the next mathematically significant figure" with respect to a term modified by a term of approximation. Because some terms in the 618 patent are so modified and others are not, and the numencal terms at issue are not modified by a term of approximation, the court finds Viskase less persuasive than Jenenc.

Thus, the court construes the numerical limitations of the 618 patent strictly and the numbers are as stated with no modifications by approximation or otherwise. The underlined portions below should not be construed to include values stated to one or more decimal places that can be rounded to that same whole number.

1) from 9% to 20% of polysacchande chains having a molecular weight less than 2,000 daltons

2) from 5% to 20% of polysacchande chains having a molecular weight greater than 8,000 daltons,

3) from 60-86% of polysacchande chains having a molecular weight of between 2,000 and 8,000 daltons,

4) the ratio between the weight average molecular weight and the number average molecular weight thereof ranging from 1 3 to 1 6

5) esterifying the salt thus produced to a degree of estenfication ranging from 9 5% to 14.
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D.

Finally, both parties seek construction of the phrase "nutritionally effective amount" as used in Claim I of the patents-in-suit. Plaintiff argues that the phrase should be construed to mean "that amount which will provide a beneficial nutritional effect or response in a mammal," which is the definition found in the specification. (See Plf. Cl. Constr. Br. at 14-15). While acknowledging that "nutritionally effective amount" is defined in the specification, defendants maintain that the definition is

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"circular" and urge the court to hold the phrase invalid for indefiniteness. (See Def. Cl. Constr. Br. at 22-23). Alternatively, defendants propose that the phrase be construed to mean a "sufficient amount of each saccharide to cause a beneficial response as measured by a statistically significant improvement in a marker." (Id. at 24).

The court declines to entertain defendants' invalidity argument at the claim construction stage. See Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("Ambiguity, undue breadth, vagueness, and triviality are matters which go to claim validity . . ., not to interpretation or construction.") (emphasis in original). Although a determination of indefiniteness is intertwined to some degree with claim construction, a court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness. See Harrah's Entm't, Inc. v. Station Casinos, Inc., 321 F. Supp. 2d 1173, 1176 (D. Nev. 2004), aff'd, 154 Fed.Appx. 928, 2005 WL 3086716 (Fed. Cir. Nov. 15, 2005). Whether the patents-in-suit are invalid because the definition of "nutritionally effective amount" fails to provide one skilled in the art with any objective standards for determining what amount of a saccharide would be "nutritionally effective" is a matter more appropriately addressed on summary judgment. See Nisus Corp. v. Perma-Chink Systems, Inc., No. 3:03-CV-120, 2006 U.S. Dist. LEXIS 10901, 2005 WL 5164855 at *8 (E.D. Tenn. Jan. 25, 2006) (declining to consider issue of indefiniteness at claim construction phase); PharmaStem Therapeutics, Inc. v. Viacell Inc., No. 02-148 GMS, 2003 U.S. Dist. LEXIS 877, 2003 WL 124149 at *1, n.1 (D. Del. Jan. 13, 2003) (same); ASM America, Inc. v. Genus, Inc., No. C-01-2190-EDL, 2002 U.S. Dist. LEXIS 15348, 2002 WL 1892200 at *15 (N.D. Cal. Aug. 15, 2002) (same). 5

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5 Defendants have filed a motion for partial summary judgment on the issue of indefiniteness. (See Doc. # 87). That motion has been fully briefed and is pending before the district judge.

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Where the specification explains and defines a claim term, without ambiguity or incompleteness, there is no need to search further for the meaning of the term. See Sinorgchem, 511 F.3d at 1138; Multiform Desiccants, Inc. v. Medzam Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998). In this case, the specification expressly defines "nutritionally effective amount" as "that amount which will provide a beneficial nutritional effect or response in a mammal." (See, e.g. Plf. Cl. Constr. App. at 14, col. 9, ll. 66-67 & col. 10, l. 1). The specification goes on to explain that the precise amount of a saccharide that is "nutritionally effective" will vary from mammal to mammal depending on the substance involved. (See, e.g. id., col. 10, ll. 1-9). There is no ambiguity or incompleteness in this definition. Indeed, the Federal Circuit has concluded that the phrase "effective amount" is a common and unambiguous claim term. See Geneva Pharmacueticals, Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383 (Fed. Cir. 2003) (finding that "effective amount" is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite); Nisus Corp., 2006 U.S. Dist. LEXIS 10901, 2005 WL 5164855 at *7-8) (applying Geneva Pharmacueticals in non-pharmaceutical context); Kao Corp. v. Unilever U.S., Inc., 334 F.Supp.2d 527, 551-52 (D. Del. 2004), aff'd, 441 F.3d 963 (Fed. Cir. 2006) (same). Therefore, the court need not look any further than the express language of the specification for the definition of the disputed phrase. "Nutritionally effective amount" should be construed to mean "that amount which will provide a beneficial nutritional effect or response in a mammal."
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B. "Nutritionally Effective Amounts"

The Defendants' first objection dealing with the Magistrate Judge's treatment of the phrase "nutritionally effective amounts" was to the Magistrate Judge's refusal to consider the Motion for Partial Summary Judgment contemporaneously with the claim construction. (Defs.' Obj. to Recomm. to 3). Because this court has decided the Motion for Partial Summary Judgment, this objection is no longer relevant. In the alternative, Defendants ask that the court interpret the claim to mean "sufficient amount of each saccharide to cause a beneficial response as measure by a statistically significant improvement in a marker." (Defs.' Cl. Constr. Br. at 24). Defendants begin with the embodiment that is present in all of the specifications and tightens the interpretation even more. This interpretation is unsatisfactory for two reasons. First, the court must be careful to not import limitations from the specifications into the claims, because the specification contains only one preferred embodiment. LizardTech, Inc. v. Earth Res. Mapping, Inc. 433 F.3d 1373, 1377 (Fed. Cir. 2006) (per curiam).

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Second, like the Magistrate Judge stated, when the specification defines a claim term unambiguously, there is no need to search further for the meaning of that term. Sinorgchem Co., Shandong v. Int'l Trade Comm'n, 511 F.3d 1132, 1138 (Fed. Cir. 2007); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998). Thus, this court ACCEPTS the Magistrate Judge's construction that "nutritionally effective amounts" is to be construed as "that amount which will provide a beneficial nutritional effect or response in a mammal."
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3. "Oat grain derivative product": Material derived from the grain of an oat (which consists of the kernel and the husk of the grain).

('062 patent, col. 2, ll.34-38; col. 4, ll. 22-27, 55-65)
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5. "Oatmeal"; Material that is derived from the kernel of an oat grain (including liquid extracts and powders).

('062 patent, col. 4, ll. 51-62; D.I. 270, ex. J at LPM 000186)
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3. "obtainable by"

In this case, Abbott's plain language argument, that "obtainable by" introduces an optional process, even if "obtained by" would introduce limiting process steps, is also unavailing. The BASF case, an analogous situation to this case, controls. As noted above, the Supreme Court in BASF considered the following claim language: "Artificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296 (emphasis added). The patentee argued that even though the defendant did not make artificial alizarine by "either of the methods herein described," the claim should capture the product because of the "or by another method" language. Id. at 309. The Supreme Court refused to attach importance to those expansive words: "No. 4,321 furnishes no test by which to identify the product it covers, except that such product is to be the result of the process it describes." Id. at 305. Abbott's claims 2-5, like those in BASF and like product-by-process claims in general, do not furnish any test by which to identify the cefdinir crystals except that they are the result of their respectively claimed processes. As per BASF, Abbott's claim cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims.

If this court were to strip the process elements from the claims, as Abbott would urge, for infringement purposes, there would then be nothing to differentiate independent claim 2 from independent claim 5. After all, if those claims are not bound by the process terms but only "define" the basic cefdinir compound, then each of the claims recite the same thing, over and over again. Though Abbott argues that it merely intends to give meaning to the word "obtainable," it instead seeks to have this court render meaningless the explicit process limitations that the applicant chose to define its invention.

The intrinsic evidence in this case further rebuts Abbott's contention that its claims are not limited to those products actually obtained by the processes recited. In column 2 of the '507 patent, under the title heading "The Process for Preparing Crystal A of the Compound (I)," the patentee used specific language to describe the very two processes that are mirrored in claims 2 and 5. '507 patent col.2 ll.13-51. This language is not open-ended, nor does it constitute a mere description of the product by reference to the manner in which it can be made, as Abbott argues. By drafting claims 2 and 5 to incorporate these specific processes, Abbott made a conscious choice to place process requirements on its claimed product. If Abbott had wanted to obtain broader coverage for crystalline cefdinir devoid of any process limitations, as it seeks to do here, it could have simply done so (if indeed, as it argues, it is really the product that is the heart of the invention, not the process). But it did not. The crystals of claims 2 and 5 are simply not identifiable other than by the processes disclosed in column 2. This court must

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enforce the ways and terms that a party chooses to define its invention.

The prosecution history also does not support Abbott's contention that "obtainable by" offers merely an optional set of definitional process conditions. During prosecution, Abbott faced obviousness rejections based on application claims 6-9, which were process claims that mirrored the very process limitations of issued claims 2-5. The PTO refused to issue the claims until one set of duplicates was cancelled. Abbott's action in cancelling claims 6-9 demonstrates its acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims. In addition, in a response to the PTO's office action, Abbott chose to differentiate a cited § 103 reference, Takaya, on the basis that Abbott's claimed processes are different. For these reasons, the applicant's statement in the file wrapper that "the method of preparation . . . is not considered the heart of the present invention" should not be afforded undue gravitas. The process limitations cannot be haphazardly jettisoned for an infringement analysis when they were so important in the patentability analysis.

In sum, a patentee's use of the word "obtainable" rather than "obtained by" cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine. Claims that include such ambiguous language should be viewed extremely narrowly. If this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply because of the patentee's choice of the probabilistic suffix "able," the very recitation of that process becomes redundant. This would widen the scope of the patentee's claims beyond that which is actually invented--a windfall to the inventor at the expense of future innovation and proper notice to the public of the scope of the claimed invention. For all the above reasons, the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims 2-5 as limiting the asserted claims to products made by those process steps.

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Claims 4-9 of the '880 patent read:

4. A process comprising obtaining progeny from a fertile transgenic plant obtained by the process of claim 1 which comprise said DNA.

5. The process of claim 4 wherein said progeny are obtained by crossing said fertile transgenic plant with an inbred line.

6. The process of claim 4 comprising obtaining seed from said progeny plants comprising said DNA from said seed.

7. The process of claim 5 wherein the progeny obtained are crossed back to the inbred line, to obtain further progeny which comprise said DNA.

8. The process of claim 6 wherein seed are obtained from said further progeny plants and plants comprising said DNA are recovered from said seed.

9. The process of claim 7 wherein said further progeny are crossed back to the inbred line to obtain progeny which comprise said DNA.

(emphases added). Claims 5-6 of the '863 patent read:

5. The process of claim 1 further comprising obtaining transgenic glyphosate resistant progeny plants of subsequent generations from said fertile transgenic plant.

6. The process of claim 5 further comprising obtaining seed from one of said progeny plants.

After claim construction, the Delaware District Court granted Syngenta's motions for summary judgment on May 10, 2006, finding the Lundquist patents not infringed because the patent holder (Monsanto through Dekalb) performed the initial steps of the claimed processes. The trial court also found claims 1, 5 and 6 of the '835 patent invalid for lack of enablement. Monsanto, 431 F. Supp. 2d at 490. The district court specifically noted that Syngenta lawfully obtained the GA21 seeds from Monsanto's licensees, such as Garst and Golden Harvest. Upon obtaining the seeds, Syngenta also acquired the right to further produce GA21 progenies containing the glyphosate resistance trait. Id. at 487. Also, Monsanto itself (through its

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subsidiary Dekalb) made the original GA21 R0 plant, at a time before issuance of the Lundquist patents. Id.

On June 6, 2006, the district court entered a final judgment in favor of Syngenta and against Monsanto on both Monsanto's claim of infringement and Syngenta's counterclaim of invalidity under 35 U.S.C. § 112.

II

This court reviews a district court's grant of summary judgment without deference. Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353 (Fed. Cir. 1998); Conroy v. Reebok Int'l, Ltd., 14 F.3d 1570, 1574 (Fed. Cir. 1994). Thus, this court decides for itself "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). In applying this standard, this court draws all reasonable inferences in the nonmovant's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996) (citations omitted). The claim construction part of this test receives review as a question of law, see Cybor Corp. v. FAS Techs. Inc., 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc), while infringement, whether literal or under the doctrine of equivalents, is a question of fact. Optical Disc Corp. v. Del Mar Avionics, 208 F.3d 1324, 1333-34 (Fed. Cir. 2000); Bai v. L&L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998).

This court reviews determinations of enablement under 35 U.S.C. § 112, first paragraph, without deference. Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1268 (Fed. Cir. 1986). Factual issues underlying enablement are reviewed for clear error. Gould v. Quigg, 822 F.2d 1074, 1077 (Fed. Cir. 1987); Atlas Powder Co. v. E. I. Dupont de Nemours & Co., 750 F.2d 1569, 1573 (Fed. Cir. 1984) (appellant must establish that the district court's legal conclusions were erroneous, or that the underlying findings were clearly erroneous); see also Anderson v. Bessemer City, 470 U.S. 564, 573, 105 S. Ct. 1504, 84 L. Ed. 2d 518 (1985).

Because Dekalb performed all the steps of claim 1 of both Lundquist patents, Monsanto necessarily asserted claims other than claim 1 (4-9 of the '880 patent and 5-6 of the '863 patent). Monsanto proffers two theories of infringement. First, Monsanto argues claim 4 of the '880 patent is an independent claim, thus not requiring an alleged infringer to perform the steps of claim 1. Second, Monsanto argues that, even if claim 4 is dependent on claim 1, Syngenta infringes because Syngenta's performance of the last step of the process of claim 4 resulted in performance of all of the claimed steps of claim 4, albeit with the first three steps performed by Monsanto. Syngenta responds that claim 4 of the '880 patent depends on claim 1 and therefore includes all the steps of claim 1. Thus, claim 4 can only be infringed by the unauthorized performance of all the steps of claims 1 and 4. Consequently, because Monsanto (the patent holder) admittedly performed the steps of claim 1, Syngenta cannot infringe as a matter of law.

A. Claim Construction

The district court construed claims 4-9 of the '880 patent and claims 5-6 of the '863 patent as dependent from claim 1 of their respective patents. Claim 1 of the '880 patent recites a three-step process for generating an original RO fertile transgenic plant containing DNA that provides herbicide resistance. The district court construed claim 4 as further adding a fourth step of obtaining progeny from a fertile transgenic plant produced by the process of claim 1. Monsanto, 431 F. Supp. 2d at 485.

Claims 5-9 of the '880 patent and claims 5-6 of the '863 patent fit the traditional dependent format. Claim 4 of the '880 patent features a format closely following the traditional dependent format. Although suggesting the correctness of the trial court's construction, this format, however, does not answer the entire question. Monsanto urges that claim 4 of the '880 patent is not "simply" a dependent claim because it entails significantly more than the process of claim 1. According to Monsanto, claim 4 is by itself a single-step process (process of obtaining progeny). Under Monsanto's construction, the dependent language refers instead to the novel starting material (a fertile transgenic plant previously obtained using the claim 1 process) of the new process in claim 4. To bolster its point, Monsanto draws attention to the form of claim 4, which differs a bit from the customary dependent claim format (i.e., "the process of claim 1 further comprising . . .").

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To establish whether a claim is dependent upon another, this court examines if the new claim both refers to an earlier claim and further limits that referent. 35 U.S.C § 112, P 4 (2000) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."). A claim's status as dependent or independent depends on the substance of the claim in light of the language of § 112, P 4, and not the form alone. See also Manual of Patent Examining Procedure (MPEP) § 608.01(m), (n) (August 2006); 37 C.F.R. § 1.75 (2007) (setting forth proper drafts for independent and dependent claims).

Claim 4 expressly recites the process of claim 1 and specifically requires a fertile transgenic plant obtained by the performance of the steps in claim 1. Further, it includes the additional step of obtaining progeny. Claim 4 thus incorporates the format specified by the statute for dependent claims. Contrary to Monsanto's argument, claim 4 clearly references another claim, not simply a starting material. The claim might have used express language to clarify that it only invoked the product of the process in claim 1 as a starting material, but did not do so. Instead, the claim language reads claim 1 into claim 4.

At oral argument on appeal, Monsanto argued that claim 4 is a process claim that merely recites a product made by an earlier process claim. Specifically, Monsanto stated that claim 4 is claiming a process using the starting material of a product which has been made by the process of steps 1, 2 and 3 of claim 1. This court finds this argument irrelevant to the resolution of the issue. Even if claim 4 is a product by process claim, Syngenta would still have to perform the steps of the process of claim 1 to infringe the product by process claim, i.e., claim 4 would only have meaning according to the incorporation of the limitations of claim 1. Claim 4 would contain the process steps of claim 1, which by its language requires this court to read the limitation of claim 1 into the new claim.

Although in a somewhat unusual format, claim 4 is dependent from claim 1 because it only stands if all three steps recited in claim 1 have been performed. In other words, the additional fourth step of obtaining progeny depends on the performance of the process comprising the three steps recited in claim 1 for obtaining a fertile transgenic plant. Claim 4 contains each element of a dependent claim.

Further, the prosecution history of the '880 patent provides additional insight into the scope of claim 4. Originally-filed claim 30, which corresponds to patent claim 4, was incontestably a dependent claim. Original claim 30 recited:

30. The process of claim 23 further comprising (iv) obtaining progeny from said fertile transgenic plant of step (iii), which comprise said DNA.

(emphasis added). This language even more expressly required performance of all three steps of the process of claim 23 (which corresponded to issued claim 1).

Upon later amending original claim 30 after the prosecution closed, Monsanto carefully explained that its amendments "do not introduce new matter and are allowable without further search and consideration." Moreover, the examiner accepted the amendment indicating the amendment was "directed to matters of form not affecting the scope of the invention." These two statements underscore that Monsanto did not change a four-step claim (original claim 30) into a single-step claim (claim 4) with its amendment. Instead, claim 4, like its predecessor claim, as attested by the prosecution history, is in dependent form and incorporates the limits of the overarching independent claim.

The district court correctly interpreted and applied 35 U.S.C. § 112, P 4 to read claims 4-9 of the '880 patent and claims 5-6 of the '863 patent as dependent. Therefore, this court affirms the district court's claim construction.
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V. "Obtained from Lung Tissue of a Mammal"

Claim 1 of both the '301 and the '839 patents states that the surface active material is "obtained from lung tissue of a mammal." The parties appear to agree that there are two generally accepted methods for obtaining lung surfactant from the

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lungs of mammals. One method, which is the one used by plaintiffs, is called the lavage method, in which the surfactant is washed off the surface of lungs that have been removed intact from the mammal. The other method, which is the one used by defendants, is called the mincing method, in which the lungs are minced and then go through a process to extract the lung surfactant from the minced tissue. Plaintiffs argue that the "obtained from lung tissue" claim limitations in the '301 and '839 patents refer only to the mincing method. Defendants, on the other hand, argue that the "obtained from lung tissue" claim limitations are broad enough to include both the mincing method and the lavage method. The Court finds defendants' interpretation of the "obtained from lung tissue" language to be the correct one.

None of the claim language in either of the patents limits the method by which the lung surfactant can be derived. Nor is there any express limitation on the definition "obtained from lung tissue" included in the specification.

Defendants' interpretation is supported by the presence of Claim 13 in the '301 patent and Claim 16 in the '839 patent, both of which describe the mincing method for obtaining the surfactant from the lung tissue of a mammal. If the "obtained from lung tissue" language was already limited to the mincing method, then these claims would be unnecessary and superfluous. As stated above, a claim construction that would make other claims of the patent superfluous must be rejected.

Plaintiffs argue that the "obtained from the lung tissue" language should be construed as only including the mincing method because all of the examples cited in the patents teach a mincing technique for obtaining the lung surfactant. They also point out that neither patent says anything about obtaining the lung surfactant through the lavage method. This argument must be rejected, however, because, as stated above, it is well settled that particular embodiments appearing in a specification cannot be read to limit the claims when the claim language is broader than such embodiments. Although the language in a specification may be used to interpret claim limitations, it may not create claim limitations.

Plaintiffs further argue that inclusion of the word "tissue" in the claims confirms that they are directed to the mincing process. Plaintiffs argue that the term "lung tissue" is narrower than the term "lung" itself, and that had the patentees wished to include the lavage method within the scope of the claims, the claims would not have included the word "tissue." The Court finds this argument unpersuasive. Lung surfactant is produced by cells located within the lung tissue. Thus, the use of the word "tissue" is simply a more accurate description of where the surfactant is obtained and does not connote a certain procedure for obtaining the lung surfactant.

Accordingly, for the reasons stated, the Court will adopt the defendants' interpretation of the phrase "obtained from lung tissue of a mammal" and will instruct the jury as follows:

The claims of the '301 and '839 patents include the phrase "obtained from lung tissue of a mammal." The phrase "obtained from lung tissue of a mammal" means that the components included within the surface active material are acquired from the lung tissue of a mammal. The manner in which the material is acquired from the lung tissue is not limited to any specific process. Thus, the phrase "obtained from lung tissue of a mammal" can mean either the mincing process or the lavage process.

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Claim 1 of the '602 patent has four elements:

I. A method for diagnosing viral infection in a susceptible host, said method comprising:

II. obtaining a physiological specimen from said host; and

III. determining the presence of feline T-lymphotrophic virus [FIV] or antibodies to [FIV]

IV. in a physiological specimen from said host.

See '602 patent, attached as exh. A to Consalvi Declaration (paragraph numbers added to comport with the parties' referencing system). Defendants claim that their activities do not meet the second element -- obtaining a physiological specimen from said host. They accede that their activities otherwise fall within the language of claim 1.

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1. Element II

It is undisputed that Dr. Hansen performs IFA assays on cat blood or serum samples sent to him by other veterinarians and laboratories. The parties dispute whether receiving samples from others meets the test of "obtaining" a physiological specimen under element II. Plaintiffs argue that "obtaining a physiological specimen from said host" simply means the "person performing the test has to obtain, or take physical possession of a physiological specimen from the host suspected of being infected" (here, the cat). See Plaintiffs' Motion 11:27-28, 12:1-2. Defendants claim, however, that element II requires a positive, active step of obtaining a specimen and that Dr. Hansen did not meet this step because people sent him specimens rather than Dr. Hansen collecting them himself.

Defendants appear to draw the language of requiring a "positive, active step" from Ex Parte Erlich, 3 U.S.P.Q.2D (BNA) 1011, 1016 (Bd. Pat. App. & Interf. 1987). They interpret the language out of context. Under Erlich, "a method claim should at least recite a positive, active step(s) so that the claim will 'set out and circumscribe a particular area with a reasonable degree of precision and particularity' and make it clear what subject matter these claims encompass, as well as making clear the subject matter from which others would be precluded." See id.

Defendants go through a complicated analysis of plaintiffs' parent patent application to conclude that the plaintiffs meant for the element of "obtaining a physiological specimen from said host" to be the positive active step required by Erlich. For purposes of this motion, the court accepts defendants' representation.

Plaintiffs' interpretation that "obtaining" means "taking into possession" is consistent with a positive, active step. In Erlich, the Board interpreted the second paragraph of 35 U.S.C. § 112. This paragraph states, "the specification shall conclude with one or more claims particularly pointing out and distinctively claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. The Board decided that to meet the criteria of § 112, the applicant needed to show positive, active steps as to how a method would be practiced. See id. at 1017 (Board dismissed two claims because they "simply recited a use without any active, positive steps delimiting how this use is actually practiced.") The importance of these steps is to "set out and circumscribe a particular area with reasonable degree of precision and particularity and make it clear what subject matter these claims encompass." Id.

Interpreting element II to mean "taking possession of a physiological specimen from said host" meets the goals of 35 U.S.C. § 112 and of Erlich. The subject matter is clear -- a physical specimen from a cat. The use of the patent is similarly clear -- diagnosing a viral infection in a host by taking a physical specimen from the host. How possession is gained is not important to either 35 U.S.C. § 112 or to the Erlich decision. Defendants try to twist the language of Erlich to make "active" mean that the person practicing the claim has to go out and draw the blood or serum themselves. The reasoning behind Erlich does not require such a narrow interpretation.

When construing a claim, the court must look to the intrinsic evidence including the claim itself and the specification. 6 See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581 (Fed. Cir. 1996). To meet the purpose of the patent claim, the court need not narrowly interpret "obtain." The patent claim shows a method for diagnosing viral infection in a susceptible host. Who gathers the specimen is not important to the diagnosis. Furthermore, nothing in the specification supports a narrow interpretation of "obtain." The specification states that FIV may be isolated "from the sera of infected cats." See '602 patent, col. 3, attached as exh. A to Consalvi Declaration. Sera can be isolated from blood. See id. FIV may also be "obtained from other specimens particularly from the lymph tissues of infected animals." Id. at 4. Nowhere does the specification require that the person using the method for diagnosing the infection must be the one who gathers the sera, blood, or lymph.

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6 The specification is the term given to the portion of the printed patent which precedes the claims. The specification included written descriptions of the invention or discovery and the matter and process of making and using it.

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The dictionary definition of "obtain" is "to gain or attain possession or disposal of, usually by some planned action or

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method." See Webster's 3rd New World International Dictionary, unabridged edition, G + C Meriam & Co, 1976. The court sees no reason to limit the ordinary definition. The dictionary definition is consistent with the case law, the statute, the language of the claim itself, and the specification. Consequently, the court interprets "obtain" in this context to mean take physical possession of the physiological specimen.
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Defendant also seeks to limit the construction of the phrase "fenofibrate/solid surfactant mixture" in claim 10 to exclude any other ingredients other than fenofibrate and solid surfactant. Plaintiff does not dispute this construction.

"Mixture" is defined as "a combination of different drugs or ingredients". Dorland's Illustrated Medical Dictionary 1122 (29th ed. 2000). Accordingly, a fenofibrate/solid surfactant mixture would be defined as a combination of fenofibrate and solid surfactant. No other materials are included in the description of the mixture; and the claims, patent description, and prosecution history support the conclusion that no other materials are included in the mixture.

Defendant also seeks to limit the phrase "mixture of particles of fenofibrate and a solid surfactant" to mean a "mixture wholly of fenofibrate and a solid surfactant, to the exclusion of any other excipients". Plaintiff opposes such construction, arguing that the phrase is properly construed to mean "a resultant mixture composed of (but not necessarily wholly of) particles that are composed of (but not necessarily wholly of) fenofibrate and a solid surfactant".

"Of" is defined as "a function word to indicate the material, parts, or elements composing something". Webster's Third New Int'l Dictionary 1565 (3rd ed. 1986).

In a similar claim, the Eastern District Court of New York construed the language 'net supporters made of PFA, FEP or EPE' to mean that the 'net supporters must be made wholly of PFA, FEP or EPE, and cannot include any other fluorocarbon resin...' Pall Corp. v. PTI Tech. Inc., 259 F.3d 1383, 1390 (Fed. Cir. 2001) (Pall), quoting Pall Corp. v. PTI Techs., 1999 U.S. Dist. LEXIS 22893, Nos. CV-97-1134, CV-98-2871 (E.D.N.Y Dec. 22, 1999). On appeal, the parties did not dispute this claim construction, and the Federal Circuit "agreed with the district court's claim construction requiring the net supporters to be made of 100% of one of the recited ... resins." Pall, 259 F.3d at 1390.

In light of the claim language, and the patent description and prosecution history discussed above, the phrase "mixture of particles of fenofibrate and a solid surfactant" means a "mixture of particles wholly of fenofibrate and a solid surfactant".
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A. Construction of "heterogeneous mixture of labeled unique sequence nucleic acid fragments"

Dako filed its summary judgment motion based on the court's observations in the preliminary injunction as to the likely construction of "heterogeneous mixture of labeled unique sequence nucleic acid fragments." The court revised its interpretation of this phrase in light of the more thorough claim construction briefing submitted by the parties, ultimately accepting Abbott's argument that the word "of," read in the context of the dependent claims of the '479 patent, should be construed to mean "comprising." Although the court expressed concerns about adopting the broad construction proposed by Abbott -- particularly in light of the inoperative subject matter encompassed in Abbott's interpretation of the claim-the court found that the relationship among the independent and dependent claims provided clear evidence that the patentee intended to allow the heterogeneous mixture recited in claim 1 to include repetitive as well as unique fragments.

In the briefs accompanying the instant motion, however, Dako has discussed additional excerpts from the prosecution history which call the court's previous construction into question. The excerpts were included in the declarations accompanying the parties' Markman submissions but were not cited in the accompanying briefs or highlighted at argument. n1 The cited excerpts follow the development of the claims of the '479 patent in some detail, and bear careful review.

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n1 The court points out that it is not the court's responsibility to comb the record in search of evidence or arguments not raised in the parties' briefing. That is the lawyers' job. Had this been done in the claim construction phase this issue would have been resolved at that time -- the proper time -- and would not need to be revisited here.

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Originally filed application claim 17, which is the predecessor to claim 1 of the '479 patent, read as follows:

17. A method of staining chromosomal DNA of a particular chromosome type or portion thereof, or a particular group of chromosome types, the method comprising the steps of:

providing a heterogeneous mixture of labeled nucleic acid fragments, substantial portions of each labeled nucleic acid fragment in the heterogeneous mixture having base sequences substantially complementary to base sequences of the chromosomal DNA; and

reacting the heterogeneous mixture with the chromosomal DNA by in situ hybridization.

Hoffman Dec., Exh. N at 47. Of particular note is that claim 17 recited a "heterogeneous mixture of labeled nucleic acid fragments," without the "unique sequence" modifier. See id. The examiner rejected the claim under 35 U.S.C. section 112 for lack of enablement, noting that
the disclosure is enabling only for claims limited to reacting practice (last 2 lines of claim 17) which promotes at least some specificity of hybridization so as to stain only the desired target chromosome or portion thereof. As worded there is no specificity practice in the actual claim steps that would result in staining of the target only without so much background that the desired target nucleic acid would be obscured.

Id., Exh. O at 2 (emphasis added). In other words, claim 17 as drafted contained no provision for reducing nonspecific binding. This court noted precisely the same concern in its Markman order. Slip op. at 8-9.

In response to the rejection, the applicants canceled the pending claims and submitted amended claims. Amended application claim 18, which is also the predecessor to claim 1 in the final patent, read as follows:
18. A method of staining target interphase chromosomal DNA to detect amplifications, deletions, and rearrangements comprising:
(a) providing a heterogeneous mixture of labeled unique sequence nucleic acid fragments which are substantially complementary to nucleic acid segments within the interphase chromosomal DNA for which detection is desired; and

(b) employing the heterogeneous mixture and interphase chromosomal DNA in in situ hybridization to permit detection of labeled nucleic acid fragments which are hybridized to interphase chromosomal DNA, wherein the chromosomal DNA is present in a morphologically identifiable cell nucleus during the in situ hybridization.

Hoffman Dec., Exh. P at 2. Although the claim language changed in several ways in the progression from claim 17 to claim 18-such as adding the types of conditions to be detected, the requirement that the process be performed on interphase DNA, and the "morphologically identifiable cell nucleus" limitation-the only changes to address the examiner's concern regarding nonspecific binding were the addition of the phrase "unique sequence" and the clarification that the recited fragments are "substantially complementary to nucleic acid segments within the interphase chromosomal DNA for which detection is desired."

The applicants did not provide a detailed explanation of the significance of their changes, but argued that the previous rejection under section 112 was moot in light of the newly drafted claims. The examiner accepted the applicants' argument that the change adequately addressed the enablement concern. Id., Exh. Q at 3-4. It is also apparent that the examiner recognized that the fragments in the heterogeneous mixture were intended to bond only to the target region, as demonstrated by the examiner's question as to whether use of the word "unique" was appropriate to cover "detecting apparently non-unique 'extra' chromosomes"-i.e., targets which occurred more than once per haploid. Id., Exh. Q at 4.

The dependent claims added as part of the same amendment are also revealing, as they do not include the later-added

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dependent claims which this court found to support Abbott's proposed construction. See id., Exh. P at 1-4. Dependent claim 12, which recites the inclusion of repetitive sequence fragments in the heterogeneous mixture, was not added until March 1999, almost two-and-one-half years after the applicants added the "unique sequence" limitation. Id., Exh. V at 2.

The cited excerpts are significant because they evince a disclaimer of methods employing labeled repeat sequence fragments, the inclusion of which in the probe mixture would result in "so much background that the desired target nucleic acid would be obscured." Cf. id., Exh. O at 2. Based on the approaches to reducing nonspecific binding set forth in the specification, the applicant could have chosen to address the examiner's section 112 rejection in two ways: the addition of blocking nucleic acid to prevent the repeat sequence fragments from hybridizing to the target, or the elimination of repeat sequence probes from the heterogeneous mixture. By representing to the examiner that the amended claim, which did not include any limitation requiring blocking, addressed the problem of nonspecific binding, the applicants represented that the claimed heterogeneous mixture would not bind to undesirable locations -- in other words, that the claimed mixture was free of repeat sequence fragments.

In addition, as the court observed in the claim construction order, the applicants argued to the examiner that "'[u]nique sequence nucleic acid fragments are in contrast with, and free of, 'repetitive sequence' nucleic acid." Slip op. at 10. The court previously noted in its Markman order that this definition for "unique" is compatible with Abbott's proposed construction, which depends on the word "of" for inclusion of repetitive sequence fragments in addition to the unique sequence fragments which are expressly recited in the claim. Id. Viewed in the broader context of the purpose for adding the "unique sequence" modifier, however -- overcoming the examiner's rejection for inoperability -- the applicant's definition of the word "unique" provides further evidence that the applicant disclaimed embodiments using repeat sequence fragments and blocking as part of the amendment.

A patent applicant may relinquish subject matter through claim cancellation or amendment during prosecution. "The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003). Under the doctrine of prosecution disclaimer, which is distinct from prosecution history estoppel, the literal scope of claim terms is limited as a result of disclaimers made during prosecution: "a claim in a patent as allowed must be read and interpreted with reference to claims that have been canceled or rejected, and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent." Id. (citing Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 220-21, 61 S. Ct. 235, 85 L. Ed. 132, 1941 Dec. Comm'r Pat. 802 (1940)).

Here, it is clear from the file history that the "unique sequence" limitation was added to address the examiner's concern about the lack of any claim element which would reduce nonspecific binding. Abbott's proposed construction in this case -- that the heterogeneous mixture might include repeat sequence fragments-is equivalent in scope to the broader claim limitation rejected by the examiner. Abbott cannot reclaim what it relinquished.

Abbott argues that the words "unique sequence" were added only to clarify that the heterogeneous mixture must contain some unique sequence fragments, in addition to whatever repeat sequence fragments might be present. In support of this argument, Abbott notes that as part of the same office action in which the examiner rejected claim 17 under section 112, the examiner also rejected claim 17 under section 102(b) as anticipated by three pieces of prior art. Two of the references described the use of heterogeneous mixtures of labeled repeat sequence DNA; the third reference described the use of labeled unique sequence DNA. Hoffman Dec., Exh. O at 3-4. Abbott notes that none of the cited references used a mixture of unique and repeat sequence fragments and argues that the modified version of claim 17 is distinct because it includes both.

Abbott's alternate explanation is not plausible because the applicant did not distinguish the amended claim 17 from the cited prior art on the basis of the "unique sequence" limitation. Instead, the applicant distinguished the prior art by limiting the use of the claimed method to interphase DNA and by requiring that the method detect amplifications, deletions and rearrangements: "The prior art fails to disclose or even suggest the methods of staining target interface [sic: interphase] chromosomal DNA to detect amplifications, deletions and rearrangements, as now claimed." Id., Exh. P at 5. Also, as Dako correctly points out, the phrase "heterogeneous mixture" as defined generally in the specification for the '479 patent clearly includes unique sequence fragments: "In particular, chromosome specific staining reagents are provided which comprise heterogeneous mixtures of labeled nucleic acid fragments having substantial portions of substantially complementary base sequences to the chromosomal DNA for which specific staining is desired." '479 patent at 3:51-56. Thus it was not

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necessary to add the "unique sequence" modifier to suggest that the heterogeneous mixture included some unique sequences.

Abbott also argues, as it did at the claim construction hearing, that the examiner must have understood the claim to include repeat sequence fragments when she allowed dependent claims 12 through 14 to be added without objection. Abbott, however, does not cite any portion of the file history suggesting that the examiner considered the tension between her previous rejection under section 112 and her subsequent allowance of claim 12. Absent some explanation for or qualification of the otherwise clear disclaimer, Abbott is not entitled to recover the disclaimed scope. The court therefore modifies its construction of the phrase "heterogeneous mixture of labeled unique sequence nucleic acid fragments" to mean "a heterogeneous mixture of labeled nucleic acid fragments that includes only unique sequence fragments."
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1. an "oil"

This disputed term appears in Claims 1 and 22 of the '529 patent, and in claims 1 and 26 of the '660 patent. The parties dispute the meaning of this term for the same basic reasons in each patent. Plaintiff argues that the term should be broadly construed, and offers the following proposed construction: "a slippery or viscous liquid or liquifiable substance that is substantially immiscible in water, including any such substance that would find value in a cosmetic preparation." Joint Claim Chart 3 ("Chart") at 2. Plaintiff bases its construction on the non-limiting language in the patents' specifications, each of which indicate that the oil referred to can be "any oil" but "usually will be an oil which finds value in a cosmetic preparation." '529 patent, col. 4, lines 1-3; '660 patent, col. 3, lines 13-15. The specifications further state that such oils "usually" are vegetable oils, and they list "typical examples" of the same. '529 patent, col. 4, lines 3-11; '660 patent, col. 3, lines 15-22. Citing the dictionary (Dictionary.com and the American Heritage Dictionary) Plaintiff argues that "oil" should be defined more in terms of its functional qualities rather than the material of which it is comprised. Under Plaintiff's proposed construction, the term "oil" would include silicone oils, esters and alcohols.

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3 This chart is attached as Exhibit 1 to the Certification of James Calve (filed July 12, 2007), and is the chart that counsel referred the Court to at Markman hearing in December 2008. Tr. 90:20-23; 91:2-4. The Court notes that this chart differs from the claim chart that was submitted to the Court on April 11, 2008, even thought this later-filed claim chart was described in an accompanying letter as the "claim chart finalized by the parties in June of 2007." Based on counsel's representation (without objection) that the chart attached to the Calve certification is "the claim chart," Tr. 91:4, the Court shall use the proposed constructions in the claim chart accompanying the Calve certification with respect to the instant decision.

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Defendant argues for a more narrow construction, and contends that the term "oil" as used in the patents should be construed as

vegetable oils, sunflower oil, caster oil. This term is limited to materials which are greasy, sticky and viscous liquid substances that are non-volatile and substantially immiscible in water and comprise at least one carbon chain. The term "oil" does not include metal based fluids, such as silicon based materials, such as silicone fluids, for example, cyclotetrasiloxane, cyclopentasiloxane and other cyclomethicones.

Chart at 2-3. In essence, Kobo is arguing that the term "oil" should be limited to those materials identified in the patents' specifications to the exclusion of other materials. In support of its position, Kobo also refers to extrinsic evidence such as the definition of "oil" in the International Cosmetic Ingredient Dictionary and Handbook (11th ed., 2006) ("Dictionary"), which limits the term to "triglicerides of plant or animal origin" and the Handbook of Chemistry and Physics, which lists as "oils" only materials of animal or plant origins. Kobo also relies upon an affidavit from Eric Abrutyn, a scientist in the cosmetic industry, who states "the term 'oil' has never been considered applicable to mono or diester fluids, siloxane based chemistry, nitrogen based chemistry, or low molecular weight hydrocarbons such as isododecane." Abrutyn Affidavit P 36.

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In response to the extrinsic evidence cited by Kobo, Plaintiff points to other extrinsic evidence that Plaintiff argues establishes that persons skilled in making cosmetics and sunscreens would readily understand that the term "oil" covers a broad range of cosmetic oils that includes vegetable oils, silicone oils, esters, and alcohols. Pl. Resp. at 10. Plaintiff refers to a number of articles from trade publications as well as various definitions from industry reference materials that discuss the use of silicones, alcohols, esters, and others as "oils" that are used in cosmetic formulations. See Certification of James Calve ("Calve Cert.")., Exs. 10-16.

Turning first to the patent itself, the Court notes that the plain language of the specifications of the patents is clear that the specific oils referenced therein are provided as examples and not limitations. See, e.g., '660 patent, col. 3, lines 12-16 ("The oil can be any oil . . . but usually will be an oil that finds value in a cosmetic preparation . . . [which] oils are usually vegetable oils."); '529 patent, col. 4, lines 1-4 (same). As such, it would appear that acceptable oils are not necessarily limited to materials that are of plant or animal origin. Indeed, nothing in the specification or the patent history expressly excludes, for example, "metal based fluids, such as silicon based materials, such as silicone fluids, for example, cyclotetrasiloxane, cyclopentasiloxane and other cyclomethicones," as does Kobo's proposed claim construction.

Additionally, to the extent it is necessary to consider extrinsic evidence, the Court finds the extrinsic evidence relied upon by the Plaintiff to be more consistent with the intrinsic evidence, as the language of the patent itself dictates that the term "oil" be construed broadly. Phillips, 415 F.3d at 1319 ("extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."). Consequently, the Court shall construe "oil" consistent with Plaintiff's proposed construction to mean "a slippery or viscous liquid or liquifiable substance that is substantially immiscible in water, including any such substance that would find value in a cosmetic preparation."

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D. Oil-Based Substance

For the reasons set forth below, this court interprets the term "oil-based substance" in the '328 patent to mean:

a lotion or a greasy or oily substance.

Shen Wei argues that this term should be construed as a "lotion or a greasy or oily substance that has an adverse affect on natural rubber latex." (Pl.'s Resp. at 12.) This court adopts the first part of Shen Wei's proposed construction because Ansell agrees that this first part is the generally understood meaning of "oil-based substance." (Def.'s Reply at 7.) This court rejects the second part of Shen Wei's definition -- "that has an adverse affect on natural rubber latex" -- as being an impermissible limitation on the claim language. Shen Wei supports its argument that "oil based substance" should be further limited to substances having an adverse affect on natural rubber or latex with excerpts from the specification allegedly defining "oil-based substance," and expert testimony. This court will address each in turn.

It is well understood that a patentee may act as his or her own lexicographer by establishing definitions of a term different than that term's customary meaning. Vitronics Corp. v. Conceptronic, Inc. 90 F.3d 1576, 1582 (Fed. Cir. 1996). Despite Shen Wei's arguments to the contrary, the patentee in this case has not defined oil-based substance as a substance that has an adverse affect on natural rubber latex. See Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998) (explaining that a special definition provided by the patentee "must be sufficiently clear in the specification that any departure from common usage would be understood by a person of experience in the field of the invention."). In a number of places, the specification explains that a major advantage of using non-oil-based substances is an increased shelf life of a natural rubber glove. But explaining an advantage of using oil-based substance is not the same as signaling to the reader of the patent that the customary meaning of a term is no longer applicable. In both cases cited by Shen Wei the patentee clearly limited the meaning of a claim term by providing a definition in the specification. See Multiform, 133 F.3d at 1477 (patentee limited to specific description in the specification of how an envelope is "degradable," and could not broaden the scope of that term with a general dictionary definition); Scimed Life Systems v. Advanced Cardiovascular, 242 F.3d 1337, 1343 (Fed. Cir. 2001) (explaining that while it is not necessary to use a "definitional format" to limit a claim, a claim term is defined and thereby limited to that definition when the patentee describes a certain structure as that which applies for "all

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embodiments of the prevent invention contemplated and disclosed"). The specification in this case does not state that an oil-based substance is a substance that is (or is defined to mean) a substance that degrades rubber or latex. And the fact that the proposed limitation is simply consistent with, and not contradicted by, the specification is certainly not enough to rebut the presumption that a term should be given its ordinary meaning. The law requires a clear departure from common usage. No such definition or limitation has been provided in this case.

Furthermore, as Ansell points out, the '328 Patent discloses two advantages of using non-oil-based substances, not just the advantage Shen Wei claims acts as a definition, but also the advantage that non-oil-based substances will not make hands look or feel greasy. ('328 Patent, Col. 2, 5-9.) Thus, if it were possible to limit a claim term by describing its benefits, it seems that a further limitation on the term oil-based substance would be that the substance does not leave the skin feeling or looking greasy. This construction however, which Shen Wei would presumably object to, is improper because no clear definition of the term "oil-based" substance has been provided by the patentee. Therefore, the term will be given its ordinary and customary meaning to those skilled in the art.

Shen Wei has provided extrinsic evidence it believes supports the argument that those skilled in the glove making industry ordinarily consider "oil-based substance" to include the limitation of not having an adverse affect on rubber or latex. Shen Wei has made no showing that resort to extrinsic evidence is necessary to construe this term, nor does this court make any such conclusion. Dow Chemical Co. v. Sumitomo Chemical Co., 257 F.3d 1364, 1373 (Fed. Cir.2001) ("In the rare circumstance that the court is unable to determine the meaning of the asserted claims after assessing the intrinsic evidence, it may look to additional extrinsic evidence to help resolve any lack of clarity.") (citation omitted). Moreover, none of the evidence Shen Wei asserts is on point. The extrinsic evidence Shen Wei posits consists of expert testimony which generally can be described as supporting one of the following two propositions: first, that the '328 Patent either defines oil-based substance with the limitation that it not damage rubber or latex, see (Pl.'s 56.1(a) Stmt., PP47, 49, 50); or second, that such a definition would be consistent with the common knowledge that oil-based substances damage rubber (Id., P47, 48). This court, whose function it is to construe the patent, has already rejected the former, and the latter does not purport to define the claim term. Therefore, this court finds that the extrinsic evidence provided by Shen Wei does not support the conclusion that those skilled in the art consider the ordinary meaning of "oil-based substance" to include the limitation that the substance adversely affects rubber or latex.

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Before this Court is relatively narrow issue of claim construction. The parties have submitted a Joint Claim Construction Chart, indicating that they disagree as to the meaning of only one claim term in the '373 patent, namely the term "oil-in-water emulsion." (ECF # 24.) Defendant requests that the Court adopt the following definition of oil-in-water emulsion:

a mixture of two or more immiscible liquids held in suspension by one or more emulsifiers, which consists of two phases, an oil phase (disperse phase) and a water phase (continuous phase) such that the two phases are in equilibrium, and the system is kinetically stable and thermodynamically unstable.

(ECF # 32 at 2.) Plaintiff requests that the Court adopt the following construction for the same term:

A mixture of two or more immiscible liquids stabilized by one or more emulsifiers. (ECF # 33 at 2.) Both parties argue that the intrinsic evidence supports their definition of the disputed claim term.

After a thorough review of the '373 patent, the argument presented at the Markman hearing, as well as the extensive briefs filed by the parties in this case, the Court hereby adopts Defendant's definition of oil-in-water emulsion. The Court makes this finding based upon a review of the record before it, including but not limited to the incorporation of the '520 patent, n2 which sets forth the following definition for oil-in-water emulsion:

By an oil-in-water emulsion we mean a distinct two-phase system that is in equilibrium and in effect, as a whole, is kinetically stable and thermodynamically unstable.

(U.S. Patent No. 5,714,520, col. 4, lines 46-48.) The Court finds it consistent with logic that the '373 patent, which is a generic version of Diprivan(R), incorporates the definition of oil-in-water emulsion set forth in the '520 patent. n3

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n2 The '373 patent provides that, "The compositions of the present invention may be prepared by conventional processes as for example that disclosed in [the '520 patent.]" (U.S. Patent No. 6,140,373, col. 2, lines 29-31.) In addition, the specification expressly incorporates the '520 patent, stating, "Specific reference is made to U.S. Pat. No. 5,714,520 which is hereby incorporated by reference." (Id. at col. 3, lines 1-2.)

n3 This Court has carefully reviewed Schwarz Pharma, Inc. v. Warner-Lambert Co., 95 Fed. Appx. 994 (Fed. Cir. 2004), the unpublished decision relied upon by Plaintiff in support of its position, and finds it to be distinguishable from the instant case. Unlike in that case, Plaintiff has failed to establish that its suggested definition of the term oil-in-water emulsion is the ordinary, art-recognized meaning. Moreover, the language incorporating the '520 patent in the '373 patent is not so limited as the incorporating language in Schwarz Pharma. Hence, the Court finds Plaintiff's argument concerning the relevance of the '520 patent to be without merit.

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Based upon the foregoing, oil-in-water emulsion shall mean a mixture of two or more immiscible liquids held in suspension by one or more emulsifiers, which consists of two phases, an oil phase (disperse phase) and a water phase (continuous phase) such that the two phases are in equilibrium, and the system is kinetically stable and thermodynamically unstable.
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B. The Meaning Of The Disputed Phrase "Oil-In-Water Microemulsion"

Abbott contends that the phrase "oil-in-water microemulsion" should be construed to mean a colloidal dispersion that contains cyclosporin, a hydrophilic component, a lipophilic component, a surfactant, and water, all in certain relative proportions to one another such that combining the components (including water) results in the spontaneous or substantially spontaneous formation of a dispersion of the lipophilic phase component as droplets of an average size of between 10 and 200nm in the water and which is: (1) optically clear; (2) monophasic; (3) visually optically isotropic; and (4) stable at ambient temperatures, e.g., as evidenced by absence of any observable clouding or regular emulsion size droplet formation or precipitation, for at least two hours. (D.I. 131 at 39).

Novartis contends that no genuine claim construction dispute exists concerning the phrase "oil-in-water microemulsion." (D.I. 135 at 31). Rather, Novartis contends that the issues raised by Abbott's construction of this phrase relate to infringement, and thus, should be reserved for the trier-of-fact. (D.I. 135 at 31-32). However, in the event the Court decides to construe the phrase "oil-in-water microemulsion," Novartis contends that the phrase should be construed to mean a colloidal dispersion of lipophilic droplets, having an average particle size of less than about 1,000 A, that contains cyclosporin, a defined hydrophilic phase component, e.g. 1,2-propylene glycol, a lipophilic phase component, a surfactant and water, which dispersion is identifiable as possessing one or more of the following characteristics: a) formed spontaneously or substantially spontaneously, that is without substantial energy supply, e.g. in the absence of heating or the use of high shear equipment or other substantial agitation; b) substantially non-opaque, i.e. are transparent or opalescent; c) monophasic; d) optically isotropic; or e) thermodynamic stability, that is it will remain stable at ambient temperatures, e.g. without clouding or regular emulsion droplet formation of precipitation. (D.I. 135 at 38-39).

After reviewing the parties' arguments in light of the claims and specification of the '625 Patent, the Court is convinced that the plain language of the '625 Patent clarifies any possible dispute surrounding the phrase "oil-in-water microemulsion." Claim 1 of the '625 Patent provides that oil-in-water microemulsions produced by diluting the microemulsion pre-concentrate with water have an "average particle size of less than about 1,000 A." (D.I. 129, Ex. A, '625 Patent, col. 33, lns. 15-35). In addition to the size of the oil-in-water microemulsion, the specification of the '625 Patent goes on to define the microemulsion's other characteristics. Specifically, the specification provides in relevant part:

... The term microemulsion as used herein is used in its conventionally accepted sense as a non-opaque or substantially non-opaque colloidal dispersion comprising water and organic components including hydrophobic (lipophilic) organic

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components. Microemulsions are identifiable as possessing one or more of the following characteristics. They are formed spontaneously or substantially spontaneously when their components are brought into contact, that is without substantial energy supply, e.g. in the absence of heating or the use of high shear equipment or other substantial agitation. They exhibit thermodynamic stability. They are monophasic. They are substantially non-opaque, i.e. are transparent or opalescent when viewed by optical microscopic means. In their undisturbed state they are optically isotropic, though an anisotropic structure may be observable using, e.g. x-ray technique.

Microemulsions comprise a dispersed or particulate (droplet) phase, the particles of which are of a size less than 2,000 A, hence their optical transparency. the particles of a microemulsion may be spherical, though other structures are feasible, e.g. liquid crystals with lamellar, hexagonal or isotropic symmetries. generally, microemulsions comprise droplets or particles having a maximum dimension (e.g. diameter) of less than 1,500 A, e.g. typically from 100 to 1,000 A. (D.I. 129, Ex. A, '625 Patent, col. 5, ln. 61-col. 6, ln. 18).

Microemulsions obtained on contacting the "microemulsion pre-concentrate" compositions of the invention with water or other aqueous medium exhibit thermodynamic stability, that is they will remain stable at ambient temperatures, e.g. without clouding or regular emulsion size droplet formation or precipitation, over prolonged periods of time. (D.I. 129, Ex. A, '625 Patent, col. 6, Ins. 63-68).

Because the '625 Patent describes the characteristics of an oil-in-water microemulsion in such detail, the Court concludes that it is not necessary to provide a construction of this phrase. Additionally, to the extent the parties' dispute centers on issues that are not addressed by either the claim or specification language, the Court concludes that such issues are properly reserved for the trier-of-fact.

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1. Claim Construction:

A short word is necessary here on the legal effect of a decision by Judge Zagel of the Northern District of Illinois in a similar case. This case is not the first time that Abbott has litigated an infringement issue related to DEPAKOTE. In 1997, Judge Zagel granted summary judgment in favor of Abbott, finding that a proposed generic form of DEPAKOTE infringed the '731 and '326 patents. See Abbott Labs. v. Alra Labs., Inc., 1997 U.S. Dist. LEXIS 16611, No. 92 C 5806, 1997 WL 667796 (N.D. Ill. Oct. 24, 1997). Abbott argues that this court should give Judge Zagel's claim construction stare decisis effect, while Torpharm urges the court to conduct its own construction analysis.

Abbott's authority for the stare decisis argument is Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), where the Supreme Court noted the need for intrajurisdictional uniformity of patent claim construction. Whether Markman gives district court claim construction binding effect is a question the court need not answer. The court has reviewed Judge Zagel's claim construction and agrees with it. Thus, regardless of whether stare decisis applies, as explained below, the court adopts Judge Zagel's construction of the patents.

The '731 patent claims:

1. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and containing about 4 such units.

2. An oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions, containing as the active principal an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and containing about 4 such units.

(Pl.'s Local Rule 56. 1 Ex. 1.)

The '326 patent claims:

1. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])

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[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and containing about 4 to 6 such units.

2. An oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions, containing as the active principal an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and containing about 4 to 6 such units.

3. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and containing about 6 such units.

4. An oral pharmaceutical dosage form for treating the symptoms of epileptic seizures or convulsions, containing as the active principal an oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and containing about 6 such units.

5. An oligomer having a 1:1 molar ratio of sodium valproate and valproic acid of the unit formula, (CH[3]CH[2]CH[2])[2]CHCO[2]Na/(CH[3]CH[2]CH[2])[2]CHCO[2]H, and having physical/chemical properties as follows:

a. stable, white crystalline powder:

b. melting point of 98[degrees] - 100[degrees] C; and

c. an infrared spectrum having strong absorption bands at about 2957, 2872, 2932, 1685, 1555 and 1370 cm<-1>.

(Pl.'s Local Rule 56. 1 Ex. 2.)

The parties dispute two portions of these claims: (1) the meaning of "oligomer;" and (2) the required number of repeating units. Abbott argues that the ordinary definition of oligomer applies, and that the number of repeating units are "about 4," "about 4 to 6," and "about 6." Torpharm seeks to define oligomer negatively, in that the court should not allow the definition to encompass a "salt," "mixed salt," "derivative," "dimer," or "ionic complex." Those terms were used during the patent prosecution prior to the use of "oligomer" to describe the new compound's structure. Torpharm also argues that the number of repeating units must be limited to "about 4" because of the PTO's rejection of an earlier application. The repeating unit argument goes to the validity of the patents, not their construction, and is analyzed infra at pages 16-18.

In general, claim terms are to be given their ordinary and accustomed meaning. Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). This general rule is subject to two exceptions; where the patentee acts as his own lexicographer by setting forth an explicit definition for a claim term, or where the patentee's chosen term is so unclear that the court cannot ascertain the scope of the claim. Id. (citing cases). In construing a claim, the court should first look to the intrinsic evidence of record, such as the claims, specifications, and prosecution history. Vitronics Corp, 90 F.3d at 1582. Of this intrinsic evidence, the specifications are the single best guide to construing the claim. Id. It is important in this case to remember that "claim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources." Johnson Worldwide, 175 F.3d at 989-90 (citing McCarty v. Lehigh Val R.R., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240 (1895) ("If we once begin to include elements not mentioned in the claim in order to limit such claim . . ., we should never know where to stop.")). "In other words, there must be a textual reference in the actual language of the claim with which to associate a proffered claim construction." Johnson Worldwide, 175 F.3d at 989-90; see also 5A Donald S. Chisum, Chisum on Patents, §§ 18.03(2)(c)(i) (discussing the ban on "reading in" and "reading out" claim limitations) & (iv) (discussing claim construction where the specification discusses a problem solved by the invention).

Thus, the court begins with the general definition of oligomer. In the Alra case, Judge Zagel described the generally accepted definition of oligomer as "a composition made up of a relatively small number of repeating units joined end to end." Alra, 1997 U.S. Dist. LEXIS 16611, 1997 WL 667796 at *3 (citing Maitland Jones, Jr. Organic Chemistry, 821 (1997)). This court's own research shows similar definitions. See e.g. McGraw-Hill Dictionary of Scientific and Technical Terms 1314 (4th Ed. 1989) (defining oligomer as "A polymer made up of two, three, or four monomer units."); Webster's II New Riverside University Dictionary, 819 (1988) (same). The court accepts Judge Zagel's description of oligomer as a generally accepted definition.

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Next, the court looks at the specifications to ascertain if oligomer means something other than its generally accepted definition. The specifications teach that the inventions relate to salts of valproic acid. Valproic acid and sodium valproate have each been used to treat epileptic seizures or convulsions, but both substances have significant drawbacks. Valproic acid is a liquid, which makes it less desirable for oral dosages. Sodium valproate is a solid that is unstable due to hygroscopicity, which is a change in physical characteristics due to atmospheric moisture.

The inventor was able to bond valproic acid and sodium valproate to form a new compound consisting of one molecule each of valproic acid or diethylacetic and a sodium valproate salt. The new compound is a solid material that does not have the moisture instability problems associated with sodium valproate. The new compound retains the beneficial therapeutic effects of valproic acid and sodium valproate, while eliminating the drawbacks associated with both of those materials.

As reflected in the specifications, there was some uncertainty over the structure of the new compound, which was first believed to be a dimer, but was then found to be an ionic oligomer. The specification goes on to elaborate that "one mole each of the valproic acid moieties form coordinate bonds with the sodium of the sodium valproate molecule, and the valproate ion is ionically bonded to the sodium atom." (Pl.'s Local Rule 56. 1 Ex. 1, col. 1, line 56-60 & Ex. 2, col. 1 line 58-62.)

Torpharm urges the court to delve into the prosecution history of the patents, which shows that the patentee had difficulty characterizing the structure of the new compound. At various times the compound was called a "salt," "mixed salt," "derivative," "dimer," and "ionic complex." Torpharm claims, without citation to authority, that court cannot legally construe "oligomer" to cover these structures. The argument is not persuasive.

It is undisputed that there has been uncertainty as to the exact structure of the new compound. This uncertainty should not be held against Abbott, so as to exclude from the claims any and all terms that may have been used to describe the structure during its development. See e.g. Johnson Worldwide, 175 F.3d at 989-90 (citing cases and noting the prohibition on limiting claim language unless the claim specifically references the limitation); 5A Donald S. Chisum, Chisum on Patents, § 18.03(2)(c)(i) (same). Moreover, the specifications teach that the structure of the new compound is not nearly as significant as its physical properties, which is a solid hygroscopically stable substance. The uniqueness of the invention lies in the new compound created by bonding valproic acid and sodium valproate, rather than the label attached to the bond. This is not a case where Abbott has acted as its own lexicographer for "oligomer," or assigned it an unclear meaning so that the court cannot define the scope of the claims. Johnson Worldwide, 175 F.3d at 989. (Fed. Cir. 1999). Accordingly, the court construes oligomer according to its generally accepted definition, which is "a composition made up of a relatively small number of repeating units joined end to end." Alra, 1997 U.S. Dist. LEXIS 16611, 1997 WL 667796 at *3.

Torpharm's construction would impermissibly read in limitations that are not part of the specification. See generally 5A Donald S. Chisum, Chisum on Patents, § 18.03(2)(c)(i). At the same time, the court's construction does not read out limitations that are not part of the claims. Id. The specifications clearly contemplate that the new compound has been described by various terms, such as salt, ionic oligomer, and complex, which are consistent with the general definition of oligomer.

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TorPharm first takes issue with the district court's claim construction, a question of law that we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1174 (Fed. Cir. 1998) (en banc). Neither Abbott nor TorPharm questions the district court's definition of "oligomer" as "a composition made up of a relatively small number of repeating units joined end to end." TorPharm, however, contends that the district court erred by refusing to exclude from the definition of "oligomer" any material described as a "complex," "ionic complex," "dimer," "derivative," "mixed salt," or "salt," asserting that Abbott abandoned all these terms as representative of the claimed oligomers during prosecution of the patents in suit. We note that although TorPharm disclaims any intent to limit the claims to covalently 1 associated oligomers only, little but covalent oligomers would seem to remain if the claims were so constricted. We further note that TorPharm has neither defined these terms nor demonstrated their applicability to any species appearing in this suit, rendering the alleged error of questionable significance.

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1 Covalent bonds involve sharing of electrons by a pair of atoms, and, as compared to compounds formed from noncovalent bonds, covalently associated molecules tend to remain associated when dissolved in solvents.

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We need not muse on these questions, however, because we find no error in the district court's claim construction. Of course, prosecution history may limit claim scope if the patentee disclaimed or disavowed a particular interpretation of the claims during prosecution. Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452, 227 U.S.P.Q. 293, 296 (Fed. Cir. 1985). This principle does not, however, mean that any words appearing in the prosecution history but not in the issued claims are forever banished. The prosecution history inquiry asks not what words the patentee discarded, but what subject matter the patentee relinquished or disclaimed. Our review of the relevant prosecution history shows that while Abbott and the examiner may have disagreed about which words best described the compounds disclosed by the specification, their colloquy reveals no intent or requirement to surrender any or all compounds that might be described as a "complex," "ionic complex," "dimer," "derivative," "mixed salt," or "salt."

Furthermore, as TorPharm admits, TorPharm's construction would exclude the preferred embodiment (as well as all other embodiments) disclosed by the patent specifications. Such claim constructions are "rarely, if ever, correct," Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 U.S.P.Q.2D (BNA) 1573, 1578 (Fed. Cir. 1996). TorPharm contends that the ordinary reluctance to reach such an interpretation should be overcome here because the preferred embodiment described by the specification does not actually exist. However, as we explain below, TorPharm has not substantiated its challenges against the existence of the oligomeric structure described by the specification and encompassed within the district court's claim construction. We thus conclude that TorPharm has shown no error in the district court's claim construction.
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There are two main disputes regarding the scope and meaning of these patents. First, the parties dispute the meaning of the term oligomer. Second, the parties dispute the number of repeating units.

There is no dispute that the term "oligomer" is the patentable element of this invention. The oligomeric structure is what distinguishes the invention from a simple mixture of valproic acid and sodium valproate. The combination of the two chemicals results in a compound that has different physical characteristics from either of the starting materials. As stated in both patents, the new compound represents a single chemical molecule which does not have the detrimental physical characteristics of either of the two starting materials, rather it is a crystalline, stable solid. The term oligomer appears in every claim of the '731 and '326 patents, but it is not defined in the claims. The generally accepted definition of oligomer among chemists is a composition made up of a relatively small number of identical repeating units joined end to end. Maitland Jones, Jr., Organic Chemistry, 821 (1997). Abbott seeks to have this definition represent the complete meaning of the term oligomer as used in the patents. Abbott asserts that the claims, specifications and patent history do not limit the oligomer to a joining of the units in any particular manner. Alra asserts the term oligomer must be given a more narrow definition in relation to the patents because Abbott specifically narrowed the definition to exclude the possibility that the oligomer could contain ionic bonds or be a salt.

A technical term, such as oligomer, is generally interpreted to have the meaning that it would be given by persons experienced in the field of the invention. However, if it is apparent from the patent and prosecution history that the inventor used the term with a different meaning then the term is defined in this manner. Hoechst, 78 F.3d at 1578. Abbott admits that it added the term oligomer to the claims as a shorthand to describe the structure of the compound which is described and pictured in the specifications. So we must carefully examine the specifications and prosecution history to determine if there is a special meaning Abbott attributed to the term "oligomer," including any meanings that may have been excluded in the prosecution history.

There is no question that the basic definition of an oligomer applies here. The patented invention is made up of a relatively small number of identical repeating units joined end to end. At issue is whether Abbott narrowed the definition to explain how the units that make up the oligomer are joined together. Alra asserts that the patent specifically excludes any possibility that units can be joined by ionic bonds n1, and claims the oligomer is restricted to covalent n2 or coordinate bonds n3 only

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and the new chemical composition is not a salt. We look first to the specifications for guidance. The specifications of the '731 and '326 patents state:
the compound consists of one molecule each of valproic acid or diethylacetic acid and sodium valproate...the molecules are distributed as an ionic oligomer rather than as a dimer as originally believed.

emphasis added.

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n1 Ionic bonds are the simplest type of chemical bond in which an electron is transferred from one neutral atom to another, and the resulting charged species are held together by electrostatic attraction. 3 Encyclopedia Britanica Micropaedia 154 (Gwinn 1990).

n2 Covalent bonds are the most common type of bond; they share electrons between atoms. Id. at 154 & 156.

n3 Coordinate bonds are not typically covalent because the electrons are donated by only one of the atoms involved. Id. at 156.

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The specifications clearly state that the compound contains ionic bonds. This reference to an ionic oligomer thus clearly refutes Alra's claim that the patent excludes the presence of ionic bonds and restricts the invention to units joined together by covalent bonds. The specifications also contain a diagram of the invention and describe its structure as follows:
one mole each of the valproic acid moieties form coordinate bonds with the sodium of the sodium valproate molecule, and the valproate ion is ionically bonded to the sodium atom.

emphasis added. This language again refutes Alra's claim that the patent rejected the possibility of the compound being bound solely by covalent bonds and not by any ionic bonds.

Alra maintains that the ionic bonds referred to in the specifications have no consequence to the oligomeric structure because it refers to the bonding within the divalproex sodium molecule of the valproic ion of valproic acid and the sodium ion of sodium valproate. Alra maintains that the bond of significance to this patent is between the divalproex sodium molecules which are held together by covalent bonds.

The diagram and wording of the specifications are definitive on the structure of the molecule here. The specifications indicate that several pairs of sodium valproate and valproic acid are held together through ionic interactions, but you cannot tell much more about the structure from the specifications than that. Abbott makes a distinction in the specifications between the way valproate binds to sodium and the way valproic acid binds to sodium, but this is not related to the way in which each divalproex sodium molecule is joined to the next as Alra suggests. In fact, Abbott does not explain how each divalproex sodium molecule is joined together in the specifications or the prosecution history, likely because it did not know at the time. What Abbott did know, and I read into the claims, is that sodium hydrogen divalproate oligomer contained ionic bonds which made this new compound unique, but the location of those bonds was not relevant to the patent.

Alra further contends that the prosecution history clearly estopps Abbott from claiming the compound is a salt or acid salt because Abbott specifically rejected any description of the compound as a salt in the prosecution history. In 1979, in the original patent application, Abbott described the new compound as salts of valproic acid. In 1987, Abbott filed an amended application and replaced the description of "salts" of valproic acid with "sodium hydrogen divalproate oligomer." Along with this change, Abbott deleted the sentence, "it is possible that two molecules bind to one another in some other fashion."

While Abbott did change the name of the compound and deleted the use of the term salt, I do not find Abbott abandoned the use of the term salt to describe its invention. A salt is "a chemical compound created when the 'parent' substance reacts with another chemical. A salt is 'formed when the hydrogen of an acid is replaced by a metal or its equivalent.'" Abbott Laboratories v. Young, 287 U.S. App. D.C. 190, 920 F.2d 984, 986 (D.C. Cir. 1990). Ionic bonds are specifically referenced in the specifications. If Abbott abandoned a salt in the prosecution history, the specifications would not now refer to ionic bonds. Alra's argument implies that an oligomer, as the term is used in the patent, is mutually exclusive of a salt. This

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reading ignores the fact that the specifications clearly refer to the inventive compound as a salt. The '731 patent first states that "this invention relates to salts of valproic acid." And, just above the diagram of the molecular structure, it states "the sodium salt may be illustrated:..."
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Oligonucleotide

With respect to the '535 and '266 patents, plaintiffs indicate agreement with the construction advanced by Dyax with the exception of the meaning of the limitation "oligonucleotide." Plaintiffs' Response, at 12-13. Plaintiffs maintain that "oligonucleotide" as used in these two patents would be understood by a person of ordinary skill in the art "to mean a polymor [sic] of nucleotides comprising at least a few nucleotides in length and not usually more than about 100," although they insist that the term is given a "broader" meaning in the '363 patent. Plaintiffs' Brief, at 18, 19. According to plaintiffs, the file history of the '363 patent "makes clear" that the term "oligonucleotide" as used in that patent signifies an oligonucleotide with "an upper limit at about 600 to about 750 nucleotides triplets in length." Id., at 8. This assertion is apparently based on a reference by Dr. Pieczenik in the prosecution file history to an oligonucleotide containing 50 tandem sequences of from about 4 to about 12 nucleic acid triplets (hence 50 x 12 = 600). Id. 11

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11 The source of the 750 figure is not revealed.

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I find no support in the patent for plaintiffs' narrow or broad definition of oligonucleotide. An oligonucleotide is defined in scientific and medical texts as a compound created by the condensation of a small number of nucleotides with 20 specified as the upper limit. See, e.g., Stedman's Medical Dictionary (26th ed. 1995) 1244. As for the idea that the upper limit might be as high as 600 or 750 triplets based on Dr. Pieczenik's stray remark, neither claim 24 nor claim 34 makes any reference to an oligonucleotide made up of tandem sequences. See Markman, 52 F.3d at 980 ("Although the prosecution history can and should be used to understand the language used in the claims, it too cannot 'enlarge, diminish, or vary' the limitations in the claims").

ORDER

For the foregoing reasons, the court for Markman purposes will construe the disputed terms as follows. The limitation "from about 4 to about 12 nucleotide triplets," as used in claims 24 and 34 of the '363 patent, is sufficiently indefinite to include a range whose boundaries are delimited by 3 and 13. Similarly, the limitation "from about 4 to about 12 L-amino acid residues" means a range of from 3 to 13 of such residues. The limitation "represents at least about 10% of all possible peptide sequences" means approximately 10% or more of the possible peptide sequences of a given length within the range of 3 to 13 L-amino acids where the number of possible peptide sequences is equal to 20<L>. "Oligonucleotide" means a compound created by the condensation of typically fewer than 20 nucleotides.
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Lastly, Dr. Pieczenik challenges the construction of "oligonucleotide." Rather than construe the claim blindly, this court begins with a careful consideration of the district court's opinion regarding this claim term. Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 713 (Fed. Cir. 1998). With respect to the '535 and '266 patents, Dr. Pieczenik argued before the district court that "'oligonucleotide' as used in these two patents would be understood by a person of ordinary skill in the art to mean a polymer of nucleotides comprising at least a few nucleotides in length and not usually more than about 100.'" Pieczenik, 226 F. Supp. 2d at 322 (quoting Dr. Pieczenik's Markman Brief at 18). With respect to the '363 patent, however, Dr. Pieczenik argued that the file history "'makes clear' that the 'oligonucleotide' as used in that patent signifies an oligonucleotide with 'an upper limit at about 600 to about 750 nucleotide triplets in length.'" Id. (quoting Dr. Pieczenik's

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Markman Brief at 8). But the district court dismissed Dr. Pieczenik's attempt to broaden the plain meaning of oligonucleotide using the '363 patent's prosecution history, instead construing the term according to scientific and medical texts. The district court thus construed oligonucleotide as "a compound created by the condensation of a small number of nucleotides with 20 specified as the upper limit." Id.

Because the '535 and '266 patents 2 do not share the same lineage as the '363 patent, their claim terms in the first two patents must be construed separately. See Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1301 (Fed. Cir. 2001). Independently evaluating the specifications of the '535 and '266 patents, this court agrees that there is no "express intent to impart a novel meaning." Elekta Instrument, 214 F.3d at 1307. Thus, "oligonucleotide" takes its common, ordinary meaning with respect to these patents. Dyax provides three references that define "oligonucleotide." 3 The first defines it as "[a] compound made up of a small number of nucleotides (2 to 10)." Melloni's Illustrated Medical Dictionary 343 (1979). The second defines it as "a polymer made up of a few (2 to 10) nucleotides." Dorland's Illustrated Medical Dictionary 920 (26th ed. 1981). And the third defines it as "[a] compound made up of the condensation of a small number of nucleotides." Stedman's Medical Dictionary 980 (24th ed. 1982). 4 Because these definitions do not vary significantly, this court holds that "oligonucleotide" means, for the purposes of the '535 and '266 patents, "a compound made up of two to ten nucleotides." Even though this court adopts a slightly different claim construction than the district court, any error is harmless. A determination of noninfringement under a broader claim construction compels a determination of noninfringement under a narrower claim construction. Cf. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1329 (Fed. Cir. 2002) ("If a reasonable juror could have found literal infringement under a more narrow reading of claim 1, then the same reasonable juror could not have avoided finding literal infringement under the correct, broader construction of the claim. Thus, the district court's error was harmless.").

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2 Neither party has argued that because the '266 patent is a divisional of the '535 patent, they should be analyzed separately. Thus, the court assumes that the same interpretation should be treated as the same. See Desper Prods. v. Qsound Lab., 157 F.3d 1325, 1338 n.5 (Fed. Cir. 1998).

3 The ordinary, common meaning of "oligonucleotide" is not alleged to have changed between the filing date of the '535 patent, i.e., Oct. 1, 1979, and the issue dates of the '535 patent, i.e., Nov. 16, 1982, or the '266 patent, i.e., Jul. 9, 1985. Thus, this court need not decide which precise date among those should fix the meaning. Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1370 n.1 (2002).

4 A later version, published after the relevant timeframe, refines the definition: "A compound made up of the condensation of a small number (typically less than twenty) of nucleotides." Stedman's Medical Dictionary 1244 (26th ed. 1995).

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The '363 patent, however, yields a different conclusion. The patentee became a lexicographer and particularly defined "oligonucleotide." See Beachcombers Int'l, Inc. v. Wildewood Creative Prods., Inc., 31 F.3d 1154, 1158 (Fed. Cir. 1994). In part, the patent states:

The oligonucleotide population may also be composed of members, each of which contains the same number of tandem repeats of each peptide coding sequence, where the number of tandem repeats is from two to about fifty.

* * * *

The recombinant vector population can also be made up of individual vectors each containing the same number of tandem repeats of an oligonucleotide sequence as defined above. The number of tandem repeats can be from two to about fifty in number.

The recombinant vector population can also be made up of individual vectors each containing the same number [of] tandem repeats of an oligonucleotide sequence as defined above. The number of tandem repeats can be from two to about fifty in number.

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'363 patent, col. 3, ll. 58-62; col. 4, ll. 41-51. These passages indicate that an oligonucleotide has from two to about fifty tandem repeats, i.e., an oligonucleotide is a polymer with a number of nucleotides ranging from four to about one-hundred. Nevertheless, the context of the disputed claims of the '363 patent demonstrate that any error on the part of the district court was harmless.

As noted above with respect to "having," claims 24 and 34 recite similar limitations: "said oligonucleotide population has a coding region having a length from about 4 to about 12 nucleotide triplets" and "each structural gene having inserted therein one member of an oligonucleotide population wherein each member of said oligonucleotide population has a length from about 4 to about 12 nucleotide triplets." '363 patent, col. 46, ll. 55-57; col. 47, ll. 56-60. While "oligonucleotide" has a more expansive meaning set forth in the written description, these claims particularly limit the number of nucleotide triplets to a number ranging from about 4 to about 12. In other words, the claimed oligonucleotides are chosen from a oligonucleotide population with lengths ranging from about 4 to about 12. The claimed oligonucleotides, therefore, are a subset of oligonucleotides as defined by the '363 patent. It is undisputed that the smallest Dyax library is 18 nucleotide triplets in length. Pieczenik, 2003 U.S. Dist. LEXIS 18445, Civ. Action No. 00-11370-RGS, slip op. at 4. Accordingly, Dyax does not infringe claims 24 and 34 of the '363 patent.
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1. oligonucleotides is construed to mean polymers of nucleotides ranging in length from 2 to about 100 nucleotides.

Affymetrix contends that "oligonucleotides" means polymers, or small polymeric stretches, of nucleotides, ranging in length from 2 to about 100 nucleotides.

Incyte contends that "oligonucleotides" means single-stranded polymers of nucleotides synthesized monomer by monomer and less than about 20 nucleotides in length. 5

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5 This is the construction originally proffered by Incyte and provided in the Joint Claim Construction Statement. Incyte later attempted to modify its construction in its Opening Brief in support of its claim construction. Affymetrix objected, and the Court granted Affymetrix's Ex Parte Request for an Order Prohibiting Defendants from Asserting Claim Construction Definitions not in the Parties' Joint Claim Construction Statements. (Order of November 9, 2000). The Court nevertheless notes that Incyte's attempted revised construction agrees with Affymetrix to the extent that oligonucleotides range in length from 2 to 100 nucleotides.

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The Court looks to the plain meaning of the term, which suggests small polymers of nucleotides. At the time of the hearing, the parties agreed that oligonucleotides range from 2 to 100 nucleotides in length. The Court rejects Affymetrix's assertion that the term also encompasses small polymeric stretches, given that such a definition would effectively expand "oligonucleotides" to include polynucleotides of unlimited length. A patentee may be his own lexicographer, provided the definition is clearly set forth in the specification. Beachcombers v. Wildewood Creative Prods., Inc., 31 F.3d 1154, 1158 (Fed. Cir. 1994). However, Affymetrix fails to cite any intrinsic evidence to support its unconventional interpretation.

The Court rejects Incyte's argument that the term, "oligonucleotides," must be limited to single stranded synthetic nucleotides made monomer by monomer. Incyte has failed to cite any portion of the specification or prosecution history indicating that patentee intended the specific term, "oligonucleotide," to be limited in this manner. 6 Instead, Incyte relies exclusively on the argument that, without this limitation, the claim would be invalid for non-enablement. The Court rejects this argument for the reasons discussed above. Further, the Court finds that in this case, "oligonucleotide" is not reasonably amenable to a definition restricting it to single stranded synthetic nucleotides made monomer by monomer. In such a case, the Court cannot rewrite the claims, even if necessary to avoid a finding of invalidity. Process Control, 190 F.3d at 1357.

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6 The Court disagrees with Incyte's characterization of the 9/30/92 Information Disclosure Statement (Livornese Decl., Exh. 11 at 2-3) as limiting the meaning of "oligonucleotides." Although the cited portion of the IDS states that the prior art does not disclose light directed techniques of oligonucleotides and the resulting claimed arrays, the Court discerns no explicit limitation of the term "oligonucleotide" from this passage.

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As to the term "materials" defining the subcoating, the district court reached the correct construction by placing the term in its proper context. The claims recite "one or more layers of materials" ('505 patent) and "one or more layers comprising materials" ('230 patent). The use of the plural "materials," as the district court notes, represents an effort to match the tense of "layers." In other words, the plural term does not necessarily require multiple compositions, but instead reflects an attempt to achieve grammatical consistency. This court finds no support in the intrinsic evidence for a narrower interpretation that would exclude a subcoating of only one material. This term therefore does not exclude subcoatings of only one material.

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The term "sprayable" has a common accepted meaning. "Spray," according to Webster's Third New International Dictionary, means "to apply something by atomizing and allowing to strike the surface in a uniform manner." The patentee added the suffix "-able" to indicate that the claimed formulation must be capable of being sprayed. To vary from the common meaning of the term "sprayable," UVC would need to show either that the written description of the '451 patent specified a different meaning, see Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249, 48 U.S.P.Q.2D (BNA) 1117, 1121 (Fed. Cir. 1998), or that artisans of ordinary skill at the time of the invention would have understood the term to have a different meaning, see K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1365, 52 U.S.P.Q.2D (BNA) 1001, 1006 (Fed. Cir. 1999). The '451 patent's written description does not specify a meaning of "sprayable" beyond its common definition. Moreover, nothing in the written description requires "sprayable" to include the concept of homogeneity. The record also shows no common understanding by artisans of ordinary skill that "sprayable" had a definition that varied from its ordinary meaning.

Although UVC claims that "one part" modifies "sprayable" to include a homogenous requirement, the prosecution history of the '451 patent undercuts this argument. During prosecution of the '451 patent, Mr. Sokol, the '451 patent's inventor, distinguished a prior art reference by arguing that the reference taught a two-part rather than a one-part coating. The prior art reference employed a second activating agent added just prior to application. Mr. Sokol's representations to the patent office during prosecution indicate that the "one-part" limitation means that the composition could be mixed long before application, as opposed to a multi-part composition mixed only upon application. Moreover, Mr. Sokol did not argue that "one-part" required homogeneity. The patent specification is devoid of evidence that supports UVC's argument that "one-part" requires homogeneity.

Based on the specification and prosecution history, this court holds that "one-part" in the '451 patent denotes a composition that can be mixed in a single container without triggering unwanted reactions but does not require homogeneity. Consequently, the record shows that the district court correctly rejected UVC's attempt to import a homogeneous requirement into the phrase "sprayable one-part composition." Under the proper construction of the "sprayable" and "one-part" limitations, there is no genuine issue of material fact as to whether the formula recited in the Tu patent is a sprayable one-part composition. As the record shows, the Tu patent's formula meets the sprayability limitation of claim 1, properly construed. The Tu patent's formula further meets the one-part limitation because it can be mixed before application.

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1. Oocyte

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Defendants assert that the patent distinguishes between enucleated "oocytes" and nuclear-transferred "embryos," both in its language and by the specifications' exclusive reference to the activation of enucleated oocytes, but a reading of the patent does not bear out defendants' assertion. The inventors do not use "oocyte" to refer only to a pre-fused cell and nothing in the patent suggests that the term should be read in this restricted manner. The inventors define oocyte in three ways: 1) as developed from an oogonium; 2) as a structure able to enter meiosis; and 3) a structure able to reach metaphase II of meiosis. Throughout the patent, the inventors use the term oocyte broadly to refer to cells that are enucleated and to cells that are transferred and fused. Because the inventors did not adopt the distinction between embryo and oocyte that defendants might wish they had and because nothing in the patent indicates that they intended to make such a distinction, it is not possible to infer from the patent language that the patented method refers only to a cloning method in which activation precedes fusion.

Except when the inventor uses a special meaning for a word, a court must give the term its ordinary meaning. If there were any doubt that scientists such as the inventors of the '720 patent use the term oocyte as well as embryo to refer to the product of a recipient, enucleated oocyte and a donor cell, it would be resolved by the evidence that other scientists, including defendant Stice, used "oocyte" in this manner in scientific papers they wrote as recently as last year, as well as in others they wrote before the application for the '720 patent was filed in 1993. Although I do not believe that the interpretation is in doubt and am not relying on the evidence in the scientific papers, it would be permissible to do so to resolve any remaining ambiguity in the use of the term. For that reason, I am denying defendants' motion to strike all references to extrinsic evidence from plaintiff's brief. See Vitronics Corp., 90 F.3d at 1583 (extrinsic evidence may be considered, if needed, to assist in determining meaning or scope of technical terms after court has looked to language of claims, specification and prosecution history).

Defendants are correct that the '720 patent specification describes a cloning process in which activation precedes fusion, but incorrect in arguing from this that the patent is limited to the activation of pre-fused, enucleated oocytes..It is black letter law that claims are not limited to the embodiment described in the patent specifications. See, e.g., Electro Medical Systems, SA, 34 F.3d at 1054. Moreover, a patent claim may encompass uses not anticipated by the inventor and therefore not described in the patent. See SRI Int'l v. Matsushita Electric Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (patent applicant is not required to describe in specification every conceivable future embodiment of invention). Therefore, it is irrelevant that the '720 patent specifications describe experiments in which activation precedes fusion, provided that the claim language is broad enough to include a process in which fusion precedes activation. The language of claims 1 and 18 is not limited to either sequence; the claims cover the method of activation without specifying when in the cloning process it must occur.
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E. Open, Non-Pressurized Reactor

Magistrate Judge Ellis recommends that the phrase in Claim 23, "'the process is conducted in an open, non-pressurized reactor," means "a reactor that allows gases to escape during the reaction,' where 'substantial pressures are not applied or allowed to build up during the reaction requiring a pressure or sealed reactor.'" 83 Defendants object and argue the phrase should be construed to mean that "'the process is conducted at atmospheric pressure in a reactor where there is a bidirectional exchange of gases between the reactor and the atmosphere.'" 84

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83 R & R at 15.

84 Def. Obj. at 32.

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Nothing in the claim supports defendants' contention that the term "open" should be construed to mean "a bidirectional exchange of gases." Nor do defendants point to intrinsic or extrinsic evidence supporting that proposed construction. Dr. Scott's declaration, however, supports the R & R's construction that "open" means permitting gases to escape. He described an open system as "one in which the gases generated in a reaction are allowed to escape from the reaction vessel." The gases

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may be permitted to escape simply by venting them to the air, or may involve "their collection by use of condensers and/or scrubbers or catalytic burners" as maybe appropriate in an industrial setting. 85

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85 Pl. Ex. E P 42.

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Defendants contend also that "non-pressurized" means "conducted at atmospheric pressure." But the specification supports Magistrate Judge Ellis's construction. It states that the prior art process required "pressure reactors" when conducted on an industrial scale. 86 In contrast, the process described in the '973 patent may be conducted in "no[n-]pressurized reactors." 87 A non-pressurized reactor therefore does not necessarily mean that the process must be conducted at atmospheric pressure, although it includes reactions run at atmospheric pressure, but rather that a purposely pressurized reactor is not required. 88 This objection is overruled.

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86 Pl. Ex. Bat col. 2:12-14.

87 Id. at col. 2:17-25.

88 See Pl. Ex. E P 46.

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(4) Said DNA construct containing the following operably linked DNA segments . . . The Court construes the term "said DNA construct" to mean the nonnative DNA construct as interpreted in element (2). The term "operably linked" means that the segments must function together as they are attached to create the DNA construct.

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G. Operatively Linked

"Operatively linked" is located in Claim 4 of the '698 patent and related by dependency to Claims 5 and 9. In context, the phrase relates to the relationship between promoter DNA 15 and the DNA that is transcribed downstream from the promoter DNA. Amgen contended that the phrase means "positioned such that it provides for initiation of transcription of a gene." Pl.'s Markman Hr'g (Apr. 10, 2000) Demontrative Ex. Amgen's '698 Patent Claim 4. TKT argued that the term means "[positioned adjacent] to the DNA encoding EPO in a way that maintains the capability to initiate transcription of EPO DNA." Defs.' Markman Hr'g (Apr 10, 2000) Demonstrative Ex. 69 (alteration in original). The parties disputed, once again, the issue of the location of the promoter relative to the gene to be expressed. Amgen argued that the words "operatively linked" imposed no locational restriction, whereas TKT contended that because the patent taught placing the promoter DNA immediately adjacent to the DNA encoding EPO, the term "operatively linked" ought be limited by location.

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15 Promoter DNA is a segment of DNA that serves to determine where RNA polymerase begins synthesis of RNA from DNA. Here, promoter DNA refers to the DNA segment that determines where RNA polymerase begins the synthesis of RNA that transcribes from the DNA encoding EPO.

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The term "linked" could, if unmodified by "operatively," imply a spatial relationship in that a link could fix the maximum distance between the two linked objects. Yet modification by the term "operatively" implies a functional rather than physical link between the two objects -- in this instance one entity's exertion of influence on another entity. More specifically, in this case, the link between the promoter DNA and DNA encoding EPO consists of the influence possessed by the promoter DNA to initiate the transcription from the DNA encoding EPO. As a result, the term "operatively linked" is not defined by the physical location of the promoter DNA relative to the DNA encoding erythropoietin, but rather by the functional effect the promoter DNA has on the EPO DNA. Thus, contrary to TKT's contentions, the term "operatively linked" could not reasonably be construed to impose a locational restriction, because the link is limited only in the sense that the promoter DNA must initiate transcription of the EPO DNA. Consequently, the Court determined that "operatively linked" means "the promoter DNA is linked to the EPO DNA in a way that maintains the capability of the promoter DNA to initiate transcription of the EPO DNA." Tr. of Markman Hr'g, Vol. III at 43:8-10.
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1. "optical purity"

This disputed term is found in claims 1, 2, 4, 5, 7, 8, 10, and 11 of the '872 patent. Plaintiff asserts that this phrase means "a measure of the purity of one enantiomer expressed as a percentage of a 100% pure sample of that enantiomer." 1 DRL argues that this term should be construed as meaning "essentially free of R-omeprazole." The key difference between the two constructions boils down to basic grammar; Astra's proposed construction recognizes that the word "purity" in the disputed term is a noun while DRL's proposed construction seems more suited for an adjective. Indeed, the term is clearly used as a noun in the specification and claims of the '872 patent. For example, the specification refers to "high optical purity" or "very high optical purity" a number of times. See, e.g., '872 patent, col. 1, line 15 ("The present invention is directed to new compounds of high optical purity…"); col 3, lines 49-50 ("they can be obtained in very high optical purity"). Claim 1 refers to "an optical purity of at least about 94% enantiomeric excess." Similarly, claim 2 similar refers to an "optical purity" of "at least 94% enantiomeric excess."

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1 The parties were unable to provide the Court with a joint claim construction chart and each submitted their own summary of the terms in dispute along with the proposed constructions of the parties. For the purposes of this decision, the parties' proposed constructions are taken from the chart accompanying Plaintiff's letter to the Court of February 3, 2010, to which counsel for Astra referred the Court (without objection) as the final summary of the claim terms that are in dispute. Tr. at 19-20.

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Furthermore, Astra's proposed construction is based upon the plain meaning of the claim language. See Phillips, 415 F.3d at 1314 (claim language is first source for claim construction). As Astra points out, each time "optical purity" appears in a claim it is used in conjunction with a percentage range of enantiomeric excess. The Court, therefore, shall adopt Plaintiff's proposed construction, and construe the term "optical purity" to mean "a measure of the purity of one enantiomer expressed as a percentage of a 100% pure sample of that enantiomer."
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3. An optical quality capable of providing a visual appearance of Newtons' [sic] rings of interference

The plaintiffs urge that the disputed phrase should be construed to mean "optical characteristics such that the material is capable of exhibiting visible dark, bright, and/or colored rings or lines." The plaintiffs submit that the specification and the prosecution history teach that the appearance of these interference patterns arises from the internal reflection of light within

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the films. The defendant proposes that the disputed phrase should be construed to mean that "the film taken as is at its actual thickness and on its actual substrate has optical characteristics such that the film is capable of exhibiting multiple alternating, visible dark and bright (or colored) interference rings or lines." The defendant contends that a film is not capable of providing a visual appearance of Newton's rings of interference if that film cannot display bands of interference colors at the film's actual thickness and on the film's actual substrate.

The court is persuaded that the plaintiffs are correct. The defendant does not provide any support for the limitations it attempts to read into the claims. The court therefore adopts the plaintiffs' construction of the disputed phrase. Accordingly, the court construes "an optical quality capable of providing a visual appearance of Newtons' [sic] rings of interference" to mean "optical characteristics such that the material is capable of exhibiting visible dark, bright, and/or colored rings or lines."

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3. "optically pure"

This term is found in claim 2. Plaintiff asserts that this term, as used in the '504 patent, means "essentially free of the (+)-enantiomer of omeprazole" and means "at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity)." DRL's proposed construction is as follows: "essentially free of Romeprazole." The only difference between the two proffered constructions is that Plaintiff's further provides a clear, quantitative limit in that it specifies that "essentially free" means "at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity)."

The Court having construed the term "(-)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole" in claim 1 as meaning enantiomers of with an optical purity of least 94% enantiomeric excess, the doctrine of claim differentiation would require that the "optically pure" material in claim 2 exhibit an optical purity higher than that required by claim 1. See Phillips, 415 F.3d at 1315;. RF Delaware. v. Pacific Keystone Techs., 326 F.3d 1255, 1263 (Fed. Cir. 2003) (Under claim differentiation doctrine, the presence of a dependent claim adding a further limitation raises a presumption that the same limitation is not present in the independent claim.). Thus, Astra asserts that the "optically pure" alkaline salt of claim 2 must have an optical purity in excess of 94% enantiomeric excess.

In further support of this assertion, Astra points to the examples 1 and 2 in the specification. In each of those examples, the starting material is described as being "contaminated" with 3% of the undesired enantiomer (94% enantiomeric excess). Astra argues that because "contaminated" material cannot properly be considered "optically pure," the term "optically pure" in claim 2 is being used to describe an optical purity greater than 94% ee.

Astra also notes that the alkaline salts of examples 1 through 7 have optical purities of at least 98% enantiomeric excess or higher. As such, the Court agrees with Plaintiff's assertion that the alkaline salts in these examples define the lower limit for the term "optically pure" as found in claim 2 of the '504 patent. Therefore, this term shall be construed as proposed by Plaintiff, namely to mean "essentially free of the (+)-enantiomer of omeprazole" and "at least 98% enantiomeric excess (e.e.) of one enantiomer over the other (99% optical or enantiomeric purity)."

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Claim 1 of the '874 patent recites:<$=S>

1. Optically pure cis-oxalato (trans-l-1,2-cyclohexanediamine) Pt(II) having a general formula of Formula (1).

[SEE FIGURE IN ORIGINAL]

Claim 2, the only other claim at issue on appeal, depends from claim 1 and adds a melting point limitation. The district court

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construed the term "optically pure oxaliplatin" as "optically pure oxaliplatin that has been resolved by means of the HPLC method described in the '874 patent specification." 1 Claim Construction Opinion at 16.

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1 Mayne views this construction as an interpretation of the level of purity required by term "optically pure." Tr. of Oral Argument at 23:51-23:59, Sanofi-Aventis U.S. LLC v. Sandoz, Inc., No. 2009-1427, 2009 U.S. App. LEXIS 20294 (Fed. Cir. Sept. 2, 2009), available at http://oralarguments.cafc.uscourts.gov/. However, the district court stated that it did not determine the level of purity required by the term "optically pure." See Claim Construction Opinion at 3 n.6. On remand, the district court may, if necessary, determine the level of purity required by the term "optically pure," by looking to "'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean,'" including "'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" Phillips, 415 F.3d at 1314 (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

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On appeal, Sanofi argues that the district court erred when it construed claim 1 as limited to optically pure oxaliplatin purified by the HPLC process. Sanofi argues that this claim is a composition claim and does not contain a process limitation. Defendants argue that in light of the specification and prosecution history, the district court properly limited claim 1 to optically pure oxaliplatin purified by the HPLC process.

As the district court noted, "[t]here is no dispute that nothing on the face of the claims of the '874 patent limits the claims to 'optically pure' oxaliplatin that is produced through the use of HPLC." Claim Construction Opinion at 16. Claim 1 is a straight forward composition claim. The district court held that the claims were nonetheless limited to oxaliplatin purified by the HPLC method in view of the specification and prosecution history. We do not agree.

We have repeatedly warned of "the danger of reading limitations from the specification into the claim." See, e.g., Phillips, 415 F.3d at 1323. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." Home Diagnostics, Inc. v. Lifescan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004). To narrow the plain language of a claim, a disclaimer must be clear and unmistakable. Cordis Corp. v. Boston Sci. Corp., 561 F.3d 1319, 1329 (Fed. Cir. 2009). We see no such disclaimer in the specification or prosecution history of the '874 patent.

The defendants point to examples in the specification that compare the purity of oxaliplatin produced using the process discussed in a prior art reference, the Kidani process, with the purity of oxaliplatin after the HPLC process. In the "Comparative Example," the results indicate that following the Kidani process yields oxaliplatin having an optical purity of 90%. Id. col.7 ll.25-50, col.8 ll.13-15. Table 1 compares the purity of the samples obtained in all of the examples before and after resolution by HPLC. '874 patent col.8 ll.3-15. The results indicate that using HPLC optical purity was obtained. Id. col.8 ll.3-15. Thus, the examples illustrate how to obtain optically pure oxaliplatin. They do not clearly and unmistakably disclaim any process, and they do not justify reading a process limitation into a composition claim.

The district court relied on Andersen Corp. v. Fiber Composites, L.L.C., 474 F.3d 1361 (Fed. Cir. 2007), when construing claim 1 as a product-by-process claim. In Andersen, this court held that claims to composite structures included a pelletizing process limitation where the patentee relied on that process both to define the invention and to distinguish the prior art. Andersen, 474 F.3d at 1372-74. We determined that the specification attributed the claimed physical properties to the process and that the specification indicated that the pelletizing step was a requirement, not a preference, of the invention. Id. at 1372. We further determined that the patentee had clearly disavowed other processes during prosecution. Id. at 1373-74; see also Chimie, 402 F.3d at 1385 (holding that "atomized precipitated silica particulates" was limited to a those silica particulates formed by the patentee's process because of an unequivocal disclaimer of other processes to overcome prior art).

By contrast, here, the patent specification and prosecution history focus on the property of the composition (optical purity) and not the process used to obtain that property. The specification defines the invention as oxaliplatin of optically high

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purity, not oxaliplatin prepared by the disclosed HPLC process. '874 patent col.2 ll.3-5 ("The present invention is cis-oxalato (trans-l-1,2-cyclohexanediamine) Pt(II) of optically high purity having general formula of Formula (1)."). The specification never asserts that HPLC is required to obtain optically pure oxaliplatin. It characterizes HPLC as an "illustrative method" and a "representative process" by which the claimed compound "may be prepared." Id. col.2 l.16, col.2 l.52, col.3 l.65. Moreover, the specification does not define the property (optical purity) by reference to the process of purification by HPLC. Thus nothing in the specification limits the invention to optically pure oxaliplatin purified using HPLC.

The prosecution history also illustrates that it is the optical purity of oxaliplatin that distinguished it from the prior art, not the process used to obtain that purity. The Examiner rejected the initially filed claims to oxaliplatin "of optically high purity" as anticipated or rendered obvious by Kidani. 2 The Examiner stated that Kidani disclosed "a single isomer [oxaliplatin] useful as an antitumor agent. Note that since the single isomer complex was prepared, the optical purity of such material is very high or almost pure isomer." In response, the applicant (Tanaka Kikinzoku Kogyo K.K., referred to herein as Sanofi) explained that it had repeated Kidani's process "using identical reactant materials and the subsequent testing thereof. . . . The resultant material was tested and found to be 90% [oxaliplatin] not optically pure . . . ." Sanofi explained that "[o]nly after HPLC resolution (in accordance with the teachings of the present application) was optical purity obtained." Sanofi further asserted that the products prepared using Kidani's method "do not have the presently claimed optical purity." Therefore, Sanofi argued that the claimed oxaliplatin "having high optical purity[] is not found or taught in the prior art either by inherency or by being obvious thereover." Following a telephone interview, Sanofi agreed to amend the claims to "optically pure" oxaliplatin, rather than oxaliplatin "of high optical purity." The Examiner entered the amendment and allowed the claims, stating that "[t]he Examiner agrees with applicants that Kidani et al. does not teach[] the cis-oxalato(trans-l-1,2-cyclohexanediamine)Pt(II) as an optically pure isomer. It is clear from Kidani et al. that also other isomers can be in the final product." Thus, Sanofi argued that the defining feature of the claimed oxaliplatin was its optical purity, not the HPLC process. Nothing in the prosecution history amounts to a clear and unmistakable disclaimer of optically pure oxaliplatin prepared using other (non-HPLC) processes.

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2 The Examiner's rejection was based on an article (Kidani et al., J. Med. Chem. 21(12) 1315-18 (1978)), which does not substantively differ from the Kidani patent.

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We conclude that the district court erred in its construction of claim 1. Claim 1 of the '874 patent is not limited to optically pure oxaliplatin produced by HPLC; this is a composition claim, not a product-by-process claim.
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2. "Orange oil / forty-five percent (45%) or less by volume of orange oil": At least 5% by volume of the non-water soluble liquid derived from an orange.

Plaintiff argues that this claim limitation should be construed broadly, without a minimum percentage of orange oil required. The court acknowledges in this regard that independent claim 1 includes the 5% by volume limitation, and the 5% by volume limitation is described in the patent as a preferred embodiment. The problem with plaintiff's construction, however, is that there is no indication in the intrinsic record that anything less than 5% by volume of orange oil effectively cleans anything, let alone the industrial type substances discussed in the patent.

Plaintiff argues that there is extrinsic evidence that as little as 0.01% by volume of orange oil is considered an effective cleaning compound; the evidence indicates otherwise. More specifically, United States Patent No. 5,013,485 ("the '485 patent"), captioned "Liquid Detergent Composition Containing Terpene and Calcium or Magnesium Salts," describes a liquid detergent composition "which comprises an anionic surface agent, a terpene-type hydrocarbon selected from monoterpenes and sesquiterpenes, and a water-soluble divalent metal salt" which does "not require dilution prior to use, nor an after-rinse," has "a high degree of safety," and "easily remove[s] soiling." ('485 patent, col. 1, ll. 62-68) The composition has as essential components: "(A) 0.01-1.0% by weight of an anionic surface active agent, (B) 0.01-1.0% by weight of a

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terpene-type hydrocarbon solvent selected from monoterpenes and sesquiterpenes, and (C) 0.001-0.1% by weight of a water-soluble divalent metallic salt." ('485 patent, Abstract) D-limonene, contained in orange oil, was given as an example of component (B). ('485 patent, col. 2, ll.57-59; col. 3, ll. 2-4) Detergent compositions were prepared and tested according to three parameters: detergency, wiping traces and solvent odor. The results of these tests demonstrate that, of the 15 compositions tested, only six contained either D-limonene or orange oil, with none of the examples containing less than 0.3% by weight of D-limonene or orange oil. It is clear from a careful reading of the patent that the invention disclosed therein is directed to the combination of three compounds that exhibit, when combined, cleaning and other properties. The '485 patent does not demonstrate that orange oil, on its own (particularly at quantities as small as 0.01% to 1.0% by volume), is an effective cleaning composition.
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2. Order of process steps in plaintiff's claims

The parties dispute whether claims 1-6, 8, 11, 16, 34, 36-40, 42 and 45-48 of the '637 patent and claims 1 and 3 of the '817 patent cover only the exact sequential order of the process steps set forth therein. Defendant asserts that plaintiff's claims must be read to encompass only reactions that follow the specific order laid out in the patent claims. Plaintiff says that defendant's position is too narrow a reading of plaintiff's claims.

In support of its position, defendant cites Loral Fairchild Corp. v. Victor Co. of Japan, Ltd., 906 F. Supp. 798 (E.D. N.Y. 1995) and Thorn EMI N. Am., Inc. v. Intel Corp., 928 F. Supp. 449 (D. Del. 1996). According to defendant, Loral and Thorn stand for the proposition that process claims should be limited to the chronological sequence of the steps that make up the claims. In Loral, the court explained:

Predominant language norms suggest recounting process steps in a chronological sequence. A process description flows most naturally from one step in the sequence to the next in chronological order. The process step described third in sequence thus generally precedes the step described fourth.

906 F. Supp. at 805. The court cited this language with approval in Thorn, 928 F. Supp. at 457. However, neither of the courts adopted a position as broad as defendant suggests. Although in Loral the court relied on "predominant language norms" to a certain extent, it found other evidence in the patent itself that the patentee intended to specify an exact procedural sequence. Loral, 906 F. Supp. at 805. For example, the court determined that because the "edges of [the] implanted barrier regions" could not be "aligned" with the "vertical edges of the insulation layer" (as required by the patent claim at issue) until the insulation layer was in place, the claim was limited to a process in which the insulation layer always preceded the implanted barrier regions. Id. Moreover, language in the specification and in the prosecution history of the patent supported a chronological sequence interpretation of the claim. Id. (specification discussed "next" step; prosecution history included dependent claim that mentioned "prior" step). The patent claims at issue in Thorn, 928 F. Supp. 449, were even plainer in specifying an exact sequential order. The steps of the claims were separately ordered (step (a), step (b), etc.) and two of the claims stated step (a) "then" step (b). Id. at 457.

There is scant indication in plaintiff's claims themselves that plaintiff intended the patent to cover only the exact sequential addition of ingredients. If plaintiff had sought to limit its claims to a specific sequence, it could have added language such as "then" or "and thereafter" to the steps of the claim. See Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp., 739 F.2d 604, 614 (Fed. Cir. 1984). Without such an indication in the language of the claims themselves, I cannot find that plaintiff intended to limit the scope of its claims in the manner defendant suggests. See Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 880 (Fed. Cir. 1991) (exact order of steps "not specifically set forth" in claim).
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"ORFs 1-13"

Thedistrict court's claim construction of ORFs 1-13 defines the claim scope as consisting of the DNA sequence of the

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thirteen ORFs enumerated in Example 13 of the patent specification as those ORFs apply to SEQ ID 4. Merial argues that the term should instead read on any translatable length of DNA between a start and stop codon in the PCV-2 gene sequence. Although the district court is correct that the disclosed ORFs define the claim term, the court erred in confining the scope of the term to the precise limits of the representative ORFs listed in Example 13, and the exact DNA sequence of SEQ ID 4.

The ORFs listed in Example 13 are identified as corresponding to one representative PCV-2 sequence, designated in the patent as SEQ ID 4. Although the patent explains that the listed ORFs are identical for some of the deposited strains of PCV-2, it also identifies some variation. The specification explains that the ORFs listed in the table are representative, and one of skill in the art would understand that slight natural variation is to be expected. Indeed, limiting the construction of the term to the exact ORF sequences of SEQ ID 4 would even exclude from the claimed ORFs two of the foursequenced strains of PCV-2, the ORF variations for which sequences are expressly disclosed following the table in Example 13. Thus, we hold that the district court's construction is improperly narrow in scope.

We reject the dissent's position that the specification limits "ORFs 1-13" to the ORFs of the four sequenced strains. The discussion in Example 13, which explains that the limits of ORFs 1 to 13 are "identical" for certain sequenced strains (and not for others), strongly implies that the term "ORFs 1-13" does not refer to a specifically defined list of limits, but instead contemplates the potential for variation in any given strain of PCV-2. Furthermore, the specification describes the analysis set forth in Example 13 as "representative of the other circovirus strains associated with the multi-systemic wasting syndrome." We have already construed that set of circovirus strains to be broader than just the four sequenced strains, so it would be incongruous to selectively impose the narrower construction here, as the dissent suggests.

We note that because isolates of the same viral type will have essentially the same proteins, they will have the same number of ORFs. The ORFs willbe approximately the same size and located in the same relative regions of the genome. By identifying the thirteen ORFs of representative sequence SEQ ID 4, the specification purports to disclose to one of skill in the art the expected ORFs of all PCV-2 isolates. Thus a broader claim construction that allows for some variation in the precise limits of the ORFs and of the underlying DNA sequence is consistent with the expectations of a skilled artisan reading the patent disclosure.

Thus the term ORFs 1-13 is properly construed as "lengths of translatable DNA between pairs of start and stop codons, corresponding to the 13 ORFs identified in the patent specification." ORFs of some PCV-2 strains may not have limits 100% identical to the thirteen illustrated in the patent, but one of skill in the art would readily recognize those ORFs as corresponding to ORFs identified in the patent. Indeed, ORFs 1-13 could correspond to ORFs in other circoviruses, or even other specie s, as indicated by the examiner's initial rejection of the claim. It is the "of porcine circovirus type II" limitation, rather than Example 13, that confines the claim scope to ORFs of PCV-2.
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Finally, I disagree with the majority with respect to its construction of "ORFs 1-13" in claim 9. 3 Merial argues, and the majority appears to accept, the proposition that one of ordinary skill in the art would read the phrase "ORFs 1-13" to readon any translatable length of DNA between a start and stop codon in the PCV-2 sequence that could encode for a protein greater than twenty amino acids in size. In contrast, the district court concluded that the plain language of the claims indicated that ORFs 1-13 were limited to the ORFs in the disclosed isolates. 4

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3 An Open Reading Frame ("ORF") is a region or length of DNA that contains a sequence of nucleotides that contains the instructions for making proteins. All ORFs begin and end with a set of three nucleotides known respectively as a start and stop codon.

4 It is unclear whether the district court's claim construction limited "ORFs 1-13" to the relevant ORFs in Imp. 1010, or whether the phrase also encompasses ORFs 1-13 of the other isolates disclosed in the patent, namely, Imp. 1011-48121, Imp. 1011-48284, and Imp. 999. The court's infringement determination is also unclear. See Intervet, Inc. v. Merial Ltd., 643 F. Supp. 2d 97, 103 (D.D.C. 2009) ("Example 13, however, also states that the positions of the start and end of each ORF refer to the sequence presented in figure 4. Figure 4 contains the precise DNA sequence of one of the five listed strains and

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thus Example 13,while it does not include the specific DNA sequence of each ORF, refers to a figure from which those specific DNA sequences can be determined. Given this, the Court declines to read the language 'specific DNA sequence' out of its claim construction, and therefore concludes that Intervet's vaccine does not contain one of ORFs 1-13.").

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I agree with the district court that the phrase must be limited to the specific DNA sequences defined as ORFs 1-13 in the '601 patent based on the intrinsic evidence. The majority holds that the district court's construction is improperly narrow in scope because "limiting the construction of the term to the exact ORF sequences of SEQ ID 4 would even exclude from the claimed ORFs two of the four sequenced strains of PCV-2." Majority Op. at 10. I disagree. The specification appears to specifically define "ORFs 1-13" to include the ORFs from all four of the sequenced strains, not just Imp. 1010, 5 represented by SEQ ID 4. The specification provides:

It was possible to detect 13 open reading frames (or ORFs) of a size greater than 20 amino acids on this sequence (circular genome). These 13 ORFs are the following:

'601 patent col.13 ll.33-34 (emphasis added).The specification then proceeds to detail the ORF sizes and stop and start codons for the Imp. 1010 isolate in table form, and describes the stop and start codons for the other three isolates by reference to Imp. 1010:

The positions of the start and end of each ORF refer to the sequence presented in FIG. No. 4 (SEQ ID No. 4), of the genome of strain 1010. The limits of ORFs 1 to 13 are identical for strain 999. They are also identical for strains 1011-48121 and 1011-48285, except for the ORFs 3 and 13:

ORF3 1432-1549, sense, 108 nt, 35aa

ORF1,3 314-1377, antisense, 705 nt, 234 aa.

Id.col.13 ll.53-61. Thus, "ORFs 1-13" is properly read to include the relevant ORFs on all of the disclosed isolates, because a description of those ORFs follows the assertion that "[t]hese 13 ORFs are the following." Id.col.13 ll.33-34. Because the patentee acted as his "own lexicographer and clearly set forth a definition of the disputed claim term," Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322, 1329 (Fed. Cir. 2009), the definition in the specification controls, see Phillips, 415 F.3d at 1321. In my view, claim 9 is not literally infringed, and I would also hold that it is not infringed under the doctrineof equivalents.

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5 The "Imp." designation, an abbreviation for "imported," is a tracking number assigned by the inventors to their pig tissue samples and to any virus they isolated from that tissue.

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2. "Organic Material"

Both Claim 1 and Claim 67 also use the phrase "organic material." HISI requests that "organic material" be interpreted to mean "carbon containing materials (including wood, wood sawdust, and charcoal)." (HISI Brief 18). TPI, on the other hand, argues that "organic" should be limited to things that are "of, relating to, or derived from living organisms," such as wood, wood sawdust, leaves, bagasse from sugar cane, pineapple husks, and rice hulls. 2 (TPI Brief 14-15.)

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2 TPI also requests that "organic" be limited to materials which can burn at temperatures of 510 [degrees] C or less. TPI argues that charcoal should be excluded because it burns above 510 [degrees] centrigade. TPI's temperature arguments,

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however, have already been addressed above.

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Both the broad definition of "organic" proposed by HISI and the narrower definition of "organic' advanced by TPI appear equally valid and equally plausible. The claims themselves provide no insight into the intended meaning of "organic." The specifications, however, do describe the types of burning material utilized in this process, albeit without explicitly defining the term "organic." The patent states that "[t]ypical wood fuels for smoking contain primarily a hydrocarbon composition of hydrogen and carbon along with other elements . . . ." (Kowalski Patent, Col. 7, at 4-5 (emphasis added).) This language, focusing on the chemical component of smoking materials, and in particular, the presence of carbon, as opposed to focusing on the materials' relation to living organisms, indicates that Kowalski did not intend to limit his patent to the narrower definition of "organic." The Court therefore finds that "organic material," as used in the Kowalski Patent, means carbon containing materials, including wood, wood sawdust, and charcoal.
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(i) "Organic Solvent"

Turning first to "organic solvent," the intrinsic record indicates, andthe parties agree (GSK Opening 13-14; Apotex Resp. 2), that "organic" means "carbon-based" and that the "solvent" referenced in the '759 Patent is "substantially free of water." As to "organic," Claim 11 lists several organic solvents that may be used to crystallize Form A, all of which are carbon-based, as does the specification. 3 Moreover, "organic" is defined in Merriam-Webster's Collegiate Dictionary as being "of, relating to, or containing carbon compounds," Merriam-Webster's Collegiate Dictionary 819 (10th ed. 1995). As for "solvent," the specification provides that "[t]he organic solvents should be substantially free of water," '759 Patent, col. 5, l. 58, and that the only water that the invention can contain is "unbound water that is to say water which is other than the water of crystallization," id. col. 2, ll. 38-39. A declaration submitted by Dr. George Wellman during the prosecution of the parent patent application (08/733.874) differentiated the invention from prior art that "inevitably resulted in the production of hemi-hydrate," and therefore, failed to be substantially free of water. (GSK's Opening, Ex. 12, at GSK00757301.) 4

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3 In particular, Claim 11 lists "propan-2-ol,propan-1-ol, ethanol, acetic acid, pyridine, acetonitrile, acetone, tetrahydrofuran, [and] chloroform," '759 Patent, col. 18, ll. 27-30, and the specification provides "alcohols especially alkanols such as propan-2-ol, ethanol and propan-1-ol; organic acids such as acetic acid; organic bases such as pyridine; nitrites such as acetonitrile; ketones such as acetone; ethers such as tetrahydrofuran and chlorinated hydrocarbons such as chloroform," id. col. 5, ll. 10-14, as examples of organic solvents for purposes of the '759 Patent.

4 In its supplemental brief, Apotex contends that "the construction limits . . . carbon-based solvents to organic solvents substantially free of water," and therefore proposes that the construction of the term "crystallizing a paroxetine hydrochloride in an organic solvent or mixture of organic solvents" to be "crystallizing paroxetine hydrochloride in one or more organic carbon-based solvents that are substantially free of water." (Apotex Supp. Br. 2.) The Court declines to add the word "organic" in its construction of "organic solvent," because doing so would be redundant, and the word "organic" seems to mean "carbon-based."

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The Court turns next to Apotex'sargument that "organic solvent" should be construed to specifically list as examples IPA and acetone. In Phillips, the Federal Circuit explained that "although the specification often describes very specific embodiments of the invention, [the court] ha[s] repeatedly warned against confining the claims to those embodiments." 415 F.3d at 1323. Here, Apotex does not seek to restrict "organic solvent" to only IPA and acetone, and therefore, is not proposing a construction that runs afoul of Phillips' teaching respecting reading limitations into the patent. Nonetheless, the inclusion of those two solvents in the construction of "organic solvent" is unwarranted because doing so would interfere with the factfinder's right to decide the factual question of which particular solvents in the accused product and prior art fall within the claim limitations. The Federal Circuit has clarified that "a court, under the rubric of claim construction, may [not]

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give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998), nor is it appropriate at theMarkman stage to determine how the claim terms apply to the "accused device to determine infringement," SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed. Cir. 1985). The Court, therefore, will construe "organic solvent" to be "carbon-based solvent that is substantially free of water."
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(ii) "Organic Solvent Not Removable by Drying"

As a preliminary matter, the Court will not construe "organic solvent not removable by drying" to be the same as "organic solvent." Apotex urges the Court to do so under the rationale that the terms are "used interchangeably in claim 10." (Apotex Supp. Br. 2.) The Court disagrees, because the Claim first uses the word "organic solvent" to identify where the crystallization process occurs, '759 Patent, col. 18, ll. 8-11, and then goes on to explain that the process prepares "a paroxetine hydrochloride having organic solvent not removable by drying," id. col. 18, ll. 11-12, thereby using the terms in different ways.

As for the proper construction of "organic solvent not removable by drying," the specification states that "[s]ubstantially free of bound organic solvent is to be interpreted to be less than the amount . . . which would remain . . . bound. . . under conventional vacuum oven drying conditions." '759 Patent, col. 1, ll. 62-63. The specification then provides that the product is "dried by conventional methods such as drying in vacuo" before the displacing agent is applied to remove further solvent. Id. col. 5, ll. 15-22. As a result, the specification, which is the "single best guide to the meaning of a disputed term,'" Phillips, 415 F.3d at 1315, indicates that the inventors intended for "drying" to refer to "conventional" vacuum oven drying conditions, thereby supporting GSK's proposed construction. The prosecution supports this definition by providing that the inventors "managed to prepare paroxetine hydrochloride anhydrate . . . which was so tightly bound that [organic solvent] could not be removed by conventional drying conditions." (GSK Opening Ex. 12 at GSK 00757301.)

In addition, the Court does not take into account Apotex's contention that two percent is the dividing line between the solvate and anhydrate (Apotex Opening 19-20), because neither the specification nor the claim language refer to the two percent cutoff. In addition, Apotex did not include this two percent cutoff in its proposed definition, or otherwiseexplain how this affects the construction of the disputed claim term, such as by showing that the process covered by the '759 Patent does not require the removal of more organic solvent than can be removed by conventional drying alone. Thus, the Court will not include any reference to the two percent. The Court will construe "organic solvent not removable by drying" as "having organic solvent that cannot be removed by conventional drying conditions."
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1. Organic Synthesis

Genentech argues that the term "organic synthesis" as used in the '832 patent means "providing by chemical DNA synthesis, rather than by the use of the enzyme reverse transcriptase, which creates cDNA," and includes not only DNA which is directly made by chemical synthesis but also "replications (or copies) of that synthetic DNA." BM does not dispute this definition but contends that it does not adumbrate cloning methods known as site-directed mutagenesis ("SDM") and polymerase chain reaction ("PCR") which operate by enzymatic synthesis, as distinct from "organic synthesis."

a. Intrinsic Evidence

Neither the '832 patent nor its specification expressly defines what is meant by the term "organic synthesis" as used in the claim. The Court, therefore, looks to the extrinsic evidence for clarification.

b. Extrinsic Evidence

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All the experts agree that in 1979, the term "organically synthesized" as used in the '832 patent refers to an oligonucleotide or a fragment of a gene that is "synthesized using organic chemistry," meaning that it is made by a machine or human, outside of an organism, without the use of enzymes. (Tr. 3-13 - 3-14; Tr. 2-37 - 2-38, Ex. I.) Also, Drs. Ravetch and Cepko agreed that one skilled in the art at the time of the invention would understand that a replicated synthetic fragment of DNA is still considered a fragment that is organically synthesized. (Tr. 1-60 - 1-68 and 3-17 - 3-21.) Dr. Webb did not disagree with the testimony on this point.

c. Claim Construction

The term "organically synthesized" in the '832 is construed to mean the production of a oligonucleotide or fragment of a gene using organic chemistry without the use of an enzyme. It includes DNA made by replication of synthetic DNA.
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C. Claim Construction

The district court construed the phrase "osmolality . . . of between about 400-500 mOsmol" in the corrected claims to allow for an osmolality between 385-515 mOsmol/kg. Since that construction interprets language that is not validly part of the claims, it cannot stand exactly as issued. However, the correct construction of the originally issued claims is basically the same, except for the substitution of units: "osmolarity . . . of between about 400-500 mOsmol" encompasses osmolarities as low as 385 mOsmol/L. Rather than basing this broadening of the enumerated range on the alleged interchangeability of the terms "osmolarity" and "osmolality," as the district court did, we base it on the presence of the word "about" in the claim.

The use of the word "about[]" avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter.

Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007) (ellipses omitted) (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)). Here, the intrinsic evidence indicates that the overall osmolarity of the solution is crucial to its effectiveness, and that osmolarities over 400 mOsmol/L are most consistently effective. See '515 patent Figs. 2-3. However, that evidence also shows that osmolarities below 400 mOsmol/L are effective. The patent's Figure 2 details the result of an experiment measuring the effect of solution osmolarity on systolic shortening, an indicator of the health of cardiac tissue. The figure makes clear that as osmolarity increases from about 360 mOsmol/L to about 480 mOsmol/L, systolic shortening improves. It includes a trend line that extrapolates a linear relationship between osmolarity and shortening; that line crosses the figure's x-axis near to 385 mOsmol/L, indicating that the break-even point for effectiveness is found close to that concentration. Since the intrinsic evidence indicates that the solution begins to be effective near a concentration of 385 mOsmol/L, the word "about" extends the range of the claim downward to that point.
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A. Alcon's Motion for Summary Judgment of Non-Infringement

Alcon first argues that its brimonidine product does not infringe the '337 patent. A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A patent infringement analysis entails two steps: "(1) claim construction to determine the scope of the claims, followed by (2) determination of whether the properly construed claim encompasses the accused device." Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998) (citations omitted). The first step, claim construction, is a matter of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). The second step, the determination of infringement, is a question of fact. Bai, 160 F.3d at 1353. "Literal

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infringement of a claim occurs when every limitation recited in a claim appears in the accused device, i.e., when 'the properly construed claim reads on the accused device exactly.'" KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1358 (Fed. Cir. 2000) (citation omitted). Thus, summary judgment on the grounds of literal infringement is proper when no reasonable jury could conclude that every limitation recited in the properly construed claim is present in the accused device. See Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 974 (Fed. Cir. 1999).

Alcon contends that Allergan cannot establish infringement of the '337 patent because povidone, the "viscosity agent" in its proposed product, is not an SEC as that term is used in the '337 patent. According to Alcon, Allergan expressly disclaimed povidone, as well as all other non-ionic SEC's, during prosecution of the parent application from which the '337 patent derived. (D.I. 55, at 14.) Alcon further contends that Allergan's "unambiguous statements and the representations of one of the named inventors characterizing the invention during prosecution of the Parent Application from which the '337 patent is derived" support limiting the claim scope to anionic SECs. (Id. at 15.) Lastly, Alcon contends that the non-infringement ground for its summary judgment motion "can be resolved by the court's claim construction determination." (Id. at 14.)

The court agrees that Alcon's non-infringement ground for summary judgment is resolved by the court's claim construction. However, Alcon's argument fails because, in making it, Alcon presumed that the court would construe the term "solubility enhancing component other than an cyclodextrin" to exclude non-ionic SECs when, in fact it did not. In its July 26, 2005 Order (D.I. 109), the court construed the term "solubility enhancing component other than an cyclodextrin" to mean "a component that enhances the solubility of the alpha-2 adrenergic agonist component other than a cyclodextrin." (D.I. 109 P 1.) In doing so, the court rejected Alcon's proposed construction of an SEC as being limited to anionic SECs. Accordingly, summary judgment of non-infringement is not appropriate.
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1. "otopathy"

The parties disagree as to the proper interpretation of "otopathy," a term used in Claims 1, 2, and 3 of the patent. Daiichi argues that it should be construed to mean "otitis externa and/or otitis media." By contrast, Apotex argues that it should be construed as "any disease of the ear." The Court does not find either argument persuasive.

The doctrine of claim differentiation requires each claim to have a different scope. As the Court of Appeals for the Federal Circuit explains:

There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.

Comark Comms., Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998).

Daiichi's proposed construction plainly violates the principle of claim differentiation. Claims 1, with Daiichi's proposed language italicized, reads as follows:

Claim 1
A method for treating otitis externa and/or otitis media which comprises the topical otic administration of an amount of ofloxacin or a salt thereof effective to treat otitis externa and/or otitis media in a pharmaceutically acceptable carrier to the area affected with otitis externa and/or otitis media.

Such a construction would clearly render Claims 2 and 3 redundant:

Claim 2
The method of claim 1 wherein the said otopathy is otitis media.

Claim 3
The method of claim 2 wherein the said otopathy is otitis externa.

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The Court declines Daiichi's invitation to cast aside well-settled principles of claim construction analysis in construing the disputed term.

Rather, the proper course is to adhere to the rule that "the presence of a dependent claim that adds a particular limitation raises the presumption that the limitation in question is not found in the independent claim." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004); see also Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302-03 (Fed. Cir. 2003). Accordingly, the fact that Claim 2 is limited to otitis media and Claim 3 to otitis media and otitis externa persuades this Court that Claim 1 is not limited to otitis media and/or otitis externa.

The Court notes that, at the Markman proceeding, Daiichi raised one argument, not previously presented in its briefs, concerning the issue of claim differentiation. The argument is that all of the claims are in fact different under its proposed interpretation because: (1) Claim 2 relates to otitis media; (2) Claim 3 relates to otitis externa; and (3) Claim 1 refers to otitis media and otitis externa. Daiichi's argument simply does not work.

It is well-established that "claims in dependent form shall be construed to include all limitations of the claim incorporated by reference into the dependant claim." See 37 C.F.R. §1.75(c). Therefore, Claim 3 must be read to include all of the limitations, contained in Claim 2, which would mean that the "otopathy" referred to in Claim 3 is both otitis externa and otitis media, rendering Daiichi's proposed interpretation of Claim 1 redundant.

Daiichi's proposed construction is not only contradicted by the language of the claims themselves, it is also inconsistent with the patent specification as whole. Several sections of the specification explicitly state that otitis externa and otitis media are among the types of otopathy, not the only types of otopathy, to which the '741 patent is directed. For example, the specification states:

The otopathy on which the preparation of the present invention is effective includes inflammatory otopathy, such as otitis media and otitis externa . . .

(Krol Decl., Exh. A (emphasis added).) Another section of the specification states:
The preparation according to the present invention exhibits marked improvements over the conventional drugs in terms of not only ototoxicity but also tissue distribution and excellent therapeutic effects on otopathy, particularly otitis media and otitis externa.

(Id. (emphasis added).) n8 In light of the claim language and the specification, the Court fails to see a principled basis for adopting Daiichi's proposed construction.

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n8 Daiichi points out that otitis media and otitis externa are the only forms of bacterial ear infections known to be susceptible to topical administration of ofloxacin. In the Court's view, that fact does not foreclose the possibility that the term "otopathy," as used in the '741 patent, was intended to encompass more than just otitis media and otitis externa. As one treatise on patent drafting explains, "it is the claim drafters job to have written the claims in the application to not only cover what they attorney and the inventor/client could at the time of the application prosecution have envisioned as competing products, but to cover competitive products which neither the inventor nor the attorney thought of or could even have imagined at the time . . ." Faber, supra note 2, at § 10:1-1.

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Unfortunately, Apotex' proposed construction is no more persuasive. Apotex argues that the "plain and ordinary meaning" of the term "otopathy," and the one which the Court should adopt, is "any disease of the ear." In support of its argument, Apotex points out that during the patent prosecution process, Daiichi submitted to the PTO an excerpt from Dorland's Medical Dictionary, 26th edition, which defines "otopathy" as "any disease of the ear." (Krol Decl., Exh. I.) Apotex' argument is unconvincing for two reasons.

First, Daiichi represents to the Court that it submitted Dorland's Medical Dictionary definition of "otopathy" to the PTO

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only because Daiichi was required to do so pursuant to Patent Office Rule 56, 35 C.F.R. § 1.56. Specifically, the Dorland's Medical Dictionary definition had been submitted during the prosecution of the foreign counterpart to the '741 patent and, therefore, was required to be disclosed to the PTO pursuant to Daiichi's duty of good faith and candor. (Daiichi Brief in Response to Apotex' Brief on Claim Construction ("Daiichi Reply"), at 5.) In fact, the record shows that the Patent Examiner crossed the definition off of Daiichi's Form PTO-1449, indicating, as the Form PTO-1449 itself instructs, that the Patent Examiner did not rely on Dorland's Medical Dictionary in its consideration of the '741 patent application. Apotex offers nothing to rebut these facts.

The second, and perhaps more important, reason why the Court rejects Apotex' proposed construction is the recent and much-anticipated Phillips decision, in which the Court of Appeals for the Federal Circuit, sitting en banc, issued a strongly worded caution against the blind use of dictionary definitions in claim construction analysis. As stated in Phillips:

The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent . . . heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is its specification.

Phillips, 2005 U.S. App. LEXIS 13954, [WL] at *14 (emphasis added). The Court of Appeals further elaborated, "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." Id. This Court finds the Court of Appeals' warning in Phillips especially pertinent here.

Neither the Court, nor Daiichi, dispute that the term "otopathy" may be literally translated into "a disorder of the ear." That does not, however, mean that this is how the term should be construed in the context of the '741 patent. Rather, viewing the disputed term from the perspective of the ordinary person skilled in the art, as this Court is required to do, precludes such an interpretation.

A pediatrician or general practitioner, let alone an otolaryngologist, would know that ofloxacin is an anti-bacterial agent whose only therapeutic purpose is to kill or eradicate bacteria. The pediatrician or general practitioner would therefore assume that the otopathy to which the '741 patent is directed must be amenable to antibiotic treatment--that is, infections caused by the presence of bacteria. n9 Accordingly, the Court concludes that the most sensible construction of the term otopathy, as used in the '741 patent, is "bacterial ear infection."

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n9 The only other drugs mentioned in the patent specification are also antibiotics, including fradiomycin, kanamycin, chloramphenicol, and cefmenoxime." (Krol Decl., Exh. A.)

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After holding a Markman hearing on July 22, 2005, the Court held that a person ordinarily skilled in the art would have a medical degree, experience treating patients with ear infections, and knowledge of the pharmacology and use of antibiotics. Daiichi Pharm. Co., 380 F. Supp. 2d at 485. Additionally, that person would be a pediatrician or general practitioner-those doctors who are often the first line of defense in treating ear infections. Id. Furthermore, the Court construed the term "otopathy" to mean "bacterial ear infection," the words "effective to treat" to be interpreted as "safe and efficacious," and the phrase "intratympanically injected through a puncture of the tympanic membrane" to mean "introduced into the middle ear with an instrument such as a syringe." Id. at 485-89.

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3. Over a Period of Time

The term "over a period of time" appears in Claim 6. The claim states, in part, "the step of collecting a plurality of said samples over a period of time." (Col. 18, lines 21-22). Metametrix argues that "over a period of time" is "over a period of at least seven days, separated by non-insignificant time intervals." Plaintiffs contend that over a period of time means "separately and not during the same occurrence."

The claim language does not define "over a period of time," though the specification includes reference to the term. For example, in the summary of the invention, the inventor states that "the urine samples should be collected over a period of time, e.g., on a daily basis over a period of at least seven days." (Col. 2, lines 49-51). The notation "e.g." indicates that as an example the inventor suggests on a daily basis over a period of at least seven days. The example should be considered only one possible approach rather than an attempt to limit the claim. Thus, any definition should not include a specific timetable of days.

Besides the specification of a minimum period of time, the court does not see a significant difference between the parties' proposed definitions. Both definitions note that the time is separated, with Metametrix emphasizing that the intervals are "non-insignificant" and plaintiffs emphasizing the intervals are "not during the same occurrence." The meanings are slightly different, the significance of which the court cannot fully appreciate at this stage of the litigation. Both definitions, however, do not contradict the claim language and specification and may co-exist. Thus, the court incorporates elements of both definitions and defines "over a period of time" as "separated by non-insignificant time intervals and not during the same occurrence." The court does not find it appropriate to include a specific time limitation. There is no evidence that the inventor intended this time limitation to occur in every instance and in every claim step.
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B. CLAIM CONSTRUCTION

This Court's analysis involves a two step process: 1) construction of the patent claim (a question of law); and 2) a determination whether the accused product or process contains every element of the properly construed patent claim at issue (question of fact). General Mills Inc. v. Hunt-Wesson Inc., 103 F.3d 978, 981 (Fed. Cir. 1997).

While Durel bears the burden of proving infringement, OSI bears the burden as the moving party that summary judgment for non-infringement is appropriate. Fed. R. Civ. P. 56(c). As in any other case, if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law, summary judgment is appropriate. General Mills Inc., 103 F.3d at 980.

In construing a patent claim limitation, this Court looks to the intrinsic evidence--the patent itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995 (en banc), aff'd 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)). Claim terms are to be given their ordinary and customary meaning, although an inventor may choose to be "his own lexicographer" and give a term a non-standard meaning (if the special definition is clearly stated in the patent specification). 90 F.3d at 1582.

In its patent specification, Durel defined "oxide coating" as follows: As used herein, "oxide coating" means a material made up primarily of metal cations and oxygen, but which may contain minor amounts of other elements or compounds originating in the precursor materials or phosphor particles.

Applying common sense and basic English grammar, Eastman Kodak Co. v. Good year Tire & Rubber Co., 114 F.3d 1547 (Fed. Cir. 1997), Durel's definition of "oxide coating" means a coating that is composed of metal cations and oxygen. Further, elements other than oxygen or metal cations, specifically, other elements or compounds found in the original precursor "ingredients" or phosphor particles may be found in the coating. Without resorting to a dictionary, "primarily or mostly" are words that encompass coatings that are significantly more than 50% metal cations and oxygen. The dispositive question is how one skilled in the art calculates the percentage which identifies the components of the coating.

Whether the atomic mass of each atom or the number of individual atoms present in the coating is the proper method of

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measurement is a question that must be asked of one skilled in the art at issue. See 35 U.S.C. § 103. The parties' experts have conceded both that a synthetic chemist is one skilled in the art covered by the Budd patents, and that a synthetic chemist would interpret the Budd patent by using atomic mass to determine whether a coating is primarily metal cations and oxygen atoms with minor amounts of other elements and compounds found in the precursors. This Court finds that the atomic mass of each element of the OSI coating must be calculated to determine whether OSI's coating contains every element of the claims at issue in the Durel patents.

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A. Claim Construction

Sylvania argues that the district court erred in its construction of the term "oxide coating," urging that the definition in the specification requires that the coating be primarily composed of metal oxides, which are binary compounds, and that the "other elements and compounds" it may contain are only impurities of the coating. Thus, according to Sylvania, the primary metal oxide molecule of the coating may not itself contain other elements such as hydrogen that would make that molecule something that is not classifiable as a metal oxide. Sylvania also argues that the court erred in its conclusion that claim 1 of the '062 patent is not limited to phosphors produced by hydrolysis.

Durel responds that the court correctly adopted the special definition of the term "oxide coating" set forth in the specification, which includes metal cations, oxygen, and minor amounts of another element such as hydrogen. Durel urges that a definition that excludes the presence of hydrogen would exclude a preferred embodiment in the specification because all of the examples of metal oxides in the specification inherently include some hydroxide in their hydrated form. Durel also urges that claim 1 of the '062 patent is not limited to phosphors produced by hydrolysis.

We agree with Sylvania that the district court erred in its construction of the term "oxide coating." We rely primarily on the definition in the specification, which defines "oxide coating" as "a material made up primarily of metal cations and oxygen, but which may contain minor amounts of other elements and compounds originating in the precursor materials or phosphor particles." '062 patent, col. 5, ll. 37-40 (emphasis added). We conclude that this language requires that the "oxide" coating must primarily comprise metal oxide compounds, viz., binary compounds containing only metal cations and oxygen. This definition is supported by the examples that immediately follow in the specification, all of which are binary compounds containing only metal cations and oxygen: TiO[2], TiO[2]/SiO[2], SiO[2], Al[2]O[3], SnO[2], ZrO[2], and 3Al[2]O[3] . 2SiO[2]. According to the specification, the coating may indeed contain "minor amounts of other elements and compounds originating in the precursor materials or phosphor particles," such as water or hydroxides, but it may not be composed primarily of compounds that are not binary metal oxides.

This interpretation is also supported by dictionary definitions of "metal oxide," which we are free to consult to interpret claim terms, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.3, 39 U.S.P.Q.2D (BNA) 1573, 1578 n.3 (Fed. Cir. 1996). Compounds containing additional elements other than metal and oxygen are not generally classified as metal "oxides." See, e.g., McGraw-Hill Dictionary of Scientific and Technical Terms 1425 (5th ed. 1994) (defining "oxide" as a "binary chemical compound in which oxygen is combined with a metal"); Hawley's Condensed Chemical Dictionary 861 (12th ed. 1993) (defining "oxide" as "[a] mineral in which metallic atoms are bonded to oxygen atoms"). The district court's principal error in its claim construction was in using calculations of atomic mass percent to interpret the "primarily" language. In doing so, it failed to give meaning to the established term "metal oxide" and to the specification's consistent use of that term.

We are not persuaded by Durel's argument that this definition excludes a preferred embodiment of metal hydroxides that are (allegedly) inherently present in the disclosed metal oxides. We find no disclosure of metal hydroxides in the specification. Durel cites a reference showing that the term alumina trihydrate (Al[2]O[3]. 3H[2]O) may be used interchangeably with aluminum trihydroxide Al(OH)[3]. 4 Even accepting that this may be true in some circumstances, it is not relevant here. The specification teaches that oxide hydration should be minimized, see, e.g., '062 patent, col. 7, ll. 15-22 (stating that the ratio of tetrachloride molecules to water molecules should be high to promote the formation of optimal anhydrous titania films) (emphasis added), thereby indicating that compounds that are primarily hydrates and hydroxides are not intended. Moreover, if the inventor had intended to equate metal oxides with metal hydroxides, he could have so stated and avoided

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exclusively exemplifying metal oxides as binary compounds. Therefore, according to the specification's explicit definition of "oxide coating" and its description of such coatings, the claimed oxide coating must primarily comprise binary metal oxides containing only metal cations and oxygen. Other elements and compounds originating in precursor materials, such as hydrated metal oxides or metal hydroxides, if present at all, may only be present in minor amounts as impurities. Accordingly, we conclude that the district court erred in construing the term "oxide coating" as not requiring a primary component that is a binary metal oxide.

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4 Alumina as a Ceramic Material 3-4 (Walter H. Gitzen, ed., 1970).

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1. "Oxidizing PVP"

In its ordinary context, to oxidize means "to combine with oxygen." WEBSTER'S COLLEGIATE DICTIONARY 832 (10th Ed. 1999). The ordinary meaning of the term PVP is "a polymer made of a series of vinylpyridine units, and each of those vinylpyridine units contains a nitrogen atom that can potentially bond with oxygen." Reilly Br. In Support, p. 22. To this point, it appears that the parties agree. The dispute is whether PVP, as used in Claim 1, includes PVP that is already partially oxidized, as argued by BASF, or whether it is limited to only "true" PVP, as Reilly contends, that is, without any oxygen bonded to the nitrogen atoms of the molecule.

The plain meaning of the term PVP, as recited above, dictates that Claim 1 begins with PVP to which oxygen is added. Nothing in the term itself suggests that the PVP must be completely free of any oxygen already bonded to the nitrogen atoms. Reilly's own experts agree that simply adding oxygen atoms to some of the nitrogen atoms does not cause the molecule to fall outside the scope of Claim 1. See Deposition of Paul L. Dubin, Ph.D., Affidavit of Daren P. Nicholson, Exhibit 1 ("Dubin Dep."), p. 105, 1. 23 -- p. 106, 1. 6 (stating that at least 25% oxidation is required for a PVP outside of the meaning of the term in Claim 1); Deposition of Eric F.V. Scriven, Ph.D., Affidavit of Daren P. Nicholson, Exhibit 2 ("Scriven Dep."), p. 41, 1. 12 -- p. 42, 1. 12 (stating that one oxygen on a PVP was not outside of the PVP claimed in Claim 1, but unable to state how many oxygen atoms would be required to differentiate a partially oxidized PVP from that claimed in Claim 1).

Similarly, the court does not find anything in the patent's specification that suggests the limitation contended by Reilly. In the specification, the patentee consistently refers to PVP as the agent to be oxidized and PVNO as the result. Thus, it is clear that PVNO is not the same compound as PVP. Instead, it is the end product created by oxidizing PVPs as described in the 684 patent. This does not, however, warrant the court imposing any limitation on the oxygen content of the PVP molecules during this process. Consequently, the court can conclude the process described in the patent must begin with PVPs and continue with PVPs until the reaction is complete, at which time the end product is known as PVNO. Nothing in the specification or prosecution history dictates a meaning for these terms.

Therefore, the court concludes that "oxidizing PVP," as used in Claim 1 of the 684 patent must be given its plain, ordinary meaning. That is, the process of combining oxygen atoms with a PVP molecule, from the beginning to the end of the process, without regard to the number of oxygen molecules present in the starting PVP and with an eventual end product of PVNO.

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3. 3-oxo-glutaric Acid

The term "3-oxo-glutaric acid" is used in Claim 1, Step 2, and Claim 4(g) of the '311 patent. As related to 3-oxo-glutaric

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acid, Metametrix argues that this term should only include 3-oxo-glutaric acid and 3-oxo-pentanedioic acid. However, plaintiffs argue for a broader definition and advocate for inclusion of any form of 3-oxo-glutaric acid, including 3-oxoglutarate, 3-ketoglutaric, 3-ketoglutarate, beta-ketoglutarate and 3-oxo-pentanedioic acid. Thus, the parties do not dispute the inclusion of 3-oxo-glutaric acid and 3-oxo-pentanedioic acid. The only issue is whether 3-ketoglutaric acid and the conjugate bases 3-ketoglutarate, beta-ketoglutarate and 3-oxoglutarate may also fall within the claim term "3-oxo-glutaric acid."

The term "3-oxo-glutaric acid" has several synonyms including 3-ketoglutaric acid, beta-ketoglutaric acid and 3-oxo-pentanedioic acid. See Chemical Abstracts Service, a division of the American Chemical Society, SciFinder database available at http://www.cas.org (subscription required) (last accessed July 12, 2006) (listing the other names of 3-oxo-glutaric acid, registry number 542-05-2). Since 3-ketoglutaric acid is a synonym of 3-oxo-glutaric acid, 3-ketoglutaric acid should be included in the definition of the claim term. The conjugate base of 3-ketoglutaric acid, 3-ketoglutarate, falls within the claim term. The conjugate base of beta-ketoglutarate and 3-oxoglutarate are also properly construed as within the claim term "3-oxo-glutaric acid." Nothing in the claim language indicates that 3-oxo-glutaric acid should be construed narrowly. The inventor is not required to include every synonym of 3-oxo-glutaric acid. Furthermore, since the patent requires collection of bodily fluids that are inherently aqueous, it is only logical to conclude that the conjugate bases of compounds will be present in the fluids.

Accordingly, the court adopts plaintiffs' construction of the claim term "3-oxo-glutaric acid."
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E. "oxygen scavenger"

MacDermid defines the term, "oxygen scavenger", as "[a] chemical compound that is included in the photocurable layer that reacts with oxygen and/or oxygen derived species in order to mitigate the deleterious effects of oxygen and/or oxygen derived species on the photocurable layer." (MacDermid Responsive Br. at 21.) DuPont defines the term as "[a] chemical compound, added to a photocurable material, that is oxidized by (i.e., reacts with) oxygen." (DuPont SurReply at 6.)

MacDermidargues that its proposed construction is supported by (1) the '835 Patent specification, and (2) the dictionary definition of scavenger. (MacDermid Responsive Br. at 22.) It looks to two dictionaries that define scavenger as "any substance added to a system or mixture to consume or inactivate traces of impurities," and a "substance or species which scavenges free radicals or other species." (Id.) As such, it argues a person of ordinary skill in the art would agree with its proposed construction.

MacDermid criticizes DuPont's construction for its failure to specify how the compound reacts with oxygen. (Tr. at 49.) MacDermid emphasizes that the purpose of the scavenger is to counter the effects of oxygen inhibition and that this purpose is integral to the construction. (Id. at 50.) MacDermid contends that DuPont's construction ignores the purpose and is thus incomplete. (Id. at 51.)

DuPont contends that its proposed construction is supported by both the specification of the '835 Patent and the prosecution history for the original '699 Patent. (DuPont SurReply at 6.) DuPont notes that the '835 Patent instructs that the oxygen scavenger should be incorporated into the photocurable materialto counter the effects of oxygen inhibition, but provides no other information that proves helpful in construing the claim. (Id.) DuPont then looks to the prosecution history of the original '699 Patent in which MacDermid distinguished the patent over prior art by stating that there was no indication that the compounds in the prior art "could react with, and thereby 'scavenge' oxygen." (Id.) DuPont further states that the dictionary provides that a scavenger is "a chemically active substance acting to make innocuous or remove an undesirable substance" or "any substance added to a system or mixture to consume or inactivate traces of impurities." (Id.) As such, it contends that its definition is consistent with both the intrinsic evidence of the '835 Patent and the ordinary meaning of scavenger. (Id.)

DuPont contends that the two parties agree on the first portion of the construction. (Tr. at 92.) DuPont takes issue with MacDermid's construction, insofar as it includes, the inclusion of the phrases "oxygen derived species" and "mitigate the deleterious effects." (Id. at 93.) DuPont argues that "oxygen derived species" is found nowhere in the specification, the

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prosecution history, orin any extrinsic evidence. (Id. at 93.) It further contends that the term "deleterious effects" is vague and could encompass different meanings. (Id.) DuPont states that the specification is illuminating in this situation and it dictates that the oxygen scavenger serves to counter the effects of oxygen. (Id. at 93-94.)

The Court, upon considering the parties' respective arguments, finds that the claim "oxygen scavenger" should be construed consistent with the specification, as "a chemical compound included in the photocurable layer that reacts with oxygen to counter the effects of oxygen inhibition." (See '835 Patent at col 2, lines 45-50; col. 5, lines 24-29.) DuPont's concerns with MacDermid's construction focused on the inclusion of the terms "deleterious effects" and "oxygen-derived species." MacDermid's primary concern with DuPont's construction was that it failed to identify the purpose of the oxygen scavenger. Using the language found in the specification serves to allay both parties' concerns. It includes the purpose of the oxygen scavenger without including MacDermid's proposed vague language. DuPont, itself, noted during oral argument that the scavenger must have an impacton the adverse effects of oxidation. As such, construing the claim using the language of the specification will best serve both parties' goals.
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F. "parenteral," "administering," and "patient"

Lilly urges that "parenteral" means "for subcutaneous injection into a patient." D.I. 156 at 3. Novo counters that "parenteral" means "taken into the body or administered in a manner other than through the digestive tract (e.g., not by mouth or through the alimentary canal)." D.I. 154 at 33. The court holds that Novo's interpretation of "parenteral" is correct.

Lilly maintains that "administering" means "subcutaneous injection." D.I. 156 at 2. Novo argues that "administer" means "to apply as a remedy." D.I. 154 at 34. The court holds that Novo's interpretation of this term is correct.

Lilly argues that "patient" means "a human being." D.I. 156 at 2. Novo replies that "patient" means "an animal, including a human being." D.I. 154 at 34. This Court holds that "patient" means an animal, including a human being, awaiting or under medical treatment.

The meanings of "parenteral," "administering," and "patient" are not immediately apparent from reading the plain language of the claim. 48 Moreover, the specification and the prosecution history fail to explicitly define these terms as they have done for terms such as "isotonicity agent" and "treating." See '978 Patent at 4:9-20. Therefore, it is appropriate to turn to extrinsic sources of evidence.

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48 Novo argues that the doctrine of claim differentiation precludes defining the term "administering" to mean "subcutaneous injection" and the term "parenteral" to mean "subcutaneously." D.I. 154 at 35. Because the Court concludes that neither term is limited to only subcutaneous injection, the Court need not address this argument.

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The dictionary definitions uniformly support Novo's definition of "parenteral" as "taken into the body or administered in a manner other than through the digestive tract (e.g., not by mouth or through the alimentary canal)." 49 Also, the dictionary definitions of "administer" support Novo's definition of "administer" as "to apply as a remedy." 50 Finally, the dictionary definitions of "patient" support the definition of "patient" as "an animal, including a human being, awaiting or under medical treatment." 51

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49 See Oxford Dictionary of Biochemistry and Molecular Biology 484 (1997) ("any route other than via the gastrointestinal tract, especially by injection"); Dictionary of Biochemistry and Molecular Biology 347 (2d ed. 1989) ("referring to the introduction of a substance into an animal organism by ways other than that of the digestive tract"); Merriam-Webster's New Collegiate Dictionary 844 (1981) ("introduced other than by way of the intestines"); Grant & Hackl's Chem. Dictionary 423

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(1987) ("describing a route of administration of drugs or food, other than by mouth or into the intestine"); Webster's Third New Int'l Dictionary 1641 (1981) ("1: not intestinal: situated or occurring outside the intestine…2: injected or for injection subcutaneously, intramuscularly, or intravenously").

50 See Merriam-Webster's Collegiate Dictionary 57 (10th ed. 1998) ("to give as a remedy"); Webster's Third New Int'l Dictionary 27 (1981) ("to give remedially (as medicine)"). There is no limitation in these dictionary definitions that administer be limited to only subcutaneous injection.

51 See Merriam-Webster's Collegiate Dictionary 863, 825 (10th ed. 1998) ("patient" means "an individual awaiting or under medical care or treatment" and "individual" means "a particular being. . . as distinguished from a class"); Merriam-Webster's New Collegiate Dictionary 833 (1981) ("patient" means "an individual awaiting or under medical care or treatment"); Webster's Third New Int'l Dictionary 1152, 1655 (1981) ("patient" means "a sick individual" or "a client for medical services" and "individual" means "a particular being or thing as distinguished from a class"). These definitions are in no way limited to only human, and not animal, patients.

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Other extrinsic evidence further supports the Court's definitions of these three terms. Regarding "parenteral" and "administer," both parties agree that, at the time of the invention, it was known in the art to administer insulin to diabetics intravenously. See Tr. at 422:5-424:22. In addition, Lilly's expert, Dr. Michael Weiss, testified that scientists have researched nasal and pulmonary administration of insulin to diabetics. See id. at 105:4-11. At the time the patent claims were written, one of ordinary skill in the art would have anticipated the use of the formulation by routes other than subcutaneous injection. It follows the terms "parenteral" and "administer" are not limited to subcutaneous injection.

Regarding the term "patient," extrinsic evidence supplied by both parties supports the Court's definition by showing that animals suffer from diabetes mellitus and are treated with injections of insulin. See Tr. at 65:17-66:11 98:21-101:7 (testimony of Lilly expert Dr. Weiss); 219:3-15 (testimony of Novo expert Dr. Dunn). Therefore, at the time of the invention, one of ordinary skill in the art could have anticipated that an insulin analog formulation would be administered to animals, as well as human patients.

As to all three terms, Lilly urges that the disclosure of preferred embodiments in the specification limits the definition of the terms. First, Lilly takes the position that "parenteral" is limited to subcutaneous injections because the specification only discloses formulations that have rapid action when injected subcutaneously. 52 Second, Lilly argues that the specification infers "administer" is limited to subcutaneous injections because the specification only discloses formulations that have rapid action when injected subcutaneously. 53 Finally, Lilly insists that "patient" is limited to humans because the specification only discloses using rapid acting human insulin analogs for human patients. 54

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52 See D.I. 173 at 26 (citing '978 patent at 1:15-18; 1:28-31; 1:34-38). At the Markman hearing, Lilly further argued that "parenteral" must mean "subcutaneous" because the rapid action of the patented invention is only needed for subcutaneous injection of the insulin analog. See Tr. at 420:5-20.

53 See D.I. 173 at 26 (citing '978 patent at 1:15-18; 1:28-31; 1:34-38).

54 See D.I. 173 at 25 (citing '978 Patent at 5:21; 1:23-25).

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However, the claims of the patent cannot be limited by disclosure of a preferred embodiment in the specification. See Rhine v. Casio, Inc., 183 F.3d 1342, 1346 (Fed. Cir. 1999). The subcutaneous method of using the insulin analog formulations and the use on humans are only preferred embodiments disclosed in the specification. As to "parenteral" and "administer," if Lilly had desired to limit the claims to only "subcutaneous" injection, it could have done so by defining these terms to mean "subcutaneous injection" or by using the term "subcutaneous" in the claims. Likewise, if Lilly had desired to limit the claims to "human patients," it could have used that language instead of "patient." Since Lilly chose to use the broader terms

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"parenteral," "administer," and "patient," the scope of the claims should reflect its choice of words.

The Court holds "parenteral," "administer," and "patient" have the definitions discussed above.

V. Conclusion

In summary, the Court construes the disputed claim language as follows:

1. "human insulin analog complex" or "complex" (claims 1, 12) means an individual molecular structure, defined as "a chemical association state of two or more molecules held together by non-covalent bonds."

2. In claims 1 and 12, "hexamer" refers to the Zn-hIA structure, i.e., "a type of complex where six molecules of humin insulin analog are held together in a single structure." In claim 13, "LysPro-human insulin is a hexamer" is shorthand meaning "in the equilibrium, most of the LysPro-human insulin molecules are in Zn-hIA structures."

3. "formulation" (claims 2-11, 13) means "an equilibrium containing molecules and molecular structures."

4. "pharmaceutical" (claims 2-11, 13) means "containing a medicinal drug" where "medicinal drug" means "a substance or preparation used in treating disease."

5. "comprises" and "two zinc ions" (claim 1) means that the claimed human insulin analog complex can have other components in the complex, in addition to the named components, but the named components, including the two zinc ions, must be in the specified amounts.

6. "consisting of" and "two zinc ions" (claim 12) indicates closed claim language and closes the claim to the inclusion of unrecited elements, except for impurities ordinarily associated therewith.

7. "wherein the human insulin analog is human insulin wherein Pro at position B28 is substituted with Asp, Lys, Leu, Val, or Ala, and Lys at position B29 is Lys or Pro; des(B28-B30)-human insulin; or des (B27)-human insulin" does not include a T[6] limitation;

8. "hexamer" (claims 1, 12, 13) does not include the R[6] limitation;

9. "parenteral" (claims 2-11, 13) means "taken or administered into the body by a means other than through the digestive tract."

10. "administering" (claim 10) means "to apply as a remedy."

11. "patient" (claim 10) means "an animal, including a human being, awaiting or under medical treatment."
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3. "parenterally"

This disputed term is found in claims 1 and 2 of the '781 patent, claim 1 of the '146 patent and claim 2 of the '728 patent. Claim 1 of the '781 is representative of how the term appears in the asserted claims:

A method of treating restenosis in a mammal resulting from saidmammal undergoing a percutaneous transluminal coronary angioplasty procedure which comprises administering an antirestenosis effective amount of rapamycin to said mammal orally, parenterally, intravascularly, intranasally, intrabronchially, transdermally, rectally, or via a vascular stent impregnated with rapamycin.

'781 patent, Claim 1.

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Plaintiff contends that "parenterally" means "other than by way of the intestines." Abbott and Medtronic propose that the term means "systemic administration of a substance by injection given either intervenously, intra-arterially, subcutaneously, intramuscularly, or intraperioneally." BSC proposed construction is "systemic administration of a substance by means other than through the gastrointestinal tract, in particular via intravenous, subcutaneous, intramuscular or intramedullary injection."

"[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms. . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive." Phillips, 415 F.3d at 1314. As set forth above, the Morris patents claim eight different routes of administration -- "orally, parenterally, intravascularly,intranasally, intrabronchially, transdermally, rectally, or via a vascular stent impregnated with rapamycin." Plaintiff's proposed construction, as Defendants assert, is simply too broad; there is far too much overlap with to other described routes of administration for the Court to be persuaded that a person of skill in the art would understand the term, as it is used in the Morris patents, to mean "other than by way of the intestines."

The Court finds Defendants proposed constructions to be more consistent with the ordinary meaning of the term. As defined in one medical dictionary, "parenteral" administration of a drug includes administration "[b]y some other means than through the gastrointestinal tract; referring particularly to the introduction of substances into an organism by intravenous, subcutaneous, intramuscular, or intramedullary injection." (DeWitt Decl. Ex. 22 at 1139-40). Considering the totality of the intrinsic and extrinsic evidence, the Court shall construe the term "parenterally" as "by means other than through the gastrointestinal tract, in particular via injection."
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3. Parthenogenic activation

The '720 patent claims a process for "in vitro parthenogenic activation of a bovine oocyte." The patent defines "parthenogenic" as "the 'production' of embryonic cells, with or without eventual development into an adult, from a female gamete in the absence of any contribution from a male gamete (Kaufman 1981)." '720 pat., col. 2, ln. 43-46. Although this definition is included in the "Description of Prior Art," it is the only definition given in the patent specifications. Defendants argue that this definition cannot be read to cover the activation of a recipient oocyte containing a blastomere because by definition, a blastomere contains genetic material contributed by both a female and a male gamete.

Oddly enough, despite having made this argument in their brief on claim construction, defendants say in their brief in opposition to plaintiff's motion for partial summary judgment, that "defendants have activated only nuclear transfer embryos parthenogenically." Br. at 7 (emphasis added). In making this statement and using "parthenogenically" to refer to the activation of a oocyte recipient that has had a blastomere fused to it, defendants seem to be conceding the very point they argue on claim construction. At the least, defendants' statement is a strong indication that the term parthenogenic covers any activation that takes place without the use of sperm, whether the oocyte being activated has received a blastomere or is still waiting for one. This conforms to the logical reading of the definition, in which it is clear that it is the process (i.e., activation) that takes place in the absence of any contribution from a male gamete. Even if a blastomere is fused with the oocyte before activation, the male chromosomes in the blastomere do not play any role in the activation process. I conclude that production of embryonic cells is parthenogenic if the activation process does not involve spermatozoa, regardless whether the recipient of activation contains male genetic material.
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6. Disputed claim terms "modafinil particles"/ "said particles"/ "particles" mean: an aggregated physical unit of acetamide compound, i.e., a piece or a grain of acetamide.
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III. "Particles"

For the claim construction hearing, Claims 2-4 of the '358 Patent were at issue. The parties agree that the only claim term that is in dispute is the word "particles" as it appears in independent Claim 2. 2 Thus, the purpose of the Markman hearing was to determine the meaning of the word "particles." Independent Claim 2 of the '358 Patent, in its entirety, reads as follows: (See Column 6, Lines 5-20).

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2 The term "particles" is also found in Claims 1 and 8 of the '342 Patent and Claim 1 of the '358 Patent.

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2. A semi-resilient exercise grip comprising:

a core containing a deformable mixture of tightly packed individual dry particles that are in continuous contact with each other; and

a resilient covering surrounding said core, wherein said covering is in the form of a plurality of nested sacks, wherein each sack is made of a resilient material and includes an opening, and wherein the sacks are located about the core, the openings of adjacent sacks are spaced apart from each other, and wherein each sack applies its own inward force on the core and the total inward force on the core is the combined total of the individual inward forces exerted on the core by each of the sacks making up the covering.

Claims 3 and 4 of the '358 Patent further limit the coverings of the exercise grip. Dependent Claims 2 and 3, in their entirety, read as follows: (See Column 6, Lines 21-25).

3. The grip of claim 2 wherein each of the sacks that make up the covering are substantially ball-shaped when in a non-stressed state.

4. The grip of claim 2 wherein each of the sacks are made of a latex rubber material.

Sport Squeeze contends that the term "particles" is limited to particles that are similar in size and shape to millet (roughly the size of bird seed), which is one of the examples of particles disclosed in the Scatterday patents. The allegedly infringing Ad Squeeze product uses silicon beads which are much smaller in size than millet. Accordingly, Sport-Squeeze contends that the term "particles" is limited to larger, millet-sized particles, which, under its proffered construction, would result in the Ad Squeeze product not infringing the asserted claims.

In opposition, Pro-Innovative contends that the term "particles" should be given its broad and ordinary meaning which includes particles not limited in size and shape to millet. Specifically, Pro-Innovative requests the court to construe the term "particles" to mean "small specks of matter which include starch particles, microsphere particles, hard plastic or silicon beads and millet."

IV. Discussion

A. Legal Standards

a. Construing the Term "Particles" in the '342 and '358 Patents is a Question of Law for the Court

Construing a claim to determine its scope and meaning, also known as "claim construction," is a pure question of law for the court. Markman, 52 F.3d 967, 970-71. The language of the claim defines the scope of the protected invention. Bell Communications Research v. Vitalink Communications Corp., 55 F.3d 615, 619-620 (Fed. Cir. 1995). "Words in a patent claim are construed as they would be understood by a reader skilled in the relevant art unless it appears that the inventor used the words differently." Cole v. Kimberly-Clark Corp., 102 F.3d 524, 531 (Fed. Cir. 1997).

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When interpreting disputed claim language, the court must first look to "intrinsic" evidence, including "the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman, 52 F.3d at 979). The parties agree that the disputed claim language can be construed with reference to intrinsic evidence only. Thus, it would be improper to look to extrinsic evidence. Id. at 1583.

b. The Doctrine of "Claim Differentiation"

"There is presumed to be a difference in meaning and scope when different words or phrases are used in separate [patent] claims. To the extent that the absence of such [a] difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987). The doctrine of claim differentiation has its greatest force when an interpretation of a dependent and independent claim would render the dependent claim superfluous. Beachcombers v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1162 (Fed. Cir. 1994) (interpretation that renders dependent claim superfluous is "presumptively unreasonable" under doctrine of claim differentiation); United States v. Telectronics, Inc., 857 F.2d 778, 783 (Fed. Cir. 1988) (where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad claims). The doctrine may also be used to interpret an independent claim in light of another independent claim. See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1055 (Fed. Cir. 1988); Caterpillar Tractor Co. v. Berco, SPA, 714 F.2d 1110, 1116 (Fed. Cir. 1983).

"Although the doctrine of claim differentiation may at times be controlling, construction of claims is not based solely upon the language of other claims; the doctrine cannot alter a definition that is otherwise clear from the claim language, description, and prosecution history." O.I. Corp. v. Tekmar Co., Inc., 115 F.3d 1576, 1582 (Fed. Cir. 1997); see also Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) ("While we recognize that the doctrine of claim differentiation is not a hard and fast rule of construction, it does create a presumption that each claim in a patent has a different scope.").

B. Claim Differentiation Supports Pro-Innovative's Construction

Pro-Innovative argues that its three exercise grip patents contain a wide spectrum of language regarding certain "particles," describing them in narrow and broad terms. It argues that the claims of the '342 Patent use the term "particles" both with and without qualifying language, and that the '358 Patent includes no language limiting "particles" based on size and shape. Upon review of the three patents, the court finds that the doctrine of claim differentiation supports Pro-Innovative's position.

1. The '504 Patent

Claim 1 of the first patent issued to Scatterday, the '504 Patent issued in 1993, limited the "particles" used to fill the exercise ball to millet-sized particles. (See Column 5, Lines 23-26).

1. A semi-resilient exercise grip comprising a nonresilient core containing a deformable mixture of individual particles identical in size and shape to millet

Claim 7 of the '504 Patent is also limited to "millet-sized" particles. (See Column 6, Lines 15-19). The parties do not dispute that the plain language of Claim 1 of the '504 Patent and the patent's prosecution history confirm that Claim 1 is limited to millet-sized particles.

2. The '342 Patent

However, the term "particles" in the subsequently issued '342 Patent is not expressly limited to "millet-sized" particles. Specifically, Claims 1-3 of the '342 Patent read: (See Column 5, Lines 27-43; Column 6, Line 1).

1. A semi resilient exercise grip comprising a non-resilient dry core containing a deformable mixture of tightly packed individual particles that are in continuous contact with each other.

2. The grip of claim 1 wherein the particles are hard and are similar in size and shape to millet.

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3. The grip of claim 2 wherein the particles are millet.

Applying the doctrine of claim differentiation, the term "particles" in Claim 1 cannot be limited to particles "similar in size and shape to millet." Under such a construction, Claim 2 would have the same scope as Claim 1, rendering Claim 2 superfluous--a construction that is "presumptively unreasonable. " Beachcombers, 31 F.3d at 1162. Sport Squeeze presented no evidence during the hearing or in its papers rebutting the strong presumption that the "millet-sized" limitations in dependent Claim 2 should not be incorporated into Claim 1.

Sport Squeeze argues that the prosecution history of the '342 Patent supports a narrow reading of the term "particles." Specifically, Sport Squeeze emphasizes that the Patent Office rejected the initial Claim 7 as obvious under U.S. Patent No. 3,601,923 issued to Rosenberg. (See Sport Squeeze Exhibit G). 3 To overcome the Patent Office's rejection, Scatterday limited the "particles" in initial Claim 7 to "substantially millet-sized" particles and explained to the Patent Examiner that the "millet-sized" particles in the revised claim distinguished the claim from Rosenberg, which used considerably smaller starch particles. (See Sport Squeeze Exhibit B, at 6-7 (Stamp no. 122-123) (stating that "the tiny particles used by Rosenberg form a crucial component of his invention.")). 4

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3 The claim which became Claim 7 of the '342 Patent was originally designated as Claim 15 in Scatterday's earlier applications. For purposes of this Order, the court will refer to Claim 15 as the "initial Claim 7," and the claim issued by the patent office as "issued Claim 7."

4 The Patent Office also rejected various claims of the '342 Patent under the doctrine of "double-patenting." Scatterday subsequently filed a terminal disclaimer to cure the rejection so that all three patents ('504, '342, and '358) would expire on the date of the first patent. See In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (filing of terminal disclaimer cures double patenting rejection).

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In essence, Sport-Squeeze argues that the prosecution history of Claim 7 (which resulted in a claim dependent upon "millet-sized" particles) supports its contention that the "millet-sized" limitation should be implied into claims that do not contain this limitation. This argument is unpersuasive. The fact that Scatterday limited "particles" in initial Claim 7 to "millet-sized" particles while leaving "particles" in Claim 1 without such a limitation supports Pro-Innovative's contention that the term "particles," standing alone, is not limited to particles that are millet-sized. Moreover, the difference between the "particles" in Claim 1 and issued Claim 7 provides additional support for Pro-Innovative's arguments that claim differentiation forecloses a construction of the term "particles" limited to particles that are millet-sized. 5

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5 Sport-Squeeze argues that Scatterday represented to the Patent Office during prosecution of the '342 Patent that millet-sized particles were essential to the semi-resilient nature of the exercise grip. (See Sport-Squeeze's Opening Brief at 9-10 (quoting Sport-Squeeze's Exhibit I, at 6)). However, those comments were made in reference to a claim which explicitly contained a "millet-sized" limitation. Thus, Sport-Squeeze's "file wrapper estoppel" arguments concerning the other claims are without merit as this explanation was not offered to obtain allowance on any other claim. Moreover, Sport-Squeeze presented no evidence during the Markman hearing that the invention's semi-resilient characteristics depend upon millet-sized particles. In any event, this statement does not overcome the presumption raised by the doctrine of claim differentiation.

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3. The '358 Patent

Approximately two years after the '342 Patent was issued, the Patent Office awarded Scatterday the '358 Patent, the primary patent at issue here. Significantly, unlike the '504 and '342 Patents, the term "millet" does not appear in any of the issued claims of the '358 Patent. The sole mention of "millet" appears in the specification: (See Column 3, Lines 10-15):

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In practice, seeds such as millet have been used as the particles. As an alternative, the particulate [sic] material can be hard plastic or silicon beads or any other matter that is similar in size and shape to millet and that is hard enough to withstand the compressive pressures experienced when the grip is being squeezed by a user.

Sport-Squeeze argues that this language discloses that the "particles" in the '358 Patent are limited to millet-sized particles. However, while "the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims." Comark Communications, Inc., 156 F.3d 1182 at 1187; see also Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."). Sport-Squeeze has provided no basis for reading the specification's illustrative use of "millet-sized" into the claims of the patent. The court has found nothing in the long and somewhat confusing prosecution history of the '358 Patent which would warrant a narrow reading of "particles" inconsistent with its plain meaning and the construction of that term in the '342 Patent.

With all three patents, when Pro-Innovative sought to limit the "particles" in its claims to a particular size or shape, it qualified that term by including the limitation that the particles be the size or shape of "millet." When Pro-Innovative did not wish to limit the size or shape of the "particles," it did not include any size or shape limitation.

i. Application of Claim Differentiation to the '358 Patent

Sport-Squeeze contends that the doctrine of claim differentiation cannot be applied to the '358 Patent because the doctrine is "inapplicable to continuation patents." The sole case Sport Squeeze relies upon, Jonsson v. Stanley Works, 903 F.2d 812 (Fed. Cir. 1990), held that the prosecution history of one patent can be used to determine the scope and to interpret the meaning of another patent where both patents stem from a common parent application. 903 F.2d at 818. The court found it unnecessary to apply the doctrine of claim differentiation because the court's finding that the claim contained a limitation existing in a separate dependent claim was supported by the prosecution history, the patent, the specifications, and deposition testimony. Id. at 820 ("Hence, since it is apparent that the court had ample evidence to determine the scope of the '912 patent, Jonsson's reliance on claim differentiation requires no discussion."). Thus, Jonsson merely reinforces the rule that the doctrine of claim differentiation can be overcome by a patent's prosecution history. 6

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6 Most of the sections of Jonsson quoted in Sport-Squeeze's Opening Brief were not the opinion of the court, but rather arguments asserted by the parties.

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In this case, however, the court need not necessarily rely upon the doctrine of claim differentiation to conclude that the "particles" in the '358 Patent are not limited to "millet-sized" particles. As discussed in the preceding section of this order, nothing in the prosecution history or specifications justifies departing from the plain meaning of the term "particles." Rather, the prosecution history of all three patents reveals that both Scatterday and the patent examiner understood that differing particle sizes were significant in light of Tarnoff and Rosenberg.

Although not necessary to the court's conclusion, it notes that the doctrine of claim construction may provide additional support for Pro-Innovative's position. All three patents (1) involved the deformable exercise grip, (2) were issued over a relatively short period (three years), (3) involved the same patent examiner (Stephen Crow), and (4) made reference to the same prior art references. These facts support the court's conclusion that the term "particles" in the '358 Patent should be construed consistently with that term in the '342 Patent.

V. Sport-Squeeze's Arguments in Opposition

Sport-Squeeze presents two main arguments to support its contrary position that the "particles" in the '358 Patent must be millet-sized. First, Sport-Squeeze argues that the term "particles" should be narrowly construed to avoid conflict with prior art patents. Second, Sport-Squeeze argues that Judge Moskowitz previously ruled that the "particles" in the '342 and '358

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Patents are millet-sized and that this determination is "law of the case."

a. Sport-Squeeze's Argument that a Narrow Reading of "Particles" is Necessary to Avoid Invalidation in light of Tarnoff is Logically Flawed

Sport-Squeeze argues that a broad construction of "particles" should be avoided because such a construction would read back on the Tarnoff prior art. According to Sport-Squeeze, a broad reading of the term "particles" would render the '342 and '358 Patents invalid under Tarnoff and Rosenberg because both of these patents use microspheres that are substantially smaller than millet.

Sport-Squeeze's argument is logically flawed because it assumes the term "particles" must be analyzed as an isolated term, construed outside the context of the claim it limits. In fact, it is of little consequence that a single term in a patent claim reads back on a term in a prior art patent so long as the claim as a whole does not read back on a claim in the prior art. Here, particle size is only one of many possible limitations contained in the claims of the '342 and '358 Patents. (See, e.g., Pro-Innovative's Exhibit 369). Claim 2 of the '358 Patent, for example, contains numerous limitations not found in Tarnoff or Rosenberg, including: (1) a plurality of nested sacks, (2) openings of adjacent sacks that are spaced far apart from one another, (3) each sack applies inward force on the core, and (4) the total inward force is the combined total of the individual inward forces. Id. These limitations, rather than an implied limitation on particle size, likely formed the basis for patentability of Claim 2. 7

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7 In its Reply brief, Sport-Squeeze contends that "to have any differentiation between the claimed squeeze ball and the prior art, the term 'particle' must be defined as including particles approximately millet-like, but excluding microspheres ranging from 0.0001 inches to 0.06 inches." (See Sport Squeeze's Reply at 6:17-19). A similar argument appears in its Opening brief, where Sport-Squeeze argues that a narrow reading of the term "particle" is necessary to avoid conflict with Tarnoff. (See Sport-Squeeze's Opening Brief at 5:11-15). This arguments are rejected for the reasons stated in the text.

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Thus, the court rejects Sport-Squeeze's argument that the term "particles" must be construed narrowly because the term may read back on the microspheres of Tarnoff. Moreover, Sport-Squeeze made no arguments during the Markman hearing or in its briefs that the broad construction of "particle" urged by Pro-Innovative would cause any of the claims of the '342 or '358 Patents to read back on Nichols, Rosenberg, Cherk, or Tarnoff.

b. Judge Moskowitz's Previous Ruling is not "Law of the Case"

Sport-Squeeze relies heavily upon the language of two orders from Judge Moskowitz, both dated August 10, 1998. (See Sport-Squeeze Exh. D, E). Sport-Squeeze relies particularly on page 5 of Judge Moskowitz's August 10, 1998 order denying Pro-Innovative's motion for summary judgment. (See Order Denying Motion for Summary Judgment on Patent Infringement (Doc # 106)). In that order, Judge Moskowitz rejected Pro-Innovative's contention that the term "particles" in the '358 Patent consisted of particles of any shape and size. He noted that this construction was "incredibly broad" and "unsupported by the record." (See id. at 5:15-23). Sport-Squeeze contends that Judge Moskowitz's ruling is "law of the case" and is binding on this court. The court finds this argument unpersuasive for two reasons.

First, the sole issue before Judge Moskowitz was whether Pro-Innovative was entitled to summary judgment on the issue of Sport-Squeeze's alleged infringement of the '358 patent. Since a Markman hearing had not been conducted, the question of claim construction was not before the court. In fact, in a footnote Judge Moskowitz observed that the parties had failed to lodge the Rosenberg and Tarnoff patents, and that without those references, "the Court cannot at this time determine whether 'particles' should be construed to include the 'size and shape of millet' limitation urged." (See id. at 6 n.2). 8 At the conclusion of his order, Judge Moskowitz scheduled a Markman hearing and set a briefing schedule, negating any inference that he intended his previous order to serve as the final word on the construction of the three Scatterday patents.

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8 Judge Moskowitz's order adopted Sport-Squeeze's argument that the term "particles" must be narrowly construed to avoid reading back on the particle-size aspect of the Tarnoff prior art. (See Part IV.a, supra). This conclusion was understandable since Judge Moskowitz did not have the Tarnoff prior art available to him at the time of the ruling.

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Second, the court notes that, to the extent "law of the case" is applicable, it "merely expresses the practice of [a] court[] generally to refuse to reopen what has been decided." Christianson v. Colt Industries Operating Corp., 486 U.S. 800, 817, 100 L. Ed. 2d 811, 108 S. Ct. 2166 (1988) (quoting Messenger v. Anderson, 225 U.S. 436, 444, 56 L. Ed. 1152, 32 S. Ct. 739 (1912)) (Holmes, J.). It is not a limit to the court's power. Id.; Capital Investors Co. v. Executors of Morrison's Estate, 584 F.2d 652, 654 (4th Cir. 1978) ("The principle [of law of the case] is not absolute nor inflexible."). The court retains inherent authority to revise interim or interlocutory orders any time before judgment, including orders denying motions for summary judgment. See, e.g., FED. R. CIV. P. 54(b) (any order not certified under Rule 54(b) and which adjudicates fewer than all the claims as to all the parties "is subject to revision at any time before the entry of [final] judgment"); Balla v. Idaho State Bd. of Corrections, 869 F.2d 461, 465 (9th Cir. 1989) ("Courts have inherent power to modify their interlocutory orders before entering a final judgment."); Curran v. Kwon, 153 F.3d 481, 487 (7th Cir. 1998) ("When a district judge is presented with additional evidence, therefore, he is free to revisit a denial of summary judgment."). Thus, even assuming the issue of claim construction was addressed in the court's August 10, 1998 Order, the doctrine of "law of the case" would not preclude this court from revisiting the issue, especially where, as here, the parties presented evidence and argument they did not present at the time the court issued its previous order.

VI. Conclusion

For the foregoing reasons, the court concludes that the term "particles" in the claims of United States Patent Nos. 5,350,342 and 5,556,358 means particles in its ordinary sense without limitation based on the size or shape of millet. Specifically, the court finds that the term "particles" contemplates small specks of matter, including but not limited to, starch particles, microsphere particles, hard plastic or silicon beads and millet. 9

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9 This order resolves only the issue of claim construction. The court expresses no opinion on the determination of infringement, the applicability of any defenses Sport-Squeeze may wish to assert, or the viability of the non-patent claims.

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II

TAP's cross-appeal involves the '663 patent, the '021 patent, and the '020 patent. Those three patents are directed to extending the period during which certain microcapsules can be stored by interspersing molecules of sugars among the microcapsules. Claim 1 of the '663 patent is representative of the asserted claims. It provides:

A prolonged release microcapsule for injection, which comprises particles containing a water-soluble drug, the particles being dispersed in a spherical microcapsule matrix composed of a copolymer of lactic acid and glycolic acid having a comonomer ratio within the range of about 100/0 to 50/50 and an average molecular weight within the range of about 5,000 to 200,000, the spherical microcapsule matrix having an average diameter of 2 to 200 m and an excipient selected from the group consisting of mannitol, sorbitol, lactose and glucose, which particles are produced by in-water drying.

TAP disputes the district court's construction of the claim term "particles containing a water-soluble drug, the particles being dispersed in a spherical microcapsule matrix." Relying on language from the specification and testimony by OWL's expert, Dr. Pitt, the district court construed the term "particles" in that limitation to contain both a drug and a drug-retaining substance.

We agree with the district court's construction. While nothing in the claim specifically refers to a "drug-retaining substance,"

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the specification makes clear that the phrase "particles containing a water-soluble drug" must be interpreted as requiring both a drug and some substance in which to retain the drug. As the district court noted, not only do all of the 31 examples in the specification describe the use of particles containing a drug and a drug-retaining substance, but the specification provides that a drug-retaining substance "must be used in sufficient amount to ensure that the initial viscosity of the inner aqueous layer in the water-in-oil emulsion described hereinafter will not be lower than about 5000 centipoises ...." '663 patent, col. 4, ll. 49-52 (emphasis added). The specification further describes the drug-retaining substance as a benefit of the invention, stating that "since a drug retaining substance is employed, the water-soluble drug can be incorporated in the microcapsule more easily and efficiently than by the conventional drying in solvent technique." Id., col. 10, ll. 11-14. That description is supported by the comparative data found in Table 3 and the accompanying explanation, which show that the drug is more easily incorporated in the microcapsule due to the addition of a drug retaining substance such as gelatin. See id., col. 12, ll. 48-53 ("when the in water drying technique ...is carried out without gelatin ...,the takeup ratio are as low as 1.9 to 6.7% whereas the takeup ratio for the microcapsules according to this invention are as high as 44.0% to 71.5%"). Finally, in describing how the microcapsules are made, the specification provides that "the prolonged release microcapsule of the present invention is made by preparing a water-in-oil emulsion comprising an inner aqueous layer containing said water-soluble drug and a drug retaining substance ...." Id., col. 1, ll. 33-34.

TAP contends that the claims do not require inclusion of a "drug-retaining substance," for two principal reasons. First, TAP argues that the district court's construction is too narrow because the claim employs the word "containing," which TAP asserts has a well-established meaning identical to "comprising." TAP argues that the meaning of "containing" is "having at least the named component" and therefore that "particles containing a water-soluble drug" means that the particles must be composed "either (1) wholly of water-soluble drug or (2) partially of water-soluble drug plus additional ingredients." The word "containing," however, has two possible meanings as applied to the claims at issue in this case: (1) the one TAP suggests, and (2) the one adopted by the district court, i.e., one substance encompassed within another. In light of the two different possible meanings for the term "containing," it was entirely reasonable for the district court to look to the specification as well as extrinsic evidence to determine the manner in which the term was used in the three patents at issue. Intel Corp. v. VIA Techs., Inc., 319 F.3d 1357, 1367 (Fed. Cir. 2003).

TAP's second argument is that the district court improperly relied on the testimony of OWL's expert, Dr. Pitt, in finding that the claimed particles require a drug-retaining substance because the word "containing" is not a technical term and the court therefore should not have resorted to extrinsic evidence to determine the meaning of the term as used in the patents. TAP, however, relies too heavily on the characterization of the word "containing" as a non-technical term. As the district court correctly pointed out, a word describing patented technology takes its definition from the context in which it was used by the inventor. See Anderson v. Int'l Eng'g & Mfg., Inc., 160 F.3d 1345, 1348-49 (Fed. Cir. 1998). While the term "containing" is not a technical term, the term is essential in helping to describe the patented technology. As a result, the term cannot be defined by some ordinary meaning isolated from the proper context, and it was appropriate for the district court not only to consider the intrinsic evidence, but also to consider Dr. Pitt's interpretation of that evidence, both in context and from the perspective of a person of ordinary skill in the art. See Phillips v. AWH Corp., 415 F.3d 1303, 2005 U.S. App. LEXIS 13954, No. 03-1269, slip op. 18-19 (Fed. Cir. July 12, 2005) (en banc).

We therefore uphold the district court's interpretation of the phrase "particles containing a water-soluble drug" to require the presence of a drug-retaining substance along with the drug. TAP does not dispute that, under the district court's claim construction, summary judgment of no literal infringement is proper. Moreover, we agree with the district court that a finding of infringement under the doctrine of equivalents would vitiate an essential limitation of the claim, i.e., the presence of the drug-retaining substance. Because OWL' s product does not infringe the '663 patent, the '021 patent, or the '020 patent, either literally or under the doctrine of equivalents, this court affirms the district court's grant of summary judgment of noninfringement as to those patents.

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2. "particles of titanium dioxide"

Claims 1 and 7-10 contain this term. 4 Plaintiff proposes that this term be construed broadly as "particles that include titanium and oxygen." Chart at 18. Plaintiff argues that this definition is plain on the face of the claim. In its briefing, Plaintiff further refines its proposed construction and explains that the chemical nomenclature of the referenced particles is

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TiO[2], and that the "particles are not limited solely to particles containing titanium and oxygen per se but may additionally include other materials such as coatings." Pl. Brf. at 19.

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4 Claim 22 contains a similar term, "particulate titanium dioxide," which the parties treat in their briefing as being subject to the same construction as "particles of titanium dioxide."

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In support of its proposed construction, Plaintiff notes that the specification expressly states that the "titanium dioxide particles to be used to form the dispersions . . . may be uncoated or coated as is desired." '529 patent, col. 1, lines 61-65. The specification then discloses several exemplary coatings. See col. 1, lines 65-67. The specification further notes that the "particulate material may carry a coating of one or more organic materials" and follows with several exemplary organic coatings. Id., col 2, lines 21-25.

Defendant's proposed construction of the disputed phrase is much more narrow than Plaintiff's construction. Defendant argues that the proper construction limits the particles to those that are "hydrophilic," as opposed to being "hydrophobic." A "hydrophillic" particle is one that is attracted to and thus easily mixes with water (and, conversely, is more difficult to mix with oil), while a "hydrophobic" particle resists mixing with water and is generally more attracted to other hydrophobic materials such as oil. According to Defendant, the proper construction of phrase "particles of titanium dioxide" is as follows: "Hydrophilic particles consisting only of titanium dioxide whose chemical nomenclature is TiO[2], exclusive of any coating. '[P]articles of titanium dioxide' does not include hydrophobically-treated titanium dioxide." Chart 18-19.

In support of its proposed construction, Defendant relies upon the affidavit of its expert, Eric Abrutyn, who explains that the titanium dioxide particles referenced in the '529 patent are inherently hydrophyilic and remain so unless they are put through a hydrophobizing process to make them hydrophobic. Abrutyn Aff. P 13. According to Abrutyn, the '529 patent only mentions hydrophilic pigments and hydrophilic coatings for the particles. Abrutyn Aff. P 18-20. As such, Defendant argues that one skilled in the art would have viewed Plaintiff's patent application as directed to the "trick" of loading hydrophilic pigments in oil. Id. P 21. Consequently, Defendant argues that the claims of the '529 patent would not have been seen as being directed to hydrophobized particles of titanium dioxide.

The intrinsic evidence, however, does not support Defendant's assertions. As an initial matter, it does not support Kobo's claim that the invention of the '529 patent is the "trick" of dispersing hydrophilic particles in oil. As Plaintiff points out, the applicant defined the invention as follows:

> The subject invention is an oil dispersion comprising three essential ingredients: an oil, titanium dioxide particles of a particular size, and an organic dispersing agent for the titanium dioxide. The dispersion as claimed possesses two characterizing features which are (a) the solids content is greater than 40% by weight, and (b) it is substantially transparent to visible light and substantially absorbent to UV light, the latter being defined by reference to a minimal value for the maximum extinction coefficient.

Kobo Ex. D at 109. This description is consistent with the specification and claims. Importantly, the claims themselves do not expressly limit the particles to those that are hydrophilic, and the specification does not mention that the invention is directed to dispersing only hydrophilic particles in an oil carrier. Rather, the claims and specification are clear that the invention relates to dispersions of titanium dioxide comprised of an oil, particles of titanium dioxide having an average size from 0.01 to 0.15 micron and a dispersing agent. '529 patent, col 1, lines 6-8. The dispersion has a solids content that is greater than 40% by weight, and the above combination of ingredients results in a dispersion with certain functional benefits, including being substantially transparent to visible light and substantially absorbent to UV light. Id., col. 1, lines 9-15.

Claim 22 is directed to a method of making this dispersion. The claimed dispersion is prepared by milling the titanium dioxide with a particulate grinding medium along with the oil and dispersing agent. Milling continues until the titanium dioxide particles have an average size of 0.01 to 0.15 micron and the dispersion has obtained a maximum extinction coefficient of at least 40 liters per gram. The focus of the invention is on resulting functional properties with respect to

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visible and UV light, not solving the problems of putting a hydrophilic pigment into oil.

Defendant also claims that limiting the construction of the disputed term to hydrophilic particles is required because the '529 patent applicant expressly disclaimed hydrophobic particles. Among others, Defendant cites Rhodia Chimie v PPG Industries Inc., 402 F.3d 1371 (Fed. Cir. 2005), in which the Federal Circuit affirmed the construction of a claim covering "silicia particulates" to include the patentee's process for producing the particulates. The court found the limitation appropriate because, during patent prosecution, the patentee distinguished "both its product and process claims from [the prior art] and did so by focusing on the necessity of using [its process] to obtain the claimed product." Chimie, 402 F.3d at 1384. In particular, the patentee distinguished a certain prior art reference because that reference did not use a particular step found in the patentee's process. Therefore, according to the patentee, the prior art process was not be capable of "ultimately providing a homogeneous and solid particulate product" as the claims required. Id. at 1384-85.

Case law is clear that statements made during prosecution may affect the scope of the claims. See, e.g., Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282, 1289 (Fed. Cir. 2009) (statements during prosecution may disavow claim scope). Specifically, "a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008) (quoting Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). Indeed, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. However, due to "the inherent ambiguities of prosecution history, the doctrine of prosecution disclaimer only applies to unambiguous disavowals." Dell, Inc., 519 F.3d at 1375.

In the present case, the Court finds that Kobo has not identified any such "clear and unmistakable" disclaimer in the prosecution history. In response to the examiner's first rejection, the applicant undertook to distinguish the prior art upon which the rejection was based. Kobo Ex. D. at 109. The applicant explained that each prior art reference was lacking one or more of the claimed ingredients and/or functional properties of the current invention. Similarly, in responding to a later rejection, the applicant stated that the invention was distinguishable from the cited prior art "based on composition, and these references alone or together do not suggest a dispersion comprising the three ingredients of the Applicant's invention will possess the characterizing features taught."

It is true as Kobo states, that in response to this second rejection the applicant discussed, for example, the hydrophobizing treatment taught by the Shiseido (I), JP 58043912, and Shiseido (III), JP 58062106. Nevertheless, the applicant distinguished this prior art not based upon the presence or absence of any coating that rendered the particles hydrophobic, but rather based upon the claimed ingredients, most notably the dispersing agent. Indeed, this is demonstrated in the prosecution history by the Declaration of Jennifer Lindsay Robb, who conducted a number of experiments to show the examiner that, because it lacked a dispersing agent, the prior art did not achieve the claimed solids content, UV absorbency or visible light transparency. Robb's experiments showed that the invention of the '529 patent worked with both hydrophobically-coated and hydrophillically-coated particles, as well as uncoated particles.

In sum, the selective quotations from the prosecution history cited by Kobo, when read in context and considered with the prosecution history as a whole, fail to establish an unambiguous disclaimer so as to require "particles of titanium dioxide" to be limited to solely hydrophilic particles. Consequently, the Court shall construe the phrase consistent with Plaintiff's proposed construction.

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3. "particles of zinc oxide"

Claims 1, 4, 6, 16, 17 and 26 5 of the '660 patent contain this term. Plaintiff's proposed construction defines this term as "particles that include zinc and oxygen having the chemical nomenclature ZnO that may additionally include lesser amounts of other materials or impurities." Chart at 3. Plaintiff argues that the meaning of this term is plain on its face. As with the similar phrase found in the titanium dioxide patent, Plaintiff argues that the term is not limited to particles containing solely zinc oxide or otherwise limited to only hydrophilic particles. Pl. Brf. at 32 (citing '660 patent, col. 2, lines 5-7 ("The particles to be used to form the dispersions of the present invention may be uncoated or coated as desired.")).

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5 Claim 26 contains the term "particulate zinc oxide."

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Kobo, similar to its position with respect to the '529 patent, argues that the term should be construed as "[h]ydrophilic particles consisting only of the compound zinc oxide whose chemical nomenclature is ZnO. Particles of zinc oxide may additionally include trace amounts of impurities as are normally found in commercially available microfine titanium dioxide [sic] products." Chart at 3. Kobo argues that because the wording used to claim the particles in the '660 patent is identical to the wording '529 patent (and, Kobo argues, the '529 patent was intended to cover only hydrophilic particles), it follows that the '660 patent covers only hydrophilic particles. However, as set forth above, the Court rejects Kobo's assertion that the '529 patent is limited to hydrophilic particles.

Kobo's remaining arguments regarding the construction of "particles of zinc oxide" are similar to many of those Kobo asserted with respect to the phrase "particles of titanium dioxide" in the '529 patent. As with the '529 patent, the Court finds that Kobo has not established that the term "particles" in the '660 patent excludes those that are hydrophobic. Consequently, the Court shall construe "particles of zinc oxide" to mean "particles that include zinc and oxygen having the chemical nomenclature ZnO that may additionally include lesser amounts of other materials or impurities."
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Claim 21

The process according to claim 1, wherein the ladle metallurgy addition comprises particles that pass through the screen having four inch square openings.

The dispute here centers on the phrase "particles that pass through a screen" (emphasis added). The Court agrees with Plaintiff's reading. Plaintiff claims that the verb "pass" refers to particles and that particles does not mean briquettes alone.

Defendant argues that this claim refers to the additive -- something that is added either as a granular, mixture or briquette -- and that is made up of particles (Tr. 42-43). The Court agrees that this claim further refines the metallurgy addition referenced in Claim 1. However, Defendant's explanation that "pass" refers to "addition" is strained. The verb "pass" describes the closest preceding noun: "particles" (Tr. 46). To paraphrase the meaning of this claim, the additive is made up of particles which are of a size small enough to pass through a screen with four inch square openings.
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(G) "remains in particulate form"

When the fluorocarbon polymer is processed under typical processing conditions, the fluorocarbon polymer continue to be well-defined solid pieces and do not lose their solid boundaries.
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c. "particulate material"

The term "particulate material" presents the same set of circumstances as the term "filler." MacDermid proffers this construction: "A fine powder. The particulate matter may be colorless and transparent or have color and be nontransparent." (MacDermid Opening Br. at 41.) Yet again, DuPont contended for the first time at the Markman hearing that no construction

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is necessary because it does not assert the specific Markush member containing this term and because the term "particulate material" would be readily understood by a person of ordinary skill in the art. (Tr. at 48-50.) DuPont also attacks the proffered construction as improperly reading specification examples regarding color and transparency into the term's definition. (Id.) MacDermid asserts that this term must be construed in order to assess the validity of the overall Markush claim and that its own proposed construction is mandated by the specification itself. (MacDermid Opening Br. at 41; Tr. at 175-77.)

The Court reaches the same conclusion as to "particulate material" that it does with respect to the proper construction of the term "filler": there is no need for a construction at this point.The Court also notes that the parties themselves appear to concur that the specification explicitly defines "particulate material" as a "fine powder." ('859 Patent at col. 14, lines 3-4; MacDermid Opening Br. at 41; Tr. at 50.)
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Claim 1 of the '937 patent is an independent claim that provides as follows, with the court's claim construction of disputed terms bracketed and underlined:

A process for producing a moisture absorbing desiccant entrained polymer, said process comprising:

causing a polymer to assume a molten state, said polymer acting as a moisture barrier in a solidified state;

blending a desiccating agent into the polymer so that the desiccating agent is distributed within the polymer;

blending a channeling agent [a hydrophilic material (having a greater moisture transmission rate than the polymer based material) that is melted and forms passages throughout a polymer base] into the polymer so that the channeling agent is distributed within the polymer thereby creating a blended mixture; and solidifying the mixture so that the channeling agent forms passages [solid pathways that extend throughout the polymer base from the exterior surface of the plastic structure into its interior] in the mixture through which moisture is communicable to desiccating agent entrained within the mixture.
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F. "Patient diagnosed with Alzheimer's disease"

The parties' disagreements with respect to the claim term "patient diagnosed with Alzheimer's disease" largely rehash the disputes already discussed with respect to "Alzheimer's disease." Here, again, I believe that the accepted diagnostic criteria should single out the DSM-III-R, which would have been relied on by one having ordinary skill in the art, but should not be limited to the diagnostic criteria listed in this single reference, given the evidence that those having ordinary skill in the art would have consulted other sources as well. With respect to the "plaques and tangles" issue, because a determination of whether a patient's brain contained such "plaques and tangles" was not part of the accepted diagnostic criteria - and, by contrast, could only be accomplished post-mortem or by a risky, inadvisable brain biopsy (D.I. 224 at P 23) - there is no basis to refer to "plaques and tangles" in a term focused on diagnosis in a live patient, which is how this term is used in the patent. Accordingly, I recommend that "patient diagnosed with Alzheimer's disease" be construed as "a live patient diagnosed with dementia of the Alzheimer's type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R."
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L. "Patient in need thereof" and "patient in need of such treatment"

Plaintiffs argue that these last two "patient" terms do not require construction as they are unambiguous and should be construed according to their plain and ordinary meaning. Defendants, on the other hand, propose these constructions: "A

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patient in whom the need for prevention or treatment of cerebral ischemia is recognized and appreciated, and the adamantane derivative is administered with the intent of preventing or treating cerebral ischemia" (claims 1 and 14) and "A patient in which the need for treatment of imbalance of neuronal stimulation is recognized and appreciated, and the adamantane derivative is administered with the intent of treating the imbalance of neuronal stimulation" (claim 17). Defendants' constructions would, improperly, require that the patient be diagnosed with and treated for cerebral ischemia (which Defendants construe as a disorder relating to blood supply) or imbalance of neuronal stimulation, in addition to being diagnosed with and treated for Alzheimer's disease. This is not a proper construction, given that all of the independent claims (1, 14, and 17) refer to a "patient diagnosed with Alzheimer's disease," yet none refer to a "patient diagnosed with cerebral ischemia" or "a patient diagnosed with imbalance of neuronal stimulation." Thus, I agree with the Plaintiffs that "patient in need thereof" and "patient in need of such treatment" have a plain and ordinary meaning readily understood even to a lay judge and do not require any construction. See Phillips, 415 F.3d at 1304.
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E. "Patient in need thereof" and "patient in need of such treatment"

The Magistrate Judge recommends that the term "patient . . . in need thereof" as that term is used in claims 1 and 14 and the term "patient . . . in need of such treatment" as that term is used in claim 17 be given their plain and ordinary meaning. (D.I. 373 at 28-29.) The court agrees that these terms are clear and unambiguous as they are and sees no need to expand further on the Magistrate Judge's reasoning. Thus, for the reasons set forth in the Report and Recommendation, the court will adopt the Magistrate Judge's construction for these terms.
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2. "The"

The word "the" in "shows the peaks" is significant primarily because the position advanced by Abbott and Astellas essentially reads the word "the" out of the phrase entirely, thereby rendering "shows the peaks" identical to "shows peaks." Such a reading would seem to be unacceptable because claims, no less than statutes, should be interpreted to avoid superfluity. See Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362, 1370 (Fed. Cir. 2000). Moreover, definite articles, like "the," which particularize the subjects they precede, cannot be read as if they are indefinite articles, like "any." NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1306 (Fed. Cir. 2005) (citing Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1356 (Fed. Cir. 2003). However, after a careful reading of the context in which "shows the peaks" is used, the Court is unable to ascribe any significance to the word "the" which would permit the Court to assign material limitations to the word "peaks."

The phrase "shows the peaks" appears in the following sentence from Claim 1 of the '507 patent: "Crystalline [cefdinir] which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern." '507 Patent col.16 ll.13-17. A fair reading of the position advanced by Abbott and Astellas would allow them to allege infringement whenever any peaks (which are defined below) exist at the PXRD angles listed in Claim 1, so the phrase "shows the peaks" could be replaced, under their claim construction, with "shows peaks." Lupin argues that "the" cannot be rendered meaningless, and that "the peaks" must refer to some particular peaks. (See Supplemental Claim Construction Br. of Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Supplemental Br.") at 4-8.) Those peaks, according to Lupin, are the most intense peaks displayed in Figure 1 and in the charts found in columns 12 and 14 of the '507 patent's specification. Id. As Lupin points out, the most intense peaks in those displays correspond directly to the PXRD angles listed in Claim 1. Accordingly, Lupin argues that the term "the peaks" requires some absolute or relative intensity limitation on the peaks that would be found at the PXRD diffraction angles listed in Claim 1.

Abbott and Astellas argue that "the" in "the peaks" has no such significance. To the contrary, Abbott and Astellas argue that "the" is required "for grammatical accuracy and consistency, since the claim recited 'crystalline [cefdinir] which shows the peaks . . . shown in the following table.'" (Abbott Laboratories' and Astellas Pharma's Mem. Supporting Their Proposed Construction of the Word "Peaks" ("Abbott and Astellas Supplemental Br.") at 11 (emphasis in original).) For that reason,

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Abbott and Astellas contend that "the" may not be used as a vehicle for importing intensity requirements on the peaks listed in Claim 1.

While the Court does not agree precisely with the argument made by Abbott and Astellas, it is not clear that "the" is as significant as Lupin contends. The reading given by Abbott and Astellas makes little sense because what is "shown in the following table" is not "the peaks" but, rather, "the diffraction angles." Therefore, "the peaks" is not required grammatically for the purposes cited by Abbott and Astellas. Nevertheless, it is not clear that "the peaks" does not refer simply to those peaks which exist at the diffraction angles listed in Claim 1. Therefore, the significance of "the" is not clear enough to require the limitations proposed by Lupin. Moreover, Astellas can be assumed to have intentionally excluded intensity limitations from Claim 1 because it included such limitations in parts of the specification and in the Japanese priority application. See, e.g., '507 Patent col.12 ll.52-68, col.14 ll.1-17; '199 Application col.1 ll.16-38, col.2 ll.7-34. Given that inferred intent, the meaning of "the peaks" is certainly not clear enough to justify importing intensity requirements into Claim 1. Accordingly, the only limitations on the word peaks are those explained below.

3. "Peaks"

The definition of "peaks" is critically important because the invention in Claim 1 is defined in terms of its peaks. The parties have proposed vastly different constructions of the word "peaks." Abbott and Astellas define "peaks" as "the locations of all numerical apexes of X-ray intensity at particular diffraction angles." 17 (Abbott and Astellas Supplemental Br. at 3.) Lupin, on the other hand, argues that "peaks" refers to the most intense features in the PXRD pattern, such that Crystal A, as described in the '507 patent's specification, can be readily identified and distinguished from other crystals. (See Lupin Supplemental Br. at 4-8.) Neither definition is appropriate, however, given the significance of "peaks" in the '507 patent.

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17 Abbott and Astellas also describe a "peak" as "the apex of intensity for a given diffraction angle." (Abbott Laboratories' and Astellas Pharma's Resp. Mem. Supporting Their Proposed Construction of the Word "Peaks" ("Abbott and Astellas Supplemental Resp.") at 7.)

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The word "peaks" is used only twice in the '507 patent. It is used first in the specification, where Crystal A is defined according to its "distinguishing peaks" located at the diffraction angles listed in column 1 of the specification. '507 Patent col.1 ll.51-62. As discussed above, those same angles are used to define the invention of the '507 patent (Crystal A) in Claim 1, where the word "peaks" occurs for the second time. Id. col.16 ll.15-27. The word "peaks" is not given any definition within the context of Claim 1, but its use in the specification offers some guidance for how it should be construed within the context of the claims. Specifically, the only "peaks" listed in the '507 patent correspond with distinctive features of significant intensity, which, as indicated by Figure 1, have obvious rises and falls before and after reaching a single apex. See, e.g., id. col.12 ll.51-68, col.14 ll.1-17, fig. 1. For example, in Claim 1 and column 1 of the specification, the PXRD angles listed correspond with the seven most intense and pointed features in Figure 1 of the patent's specification. Similarly, the charts displayed in columns 12 and 14 of the specification, which mathematically describe "peaks," list no peak smaller than eight percent of the tallest listed peak's intensity. 18 Thus, the construction of "peaks," as used in Claim 1, certainly cannot conflict with those descriptions of "peaks" in the '507 patent's specification.

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18 Abbott and Astellas acknowledge that the charts in columns 12 and 14 list "peaks," even though the word "peaks" is not used in connection with those charts. (See Abbott and Astellas Br. at 15.)

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With the specification and other considerations, which are discussed below, in mind, each party's definition of "peaks" presents problems. First, the definition proposed by Abbott and Astellas would allow for peaks that are nothing like the features displayed in Figure 1. Indeed, their definition eviscerates any limiting feature of the word "peaks." If a peak is merely the numerical apex at any given diffraction angle, then a "peak" would exist at each and every diffraction angle in a PXRD pattern (so long as that measured intensity is above the so-called background "noise" -- a concept discussed below). 19 Such an interpretation of "peaks" is nonsensical. Not only is it totally unrelated to the "peaks" identified in the

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specification, but it would fail to describe "distinguishing" features at all.

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19 The definition of "peaks" submitted by Abbott and Astellas does not incorporate any concept of "noise," but a fair reading of the briefs submitted by Abbott and Astellas, combined with their proffered definition, indicates that a peak could exist only if the measured intensity at a particular diffraction angle rises above the so-called "noise." (See Abbott and Astellas Supplemental Resp. at 3.) Nevertheless, the '507 patent simply does not support a reading of "peaks" under which a "peak" would exist at every point of measured intensity above the background noise, and nothing in the record indicates that a person of ordinary skill in the art would accept such a definition of "peaks."

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Lupin's definition suffers from a different problem. Lupin urges the Court to impose some PXRD intensity limitation on the word "peaks" as used in Claim 1. However, Claim 1 does not include any explicit intensity limitations, in contrast both to the charts in columns 12 and 14 of the specification and the claims in the Japanese priority application. '507 Patent col.12 ll.52-68, col.14 ll.1-17; '199 Application col.1 ll.16-38, col.2 ll. Moreover, nothing in the patent indicates that Crystal A is claimed only in its pure form. As even Lupin acknowledges, mixing Crystal A with other materials might cause the peaks featured in Figure 1 to have reduced absolute intensity in a PXRD pattern. (See Lupin Resp. Br. at 11.) Additionally, the record does not permit the conclusion that even the relative intensities of those peaks (their intensities with respect only to one another) would be unaffected if Crystal A were mixed with other materials. Therefore, any intensity requirement, whether absolute or relative, might unjustifiably limit the scope of the '507 patent to cover only the pure form of Crystal A.

Because the definitions advanced by the parties are each deficient in some way, neither can be adopted. Even though those definitions are largely unhelpful, the expert reports submitted by the parties, along with the use of "peaks" in the '507 patent, provide a sufficient basis on which to construe the term "peaks." Indeed, the experts appear to be in general agreement about some basic features that signify a "peak" in a PXRD pattern. Dr. Atwood, the expert employed by Abbott and Astellas, says that peaks are defined by an apex, regardless of whether a peak has a broad or narrow base. (See Third Atwood Decl. P 8.) Dr. Atwood also offers a graphical representation of a PXRD pattern which displays, visually, the sorts of features he considers to be peaks. (Id. P 9.) Those peaks, like the peaks shown in Figure 1 of the '507 patent, are characterized by having a single apex surrounded on each side by a lower intensity value. Dr. Atwood is careful to point out that two "peaks" may share the same base, but he explains that they are still two separate "peaks" so long as they are distinguishable by their different apexes (surrounded on each side by a lower intensity value). (See id. PP 9-11.)

Dr. Atwood's description of peaks basically comports with the definition forwarded by Dr. Eli Shefter, Lupin's expert. Dr. Schefter explains that "[i]n its most basic sense, a 'peak' is defined as the highest point in a series where there are simultaneously visible lower points surrounding the highest point." (Shefter Decl. P 17.) While he expands on that simple definition for purposes of accuracy, his definition at least requires an apex that is surrounded on each side by a point of lesser intensity. Like Dr. Atwood, Dr. Schefter also offers graphical depictions of peaks that are quite similar to the peaks seen in Figure 1 of the '507 patent. (Id. at PP 24-25.)

In perspective of the basic agreement between the experts from each side, the use of the word "peaks" in the '507 patent, considerations respecting the intensity of a "peak," and the way in which "peaks" has been discussed by the parties in their papers and at oral argument, the Court concludes that a "peak" corresponds at least to a PXRD angle with an intensity measurement that is immediately preceded by and immediately followed by a PXRD angle with a smaller intensity measurement. However, because of errors inherent in PXRD testing, that definition of "peaks" requires further refinement.

The parties and their experts have each concerned themselves with PXRD measurement errors commonly referred to as "noise." (See id. P 20; Fourth Atwood Decl. PP 4-5.) Dr. Atwood describes "noise" as the random signal variation that is seen in the baseline of a PXRD pattern. (Fourth Atwood Decl. P 4.) Dr. Shefter describes "noise" as "measurement errors" that result in "some random scattering" in a PXRD pattern. (Shefter Decl. P 20.) The parties each agree that peaks must, at the very least, rise above this so-called "noise." (See Lupin Supplemental Br. at 5; Abbott and Astellas Supplemental Resp. at 3.) Therefore, a definition of "noise" is required. Based on the expert descriptions of "noise" and the use of "noise" by the parties in their papers and at oral argument, the Court finds that the "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test.

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Accordingly, the Court holds that a peak exists at a PXRD angle that corresponds to an intensity measurement greater than measurements attributable to "noise," as defined above, if that angle is immediately preceded by and immediately followed by a PXRD angle with a lower intensity measurement.

* * *

CONCLUSION

For the reasons set forth above, Claims 2-5 of the '507 patent are construed as product-by-process claims. The '507 patent's disputed claim terms have the following definitions:

(1) "Crystalline" means "Crystal A;"

(2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;

(3) "peaks" is the plural of "peak;" a "peak" exists at a powder X-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;
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2. "Material, peculiarly responsive to a particular form of radiant energy not normally present in ambient light in amounts sufficient to cause said material to discolor." Used in Claim 1.

Flashmark suggests that no construction is necessary. In the alternative, Flashmark proposes "a material that responds distinctively to an intensity of light in a range of wavelengths, or of heat, which is not normally encountered in ordinary use in amounts sufficient to cause said material to discolor." GTECH has suggested:

a material, including an infra-red absorbing dye, formulated to dramatically enhance sensitivity to radiant energy and to reduce the amount of time and energy required to cause the material to become visible in response to radiant energy in infrared wavelengths, in comparison to dry silver materials. 5

A construction of this term requires a definition of "radiant energy," which is addressed above. The court must also construe the "ambient light" in which the "radiant energy" is not normally present.

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5 In the responsive brief, GTECH suggested: "a material including an infra-red absorbing dye, formulated to dramatically enhance sensitivity to radiant energy and to reduce the amount of time and energy required to cause the material to become visible in response to wavelengths of radiant energy outside the visible spectrum in the range of about 750-950 nm, and at intensity levels not normally encountered in ordinary use, namely about 50 ergs per square centimeter."

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a. Use of Term in Claims and Specification

Claim 1 describes the material as being responsive to radiant energy that is "not normally present in ambient light in amounts sufficient to cause said material to discolor." '153 patent, col. 7, 11. 22-23. It does not place any further restrictions on the type of material that can make up the article.

The specification states that the "material" is normally invisible, which means that the "material is only slightly visible or

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visible as background, and does not interfere with the genuinely visible markings on the coupon." '153 patent, col. 3,11.25-30. "The material 13 may be responsive to radiant energy such as heat or light. Upon being exposed to heat or light energy not normally encountered in ordinary use, the material 13 will become visible." '153 patent, col. 3, 11. 33-37.

In a preferred embodiment, the specification states that the "presently preferred material 13 is a photosensitive material formed by a mixture of a dry silver material and an infrared absorbing dye." '153 patent, col. 3, 11. 42-44. "The preferred materials exhibit high absorption of light wavelengths in the approximate range of about 750 nanometers to 950 nanometers." '153 patent, col. 3, 11. 61-63.

This preferred embodiment is seen in Claims 5 and 6, which are dependent on Claim 1. Claim 5 states: "The article of claim 4 wherein said range of light wavelengths covers about 750 nanometers to about 950 nanometers." Claim 6 states: "The article of claim 5 wherein said material comprises a mixture of dry silver and infra-red absorbing dye."

GTECH's proposal, therefore, is based upon limitations in a preferred embodiment and the dependent claims. In general, an independent claim is presumed to be broader in scope and to encompass the dependent claim. See Phillips, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.")

Flashmark argues that in defining this term, the words "ambient light" be changed to "ordinary use," relying upon a single appearance of that phrase in the specification at Col. 3, 1. 36. If "ambient light" could just be changed to "ordinary use" then "radiant energy" would be more likely to refer to "heat" in forms other than electromagnetic wavelengths. The patentee could have picked any words he wanted for the claims, but he chose to add "ambient light," not "ordinary use," to Claim 1 to overcome the Examiner's initial rejection. Amendment, 6/ 25/1991 p. 2, FLASH 0000078 in GTECH's Ex. E [Doc. # 107, Attach. # 11, p. 18 of 76]. And, in distinguishing prior art while trying to overcome that rejection, the patentee stressed that prior inventions discolored in ambient light. Amendment, 6/25/1991, pp. 4-5, FLASH 0000080-81 in GTECH's Ex. E [Doc. # 107, Attach. # 11, p. 20-21].

A further indication of what the patentee intended by the use of "ambient light" is found in the same amendment: "As stated in the description, color formation is caused in DYLUX by UV found in daylight or artificial light which contains UV. To prevent discoloration in ambient light the DYLUX paper must be deactivated . . . ." Amendment 6/25/1991, p. 8, FLASH 0000084 in GTECH's Ex. E [Doc. # 107, Attach. 11, p. 24] (emphasis added). The court need not consider at this point whether the "ordinary use" term is a disclosure of an invention in the specification which was not claimed, and so is donated to the public. Johnson & Johnston Assoc. V. R.E. Serv. Co., 285 F.3d 1046, 1054 (Fed. Cir. 2002) ("[W]hen a patent drafter discloses but declines to claim subject matter, . . . this action dedicates that unclaimed subject matter to the public.").

At the hearing the court discussed a proposed definition, together with numerous changes suggested by the parties. In the end, Flashmark would not agree to a construction that defined "ambient light" as anything but "ordinary use." For the reasons noted above there is no basis to adopt "ordinary use," especially when the patentee chose not to use the phrase in amending the claim.

Flashmark's expert stated that while "direct" light would be "focused," ambient light would include "normal lighting" in a room and direct sunlight outdoors, or "conditions of the environment without that presence of the directed light." This is a more expansive definition of ambient light than that suggested by the court, and agreed to by GTECH. However, it is not outside the ambit of the use of the term in the specification and in the prosecution history references set out above, and it comports with its use in some dictionaries.

The court was concerned about imposing a limitation requiring that the "material" of the invention not discolor even in direct sunlight, as will a newspaper and many other papers. However, Flashmark insisted that "ambient light" included direct sunlight, perhaps because their idea of "ordinary use" includes using the articles in direct sunlight. The court is not adverse to adopting this concept as it is reasonable and narrows, rather than expands, the scope of the claim. This term will be construed as follows:

Material peculiarly responsive to a particular form of radiant energy not normally present in ambient light in amounts sufficient to cause said material to discolor means "a substance which darkens or changes color when exposed to radiant energy (as previously defined by the court) of a type or intensity (or both) that is not ordinarily present in sunlight or normal

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indoor lighting."
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B.

Merck contends that the district court erred in construing the asserted claims of the '525, '997, and '237 patents to embrace both linear and cyclic RGD peptides. Representative claim 8 of the '525 patent reads:

A substantially pure peptide including as the cell-attachment-promoting constituent the amino acid sequence Arg-Gly-Asp-R wherein R is Ser, Cys, Thr or other amino acid, said peptide having cell-attachment-promoting activity, and said peptide not being a naturally occurring peptide.

The '237 patent claims methods of controlling Arg-Gly-Asp mediated attachments of animal cells to substrates. The '997 patent claims recite methods of altering cell attachment activity by bringing cells into contact with peptide RGDX.

In construing claim 8 of the '525 patent, the district court concluded that the claim "imposes no limitations on the three-dimensional structure of the peptides at issue." The district court found the claim's terms, in light of the specification, fully support Integra's contention that claim 8 embraces RGD peptides of any linear or cyclic structure.

Because the patents do not expressly refer to cyclic configurations, Merck would limit the term "peptide" to linear peptides. As the district court noted, however, the term "peptide" is understood in the art to represent "two or more amino acids covalently joined by peptide bonds." By this definition, the general term "peptide" encompasses peptides of differing structural forms. The '525 patent specification refers to RGD peptides as having carboxyl and amino termini without expressly discussing cyclic RGD peptide structures. However, the specification as a whole embraces the claimed RGD peptides in both cyclic and linear conformations. The preparation of cyclic peptides was well known to those of skill in the art in 1984. As the district court correctly noted, the asserted patents need not teach that which is already known. The '525 specification references a journal article authored by Merrifield, which discloses the general knowledge of skilled artisans in making cyclic peptides at the filing date of the '525 patent. '525 patent, col. 3, ll. 60-64. The record also includes a declaration from Dr. Dedhar that the Merrifield method makes cyclic peptides. Dr. Dedhar stated that a skilled artisan "would have known from reading the patent specification in 1985 that this recognition site exists on all peptides that contain the Arg-Gly-Asp sequence, including cyclic peptides or peptides containing D-form amino acids."

Merck also contends that the patent applicant, while arguing the patentability of claims to cyclic peptides in a later-filed, unrelated application, admitted that the '525 and '997 patents do not teach cyclic peptides. Specifically, the applicant distinguished the claims of unrelated U.S. Patent No. 5,880,092 to Ruoslahti et al. (the '092 patent) over U.S. Patent No. 4,614,517 (the '517 patent), a divisional of the parent of the '525 and '997 patents. In essence, Merck would limit the reach of the '517 patent due to statements the applicant made in another patent application, not in the application leading to the '517.

The Patent and Trademark Office cited the '517 patent as prior art against the Ruoslahti '092 patent. During prosecution of the '092 patent, the applicant stated:

The Examiner argues that the generic peptide taught by Ruoslahti et al. anticipates the claimed peptide. . . . The reference does not disclose a subgenus or species from which a subgenus of peptides can be fashioned. As a result, one skilled in the art would not immediately envisage the claimed peptide because of the very large number of peptides encompassed by the generic teaching of this reference. . . . The reference does not suggest cyclizing a peptide to conformationally stabilize it. As a result, one skilled in the art would not immediately envisage the claimed peptide because the reference does not teach a cyclic Arg-Gly-Asp peptide.

According to Merck, this statement limits the term "peptide" in the '517 patent to non-cyclic structures. In the first place, of course, the '092 patent prosecution does not directly limit the '517 patent. See Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1104-05, 62 USPQ2d 1545, 1550 (Fed. Cir. 2002) (stating that as between two patent applications sharing an inventor and the same assignee, but having no formal relationship, "the relationship, if any, between the '4,397,839 and '4,338,301 patents

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is insufficient to render the particular arguments made during prosecution of the '301 patent equally applicable to the claims of the '839 patent"). Those comments arise in a context different from the patentability of the '517 patent. Moreover, the above statement loosely describes the patentee's understanding of the '517/'525/'997 specification, but does not definitively limit the scope of the Integra inventions. These comments in the '092 prosecution evince the patent applicant's understanding that the '525 specification generically teaches "a very large number of peptides." The applicant notes that one of skill in the art would not "immediately envisage" conflict with the '092 invention. This characterization does not compromise the scope of the Integra inventions. The '525 patent is a genus patent. Such genus patents do not estop the applicant from later filing an improvement patent, such as the '517, to claim species with particularly useful properties. See In re Borah, 53 C.C.P.A. 800, 354 F.2d 1009, 148 USPQ 213 (CCPA 1966). Accordingly, Merck's reliance on this ambiguous and unrelated prosecution history is misplaced, as it does not limit the asserted claims to linear peptides.

Thus, the specification of Integra's invention does not limit the term "peptide" to only a linear structure. As the record indicates, the patentee discloses to those skilled in the art both linear and cyclic peptides. The district court correctly construed the term to have its full ordinary meaning in the art.
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"Percentage of body fat"

This term appears in Claim 13 of the '624 Patent. GNC's proposed construction of the term as "body fat as calculated from the sum of the thickness of the triceps, subscapular and chest skinfolds" reads a limitation into Claim 13 from the measurement protocol used in Example 5 of the specification. See '624 Patent, col. 11:20-43. Example 5 describes a study evaluating the anabolic effect of CP in male subjects. The study's description identifies the methodology used to measure the percentage of body fat in subjects. However, GNC cites no evidence demonstrating that persons of ordinary skill in the art would interpret "percentage of body fat" to exclusively mean a value derived from that methodology.

Likewise, GNC cites no evidence from the prosecution history that the patentees intended to limit the term to a value derived exclusively from that methodology. Conversely, Nutrition 21 cites evidence from the prosecution history that the inventors defined the percentage of body fat in terms of its inverse relationship to lean body mass; the prosecution history, in turn, cited the specification as support for that relationship. Sept. 1991 Amendment at 4; see '624 Patent, col. 11:39-43. The term's inclusion of the word "percentage" plainly indicates that the term refers to a portion of a greater whole. That greater whole is body mass. Therefore, the Court adopts Nutrition 21's proposed construction and construes "percentage of body fat" to mean "the percentage of body mass that excludes the lean body mass fraction."
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3. Perforating

The next claim term at issue is "perforating." AVI construes perforating to mean using any device that creates "channels" in the foam, which channels may be any cross-sectional shape, including rectangular. Dow does not disagree with that definition insofar as it goes; however, it seeks to add a functional limitation that the channels formed must "allow accelerated release of the blowing agent so that the cure time is substantially reduced."

As I have already noted, accelerated release is to be read into the claim to the extent stated above. Accordingly, I construe "perforating" to mean using any device that creates "channels" in the foam, which channels may be any cross-sectional shape, including rectangular, that allow for the accelerated release of a blowing agent.
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(E) "Perfluorinated Cure Site Monomer which includes a functional group which permits crosslinking of the terpolymer"

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A fluorinated molecule which is incorporated into the terpolymer as a third monomer, which contains a functional group where crosslinking occurs, which can be any functional group including hydrogen.
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(D) "perfluroalkyl vinyl ether"

Perfluoro alkyl vinyl ether (PAVE) has the meaning as reflected in the monomer of structure (II) in the terpolymer where no hydrogen atoms are present, and where the alkyl ether chain (O-R[f]) may contain one or more oxygen atoms.

[SEE ILLUSTRATION IN ORIGINAL]
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(B) "Perfluoroelastomer"

Perfluoroelastomer means an amorphous polymer of one or more perfluorinated monomers being substantially free of hydrogen substituents.
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1. Safety, Efficacy, Stability, and the Construction of "Perfusion"

The court was not asked to construe "perfusion" at the claim construction phase, since the parties indicated in theirjoint claim chart that they had agreed to a construction of this term. The parties' proposed construction of perfusion was "a solution suitable for infusion into patients including at least active pharmaceutical ingredient and an aqueous infusion fluid such as physiological saline or glucose." (D.I. 44 at 3.) The parties later realized, however, that there had not been a meeting of the minds on the meaning of the phrase "suitable for infusion into patients" in their agreed construction. The defendants filed a motion in limine seeking to preclude the plaintiffs' experts from testifying at trial as to the construction of "perfusion." (See D.I. 272.)

At the pretrial conference, the court heard argument on this motion and indicated that it would hear testimony at trial as to the meaning of term "perfusion." The court now recognizes that its decision was based on a misapprehension as to the source of the phrase "suitable for infusion into patients." The parties' lengthy discussion at the pretrial conference regarding the meaning of that phrase caused the court to believe that the phrase appeared either in the claim itself or in a construction that had been adopted as part of the court's Markmanorder. In reality, however, "suitable for infusion into patients" appears nowhere in the patent or in the court's order. In effect, the parties are not asking the court to construe "perfusion" or clarify a construction that appears in the court's Markman order; rather, they are asking the court to construe a phrase that appears in the parties' claim construction chart.

Specifically, the plaintiffs' argue that the court should impose limitations for safety, efficacy, and stability on claim 5 of the '561 Patent (the only asserted claim including the word "perfusion") because of the appearance of "suitable for infusion into patients" in the parties' chart.5 Of course, the parties' proposed constructions do not bind the court. Consequently, the court need not consider arguments that stem solely from the parties' proposed constructions, even if the parties themselves thought they had agreed on a construction. The parties did not propose alternative constructions of the term "perfusion" at trial, nor are proposed constructions included in either of the parties' post-trial briefs. Instead, the parties' arguments before and during the trial focused on whether the term "perfusion" includes theplaintiffs' proposed limitations relating to safety, efficacy, and stability.6

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5 See, e.g., D.I. 289 at 2 ("Hospira's proposal is clearly at odds with any rational understanding of the phrase 'suitable for infusion into patients.'"); D.I. 383 at 8 ("At the Pretrial Conference, it became apparent that the parties did not have a common understanding as to what it meant to be "suitable for infusion into patients . . . .").

6 Neither the claims nor the specification of the '561 Patent mention the terms "safe," "effective," or any derivatives thereof. The specification does indicate that the claimed perfusion was physically stable for at least 8 hours, but nothing in the specification or otherwise suggests that a solution with less than 8 hours of stability cannot be a "perfusion." The court will not import this statement from the specification to the claims so that it imposes a general limitation on what solutions qualify as "perfusions." See, e.g., Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc., 261 F.3d 1329, 1338 (Fed. Cir. 2001) ("While it is true that claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does notfollow that limitations from the specification may be read into the claims . . . .") (internal quotation omitted).

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Based on the evidence presented at trial, the court concludes that a person of ordinary skill in the art reading the term "perfusion" in the context of the claim would not understand that term to include the plaintiffs' proposed limitations. At the formulation stage, researchers simply cannot know whether a perfusion will be sufficiently safe and effective to be useful in clinical settings. Indeed, this is why clinical trials are necessary before patented pharmaceutical compositions can be marketed to the general public.7 Under the plaintiffs' proposed construction, a formulator could not know whether his solution was a "perfusion" — and therefore whether it infringed claim 5 — until after clinical trials demonstrated that the solution was sufficiently safe and effective. The court concludes that this is neither true of the term "perfusion" as it is generally used nor of the term as it was used in claim 5.8

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7 See, e.g., Tr. 926:25-927:3 (Dr. Myrdal describing how a prior art formulation "worked from a solubility perspective . . . That's what I'm worried about [with] my formulation.It's the chemistry that we're doing. What happens to it afterwards, that's a regulatory affairs issue").

8 Despite the fact that the word "perfusion" only appears in claim 5, Dr. Park seemed to blur this issue at trial by arguing that all five asserted claims of the patents-in-suit require safety, efficacy, and stability. (See Tr. 1492:3-11.) Dr. Park's attempt to impose these limitations on all asserted claims is emblematic of the plaintiffs' failure to start with the actual language of the claims in many of its arguments concerning the scope of the asserted claims.

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The court agrees with Dr. Myrdal, who explained that a "perfusion," as that term is used in pharmaceutical composition claims, is simply an injectable solution containing the active pharmaceutical ingredient and an aqueous infusion fluid.9 The word "perfusion" applies to any such solution, regardless of whether later testing and use reveals the composition to be stable for less than eight hours (which is the plaintiffs' proposed cutoff point for stability), unacceptably toxic to patients, or insufficiently effective in treating the condition it was designed to treat. (See Tr. 929:9-21.) Dr. A. Hilary Calvert agreed, notingthat this definition is consistent with the NCI definition of the related term "infusion" ("a method of putting fluids including drugs into the bloodstream"). (Tr. 1031:24-1032:22; HTX 357, at 17 (NCI Glossary).)

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9 In the asserted claims, a perfusion is formed by diluting a "stock solution" as defined in the court's claim construction order with the aqueous infusion fluid. (See, e.g., Tr. 929:9-16; 1212:16-1213:1; 1214:14-18.) A perfusion is distinguished from other injectable pharmaceutical solutions in that it is administered intravenously rather than through, e.g., an intramuscular or subcutaneous injection. This does not mean, however, that for the purposes of determining invalidity, a person of ordinary skill in the art — which, in this case, is a formulator rather than a clinician (See section III.C.2, infra) — would ignore prior art injectable cancer drug formulations that were administered by a route other than intravenous infusion.

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The plaintiffs' witnesses also seemed to recognize that the word "perfusion" is not generally understood to include the limitations the plaintiffs assert. The '470 patent used the term "perfusion" to describe a docetaxel formulation even before Sanofi "determined whether docetaxel would be safe and effective," yet plaintiffs' witness Dr. Kinam Park did not dispute that this "was a proper use of the word perfusion." (Tr. 1493:21-1494:12.) Similarly, Dr. Howard Burris acknowledged that Taxol is a "perfusion" even though it has "caused death" and "sometimes . . . does not make a difference" in treating a patient's cancer. (Tr. 236:2-18.)

Consequently, the court concludes that the claims do not include limitations relating to safety, efficacy, and stability other than the two explicit limitations that actually appear in the claims: 1) the asserted claims of the '561 Patent require that the injectable solution must be "capable of being injected without anaphylactic or alcohol intoxication manifestations being associated therewith;" and 2) all asserted claims require that the docetaxel be "dissolved" in polysorbate 80 and (in the case of the '561 Patent) ethanol.10 The court will not shoehorn the plaintiffs' proposed limitations into the claims based on the parties' construction of a single term in a single claim. Consequently, the court rejects the plaintiffs' construction of "perfusion" and their proposed limitations for safety, efficacy,and stability.

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10 The "dissolved" limitation does not require that the resulting composition be stable for any period of time after the initial dissolution is complete, and certainly not for eight hours, as the plaintiffs argue. The plaintiffs note that the specifications of the patents-in-suit state that "the new perfusions are stable from a physical standpoint, that is to say no precipitation phenomenon is seen to appear within approximately 8 hours." '561 Patent 2:43-45. See also '512 Patent 3:42-46. It is axiomatic, however, that courts should not import limitations into the claims from the specification. See, e.g., Abbott Laboratories v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009); Kara Technology Inc. v. Stamps.com Inc., 582 F.3d 1341, 1347-48 (Fed. Cir. 2009). But the plaintiffs cite no basis for importing this description as a limitation on the claims beyond the mere presence of the word "perfusion," which only appears in one of the five asserted claims. Even for that claim, the patent gives no indication that the word "perfusion" should be limited by that description. Consequently, the court will not import a stability limitation into the claims.

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In its first objection, Gore has cited paragraph 55 of the Report wherein the Special Master recommends that "all claims mentioning 'ingrowth' in the body or the whereby clause require that the ePTFE structure, at a minimum, allows fibroblasts and red blood cells to enter the pores of the node and fibril microstructures of the ePTFE component of the graft." It is further stated in this paragraph that "the Special Master recommends that for those claims that recite that the ePTFE structure 'permits tissue 'ingrowth,' i.e., claims 20-24 and 27, the structure must allow organized host tissue to grow into the pores of the node and fibril microstructure." Gore contends that this proposed construction is partially erroneous because it does not add that all such ingrowth must be "transmural", i.e., through the wall. Gore argues in support of this contention that the Special Master failed to apply clear and consistent teaching of the patent specification describing ingrowth as "transmural" and that Dr. Goldfarb asserted "transmural" ingrowth to overcome a rejection by the patent examiner.

As to the first prong of its argument, Gore refers to a recitation in the specification at Col. 3, lines 40-55 which states as follows:

. . . the invention constitutes a prosthetic vascular device formed from a small bore tube of polytetrafluoroethylene which has been heated, expanded and sintered so as to have a microscopic superstructure of uniformly distributed nodes interconnected by fibrils and characterized by: (a) an average internodular distance which is (i) large enough to allow transmural migration of typical red cells and fibroblast, . . .

Gore claims that this language indicating that the invention "constitutes" a prosthetic vascular device that "allow[s] transmural migration of typical red cells and fibroblast" refers to required "transmural ingrowth" since that is the description of what the invention "constitutes."

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The Court concludes that the Special Master's recommended findings are not erroneous on this issue. The specification does not require complete transmural ingrowth as indicated by the words "to allow" which is permissive rather than restrictive. The Special Master indicated that the specification actually discloses that the objective is that the invention provides a structure that "will allow" transmural cellular ingrowth and assure the establishment of a viable neointima. (Report, para. 46). As noted by the Special Master, Gore made this argument even though claims 1-6, 8-11 and 17-19 mention ingrowth in the "whereby" clause; claims 20-24 and 27 recite "which permits tissue ingrowth"; and claims 14-16 and 25-26 do not mention ingrowth at all. (Report, para. 39). The Special Master further based his recommended finding on the recitation in claim 20 that the structure "prevent transmural blood flow" indicating that the applicant knew how to use the term "transmural" when he wanted to but did not use it when describing ingrowth in the claims. (Report, para. 44). As discussed by the Special Master, providing objectives in a specification does not create claim limitations, citing Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed.Cir. 2005). (Report, para. 45).

In support of its objection, Gore relies on Nystrom v. Trex Co., Inc., 424 F.3d 1136 (Fed. Cir. 2005), as holding that the true test is what the patentee actually described in his specification as his invention. In Nystrom, in the Summary of Invention, the patent described the invention as a "decking board . . . which also yields a superior product when cut from a log, . . ." Id., 424 F.3d at 1139. The Federal Circuit affirmed the district court's claim construction that the word "board" in independent claim 1 meant a "piece of elongated construction material made from wood cut from a log." Id., at 1142-46. After noting that the claims at issue did not include any language describing the "board" as cut from a log or necessarily being made of wood, the court examined the term "board" in the context of the written description and prosecution history of the patent and concluded that the term "board" must be limited to wood cut from a log. Id., at 1143. It was determined that the patentee had consistently used the term "board" to refer to wood cut from a log. Id., at 1145. In the other cases Gore has cited, Kinik Co. v. ITC, 362 F.3d 1359 (Fed. Cir. 2004), and Lizardtech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336 (Fed. Cir. 2005), the patentee's repeated references in the specification limited the construction of the claims.

As discussed above, however, the description at issue in the case at bar does not require complete transmural ingrowth as indicated by the words "to allow" which is permissive rather than restrictive. The Court agrees with the Special Master that the applicant did not use the term "ingrowth" in a manner consistent with only one meaning. The Court also agrees with the Special Master that the reference to transmural ingrowth and neointima formation as objectives in the specification does not create a claim limitation. See Col. 3, lines 27-30 (". . . it is a major objective of the present invention to provide a homogeneously porous vascular prosthesis characterized by small nodes interconnected by extremely fine fibrils to form an open superstructure which will allow uniform, controlled transmural cellular ingrowth and thereby assure the establishment and maintenance of a thin, viable neointima . . .").

As for the second part of Gore's objection, Gore cites Seachange Intern., Inc. v. C-COR, Inc., 413 F.3d 1361 (Fed.Cir. 2005), which involved a method and apparatus for redundantly storing video data in "distributed computer systems." Claim 1 of the patent was said to require "interconnecting each one of said processor systems in a point-to-point two way channel interconnection with each other one of said processor systems." Id., at 1369. Claim 37 was identical to claim 1 except that claim 37 required only that the interconnection be through a "network for data communications." Id. The applicant argued during the prosecution to overcome and to distinguish references that the prior art did not suggest connecting each processor via point-to-point, two-way channel interconnections. The Federal Circuit agreed with C-COR that the "[a]pplicant's arguments made during the prosecution narrowed the scope of the 'network for data communications' limitation in claim 37(40) to cover only a point-to-point network." Id., at 1372. The Federal Circuit set forth the applicable principles as follows:

> Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language. [Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325(Fed.Cir. 2002)] ("Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations"); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir. 1997)("[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."). A disclaimer must be clear and unambiguous.

Id., 413 F.3d at 1372-73.

In this case, the Special Master has recommended that the applicant distinguished the prior art on the basis that it had no

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ingrowth at all, not on the degree of the ingrowth. (Report, para. 53). The Special Master found no unambiguous statement that the ingrowth in the patented invention must be complete and transmural, even though that is an objective of the invention. (id.). The Special Master based his recommended conclusion on a thorough review of the record and applicable case law. The Court agrees with the Special Master's recommendation and does not find this recommended conclusion erroneous in light of Gore's argument or the case law cited in support. Gore's objections regarding the Special Master's recommended construction of the phrase "which permits transmural ingrowth" are overruled.
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In construing the term "pH buffering alkaline compound," the district court reasoned as follows:
The terms "pH-buffering compound" and "pH-buffering alkaline reacting compound" are used interchangeably with the term "alkaline reacting compound" throughout the patent. (See Lvgren Tr. 4477:21-4478:5 ("I think an average skilled formulator reading this patent will see these terms used interchangeably so many times in the specifications.").) The person of ordinary skill in the art would, therefore, understand that the term "pH- buffering" generally was not used in the patent to convey the traditional characteristics of a buffer in chemistry.

Astra, 222 F. Supp. 2d at 478. Given the context of the patents and the supporting testimony in the record, this court affirms this reasoning.
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2. The Terms "pH-Buffering Compound" and "pH-Buffering Alkaline Reacting Compound"

As apparent from the court's discussion of the "alkaline reacting compound" claim limitation, one of the central disputes in this case has been the meaning of the phrase "alkaline reacting compound" as that phrase is used in the claims of the '505 and '230 patents. That dispute also extends to other variations of that term, such as "pH-buffering compound" and "pH-buffering alkaline reacting compound." The term "alkaline reacting compound" appears in claims 1 and 14 of the '505 patent and claims 1 and 12 of the '230 patent. The terms "pH-buffering alkaline compound" and "alkaline buffering compound" appear in claims 5 and 11 of the '505 patent, respectively. The terms "pH-buffering alkaline reacting compound" and "alkaline buffering compound" appear in claims 6 and 15 of the '230 patent, respectively. Originally, the parties agreed that those variations of the term all have the same meaning as "alkaline reacting compound." (See, e.g., Joint Mem. of Defs. KUDCo & Genpharm on Claim Construction of the Term "Alkaline Reacting Compound" at 1 n.2, 4-5; Mem. in Supp. of Cheminor Defs.' Construction of Certain Terms of the Claims of 11/5/01, at 13 n.11.) Now the definitions of all those terms are disputed, and different definitions are proposed.

Until about a month after Astra's last witness on infringement with respect to the '505 and '230 patents, Dr. Lovgren, left the stand on January 4, 2002, no Defendant disputed Astra's construction of the term "buffering," which is used in the phrase "pH-buffering" in claim 5 of the '505 patent and claim 6 of the '230 patent, and in "alkaline buffering compound" in claim 11 of the '505 patent and claim 15 of the '230 patent. (See, e.g., Genpharm's Cl. Constr. Br. of 11/5/01, at 20 ("Astra and Genpharm agree that, properly construed, alkaline reacting compounds are the same in the patents as alkaline buffering compounds.").) Astra has consistently argued that those phrases have the same meaning as the phrase "alkaline reacting compound" in claims 1. In the middle of trial, three defendants--Genpharm, Cheminor, and KUDCo--changed their positions and began to urge that the narrower, "classical" definition of "buffer," 34 which generally is not required of an ARC, should be used in construing the patents. (See Tr. 3754:6-3755:24 (Astra's objection to the testimony of Dr. Story on this new theory of infringement); see also Letter from Cheminor to court of 2/6/02; Letter from KUDCo to court of 2/11/02.) At the time, the court expressed concern about new claim construction theories. (Tr. 3989:19-3991:1.) As Astra predicted, those new theories of claim construction ultimately led to additional noninfringement positions urged by Defendants. (See KUDCo FF 36, n.4; Cheminor PFF 4.6(b), n.6, 8.7.) In the interest of attempting to resolve the claim construction disputes as comprehensively as possible in this case, the court reserved ruling on Astra's objection at the time. (Tr. 4045:19-22.)

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34 Generally a buffer, in the classical or traditional sense, is defined to mean a solution containing an acid-base pair--both a weak acid and its conjugate weak base--whose pH changes only slightly on the addition of an acidic or alkaline substance because the buffer has the ability to maintain a constant pH despite assault from basic or acidic groups. (Pilbrant Tr. 1426:7-1427:10.)

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Despite the utter tardiness with which they were raised, the court will address Defendants' new claim construction arguments in the interest of ensuring that the court's claim construction is as accurate as possible; the court has no interest in precluding any party from pursuing the correct claim construction. It is not the claim construction arguments, but rather the previously undisclosed, undiscovered noninfringement positions that result from them that present potential prejudice to Plaintiffs. At this time, the court finds that Defendants' attempts to utilize these new claim construction arguments to assert novel noninfringement defenses after the close of Astra's direct case severely prejudiced Plaintiffs. Astra had no reasonable opportunity to have its expert witnesses address these "buffer" theories or to question Defendants' experts effectively on these new theories. Given the chance to develop the information during discovery, Astra surely would have introduced evidence specifically directed to those constructions and their implications for Astra's infringement claims. Therefore, the court precludes Defendants from arguing noninfringement of any of the patent claims at issue in this suit on the basis of their new construction that the phrases "pH-buffering compound" and "pH-buffering alkaline reacting compound" mean something different from the term "alkaline reacting compound."

Now Defendants argue that the terms "pH-buffering alkaline compound" recited in claim 5 of the '505 patent and "pH-buffering alkaline reacting compound" recited in claim 6 of the '230 patent require a compound that can maintain a constant pH in an aqueous solution when an acid or base is added to it within the buffering capacity of the compound. The reasons Defendants did not think to dispute Astra's initial construction until this time are evident in the patents. In both patents, the examples of alkaline reacting compounds largely overlap the substances described as "pH-buffering compounds." (Compare P1, col. 3:47-59, with P1, col. 4:14-27; compare also P2A, col. 8:43-55, with P2A, col. 9:9-23.) During the initial rounds of claim construction briefing, Cheminor even conceded that with respect to the categories of ARCs listed in the patent, "the patent makes clear that the specified 'alkaline reacting compounds' are all 'conventional buffering substances.'" (Mem. in Supp. of Cheminor Defs.' Constr. of Certain Terms of the Claims of 11/5/01, at 13 (emphasis added).) The patents also repeatedly describe substances that are not buffers in the traditional sense as compounds that have buffering characteristics or create buffering zones. For example, the patents provide a lengthy list of substances can be added to the subcoating to "strengthen" its "pH-buffering properties," and those substances are referred to as "pH-buffering compounds." (P1, col. 4:14-27 (emphasis added).) This disclosure indicates to a person of ordinary skill in the art that even a subcoating that does not contain the optional pH-buffering compound has "pH-buffering properties," albeit properties capable of improvement. Additionally, magnesium hydroxide, which is not an acid-base pair but which is listed as an ARC, (P1, col. 3:53), is called a "buffering substance" in the '505 patent, (P1, col. 15:28). The use in the patents of a broad definition of the term "buffer" as something that provides a barrier between the active ingredient and other potentially harmful substances or that helps to stabilize the active ingredient, like an ARC, is exemplified further by the use of the phrase "pH-buffering zone" in the patents to describe the subcoating as possessing "pH-buffering properties." (P1, col. 4:10, 14; P2A, col. 9:5, 9.) KUDCo's expert Dr. Auslander testified that the "pH-buffering zone" was "providing a barrier" and that the term "buffer" in that phrase was not used in the "classical sense of chemistry." (Auslander Tr. 2703:19-2704:13.)

As discussed earlier in this opinion, the patentees acted as their own lexicographers and defined the term "alkaline reacting compound," which would not be have been readily understood by someone of skill in the art at the time of the patents, in the specifications. Based on a detailed review of the intrinsic evidence, particularly the claims and the specifications, the court finds that a person of ordinary skill in the art of pharmaceutical formulation, who read the patents and understood the term "alkaline reacting compound" in light of the specifications, would realize that the terms "pH-buffering compound" and "pH-buffering alkaline reacting compound" are used interchangeably with the term "alkaline reacting compound" throughout the patent. (See Lovgren Tr. 4477:21-4478:5 ("I think an average skilled formulator reading this patent will see these terms used interchangeably so many times in the specifications.").) The person of ordinary skill in the art would, therefore, understand that the term "pH-buffering" generally was not used in the patent to convey the traditional characteristics of a buffer in chemistry. Instead of relying on the ordinary meaning of the term "pH-buffering," the patentees made it clear that they had something special in mind--an ARC. Thus, the patentees assigned their own definition to the terms "pH-buffering compound" and "pH-buffering alkaline reacting compound" by equating them with an ARC, a concept the patentees clearly

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and specifically defined in the specifications. The court rejects Defendants' late-raised claim construction as unsupported by the intrinsic evidence; therefore, the court construes the terms "pH-buffering alkaline compound" and "pH-buffering alkaline reacting compound" to mean the same thing as the term "alkaline reacting compound" in the patents.
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B. "pharmaceutical"

Lilly maintains "pharmaceutical" does not have a separate meaning outside the context of "pharmaceutical formulation." Lilly then reasons that "pharmaceutical" means "an aqueous solution formulated to be of appropriate safety and efficacy for treatment of patients." D.I. 156 at 2. Like Lilly, Novo does not define "pharmaceutical" independently of "formulation." However, Novo urges a different definition, namely, "pharmaceutical" means "containing a medicinal drug or a biologically active agent and. . . suitable for administration to an animal." D.I. 154 at 33. The Court holds "pharmaceutical" means "containing a medicinal drug" where "medicinal drug" means "a substance or preparation used in treating disease." 39

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39 Although the Court's definition of "pharmaceutical" is not identical to the definitions proffered by the parties, this definition is more accurate. See Exxon Chemical Patents, 64 F.3d 1553 at 1556 ("the judge's task is not to decide which of the adversaries is correct. Instead the judge must independently. . . declare the meaning of the claims").

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The intrinsic evidence does not provide a clear definition of the term "pharmaceutical." First, the meaning of "pharmaceutical" is not immediately apparent from the text of the claims. Second, the specification does not define the term "pharmaceutical" and uses the term only once, without defining it:

Because all commercial pharmaceutical formulations of insulin contain insulin in the self-associated state and predominately in the zinc-hexamer form, it is believed that the rate-limiting step for the absorption of insulin from the subcutaneous injection depot to the bloodstream is the dissociation of the self-aggregated insulin hexamer.

'978 Patent at 1:33-39. This discussion sheds no light on the meaning of "pharmaceutical." Finally, the prosecution history provides no guidance as to the meaning of "pharmaceutical." See Novo Ex. D.

With the intrinsic evidence not being helpful, the Court turns to extrinsic evidence. Various dictionary definitions support the Court's definition of "pharmaceutical" as "containing a medicinal drug." 40 Moreover, the dictionary definitions support the Court's definition of "medicinal drug" as "a substance or preparation used in treating disease." 41

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40 See Oxford Dictionary of Biochemistry and Molecular Biology 495 (1997) ("of or pertaining to drugs or pharmacy" or "any medicinal substance, mixture or formulation"); Dictionary of Biochemistry and Molecular Biology 355 (2d ed. 1989) ("a drug" or "of, or pertaining to pharmacy" where "pharmacy" means "the branch of pharmacology that deals with the origin, the composition, the preparation, and the dispensing of drugs"); Merriam-Webster's Collegiate Dictionary 870 (10th ed. 1998) ("of, relating to, or engaged in pharmacy" where "pharmacy" means "the art, practice, or profession, of preparing, preserving, compounding, and dispensing medical drugs"); Merriam-Webster's New Collegiate Dictionary 852 (1981) ("of, relating to pharmacy" where "pharmacy" means "the art or practice of preparing, preserving, compounding, and dispensing drugs"); Grant & Hackl's Chem. Dictionary 437 (1987) ("pertaining to drugs; the analysis of drugs and isolation of their active constituents"); Hawley's Condensed Chem. Dictionary 891 (1993) ("a broad term that includes not only all types of drugs and medicinal and curative products but also ancillary products such as tonics, dietary supplements, vitamins, deodorants, and the like"); Webster's Third New Int'l Dictionary 1694 (1981) ("of or relating to pharmacy" where "pharmacy" means "1. the administering of drugs: treatment by drugs; 2. the art or practice of preparing, preserving, compounding, and dispensing drugs").

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41 See Webster's Third New Int'l Dictionary 695, 1403 ("drug" means "a substance used as a medicine" and "medicine" means "a substance or preparation used in treating disease").

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The Court's definition of "pharmaceutical" comports with the idea behind the patent, to create an insulin analog formulation that is useful as a drug to treat diabetes. See '978 Patent at 1:11-60. Indeed, claim 10 recites a method of using a "pharmaceutical formulation" of the complex for "treating a patient suffering from diabetes mellitus." The specification defines "treating" as:

the management and care of a patient for the purpose of combating the disease, condition, or disorder and includes the administration of a compound of present invention to prevent the onset of the symptoms or complications, alleviating the symptoms or complications, or eliminating the disease, condition, or disorder.

'978 Patent at 4:9-15. It follows that the Court's definition of "pharmaceutical" is consistent with the invention disclosed in the specification.

Lilly maintains that the term "pharmaceutical" also means that the formulation is safe and effective for treatment of diabetes. Lilly argues that "safe" means that the formulation is chemically stable and has a low rate of polymer formation. See D.I. 156 at 15 (citing '978 Patent at 1:57-60; 2:62; 3:5-7; 4:60-61; 5:32-34). Lilly also argues that "effective" means that the hexameric hIA retains the rapid action of monomeric hIA. See id. However, the specification does not state anywhere that the term "pharmaceutical" means safe and effective, as Lilly has defined the terms. Moreover, a pharmaceutical can be a medicinal drug, used in the treatment of disease, without necessarily being safe or effective. See, e.g., In re Bendectin Litigation, 857 F.2d 290, 321 (6th Cir. 1988) (referring to the teratogenic properties of thalidomide, a medicinal drug).

Lilly also relies on the Food, Drug and Cosmetic Act definition of "drug" and criteria for "drug" approval for support of its definition. See 21 U.S.C. § 321(g)(1) (1999) ("drug" means "a substance intended for use in the diagnosis, cure, mitigation, or prevention of disease"); id. at § 355(b)(1)(A) (the FDA will only approve a "drug" if it is both safe and effective). However, reliance on this definition is inappropriate because the FDA, not the Patent and Trademark Office, is responsible for determining whether drugs are safe and effective and because drugs not approved by the FDA are still patentable. See Application of Anthony, 56 C.C.P.A. 1443, 414 F.2d 1383, 1395 (C.C.P.A. 1969).

Novo's interpretation of "pharmaceutical" is also too limiting because it includes the possibility that the formulation is "a biologically active agent" and that the formulation is "suitable for administration to an animal." A formulation containing only one hexamer complex of hIA would suffice as a "biologically active agent" but would not be "pharmaceutical" because it alone could not be used to treat a disease. Also, there is no limitation in the claims, specification, or prosecution history that a "pharmaceutical" formulation must be "suitable for administration to an animal." Instead, the touchstone is whether the formulation is "a substance or preparation used in treating disease."

For these reasons the Court declines to adopt the respective claim constructions proffered by the litigants, and instead holds that "pharmaceutical" means "containing a medicinal drug" where "medicinal drug" means "a substance or preparation used in treating disease."
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2. "Pharmaceutical Composition"

Ortho-McNeil and Kali n17 also disagree over the proper construction of the Claim 6 limitation: "pharmaceutical composition [comprising a tramadol material and acetaminophen]." (emphasis added). Kali argues that the co-administration of tramadol and acetaminophen in separate but concurrent or sequential doses qualifies as a "pharmaceutical composition." Ortho-McNeil counterargues that the term is limited to "a medicinal preparation comprising an 'intimate admixture' of" tramadol and acetaminophen, "prepared outside the body, generally in the form of a 'dosage unit' such as a 'tablet' or 'capsule.'" (Pl.'s Opp. Br., p. 27.) The Court concludes that the intrinsic evidence favors Ortho-McNeil's construction.

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n17 For purposes of their summary judgment motion, Teva/Barr do not challenge Ortho-McNeil's construction of "pharmaceutical composition."

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The specification describes "[p]harmaceutical compositions comprising the tramadol material and acetaminophen," as "an intimate admixture with a pharmaceutical carrier . . . ." '691 patent, col. 4, ll. 42-45. The pharmaceutical carrier can take various forms, such as water, alcohols, starches, or sugars, depending on whether the composition is to be administered orally, intravenously, or parenterally. Id. at ll. 47-49, 53-59. The specification further explains that the "pharmaceutical compositions will generally be in the form of a dosage unit, e.g., tablet, capsule, powder, injection, teaspoonful and the like," and that this dosage unit will "contain[] . . . preferably from about 0.3 to 200 mg/kg of the active ingredients," id. at col. 5, ll. 3-7 (emphasis added). Therefore, a "pharmaceutical composition" necessarily contains both tramadol and acetaminophen. Additionally, examples one, two, and three of the specification, which give instructions on the "Preparation of the Combined Doses of Tramadol and [acetaminophen]," all state that the tramadol/acetaminophen "combinations are . . . made by adding 10 mL of each [tramadol] dilution to the appropriate mg of [acetaminophen]." '691 patent, col. 5, ll. 38-53; col. 6, ll. 32-44; col. 7, ll. 23-36. Thus, the specification makes clear that a pharmaceutical composition was intended to be a single dosage unit containing a mixture of both active ingredients.

The prosecution history also supports this construction. In an April 2, 1993 letter, the PTO informed the inventors that their claims had been rejected as obvious over the Flick patent, because "it would have been obvious to one with ordinary skill in the art to combine two compounds (i.e. tramadol and acetaminophen) in varying amounts in the same composition since both compounds are known to useful (sic) for treating the same condition (i.e. pain)." (Kushan Decl., Ex. 10, at KAL016264 (emphases added).) Thus, it is apparent that the patent examiner understood "pharmaceutical composition" to require the combination of the two compounds in the same unit. In its response, Ortho-McNeil did not attempt to change the examiner's understanding of the invention. (Kushan Decl., Ex. 10, at KAL016271-73.)

Ortho-McNeil also presents extrinsic evidence supporting its construction. First, in the expert opinion of Dr. Stanski, based on how the phrase is "commonly used in medical terminology, a pharmaceutical composition of Tramadol and [acetaminophen] would not extend to tablets in which the Tramadol and the [acetaminophen] were not in an 'intimate admixture' (e.g., two tablets, one solely containing tramadol and one solely containing [acetaminophen])." (Stanski Inf. Rep., at p. 5.) Second, Ortho-McNeil notes that the word "pharmaceutical" is defined as "relating to the preparation, use, or sale of medicinal drugs," The Oxford English Dictionary, at p. 662 (2d ed., Vol. XI, 1989)), and that "composition" is defined as "[t]he forming (of anything) by combination of various elements, parts, or ingredients," id., vol. III, p. 624. Accordingly, it argues, a "pharmaceutical composition" should be understood as a medicinal drug formed by combining two or more active ingredients.

In response, Kali points out that Dr. Raffa, a co-inventor of the '691 patent, stated in his deposition testimony that he "would not expect it to make a difference" whether tramadol and acetaminophen were administered mixed together or separately to test mice, "as long as they were given within a reasonable proximity in terms of time." (Brown Decl., Ex. 16, p. 301, ll. 6-12.) While this testimony may indicate that the two methods of administration are equally effective, Dr. Raffa was not purporting to construe "pharmaceutical composition" in his testimony. He was only asked whether the method used to administer the two drugs would affect the test results in the specification. Furthermore, although Dr. Raffa could not recall which method of administration was used during the mice testing (Brown Decl., Ex. 16, p. 300, ll. 16-21), the specification indicates that the mice were indeed given "combined doses of tramadol hydrochloride and acetaminophen." '691 patent, col. 8, ll. 16-17.

Kali also cites for support the Federal Circuit's decision in PIN/NIP, Inc. v. Platte Chem. Co., 304 F.3d 1235, 1245 (Fed Cir. 2002), where the Court construed the claim limitation, "composition," to mean "a mixture that is formed at any time during use, such as through simultaneous application of the constituent chemicals, as long as a mixture is indeed formed." PIN/NIP, however, did not involve pharmaceuticals, or the limitation "pharmaceutical composition," and in any event, there is nothing in the intrinsic evidence that supports Kali's proposed claim construction, and much that supports Ortho-McNeil's.

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In sum, after examining the intrinsic and extrinsic evidence, the Court construes "pharmaceutical composition" to mean a medicinal preparation comprising an intimate admixture, prepared outside the body, generally in the form of a dosage unit, such as a tablet or capsule.
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In light of this analysis, the term "pharmaceutical composition", contained in the preamble n9 of claims 1 and 2, takes on special significance. Although the parties have not presented extensive evidence relating to the specific meaning of that term, both parties appear to agree that as a general matter n10, pharmaceutical compositions can take the form of the solid unit dosage forms listed in the '872 patent specification (namely, tablets, coated tablets, powders, dragees, and hard or soft gelatin capsules, etc.). n11

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n9 "A patent claim typically has three parts: 1) the preamble; 2) the transition; and 3) the body." E.I. DuPont De Nemours v. Monsanto Co., 903 F. Supp. 680, 693 (D. Del. 1995) (citing 2 DONALD S. CHISUM, PATENTS § 806 [1][b] (1994)). In this case, the portion of the claims' language that is before the word "comprising" is the preamble. "Generally, the preamble will be construed to be a claim limitation if it is necessary to give "life, meaning, and vitality to the claim," or if it "recites essential structure." Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). "Where a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage." Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997) (emphasis added).

n10 See Tr. 9/24/04 at 8 -10, Testimony of Dr. Chowhan.

n11 The patent specification states, "The pharmaceutical composition of the present invention is administered orally in the form of a solid unit dosage form. Examples of solid unit dosage forms are tablets, coated tablets, powders, dragees, and hard or soft gelatin capsules and the like." ('872 Patent, col. 7, lines 62-66.)

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Notwithstanding the language in the patent specification, Aventis argues that "pharmaceutical composition" as set forth in claims 1 and 2 does not encompass pharmaceutical compositions in solid unit dosage form. In support of this theory Aventis points out that claims 1 and 2 are the only claims that use the precise language "pharmaceutical composition." Every other claim of the patent calls for a pharmaceutical composition in "solid unit dosage form" (claims 3-17), or "solid form" (claim 18). Aventis also refers this Court to the "Background of the Invention" portion of the patent which states, "the present invention relates to pharmaceutical compositions and pharmaceutical compositions in solid unit dosage form . . . ." ('872 patent, col. 1, lines 47-49.)

Aventis claims that ignoring the distinction between "pharmaceutical composition" and "pharmaceutical composition in solid [unit dosage] form" would render the claim language "solid [unit dosage] form" superfluous. To be sure, "no claim language may be interpreted as mere surplusage." British Telecommunications PLC v. Prodigy Communications Corp., 189 F. Supp. 2d 101, 113 (S.D.N.Y. 2002) (citing Texas Instruments v. United States ITC, 988 F.2d 1165, 1171 (Fed. Cir. 1993)). This maxim, however, does not mandate the conclusion that the '872 claim term "pharmaceutical composition" in the absence of the terms "in solid [unit dosage] form" therefore describes only pharmaceutical compositions that are not in solid unit dosage form.

This Court finds the more plausible construction to be that "pharmaceutical composition", in the absence of other stated limitations, encompasses pharmaceutical compositions in all forms. The terms "pharmaceutical compositions in solid [unit dosage] form" encompasses the subset of pharmaceutical compositions which are in solid unit dosage form. Such a construction avoids the surplusage issue raised by Aventis.
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None of the following elements are disputed and each term is assigned its plain and ordinary meaning as understood by a skilled artisan. The term "pharmaceutical composition" means an aggregated product formed from two or more substances for use as a drug in medical treatment. The term "gastrointestinal environment" means the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus. The term "mean fluctuation index" means the average degree of fluctuation ((Cmax-Cmin)/Cavg) over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma.
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3. "a pharmaceutical composition comprising. . . a pharmaceutically acceptable diluent, adjuvant or carrier" ('422 claim 1, '933 claims 9 and 12).

Amgen	Roche/Hoffmann	This Court (earlier case)
A composition suitable for administration to humans containing at least a diluent, adjuvant or carrier	A mixture having in addition to the active ingredient (as defined in the claim), an additional distinct and separate ingredient that acts as a diluent, an adjuvant or a carrier	Did not consider

Basically the discussion on this construction centers around Roche/Hoffmann's intention to (1) distinguish the "diluent, adjuvant or carrier" from the active ingredient with (2) the understanding that the word "comprising" requires either a diluent and adjuvant, or a carrier. Tr. 63:6-76:23.

Roche/Hoffmann relies on the claim and two cases. Def.'s Brief [Doc. No. 311] at 7-8. The disputed claim limitation is found in claims 9 and 12 of the '933 patent and claim 1 of the '422 patent. Claim 9 states:

9. A pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy according to claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.

Likewise, claim 1 of the '422 patent states:

1. A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.

Roche/Hoffmann relies on Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed. Cir. 1995) and Northern Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281 (Fed. Cir. 2000). In both of those cases the Federal Circuit taught that in order to prove infringement the plaintiff would have to prove that the defendants used "each of the claimed recipe ingredients in the amounts specifically claimed". Exxon Chem. Patents, Inc., 64 F.3d at 1558. Therefore, Roche/Hoffmann argues that the use of the term "and" implies that the active ingredient must be "distinct" from the diluent, adjuvant or carrier. Def.'s Brief at 7-8.

The Court concedes that from a plain reading of the claims it seems that the active ingredient could well be different from the diluent, adjuvant, or carrier. There is no evidence either in the claims, the specification, or the prosecution history that

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the ingredients could not be the same. Thus, adding the limitation that the active ingredient needs to be different from the diluent, adjuvant, or carrier is to read something into the claim that it does not state. Therefore, the better construction is to omit the "additional, distinct and separate" language and allow for potential coincidence or distinction between the active ingredient and the diluent, adjuvant, or carrier.

The same argument works for the second part of the construction. The claim reads: a "diluent, adjuvant or carrier." There is no reason to determine now if that means all three need to be present or that just one suffices. It is better just to construe the claim terms giving them "their ordinary and customary meaning." Phillips, 415 F.3d at 1312-13.

Furthermore, the Court is reluctant to read in limitations that do not necessarily flow from the patent claims and specifications, which is one of "the cardinal sins" of claim construction. Id. at 1320. Accordingly, this Court adopted and now confirms the following construction:

"a pharmaceutical composition comprising… a pharmaceutically acceptable diluent, adjuvant or carrier": a composition suitable for administration to humans, containing a diluent, adjuvant or carrier.

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2. Pharmaceutical Composition

Genentech contends that the term "pharmaceutical composition" means "a stable composition suitable for administration into patients, for example, a solution designed for parenteral administration or a lyophilized [freeze-dried] form thereof." BM contends that the term "pharmaceutical composition" is defined as a "highly purified preparation."

The relevance of the term is that BM first adds arginine in the production and purification of Reteplase to the refolding solution, which is "at least six steps before Reteplase is in the pharmaceutical composition stage."

a. Intrinsic Evidence

The '225 patent specification provides: "Pharmaceutical compositions must be stable for appropriate periods of time, must be acceptable in their own right for administration to humans, and must be readily manufacturable." (Col. 1, ll. 57-60.) It also states:

A particular method for preparing a pharmaceutical composition of t-PA hereof comprises employing purified (according to any standard protein purification scheme) t-PA in any one of several known buffer exchange methods, such as gel filtration. This preferred method was used to isolate and purify the t-PA used as starting material in the stability and solubility studies.

(Col. 3, ll. 37-41.) In each example given in the '225 patent, and in the methods for production of Figures 1-3, purified t-PA was used. (Cepko Report, at 7.) The preferred embodiment in a specification is helpful in construing the terms of a patent, although not conclusive. See Vitronics, 90 F.3d at 1583.

b. Claim Construction

Because the patent specification is the "single best guide to the meaning of a disputed term," Vitronics, 90 F.3d at 1582, and the term is clearly defined in the '225 patent specification, the Court has no need to turn to the extrinsic evidence. Therefore, the Court construes the term "pharmaceutical compositions" to mean those that are stable for appropriate periods of time, acceptable in their own right for administration to humans, and readily manufacturable. A pharmaceutical composition is comprised of purified t-PA.

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4. Pharmaceutical Dosage Unit

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Claim 17 provides: "A process for making a solid preparation. . . incorporating the resulting solution or dispersion into a suitable release controlling system to form a pharmaceutical dosage unit." (Emphasis added). Astra argues that the term pharmaceutical dosage unit should be given its ordinary meaning and construed as a dosage form such as a tablet or capsule containing a dose of a drug. Mutual contends that the '081 patent refers to tablets, capsules containing granular material, and gelatin-filled capsules (gel caps) as suitable oral dosage forms (citing the specification, Col. 4, lns. 11-26); accordingly, the limitation should be construed to include orally-administered pharmaceutical dosage forms, examples of which include tablets, capsules and gel caps. Astra acknowledges that claim 17 is directed to "solid preparations," but argues that Mutual's example of "gelatin-filled capsules (gel caps)" is not anywhere in the '081 patent; rather, the use of the phrase "gel tablets" in the specification refers to the preferred embodiment of a gelling matrix tablet, (citing Ex. 1, Col. 4, lns. 11-15).

This Court concludes that persons skilled in the art would recognize the term pharmaceutical dosage unit to mean a dosage form such as a tablet or capsule containing a dose of a drug, and that Mutual has not directed this Court to any portion of the intrinsic record which would indicate that this ordinary meaning should be varied.
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5. "a pharmaceutical formulation"

This term is found in claims 1-7. Astra proposes the following construction: "a composition or mixture in a form suitable for administration to a patient for medical use, such as diagnosis, mitigation, or prevention of disease or disorders." DRL contends that no construction of this term is necessary and the ordinary meaning as understood by those skilled in the art should apply. Alternatively, DRL proposes that the term be construed as "a medicament."

Astra's basis for its proposed construction of this term is not addressed anywhere in Astra's claim construction papers. Moreover, the Court discerns no ambiguity in the term and finds that its ordinary and customary meaning would be clear to one skilled in the art. Consequently, the Court agrees with DRL that no construction of this term is necessary. Rather, the plain meaning of the term as understood by someone of ordinary skill shall apply.
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First we will address Barr's contention that the patents claim a pharmaceutically-pure form of fluoxetine hydrochloride. Claim construction is a matter of law exclusively for the Court to determine. See Markman v. Westview Instruments, Inc., 517 U.S. 370, 384, 116 S. Ct. 1384, 1393, 134 L. Ed. 2d 577 (1996). "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (citing Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)).

After examining the claim language in question, we agree with Lilly's assertion that the term "pharmaceutically-acceptable" as used in the patents does not apply as a restriction on the purity of the fluoxetine hydrochloride compound itself, but rather defines the acids that may be used to form the salts of the claimed compounds: pharmaceutically-acceptable or non-toxic acids which form pharmaceutically-acceptable or non-toxic salts. In other words, the claim language refers to toxicity of the components used to create the compound and the toxicity of the resultant compound, rather than a particular level of purity in the final product, as may be achieved through a process like recrystallization.

For example, claim 5 of the '081 patent, which claims fluoxetine hydrochloride, depends upon claim 4, which claims fluoxetine "and pharmaceutically-acceptable acid addition salts thereof formed with non-toxic acids." Claim 4 depends in turn upon claim 1, which claims a family of compounds that includes fluoxetine "and acid addition salts formed with pharmaceutically-acceptable acids." The '549 patent claims use the same language as the '081 patent. In addition, the description portions of the patents, which are identical, set forth:

This invention provides [amine compounds] of the formula . . . and acid addition salts thereof formed with pharmaceutically-acceptable acids.

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['081 patent at col. 1, lines 22-23, 43-44]

* * * *

Also included within the scope of this invention are the pharmaceutically-acceptable salts of the amine bases represented by the above formula formed with non-toxic acids. These acid addition salts include salts derived from inorganic acids such as: hydrochloric acid, nitric acid, phosphoric acid . . . and the like, as well as salts of non-toxic organic acids including aliphatic mono and dicarboxylates . . . etc. Such pharmaceutically-acceptable salts thus include: sulfate, pyrosulfate . . . and the like salts.

['081 patent at col. 2, lines 31-58]

* * * *

. . . It is preferred to use an acid addition salt of the compound formed with a pharmaceutically-acceptable non-toxic acid.

['081 patent at col. 16, lines 48-50]

Lilly Opp. Exh. 8. In addition, Lilly provides evidence that the common meaning of the term "pharmaceutically-acceptable addition salts formed with non-toxic acids" in the patent context merely refers to limiting claims to salts that are non-toxic. See Lilly Opp. Exhs. 3, 4, 5. 7 As Lilly argues, "The claim language merely excludes salts of toxic acids such as hydrogen cyanide. It has nothing to do with the form or purity of the claimed compounds." Lilly Opp. Br. to Barr Mot. Summ. Judg. at 14. Barr's argument to the contrary is clearly unavailing.

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7 Lilly Opp. Exh. 3 is an excerpt from Howard I. Forman, The Law of Chemical Metallurgical and Pharmaceutical Patents (1967), in which the author explains, "Since claims in pharmaceutical patents are sensitive to being rejected as being too broad, there has evolved some terminology which has found acceptance by the Patent Office to avoid excessive breadth in claims. For example, if you claim a compound of the group consisting of A and "the salts thereof" the Examiner will in all likelihood reject the claim as "unduly broad in salts," in that this includes toxic as well as nontoxic materials . . . . But if you have basis therefor in the specification, he will permit you to overcome this rejection by using the widely employed expression[] 'the acid addition salts thereof formed with a pharmaceutically acceptable acid' . . . ."

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IV. "Pharmaceutically Acceptable Carrier"

GSK's Proposed Construction	Teva's Proposed Construction
Material that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof for the life of the formulation.	Carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof.

The parties propose essentially identical constructions, both of which are derived from a portion of the specification stating that "[t]he carrier(s) must be 'acceptable' in the sense of being compatible with other ingredients in the formulation and not deleterious to the recipient thereof." ('021 patent at 5:1-4.) GSK construction differs from Teva's only in that it tacks on the additional limitation that the carrier not be deleterious to the recipient "for the life of the formulation." The Court will not adopt this aspect of GSK's construction.

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GSK offers very little support for this aspect of its construction. Briefly, GSK asserts that "[a] person of ordinary skill in the art would understand that any pharmaceutically acceptable carrier must be 'compatible' and 'not deleterious' during the formulation's life, however short or long it is expected to be." (D.I. 32 at 11.) GSK then cites some passages from a textbook on pharmaceutical sciences explaining that incompatibility of ingredients in a pharmaceutical formulation can be a source of instability. (Id. (citing Remington's Pharmaceutical Sciences 1504-07 (18th ed. 1990).)

In the Court's view, this is but another attempt by GSK - without any meaningful support from the internal record - to introduce another extraneous and vague limitation into the claims. The Court will not do this.

Instead, the Court will construe the claim term "pharmaceutically acceptable carrier" to mean, as Teva contends, a "carrier that is compatible with the other ingredients of the formulation and not deleterious to the recipient thereof."
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6. "Pharmaceutically-acceptable moisturizer": Material that has the effect of adding moisture to or keeping moisture in human skin that is also safe and effective for use on human skin.

('062 patent, Abstract; col. 2, ll. 68 to col. 3, ll. 2; col. 3, ll. 11-14; col. 8, ll. 45-58)
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Turning to the first of these arguments, Andrx asserts that the district court erred in granting a preliminary injunction based on the '718 and '616 patents because Abbott did not show that it is likely to succeed in proving infringement of the "pharmaceutically acceptable polymer" claim limitation. Andrx asserts that it cannot infringe literally or under the doctrine of equivalents because its product does not include a "pharmaceutically acceptable polymer" as required by the claims. All of the asserted claims of the '718 patent -- claims 1, 4, and 6 -- and claim 2 of the '616 patent contain this limitation.

The "pharmaceutically acceptable polymer" in the '718 and '616 patent serves as the release controlling agent for the claimed extended release clarithromycin compositions. '718 patent, col. 1. l. 67 - col. 2 l. 2. Both sides concede that Andrx's product does not contain a polymer, but instead uses glycerylmonostearate ("GMS") as its release controlling ingredient. Abbott therefore does not assert that Andrx infringes the claims of the '718 and '616 patents literally, but solely under the doctrine of equivalents. The parties dispute whether GMS is properly referred to as a wax or a fat and whether it can be found to be an equivalent of the claimed polymer.

1. Claim Construction

When determining whether the Andrx product is likely to infringe the "pharmaceutically acceptable polymer" claim limitation as an equivalent, we start with construction of that claim term. The district court construed the term "pharmaceutically acceptable polymer" in its preliminary injunction order for defendant Teva.

The '718 patent description of the "pharmaceutically acceptable polymer" uses a closed term. Claim drafters often use the term "group of" to signal a Markush group, which lists specified alternatives in a patent claim . . . . By its nature, a Markush group is closed. The '718 patent describes the "pharmaceutically acceptable polymer" as "a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof.". . . The term excludes other forms of polymers, such as hydrophobic or water insoluble substances (e.g., wax).

Teva I, 2005 U.S. Dist. LEXIS 27753, *17-18. The court subsequently adopted that construction for purposes of the preliminary injunction proceedings against Andrx despite Abbott's protest that the district court's construction in Teva I was overly narrow.

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Abbott urges this Court to modify its construction of the phrase "pharmaceutically acceptable polymer" from its previous opinion in the related Teva matter. . . . When a term is undefined, the first place a court is to look for a definition is the specification. This Court followed that procedure, looked in the specification, and read the Markush group containing definition there. It is not persuaded by the case law Abbott cites that it erred in so doing and declines to alter its construction.

Ranbaxy-Andrx, 2005 U.S. Dist. LEXIS 27753, *66 (citation omitted).

Abbott argues, as it did to the district court, that the district court erred in its claim construction because it relied on "Markush group" language in the specification, i.e., language indicating that the claimed pharmaceutically acceptable polymer is "selected from the group consisting of" the polymers expressly identified in the specification. Given that the specification used the "selected from the group of" language, the district court limited the pharmaceutically acceptable polymers to those listed. Abbott argues that this was erroneous because limiting claim scope based on Markush language only applies when the phrase is used in the claims, not in the written description.

Abbott also disagrees with Andrx's contention that the written description provides an explicit definition of "pharmaceutically acceptable polymer" that should overcome the canon that the term should be given its ordinary meaning to one of skill in the art in the context of the patent. Further, Abbott argues that the patent does not include any intentional disclaimer or disavowal of claim scope of the polymer limitation. It urges that the specification merely identifies exemplary polymers that are suitable for use in the invention and does not provide a definition. It notes that when defining other terms in the patent, the '718 patent explicitly states what the term "means."

The district court's claim construction, Abbott argues, would also violate the doctrine of claim differentiation because claims 2 and 3, which depend from claim 1 expressly claim the more specific types of polymers to which the court limited the term. Accordingly, Abbott asserts that the correct construction of "pharmaceutically acceptable polymer" is according to the plain and ordinary meaning that one of skill would understand it to have in the context of the patent -- "any polymer, suitable for use in pharmaceutical compositions to be administered in humans that, alone or together with other polymers, is capable of forming a matrix to control and extend drug-dissolution release into the bloodstream."

Andrx responds that Abbott wrongly relies on these principles of claim construction to argue that the district court's construction was impermissibly narrow. First, Andrx argues that Markush language is just as limiting when used in the written description as when it is used in a claim. Second, Andrx argues that Abbott misapplies the doctrine of claim differentiation. Finally, Andrx asserts that Abbott's construction ignores an express definition of the term "pharmaceutically acceptable polymer" given in the specification and instead imports limitations from preferred embodiments.

This court reviews the district court's claim construction de novo on appeal. Cybor Corp. v. FAS Techs, Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Further, "the ordinary and customary meaning of claim term is the meaning that the term would have to a person of ordinary skill in the art in question." Id. at 1313. The court looks to sources such as the words of the claims themselves, the written description of the patent, and extrinsic evidence to ascertain the meaning of the term "pharmaceutically acceptable polymer." Id. at 1314.

First, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Id. at 1314. Claim 1 of the '718 patent requires a composition that includes only a "pharmaceutically acceptable polymer." '718 patent, col. 11 ll. 31-32. Claim 2, not asserted here, depends from claim 1 and further requires that the pharmaceutically acceptable polymer "is a hydrophilic water-soluble polymer." Id., col. 11 ll. 39-40. Claim 3, also not asserted in this case, depends from claim 2 and more specifically requires that
the polymer is selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof.

Id., col. 11 ll. 42-47. Therefore, the language of the claims and claim differentiation imply that the "pharmaceutically acceptable polymer" term in claim 1 is likely broader than the "hydrophilic water-soluble polymer" described in claim 2 and encompasses more compounds than those listed in claim 3.

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Next, the claims "'must be read in view of the specification, of which they are a part.'. . . [I]t is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citations omitted). Here, the specification describes:

The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Preferably, the polymer is selected from hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and methyl cellulose. More preferably, the polymer is hydroxypropylmethyl cellulose. Most preferably, the polymer is a low viscosity hydroxypropylmethyl cellulose with viscosity ranging from about 50 cps to about 200 cops. The most preferred low viscosity polymer is a hydroxypropylmethyl cellulose with a viscosity of about 100 cps, commercially available under the Tradename Methocel TM K 100 LV from The Dow Chemical Company.

'718 patent, col. 3 l. 65 - col. 4 l. 14.

The district court focused on the "selected from the group consisting of" phrase in the specification to hold that there was a Markush group and therefore Abbott was limited to the listed polymers. A Markush group is a form of drafting a claim term that is approved by the PTO to serve a particular purpose when used in a claim -- to limit the claim to a list of specified alternatives. Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005); Manual of Patent Examining Procedure § 803.2 (8th ed. 2001). The term "Markush group" does not have any meaning within the context of a written description of a patent and therefore to the extent the district court relied on the Markush group language to limit its construction to the compounds listed in the written description, it erred.

The district court also appears to have grounded its claim construction on the theory that the "pharmaceutically acceptable polymer" is explicitly defined in the written description when it states, "The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer . . . ." '718 patent, col. 1 ll. 65-66 (emphasis added). Although a term may have an ordinary meaning to one of ordinary skill in the art, the patentee may "expressly define terms used in the claims." Phillips 415 F.3d at 1321 (quoting Vitronics, 90 F.3d at 1582. The patentee here states in the written description that "a pharmaceutically acceptable polymer is" a specific subset of polymers. The word "is" may signify that a patentee is serving as its own lexicographer. However, there is significant evidence at this stage of the litigation to believe that the patentee here was not providing a definition of the "pharmaceutically acceptable polymer" claim term in the written description. First, the '718 patent unambiguously provides definitions of other claim terms, that may be different from the ordinary understanding of a person of skill in the art, by stating that the term has a particular meaning within the patent. See, e.g., '718 patent, col. 3 ll. 34-35 ("'Erythromycin derivative' as used herein, means . . . ." (emphasis added)); col. 3, ll. 40-41 ("'Pharmaceutically acceptable' as used herein, means . . . ." (emphasis added)). In contrast, the written description states that the "pharmaceutically acceptable polymer is . . . ," which does not as unambiguously signify that the description provided is definitional. Further, neither party's expert declared that the language in the written description is purely definitional from the point of view of one of skill in the art. Indeed, the two experts offer differing constructions as to how the term "pharmaceutically acceptable polymer" would be understood by one of ordinary skill in the art, neither construction limiting the polymer to hydrophilic, water-soluble substances. Decl. of Arthur H. Kibbe Ph.D. in Opp'n to Abbott Labs. Mot. for a Prelim. Inj. Against Andrx Pharms. at 21-22, P 46, 48 ("Kibbe Declaration"); Decl. of Gilbert Stephen Banker, Ph.D, D.Sc., in Supp. of Abbott Labs.' Application for a TRO and Mot. for a Prelim. Inj. Against Andrx Pharms., Inc. at 12. Also, it appears that if the "pharmaceutically acceptable polymer" is defined to be "a water-soluble hydrophilic polymer," that definition would not cover some of the very polymers listed because they are not water-soluble. See Kibbe Declaration at 22, P 49. Finally, as noted above, the claims of the '718 patent do not support a conclusion that the "pharmaceutically acceptable polymer" in claim 1 is limited by the "hydrophilic" or "water-soluble" limitations in claim 2, or to the specific compounds listed in claim 3. We therefore conclude that the district court erred at this preliminary stage in limiting the "pharmaceutically acceptable polymer" term to hydrophilic, water-soluble compounds selected from a list given in the written description of the '718 and '616 patents.

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The primary dispute in this matter is over the meaning of the term "pharmaceutically acceptable polymer." The term is not defined in the claim. Even the claims of a patent that are not at issue in an infringement suit are nonetheless part of intrinsic

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evidence to be considered during claim construction. Claim 1 of the '718 patent requires a composition that includes a "pharmaceutically acceptable polymer." col. 11:ll. 31-32. Claim 2, not at issue here, depends from claim 1 and further requires that the pharmaceutically acceptable polymer "is a hydrophilic water-soluble polymer." Id., col. 11 ll. 39-40. Claim 3, also not asserted in this case, depends from claim 2 and more specifically requires that "the polymer is selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof." Id., col. 11 ll. 42-47. "The presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not presenSandoz's product uses clarithromycin as its pharmaceutically active compound. As noted in an earlier decision, Abbott defined "erythromycin derivative" in the '718 patent in such a way as to leave out azithromycin. Azithromycin is the name for 9a-aza-9a-methyl-9-deoxo-9a-homoerythromycin A. Pfizer, the patent holder on azithromycin, describes azithromycin as a "broad spectrum antimicrobial compound derived from erythromycin A." WO 95/30422 (the "'422 patent"). It is likely that Abbott consciously defined "erythromycin derivative" as it did to avoid infringing Pfizer's existing '422 patent.
t in the independent claim." Phillips, 415 F.3d at 1315. Furthermore, independent claims are generally given broader scope so as to avoid rendering corresponding dependent claims redundant. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341 (Fed. Cir. 2000)). Therefore, the language of the claims and the doctrine of claim differentiation imply that the "pharmaceutically acceptable polymer" limitation in claim 1 is most likely broader than the "hydrophilic water-soluble polymer" limitation described in claim 2 and involves more compounds than those contained in claim 3.t in the independent claim." Phillips, 415 F.3d at 1315. Furthermore, independent claims are generally given broader scope so as to avoid rendering corresponding dependent claims redundant. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341 (Fed. Cir. 2000)). Therefore, the language of the claims and the doctrine of claim differentiation imply that the "pharmaceutically acceptable polymer" limitation in claim 1 is most likely broader than the "hydrophilic water-soluble polymer" limitation described in claim 2 and involves more compounds than those contained in claim 3.

When the claim does not define a term, a court will turn to the specification. The claims "'must be read in view of the specification, of which they are a part,...' because "it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citing Vitronics, 90 F.3d at 1582). Here, the patent specification provides as follows:

The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Preferably, the polymer is selected from hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and methyl cellulose. More preferably, the polymer is hydroxypropylmethyl cellulose. Most preferably, the polymer is a low viscosity hydroxypropylmethyl cellulose with viscosity ranging from about 50 cps to about 200 cps. The most preferred low viscosity polymer is a hydroxypropylmethyl cellulose with a viscosity of about 100 cps, commercially available under the Tradename Methocel TM K 100 LV from The Dow Chemical Company.

'718 patent, col. 3 l. 65-col. 4 l. 14.

Previously, this Court found that the phrase "selected from the group consisting of" in the specification signaled a Markush group, which limited the term "pharmaceutically acceptable polymer" to the polymers listed. Claim drafters often use the term "group of" to signal a Markush group, which lists specified alternatives in a patent claim. The typical form of a Markush group is "a member selected from the group consisting of A, B, and C." See Manual of Patent Examining Procedure § 803.2 (2004) (quoted in Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005)). The Federal Circuit explained that while a Markush group can be used to limit a claim to a list of specified alternatives, a Markush group has no "meaning within the context of a written description of a patent" and a court should not rely on Markush group language to limit the construction of a claim term to certain items listed in the written description.

The presence of the "hydrophilic water-soluble" and the "group consisting of ..." limitations in dependent claims 2 and 3 implies that Abbott intended the "pharmaceutically acceptable polymer" limitation of claim 1 to be broader than the limitations of claims 2 and 3. But Sandoz explains the appearance of the polymer limitation in claims 1, 2 and 3 differently. According to Sandoz, the specification's description of "pharmaceutically acceptable polymer" merely teaches one skilled in the art that this limitation appearing in claims 1, 2 and 3 is the same limitation. If the "pharmaceutically acceptable polymer" limitation meant the same thing in claim 1 as it did in claims 2 and 3, then Abbott would have no need to include claims 2 and 3, as they would become superfluous. "The presumption [created by the doctrine of claim differentiation] is especially

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strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." Sunrace Roots Enter. Co., Ltd. v. SRAM Corp., 336 F.3d 1298, 1303 (Fed. Cir. 2003) (citation omitted).

This Court also focused on the phrase "the pharmaceutically acceptable polymer is" as a signal that Abbott was acting as it own lexicographer and defining the term to what followed- "a water-soluble hydrophilic polymer selected from the group consisting of..." In doing so, this Court ignored other intrinsic and extrinsic evidence relevant to the meaning of "pharmaceutically acceptable polymer" in claim 1.

First, in addition to claims 2 and 3 and the passage describing what a "pharmaceutically acceptable polymer is," the specification unambiguously defines "pharmaceutically acceptable" as meaning "those compounds, which are, within the scope of sound medical judgment, suitable for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections." '718 patent, col. 3:ll. 40- 47.

Second, as the Federal Circuit noted, the '718 patent explicitly defines other claim terms, which were susceptible to different meanings according to the ordinary understanding of a person of skill in the art, by stating that those terms have particular meanings within the patent. See, e.g. '718 patent, col. 3 ll. 34-35 ("'Erythromycin derivative' as used herein, means ...."); col. 3, ll. 40-41 ("'Pharmaceutically acceptable' as used herein, means ...."). Had Abbott intended the text that follows the phrase "the pharmaceutically acceptable polymer is" to be the term's definition, it stands to reason that Abbott would have employed the same method of assigning a particular meaning to the term by stating that "pharmaceutically acceptable polymer, as used herein, means ...." Sandoz argues that this view of Abbott's definitional format ignores long-standing Federal Circuit precedent that "the written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format." SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001). Sandoz is incorrect. This Court is (and the Federal Circuit advised) rejecting the assertion that the phrase "the pharmaceutically acceptable polymer is" signals the definition here, not because it is not explicit definitional language per se, but rather because Abbott used explicit definitional language elsewhere in the patent description to define terms susceptible to different meanings but did not use similar explicit language here.

Sandoz also incorrectly argues that Abbott's use of "is" unambiguously identified the term "erythromycin derivative" as a "pharmaceutically active compound" such that its use of "is" should also unambiguously identify "a water-soluble hydrophilic polymer selected from the group consisting of..." as a "pharmaceutically acceptable polymer." The term "pharmaceutically active compound" is not an element of any disputed claim so this analogy is not even a relevant one. Furthermore, the '718 patent is drafted in such a manner that there is no ambiguity as to what constitutes a "pharmaceutically active compound" whereas the same is not true for "pharmaceutically acceptable polymer."

Third, Eudragit RS and Eudragit RL are water-insoluble methacrylic acid co-polymers. Methacrylic co-polymers are specifically listed in the passage where Abbott describes the "group" from which the pharmaceutically acceptable polymer is selected. Sandoz contends that the existence of known water insoluble Eudragit polymers supports this Court adopting a narrow construction of "pharmaceutically acceptable polymer" that excludes polymers from the groups outlined in the passage that are not "water soluble" or "hydrophilic." But given the evidence already discussed, this Court finds that the existence of water-insoluble polymers from the specifically-mentioned methacrylic acid co-polymer subset actually militates towards a broader construction urged by Abbott that would encompass water-insoluble methacrylic acid co-polymers (such as Eudragit E, L and S, all three of which have powder or granule versions the Handbook of Pharmaceutical Excipients, 4th edition, regards as insoluble) instead of the narrow construction offered by Sandoz, which would exclude all water-insoluble polymers.

Abbott asserts that "pharmaceutically acceptable polymer" should be construed so as to include "any polymers, suitable for use in pharmaceutical compositions to be administered in humans that, alone or together with other polymers, are capable when mixed with the drug of forming a matrix to control and extend drug dissolution and release into the bloodstream."

The Federal Circuit's opinion at 452 F.3d 1331, at 1337-38 (June 22, 2006) and its later opinion at 473 F.3d 1196, 1209-11 (Jan. 5, 2007) are not in direct conflict as to the legal significance of Markush language, so this Court is not bound to afford precedential value to the first opinion as Sandoz argues. See e.g. Newell Cos., Inc. v. Kenney Mfg. Co., 864 F.2d 757, 765

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(Fed. Cir. 1988). Only in the extremely unlikely situation where two opinions stand in direct contrast as to the legal significance of a certain element, the first opinion prevails. Id. In the first opinion, the Federal Circuit merely approved of turning to the specification in construing the claim; it made no mention of this Court's specific reliance on Markush language. In short, the first opinion is no bar to this Court adopting a broader claim construction than it in previous rulings.

This Court finds that a person of ordinary skill in the art of this invention who read the entire '718 patent would read the term "pharmaceutically acceptable polymer" in claim 1 and construe it to mean any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, and is capable of forming a matrix to extend drug release into the bloodstream. Such a "pharmaceutically acceptable polymer" must constitute 5 to 50% by weight of the product.
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(a) Claim 1

First, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314. Claim 1 reads as follows:

A pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and from about 5 to about 50% by weight of a pharmaceutically acceptable polymer, so that when ingested orally, the composition induces statistically significantly lower mean fluctuation index in the plasma than an immediate release composition of the erythromycin derivative while maintaining bioavailability substantially equivalent to that of the immediate release composition of the erythromycin derivative.

U.S. Patent No. 6,010,718 col.11 ll.28-38 (filed Apr. 11, 1997).

None of the following elements are disputed and each term is assigned its plain and ordinary meaning as understood by a skilled artisan. The term "pharmaceutical composition" means an aggregated product formed from two or more substances for use as a drug in medical treatment. The term "gastrointestinal environment" means the organs that make up the GI tract, including the stomach, intestines, and to a lesser extent the mouth, pharynx, esophagus and the anus. The term "mean fluctuation index" means the average degree of fluctuation ((Cmax Cmin)/Cavg) over a specified period of time (usually twenty-four hours) by which pharmacokineticists can distinguish rates of release into the plasma.

The term "bioavailability" in the context of the '718 patent means the total exposure of the erythromycin derivative in the bloodstream as measured by the logarithm-transformed area under the plasma concentration-time curve ("AUC"), which is a mathematical and visual representation of the aggregate amount of the drug reaching systemic circulation over a given period of time. Bioavailabilty does not encompass both the rate and effect of release because extended release and immediate release formulations have different rates of release by definition. That is also why the claim calls for a lower mean fluctuation index for the extended release formulation versus the immediate release formulation- to highlight the importance of changing the rate of release without changing the overall amount of erythromycin derivative in the plasma. Both parties agree that in claim 1, the term "substantially equivalent to that of the immediate release composition" means the extended release composition AUC values must be between 80% to 125% within a 90% confidence level as compared to the immediate release composition AUC values.

The parties do not dispute that clarithromycin is an "erythromycin derivative." The extended release composition at issue is designed for release in the gastrointestinal environment (e.g., oral administration). The patent specification defines "erythromycin derivative" as meaning "erythromycin having no substituent groups, or having conventional substituent groups, in organic synthesis, in place of a hydrogen atom of the hydroxy groups and/or a methyl group of the 3'-dimethylamino group, which is prepared according to the conventional manner." U.S. Pat. No. 6,010,718, at col. 3:ll. 34-39. The patent specification further states that the "pharmaceutically active compound" of the composition "is an erythromycin derivative." Id., at ll. 58-61. It goes on, "[p]referably, the erythromycin derivative is 6-O-methoxy erythromycin A, known as clarithromycin." Id. The language of the claim is definite ("an erythromycin derivative") but not

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closed. It does not specify that the pharmaceutically active compound "is a member selected from the group consisting of A, B, and C." Thus, clarithromycin is an erythromycin derivative under this meaning.

Sandoz's product uses clarithromycin as its pharmaceutically active compound. As noted in an earlier decision, Abbott defined "erythromycin derivative" in the '718 patent in such a way as to exclude azithromycin. Azithromycin is the common name for 9a-aza-9a-methyl-9-deoxo-9ahomoerythromycin A. Pfizer, the patent holder on azithromycin, describes azithromycin as a "broad spectrum antimicrobial compound derived from erythromycin A." WO 95/30422 (the "'422 patent"). It is likely that Abbott consciously defined "erythromycin derivative" in claim 1 of the '718 patent so as to avoid infringing Pfizer's existing '422 patent.

The primary dispute in this matter is over the meaning of the term "pharmaceutically acceptable polymer." The term is not defined in the claim. After engaging in an extensive analysis in which the arguments of both litigants, the applicable law and available facts, and the Federal Circuit's decision in Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196 (2007) were all considered, this Court held that a person of ordinary skill in the art who read the entire '718 patent would construe the term "pharmaceutically acceptable polymer" in claim 1 to mean "any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions involving contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, and is capable of forming a matrix to extend drug release into the bloodstream." Such a "pharmaceutically acceptable polymer" must constitute 5 to 50% by weight of the product. Sandoz contends that this construction is incorrect and that after a fresh look and consideration of arguments that were not previously before any court, this Court should be persuaded to accept the construction attributed to the term in Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331 (2006). Sandoz construes the term to be "a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl either copolymers and derivatives and mixtures thereof," based upon this Court's previous construction in Abbott, 2005 U.S. Dist. LEXIS 10846, 2005 WL 1323435 at * 6.

The first place to look when inquiring into the meaning of a claim term is the claim language. Phillips, 415 F.3d at 1314. Even the claims of a patent that are not at issue in an infringement action are nonetheless part of intrinsic evidence to be considered during claim construction. Claim 1 of the '718 patent requires a composition that includes a "pharmaceutically acceptable polymer." col. 11:31-32. Claim 2 depends from claim 1 and further requires that the pharmaceutically acceptable polymer be "a hydrophilic water-soluble polymer." Id., col. 11: 39-40. Claim 3 depends from claim 2 and requires that "the polymer is selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof." Id., col. 11: 42-47. "The presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Furthermore, independent claims are generally given broader scope so as to avoid rendering corresponding dependent claims redundant. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341 (Fed. Cir. 2000)). Therefore, the language of the claims and the doctrine of claim differentiation imply that the "pharmaceutically acceptable polymer" limitation in claim 1 is most likely broader than the "hydrophilic water-soluble polymer" limitation described in claim 2 and involves more compounds than those contained in claim 3.

Sandoz contends that the doctrine of claim differentiation merely creates a presumption, North Am. Vaccine v. American Cyanamid Co., 7 F.3d 1571, 1577 (Fed. Cir. 1993), and that here the presumption is rebutted given that "the written description unequivocally discloses only one embodiment of the claimed invention," which is of a "pharmaceutically acceptable polymer" that is water soluble, hydrophilic, and selected from the specified group of polymer classes. Sandoz's Memorandum in Opposition, p. 6 (citing Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1367-68 (Fed. Cir. 2000)). When the claim does not define a term, a court will turn to the specification. The claims "'must be read in view of the specification, of which they are a part,?' because "it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (citing Vitronics, 90 F.3d at 1582). Here, the patent specification provides as follows:

The pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Preferably, the polymer is selected from hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and methyl

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cellulose. More preferably, the polymer is hydroxypropylmethyl cellulose. Most preferably, the polymer is a low viscosity hydroxypropylmethyl cellulose with viscosity ranging from about 50 cps to about 200 cps. The most preferred low viscosity polymer is a hydroxypropylmethyl cellulose with a viscosity of about 100 cps, commercially available under the Tradename Methocel TM K 100 LV from The Dow Chemical Company.

'718 patent, col. 3: l. 65-col. 4: l. 14.

Previously, this Court found that the phrase "selected from the group consisting of" in the specification signaled a Markush group, which limited the term "pharmaceutically acceptable polymer" to the polymers listed. Claim drafters often use the term "group of" to signal a Markush group, which lists specified alternatives in a patent claim. The typical form of a Markush group is "a member selected from the group consisting of A, B, and C." See Manual of Patent Examining Procedure § 803.2 (2004) (quoted in Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005)). The Federal Circuit explained that while a Markush group can be used to limit a claim to a list of specified alternatives, a Markush group has no "meaning within the context of a written description of a patent" and a court should not rely on Markush group language to limit the construction of a claim term to certain items listed in the written description. 473 F.3d at 1210. Sandoz is free to disagree with the Federal Circuit's interpretation of the law, but it is folly to deny that it is what that court held.

The presumption afforded by the doctrine of claim differentiation is not rebutted on the facts presented here. As explained in the previous opinion and above, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Furthermore, independent claims are generally given broader scope so as to avoid rendering corresponding dependent claims redundant. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341 (Fed. Cir. 2000)). Therefore, the language of the claims and the doctrine of claim differentiation imply that the "pharmaceutically acceptable polymer" limitation in claim 1 is most likely broader than the "hydrophilic water-soluble polymer" limitation described in claim 2 and involves more compounds than those contained in claim 3. "The presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." Sunrace Roots Enter. Co., Ltd. v. SRAM Corp., 336 F.3d 1298, 1303 (Fed. Cir. 2003) (citation omitted) (emphasis added).

In North American Vaccine v. American Cynamid Co., the Court held that "[w]hile it is true that dependent claims can aid in interpreting the scope of claims from which they depend, they are only an aid to interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog." 7 F.3d at 1577. That holding is inapposite here. There, the patentee attempted to construe an independent claim to include difunctional molecules (when it had only claimed monofunctional molecules) by pointing to difunctional properties of products formed from specific molecules mentioned in the dependent claim. Id. There, the monofunctional limitation was readily apparent from the independent claim itself. Id. Here, in stark contrast, the independent claim is silent as to the "pharmaceutically acceptable polymer" limitation. So even though the North American Vaccine court noted that nowhere in the specification were difunctional molecules disclosed to be included in the independent claim, such absence was not the conclusive factor in determining the scope of the independent claim.

Sandoz also cited Kraft Foods, Inc. v. Int'l Trading Co. in support of its argument that the presumption of claim differentiation is rebutted in this case. 203 F.3d 1362. In Kraft, claim 1 was an independent claim that contained a limitation (amongst others) that a back panel of a food package be "relatively stiff." Id. at 1367. Claim 2 was another independent claim that did not contain the "relatively stiff" limitation, but did contain other limitations. Id. at 1365. Kraft took the position that the claim differentiation doctrine proved that the two claims were different and the "relatively stiff" limitation should not be read into claim 2. Id. at 1368. The Court disagreed and held that the limitation was read into claim 2 and that Kraft could not depend on the doctrine of claim differentiation because in both the written description and prosecution history, the only embodiment of the invention ever offered contained a relatively stiff back panel. 203 F.3d at 1367.

There are several differences between the circumstances surrounding Kraft and those present here that support this Court's continued application of the claim differentiation doctrine. First, unlike here, where the only difference in the claims is in regard to the "pharmaceutically acceptable polymer" limitation, the two claims in Kraft contained several other limitations. Id. at 1365. Thus, if the doctrine were rebutted and the claim were construed according to Sandoz's method, the dependent claims would become entirely superfluous and redundant. That result did not occur in Kraft. Second, the claims at issue here

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are independent and dependent whereas in Kraft, the claims were both independent. Title 35 U.S.C. § 112 explains that a dependent claim must contain a further limitation than the independent claim from which it depends. See Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1380 (Fed. Cir. 2006). Thus, disregarding the doctrine here would render the dependent claims invalid. See id.

There is no question that Kraft stands for the proposition that the written description can overcome the claim differentiation presumption in certain circumstances. Id. at 1368. But those circumstances are not present here. As the cases above show, the presumption will survive where the effect of ignoring the doctrine would render the dependent claims superfluous or even invalid, where the only embodiment of the invention provided in the description is the same one appearing through the independent and dependent claims. It should be noted that Sandoz failed to cite to a single case in which a court found the doctrine rebutted where the dependent claim's only limitation was the element separating it from the independent claim. In fact, in another patent case dealing with construction of an independent claim element, the Federal Circuit went to great lengths to construe an independent claim broader than it otherwise appeared from the specification and prosecution history. See Dow Chemical Co. v. United States, 226 F.3d 1334 (Fed. Cir. 2000) cited in 5A-18 Chisum on Patents § 18.03 [6][a]. That was done mainly because the court found some support for the broader interpretation in the specification but also because the dependant claim contained a narrower limitation than the claim from which it depended. 226 F.3d at 1339-42.

Sandoz also takes issue with Abbott's use of the phrase "a pharmaceutically acceptable polymer is" and this Court's unwillingness to interpret it as unambiguous definitional language. Sandoz is of the opinion that because no authority exists for the proposition that a lexicographer must use the same method of defining terms throughout a patent and because of that, this Court erred in not concluding the phrase "the pharmaceutically acceptable polymer is" did not signal definition the term. Sandoz is correct that no authority exists for that proposition, but this Court never depended on such a proposition in reaching its conclusion. Instead, what this Court stated was that it rejected the assertion "that the phrase 'the pharmaceutically acceptable polymer is' signals the definition here, not because it is not explicit definitional language per se, but rather because Abbott used explicit definitional language elsewhere in the patent description to define terms susceptible to different meanings but did not use similar explicit language here." Abbott Labs. v. Sandoz, Inc., 500 F. Supp. 2d 807, 833-43 (N.D.Ill. 2007). This observation was made in light of the continuing and unrebutted presumption afforded by the doctrine of claim differentiation.

Sandoz also makes two new arguments regarding the '718 patent's use of "pharmaceutically acceptable excipients." First, Sandoz points out that when describing what is included within "pharmaceutically acceptable excipients," the patent uses the phrase "such as" when offering examples of what excipients, fillers and extenders come within the term's scope. Sandoz's argument is that had Abbott attempted to merely offer examples of what polymers come within the scope of the term "pharmaceutically acceptable polymer," as opposed to offering an explicit definition, it would have used terminology similar to what it used for "excipients… such as" instead of the word "pharmaceutically acceptable polymer is". Second, Sandoz argues that since both "pharmaceutically acceptable polymers" (under the current construction) and "pharmaceutically acceptable excipients" include starches and polyethylene glycol, any distinction between the two terms is not recognized under the current construction. Thus rendering such a construction incorrect.

As to Sandoz's first argument, Sandoz itself provides the explanation for the discrepant treatment of the terms "pharmaceutically acceptable polymers" and "pharmaceutically acceptable excipients." Drafters are under no obligation to draft terms the same way throughout the patent. One must look at the entire patent and the context within which the term is being used to correctly construe its meaning. The term "excipients" does not even appear in the claims of the '718 patent and there is no presumption created from the doctrine of claim differentiation affecting its construction. Thus, the juxtaposition of polymers and excipients does not, alone, counsel for construing "pharmaceutically acceptable polymers" narrowly to only include those specific polymers listed in the description.

Sandoz's second point is of little consequence. The current construction of "pharamaceutically acceptable polymer" encompasses those polymers that are capable of extending release, either alone or in a matrix united with other compounds. Sandoz's own expert, Dr. Chambliss, stated that the "starches" and "polyethylene glycol" do not extend release. The discriminating feature of the "pharmaceutically acceptable polymer" is its ability to extend release while maintaining certain pharmacokinetic limitations. Thus, those compounds, even if they are polymers generally, cannot be "pharmaceutically acceptable polymers" under the current construction of the term.

Sandoz gives the following example highlighting what it regards to be the absurdity of the current claim construction: If a

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patentee described a "vehicle" as selected from the group consisting of bicycles, skateboards and roller blades in the specification, and she drafted an independent claim using the term "vehicle", then she should not be able to expand the definition of "vehicle" to include airplanes simply because the succeeding dependant claims specify the "vehicle" to be bicycles, skateboards or roller blades or progressively narrower subspecies of bicycles, skateboards or roller blades. A more appropriate example would be where it is apparent from the patent as a whole that the vehicle's purpose is to transport people, and the description of "vehicle" is nowhere limited to bicycles, skateboards or roller blades (the Markush group has no meaning and the term "is" does not signal explicit definitional language here) then, an airplane can fit within the term "vehicle," as long as it fulfills the unambiguous purpose of the term "vehicle" in the invention (as can best be discerned from the rest of the specification and then extrinsic evidence). In sum, Sandoz's example does not persuade the Court that its construction of the term "pharmaceutically acceptable polymer" is incorrect.

Sandoz also challenges the assumption that its construction of "pharmaceutically acceptable polymer" excludes a class of water-insoluble polymers. This argument is just another variant premised on assumptions this Court has already rejected and Sandoz only confuses the issue. Claim 1 limits the invention to the use of "pharmaceutically acceptable polymers." Claim 2 limits the invention to the use of claim 1's pharmaceutically acceptable polymers that are hydrophilic and water-soluble. Claim 3 limits the invention to the use of hydrophilic, water-soluble pharmaceutically acceptable polymers that are selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof. Although it would probably make more sense if claim 3 preceded claim 2, there is nothing contradictory or confusing about these claims. The limitation of claim 1 is broader than the limitation of claim 3. Therefore, the term "pharmaceutically acceptable polymer" from claim 1 is broad enough to encompass water-insoluble methacrylic acid copolymers while the term in claim 3 necessarily only encompasses those methacrylic acid copolymers that are water-soluble and hydrophilic. Sandoz itself presents evidence that such methacrylic acid copolymers exist and were known to exist at the relevant time.

Next, Abbott makes a startling assertion that in its claims, the "pharmaceutically acceptable polymer" need not act alone to extend release in the invention. Its purported basis for this construction is the use of the term "comprising," which indicates that the patentee intended the claim to be open-ended and to allow for additional items. Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1367 (Fed. Cir. 2003). In claim 1, the composition is comprised of "an erythromycin derivative and from about 5 to about 50% by weight of a pharmaceutically acceptable polymer,…" In the description, Abbott explains that the pharmaceutically active compound is the erythromycin derivative, and the rest of the formulation consists of the pharmaceutically acceptable polymer and several optional excipients, fillers, extenders and/or lubricants.

First, it is not at all clear that the term "comprising" modifies the release-extending components of the formulation rather than merely referring to the fact that more than just the polymer and the active ingredient can go into the composition, as evidenced by the passages on excipients, fillers and lubricants appearing in the description. Second, as observed earlier, the defining feature of any "pharmaceutically acceptable polymer" is its capability to extend release in the bloodstream. Thus, to be found to read upon the '718 patent's claim, the infringer's product at a minimum must contain a polymer that possesses release-extending properties and is, in fact, contributing to the extended release of the product.

Lastly, Sandoz argues that the claims do not contain any reference to matrices and as such, claim 1 should not be construed to include such an element. In support of this, Sandoz asserts that the liquid dosage forms of the invention listed in the description are not capable of tablet matrix formulations. It also refers to Abbott's admission (made by Dr. Davis, Abbott's pharmaceutical expert, during a deposition) that the formulation of a matrix system is not compatible with liquid dosage forms. According to Sandoz, these two facts indicate the scope of the patented invention does not embrace a matrix limitation. Abbott replies that the reference to liquid dosage forms is a mistake, a vestige of earlier attempts at drafting. It contends that the description includes embodiments in the form of tablets, pills and suspensions that can be made as matrix-forming compositions. Abbott also points out that it was known in the art that matrix-forming compositions including suspensions could extend release. Thus, for Abbott, these facts lead to the conclusion that the claim 1 necessarily encompasses matrix-forming compositions.

To properly understand why Sandoz believes matrix-forming polymers should be excluded from the definition of "pharmaceutically acceptable polymers" one must first recognize that the specified polymers of claim 3 all form gels to extend release, not matrices, and that Sandoz's product contains a polymer that, along with other ingredients, forms a matrix to extend release. Thus, this is yet another attempt by Sandoz to demonstrate that the term "pharmaceutically acceptable

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polymer" does not encompass polymers beyond those specifically listed in the description and in claim 3. If matrix-forming polymers are inconsistent with liquid dosage forms of the invention but consistent with tablets, pills and suspensions, one can only conclude that the universe of polymers that can be used with the various embodiments of the patented invention must include more than non-matrix forming polymers; thus supporting the broad construction of "pharmaceutically acceptable polymers" in claim 1.

Finally, it worth noting that in the background section of the patent, it is explained that past attempts at controlled release formulations of erythromycin and erythromycin derivatives had been made including one which yielded an alginate matrix, but did not alleviate adverse gastrointestinal effects associated with erythromycin and its derivatives. This section goes on to suggest that the present invention was a direct attempt to provide an erythromycin derivative in a pharmaceutical composition that was palatable, minimized adverse GI reactions and controlled the concentration of drug in the bloodstream like or better than the immediate release tablet and liquid dosage forms then on the market. This evidence makes it all the more certain that the patent was intended to cover more than just gel-forming or matrix-forming polymers. It is also fairly clear that the release-extending component in the patented invention be the polymer.

This Court concludes that the term "pharmaceutically acceptable polymer" in claim 1 means any polymer, which within the scope of sound medical judgment is suitable for use in pharmaceutical compositions for use in contact with the tissues of humans and lower animals without undue toxicity, irritation, allergic response, and the like, in keeping with a reasonable benefit/risk ratio, and effective for their intended use in the chemotherapy and prophylaxis of antimicrobial infections, that extends drug release into the bloodstream either alone or in conjunction with other such polymers or other components, and is capable of forming a gel or a matrix to extend drug release into the bloodstream.
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Turning then to the propriety of the trial court's claim construction, Hercon's principal argument is that the court erred in relying on so-called extrinsic evidence, i.e., evidence outside of the 'patent record,' see Markman, 52 F.3d at 980, 34 U.S.P.Q.2D (BNA) at 1330 ("Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treaties."). This court has made strong cautionary statements on the proper use of extrinsic evidence, see Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 U.S.P.Q.2D (BNA) 1573, 1577 (Fed. Cir. 1996), which might be misread by some members of the bar as restricting a trial court's ability to hear such evidence. We intend no such thing. To the contrary, trial courts generally can hear expert testimony for background and education on the technology implicated by the presented claim construction issues, and trial courts have broad discretion in this regard. See Markman, 52 F.3d at 980-81, 34 U.S.P.Q.2D (BNA) at 1330-31 ("The court may, in its discretion, receive extrinsic evidence . . . . for the court's understanding of the patent . . . ."); Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1373, 47 U.S.P.Q.2D (BNA) 1732, 1737 (Fed. Cir. 1998) (extrinsic evidence "always may be admitted by the trial court to educate itself about the patent and the relevant technology . . ."); cf. General Elec. Co. v. Joiner, 522 U.S. 136, 118 S. Ct. 512, 515, 517, 139 L. Ed. 2d 508 (1997) (holding that decision to admit or exclude expert testimony is reviewed under the abuse of discretion standard).

Furthermore, a trial court is quite correct in hearing and relying on expert testimony on an ultimate claim construction question in cases in which the intrinsic evidence (i.e., the patent and its file history--the 'patent record') does not answer the question. See Vitronics, 90 F.3d at 1584, 39 U.S.P.Q.2D (BNA) at 1578 ("No doubt there will be instances in which intrinsic evidence is insufficient to enable the court to determine the meaning of the asserted claims, and in those instances, extrinsic evidence . . . may . . . properly be relied upon to understand and construe the claims.").

What is disapproved of is an attempt to use extrinsic evidence to arrive at a claim construction that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent. See Markman, 52 F.3d at 981, 34 U.S.P.Q.2D (BNA) at 1331 (extrinsic evidence may not be used "for the purpose of varying or contradicting the terms in the claims"); Vitronics, 90 F.3d at 1584, 39 U.S.P.Q.2D (BNA) at 1578. Thus, if the meaning of a disputed claim term is clear from the intrinsic evidence--the written record--that meaning, and no other, must prevail; it cannot be altered or superseded by witness testimony or other external sources simply because one of the parties wishes it were otherwise. See id. Competitors are entitled to rely on the

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public record of the patent, and if the meaning of the patent is plain, the public record is conclusive.

Hercon contends that the trial court's construction of the phrase "a pharmaceutically effective amount" violates this prohibition. According to Hercon, the patent itself defines this amount as being as low as 1.5 mg of nitroglycerin per day and that it was therefore improper to rely on FDA values--evidence extrinsic to the patent record--to reach a contrary lower limit. Hercon points to the "OBJECTS OF THE INVENTION" set forth in the patent's written description in which it is stated that one "object of the invention is to provide a dosage system wherein nitroglycerin is delivered to the skin in an amount of from about 0.3 to about 0.7 mg per square centimeter of the [adhesive] layer per 24-hour time interval," '938 patent, col. 4, l. 67, to col. 5, l. 3, and the patent's "DETAILED DESCRIPTION OF THE INVENTION" in which it is stated that "the presently contemplated preferred [patch] sizes are 5, 10, 15, 20, 25 and 30 cm2," id. col. 9, ll. 47-49.

According to Hercon, one arrives at the minimum "pharmaceutically effective amount" by multiplying the lowest stated flux rate (i.e., 0.3 milligrams per square-centimeter per day ("mg/cm2-day")) by the smallest stated preferred patch size (i.e., 5 cm2), which yields 1.5 mg/day. Hercon is certainly correct that multiplying flux rates by patch sizes yields daily dosages. However, there is no suggestion in the '938 patent that the full stated range of flux rates can be combined with the full stated range of preferred patch sizes to obtain delivery of "pharmaceutically effective amounts" of nitroglycerin. That is, there is no suggestion that each and every combination of flux and patch size from the stated ranges will be effective.

Most importantly, there is no suggestion to use the lowest stated flux rate with the smallest stated preferred patch size. To the contrary, the patent teaches that enough drug be incorporated into even the smallest preferred patch size to provide pharmaceutical efficacy: "The present invention allows for the incorporation of enough pharmaceutically active drug such as nitroglycerin to provide efficacy with a dosage system having a 5 cm2 surface area and a thickness of about 3.5 to 4 mm." Id. col. 9, ll. 51-55.

Furthermore, Hercon's argument is unconvincing because it is based on using the smallest "preferred" patch size (5 cm2), whereas the full stated range of patch sizes is 1 to 200 cm2. Id. col. 9, ll. 46-49 ("A surface area in the range of 1 to 200 cm2 is contemplated and the presently contemplated preferred sizes are 5, 10, 15, 20, 25 and 30 cm2."). Thus, under Hercon's approach one would actually expect to combine the overall smallest patch size (1 cm2) with the lowest flux rate (0.3 mg/cm2-day)--not the smallest "preferred" patch size. This combination would give a 0.3 mg/day patch, which is well below the 2.5 mg/day minimum dosage approved by the FDA. Accordingly, Hercon's assertion that the patent teaches that combining the smallest patch size with the lowest flux rate produces the minimum "pharmaceutically effective amount" is without merit.

Indeed, under Hercon's direction, its expert Dr. Guy testified that the flux rates disclosed in the patent tell one nothing about the meaning of the term "pharmaceutically effective amount":

Q. Looking at the recitations . . . relating to flux rate . . ., does that tell you anything about the meaning of the term "pharmaceutically effective amount" as used in the claims of the '938 patent?

A. No.

Tr. at 1104.

Nor did Key's expert, Dr. John K. Beasley, a Ph.D. in physical chemistry, testify that one skilled in the art would combine the extremes of the disclosed ranges of flux rates and patch sizes to determine the range of amounts represented by the term "pharmaceutically effective amount." Rather than addressing the amounts represented by this term, Dr. Beasley and Key focused on whether the disputed claim clause "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of said [nitroglycerin] over a 24-hour time interval" incorporates and therefore requires the written-description stated flux range (0.3 to 0.7 mg/cm2-day, see '938 patent, col. 4, l. 67, to col. 5, l. 3), weight percentage of nitroglycerin in the adhesive layer (20 to 60 percent, see id. col. 7, ll. 11-15) and efficacy capability with a small patch (5 cm2, see id. col. 9, ll. 51-55). See Key Pharm., 981 F. Supp. at 308-10. Key apparently sought to incorporate these parameters from the patent's written description into the claim clause to avoid the '959 reference. This attempt was rejected by the trial court. See id. We do not address the matter because neither party has raised it on appeal.

In sum, neither Hercon nor Key has pointed to intrinsic evidence establishing the numerical range of amounts represented

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by the term "pharmaceutically effective amount." Nor have we independently found any. Thus, the resort to and use of extrinsic evidence in this case was entirely appropriate.

Furthermore, we detect no error in the particular extrinsic evidence relied upon by the trial court. To the contrary, it is quite sensible to look to the FDA to determine what amounts are considered pharmaceutically effective. In 1984, the earliest effective filing date for the '938 patent, the FDA considered 2.5 to 15 mg/day to be pharmaceutically effective; in fact, that is the range of dosages approved by the FDA as effective through at least 1993, see Notice, 58 Fed. Reg. 38129, 38130-31 (1993). n3 The trial court's determination that this range corresponds to that represented by the term "pharmaceutically effective amount" is logical and appropriate; it does not constitute error. See Markman, 52 F.3d at 986, 34 U.S.P.Q.2D (BNA) at 1335 ("In construing disputed terms in claim language . . . [,] the focus is on . . . what one of ordinary skill in the art at the time of the invention would have understood the term to mean.").

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n3 The FDA's approved range of nitroglycerin dosages is expressed in terms of milligrams per hour ("mg/h"), namely 0.1 to 0.6 mg/h. See 58 Fed. Reg. at 38130-31. This corresponds to the 2.5 to 15 mg/day range in that this range of daily dosages converts to an hourly range of 0.104 to 0.625 mg/h when divided by 24 hours.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Lastly on the issue of claim construction, we address Hercon's alternative argument that, if looking to FDA-approved dosages to construe claim 14 is deemed proper, the lower limit of the term "pharmaceutically effective amount" is actually 2.0 mg/day. Hercon arrives at this conclusion by noting that the FDA considers a transdermal patch to be bioequivalent to an approved patch if the amount of drug it delivers is within plus or minus 20 percent of that delivered by the approved patch. According to Hercon, the lower limit should therefore be 20 percent less than the 2.5 mg/day minimum approved dosage--i.e., 2.0 mg/day. However, as concluded by the trial court, there is insufficient evidence in the record to establish that "one of ordinary skill in the art would have so construed 'a pharmaceutically effective amount.'" Key Pharm., 981 F. Supp. at 312.
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The Court has construed the limitations of Claim 1, in relevant part, as follows:

"Active" means producing an intended action or effect: active ingredients.
"Pharmacologically effective" means an amount that is medically effective.
"Complex carbohydrates" means a polymer comprising more than two sugar moieties, such as heparin, hyaluronic acid, chondroitin sulfate 1, dermatan sulfate, keratan sulfate and acemannan, for example.
"Amount effective" means a quantity that produces a result.
"Allow penetration of the dermis of mammals by the complex carbohydrate" means the combination of the complex carbohydrate and the essential oil produces a treatment effect by the complex carbohydrate. That treatment effect is pain relief.
"Dermis" means the sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels.
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Phenotype	An observable property of an organism or a cell as produced by the genotype in conjunction with the environment

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A. "PHN"

Generally, PHN is a complication of herpes zoster, a condition more commonly known as shingles. (See id. at 1:60-61; Novartis's Opening Claim Constr. Br. [hereinafter "Novartis's Br."], at 1.) The parties do not dispute this general characterization. The parties also "agree that PHN is a distinct condition from acute herpes zoster, and that people who develop PHN suffer from a debilitating and often intractable pan that can last for months or even years." (Roxane's Opening Claim Constr. Br. [hereinafter "Roxane's Br."], at 2; seealso 581 Patent, Col. 1:63-65.) Rather, the parties dispute when PHN begins after herpes zoster ends. Novartis proposes the following construction of the term "PHN" as used in Claims 1 and 15:

Also known as post-herpetic neuralgia, a complication of a herpes zoster infection characterized by pain at or after rash healing.

(Novartis's Responsive Claim Constr. Br. [hereinafter "Novartis's Resp. Br."], at 3 (emphasis added).) Roxane, on the other hand, defines "PHN" to mean:

The experience of pain long (i.e., more than 4 to 6 weeks) after healing of an acute herpes zoster virus rash.

(Id. (emphasis added).) The parties do not dispute that the "healing" referred to in the proposed constructions is the point "at which a patient had no papules, vesicles, ulcers, or crusts, and did not develop them at any later visit." (581 Patent, Col. 7:50-52.)

Roxane argues that pain up to four weeks after healing of the herpes zoster lesions continues to be herpes zoster pain. Roxane argues that its construction of "PHN" is correct because "the ordinary meaning of the term 'PHN' as understood by clinicians in the early 1990s was the experience of pain persisting more than fore to six weeks after healing ofthe acute herpes zoster rash." (Roxane's Br., at 11.) It further argues that "[a]bsent 'an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning.'" (Id., at 14 (citing a pre-Phillips case, York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996).) In other words, Roxane argues that, unless a patentee expressly redefines a term to depart from its ordinary meaning as it is understood in the abstract, as determined by reference to extrinsic evidence, then that "ordinary meaning" prevails. Thus, the majority of Roxane's argument and analysis begins with an examination of extrinsic evidence.

In Phillips, the Federal Circuit expressly rejected an approach that "limit[ed] the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term." 415 F.3d at 1320. The Phillips Court stated that "requiring that any definition of claim language in the specification be express . . . is inconsistent with our rulings that the specification is the single best guide to the meaning of a disputed term, and that the specification acts as a dictionary when it expresslydefines terms used in the claims or when it defines terms by implication." Id. at 1320-21 (internal quotations omitted; emphasis added); see also Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001) ("[A] claim term may be clearly redefined without an explicit statement of redefinition.") (as quoted in Phillips). The Phillips Court further noted that "[t]he main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent." Id. at 1321.

Here, the specification contains the following statements related to the meaning of PHN:

• The effect of famciclovir on PHN (defined as pain at or after healing) was evaluated by assessing pain at 5 monthly visits after healing. (581 Patent, Col. 4:31-32.)

• [S]ome [herpes zoster] patients continue to experience pain long after healing and this is commonly referred to as postherpetic neuralgia. (Id. at 6:3-5.)

• Secondary variables included . . . duration of postherpetic neuralgia (ie, time to loss of pain after healing). (Id. at 7:47-50.)

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• Postherpetic neuralgia has been definedin relationship to acute zoster onset, at time points ranging from one to six months after zoster rash appears, and in relationship to healing of zoster lesions, as was done in the current study. (Id. at 10:34-38 (internal citations omitted).)

All of these statements were made in the sections of the specification discussing a clinical study involving the use of famciclovir. It should be noted, however, that this study was the only study discussed in detail in the specification and comprised a significant portion of the specification; other studies were noted only by reference in relation to the primary study or by citation. In addition to these statements in the specification, the prosecution history contains the following statement by the Examiner distinguishing the prior art from the '581 patent:

The poster citation from ICAAC presented by Dr. Patrick Gheeraert teaches the administration of famciclovir, a derivative of penciclovir, for the treatment of pain during an active outbreak of herpes [zoster] viral lesions and throughout various stages various stages of lesion healing. The disclosed graphs show the efficacy of famciclovir with respect to time to loss of pain. Gheeraert doesnot teach or suggest the administration of famciclovir or penciclovir in methods for the treatment of postherpetic neuralgia after healing of the zoster lesion or for the prophylactic treatment of postherpetic neuralgia.

(Decl. of Dr. Donald H. Gilden [hereinafter "Gilden Decl."], Ex. 16, 581 Patent Prosecution Hist., at ROX00050348 (italics emphasis added).)

Novartis argues that PHN is expressly defined in the patent as pain at or after healing, referring primarily to the first specification excerpt highlighted above. Roxane argues that this statement is insufficient to act as an express definition in the patent. The Court need not answer that question because it finds that the term PHN is defined in the specification at least by implication.

First, the clinical study discussed in the specification clearly used a definition of PHN which is the same as or similar to the one Novartis proposes. And, although the discussion related to the clinical study does acknowledge other definitions of PHN, including one encompassing Roxane's proposed definition, it expressly states that those other definitions were not used for the study. Additionally, while the specification may contain referencesto articles and other studies that used the definition proposed by Roxane, Roxane's proposed definition is never adopted in the specification's discussion. Thus, Roxane's proposed definition of "PHN" is contrary to the only way that the term was expressly used in the specification. Second, the Examiner's statement in the prosecution history refers to a period for the treatment of PHN "after healing of the zoster lesion." The statement does not specify or state that any time lag is required after healing for the '581 patent to be differentiated from the prior art, which dealt with methods for the treatment of pain "during an active outbreak of herpes [zoster] viral lesions and throughout various stages various stages of lesion healing," i.e. before healing. Third, Roxane's expert, Dr. Gilden, testified that the "definition of 'PHN' as defined in this patent" was "pain at or after healing." (Gilden Dep. Tr. 101:4-20.) Fourth, the extrinsic evidence submitted does not support a finding that there was a common meaning of PHN even in the abstract. The specification noted that, in 1993 or before, the relevant period for construction of the '581 patent, the definition of postherpetic neuralgiavaried between studies. Roxane's expert, Dr. Gilden, agreed that there was not one and only one ordinary meaning of PHN in 1993. (See id. at 98:2-11.) The extrinsic evidence submitted by the parties indicates that PHN was defined by some as including pain at anytime after healing. (See, e.g., Whitley Decl., Ex. B, Schmader et al., Are Current Therapies Useful for the Prevention of Postherpetic Neuralgia?, J. Gen. Intern. Med. (1989), at ROX00050264 ("We suggest defining PHN as pain after the skin has healed. This definition eliminates confusion with discomfort from cutaneous lesions and avoids choosing an arbitrary point in time at which to call zoster neuralgia 'postherpetic.'").) Thus, a definition for PHN of pain after healing was not novel in 1993.

But, while the Court finds that PHN has been defined at least by implication in the specification, it does not agree with Novartis that the definition is properly construed as "at or after healing" versus simply "after healing," as was more consistently used in the specification and as used by the Examiner. Novartis argues that the distinction between the two phrases is inconsequential because healing is a split second in time. Novartis argues that the addition of the word "at" in the definition "emphasize[s] that PHN includes pain that persists at healing, as well as any pain that may later develop in persons who are pain-free at healing." (Novartis's Resp. Br., at 13.) The Court finds the addition of the word "at" to be unnecessary and not as consistent with the intrinsic evidence as a whole. The word "after" captures pain at any point after healing. Whether the pain persisted or whether it had ceased and recurred, either would be pain after healing and would be

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considered PHN. Therefore, the Court construes the term "PHN" as used in Claims 1 and 15 to mean: Also known as post-herpetic neuralgia, a complication of a herpes zoster infection characterized by pain after rash healing.
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The only disputed claim construction concerns the term "phosphoric acid source." The district court observed that "the most natural reading of the term 'phosphoric acid source' would be a source of phosphoric acid," but held that "that is not the way the term is defined in the specification." The court held that "phosphoric acid source" means "an acidic chemical that acts as a source of phosphate," explaining that the '264 specification makes clear that the term "phosphoric acid source" is an "acidic neutralizing phosphate source" including acid and acid salts. We agree that this meaning is required by the specification, which states:

The composition is formed in substantially two stages: a first stage which involves mechanical intimate mixing and milling of a calcium source, e.g., tetracalcium phosphate, tricalcium phosphate, calcium carbonate, or calcium oxide, and a phosphoric acid source substantially free of uncombined water, desirably having at least 2 protons per phosphate and not more than about 1 water of hydration per molecule, and, in addition other optional additives; and a second stage which involves mixing . . . to provide the final product, which sets up to a calcium phosphate mineral, e.g., a hydroxyapatite, having desirable mechanical properties.

The first stage involves the mechanical mixing of the primary calcium sources. The acidic neutralizing phosphate source will be free of uncombined water and may be orthophosphoric acid crystals or monocalcium phosphate monohydrate Ca(H[2]PO[4])[2] . H[2]O or another calcium phosphate acid source by itself or in combination e.g., monetite . . . .

'264 patent, col. 3, lines 7-29.

The meaning of a technical term in a patent claim is determined in accordance with its usage in the specification, elaborated if appropriate by the prosecution history and with due consideration to usage in the field of the invention. A technical term in a patent document has the meaning that it would be understood to have by persons knowledgeable in the field of the invention and the prior art. A technical term is not properly removed from its context in order to seek its meaning. See Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed. Cir. 2001) ("The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose."). Whether a term appearing in a patent claim is subject to limitations beyond its abstract general meaning is determined in the context of the invention described in the specification, the prosecution history, and the prior art. See Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999); Hoechst Celanese Corp. v. B.P. Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996).

The district court observed that the specification uses the terms "phosphoric acid source," "acidic neutralizing phosphate source," and "calcium phosphate acid source" interchangeably, illustrating such materials with orthophosphoric acid and monocalcium phosphate. The district court's claim construction accords with the chemical descriptions in the specification. No contradictory information appears in the patent prosecution; the record fully supports the district court's construction. We confirm that "a phosphoric acid source" means acidic phosphates that are sources of the phosphoric component of the composition.
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"Phosphorous-Containing Salts"

Plaintiffs contend that the plain language of the claims is that each salt of the phosphorous acid is considered separately in determining whether there is a "salt thereof" present in amount of "about 30 to about 40 weight percent." Plaintiffs read the limitation of "at least one salt" with the limitation "wherein said . . .salt . . . is present in an amount . . . to mean that the limitation is met so long as one of the salts is present in an amount of "about 30 to about 40 weight percent." Plaintiff contends that there is simply nothing within the specification or patent history that requires the interpreting the phrase

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"phosphorous-containing acid or salt thereof is present is present in amount of about 30 to about 40 weight percent" other than by reference to the plain language of the claim.

In reply, defendant argues that plaintiffs' claim construction would read in the words "at least one" to the claim limitation "wherein said phosphorous-containing acid or salt thereof is present in amount of about 30 weight percent to about 40 weight percent," and read out the upper limit of the claimed range. Morever, defendant contends that plaintiffs' claim construction is contrary to the 255 patent specification and prosecution history. Defendant argues that from the 255 specification, it is clear that no particular phosphorous-containing acid or salt has beneficial properties different from the others. In addition, the patent specification sets forth nine examples of the patented invention. Those examples describe fertilizers having from one phosphorous acid or salt to as many as seven different phosphorous acids or salts. Farone Decl. P 15-31. According to Grow More's expert, Dr. Farone, it is not even possible to calculate the percentage of any one salt in the seven examples containing two or more phosphites. Id., at P 15. Grow More further contends that the prosecution history requires aggregation of the phosphorous acids and salts. In the communications between the examiner and The Regents, there is no reference to specific individual phosphorous containing acids and salts. Rather, The Regents discussed the concentration of the fertilizer as a whole.

This court agrees with defendant that the claim must be construed to aggregate the salts as a whole. Aggregation of the phosphorous salts is supported by the claim language, the specification, and the prosecution history.
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B. Discussion

The motion for reconsideration focuses on the interpretation of the term "phosphorous-containing acid" in the subject claims of the 255 Patent. In proffering interpretations for that term, it is plaintiffs' position that "phosphorous-containing acid" as used in the claims is a representative term -- a "chemical equivalent" of what is present in the claimed composition. In contrast, Defendant's proffered interpretation, and the interpretation adopted by this Court, is that "phosphorous-containing acid" must actually be present in the claimed composition as an acid or salt.

Plaintiffs argue that reconsideration is justified based on the "strongly convincing nature of the evidence of statements made in the prosecution file history of a closely related patent -- statements pertaining directly to the meaning of the critical claim language phosphorous-containing acid.'"

The related Patent is the 655 Patent. In the 665 Patent application, a first amendment was submitted on April 12, 1999. Id. at 9:7. Plaintiffs point out that this was the first amendment submitted for either patent which introduced a lower limit on the concentration of the phosphorous-containing acid or salt thereof. Id. at 9:8-9., The remarks accompanying this amendment explain the addition of a limitation for phosphorous acid or salt thereof in an amount of 27 wt.% or greater, as follows:

"The limitation that the phosphorous acid or salt thereof be in an amount of about 27 wt.% or greater is based upon Example 9. When one calculates the amount of phosphorous acid in Example 9, one obtains an amount of about 27 wt.% (the actual calculation is 26.6 wt.% and this variation from 30 wt.% is due to an adjustment for specific gravity.) If the examiner would find the actual calculations helpful, they can be supplied." (Request for Judicial Notice filed herewith ("RJN"), p.B51.)

Id. at 9:9-15.

Plaintiffs assert that these remarks are critical because the calculation submitted by the applicant's attorney was the chemical equivalent of the phosphorous acid in example 9, and not the actual amount of phosphorous acid. (Peter Decl., P 3.) Plaintiffs argue that the examiner presumably understood this and did not request the offered calculations. Id. at 9:18-19.

On June 2, 1999, the examiner again rejected the claims of the 665 application based on an article written by Robertson and Boyer (the "Robertson and Boyer reference"). RJN, pp. B58-B63. According to plaintiffs, this rejection did not reach patent counsel which had been changed and resulted in the progress of the 665 Patent falling behind the 255 Patent. RJN, p. B64 and pp. B78-B101.

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Thus, it was the 255 reexamination that was next address by the examiner on August 11, 1999. The 255 Patent claims were also rejected in reexamination based on the Robertson and Boyer reference. Id. at 10:3-5. Claiming to be unaware of the similar rejection in the 665 Patent application, plaintiffs state that on October 18, 1999, an amendment to the 255 Patent was filed in the reexamination. Id. at 10:5-6. This amendment introduced the 30-40% concentration limitation which was similar (although more restrictive) to the 27% concentration limitation that had been previously introduced in the 665 Patent application. Id. at 10:6-9. As a result of this amendment, the Reexamination Certificate was issued on the 255 Patent. Id. at 10:9-10. Plaintiff argues, therefore, that at the time the amendment introducing the 30-40% limitation in the 255 Patent reexamination was allowed, the examiner understood, based on the 665 amendment filed 6 months earlier, that the claim language "phosphorous-containing acid" was a reference to its chemical equivalent." Id. at 10"10-13.

Thereafter, following withdrawal of the abandonment of the 665 application, on April 19, 200, an amendment was filed in response to the rejection of June 2, 1999. Id. at 10:14-15. That amendment included a clarification of the limitation relating to the concentration of phosphorous acid. Id. at 10:16-17. The April 19, 2000 Amendment reads, in pertinent part:

"Applicant apologizes for having made unclear statement in her prior amendment mailed April 12, 1999. On page 6 of that amendment was stated:

With respect to new claim 25, the limitation that the phosphorous acid or salt thereof be in an amount of about 27 wt.% or greater is based upon Example 9. When one calculates the amount of phosphorous acid in Example 9, one obtains an amount of about 27 wt.% (the actual calculation is 26.6 wt.% and this variation from 30 wt.% is due to an adjustment for specific gravity).

The calculation above noted was correct, but was a weight/weight percent" however, as stated in column 6, line 67 of the parent patent 255 (corresponding to page 11, line 20 of the subject application), all formulations are expressed in terms of weight to volume.' Consequently, Applicant believes a return to the original lower limit of 30 weight percent is appropriate. Support for the words or greater' is supported, for example, by the amount of phosphorous acid provided in Example 1 (46.3 weight/volume percent assuming density of 1.3)."

RJN, p. B112, (emphasis in original)

Plaintiffs argue that these remarks are also critical in that the applicant's attorney was again talking about the chemical equivalent of the phosphorous acid, this time in both example 9 and example 1. Peters Decl., PP 3-4. In addition to the above discussion of the concentration, plaintiffs note that the remarks accompanying this amendment also referred examiner Langel to the 255 reexamination, which he had recently conducted: "As the examiner will readily appreciate, new claims 36-67 are directly based upon claims of parent patent 5,830,255, which has been in reexamination." RJN, p. Bill. The remarks go on to state: "Applicant believes that the article by Robertson and Boyer (pages 396-401, 1956) is distinguished for the same reasons that have been articulated in the reexamination of the parent." RJN, p. B112. Plaintiffs argue that these statements demonstrate the significant relationship between the 255 and 665 Patents. Motion for Reconsideration, p. 11:9-10.

Thus, plaintiffs contend, at the time examiner Langel reviewed the October 1999 amendment in the 255 Patent reexamination (which added the 30-40% range of concentrations for the phosphorous-containing acid), he had already received some 6 months earlier in the 665 application, a similar limitation on the range of concentration (27 wt.%) together with an explanation as to how the specified concentration was determined -- based on chemical equivalents. Id. at 11:17-22. As a result, plaintiffs argue, the phrase "phosphorous-containing acid" found in the 255 Patent claims should be interpreted the same way that the same phrase would be interpreted in the 655 Patent -- as referring to the chemical equivalent of the acid present in the resulting fertilizer product. Id. at 11:22-25.

Thus, in order to be consistent, plaintiffs assert that this identical phrase in the claims of the 255 Patent should be interpreted in the same way that the phrase would be interpreted in the claims of the 665 Patent: as referring to the chemical equivalent of the phosphorous-containing acid present in the final fertilizer product.

In opposition, Defendant first argues that Plaintiffs' reference to a portion of the 665 Patent prosecution history is not new evidence. Opposition, p. 5:1-2. Defendant points out that the 665 Patent issued on September 5, 2000, so the entire

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prosecution history of that patent was complete and available to Plaintiffs since that time. Id. at 5:2-4. Thus, defendant correctly argues, the 665 Patent prosecution history was available to Plaintiffs before briefing was completed on Plaintiffs' motion for a preliminary injunction, before Grow More filed its summary judgement motion on May 11, 2001, and before Plaintiffs filed their cross-motion for summary judgement on September 14, 2001. Id. at 5:4-7.

Defendants further argue that plaintiffs had no less than four opportunities to offer the 665 Patent prosecution history to the Court. Id. at 5:12-13. Plaintiff Biagro first offered a claim construction at the time of its motion for preliminary injunction. Id. at 5:14. Next, Plaintiff Biagro offered a claim construction in response to Grow More's Motion for summary judgement of non-infringement. Id. at 5:15-16. After The Regents were added as a plaintiff, Plaintiff The Regents offered a claim construction in response to Grow More's motion for summary judgement of non-infringement. Id. at 5:16-18. Finally, Plaintiffs offered a claim construction in support of their cross-motion for partial summary judgement of infringement. Id. at 5:18-19. In none of these four separate occasions did Plaintiffs offer any portion of the 665 Patent prosecution history as support for their various claim constructions. Id. at 5:20-21. Thus, Defendant argues, Plaintiffs are not offering a new claim construction in their motion for reconsideration, but are offering evidence that was previously available to them to support the same claim construction. Id. at 6:1-3.

Likewise, Defendant argues that the Peters Declaration filed in support of Plaintiffs' motion is not new evidence. Id. at 6:7-8. As the record shows, Peters had been consulted by Plaintiff Biagro before this lawsuit was filed. Id. at 6:10-11. Thus, defendant argues that any information contained in the Peters Declaration could have been argued previously.

Addressing the merits of Plaintiffs arguments, Defendant argues that there is nothing which would justify reconsideration and reversal of the Summary Judgement Order. Quite simply, Defendant argues that the evidence offered by Plaintiffs is irrelevant to proper claim construction. Opposition, at 8:4-5. In particular, Defendant notes that there is no antecedent basis in the plain language of the 255 Patent claims for Plaintiffs' "Chemical equivalent" argument. Id. at 8:6-7. Undeniably, the term "chemical equivalent" is not present in the 255 Patent or its entire prosecution history. Id. at 8:12-13.

Defendant argues, and this Court agrees, that the evidence offered by Plaintiffs is insufficient to cause the court to reverse the Summary Judgement Order. First, it is improper for Plaintiffs to suggest that the common patent examiner of the 255 Patent and the 665 Patent understood that the term "phosphorous-containing acid" recited in the Key Clause of the Key Claims of the 255 Patent was the "chemical equivalent of the phosphorous acid" in the concentrated fertilizer, when they do not, and cannot, point to any affirmative statement by the Examiner that he understood that the phrase "phosphorous-containing acid" recited in either the 255 Patent claims or the 665 Patent claims means the "chemical equivalent" of that phosphorous-containing acid. Id. at 10:15-19.

Moreover, Defendant argues that other portions of the 665 Patent prosecution history, not cited by Plaintiffs, indicate that the Examiner's understanding of the claim language was consistent with the claim construction adopted by the Court in the Summary Judgement Oder. Id. at 11:20-22. More specifically, Defendant notes that Plaintiffs' reference to the 665 Patent prosecution history appears in The Regents' April 5, 1999 amendment and relates to "new claim 25." New claim 25 recited:

25. A concentrated phosphorous fertilizer usefully diluted with water having a pH of about 6.5 to about 8.5 at a ratio of about 1:40 to about 1:600 to form a buffered substantially fully solubilized use-dilution fertilizer for foliar application having a foliage-acceptable pH for phosphorous uptake, said concentrated fertilizer comprising at least one phosphorous acid of salt thereof, wherein said at least one phosphorous acid or salt is present in the concentrated fertilizer in an amount of about 27 weight percent or greater.

RJN, at B48.

In an Office Action, dated June 2, 1999, in which the Examiner rejected claim 25, one of the reasons the Examiner did so was:

In claims 25-32, it is indefinite as to whether the claims require a concentrated fertilizer or the fertilizer after having been diluted with water.

RJN at B60. The Examiner further stated:

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The differences between the fertilizer of Robertson and Boyer, and that recited in applicant's claims, are that Robertson and Boyer do not specifically disclose that the fertilizer should be diluted with water, and that the concentration of the orthophosphites should be in an amount of about 27 weight percent or greater. Robertson and Boyer disclose on page 396 that sodium hydrogen phosphite solutions are diluted to the desired concentration. Accordingly, Robertson and Boyer recognize that the concentrated phosphorous fertilizer may be diluted with water to obtain a use-dilution fertilizer. It would be prima facie obvious to provide orthophosphites in a concentration of at least 27 weight percent in the diluted fertilizer of Robertson and Boyer, since Robertson and Boyer suggest that the sodium hydrogen phosphite solutions are diluted to the "desired concentration." In any event, it is indefinite as to whether claims 25-32 require that fertilizer be diluted with water, or whether the claims merely embrace the concentrated phosphorous fertilizer specifically disclosed by Robertson and Boyer.

RJN at B61-B62. Defendant argues that from this discussion, it is clear that the Examiner considered the "27 weight percent or greater" limitation to apply to the "phosphorous acid or salt" present either in the concentrated fertilizer or the concentrated fertilizer after it was diluted, but not to any so-called "chemical equivalent." Opposition, p.12:20-23.

Further, defendant notes that in the same Office Action, the Examiner rejected claims 25-32 as being invalid for double patenting over the claims of another patent owned by Plaintiff The Regents, U.S. Patent No. 5,514,200. Id. at 13:1-3. The Examiner stated, in part:

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be prima facie obvious to employ the phosphorous acid or salt thereof in the concentrated fertilizer recited in the claims of Patent No. 5,524,200 in an amount of about 27 weight percent or greater.

RJN at B62. Again, Defendant argues that this language makes clear the Examiner was relating the "27 weight percent or greater" limitation to the "phosphorous acid or salt thereof in the concentrated Fertilizer," not to any "chemical equivalent of the phosphorous acid. Id. at 13:7-9.

Additionally, Defendant argues that Plaintiffs' reference to the 665 Patent prosecution history does not clearly support their "chemical equivalent" argument. Id. at 13:11-12. In particular, Defendant notes that The Regents never provided the offered calculations to the Examiner at any point during the 665 Patent prosecution, so there is nothing in the 665 Patent Prosecution history to show what the stated percentages relate to. Id. at 13:23-14:1.

Defendant adds that The Regents own affirmative statements in the 665 Patent prosecution history are inconsistent with Plaintiffs' "Chemical equivalents" argument. Id. at 14:6-7. In The Regents' April 19, 2000 amendment, The Regents state:

Applicant believes that the article by Robertson and Boyer (pages 396-401, 1956) is distinguishable for the same reasons that have been articulated in the reexamination of parent. All the new claims are patentable since all require a concentration of phosphorous-containing acid or salt thereof in an amount of about 30 weight percent (or greater), and also require that this concentrated composition be buffered. While Robertson and Boyer begin with concentrated compositions, these concentrations are not buffered. Instead, they are taught as first being diluted to 0.1 molar stock solutions, and only then are formed as buffered solutions. There is no teaching, disclosure, or suggestion in the article by Robertson and Boyer to provide a concentrated (i.e. about 30 weight percent or greater) phosphite solution which is also buffered. Not would their be in motivation from the prior art to do so.

RJN at B112 (emphasis in original). Defendant contends that The Regents affirmative statements in the 665 Patent prosecution history make clear that The Regents were claiming that the "30 weight percent or greater" limitation related to the "phosphite solution" in the "concentrated composition" and not any "chemical equivalent" thereof. Opposition at 14:15-19.

Finally, although objecting to the Peters Declaration, Defendant notes such declaration does not justify a new claim construction. Specifically, Defendant observes that while Peters claims to have "performed calculations on both example 1 and 9" of the 665 Patent and 255 patent, such calculations are absent from Peters Declaration. Id. at 15:11-13. Further, Defendant questions whether Examples 1 and 9 of the 665 are "operative" examples, that is, that they can actually be constituted and function as described in the 665 and 255 Patent specifications. Id. at 15:18-20.

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In summary, Defendant contends that Plaintiffs' motion for reconsideration is nothing more than an attempt to reargue their Second Claim Construction, relying on material that was available to Plaintiffs long ago. Id. at 17:8-10.

In addressing Defendants concerns, Plaintiffs contend that the use of chemical equivalents is so widespread among those with skill in the art that it becomes almost second nature. Id. at 2:3-4. Plaintiffs point to evidence indicating that with regard to phosphorous products, the label must indicate the amount of available phosphoric acid (P[2]O[5]). A notice, dated March 19, 1996, from the California Department of Food and Agriculture states:

The California Fertilizing Materials Law (Food and Agricultural Code, Section 14501, et seq.) also requires that phosphorous products provide the percent available phosphoric acid (P[2]O[5]) in commercial fertilizers, on the label. Until recently, the Department has been using AOAC Official Method 960.03 for the analysis of phosphorous acid-containing products. Since this method is inaccurate for phosphorous acid-containing products, the Department has opted to use an alternative method for analysis, as authorized by the California Code of Regulations, Section 2300(c).

To provide a more accurate analysis, AOAC Official Method 960.02 (AOAC) Official Methods of Analysis, 1995) will be used for analysis of phosphorous acid-containing products.

This analysis change must be reflected on the label for all products containing phosphorous acid, as such [i.e., in the following format]:

Available phosphoric acid (P[2]O[5]) (AOAC Method 960.02) . . . X% The label for the Phos-Pro fertilizer product states:

"Available Phosphoric Acid (P[2]O[5]). . . . . 25% (AOAC Method 960.02)"

Plaintiff's expert, John L. Peterson explains:

7. Attached hereto as exhibit C and incorporated herein by this reference are copies of the AOAC official methods of analysis, including the test of method 960.02. Method 960.02 is entitled "Phosphorous (Available) in Fertilizers" and provides as follows: "subtract citrate-insoluble P[2]O[5] from total P[2]O[5] to obtain available P[2]O[5]."

8. Applying method 960.02 to the Phos-Pro 0-25-20 product is as follows. First, there is no actual, molecular P[2]O[5] in the Phos-Pro 0-25-20 product, only an equivalent amount of phosphorous. There is no citrate-insoluble P[2]O[5] in the Phos-Pro 0-25-20 product, since it is completely water soluble, leaving nothing to subtract from the total P[2]O[5] amount. The total P[2]O[5] amount is determined by digesting (cooking) the product sample in a mixture of acids that chemically convert all phosphorous atoms into phosphite ions (PO[4]). The resulting mixture is tested for phosphate, and then a calculation is performed to produce the P[2]O[5] equivalent of all of the phosphorous present in the fertilizer. This calculation results in the "25" amount reflected on the label of the Pho-Pro 0-25-20 product.

9. Once the "25" value is known, it is possible to calculate the equivalent amount of elemental P-phosphorous (10.75%) and the equivalent amount of phosphorous acid (28.9% wt./wt/) . . . These are the equivalent amounts of "available" material in the Phos-Pro product.

Conversely, Grow More's expert Dr. Farone explains:

10. The elements nitrogen (N), phosphorous (P) and potassium (K) all act as plant nutrients. When considering the nutrient value of different fertilizers to plants, farmers, gardeners and others want to compare the amounts of nitrogen, phosphorous and potassium in those fertilizers. However, these nutrients can be supplied to plants in many different forms and quantities. For example, nitrogen can be present in a liquid fertilizer in many difference forms, such as ammonium and nitrate. Potassium can be present in a liquid fertilizer in many forms, such as potassium phosphate, potassium nitrate, potassium sulfate and potassium chloride. And, finally, phosphorous can be present in a liquid fertilizer in many different forms, such as phosphoric acid salts (phosphates) or phosphorous acid salts (phosphites). For different plants, different combinations of quantities of nitrogen, phosphorous and potassium are deemed desirable. So, different liquid fertilizers may be prepared for different applications.

11. In the United States, in order to help farmers, gardeners and others know which plant fertilizers are appropriate for

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specific plants, it long ago became the custom for producers of plant fertilizers to inform users of the amount of available nitrogen, phosphorous and potassium present in their fertilizers. However, because of the limited analytical tools available and the different chemicals containing each of these elements that could be present in the fertilizers, a way of standardizing the comparisons was desirable. Thus, packages of fertilizers had designations such as "10-20-10," related to the amounts of nitrogen (first), phosphorous (second) and potassium (third) that was present in the fertilizers. But these numbers did not actually indicate the actual amount of these elements in their pure form present in the fertilizer. For example, in its pure form the element nitrogen is a gas. Clearly, no liquid fertilizers had any pure nitrogen gas actually present.

12. In addition, in the early days, since a chemical reaction of various chemicals takes place to produce the final fertilizer, it was difficult to analyze the fertilizer to know exactly how much nitrogen, phosphorous and potassium was actually present. One method that early analysts used to made the element analysis was to subject the fertilizer to high heat and, literally, to burn the fertilizer in a furnace. For fertilizers with potassium-containing and phosphorous-containing chemicals, when those fertilizers where "burned," there resulted dry combustion products in the form of phosphorous oxide (P[2]O[5]) and potassium oxide (K[2]O), even though neither of these compounds were actually present in the fertilizer. But each of those dry combustion products was in solid form, so they could easily be weighed. By this procedure, the analyst could then determine the percentage of weights (weight percent) of each of these combustion products in the fertilizer. Thus, a fertilizer found to have combustion products in the percentages of 20 percent phosphorous oxide (P[2]O[5]) and 10 percent potassium oxide (K[2]O), would be reported on the label as being a "X-20-10" fertilizer. This was simply a conveniently ascertainable substitute for the task of determining the actual amount of each nutrient element in the fertilizer. This procedure made it easy, then, for farmers, gardeners and others to compare the amounts of combustion products, phosphorous oxide (P[2]O[5]) and potassium oxide (K[2]O), of different fertilizers and make decisions about which ones to use, even though there were none of these combustion products in the actual fertilizer.

Biagro's expert, John L. Peterson seems to agree. In a previous declaration, dated October 4, 2001, Mr. Peterson stated:

3. There is a well known agricultural fertilizer labeling convention known as the "guaranteed analysis" (N-P-K) in which "P" is reported on the label as phosphorous oxide (P[2]O[5]), whether or not there is any phosphorous oxide actually present in the fertilizer material. Whatever the source of "P" present in the product, it is "translated" (using Mr. Farone's terminology) into (P[2]O[5]). Thus, one skilled in the art of agricultural fertilizer products would have experience with this fertilizer product labeling convention, and would appreciate that the actual contents of agricultural fertilizers are often different from those represented by the guaranteed analysis (N-P-K) of the product label. Here are two examples:

a. The attached labels from Monterey Chemical (Exhibit A) each indicate that the product was derived from ammonium phosphate (a salt of phosphoric acid), however, the guaranteed analysis refers to this source of "P" as P[2]O[5] calling it "Available Phosphoric Acid." Thus, the label indicates that the product contains both phosphorous oxide (P[2]O[5]) and phosphoric acid, even though the product does not actually contain either of these materials.

b. The label for Grow More's Phos-Pro 0-25-20 product (Exhibit B) follows the same convention. The label lists potassium phosphite and phosphorous acid as the sources of "P" from which the product was derived. However, the guaranteed analysis refers to these sources of "P" as P[2]O[5], calling them "Available Phosphoric Acid." Thus, the label for Grow More's product indicates that it contains both phosphorous oxide (P[2]O[5]) and phosphoric acid, even though the product does not actually contain either of these materials.

Farone Decl., Exhibit C, pp. 2-3.

Dr. Farone goes on to note:

13. The California Food and Agriculture Regulations relating to Fertilizing Materials (CFAR), are consistent with this discussion. A copy of the relevant part of those Regulations is attached as Exhibit A. Section 2300(a) of CFAR states: "Labels of fertilizing materials, shall comply with the requirements of this article." Exh. A, p.1. Section 2301 of CFAR states that the numbers for a "guaranteed analysis" must be arranged" so that the first will be the guaranteed percentage of nitrogen; the second, the guaranteed percentage of available phosphoric acid; and third, the guaranteed percentage of soluble potash." Exh. A., p.3.

It is interesting to note, as stated above, that there is no actual nitrogen gas present in any of the liquid fertilizers involved

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in this case. It is present in other forms. As set forth inSection 2303(i) of CFAR, the "Total Nitrogen (N)" content in the fertilizer must be shown by showing the percentages of nitrogen in each of the nitrogen-containing chemicals (e.g., ammoniacal nitrogen, nitrate nitrogen, etc.) actually in the fertilizer. Exh. A, p.6-7.

As set forth in Sections 2303(i)(1) and 2309 of CFAR the term "available phosphoric acid" actually means the amount of phosphorous oxide, (P[2]O[5]), that would result if the liquid fertilizer was essentially burned and the dry combustion product, (P[2]O[5]), was produced. Exh. A., pp. 6-7, 15. Of course, as discussed above, this information is merely provided for comparison purposes, since there is no P[2]O[5] in the actual fertilizer.

Significantly, the regulations refer to "available phosphoric acid," not "available phosphorous acid." Exh. A, pp. 6-7, 15. Presumably, at the time the Regulations were last amended in 1991, phosphorous acid was not commonly used in plant fertilizers. The important point, however, is that the Regulation makes clear that what must actually be reported on the label is the amount of phosphorous oxide (P[2]O[5]) that would result from the burning of the fertilize, even though this is referred to as "available phosphoric acid." So, the Regulations do not require that there be any phosphoric acid in, or "available" in, the actual fertilizer. Of course, if the Regulations did require phosphoric acid to be available in the fertilizer, it would be impossible for the accused Phos-Pro product to comply with the Regulations, because there is no phosphoric acid in the final Phos-Pro product and the Phos-Pro product is not made with any phosphoric acid. Thus, the label of the Phos-Pro product, when reporting, as required by law, the "Available Phosphoric Acid (P[2]O[5])," is simply reporting, as required, the amount of phosphorous oxide (P[2]O[5]), a solid, that would result from burning the liquid fertilizer. See a copy of the Phos-Pro Label attached hereto as Exhibit B.

Finally, as set forth in Sections 2303(i)(1) and2311(c) of CFAR, the term "Soluble Potash" refers to Potash (K[2]O) which, as discussed above, is also not actually present in the fertilizer. Exh. A, pp. 6-67, 16-17. Again, this term means the amount of potash that would result if the liquid fertilizer was burned and the dry combustion product, K[2]O, was produced. Of course, as discussed above, this information is merely provided for comparison purposes, since there is no K[2]O in the actual liquid fertilizer.

Thus, if one were to review the guaranteed analysis of "Nitrogen," "Available Phosphoric Acid" (P[2]O[5]) or "Available Potash" on a label of a liquid fertilizer which conformed to CFAR, one would not learn if there was actually any phosphoric acid (or phosphorous acid) in, or "available" in, the liquid fertilizer. That information is largely irrelevant to what chemicals are actually present in the fertilizer.

14. The 255 patent claims recite the concentrated liquid fertilizer in terms of its actual constituents. In other words, the 255 patent claims recite the fertilizer as "a buffered composition" which has "at least one phosphorous-containing acid or salt thereof", where the "phosphorous-containing acid or salt there of is present in amount of about 30 to about 40 weight percent." This language makes clear that phosphorous-containing acids, or phosphorous-containing salts, or both, must actually be present in the fertilizer in an amount of about 30 to about 40 weight percent.

15. In my review of the 255 patent claims, specification and prosecution history, I have found nothing that discusses, or even suggests, that one should consider, or even refer to, the amount of phosphorous oxide P[2]O[5], (the "available phosphoric acid" on the label) that would result from burning the claimed fertilizer to produce a dry, combustion product. I found nothing that indicates that anything other than the actual amount of phosphorous acids and salts in the claimed fertilizer should be considered in determining if the 30-40% limitation of the claims is met. There is nothing in these documents that says of suggests that label information on a fertilizer package is in any way relevant to the claimed fertilizer. In fact, it is irrelevant.

The Court has reviewed the evidence, including the expert declarations presented in this matter. Despite Plaintiffs belated arguments, however, the Court is still of the opinion that the interpretation proffered by Plaintiffs is simply not supported by the claims, the specification or the prosecution history. Accordingly, Plaintiffs Motion for Reconsideration is denied.
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B. "Physiological Cooling Agent"

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Although Wrigley is not claiming infringement of Claim 5, that claim will still be analyzed throughout the course of this litigation, since it is the basis for an inequitable conduct argument by Cadbury that would render Claim 34 unenforceable. As a result, I will also construe the contested term in that claim. Wrigley proposes that "physiological cooling agent" be construed as:

A compound which is perceived as cold or cool when contacted with the human body and, in particular, with the mucous membranes of the mouth, nose and throat; excluded are traditional flavor-derivatives such as menthol or menthone; and included are those compounds listed in columns 9 and 10 of the '233 Patent.

Cadbury proposes that I use only the first part, "a compound which is perceived as cold or cool when contacted with the human body and, in particular, with the mucous membranes of the mouth, nose and throat." I will adopt Wrigley's construction, taken directly from the patent language, which describes and limits what should be considered a physiological cooling in that context.

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II. Roche's motion for summary judgment

Roche's motion concerns claim 4 of the '814 patent:

4. The diphosphonate compound of claim 1 designated 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid and the physiologically active salt thereof.

Roche contends that it is entitled to summary judgment of infringement because the active ingredient in the products proposed in Defendants' ANDAs, ibandronate sodium, is a physiologically active salt of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid. The parties do not dispute the essential underlying facts: the ANDAs propose that the active ingredient is ibandronate sodium, which is a salt of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid. There is also no dispute that the ANDAs propose that ibandronate sodium will, upon ingestion, have physiological effects.

Defendants' principal argument in opposition is that ibandronate sodium is not a physiologically active salt. This argument is premised on undisputed facts about the sequence of events which occur during the treatment process: 1) prior to ingestion, ibandronate sodiumexists as a compound; 2) at some point after ingestion, the body acts upon ibandronate sodium and dissolves it; 3) when ibandronate sodium is dissolved, it dissociates into the ibandronate anion and the sodium cation; and 4) it is the ibandronate anion that acts upon the body and produces the physiological effects. Again, the parties do not dispute these basic facts.

Defendants contend that, because it is the ibandronate anion that produces the physiological effects at the last step of this process, and not the ibandronate sodium that exists at the first step, which is the salt form, ibandronate sodium is not a physiologically active salt, within the meaning of claim 4, and does not literally infringe.

Roche counters that Defendants are improperly rearguing claim construction. This Court agrees. Defendants do not dispute the underlying facts but, rather, the meaning of the claim language, "physiologically active salt." This Court has already held a Markman proceeding to construe the meaning of the phrase "physiologically active salt," and it issued a claim construction Opinion on May 7, 2010, which stated:

Apotex and Cobalt propose that the phrase "physiologically active salt," appearingin claim 4, should be construed to mean: "A solid substance in which the salt ion provides its own active effect, separate and apart from any drug component that may be included as an anion within the final salt product." Roche proposes that this phrase should be construed to mean: "a salt form of ibandronic acid that is physiologically active, i.e., capable of producing physiological activity."

In short, Apotex and Cobalt's argument consists of these statements: "A person of ordinary skill in the art would recognize that the term 'physiologically active' when applied to the term 'salt' requires a salt component that itself produces an intended physiological effect, separate and apart from any effect caused by the drug component itself (here ibandronate) . . .

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[A] physiologically active salt is a solid product in which the salt cation has activity additional to that provided by the drug anion with which it is associated in a solid." (Apotex and Cobalt Br. 16.)

(Opinion of May 7, 2010 at 9-10.) This Court concluded: "Roche has correctly construed the phrase to mean a salt of ibandronic acid that is physiologically active." (Id. at 11.)

In the claim construction Opinion, this Court wasguided by the Federal Circuit's instruction that, in construing claims, courts should consider what the inventor actually invented:

In Phillips, the Federal Circuit instructed courts to consider what the inventor actually invented. The Court quoted Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)), as follows:

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316.

(Opinion of May 7, 2010 at 10-11 n.6.) This bears repeating because Defendants' argument can only succeed if this Court forgets about what the inventor actually invented. There is no question about what the inventor invented: ibandronic acid in various forms which are used for the treatment or prophylaxis of calcium metabolism disturbance or disease. This Court construes the phrase "physiologically active salt" in the way that best captures what the inventorinvented.

Defendants, on the other hand, seek to construe "physiologically active salt" in a way that subverts the Federal Circuit's guidance in Phillips and Renishaw. There is no reason to believe —and Defendants have not even suggested this — that the inventor invented a salt form of ibandronic acid that, after ingestion, having resisted digestion and dissolution, passes into the blood stream untouched, and has a therapeutic effect while in its pristine, undissolved state. Even if, for the sake of discussion, this Court were to allow Defendants to redo the claim construction on the fly — which it does not intend to do — this Court would not conclude that Defendants' present construction of "physiologically active salt" captures what the inventor actually invented.

Furthermore, Defendants' proposed construction has the problematic effect of making the claim invalid. Consider, for the sake of discussion, if Defendants were correct, and the phrase "physiologically active salt" were construed as implying a limitation to those pharmaceuticals that resist digestion and pass into the bloodstream unchanged, where they have their final therapeutic effect in an unchanged form. There is no disputethat, in fact, ibandronate sodium dissolves in the body. Cobalt, for example, lays out the evidence of this at length. (See, e.g., Cobalt's 56.1 Counterstmt. PP 120-176.) Cobalt quotes its expert, Dr. Gould, as follows:

162. Dr. Gould has explained that salts, like ibandronate sodium, "would necessarily have to dissolve in the fluids of the gastrointestinal tract in order for the drug to be available for absorption." (Raghavan Decl. Ex. 4, Gould Report P 28).

(Id. at P 162.) If this is true — and no one appears to be disputing it -, and salts like ibandronate sodium necessarily must dissolve in the fluids of the gastrointestinal tract in order for the drug to be available for absorption into the body, then Defendants have proposed that the patentee claimed an impossible invention. If this is true, and "physiologically active salt" means what Defendants contend, then no physiologically active salt can possibly exist as an orally administered pharmaceutical, because it is physiologically impossible. Such a claim fails because the subject matter is inoperable: "[W]hen a claim requires a means for accomplishing an unattainable result, the claimed invention must be considered inoperativeas claimed and the claim must be held invalid under either § 101 or § 112 of 35 U.S.C." Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983); see also Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1359 (Fed. Cir. 1999) ("when an impossible limitation . . . such as a nonsensical method of operation, is clearly embodied within the claim, the claimed invention must be held invalid.")

The Federal Circuit has stated that it is a "familiar axiom that claims should be so construed, if possible, as to sustain their validity." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004). Defendants propose a construction that would render the claim inoperable and invalid. Plaintiff's construction, on the other hand, preserves the claim's validity. This

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Court previously ruled on the claim construction of "physiologically active salt" and offers this commentary now only to provide belt and suspenders for its rejection of Defendants' new claim construction argument.

The claim construction that this Court stated in its Opinion of May 7, 2010 remains the one that will be used in this infringement analysis. This Court accepted Roche's proposed construction. Rocheproposed that "physiologically active salt" means a salt form of ibandronic acid that is capable of producing physiological activity. Defendants seek to further narrow this construction, as if it meant, "capable of producing physiological activity without dissolution." This impermissibly narrows the Court's claim construction; the only limitation is that the salt must be capable of producing physiological activity. Ibandronate sodium is a salt and it is capable of producing physiological activity. Were this not the case, it would mean that Defendants have applied to the FDA for permission to manufacture something that is incapable of having a pharmaceutical effect. Clearly, Defendants believe that ibandronate sodium is capable of producing a physiological effect, or they would not have sought permission to manufacture and sell it for the treatment of osteoporosis.

Furthermore, even if this Court did not reject Defendants' proposed construction for the substantive reasons just stated, as a matter of procedural fairness, it would be reluctant to be receptive to Defendants' change in position. As the Court stated in the claim construction Opinion, Defendants proposed a construction of "physiologicallyactive salt" in which both the anion and the cation have independent physiological effects. Now, Defendants seek to rely on a construction in which the anion and the cation have physiological effects only in combination. To allow Defendants to succeed with this change in position seems both unfair and untimely.

Apotex also argues that it is Roche that now seeks to disavow the very claim construction that it sought, and in so doing Apotex seeks to turn the situation on its head. This Court did not, as Apotex contends, hold that the physiological activity must be produced by the whole salt molecule, prior to dissolution. As discussed above, this Court now employs in this infringement analysis the same claim construction it previously established. Moreover, if Apotex believed that the claim construction Opinion left a key issue unresolved, it should have moved for reconsideration to bring the issue to the Court's attention. It did not do so.

Apotex also opposes Roche's motion with the argument that they cannot infringe claim 4 because claim 4 depends on claim 1, and claim 1 "recites nonsense." (Apotex Opp. Br. 14.) As Roche observes, this Court need not enter the thicket of the intelligibilityof claim 1. Even though claim 4 does depend on claim 1, claim 4 can be understood completely clearly without any reference to claim 1. Claim 4 specifies that the compound from claim 1 that it refers to is 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid. Apotex does not argue that this part of claim 4 is nonsense. As the Court observed in its claim construction Opinion, the parties have essentially agreed that this formula refers to ibandronic acid. (Opinion of May 7, 2010 at 6.) There is no question as to the meaning of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid in claim 4.

Furthermore, there are problems with the argument that claim 1 is nonsense. Apotex does not argue that claim 4 is invalid, and this Court questions how the argument that claim 1 is nonsense is relevant in the absence of raising claim 4's invalidity as an affirmative defense to its infringement. Even if, however, Apotex had challenged the validity of claim 4, it would still be possible to arrive at a ruling on infringement. The Federal Circuit has stated:

> [P]atent infringement and invalidity are separate and distinct issues. Though an invalid claim cannot give rise to liabilityfor infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity.

Pandrol USA, LP v. Airboss Ry. Prods., 320 F.3d 1354, 1365 (Fed. Cir. 2003) (citation omitted). Thus, this Court may rule on the issue of infringement without having to address a validity challenge.

This Court rejects Defendants' arguments as to the meaning of "physiologically active salt." Furthermore, Defendants have failed to show that any material factual disputes preclude the entry of judgment as a matter of law. Roche has shown that the active ingredient in the products proposed in Defendants' ANDAs, ibandronate sodium, is a physiologically active salt of 1-hydroxy-3-(N-methyl-N-pentylamino)-propane-1,1-diphosphonic acid, and that Defendants' ANDAs propose products that will infringe claim 4 of the '814 patent. Roche's motion for summary judgment of infringement will be granted.
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1. "physiologically acceptable"

a. The Parties' Proposed Constructions

Pharmacia asserts that "physiologically acceptable" means that "the substance is stable, sterile, pyrogen-free, and otherwise suitable for administration to humans or animals." (D.I. 232 at 16.) Pharmacia cites to the ordinary meaning of the term, as well as to the language of claims 1 and 8 of the '285 patent, the specification, and the prosecution history. (Id. at 16-23.) Sicor argues that "physiologically acceptable" should be construed to mean only that the solution is "suitable for administration to humans or animals." (D.I. 234 at 8.) Sicor cites to the language of claims 1 and 8, and to the doctrine of claim differentiation, in support of its proposed construction. (Id. at 8-10.) Sicor also cites to the specification and the prosecution history of the patent in further support of its arguments. (Id. at 10-12.)

b. The Court's Construction

The language of the patent makes clear that the invention of the patent is directed toward an injectable solution. (See, e.g., '285 patent at 1: 7-8 ("stable intravenously injectable ready-to-use solution"); id. at 1:53-54 ("stable, therapeutically acceptable intravenously injectable solution"); id. at 4:42, 44-45 ("administering . . . an injectable solution"; "injectable solutions are administered b[y] rapid intravenous injection").) In fact, the title of the patent is "Injectable Ready-to-Use Solutions Containing an Anti-Tumor Anthracycline Glycoside." (Id. at 1.) Based on all of these references to an injectable solution, it appears from the language of the patent that the only way that anthracycline glycoside can be administered to a human or an animal is through an injection. (See also Markman Hearing Transcript, D.I. 277 at 48:21-49:10.) The patent also describes the solution as being sterile and pyrogen-free. (See '285 patent at 1:58 (sterile, pyrogen-free, anthracycline glycoside solution").)

Sicor's lawyer admitted during the Markman hearing that "when you are talking about something that is intravenously injectable, sterility, pyrogenicity, those things are important." (Markman Hearing Transcript, D.I. 277 at 46:23-25.) He also stated "for an injectable solution to be dispensable to humans, it has to be sterile and pyrogen-free." (Id. at 53:19-21.) Thus, even under Sicor's own definition of "physiologically acceptable," which Sicor claims means only that the solution is "suitable for administration to humans or animals," (D.I. 234 at 8), the solution of the patent must be sterile and pyrogen-free. As a result, based on the language of the patent, which repeatedly describes the claimed solution as being "injectable," and based on the admissions of Sicor's lawyer, it is clear that "physiologically acceptable" must be construed to mean that the solution is sterile and pyrogen-free for it to be suitable for administration to humans and animals. n2

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n2 The best argument that can be made that sterility is not part of the term "physiologically acceptable" is that, in the written description of the invention, the patent describes a process for making the claimed solution, "which process comprises dissolving a physiologically acceptable salt ... in a physiologically acceptable solvent therefor; optionally adding a physiologically acceptable acid ... and passing the resulting solution through a sterilizing filter." ('285 patent at 3:64-70.) Thus, the patent describes sterilizing the solution made of "physiologically acceptable" reagents. However, this piece of the written description alone, describing the process for making the invention, does not change the fact that for the solution to be capable of administration to humans and animals, it must be sterile and pyrogen free. Additionally, even though the "physiologically acceptable" solvent, salt, and acid are sterile prior to use, they may have to be re-sterilized before administration to a patient.

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Sicor makes much of the fact that the '285 patent uses the term "physiologically acceptable" in claim 1, and "a stable, intravenously injectable, sterile, pyrogen-free doxorubicin solution" in claim 8. (D.I. 234 at 8-10.) Sicor argues that Pharmacia's use of the language "stable, intravenously injectable, sterile, pyrogen-free" in claim 8 shows that Pharmacia "knew how to and in fact used that specific language" when it intended to. (Id. at 9.) This argument, however, does not overcome the repeated references in the patent to an injectable solution, and Sicor's admission that for an injectable solution

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to be suitable for administration to humans and animals, it must be sterile and pyrogen-free. Therefore, I will construe the term "physiologically acceptable" to mean "the substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals." n3

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n3 Although Pharmacia's proposed construction also requires that a physiologically acceptable solution be "stable," I do not include that limitation in my construction here. Unlike the limitations of "sterile" and "pyrogen-free," the specification and prosecution history of the patent do not repeatedly discuss the importance of "stability" to the invention. (See supra at section IV.1.b.; see also D.I. 232, Ex. 4 at Pl 775 (describing solution as "sterile, pyrogen-free"); id., Ex. 6 at Pl 878-79 ("The solution must also be sterile and pyrogen free.") (emphasis in original).)

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E. "A Physiologically And Cosmeceutically Acceptable Vehicle"

Plaintiffs' Construction	Defendants' Construction
A substance that allows for the uniform application to the skin that is suitable in appearance, scent, texture and consistency and does not irritate or damage the skin.	A solvent, diluent, or dispersant for the constituents of the composition which allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution.

Plaintiffs contend that Defendants' proposed construction is incomplete. Specifically, Plaintiffs contend that Defendants only define the claim term "vehicle" and neglect to give meaning to the terms "physiologically and cosmeceutically acceptable." By requiring that the substance not irritate or damage the skin and that it have suitable appearance, scent, texture, and consistency, Plaintiffs maintain that their construction gives proper meaning to these parts of the claim term. (D.I. 175 at 18.)

Both parties rely to varying degrees on the following portion of the specification for their proposed constructions:

The compositions according to the invention also comprise a liquid, solid or semi-solid physiologically and cosmetically acceptable vehicle or carrier. A suitable vehicle, under the invention, may act variously as solvent, diluent or dispersant for the constituents of the composition, and allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution. It will be apparent to the skilled artisan that the range of possible vehicles is very broad. In general, compositions according to this invention may comprise water as a vehicle, and/or at least one physiologically and cosmetically acceptable vehicle other than water.

('516 patent at 6:18-29.) Notably, this passage refers to a "cosmetically acceptable vehicle," while the claims refer to a "cosmeceutically acceptable vehicle." Nevertheless, the Court concludes that the "vehicle" described in this passage is, in fact, the same "vehicle" required by the claims. Indeed, the Court finds that this passage contains content that gives meaning to the term "cosmeceutically." Specifically, this passage explains that a "suitable vehicle under the invention . . . allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution." (Id.) Calling for the "vehicle" to allow for application to the "skin" at an "appropriate dilution," the Court finds that this passage encompasses the concept of being "physiologically" acceptable. Likewise, requiring the "vehicle" to allow for "uniform application" to the "skin," the Court concludes that the passage also encompasses the concept of being "cosmeceutically" acceptable. Accordingly, the Court will construe the term "physiologically and cosmeceutically acceptable vehicle" to mean, as Defendants contend, "a solvent, diluent, or dispersant for the constituents of the composition that allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution."

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For several reasons, the Court has decided not to adopt Plaintiffs' proposed construction. First, in support of their position that the "physiologically and cosmeceutically acceptable vehicle" not irritate or damage the skin and that it have suitable appearance, scent, texture, and consistency, Plaintiffs rely exclusively on extrinsic evidence. Specifically, Plaintiffs rely entirely on the declaration of their expert, Dr. R. Randall Wickett. (See D.I. 144, Exh. C at 6-7.) Though the Court has no doubt that Dr. Wickett is well-respected in his field, Dr. Wickett's declaration is unsupported by any additional evidence and his proposed constructions appear to be constructed from whole cloth. In these circumstances, the Court is unwilling to place great weight on Dr. Wickett's declaration. 5 Second, the specification explains that "the range of possible vehicles is very broad." ('516 patent at 6:24-26.) However, Plaintiffs' proposed construction introduces additional requirements pertaining to the appearance, scent, texture, and consistency of the vehicle and whether the vehicle irritates the skin. Given the specification's guidance that the range of acceptable vehicles is "broad," the Court is reluctant to introduce so many additional limitations into the claims, especially when there is no support for it in the intrinsic record. Finally, the Court is concerned that Plaintiffs' proposed construction will, rather than clarify the claims, muddy the scope of the claims, possibly leading to an unnecessary debate over whether a particular vehicle has a "suitable" scent, for instance. Accordingly, the Court concludes that Defendants' proposed construction is more appropriate.

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5 Indeed, Plaintiffs themselves appear to place little weight on Dr. Wickett's declaration, explaining that they "don't really think expert testimony is necessary to understand what those words mean, but [they] did submit a declaration from Professor Wickett in which he explained his understanding from this vantage point of a person of ordinary skill in the art." (D.I. 192 at 39:9-18.)

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A. "Plasma Etching"

Samsung argues that "plasma etching" as used in the Ingrey patent has a narrow meaning. Samsung contends plasma etching means: a strictly chemical process where the wafer being etched sits in a plasma, there is no bias potential (electrical charge) intentionally applied and the pressure is so high that there is negligible ion bombardment, for purposes of etching the wafer by direct involvement of the plasma, and which results in isotropic etching. Samsung identifies a number of differences between the process it practices -- reactive-ion etching -- and its definition of plasma etching as used in the Ingrey patent.

Northern Telecom, on the other hand, argues that plasma etching as envisioned by the Ingrey patent encompasses etching conducted in a broad range of reactors and under different process conditions, so long as the initial step involves a gaseous trihalide, comprising at least in part a boron trihalide, which is broken up in a radio frequency plasma into chemically active radicals that react with aluminum and aluminum oxide to form a volatile compound that can easily be removed from the etching chamber. This definition includes reactive ion etching as practiced by Samsung. Put another way, Northern Telecom contends the Ingrey patent does not exclude processes in which mechanisms in addition to the chemical reactions in a plasma -- e.g., ion bombardment of the work surface -- contribute to the etching.

Although plasma etching is not defined in the Ingrey patent's claims themselves, it is described in the specifications as follows:

In plasma etching, etchant gas molecules are broken up in an RF plasma into chemically active radicals that react with the workpiece, etching occurs and, if the reaction products are volatile, the reaction will continue until one or other of the reactants is completely removed.

Hess Decl., Ex. A (Ingrey patent), col. 1, 1.37-42. Northern Telecom argues the court need only look to this definition to determine the meaning of plasma etching in the claims, while Samsung argues that the meaning of plasma etching must also be interpreted in light of the prosecution history, the remainder of the patent specifications, and relevant extrinsic evidence.

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While it is axiomatic that neither the prosecution history nor the specifications can be used to enlarge, diminish or vary the limitations of the claims, nothing in this rule implies the court should not consider both the specifications and the prosecution history in interpreting what the claims mean. See Markman, 52 F.3d at 980. Indeed, the Federal Circuit has clearly held that courts should interpret the meaning of claim language with reference to such evidence. Id. Accordingly, the court will consider the specifications and the prosecution history in determining the meaning of the terms used in the claims.

1. Prosecution History/File Wrapper Estoppel

The centerpiece of Samsung's claim construction argument are statements made by Northern Telecom to the Patent Examiner in the "Remarks" section of its January 7, 1997 Response to the Examiner's initial rejection. See MacPherson Decl., Ex. J (Response). Northern Telecom contends that the Remarks are irrelevant because the Examiner had already determined that claims in the amended form would be allowable, see Londen Decl., Ex. I (PTO Office Action), and thus the Examiner did not rely on the Remarks.

A patentee who construes the claims in a patent application narrowly before the Patent Office is estopped from later construing them broadly before the courts. Autogiro Co. of America v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 399 (Ct. Cl. 1967), cert. denied, 434 U.S. 1051, 54 L. Ed. 2d 804, 98 S. Ct. 903 (1978). Assertions made by a patent applicant to the Patent and Trademark Office in support of patentability are part of the file wrapper or prosecution history and may be used to interpret the claims and define their terms. Id. at 398-99. 12

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12 This is not to be confused with file wrapper estoppel used in the doctrine of equivalents. See E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1437 (Fed. Cir.), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).

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Here, it is not at all clear that the Examiner did not rely on the Remarks. While the Examiner had indicated that with the suggested amendments the claims would be allowable, the Examiner did not actually issue the Notice of Allowance until February 4, 1977, after receiving the Response which contained both the amendments and the Remarks. See Supp. MacPherson Decl., Ex. B (communication from Examiner closing prosecution on merits in view of January 17, 1977 response). Thus, it is reasonable to assume that the Examiner at least read the Remarks prior to issuing the Notice. However, whether or not the Examiner relied on the Remarks, the Federal Circuit has clearly stated that such representations, whether or not made to secure patentability, may estop the patentee from subsequently advancing a contrary interpretation and are relevant to ascertaining what the applicant meant by terms used in the claims. See E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1438 (Fed. Cir.), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988). Accordingly, Northern Telecom's assertion that the Remarks are irrelevant to claim construction is incorrect.

In its January 17, 1977 Response to the Examiner's initial rejection of the Ingrey application, Northern Telecom amended the claims in conformity with the Examiner's suggestions and also made the following Remarks:

It is not agreed that the references cited in any way disclose the present invention as defined by the claims originally filed or as now filed, nor do the references foreshadow the present invention.

The references A, B and C, U.S. patents 3,975,252; [sic] 3,985,597 and 3,436,327 are concerned with a totally different process. In sputter etching the plasma is entirely incidental to the ion bombardment, which bombardment is the etching mechanism. The effect can as readily be affected by using a non-plasma condition by bombarding the surface with ions from an ion gun. Further, a plasma is defined as neutral environment, that is one that has equal members of positive and negative ions. In ion etching (as compared to plasma etching) the target does not sit in the plasma but in a positive space charge.

In the references the plasma plays no part in the etching, being incidental. In the present invention the plasma is part of the etching process in that the etching process uses neutrals, (uncharged particles) in the reaction, these being from the

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plasma.

MacPherson Decl., Ex. J.

The court must determine whether these Remarks distinguish the Ingrey invention from sputter etching or from reactive ion etching. Unfortunately, while the question is straightforward, the answer is not, due to mistakes and poor draftsmanship which render the Remarks fundamentally ambiguous.

The parties agree that references A (Fraser) and B (Zielinski) disclose reactive ion etching processes, i.e. etch mechanisms that include both ion bombardment and chemical reactions involving plasmas, and that reference C (Shockley) discloses a sputter etching process, i.e. one that is purely mechanical.

Paragraph 2 of the Remarks begins with the statement: "the references A, B, and C . . . are concerned with a totally different process." This suggests that the Remarks define plasma etching as a purely chemical process and distinguish it from processes which include the physical component of ion bombardment. 13 Read in isolation from the surrounding sentences, this sentence appears to distinguish the Ingrey invention from prior art references disclosing reactive ion etching. The next sentence, however, refers to sputter etching ("in sputter etching the plasma is entirely incidental to the ion bombardment, which bombardment is the etching mechanism"), indicating that Northern Telecom's patent agent Sidney Jelly may have misunderstood or overlooked what references A and B disclosed.

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13 Northern Telecom attempts to construe this statement as a reference to the fact that the Ingrey patent discloses the use of a boron trihalide and the three references do not; this attempt fails completely. In context, it is clear that the Remarks are concerned with the etch mechanism, not the etch gas.

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Samsung suggests a different interpretation. Samsung argues that the second and third sentences (beginning "In sputter etching . . .") refer to reference C, which discloses a sputter etching process, while the fourth and fifth sentences refer to references A and B, which disclose reactive ion etching. Under this interpretation, Jelly used the term "ion etching" to mean reactive ion etching. This interpretation is attractive because it allows paragraph 2 to be read as internally consistent.

Samsung's interpretation of the terms "sputter etching", "ion etching", and "plasma etching" in paragraph 2 is the most sensical one presented to the court. However, Samsung's proposed interpretation of paragraph 2 is not consistent with any reasonable interpretation of paragraph 3. Paragraph 3 appears to contrast the three references as a group to the use of chemical reactions in a plasma. The parties agree that the statement in paragraph 3 that "in the references the plasma plays no part in the etching, being incidental" does not as a simple matter of fact correctly describe the processes in references A and B. In fact, references A and B disclose reactive ion processes, a process in which the plasma does play an active role in etching the work surface. Thus, paragraph 3 suggests that Jelly did not know that references A and B disclosed processes which were in part chemical. This is evidence that he used the terms "sputter etching" and "ion etching" interchangeably to refer to an exclusively mechanical process.

Samsung is correct that Northern Telecom must be held to the representations it made to the Examiner, whether factually correct or not. However, Northern Telecom is correct that the factually erroneous remark in paragraph 3, which perhaps pervades the Remarks as a whole, cannot be interpreted to hold the meaning Samsung wishes to give it -- that the Ingrey patent claims only an exclusively chemical etch mechanism. When the first sentence of paragraph 3 is placed in context with the second, which states: "in the present invention the plasma is part of the etching process . . ." (emphasis added), it is obvious that Samsung's preferred interpretation of the Remarks as a whole is not a reasonable one. If a person skilled in the art was familiar enough with references A and B to be aware of the factual error in the first sentence, that person would have to disregard that sentence as nonsensical. In that case, the first sentence would shed no light on the meaning of the second sentence, which is crucial here. If, on the other hand, a person skilled in the art was not familiar enough with references A and B to be aware of the factual error, that person would interpret paragraph 3 to mean Ingrey was claiming a process where plasma was a part of the etch mechanism. Neither situation lends itself to an interpretation that Ingrey was claiming a process in which plasma was the exclusive etch mechanism. Read as a whole, the third paragraph clearly does not indicate

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that the claimed invention is exclusively chemical, but only that it is at least partly so.

In light of the ambiguities and errors which pervade the Remarks, the court concludes that it cannot be known with certainty precisely what Jelly meant by "sputter etching", "ion etching", and "plasma etching." The Remarks are so muddled as to shed little light on the claim construction question before the court. Thus, while the court finds that Northern Telecom's interpretation is the more reasonable, the court places little weight on the Remarks in construing the disputed claims.

2. The Specifications

It is axiomatic that limitations that do not appear in the claims cannot be imported from the specification. See Markman, 52 F.3d at 979-80. "One cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused device." Stiftung v. Renishaw PLC, 945 F.2d 1173, 1178 (Fed. Cir. 1991) (quoting A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 703, cert. denied, 464 U.S. 1042, 79 L. Ed. 2d 171, 104 S. Ct. 707 (1984)). Thus, the court examines the specifications solely for the light they shed on the meaning of plasma etching as used in the claims. See Unique Concepts,
Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991). The specifications are the "single best guide to the meaning of a disputed term". Vitronics, 90 F.3d at 1582. In this case, the court must determine whether the specifications establish that plasma etching as used in Claim 1 precludes the use of a process that also involves ion bombardment.

The Ingrey specifications describe plasma etching as follows:

In plasma etching, etchant gas molecules are broken up in an RF plasma into chemically active radicals that react with the workpiece, etching occurs and, if the reaction products are volatile, the reaction will continue until one or other of the reactants is completely removed.

Hess Decl., Ex. A (Ingrey patent), col. 1, 1.37-42. This sentence does not appear on its face to describe an exclusive process.

Samsung points to two other portions of the specifications to support its theory that reactive ion etching is outside the scope of the patent. First, the specifications describe parameters for the etching equipment: "Further constraints on the plasma parameters are that the RF power should be sufficiently low as not to damage the photoresist through ion bombardment . . . ." Id. at col. 2, 1. 53-56. Second, the specifications indicate that high pressure should be used, which suppresses ion bombardment. (In reactive ion etching as practiced by Samsung, low pressure is used in order to promote ion bombardment.) Samsung interprets this language to mean that in the claimed process ion bombardment should not occur. Northern Telecom interprets the same language as evidence that ion bombardment does in fact occur in the plasma etching process described in the specifications.

The Ingrey patent is a process patent, not a patent on a particular apparatus. In a process patent, apparatus distinctions that are not specifically claimed are not controlling in determining the scope of the claims. See Polaroid Corp. v. Eastman Kodak Co., 789 F.2d 1556, 1562 (Fed Cir.), cert. denied, 479 U.S. 850, 93 L. Ed. 2d 114, 107 S. Ct. 178 (1986), and Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1482 (Fed. Cir.), cert. denied, 469 U.S. 924, 83 L. Ed. 2d 240, 105 S. Ct. 306 (1984). The specifications show that the Ingrey inventors considered ion bombardment, or at least some excessive level of ion bombardment, to be deleterious. In so showing, the cited lines also indicate that a certain amount of ion bombardment does occur in the embodiment described in the specifications. Thus, the specifications demonstrate, and all the other evidence in the record agrees, that ion bombardment will take place even in the embodiment described in the specifications.

While the embodiment set forth in the specifications minimizes ion bombardment, the claims themselves concern only the chemical reactions taking place in a plasma. They do not speak to whether the ion bombardment which will take place is minimized, as in the Ingrey embodiment, or enhanced, as in reactive ion etching as practiced by Samsung. The court discerns no language in the specifications indicating that the claims are limited to a process of chemical reaction in which ion bombardment is limited or reduced below some specified level.

3. Extrinsic Evidence

The parties agree that terminology in the field of semiconductor manufacturing was not used consistently or without ambiguity in the late 1970s. Samsung nevertheless contends that those skilled in the art in the late 1970s would understand

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the term "plasma etching" to exclude the process called reactive ion etching, and submits substantial evidence to support this position. See Supplemental Cecchi Decl. Northern Telecom submits a volume of contrary evidence. See Hess Decl. PP 24-25. There is ample evidence that each of the terms in question were used in the industry in the late 1970s in a variety of ways and without much consistency. However, in light of Vitronics, it is clear that the court should not weigh the opinions of competing experts in order to define the terms because that would likely vary or contradict the claim language. The court finds that it should and can interpret the claims based on the specifications and prosecution history. Based upon those, the court concludes that the term "plasma etching" refers to a chemical process without excluding the non-chemical process of ion bombardment. While the evidence is far from clear, and the prosecution history in particular presents serious problems of interpretation, the court finds that Claim 1, read together with the specifications and prosecution history, contains no indication that ion bombardment or reactive ion etching is specifically excluded from the claimed process.
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Samsung also argues that the district court erred when it construed "plasma etching" to allow reactive ion etching. According to Samsung, "plasma etching," as used in claim 1, specifically excludes all forms of "ion bombardment" etching. Because the accused process uses reactive ion etching -- a combination of both plasma etching and ion bombardment -- Samsung asserts that no infringement can lie. Samsung asserts that both the specification and prosecution history of the '967 patent support its view of "plasma etching". We disagree.

Some background is in order. There is no dispute between the parties that plasma etching, as that term is commonly used in the field, is a "chemical" process. In plasma etching, electrical power is applied to a gas, creating a plasma of chemically-active radicals, which react with the workpiece, causing etching. There is also no dispute between the parties that ion bombardment is a "mechanical" process, whereby an electrical field creates a plasma that emits charged particles, which physically strike the workpiece, causing etching. Reactive ion etching, used in the Samsung process, is a combination of the chemical and mechanical processes. In reactive ion etching, the plasma created by the electrical field creates both chemically-active and charged particles, allowing etching to proceed both by chemical reaction and by physical bombardment.

Claim 1 of the '967 patent requires "an initial step of plasma etching." The claim does not mention ion bombardment or reactive ion etching. Thus, there is no dispute between the parties that the '967 patent does not claim ion bombardment as an etching mechanism. But this in itself does not allow the Samsung process to escape infringement: the reactive ion etching of the Samsung process, as we noted above, uses "plasma etching" (the chemical process) as part of the etching mechanism. The use of ion bombardment as another part of the etching mechanism, an additional element of the accused process, will not ordinarily prevent a finding of infringement. See, e.g., A.B. Dick, 713 F.2d at 703, 218 U.S.P.Q. (BNA) at 967. Samsung, recognizing this tenet of the law, argues instead that the limitation "plasma etching" in claim 1, read in light of the intrinsic and extrinsic evidence, specifically requires the exclusion of ion bombardment as any part of the etching mechanism.

Samsung does not argue that the ordinary meaning of "plasma etching" itself excludes ion bombardment. See Johnson Worldwide, 175 F.3d at 989, 50 U.S.P.Q.2D (BNA) at 1610 ("The general rule is, of course, that terms in the claim are to be given their ordinary and accustomed meaning."); Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1576 ("Words in a claim are generally given their ordinary and customary meaning."). Instead, Samsung argues that the intrinsic and extrinsic evidence of record compels the conclusion that "plasma etching" in claim 1 must be limited to circumstances where chemical processes are the only etching mechanism. See Johnson Worldwide, 175 F.3d at 989-90, 50 U.S.P.Q.2D (BNA) at 1610 (describing circumstances under which a term's ordinary meaning may be set aside). Thus, the issue is not whether the '967 patent contemplates the presence of ion bombardment, but whether it contemplates it and specifically excludes it.

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We begin with the specification. See Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1577 ("It is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning."). Samsung is correct in noting that the written description broadly describes "plasma etching" in terms of a

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chemical reaction. See '967 patent, col. 1., ll. 37-42. Indeed, the only mention of "ion bombardment" is the statement that "the RF power should be sufficiently low as not to damage the photoresist through ion bombardment." See id. at col. 2, ll. 54-56. Samsung seizes upon this statement as evidence that the claimed "plasma etching" must completely exclude ion bombardment. We disagree. By suggesting -- in connection with a description of the preferred parameters for the claimed "plasma etching" process -- that steps "should" be taken to reduce or avoid ion bombardment, the patentees fall far short of excluding ion bombardment altogether. Cf. Laitram Corp. v. Morehouse Indus., Inc., 143 F.3d 1456, 1463, 46 U.S.P.Q.2D (BNA) 1609, 1614-15 (Fed. Cir. 1998) (adhering to clear assertions in written description that the invention "requires" a narrow construction of a claim term). See also Johnson Worldwide, 175 F.3d at 991, 50 U.S.P.Q.2D (BNA) at 1611 (discussing Laitram). Indeed, wholly contrary to Samsung's view, that sentence clearly contemplates that ion bombardment may be present in the claimed process, but states that the patentees prefer that it be reduced or eliminated. In other words, the low level of ion bombardment in conjunction with the claimed plasma etching is plainly a preferred embodiment of the '967 patent. This court consistently declines to construe claim terms according to the preferred embodiment. See, e.g., Johnson Worldwide, 175 F.3d at 990-92, 50 U.S.P.Q.2D (BNA) at 1610-12; Renishaw, 158 F.3d at 1248, 48 U.S.P.Q.2D (BNA) at 1120-22; Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571, 7 U.S.P.Q.2D (BNA) 1057, 1064 (Fed. Cir. 1989). We see no reason to abandon that practice in this case.

Samsung's reliance on Figure 2 of the '967 patent is no more persuasive. Figure 2 shows the wafer (i.e., the "workpiece") located in a plasma region, rather than in a DC electric field as would be the case if ion bombardment was to be the primary or only etching technique. While we can agree that Figure 2 makes clear that the patentees preferred gas plasma etching over ion bombardment, that fact, of course, cannot lead to the conclusion that ion bombardment was specifically excluded from the scope of the claims. As we note above, the entire specification plainly expresses a preference for gas plasma etching over ion bombardment. But preferred embodiments, without more, do not limit claim terms. See, e.g., Johnson Worldwide, 175 F.3d at 990-92, 50 U.S.P.Q.2D (BNA) at 1610-12; Renishaw, 158 F.3d at 1248, 48 U.S.P.Q.2D (BNA) at 1120-22; Advanced Micro-Devices, 848 F.2d at 1571, 7 U.S.P.Q.2D (BNA) at 1064.

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Samsung next points to passages in the prosecution history, where, it asserts, the patentees unambiguously disclaimed the existence of any ion bombardment in the claimed process. During prosecution of the '967 patent, the Examiner rejected several claims as obvious over Shockley, in view of Zielinski and Fraser. Shockley discloses a sputter etching process. Fraser and Zielinski disclose methods of reactive ion etching aluminum and aluminum oxide, respectively. None of the references discloses etching in the presence of boron trihalide. In response to the Examiner's rejection, the applicants amended claim 1 and remarked:

[1] It is not agreed that the references cited in any way disclose the present invention as defined by the claims originally filed or as now filed, nor do the references foreshadow the present invention.

[2] The references . . . are concerned with a totally different process. In sputter etching, the plasma is entirely incidental to the ion bombardment, which bombardment is the etching mechanism. The effect can as readily be affected by using a non-plasma condition by bombarding the surface with ions from an ion gun. Further, a plasma is defined as neutral environment, that is one that has equal members of positive and negative ions. In ion etching (as compared to plasma etching), the target does not sit in the plasma but in a positive space charge.

[3] In the references the plasma plays no part in the etching, being incidental. In the present invention the plasma is part of the etching process in that the etching process uses neutrals, (uncharged particles) in the reaction, these being from the plasma.

Response to Office Action dated January 7, 1977, pp. 1-2 (paragraph numbers supplied). Samsung argues that the above remarks clearly portray "plasma etching" as a process that must exclude ion bombardment because the inventors remarked that the asserted references (which disclosed ion bombardment and reactive ion etching) are "concerned with a totally different process," in paragraph 2.

We find the passage does not support Samsung's argument. In the main, paragraphs 1 and 2 above are descriptions of the asserted references, as opposed to a description of the "plasma etching" process of claim 1. By contrast, it is paragraph 3 which describes the invention, and the specific way that the claimed process differs from the asserted references. Paragraph

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3 describes the plasma as "part" of the etching process, and states that the "etching process uses neutrals" in the reaction. These statements, while describing features of plasma etching, do not exclude the possibility of ion bombardment. Indeed, describing the plasma as "part" of the etching mechanism rather than as "the" (or, perhaps, "the only") etching mechanism, the language instead supports the inference that other mechanisms may also be "part" of the etching process. Again, much like the specification, this language evinces the inventors' clear focus on plasma etching. It does not explicitly call for ion bombardment; but neither does it specifically state its exclusion as part of the invention. See, e.g., Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1458, 46 U.S.P.Q.2D (BNA) 1169, 1175-76 (en banc) (refusing to limit scope of claim language where prosecution history did not clearly call for a narrower definition).

The description of the asserted references as "concerned with a totally different process" in paragraph 2 is far too slender a reed to support the judicial narrowing of a clear claim term. The inventors do not specify (except in paragraph 3, of course) how the references are "totally different." Perhaps the inventors considered the references as "totally different" due to their failure to disclose plasma etching in the presence of a boron trihalide, or because of the relative importance of gas plasma etching in the '967 invention. Or, as Samsung suggests, perhaps the inventors considered the presence of ion bombardment as creating a "totally different process." Or it could be any number of other unstated reasons. Like the district court, we simply cannot tell.

In sum, we find that the prosecution history fails to prove Samsung's assertion that "plasma etching" in claim 1 of the '967 patent requires the exclusion of ion bombardment. That is, under these circumstances, we cannot conclude that Samsung has demonstrated that the patentees -- with reasonable clarity and deliberateness, see In re Paulsen, 30 F.3d 1475, 1480, 31 U.S.P.Q.2D (BNA) 1671, 1674 (Fed. Cir. 1994) -- defined "plasma etching" as excluding ion bombardment. See Johnson Worldwide, 175 F.3d at 989, 50 U.S.P.Q.2D (BNA) at 1610 (noting the "heavy presumption in favor of the ordinary meaning of claim language").

3

Samsung next argues that ambiguity in the prosecution history places this case within the ambit of our holding in Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 37 U.S.P.Q.2D (BNA) 1365 (Fed. Cir. 1996). Samsung suggests that Athletic Alternatives established a rule that when the prosecution history presents an unclear choice between a broader and narrower meaning of a claim term, then the narrower meaning controls. Accordingly, Samsung asserts that the confusing language from the prosecution history noted above requires that a narrower meaning of "plasma etching" -- that which specifically excludes ion bombardment -- applies. This is a misreading of Athletic Alternatives.

In Athletic Alternatives, our review of the prosecution history led to "two strong and contradictory interpretive strands . . . . Each strand, considered alone, leads to a coherent and distinct meaning of the disputed claim." 73 F.3d at 1580, 37 U.S.P.Q.2D (BNA) at 1371. That is, Athletic Alternatives did not turn on ambiguity -- it turned on clarity. The inventors in Athletic Alternatives had provided, in the prosecution history, two "coherent and distinct" definitions of the relevant claim limitation. When presented with the situation where two clear yet contradictory definitions are provided by the patentee, we stated that this court would choose the narrower of the two, as such a practice would "best serve[]" the notice function of the claim. Id. at 1581, 37 U.S.P.Q.2D (BNA) at 1372. Samsung appears to read Athletic Alternatives as requiring that courts choose a narrow definition of a claim limitation whenever there is a dispute over meaning and ambiguity in the intrinsic evidence. This is incorrect. The plain and ordinary meaning of claim language controls, unless that meaning renders the claim unclear or is overcome by a special definition that appears in the intrinsic record with reasonable clarity and precision. See, e.g., Johnson Worldwide, 175 F.3d at 990-91, 50 U.S.P.Q.2D (BNA) at 1610. Vagueness and inference cannot overcome an ordinary meaning of a claim term; nor can it serve to invoke the rule of Athletic Alternatives. Under Samsung's reading, Athletic Alternatives would substitute for reasoned analysis. To the contrary, Athletic Alternatives considers the case where reasoned analysis leads to two clear and distinct definitions of claim language. It does not apply here, where confusing statements in the prosecution history simply fail to overcome the ordinary meaning of the "plasma etching" limitation.

4

Samsung's final argument is that extrinsic evidence supports a construction of "plasma etching" that requires the exclusion of any ion bombardment. In particular, Samsung points to an article published in August 1976, written by Gordon Poulsen, a named inventor of the '967 patent. In that article, Mr. Poulsen described "plasma etching" as "unlike reactive ion etching,"

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being "a strictly chemical process." Poulsen, Plasma etching in integrated circuit manufacture -- A review, J. Vac. Sci. Technol., Jan./Feb. 1977, at 266-274. Samsung argues that this contemporaneous record -- the Poulsen article appeared two weeks after the '967 patent's application was filed -- demonstrates that the term "plasma etching" was intended by the inventors to exclude any ion bombardment.

We first note, of course, that extrinsic evidence is rarely, if ever, probative of a special and particular definition of a limitation found in a claim. This is because extrinsic evidence "may not be used to vary or contradict the claim language" as discerned from the intrinsic record. Vitronics, 90 F.3d at 1584, 39 U.S.P.Q.2D (BNA) at 1577. That is, claims are assumed to take on their ordinary meaning. See Johnson Worldwide, 175 F.3d at 990-91, 50 U.S.P.Q.2D (BNA) at 1610; Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1576. That ordinary meaning may in some cases be overridden by clear definitional statements in the intrinsic record, but it may not, of course, be altered by reference to extrinsic evidence -- for that would allow the public record of the patent to be changed for purposes of litigation, thus abrogating the notice function of the patent documents. See Vitronics, 90 F.3d at 1583, 39 U.S.P.Q.2D (BNA) at 1577 (warning against the loss of the public's right to ascertain the patent's scope from public documents); Southwall Techs., Inc., v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) (same).

In any event, we find Samsung's reliance on extrinsic evidence in this case to be unpersuasive. Poulsen's statement that plasma etching was "unlike" reactive ion etching merely states technologic fact: plasma etching, a chemical process, is different from reactive ion etching, which uses both mechanical and chemical techniques to etch. His statement in no way, however, makes the claim that plasma etching must exclude any ion bombardment. Indeed, the Poulsen article is much like the intrinsic evidence proffered by Samsung -- it supports the argument that plasma etching is different from ion bombardment, but it does not support the view that "plasma etching", as claimed, must preclude the presence of any ion bombardment.

Samsung also points to statements made by the inventors in the course of prosecuting a related Japanese application. There, the inventors again distinguished plasma etching from processes using ion bombardment as an etching mechanism, arguing that references disclosing sputter etching (i.e., ion bombardment) or reactive sputter etching (i.e., reactive ion etching) were not "identical" according to Japanese patent law. To the extent that statements construing terms in different claims in a different application, made to distinguish different references according to different legal standards, are relevant, we again find that they demonstrate little more than the inventors' view that plasma etching and ion bombardment are different (i.e., not "identical") etching mechanisms. But, as we noted before, such evidence cannot convince us that the inventors of the '967 patent accorded "plasma etching" a meaning in claim 1 that required the exclusion of any ion bombardment.

Even if we were to find persuasive the extrinsic evidence proffered by Samsung, we would, of course, have to balance that against the strong evidence submitted by Northern Telecom. In particular, we note that Northern Telecom's expert, Dr. Hess, explained that those of skill in the art would unquestionably recognize that ion bombardment would result from the etching process described in the '967 specification, that the depiction of Figure 2 of the '967 patent "makes clear that ions will bombard the surface" of the workpiece, and that the results reported in the written description indicate the presence of ion bombardment -- thus supporting Northern Telecom's argument that the specification specifically contemplates the presence of ion bombardment. Further, Dr. Hess testified that experts in the field used the term "plasma etching" to apply to both a purely chemical process, as well as the chemical portion of the combination chemical-mechanical reactive ion etching technique.

In sum, we find that Samsung's argument in favor of a narrow meaning of "plasma etching" -- one that requires the exclusion of any ion bombardment -- falls short. While we agree that the record makes clear that the patentees considered plasma etching to be different from ion bombardment, we cannot agree that this mandates a finding of noninfringement. That is, if a patent requires A, and the accused device or process uses A and B, infringement will be avoided only if the patent's definition of A excludes the possibility of B. See, e.g., Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 945, 15 U.S.P.Q.2D (BNA) 1321, 1332 (Fed. Cir. 1990) ("The addition of features does not avoid infringement, if all the elements of the patent claims have been adopted."); Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1057, 5 U.S.P.Q.2D (BNA) 1434, 1444 (Fed. Cir. 1988) ("Adding features to an accused device will not result in noninfringement if all the limitations in the claims, or equivalents thereof, are present in the accused device."); A.B. Dick, 713 F.2d at 703, 218 U.S.P.Q. (BNA) at 967. Statements simply noting a distinction between A and B are thus unhelpful: what matters is not that the patent describes A and B as different, but whether, according to the patent, A and B must be mutually exclusive. While Samsung's "plasma etching" argument has demonstrated that plasma etching and ion bombardment are indeed different

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techniques, it has failed to show that the '967 patent requires, as a part of claim 1, that no ion bombardment be present.

Accordingly, we hold that the district court's claim construction of "aluminum and aluminum oxide" as well as "plasma etching" was correct, and affirm the partial summary judgment based thereon.
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B. The Terms "Plasmid" and "Phage"

ADM asserts that Ajinomoto's expert has interpreted the term "plasmid" as used in the '765 claims to cover the term "bacteriophage." (D.I. 240 at 9) ADM argues that there is no support in the '765 patent specification or prosecution history for this interpretation. The '765 patent specification defines the term "vector molecules" as "DNA molecules of plasmids and phages." (D.I. 240, Ex. A, col. 1, lines 23-24) ADM explains that a vector is a means of transporting certain biological material. (D.I. 240 at 9) ADM further explains that, in the molecular biology field, a vector DNA molecule is used to "carry" certain genes. (D.I. 240 at 10)

In supporting its position, ADM argues that the prosecution history specifically supports the interpretion that the term "bacteriophage" is not included in the definition of the term "plasmid." The '765 patent claims call for combining a chromosome DNA fragment with a plasmid DNA molecule to produce a hybrid DNA molecule or a hybrid plasmid. (D.I. 240, Ex. A, col. 12, lines 1-48) As originally submitted to the PTO, the term "vector" DNA molecule was used instead of the term "plasmid" DNA molecule as the element combined with the chromosome DNA fragment. (D.I. 240, Ex. D at 42) The patent examiner required the claims to be limited to plasmids, stating:

The disclosure is not enabling to support the breadth of the term "vector DNA molecule." Only plasmids appear to be suitable and operative as the vector.

(D.I. 240, Ex. D at 99) Accordingly, the patent applicants amended the claims of the '765 patent to delete the use of the term "vector" DNA molecule and replaced it with "plasmid" DNA molecule. (D.I. 240, Ex. D at 115)

Based on this evidence and the '765 patent specification, the court concludes that the term "plasmid" cannot be interpreted to include the term "phage."
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While several claims of several related Biogen patents are at issue, the parties recognize that the construction of claim 1 of the '702 patent is at the crux of the dispute. Claim 1 reads as follows.

A plasmid vector comprising at least one DNA sequence comprising the leftward promoter and operator derived from bacteriophage [lambda], P[L]O[L], said DNA sequence further comprising at least one endonuclease recognition site located less than 300 base pairs downstream from P[L]O[L] and located between P[L]O[L] and any sequences of [lambda] DNA downstream of the HaeIII site at 73.1% of bacteriophage [lambda] in said DNA sequence.

Stated simply, claim 1 seeks to describe a plasmid vector created by the manipulation of deoxyribonucleic acid (DNA) using recombinant DNA technique, a process by which a selected segment of a DNA molecule is inserted into and combined with all or part of another DNA molecule. The vector described in claim 1 contains P[L]O[L], a promoter (cellular transcription agent) extracted from the virus bacteriophage lambda, or "phage [lambda]," and an endonuclease recognition site, a DNA sequence that is recognized by a restriction endonuclease (a cutting enzyme that isolates a specific sequence of DNA). 1

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1 The DNA segment is attached by DNA ligases at compatible cut sites in the host molecule. The technique, called "ligation," can be envisioned as a "cut-and-paste" process.

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At this point, it may be useful to simply lay out the competing constructions of claim 1, beginning with the patent holder, Biogen. 2

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2 The emboldened phrases are those elements of claim 1 that Biogen and Amgen believe are important to a resolution of the dispute.

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Biogen's Construction

A plasmid vector means a molecule which includes the DNA sequences that enable it to reproduce in a host cell, as well as a marker gene(s) used to identify host cells which have been successfully transformed by that vector. Often the marker gene(s) provides resistance to an antibiotic such as tetracycline or ampicillin.

The leftward promoter and operator derived from bacteriophage [lambda], P[L]O[L], means that the DNA sequence has both structural and functional limitations. Structurally, this element is the DNA sequence from nucleotide positions -69 through -1 as shown in Figure 6 of the '702 patent. Functionally, this element has three properties: (1) a promoter capable of initiating transcription; (2) initiation of transcription of mRNA at a characteristic distance downstream from the "Pribnow" box located at around nucleotide position -10 relative to the start site of transcription; and (3) negative regulation by the cl repressor of bacteriophage [lambda].

At least one endonuclease recognition site located less than 300 base pairs downstream from P[L]O[L] means that the DNA sequence further has an endonuclease recognition site which (1) is suitable for placement of a DNA sequence coding for a desired polypeptide in the vector, and (2) which is located less than 300 base pairs downstream from the HincII site at nucleotide position -33 in the P[L]O[L] region. An endonuclease recognition site is a sequence of nucleotides which is recognized by an endonuclease restriction enzyme.

Which site is located between P[L]O[L] and any sequences of [lambda] DNA downstream of the HaeIII site at 73.1% of bacteriophage [lambda] in said DNA sequence means that there cannot be [lambda] DNA sequences, normally found downstream of the HaeIII site at 73.1% of bacteriophage [lambda], between P[L]O[L] and the endonuclease recognition site. The term "sequences of [lambda] DNA" refers to a sequence of nucleotides having sufficient identify to a sequence normally present in the [lambda] genome that it would be statistically unlikely that such identity occurred by chance.

Amgen's Construction

A plasmid vector comprising at least one DNA sequence containing the [lambda] DNA of Figure 6 comprising the leftward promoter and operator derived from bacteriophage [lambda], P[L]O[L], said DNA sequence further comprising at least one endonuclease recognition site located less than 300 base pairs downstream from P[L]O[L] and located between P[L]O[L] and any sequences of [lambda] DNA downstream of the HaeIII site at 73.1% of bacteriophage [lambda] in said DNA sequence. 3

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3 Figure 6 of the '702 patent, which is at the core of the parties' dispute over the construction of claim 1, is attached to this opinion as Exhibit 1.

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The Legal Framework

"Construction of a patent claim is a matter of law exclusively for the court." Markman v. Westview Instruments, Inc., 52

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F.3d 967, 977 (Fed. Cir. 1995) (citations omitted). A court should first "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996), citing Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). In construing claims, the court must adopt the perspective of one skilled in the art as of the date of the application for the patent. Wiener v. NEC Electronics, Inc., 102 F.3d 534, 539 (Fed. Cir. 1996). 4 The court should also look to the patent specification. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make it and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. Finally, the prosecution history of the patent may be consulted. "The record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims." Vitronics, 90 F.3d at 1582.

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4 The application for the '702 patent was submitted to the Patent and Trademark Office on April 3, 1981. The patent claims its earliest priority from an application filed in Britain on September 8, 1980.

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The claims, specifications and file history constitute the patent's "public record . . . on which the public is entitled to rely." Vitronics, 90 F.3d at 1583. Thus, it is inappropriate for a court to consider extrinsic evidence, such as expert testimony, unless the testimony is necessary to understand the meaning or scope of a technical term in the claims. Id., citing Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995); Markman, 52 F.3d at 980-981 (same). "Where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." Vitronics, 90 F.3d at 1583.

DISCUSSION

Although much is disputed, the limitation in claim 1 of the '702 patent "located between P[L]O[L] and any sequences of [lambda] DNA downstream of the HaeIII site at 73.1% of bacteriophage [lambda] in said DNA sequence," is critical for Markman purposes. 5 It is this limitation that ultimately persuaded the Patent and Trademark Office (PTO) to issue the '702 patent.

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5 Claim 9 of the '702 patent incorporates claim 1 (which is technically not in suit).

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According to Biogen, the words "downstream from the HaeIII site" 6 modify the preceding phrase, "any sequences of [lambda] DNA," rather than serving to further define any limitation on the location of the required endonuclease recognition site. In other words, the limitation excludes only those potential sites within 300 base pairs of P[L]O[L] that follow a [lambda] DNA sequence "identical to the sequences of wild-type [lambda] DNA downstream of the HaeIII site at 73.1%." 7 Biogen Reply Brief, at 11. 8 Biogen's gloss on the disputed phrase is most clearly expressed in its Reply Brief: "Biogen always considered its invention to be the placement of the desired DNA sequence anywhere within 300 base pairs downstream from P[L]O[L] so long as there were no downstream [lambda] sequences between P[L]O[L] and that site." Endnote, at 3.

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6 "Downstream" simply refers to the direction in which the sequence of the base components of the nucleotides is read, left to right being "downstream," right to left being "upstream."

7 Similarly, the concluding phrase "in said DNA sequence," according to Biogen, refers to the downstream [lambda] DNA rather than the entire plasmid vector.

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8 Each party filed opening briefs which are designated in this opinion as "Amgen's Brief" and "Biogen's Brief." Biogen then filed a "Reply Brief" and Amgen a "Surreply Brief."

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There are several problems with Biogen's reading of the limitation. First, if this is what Fiers and Remaut meant, it is difficult to understand why the patent application did not simply say so in plain English (as Biogen in its Reply Brief proves is possible). The answer can be found by looking to what was actually known about phage [lambda] in 1980, when Fiers and Remaut were preparing to make their submission to the PTO. It is clear that at the time, Fiers and Remaut did not know the precise location of P[L]O[L] in phage [lambda], only the approximate contours. 9 This is demonstrated by Figure 6 of the patent, which does not identify the 5' site of P[L]. 10 (The HincII site which is at nucleotides -36 to -31 on Figure 6 was represented by Biogen to the PTO as the 3' site of P[L]. See October 2, 1987 Amendment, at 13*). While Biogen states that Figure 6 was drawn to conform to prior art, and not because the inventors did not know the exact location of P[L]O[L], there is nothing in either the patent or the prosecution history (or for that matter in the testimony of Fiers and Remaut) that supports Biogen in this regard. 11

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9 Fiers and Remaut were not alone. The precise boundaries of P[L]O[L] were still a matter of investigation for those practicing the art in 1980. Indeed, Dr. Panayotatos, Biogen's expert, could not identify the 5' or the 3' ends of P[L] in his deposition in 1996. Amgen Surreply Brief, at 20. From where in the patent or the prosecution history Biogen derives the assertion that P[L]O[L] has its 3' end at nucleotide -1, I cannot determine. Nor do any of the references cited in the patent specifications define nucleotide -1 as the 3' end of P[L]O[L]. See Amgen Surreply Brief, at 25-27. It is equally unclear from where Biogen gleans the information that nucleotide -69 is the 5' end of P[L]O[L]. As late as 1994, Biogen told the European Patent Office that P[L]O[L] "spanned" nucleotides -85 to +5. Id. at 24.10 5' and 3' are the terms used to describe respectively the left and right ends of a nucleic acid molecule reading in the "sense" direction.

11 This is a matter of some importance as the claim language specifies a "DNA sequence comprising the leftward promoter and operator derived from bacteriophage [lambda], P[L]O[L]." Thus, the claimed invention requires the presence of the complete P[L]O[L] sequence. As Amgen points out, a person skilled in the art in 1980 "would not have known which sequences of Figure 6 could be changed or eliminated without affecting the structure [function] of P[L]O[L]." Amgen Brief, at 18. As Amgen demonstrates, a careful student of the references cited in the patent would have likely concluded that P[L]O[L] spanned at least nucleotides -69 to +20 as shown on Figure 6. Id. at 18-19. Dr. Fiers, as late as his first deposition in 1997, was unable to say with any certainty where P[L]O[L] "starts or ends." Amgen Brief, at 17.

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The fact that Fiers and Remaut were unaware of the exact parameters of P[L]O[L] at the time of the patent application underscores a fact that is devastating to Biogen's proposed claim construction. As of May of 1981, most of the [lambda] DNA downstream of HaeIII had not been sequenced. See Daniels & Blattner, "Nucleotide Sequence of the Q Gene and the Q to S Intergenic Region of Bacteriophage Lambda," Virology, Vol. 177, pp. 81-92 (1982). As Amgen notes, "under Biogen's construction, to determine the scope of the claims, a person of ordinary skill in the art in 1980 would have had to compare certain sequences of a plasmid vector with an enormous stretch of [lambda] DNA sequence (greater than 35,000 base pairs) to ensure that the plasmid vector did not contain any of this 'downstream' [lambda] DNA sequence between P[L]O[L] and the endonuclease recognition site. . . . Worse, even if it were proper to resort to the prior art, clairvoyance would have been required to recognize and exclude the 'downstream' [lambda] DNA." Amgen Surreply Brief, at 4, 5. Biogen's response, that "it was well within the skill of the art in 1980 to compare a particular DNA sequence to the sequence of wild-type [lambda] from downstream of the HaeIII site (73.1%) to determine whether any sequence identity was present only by chance or was present because the particular DNA sequence was derived from bacteriophage [lambda]," 12 to the extent that it is intelligible, is no response at all. Without sequencing, no amount of statistical manipulation could establish such an "identity" (a concept which is given no definite meaning in the patent). The patent, in other words, fails to identify any of the downstream [lambda] DNA sequences that Biogen now contends it meant to exclude. 13

When there is no disclosure of any specific starting material or of any of the conditions under which a process can be

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carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Biogen, Inc. v. Amgen Inc., 973 F. Supp. 39, 45 (D. Mass. 1997), quoting Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

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12 Biogen Reply Brief, at 11.13 As Amgen points out, Biogen's present position that the [lambda] DNA to be excluded runs from the identified HaeIII site to the end of the genome conflicts with Dr. Fiers' deposition testimony that the [lambda] DNA to be excluded runs down to "around 38 percent." Amgen Surreply Brief, at 6. Biogen's further late-blooming suggestion, that the essence of the Fiers and Remaut invention was the elimination of coding for the N gene from the vector was, as Amgen points out, rejected three times by the PTO. Id. at 3. It is therefore foreclosed as a matter of law. See Modine Manufacturing Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

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While I am persuaded that Fiers and Remaut did not know the precise parameters of P[L]O[L], it is clear that they did know that P[L]O[L] encompassed the HincII site at -36 to -31, and designated (if not very clearly) the HincII site as the landmark for counting purposes. This is demonstrated by the reference in the patent specifications to the HaeIII-EcoRI converted site as being "about 150 nucleotides downstream from P[L]." '702 patent, col. 10, line 11. 14 (It is in fact 149 base pairs downstream, close enough to be "about"). Because the HincII cut site is between nucleotides -34 and -33, a person skilled in the art would have recognized that Fiers and Remaut intended nucleotide -33 to be the starting point for counting.

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14 In a 1987 Amendment, Biogen stated that the HincII site served to "define" the P[L] promoter, although it mistakenly described the converted EcoRI site as being approximately 140 base pairs downstream from HincII. Despite the discrepancy, I agree with Biogen that one skilled in the art would have understood that the HincII site was being used as a landmark to demarcate P[L]O[L]. Biogen Brief, at 25-26.

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From a 1980 perspective, the most plausible reading of the disputed claim language describes a plasmid vector consistent with Figure 6, containing P[L]O[L] and an endonuclease recognition site located at or downstream from the HaeIII site at 73.1% of phage [lambda], within 300 base pairs of the HincII site (counting from base pair-33), and prior to any sequences of [lambda] DNA found downstream of HaeIII. The HaeIII site, in other words, "defines the downstream end of the contiguous [lambda] DNA of Figure 6." Amgen Surreply Brief, at 7. This reading is grammatical. It gives the word "downstream" its natural meaning as a modifier of the term "sequences of [lambda] DNA," while recognizing the dangling modifier "in said DNA sequence" as a reference to "plasmid vector," the subject of the sentence. 15 It also comports with the prosecution history of the '702 patent. Biogen's original patent application was rejected several times by the PTO because of its descriptive inadequacy. On June 27, 1998, Biogen offered a "compromise" amendment that purported to "recite the specific structure of the plasmid vectors of the application." 16 by adding the contested language "located between P[L]O[L] and any sequences of [lambda] DNA downstream of the HaeIII site at 73.1% of bacteriophage [lambda] in said DNA sequence" as a limitation to claim 1.

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15 The identical phrase, "said DNA sequence," is used earlier in the sentence to refer to "plasmid vector."16 June 27, 1988 Amendment, at 6.

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According to what Biogen told the PTO, the new limitation meant that "each plasmid of the application contains the P[L]O[L]-EcoRI modified [lambda] region of the pPLa23, as depicted in Figure 6." June 27, 1988 Amendment, at 8. 17 In Figure 6, the [lambda] region is shown as spanning the sequence of nucleotides running from the BgIII site to the HaeIII site (-133 to +129). 18 As Biogen explained to the PTO,

[a] person of skill in the art, employing the methods disclosed in the specification as filed, would not place a recognition site at any location other than in the region identified more precisely by the substitute claims. The application does not refer to any site in the natural [lambda] sequence "a short distance downstream from P[L]" other than the HaeIII site.

June 27, 1988 Amendment, at 8-9.

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17 Biogen went on to tell the PTO that "the substitute claims identify a structural characteristic of the plasmids of the invention." Id. at 9.18 When the plasmid vector is constructed, the HaeIII site is converted to an EcoRI site, and the BgIII site is converted to a Sau3A site.

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Seen in the context of the prior art, Fiers' and Remaut's invention constituted a progression and improvement on the work that their predecessors had done using the P[L]O[L] sequence of [lambda] DNA. Fiers and Remaut had constructed what at the time was the shortest (and therefore most efficient) sequence of its type. 19 That this is what Fiers and Remaut thought was the essence of their invention is confirmed by the fact that every one of the plasmid vectors described in the claims specifications contains the entire, intact [lambda] DNA sequence shown in Figure 6. Amgen Brief, at 8. 20 Cf. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480 (Fed. Cir. 1998) (a limited disclosure may serve to narrow the permissible breadth of a patent's claims). 21

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19 With the exception of Horn and Wells, Fiers and Remaut were the first to use the HaeIII site as a potential end site for the P[L]O[L] vector. All earlier sequences using P[L]O[L] had placed the endonuclease recognition site further downstream. For a discussion of the Horn and Wells plasmid vector pRW601, see Biogen, Inc. v. Amgen Inc., 973 F. Supp. 39 (D. Mass. 1997).20 As Biogen, at page 9 of the June 27, 1988 Amendment, stated: "each of the plasmid constructions of this application utilizes the same regions of phage [lambda] and the same operative site, HaeIII (reconstructed to EcoRI)." Biogen's complaint that Amgen reads its patent as covering only endonuclease recognition sites inserted at HaeIII does not fairly characterize Amgen's position. As Amgen makes clear, the HaeIII site is merely the most upstream location claimed for the location of an endonuclease recognition site. As written, "the claims allow the insertion of a variety of endonuclease recognition sites to be located downstream of the P[L]O[L]-EcoRI modified [lambda] DNA region of Figure 6. . . . The only limitation is that to fall within the claims the endonuclease recognition site must be downstream of the Figure 6 [lambda] DNA and not extend further than 300 base pairs downstream of P[L]O[L]." Amgen Surreply Brief, at 10. 21 I agree with Amgen that there is nothing in the patent specifications that teaches "trimming" of the desired [lambda] DNA sequence to less than the entire [lambda] DNA segment depicted in Figure 6. See Amgen Surreply Brief, at 12-15.

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CONSTRUCTION

For the foregoing reasons, I construe claim 1 of the '702 patent as follows. To be covered by the patent, a plasmid vector must contain the entire P[L]O[L] of bacteriophage [lambda] as represented in Figure 6 of the patent and at least one endonuclease recognition site inserted at the converted HaeIII site at 73.1% of bacteriophage [lambda] or at another site downstream of HaeIIII, said endonuclease recognition site being within 300 base pairs of the HincII site at -33, and prior to any sequences of [lambda] DNA downstream of the HaeIII site.

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I

This suit involves United States Patent No. 4,438,584 (the '584 patent), issued on March 27, 1984, to Stanley Z. Baker and Benjamin H. Baker. The patent, assigned to Eaton, discloses a "Trap for Rats, Mice, and Other Vermin." Claim 1, the patent's only independent claim, reads, with emphasis added:

A commercial trap product for catching mice or rats comprised of a generally flat support formed of a non-porous, thin sheet material, said support having at least one positioning surface, at least one indented portion having a given depth below said positioning surface, and a relatively thick layer of pressure sensitive adhesive material contained within said indented portion having a thickness of at least 1/16 inch, a plastic flow temperature above 120 degrees F. and an upper surface; said indented portion having a greater depth than the thickness of said layer of adhesive and said positioning surface being spaced above said adhesive layer upper surface.

Claim 1 thus recites a dishlike container holding a pressure sensitive adhesive material in which vermin become stuck, and thereby trapped. The commercial embodiments of the invention feature two plastic containers or traps, typically packaged together, one on top of the other, face-to-face, capable of being hung in a vertical position at the point of sale.

After a bench trial, the district court issued findings of fact and conclusions of law in which it interpreted the limitation, "a plastic flow temperature above 120 degrees F." Based on its interpretation, Atlantic's accused product was found to infringe claim 1. Additionally, the district court held claim 1 not invalid under § 103 for obviousness, or under 35 U.S.C. § 102(b) (1994) for having been on sale for more than one year before the filing date of the '584 patent. For the reasons set forth in the opinion of the district court, we hold that, on the facts presented in this case, claim 1 is not invalid under § 102(b), and we thus refer no further to that issue.

Whether claim 1 is infringed by Atlantic's accused product, and whether Eaton's commercially successful product is an embodiment of the invention claimed (the latter being germane in this case to the validity of the patent under § 103), depend on what is meant by "a plastic flow temperature above 120 degrees F." As we will explain below, the correct meaning of that term is established by reading the prosecution history of the '584 patent. That is a legal exercise which we are obligated to conduct independently. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).

II

The district court construed the limitation "a plastic flow temperature above 120 degrees F," with reference to the claimed adhesive, to mean:

That the adhesive has a flow characteristic which enables the trap product to be shipped and stored at the highest ambient temperature expected to be encountered in connection with such shipping and storage, namely 120 degrees F, without the adhesive flowing from the support.

A pressure sensitive adhesive material in a trap for catching mice or rats, in accordance with the invention in Eaton's '584 patent, has a plastic flow temperature above 120 degrees F if the adhesive passes the two tests established by Mr. Kenneth A. Nelson. . ., namely (1) disposing a support, such as a tray, and the adhesive therein in an inverted horizontal orientation on an underlying substrate and exposing the support and adhesive to a temperature of 120 degrees F for sixteen (16) hours, and (2) disposing a support, such as a tray, and the adhesive therein in a vertical orientation on an underlying substrate and exposing the support and adhesive to a temperature of 77 degrees F for sixty-three (63) hours. An adhesive passes these tests and has a plastic flow temperature above 120 degrees F if the adhesive does not flow from the support onto the underlying substrate during the test. These two tests are set forth in the file history of Eaton's '584 patent.

In addition, the district court cited another test to determine if an adhesive has a plastic flow temperature above 120 degrees F. That test, devised by Findley Adhesives, Inc., called for heating the adhesive to 250 degrees F for one-half hour, allowing the adhesive to set at room temperature for 24 hours, then disposing the adhesive in an inverted horizontal orientation at a

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temperature of 120 degrees F for 16 hours. With regard to those tests, the district court held that:

The two tests devised by Mr. Nelson and the test procedure established by Findley Adhesives, Inc. are appropriate for determining that an adhesive has a plastic flow temperature of 120 degrees F in accordance with the invention claimed in the '584 patent.

Based on undisputed testimony offered by Eaton, Atlantic's mousetraps--when subjected to these tests--were found to infringe claim 1. As we will explain below, however, these tests cannot, as a matter of law, be the measurement for determining if an adhesive meets the plastic flow temperature limitation of claim 1, because the tests do not measure plastic flow at 120 degrees F in a vertical orientation, which is required when the claim is properly construed.

After a thorough analysis of the prior art, the district court found the "primary indicia of patentability . . . lacking," Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306, 227 U.S.P.Q. (BNA) 657, 675 (Fed. Cir. 1985), for claim 1, and that the claim would have been obvious when viewed in the light of the prior art and the level of skill in the art. Nevertheless, the district court held the patent nonobvious because of the strong commercial success of Eaton's commercial product. The finding of commercial success was based on Eaton's $ 17 million of sales from 1979 through 1984, and its $ 4 million of annual sales from 1985 through 1989.

III

The '584 patent emerged from claims originally set forth in Patent Application No. 338,621, which is a continuation of Ser. No. 53,381, filed on June 29, 1979. The examiner rejected the claims, inter alia, for failure to disclose the best mode of making the invention. The Nelson tests, used by the district court as the measurement of plastic flow temperature, assessed prior art adhesives and an adhesive which Nelson's employer, Findley Adhesives, had been requested by Eaton to prepare that would meet the limitations of claim 1. Even though Eaton had expressly directed Nelson to test the adhesives for plastic flow at 120 degrees F in an orientation other than horizontal, Nelson's test results did not refer to any tests or test results at 120 degrees F in a vertical orientation. Instead, the only 120 degrees F test performed by Nelson was on adhesive in a horizontal orientation. Nelson's tests for plastic flow in a vertical position at 77 degrees F were unrelated to the 120 degrees F plastic flow limitation in the '621 application, and were not requested by the performance specifications supplied to Nelson by Eaton. The results of Nelson's tests, as well as his test protocols, were introduced by the applicants to overcome the best mode rejection and to show that prior art adhesives failed to meet the Nelson tests.

The examiner, however, was troubled by the information disclosed in the Nelson tests. In particular, the examiner noted that one of the prior art adhesive traps tested by Nelson anticipated the claims under 35 U.S.C. § 102 (1994). Accordingly, the examiner requested additional tests by Nelson from the applicants to overcome the rejection. Eaton's attorney communicated the examiner's concerns to Nelson by letter dated November 6, 1981, which was introduced at trial on the public record as Defendant's nonprivileged Exhibit 197. In that letter, Nelson was instructed by Eaton's counsel to perform additional tests on the prior art adhesive. In particular, the attorney noted the need for a 120 degrees F test with the adhesive vertically oriented. The attorney recommended a vertical 120 degrees F test "for a period of a day or several days." Whether Nelson performed the particular vertical tests requested by Eaton's attorney is unknown, and the prosecution history of the '584 patent contains no reference to the results of such vertical tests. The examiner rejected the claims for failure to disclose best mode, nonenablement of the adhesive, and obviousness over the prior art.

On appeal to the Board of Appeals of the U.S. Patent and Trademark Office (Board), the claims were held not prima facie obvious over the prior art, and in any event not obvious because of the commercial success of Eaton's products. The applicants, in their brief to the Board, stated that the adhesive claimed must not flow when exposed to 120 degrees F in vertical orientation, even for unlimited periods of time. The requirement that the claimed adhesive not flow when exposed to 120 degrees F in a vertical orientation had been noted several times during prosecution up to the filing of the applicant's brief to the Board, and the same point was emphasized throughout subsequent prosecution proceedings. For example, the applicants stated in their brief to the Board:

Also importantly, the adhesive must have temperature-flow characteristics such that even if the surface of the adhesive is vertical, the adhesive will not flow or sag at ordinarily encountered ambient storage temperatures (less than 120 degrees F). That is to say, the plastic flow temperature of the adhesive must be above 120 degrees F. [Emphasis added.]

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On another occasion, in its statement to the Patent Office dated November 19, 1985, the applicant distinguished prior art references on the basis that:

Nowhere in any of these references is there any mention whatsoever of a body of adhesive having a particular plastic flow temperature which enables a vermin trap to be shipped and stored in positions other than horizontal at the highest ambient temperature expected to be encountered in connection with such shipment and storage without the body of adhesive running from the support therefor. [Emphasis added.]

In sum, the prosecution history abounds with unambiguous declarations by the applicants that their claimed traps would reasonably be exposed to 120 degrees F when vertically oriented. That history is consistent with the evidence introduced at trial showing Eaton's repeated efforts to test adhesives at 120 degrees F in vertical orientations, and refutes any notion that Eaton's only vertical flow concerns were satisfied by Nelson's 77 degrees F vertical test. However, despite the applicants' repeated emphasis on the requirement that the adhesive not flow when exposed to 120 degrees F in a vertical orientation, the file history contained no reference to any vertical test at 120 degrees F when the '584 patent issued on March 27, 1984.

In July of 1985, a request for reexamination was filed by Hampton Chemical, Inc., based on several prior art references not previously considered by the examiner or the Board. For purposes of our review, two items of the prior art are of concern: two U.K. patents, disclosing an adhesive in a mousetrap, and a domestic adhesive product, Formula 31, which were said to render obvious the mousetrap claimed in the '584 patent.

IV

When the patent was subjected to reexamination, the applicants, Hampton Chemical, and the examiner knew that the invention as claimed specified that the adhesive not flow when exposed to 120 degrees F in any orientation, including vertical. However, before the reexamination proceedings, no reference had been made in the file history to any test of plastic flow at 120 degrees F when the material is vertically oriented. All previous references to plastic flow in a vertical orientation were with respect to relatively long-term exposure at ambient room temperatures. In particular, the earlier references to vertical plastic flow cited the Nelson tests, which exposed the adhesive to 77 degrees F for 63 hours. The concern over possible flow at room temperature after exposure for several days stemmed from the inventors' understanding that at commercial points of sale, the packaged traps might remain suspended vertically for such times. The 77 degrees F test, while of interest to the inventors for shelf life marketability of their product, is irrelevant to the determination of whether an adhesive will flow when exposed to 120 degrees F for any period of time. In short, claim 1 of the '584 patent cannot be enforced against a mousetrap product with an adhesive which passes Nelson's 77 degrees F vertical test, but which fails the 120 degrees F test. Nor can a product which passes the 77 degrees F test, but which fails the 120 degrees F limitation, be used to demonstrate commercial success of the invention as part of a defense to legal challenge under § 103.

Before reexamination, a competitor of Eaton wishing to avoid infringement of claim 1 would not have known how to test his product to determine if it satisfied the 120 degrees F limitation when the adhesive is vertically oriented. Indeed, such a competitor, Southern Mill Creek Productions Company, Inc., had already appeared, in protest to the application before the patent issued, complaining that "no where in the confines of this Application have Applicants defined how one might measure the flow temperature of the pressure-sensitive adhesive material." The applicants, however, took no steps to disclose a test protocol for measuring plastic flow at 120 degrees F in a vertical orientation. The record in this case reflects that Eaton learned in 1983, while Southern Mill's complaint was pending, and before issuance of the patent, that its own product failed the 120 degrees F flow test when exposed vertically for 16 hours. We do not know, however, whether that fact affected Eaton's failure to disclose a 120 degrees F vertical test protocol to the examiner.

V

During reexamination, Hampton Chemical sought to prove that Eaton's claimed mousetrap employing a special adhesive was rendered obvious in view of the two U.K. patents and Formula 31. To make its case, Hampton employed one of ordinary skill in the art, Donatas Satas, to test the adhesive disclosed in the U.K. patents. Satas selected the test protocol for the 120 degrees F limitation, and determined that the adhesive should be tested for flow at 120 degrees F for 24 hours in a vertical orientation, and for 12 hours at 120 degrees F in an inverted horizontal orientation. Satas concluded that the prior art adhesives so tested met the limitations of claim 1.

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Eaton, also in the reexamination, sought to prove that Formula 31 did not meet the limitations of claim 1. Toward that end, Eaton hired John M. Questel, also one of ordinary skill in the art, to test Formula 31. Questel's tests were performed under his supervision by his employee, Lore Hise. The test protocol selected by Questel exposed the adhesive to 120 degrees F for 24 hours in both horizontal and vertical orientations. Questel concluded that Formula 31 did not meet the limitations of the claim, and that he lacked sufficient information to comment--one way or another--on the conclusion reached by Donatas Satas on the adhesive disclosed in the U.K. patents.

On March 10, 1986, the examiner rejected the claims on reexamination as obvious under § 103 over the references brought to the examiner's attention by Hampton Chemical. Eaton responded to that rejection, arguing that Questel's tests had shown Formula 31 not to be invalidating prior art, and that Satas's test results were inconclusive. In its response, Eaton relied on the Questel tests, and notably, did not question the propriety of the test protocols employed by Satas. From this episode in the file history of the '584 patent, a reasonable competitor of Eaton would surmise that Eaton would measure satisfaction of "a plastic flow temperature above 120 degrees F" by testing accused adhesives at 120 degrees F for 24 hours in both vertical and horizontal orientations. In short, after seven years of patent application prosecution, the file history clearly supplied the missing vertical 120 degrees F test parameter and a corresponding horizontal test.

VI

The final chapter of the file history of the '584 patent is the second appeal to the Board following another rejection of the claims by the examiner as obvious over the prior art, including the U.K. patents and Formula 31. Both Eaton and the examiner again relied on the Questel tests, with Eaton arguing the tests showed that the prior art failed to meet the 120 degrees F claim limitation, and the examiner arguing that the tests showed the prior art met the limitation. The Board, during the course of its detailed review of the prior art, relied on the 24-hour parameter in the Questel tests in concluding that the adhesive in Formula 31 met the 120 degrees F limitation. In light of the prior art, the Board concluded that the claims are prima facie obvious, but that the claims are nevertheless nonobvious under § 103 because of the commercial success of Eaton's product, as demonstrated to the Board by Eaton's submission of sales data and consumer testimonials. During this final chapter of the prosecution history, neither Eaton, the examiner, nor the Board referred to the then-ancient Nelson tests as the protocol for ascertaining the meaning of the 120 degrees F claim limitation. Instead, there was unanimous recognition that the Questel test protocols were understood by one of ordinary skill in the art to define the 120 degrees F claim limitation.

VII

We now turn to the events at trial in the district court. Both Eaton and Atlantic offered testimony through expert witnesses about the meaning of the 120 degrees F claim limitation. "Plastic flow temperature above 120 degrees F" is a term with no previous meaning to those of ordinary skill in the art. Its meaning, then, must be found somewhere in the patent. See 35 U.S.C. § 112, P 2 (1994) (inventor must particularly point out and distinctly claim the subject matter of his invention); In re Paulsen, 30 F.3d 1475, 1480, 31 U.S.P.Q.2D (BNA) 1671, 1674 (Fed. Cir. 1994) (inventor as lexicographer must define his terms in the patent disclosure). Both expert witnesses understood that the adhesive in claim 1 had to withstand plastic flow at 120 degrees F when subjected to horizontal and vertical tests. Both witnesses also understood that the claim prohibits plastic flow at 120 degrees F after the adhesive has been exposed to the specified degree of heat for such reasonable periods of time as the commercial product might experience during shipping and storage.

The experts, however, disagreed over the length of time that the patented product might remain exposed to 120 degrees F during shipping and storage. Eaton's expert, Richard Muny, testified regarding adhesive tests that he had been asked to run on Eaton's products and the accused products of Atlantic. Muny testified that he took no part in selecting the test protocols; instead, he simply ran his tests using protocols given to him by Findley Adhesives at the direction of Eaton. The tests used by Muny were those devised by Nelson (horizontal at 120 degrees F for 16 hours and vertical at 77 degrees F for 63 hours), plus a vertical test at 120 degrees F for 5 hours. Muny did not explain why he was asked to conduct the 120 degrees F vertical test. Muny also testified that it might go "too far" to describe these Findley tests as standard quality control procedure. Muny, however, testified that in his opinion the tests he had been asked to run reflected the time periods during which the products might be expected to be exposed to 120 degrees F when in shipment or storage.

Dr. Harold Zeliger testified that he had been retained by Atlantic to devise and carry out tests to demonstrate whether the products of Eaton and Atlantic met the limitations of claim 1. Zeliger read claim 1 to require the adhesive to resist plastic

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flow when exposed to 120 degrees F in a vertical orientation. Zeliger did not state whether he tested any product for plastic flow when in a horizontal orientation. His tests exposed six commercial products of both Eaton and Atlantic to 120 degrees F, vertically oriented in their packages of two trays facing one another. Zeliger periodically examined the products being tested to determine if they had experienced plastic flow. Zeliger concluded that an adhesive "failed," when the adhesive in the two trays flowed into each other. According to Zeliger's tests, two of Eaton's products resisted plastic flow for 44 hours, but the other four Eaton products "failed," or flowed, one after 11 hours and the other three after 20 hours. Of Atlantic's accused products, one failed after 24 hours, three failed after 11 hours, and two failed after 20 hours.

Zeliger testified that, in his view, all of the products of Eaton and Atlantic failed during times he considered reasonable times when the adhesives would be exposed to 120 degrees F during shipping and storage. Zeliger expressly disagreed with Muny's conclusion that five hours of exposure at 120 degrees F was the reasonable maximum exposure time. Zeliger testified that a five-hour time limit was not indicative of real world conditions. On cross-examination, Zeliger admitted that in real world conditions, one would not find exact temperatures of 120 degrees F maintained evenly over periods of time. Zeliger thus cast some doubt on his own tests as effective measurements of actual shipping and storage conditions.

After hearing all the testimony, the district court rejected Zeliger's view that infringement of claim 1 should be measured by the length of time required for the adhesive in the trap to flow when exposed to 120 degrees F in a vertical position. The district court also rejected the portion of Muny's tests that had subjected Atlantic's traps to 120 degrees F in a vertical orientation for five hours. Instead, the district court held that Nelson's tests, as conducted by Muny, proved that Atlantic's product infringed claim 1. For the reasons explained above, the district court's reliance on the Nelson tests is legal error, since those tests fail to subject the claimed adhesive to 120 degrees F when vertically oriented.

If Muny is correct that his five-hour vertical test and a 16-hour horizontal test satisfy claim 1, Atlantic's accused product would infringe claim 1 because Atlantic apparently concedes the 16-hour, 120 degrees F horizontal measurement and Zeliger proves that at least some of Atlantic's product survives for five hours when tested vertically. If, however, Zeliger is correct that the reasonable times for exposure at 120 degrees F can vary, and that his failure times are all within a zone of reasonable exposure times, then none of Atlantic's product infringes claim 1. Eaton's own product also would not meet the limitations of claim 1, and Eaton would thus be unable to claim commercial success of that product to establish that claim 1 is not obvious under § 103.

We may not rely on either Muny or Zeliger, because, as we have often stated, trial testimony regarding the meaning of a claim cannot vary the meaning of a claim that is established either by the claim itself or by the claim as correctly understood by reference to the specification and the file history. See Senmed, Inc. v. Richard-Allan Medical Indus., Inc., 888 F.2d 815, 819 n.8, 12 U.S.P.Q.2D (BNA) 1508, 1512 n.8 (Fed. Cir. 1989); see also North Am. Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1577, 28 U.S.P.Q.2D (BNA) 1333, 1337 (Fed. Cir. 1993) (patentee cannot take one position before the Patent Office and a different position before the court); Jonsson v. Stanley Works, 903 F.2d 812, 820-21, 14 U.S.P.Q.2D (BNA) 1863, 1871 (Fed. Cir. 1990) (same).

For the reasons set forth above, we have concluded that the district court erred, as a matter of law, when it construed the term "a plastic flow temperature above 120 degrees F" to exclude any amount of plastic flow when the adhesive is exposed to 120 degrees F in a vertical orientation. The 120 degrees F vertical tests proposed by Muny and Zeliger are also legally insufficient; Muny's because it sets the time for horizontal and vertical testing incorrectly, and Zeliger's because it sets no times for testing, but simply tests until failure, and then asks if the time to failure is within reasonable real world exposure times. While Zeliger's test may have some common sense appeal, it provides no certainty to Eaton's competitors, who are entitled to know the point in time at which their products will infringe claim 1. Nor does Zeliger's test give any measure of certainty to Eaton, which is also entitled to know in advance how to test competing product for infringement of claim 1.

In this case, the dispositive claim limitation is a term unknown to those of ordinary skill in the art at the time the patent application was filed. It thus fell to the applicants, as a duty, to provide a precise definition for the 120 degrees F limitation. Early in the prosecution history of the '584 patent, a competitor noted the absence of any definition of the key term. The applicants' proffer of the Nelson tests did not respond properly to the competitor's plea, because the Nelson tests failed to supply a test parameter for flow at 120 degrees F when the adhesive is vertically oriented. The record in this case amply demonstrates that the applicants intended their adhesive to withstand plastic flow at 120 degrees F when vertically oriented. Their disclosures to the examiner repeatedly stated that intention, as did their testing of products, demonstrated by evidence submitted at trial, for flow at 120 degrees F when vertically oriented. The applicants were obligated to give a meaning to the

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key limitation during the prosecution history, and they did so with the Questel tests.

VIII

Having concluded that "a plastic flow temperature above 120 degrees F" means that the adhesive must resist flow when exposed for 24 hours to 120 degrees F in both horizontal and vertical orientations, we now review the holdings of the district court that Atlantic's accused products infringe claim 1, and that the claims of the '584 patent are not invalid as obvious under § 103.

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To reach its idiosyncratic claim interpretation, this court relies on a few isolated excerpts from over 1400 pages of prosecution history. In particular, this court abstracts two paragraphs from an eleven-page declaration of John M. Questel, filed in the second reexamination, to convert a stringent vertical flow test into a claim requirement. In fact, neither Eaton, nor the Board, nor even Mr. Questel himself, relied on his 120 degrees F vertical flow test to distinguish prior art. The administrative record, when considered as a whole, does not support this court's adoption of this test as the measure of Eaton's claims.

This court need not have strained to interpret the claims. The patent record -- the claims, specification, and prosecution history -- provides ample support for the claim interpretation adopted by the United States District Court for the Eastern District of New York. In fact, the examiner, the Board, and at least two federal judges have already accepted the same interpretation -- a reading compelled by the prosecution history as a whole.

I.

The phrase "plastic flow temperature" has no fixed meaning in the adhesive art. However, an inventor may freely define unfamiliar claim terms in the specification or in the prosecution history. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1576 (Fed. Cir. 1996); Lear Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 889-90, 221 U.S.P.Q. (BNA) 1025, 1031 (Fed. Cir. 1984). Eaton took that course to define its claim term.

Eaton's Patent No. 4,438,584 (the '584 patent) distinguished its ready-to-use glue trap for mice and rats from the prior art with an adhesive having a "plastic flow temperature above 120 degrees F." The inventors, Stanley and Benjamin Baker, recognized that the adhesives used in prior art traps would melt and flow at temperatures normally encountered during shipping and storage. The Bakers learned from the United States Department of Transportation that the maximum ambient temperature encountered during shipping was 120 degrees F. To solve the problem with the prior art, the Bakers set out to stabilize their adhesive at temperatures up to 120 degrees F. Thus, the requirements of secure shipping became the benchmark for "plastic flow temperature."

Throughout the lengthy administrative proceedings, Eaton and the PTO clarified this meaning of plastic flow temperature. For example, in its Amendment filed July 24, 1981, Eaton explained:

> Because the plastic flow temperature is above 120 degrees F, the body of the adhesive will not flow plastically at normally encountered ambient temperatures while being shipped or stored. The traps can be disposed horizontally, upside down or vertically at normally encountered temperatures with no fear of touching of adjacent surfaces or the adhesive of one trap to the other.

Thus Eaton explained that its claimed adhesive would not flow upside-down or "vertically at normally encountered temperatures."

To underscore this message, Eaton submitted the declaration of Kenneth A. Nelson, the chemist who developed the claimed adhesive. Mr. Nelson's declaration disclosed a two-prong test for the claim requirement. That test requires, first, placing a 1/16 inch layer of adhesive upside-down in an oven preheated to 120 degrees F for sixteen hours. Second, the test requires that the adhesive be hung vertically in an oven at 77 degrees F for sixty-three hours. An adhesive meets Eaton's requirement if the glue does not flow from the tray during either of these tests.

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The Board understood and accepted this specific definition of plastic flow temperature. In its November 30, 1983, opinion, the Board recognized "plastic flow temperature" as the "characteristic of the adhesive . . . required to prevent the adhesive from flowing or sagging at temperatures at which the trap is shipped, stored, or used." The Board noted that prior art publications did not anticipate Eaton's claims because they lacked adhesives with these plastic flow properties:

Prior to the instant invention, glue traps were prepared by the user rather than the manufacturer in that ready made traps could not be readily shipped and stored. Workers in this art were working to find various means to solve these problems. Appellants recognized this problem and conceived of the idea embodied in the instant claims of utilizing an adhesive having special plastic flow properties.

Thus, the full administrative record gives an explicit and reasonable meaning of "plastic flow temperature" that focuses on shipping and storage of the commercial trap product without adhesive spillage. Mr. Nelson's two-prong test makes Eaton's definition unmistakable to one of skill in the art. For this reason, the Eastern District of New York adopted the Nelson tests as the definition of "plastic flow temperature." Indeed, another district court interpreted "plastic flow temperature" in the same '584 patent precisely in accordance with Mr. Nelson's declaration. See J.T. Eaton & Co. v. Bell Lab., Inc., No. 95-C-0441-S (W.D. Wis. March 29, 1996) (oral jury instructions). Thus, the examiner, the Board (twice), and two district courts read the plastic flow limitation in accordance with the Nelson tests.

Trial testimony from one skilled in the art confirmed the logic of this uniform claim interpretation. According to this testimony, Mr. Nelson's sixteen hour inverted horizontal test at 120 degrees F properly tested the product under typical shipping conditions. After all, elevated temperatures would not last longer than normal daylight hours. Testing the adhesives beyond sixteen hours made little sense in the context of shipping these products in trucks and boxcars. Likewise, according to the same testimony, the lengthy vertical test at 77 degrees F properly reflected the prolonged periods of shelf storage at normal room temperatures. Given this logical explanation, there is little wonder every other agency and court that reviewed Eaton's claims accepted the same interpretation.
II.

Despite the overall content of the prosecution history, this court stretched the vertical flow test concept out of proportion, exaggerated the stringency of that test beyond the realities of storage and shipping, and made it the sole talisman of the Eaton claim. In its brief, Atlantic urged this court to find a stringent vertical flow test in a single sentence of the voluminous prosecution history:

Plastic flow temperature, as used herein, is that temperature below which the adhesive will not flow or sag even if stored with the surface of a thick (1/16 to 1/8 inch) layer of adhesive vertical for unlimited periods of time. (Applicant's Brief to Board of Patent Appeals and Interferences, December 27, 1982)

Based on this statement, Atlantic argued that an accused trap product could not infringe unless it could dangle in a vertical position at 120 degrees F for an infinite period of time without any glue flow. Like the district court before it, however, this court recognized that one skilled in the art could not reasonably rely on such obvious hyperbole as if it affected the scope of the claim. See Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1054, 12 U.S.P.Q.2D (BNA) 1474, 1477 (Fed. Cir. 1989) (holding that claim language controls over an attorney's "erroneous remarks" made during the course of prosecution). Accordingly, the panel rejected this rationale. In so doing, it rejected the only claim interpretation proffered by Atlantic for "plastic flow temperature."

Without any basis in argument from either party or testimony from the trial record, the panel's ultimate claim construction rests on its own collection of orphaned passages from the file history. According to the panel, these passages show that Eaton did not provide a test for measuring vertical flow. To the contrary, Eaton provided Mr. Nelson's 77 degrees F vertical test -- a test designed for temperatures where the products are likely to hang on vertical displays. Nonetheless, this court created the myth of a "missing vertical test" to justify its reliance on two paragraphs in Mr. Questel's declaration (paragraphs 22 and 23) -- a declaration filed two years after the '584 patent originally issued.

This court's reading of the record goes astray in several ways. First, nowhere does the '584 patent prosecution suggest the necessity of a 120 degrees F vertical flow test. The "missing" test was not missing at all, but was simply not required by the claims. Before the PTO, Eaton consistently stressed that the Nelson tests defined "plastic flow temperature" under

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temperature conditions likely to be encountered during shipping and storage. Second, the brief extract from Mr. Questel's declaration simply lacks the meaning and the importance attributed to it by the panel.

A.

The premise underlying this court's opinion is that Mr. Questel supplied a missing test for vertical flow two years after the patent issued. The panel divines this premise from a few passages in which Eaton generally describes the advantages of the claimed adhesive. For example, the panel opinion relies on Eaton's statements to the Board on December 27, 1982:

Also importantly, the adhesive must have temperature-flow characteristics such that even if the surface of the adhesive is vertical, the adhesive will not flow or sag at ordinarily encountered ambient storage temperatures (less than 120 degrees F). That is to say, the plastic flow temperature of the adhesive must be above 120 degrees F.

According to the panel, this quote demonstrates that "plastic flow temperature" had a vertical component that Mr. Nelson did not measure. To the contrary, Eaton did not shirk its duty to define the claim terms. In the very same 1982 brief, when actually distinguishing the prior art cited by the examiner, Eaton specifically cited to the Nelson tests as the definition of "plastic flow temperature."

The record is replete with other instances in which Eaton mentioned the word "vertical" in contexts fully consistent with using the Nelson tests as the measure of plastic flow temperature. For example, in its Amendment filed July 24, 1981, Eaton argued:

A trap made [in the manner described in the application] has been evaluated by Kenneth A. Nelson and found to have acceptable plastic flow characteristics. The trap can therefore be shipped or stored in vertical or inverted horizontal positions without fear of plastic flow and thus contamination of adjacent surfaces or spilling.

Eaton simply did not argue for its patent on the basis of some undefined vertical flow capabilities. Eaton had no need to test vertical flow above 77 degrees F because its traps would be displayed vertically only at room temperature.

More importantly, the PTO understood this simple principle. The PTO did not understand Eaton to rely on a stringent vertical test for flow characteristics. Both the examiner and the Board expressly disclaimed any reliance on vertical or horizontal testing to determine patentability of the claimed invention. For example, the examiner stated on May 27, 1986:

Whether the body tests were done in vertical, inverted horizontal or flat horizontal position has no relevance. The claims do not specify what position the adhesive is in regarding vertical flow.

The Board expressed a similar view in its January 16, 1987, decision on the second reexamination:

The claims on appeal do not include any limitations restricting the orientation of the commercial trap product defined therein to any particular horizontal, vertical, or inverted disposition, nor are there any limitations requiring flow of the adhesive from the container to be prevented for any particular length of time.

These passages make absolutely clear that the PTO did not decide to issue the '584 patent based on any of Eaton's statements about vertical flow or any of Mr. Questel's tests. Instead, it is this court that first imports into the claims a supposed limitation from the prosecution history -- a limitation on which neither the applicant nor the PTO relied during acquisition of the patent.

In fact, the PTO never objected to the phrase "plastic flow temperature" as indefinite for lack of a vertical flow test. If vertical flow was the pivotal claim parameter perceived by this court, then the PTO should have noted its absence. Instead, the lengthy prosecution culminated in the issuance of the '584 patent without so much as a mention of a mythical "missing" vertical test.

Finally, Eaton did not, as the panel suggests, switch its focus from the Nelson tests to the Questel tests during the final chapter of the prosecution. Rather, at the conclusion of the second reexamination, as at the beginning, Eaton relied on its consistent definition of plastic flow temperature:

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The terminology "plastic flow temperature" in appellants' claims on appeal has that meaning which is made clear elsewhere in the patent or in the file wrapper. . . . Appellants defined their terminology "plastic flow temperature" throughout the prosecution of their application which matured as the subject patent as being a characteristic of the adhesive which would prevent the adhesive from sagging or flowing from its support at temperatures at which their product is shipped, stored, or used.

This passage shows that Eaton did not attempt to switch arguments on the PTO in the closing chapter of the prosecution.

Perhaps aware of the danger of stringing together isolated passages out of context, this court tries to correlate these passages by reference to private communications between Eaton's lawyers and scientists. Specifically, the panel relies on Eaton's attorney's instructions to Mr. Nelson about vertical flow testing. Far from supporting the missing test myth, this tactic betrays this court's flawed method of seeking claim meaning. These privileged exchanges are not part of the public record. Even if Eaton's attorneys believed patentability turned on vertical flow at 120 degrees F, such private correspondence, not a part of the public record, cannot possibly supply evidence of claim meaning. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995) (patent claims are construed in light of the public record), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Thus, this court relies not only on out-of-context extracts, but on extracts without any relevance to claim interpretation. Indeed, few of the isolated passages on which this court relies had anything to do with the meaning of the plastic flow characteristic. Neither Eaton nor the Board relied on the passages to which this court attaches dispositive significance.

For all these reasons, I must conclude that this court has created a requirement for a stringent vertical flow test that the claims, read in light of the prosecution history, do not require. Had Eaton truly acquired its patent by requiring such a test, the record would surely contain far more emphatic evidence than the few isolated passages cited in the panel opinion. See York Prods., Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1575, 40 U.S.P.Q.2D (BNA) 1619, 1624 (Fed. Cir. 1996) ("Unless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage.").

B.

Without doubt, the precedent of this court indicates that a patentee's remarks during patent prosecution can illuminate the meaning of the claims. See Markman, 52 F.3d at 980; Vitronics, 90 F.3d at 1582-83. However, our precedent makes equally clear that this court construes an administrative record in its full context, not on the basis of snippets lifted out of context. See Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1565, 19 U.S.P.Q.2D (BNA) 1500, 1506 (Fed. Cir. 1991) ("We construe claims in the light of the language of the claim itself, the specification on which it is based, and the whole prosecution history.") (Rich, J., dissenting); see also Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 292, 36 U.S.P.Q.2D (BNA) 1095, 1100 (Fed. Cir. 1995), cert. denied, 133 L. Ed. 2d 847, 116 S. Ct. 917 (1996). Moreover, the reviewing court must examine the full context of prosecution history to discern not only what the applicant said, but why he said it. Cf. Hebert v. Lisle Corp., 99 F.3d 1109, 1118, 40 U.S.P.Q.2D (BNA) 1611, 1617 (Fed. Cir. 1996) ("It is of course necessary to consider not only the amendments to the claims but the reason why they were made . . . .").

These basic legal principles disclose the infirmity of the court's reliance on two paragraphs from a single declaration at the end of the second reexamination. A fair reading of the declaration indicates that Mr. Questel distinguished the prior art Formula No. 31 adhesive on two grounds: (1) it exhibited unacceptable levels of cold flow (i.e., 72 degrees F) in a vertical orientation; and (2) it exhibited unacceptable levels of hot flow when tested at 100 degrees F in a vertical orientation. Thus, although Mr. Questel conducted twenty-four hour vertical tests at 120 degrees F, neither he nor Eaton ever relied on such tests to distinguish any prior art. Nor did Mr. Questel in any way suggest that he considered a twenty-four hour vertical test at 120 degrees F to be the measure of "plastic flow temperature." This record simply does not support the court's conclusion that Eaton's claims are measured by the 120 degrees F vertical flow test. See Ethicon Endo-Surgery, Inc. v. United States Surgical Corp., 93 F.3d 1572, 1581, 40 U.S.P.Q.2D (BNA) 1019, 1025-26 (Fed. Cir. 1996) (looking to "the prosecution history as a whole" to determine how one skilled in the art would understand a claim term) (Clevenger, J.).

Sadly, this court's fixation on the 120 degrees F vertical flow test foreclosed the one claim construction that was used repeatedly by all parties throughout the public record. The district court properly used that claim interpretation. This court errs in departing from the full context of the administrative record, and importing a false limitation from the prosecution

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history.
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C. "PLASTICIZER"

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Plasticizer	A "plasticizer" is a composition that decreases the softening temperature of the polymer to which it is added.	No need to construe. A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.	A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.

The detailed description of the invention states that "[t]he plasticizer can be an ester such as a citrate ester, an oil such as castor oil, a polyalkyleneglycol such as polyethyleneglycol of various MWs. The preferred plasticizer is polyethyleneglycol." (Ex. 1, Col. 2:62-65.) Further the detailed description of the invention states:

The proportion of plasticizer (e.g. polyethyleneglycol) in the coating may vary between 5 and 30% of the coating dry weight. The relative proportions of ingredients, notably film-forming polymer to water-soluble polymer, can be varied depending on the release profile to be obtained (where a more delayed release is generally obtained with a higher amount of water-insoluble, water-permeable film-forming polymer). [P] The coating process can be as follows. ethylcellulose and polyethylene glycol (e.g. PEG 1450) are dissolved in a solvent such as ethanol; polyvinylpyrrolidone [Povidone or "PVP"] is then added. The resulting solution is sprayed onto the tablet cores, using a coating pan or a fluidized bed apparatus.

(Ex. 1, Col. 3:9-21)

Biovail contends that the term "plasticizer" has its ordinary and customary meaning. (Biovail's Preliminary Claim Construction Brief, p. 12.) Biovail avers that to a person skilled in the pharmaceutical arts, the term "plasticizer" refers to a composition that decreases the softening temperature of the polymer to which it is added. (Williams Decl., P 16.) Further, Biovail asserts that the language in the detailed description of the '341 patent cited above is entirely consistent with the ordinary meaning for the term "plasticizer" to one skilled in the art. (Id., P 17.)

Anchen avers that there is no need to construe the meaning of the term "plasticizer," because Biovail has not claimed that any ingredient in Anchen's coating meets the plasticizer limitation. (Anchen's Opening Claim Construction Brief, p. 16; JEM Decl. Ex. C, at 4.) "[A]lthough the claims are construed objectively and without reference to the accused device, only

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those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Technologies, Inv. v. American Science & Engineering, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999).

Anchen contends that because Biovail only alleges that "oil from the core" may be a plasticizer, the only dispute is whether oil from the core can satisfy the claim limitation requiring a plasticizer in the coating. (Anchen's Opening Claim Construction Brief, p. 16; emphasis provided; JEM Decl. Ex. C, at 4.)

As recited in claim 1 of the '341 patent, the plasticizer must be an ingredient in the coating material that is mixed and sprayed onto the tablet cores. (Ex. 1, '341 patent, claim 1.) The term "plasticizer" is an ingredient in the coating preparation, which has a dry weight that may be calculated as a certain percentage of the total dry weight of the coating ingredients dissolved or mixed to prepare the coating composition, which is then applied to the tablet cores. (Ex. 1, '341 patent, claim 1; Anchen's Opening Claim Construction Brief, p. 17.) Anchen therefore concludes that the term "plasticizer" should not be construed to extend to oil used in the core of the tablet as lubricant. (Anchen's Opening Claim Construction Brief, p. 17.)

Biovail, however, avers that "Anchen has stonewalled Biovail in discovery on this issue," and that discovery is likely to explain the function of the various excipients in Anchen's proposed formulation. (Response to Anchen's Opening Claim Construction Brief, p. 17.) For this reason the court finds that it is necessary to construe the term "plasticizer."

Anchen's proposed definition is taken from the Chemical Dictionary and treatises. (DJM Decl., Ex. X. The Chemical Dictionary 822 (10th ed. 1981). As discussed above, reliance on extrinsic evidence is proper under Phillips. The Chemical Dictionary defines a plasticizer as:

[a]n organic compound added to a high polymer both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. The later is held together by secondary valence bonds; the plasticizer replaces some of these with plasticizer-to-polymer bonds, thus added movement of the polymer chain segments.

(Id.)

Anchen additionally asserts that Biovail's proposed definition of plasticizer is based solely on the declaration of Williams. (Anchen's Responsive Claim Construction Brief, p. 6.) Further, Anchen asserts, and the Court agrees, that Williams admits that Biovail's proposed definition is incomplete. Anchen points out in response to the question, "is the softening temperature the only feature of composition that defines it as a plasticizer?" Williams responded, "there would be other attributes of a plasticizer with a polymer that one could also refer to plasticizers as." (DJM Decl., Ex. W, Williams Depo. at 92:1-11.) Williams further admitted that such things would be lowering the glass transition temperature of the polymer. (Id.)

Hence the Court finds that pursuant to Phillips. Anchen's proposed construction embodies the ordinary and customary meaning of the term "plasticizer."

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"Plurality of days"

1. The '623 Patent

GNC's proposed construction of "plurality of days" as "at least 42 days" reads a limitation into Claim 5 from Table 3 of the specification. Table 3 summarizes the results of Example 4, a study that measured the effect of CP on subjects with adult onset diabetes. '623 Patent, col. 9:60-68. GNC argues that because one column in Table 3 has the heading "Cr Supplementation 6 Weeks," this means that claims directed to administering CP to reduce hyperglycemia over a "plurality of days" must be deemed to refer only to a 42-day period.

GNC's argument is baseless. The Court has already noted how the Federal Circuit cautions against limiting claim term construction to examples in the specification. Tex. Instruments, 805 F.2d at 1563. The specification makes clear that the "description[s] of the invention [are] set forth solely to assist in understanding the invention." '623 Patent, col. 15:5-6. GNC

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cites no evidence to indicate that the inventors desired to limit "plurality of days" to the period during which the experiment depicted in Example 4 took place. Nor does GNC point to any evidence that one of ordinary skill in the art would construe the inventors' use of "plurality of days" to limit the envisioned period of CP administration to the period described in Example 4.

The specification does not use the term "plurality of days," and neither the specification nor any other evidentiary source refer to a specific time period for which the inventors envisioned a real-world subject would undergo CP administration. Accordingly, the Court construes the term in accordance with its ordinary meaning to one of skill in the art: "more than one day."

3. The '156 Patent

Again, similar to its proposed construction for the '623 and '624 Patents, GNC argues that "plurality of days," as it appears in Claims 13, 19, and 20 of the '156 Patent, means "42 days." This time, GNC reads in a limitation from Example 3, a study that measured the effects of CP on blood serum lipid amounts. See '156 Patent, cols. 9:14-28, 12:4-6. GNC argues that because the study consisted of "two 42-day periods," see id. at col. 7:22, claims directed to administering CP to reduce blood serum lipids over a "plurality of days" must be deemed to refer only to a 42-day period. GNC cites no evidence to indicate that the inventors desired to limit the term to the period described in Example 3 or that one skilled in the art would construe the term as limited to a 42-day period.

For the reasons articulated in construing the '623 and '624 Patents, the Court construes "plurality of days" as found in the '156 Patent to mean "more than one day."
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The Phrase "Plurality of Pores" Is Construed To Mean A Large Number Of Pores.

The disputed claim terms from claims 1 and 13 includes the phrase "a plurality of pores." Webster's Ninth New Collegiate Dictionary (1991) gives three definitions of "plurality": "the state of being plural"; "a large number or quantity"; or "a number greater than another." (See page 20 of Defendants' Markman Brief."

However, as noted above, the specification of the Fischer patent states (see Column 5, lines 33 - 35) that "Molecular sieves are materials whose atoms are arranged in a crystal lattice in such a way that there are a large number of interconnected uniformly sized pores." From the context of the specification of the Fischer patent, one of ordinary skill in the art, upon reading the claim term "plurality of pores" and the above-noted passage from the specification that there molecular sieve should have a large number of uniformly sized pores, would understand that "plurality" should be interpreted to mean "a large number". Moreover, it is noted that this meaning of the term "plurality of pores", i.e., a large number of pores, is not contrary to the very dictionary definition cited by the Defendants which included the definition "a large number or quantity." (See page 20 of Defendant's Markman Brief).

"Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor." Texas Digital, 308 F.3d 1193, 2002 U.S. App. LEXIS 21567 at *14 (internal citation omitted). "[W]here there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meaning." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). "The objective and contemporaneous record provided by the intrinsic evidence is the most reliable guide to help the court determine which of the possible meanings of the terms in question was intended by the inventor to particularly point out and distinctly claim the invention." Texas Digital, 308 F.3d, 1193, 2002 U.S. App. LEXIS 21567 at *15.

The specification of the Fischer patent expressly describes the molecular sieve as having a large number of uniformly sized pores. Because that meaning of "plurality" is consistent with a normal dictionary definition of the word, the claim phrase "plurality of pores of substantially uniform size" is construed to mean "a large number of pores of substantially uniform size."

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A. "Pluripotent" and "p" (signifying "pluripotent") (Claim 1 of the '755 patent and Claim 2 of the '823 patent)

Claim Term	Amgen's Construction	Teva's Construction
"Human Pluripotent Granulocyte Colony Stimulating Factor" or "hpG-CSF	A species of human polypeptide, designated "hpG-CSF"	"pluripotent", which should be pulled out from the term and has its own meaning -- capable of generating numerous cell types -- is ignored by Amgen's construction

Amgen argues that the term "human pluripotent granulocyte colony stimulating factor" or "hpG-CSF" is a term the inventor, Dr. Souza, coined, which meant to refer to the newlyidentified polypeptides encoded by DNA sequences that he first cloned and characterized from human cells and which was never meant to be parsed into its individual component words. Amgen asserts that the specification confirms that "an hpG-CSF" is merely a name for a sequence-defined polypeptide, and that the name simply refers to the encoded human polypeptide that has the defining 1-174 sequence of amino acids. Amgen's Corrected Claim Construction Brief ("Amgen Br.") at 23; Amgen Resp. at 5.

Amgen contends that Teva improperly uses a dictionary and not the specificationto impart limitations not required by the claim language or supported in the specification or prosecution history. Amgen argues that the term is used in the specification merely to designate the claimed polypeptide as hpG-CSF. Amgen Resp. at 5. Dr. Souza, in order to differentiate his polypeptides from others' previous preparations, 2 "coined a hybrid term" as a naming convention, drawing a conceptual connection between the prior preparations and his claimed species of polypeptide. Id. at 6. Amgen claims that hpG-CSF is just the polypeptide's name, and does not actually indicate that the polypeptide is pluripotent. Amgen points out that hpG-CSF is used in the specification to refer to polypeptides that are variations of the common 174-amino acid core sequence, and, thus, could have one or more of the biological properties of naturally occurring hpG-CSF. Amgen Br. at 24.

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2 The others are Karl Welte and Nicos Nicola, who each contributed to the prior art.

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Amgen also argues that pluripotent polypeptides can "enhance" granulocyte production but cannot "generate" cells in the sense that pluripotent cells can. According to Amgen, pluripotent polypeptides are a different animal and do not "generate"cells. Amgen Resp. at 10-11.

Teva argues that "pluripotent" means "capable of generating numerous cell types," and that Amgen has improperly removed "pluripotent" from the claims. Teva Br. at 17. Teva also contends that Amgen's construction means that the polypeptide does not have to be actually pluripotent, but must only be designated pluripotent. Teva claims this is improper because all of the words of a claim are presumed to limit the claim and give it meaning. Id. at 18. Teva argues that the plain and ordinary meaning of pluripotent is "having the ability to generate numerous cell types." Id. at 19. This means that hpG-CSF causes human bone marrow cells to proliferate and differentiate. Markman Hr'g Tr. at 77, Aug. 13, 2010.

We must give meaning to all of the words in Amgen's claims. Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1557 (Fed. Cir. 1995). "Pluripotent" implies biological activity, of which Amgen now disputes the limiting necessity. But the specification suggests that the product is pluripotent in fact -- not just designated pluripotent: "[t]he present application pertains in particular to mammalian pluripotent colony stimulating factors...." '755 Patentat 1:18-20 (emphasis added); "Novel DNA sequences of the invention include sequences useful in securing expression in procaryotic or eucaryotic host cells of polypeptide products having at least a part of the primary structural conformation and one or more of the biological properties of naturally occurring pluripotent granulocyte colony-stimulating factors." Id. at 3:38-43 (emphasis added).

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The specification states that the claimed polypeptide has one or more of the biological properties of naturally existing hpG-CSF, id. at 2:53-55; 2:59-65, and also describes the pluripotent functionality of the product, id., at 20:12-50. The specification explains that "[i]t is noteworthy that activity is not necessary for any one or more of the products of the invention to have therapeutic utility." Id., 24:66-25:3 (emphasis added). Amgen claims that during prosecution Dr. Souza "made clear" that his claimed hpG-CSF polypeptide was distinguished by its amino acid sequence (and not, presumably, by its biological activity). Amgen Br. at 24. This does not indicate, however, regardless of necessity, whether the polypeptide will be pluripotent. The name and the details of the specification seem to suggestthat it will be actually pluripotent, or, at least, that was the understanding at the time of the patent's filing.

Amgen claimed during oral argument that the Federal Circuit has held that although every term in a claim must have meaning, this does not mean that every word must have a meaning. Markman Hr'g Tr. at 86, Aug. 13, 2010. This is not correct. The Federal Circuit has held that "[w]e must give meaning to all the words in [the patent holder's] claims." Exxon Chemical Patents, 64 F.3d at 1557 (emphasis added)(citing In re Sabatino, 480 F.2d 911, 913, 178 USPQ 357, 358 (CCPA 1973)). The specification indicates that the product in question will be pluripotent. All of the terms of a claim are presumed to limit the claim and give it meaning. Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006)("Allowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration. For that reason,claims are interpreted with an eye toward giving effect to all terms in the claim."). Because Dr. Souza understood the product to be "pluripotent" at the time the patent was filed, it is improper for Amgen to try to remove the requirement that the polypeptide be pluripotent. In addition, during prosecution, Amgen included the following amendment: "Please note that the title of the invention has been changed to make it more specific to the claimed invention: "HUMAN PLURIPOTENT GRANULOCYTE COLONY-STIMULATING FACTOR," suggesting that the name reflects the characteristics of the product. Amgen Claim Constr. Br., Ex. 18 at AMT 00002464 ('755 Prosecution History, 12/4/95 Notice of Allowability, Paper No. 31).

Amgen included "pluripotent" as a limitation in its claim, and we cannot now read that limitation out of it. Exxon Chemical Patents, 64 F.3d at 1557. Thus, Amgen "must live with the language it chose." Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1583 (Fed. Cir. 1996). We will adopt Teva's construction of this term.
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3. "polar hydrophilic salts fraction"

Plaintiff's proposed construction of "polar hydrophilic salts fraction" is: "relatively water soluble fatty alcohols that result from saponification of jojoba oil." Defendant's proposed construction is: "water soluble alkali salts that result from saponification of jojoba oil."

This dispute, like the previous dispute, turns on the inclusion of the word "relatively." For the same reason discussed in the dispute above, Plaintiff's version, which does not require absolute water solubility, will be adopted.
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poly-aluminum hydroxychloride

The parties and the Court agree that the term should be construed as "also known as aluminum chlorohydrate; an aluminum polymer formed by reacting aluminum chloride [AlCl[3]] with a base, resulting in a product that may be expressed chemically as Al[n](OH)mCl([3n-m]), normally wherein the basicity is about greater than or equal to 50%."
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poly-aluminum siloxane sulfate

The Court and the parties agree that the term should be construed as "also known as polyaluminum silicate sulfate (PASS); an aluminum polymer compromising a silicate moiety and a sulfate moiety."
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polyaluminum chloride

The Court and the parties agree that the term should be construed as "an aluminum polymer formed by reacting aluminum chloride [AlCl[3]] with a base, resulting in a product that may be expressed chemically as Al[n](OH)[m]Cl([3n-m]), normally wherein the basicity is about less than or equal to 50%."
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6. "Polycationic component"

Caliper proposes that the term "polycationic component" be construed as: "a compound that has multiple positive charges, is of sufficient size to cause a detectable, measurable change in the phosphorylated product, and binds to the phosphorylated product in a non-specific, charge dependent manner. The polycationic component may include, inter alia, large molecules having associated therewith multivalent metal ions that have a relatively high affinity for oxygen, nitrogen and sulfur groups and as a result impart a significant binding affinity to the large molecule towards, for example, phosphate groups in nucleic acids or phosphorylated substrates."

MDC proposes: "a polyionic polymer that has a net positive charge, and that binds to a phosphorylated product in a non-specific and charge dependent manner, meaning that the binding depends only on the fact that the polycationic component has a net charge that is opposite to that of the phosphorylated product, and does not depend on their structures. Moreover, the polycationic component must be large enough to change the fluorescence polarization of the phosphorylated product when it binds to it."

The Court has already construed the meaning of the term polyionic polymer. The term "polycationic component" is largely similar, with some variance. The term "polycationic " indicates that the charges are positive. The term "component" indicates that the substance may be different from a polymer. The central disputes between the parties focus on (1) whether the positive charge must be a net, or overall positive charge of the component, or whether there must simply be multiple positive charges; and (2) whether the polycationic component must be a polymer.

a. "Polycationic"

The patent describes the interaction of the polycationic component with the tested mixtures, and explains that in the case of nucleic acid assays, because nucleic acid analogs are neutral, or in some cases positively charged, they will not associate with the polycationic component of the assay, which are defined as "positively charged polyions." ('141 Patent at 11:65-12:3.) Thus, because the patent describes the whole polyion as positively charged, the ordinary meaning of the term "polycationic " as described in the patent language indicates that the overall or net charge is positive

b. "Component"

The ordinary language of the patent demonstrates that the inventor intended to indicate a possible distinction in terms by selecting the word "component" instead of polymer. In addition, MDC's argument that the only listed examples of a polycationic component are in fact polymers is not persuasive. Limitations from the specification (such as the preferred

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embodiment) cannot be read into the claims, absent an express intention to do so. Teleflex, 299 F.3d at 1326 ("The claims must be read in view of the specification, but limitations from the specification are not to be read into the claims.") (citations omitted). Therefore, the Court adopts Caliper's construction of the term "component" to denote merely a compound and not a polyionic polymer.

Accordingly, the Court adopts the construction of the term "polycationic component" to mean: a compound that has a net positive charge and is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner. Again, the polycationic component may include, among other things, a large molecule, e.g., a protein, that has associated therewith multivalent metal cations selected from, e.g., Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+>.
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As a preliminary matter, Marine Polymer contends that the claim construction issue raised by HemCon cannot be addressed because it requires construing a term used in the court's previous claim construction rather than a disputed term in an asserted patent claim. See E-Pass Techs., Inc. v. 3Com Corp., 473 F.3d 1213, 1220 (Fed. Cir. 2007). Specifically, Marine Polymer argues that HemCon is seeking interpretation of the term "high purity," used in the previous claim construction. Although parts of HemCon's brief improperly suggests an interpretation of the term "high purity," that is not the term which is being construed. Instead, the terms poly- [beta] -1-->4-acetylglucosamine and poly- [beta] -1-->4-glucosamine, as used in the asserted claims of the '245 patent, are construed to determine whether the patent claims include a protein-free limitation.

A. Claims

The terms poly- [beta] -1-->4-acetylglucosamine and poly- [beta] -1-->4-glucosamine are referred to, collectively, as p-GlcNAc. Neither the asserted claims nor any of the other claims of the '245 patent include an express limitation that the p-GlcNAc claimed is protein free. The claims do not define p-GlcNAc with respect to protein. Each claim addresses either biocompatible poly- [beta] -1-->4-N-acetylglucosamine or biocompatible poly- [beta] -1-->4-glucosamine with differing numbers of monosaccharides, molecular weights, amounts of deacetylization, or elution test scores. Therefore, the claims alone do not resolve the claim construction issue as to whether p-GlcNAc claimed in the '245 patent is protein free.

B. Specification

To determine how one skilled in the art would interpret a particular claim term, the court considers the disputed term in light of the entire patent, including descriptions of the invention provided in the specification. Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1373-74 (Fed. Cir. 2008). Limitations, however, cannot be taken from statements in the specification and imported into the claims. Id. at 1374. "[T]he distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." Phillips, 415 F.3d at 1323.

The Federal Circuit advises courts to remain focused "on understanding how a person of ordinary skill in the art would understand the claim terms." Id. "That balance turns on how the specification characterizes the claimed invention." Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1370 (Fed. Cir. 2003). The court must decide "whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment." Id.; accord Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1324 (Fed. Cir. 2008).

Patent claims are not limited to specific or preferred embodiments that are described in the specification, even if the specification describes only one embodiment. Phillips, 415 F.3d at 1323. On the other hand, "when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication.'" Bell Atl. Network Servs., Inc. v. Covad Communc'ns Group, Inc., 262 F.3d 1258, 1271 (Fed. Cir. 2001); see also Computer Docking, 519 F.3d at 1374 ("repeated and definitive remarks in the written description could restrict a claim limitation to a particular structure"); Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1366-68 (Fed. Cir. 2007). Similarly, when a family of patents shares a common specification that "repeatedly and consistently describes . . . the claimed inventions" using a particular limitation or describes the "overall inventions" in a way that leads to the "inescapable

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conclusion" that all of the patent claims share a limitation, that limitation is read into the claims by implication. Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1347-48 (Fed. Cir. 2004) (citing SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1342 (Fed. Cir. 2001)). Using a phrase such as "the present invention" in a shared specification may describe the invention as a whole, thereby limiting the meaning of the claim terms to that description, unless that conclusion is contrary to the context of the entire specification or the prosecution history. Netcraft Corp. v. eBay, Inc., 549 F.3d 1394, 1398 (Fed. Cir. 2008).

HemCon asserts that the '245 patent specification demonstrates that the p-GlcNAc of the invention is free of protein, making that limitation part of each of the claims. Marine Polymer disputes HemCon's interpretation of p-GlcNAc based on the specification. Noting that the '245 patent is one in a family of related patents, which share the same specification, Marine Polymer argues that the "free of protein" limitation included in parts of the specification applies to some but not all of the patents in the family. 4 Marine Polymer contends that the specification does not require the protein limitation in the '245 patent claims and warns against importing limitations from the specification into the claims.

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4 As the court noted in the prior claim construction order, the shared specification is an impediment to a clear understanding of the scope of each patent.

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The Abstract states: "The p-GlcNAc of the invention is a polymer of high molecular weight whose constituent monosaccharide sugars are attached in [beta] -1-->4 conformation, and which is free of proteins, and substantially free of single amino acids, and other organic and inorganic compounds." (Emphasis added.) The same definition is repeated in the Introduction, "[t]he p-GlcNAc of the invention is a polymer of high molecular weight whose constituent monosaccharide sugars are attached in a [beta] -1-->4 conformation, and which is free of proteins, and substantially free of single amino acids, and other organic and inorganic contaminants." Col. 2, ll. 65, Col. 3. ll. 1-5 (emphasis added). The "Summary of the Invention" section of the '245 specification also states that "[t]he p-GlcNAc of the invention is a polymer of high molecular weight whose constituent monosaccharides are attached in a [beta] -1-->4 conformation, and which is free of proteins, substantially free of other organic contaminants, and substantially free of inorganic contaminants." Col. 4, ll. 11-15 (emphasis added).

In the Detailed Description of the Invention, p-GlcNAc is addressed in more detail. There, the p-GlcNac of the invention is described as "a polymer of high molecular weight" with a corresponding number of "N-acetylglucosamine monosaccharides attached in a [beta] -1-->4 configuration" and with a preferred number of N-acetylglucosamine monosaccharides. Col. 9, ll. 16-25. No mention is made of protein in the first paragraph of the Detailed Description.

The Detailed Description continues in the second paragraph to explain that the p-GlCNAc of the invention has very low variability and very high purity, which are demonstrated "by chemical and physical criteria." The chemical and physical criteria referred to are "chemical composition and non-polysaccharide contaminants." Col. 9, ll. 28-31. Chemical composition and contaminant data from two different purification methods ("Mechanical Force Method" and "Chemical/Biological Method") are shown in Table I. The Detailed Description explains that "as is also shown in Table I, the p-GlcNAc produced is free of detectable protein contaminants, is substantially free of other organic contaminants such as free amino acids, and is substantially free of inorganic contaminants such as ash and metal ions . . . ." Col. 9, ll. 39-44 (emphasis added).

That section further explains that "preferably, the p-GlcNAc of the invention contains a profile as exemplified in the Experimental Data on p-GlCNAc mats in Table I." Col. 9, ll. 52-54. The part of Table I, labeled "Experimental Data on p-GlcNAc Mats," shows results for the two different production methods, the Mechanical Force Method and the Chemical/Biological Method. Under both methods, the average values for protein are "0.00." Although the specification does not define biocompatibility to require protein-free p-GlcNAc, the p-GlcNAc used in the biocompatibility tests was produced by the Mechanical Force Method, which produces only protein-free p-GlcNAc. Col. 42-43; Col. 9 - 10, Table I.

"It is true that [the court] should not import limitations from the specification into the claims." ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1375 (Fed. Cir. 2009). On the other hand, however, the specification shows what a person of

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ordinary skill in the art would understand the disputed term to mean in the context of the patent. Id. The specification describes the scope of the patent claims. Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1367 (Fed. Cir. 2009). When the specification indicates that a term is limited in a particular manner, the ordinary meaning of the term can be inferred to include that limitation. ICU Med., 558 F.3d at 1375. It is improper to adopt an expansive construction of a disputed term, which goes beyond the ordinary meaning of the term as described in the specification. Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.. 554 F.3d 1010, 1019 (Fed. Cir. 2009).

Here, the specification repeatedly refers to p-GlcNAc that is protein free. Nothing in the specification indicates that the claimed p-GlcNAc may include protein. On the other hand, while the specification includes general statements that the p-GlcNAc of the invention is free of protein, the section devoted to a detailed description of the p-GlcNAc claimed by the patent describes it as having very low variability and very high purity, without specifically limiting the amount of protein. In that section, the preferred embodiment is described as protein-free.

"Th[e] description of a preferred embodiment, in the absence of a clear intention to limit claim scope, is an insufficient basis on which to narrow the claims." Decisioning.com, Inc. v. Federated Dept. Stores, Inc., 527 F.3d 1300, 1314 (Fed. Cir. 2008). "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted).

The p-GlcNAc that is produced by the two purification methods, the results of which are shown in Table I, are protein-free. Composition claims and method claims, however, are directed to different inventions. See Pfizer, Inc. v. Teva Pharms., 518 F.3d 1353, 1357 (Fed. Cir. 2008). Because the '245 patent, with composition claims, shares the specification with patents for method claims, the description of the methods cannot be read to limit the composition claims.

The claims and specification do not resolve the meaning of p-GlcNAc with respect to a protein limitation. The protein-free limitation, which is at least a preferred embodiment, can be imported into the claims of the '245 patent only if the rest of the intrinsic evidence show a clear intent to limit the claims to protein-free p-GlcNAc. See Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1290 (Fed. Cir. 2009).

C. Prosecution History

The prosecution history of a patent also informs claim construction by showing the inventor's understanding of the invention and whether claims were limited in scope during patent prosecution. Phillips, 415 F.3d at 1317. "A disclaimer must be clear and unmistakable, and unclear prosecution history cannot be used to limit claims." Cordis Corp. v. Boston Sci. Corp., 561 F.3d 1319, 1329 (Fed. Cir. 2009). "When the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue in the patent being construed, those statements in the familial application are relevant in construing the claims at issue." Ormco Corp. v. Align Tech., Inc., 498 F.3d 1307, 1314 (Fed. Cir. 2007); see also Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990).

The family of fifteen related patents, of which the '245 patent is a part, began with Application No. 08/160,569, filed on December 1, 1993. 5 The Abstract of the Disclosure of the '569 application states, in part, that "[t]he present invention relates to a purified, easily produced biocompatible [p-GlcNAc] polysaccharide species. The p-GlcNAc of the invention is a polymer of high molecular weight whose constituent monosaccharide sugars are attached in a [beta] -1-->4 conformation, and which is free of proteins, and substantially free of amino acids, and other organic and inorganic contaminants." Pl. Br. (doc. no. 48) at 3. The '569 application explains that broad nature of the invention which includes "derivatives and reformulations of p-GlcNAc," and methods for purification, derivatization and reformulation, and uses of p-GlcNAc. Id.

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5 Some of the related patents include an explicit protein-free limitation, while others, like the '245 patent, do not.

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In support of the '569 application, the inventors submitted the declarations of David J. Cole, an assistant professor of

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surgery at the Medical University of South Carolina; George C. Ruben, a research professor of biology at Dartmouth College; and Sergio Finkielstein, one of the inventors. Each declaration addresses the chitin material produced by a method invented by J. McLachlan in 1991, along with others, and distinguishes prior art chitin from the invention that was the subject of the '569 application. The declarations used to support the '569 application were resubmitted later in support of patent applications for the progeny of the '569 application. Some of those patents have claims for protein-free p-GlcNAc, while others, including the '245 patent, do not have a protein-free limitation.

The declarants noted, as a distinguishing factor, the lack of contaminants in the p-GlcNAc of the '569 application and, in particular, that the p-GlcNAc of the invention was protein free. Dr. Cole stated that "the McLachlan material contains extensive ash and protein contamination . . . [which] could pose a possible safety threat . . ." Doc. no. 134, Ex. 4. He also said, "The '569 application [p-GlcNAc] material, on the other hand, represents an extremely promising candidate for use in biomedical applications . . . . the material shows virtually no contamination. Specifically, the '569 application contains no protein and very little ash." Id. Similarly, Dr. Ruben "expressed [his] belief that the data in the ['569] application establishes, for the first time, a method which successfully yields a protein-free, fully acetylated [p-GlcNAc] polymer." Doc. no. 129, Ex. 11. Dr. Ruben distinguished the McLachlan materials based on protein contamination.

In an amendment to the '569 patent, dated May 1, 1996, responding to a patent office action, the applicants described p-GlcNAc as protein free. In their remarks, the applicants stated: "Importantly, the protein-free, fully acetylated [p-GlcNAc] compositions described and claimed in the instant application differ not merely in degree but in kind from the chitan of the cited art." Doc. no. 129, Ex.8. "In sum, the cited art does not suggest the claim protein-free [p-GlcNAc] of the invention . . . ." Id.

HemCon argues that the prosecution history shows that the '569 application distinguished its invention based, in part, on claiming p-GlcNAc that was protein free. Because the progeny of the '569 application used the same distinguishing factors, HemCon contends that all of the p-GlcNAC claimed by the family of patents includes the protein-free limitation. Marine Polymer asserts that only the patents with a protein-free limitation are subject to the prosecution history disclaimer because the patents without the limitation do not include the same terms and, therefore, the disclaimer does not apply.

The prosecution history of a related patent can be relevant to claim construction if the history addresses a shared claim term. Adv. Cardiovascular Sys. v. Medtronic, Inc., 265 F.3d 1294, 1305 (Fed. Cir. 2001). "[T]he same claim term in the same patent or related patents carries the same construed meaning." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003). Statements made during the prosecution of related patents, about shared claim terms, may show how the inventor understood the invention. Ventana Med. Sys. v. Biogenex Labs., 473 F.3d 1173, 1184 (Fed. Cir. 2006).

Marine Polymer contends that the prosecution history cited by HemCon addresses "protein-free p-GlcNAc," claimed in some of the related patents, not the p-GlcNAc claimed in the '245 patent that lacks the "protein free" limitation. Relying on Ventana and Adv. Cardiovascular, Marine Polymer asserts that HemCon is attempting to use prosecution histories from related patents to construe different claim terms in the '245 patent and that the present dispute, as in Adv. Cardiovascular, involves the absence of a claim term, the protein-free limitation. HemCon responds that the inventors relied on the Cole Declaration, which limited the p-GlcNAc of the invention claimed in the patent family to protein-free p-GlcNAc, for both patents with an explicit protein-free limitation and patents without that limitation.

Marine Polymer acknowledges that the inventors relied on the Cole Declaration in support of applications for related patents that do not include an explicit protein-free limitation. It argues, however, that in those cases, the Declaration emphasized the importance of safety for biomedical applications, which includes both purity and batch reproducibiilty that were unique to the p-GlcNAc of those inventions. Marine Polymer also points out that the patent examiners did not mention protein content in allowing the related patents and that it made no explicit disclaimer of p-GlcNAc with protein.

D. Limitation in Related Patents

Marine Polymer further argues that because claims in other related patents include a protein-free limitation, the p-GlcNAc of the claims in the '245 patent should not be construed to include that limitation. 6 A presumption exists that, "'unless otherwise compelled, [] the same claim term in the same patent or related patents carries the same construed meaning.'" Z4 Techs., Inc. v. Microsoft Corp., 507 F.3d 1340, 1348 (Fed. Cir. 2007) (quoting Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1334 (Fed. Cir. 2003) (emphasis added)); NTP, Inc. v. Res. in Motion, Ltd., 418 F.3d 1282, 1293 (Fed. Cir. 2005)

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("Because [the plaintiff's] patents all derive from the same parent application and share many common terms, we must interpret the claims consistently across the asserted patents."). All terms in a claim are presumed to have meaning. Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1120 (Fed. Cir. 2004). A construction that avoids rendering a claim term meaningless or superfluous is preferred. See Mangosoft, Inc. v. Oracle Corp., 525 F.3d 1327, 1330-31 (Fed. Cir. 2008). On the other hand, claim construction tools provide guidance rather than rigid requirements. ICU Med., 558 F.3d at 1376; Netcraft Corp. v. eBay, Inc., 549 F.3d 1394, 1400 n.1 (Fed. Cir. 2008).

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6 Marine Polymer relies on a theory of claim differentiation, which, strictly speaking, does not apply in the context of claims in different related patents as opposed to independent and dependent claims in the same patent. See Regents of Univ. of Cal. v. Dakocytomation Cal., Inc., 517 F.3d 1364, 1375 (Fed. Cir. 2008) (doctrine of claim differentiation creates a presumption that a limitation explicit only in a dependent claim is not in the independent claim from which the claim depends); Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1251 n.3 (Fed. Cir. 2008) (same).

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Marine Polymer provides excerpts from twelve of the fourteen other patents in the family of patents related to the '245 patent. Of those, eight patents, all dated between 1997 and 2000, include a protein-free limitation. The five more recent patents, including the '245 patent, do not include a protein-free limitation. Marine Polymer argues that if p-GlcNAc were construed to mean protein-free p-GlcNAc, that limitation, which is explicit in the earlier patents, would be rendered superfluous.

E. Claim Construction

Given the rule that limitations are not to be imported from a patent specification into the claims and indications that the "protein free" limitation was intended for only some, but not all, of the related patents, it is not appropriate to add a protein-free limitation to the claims of the '245 patent. Therefore, the claim construction remains as held in the claim construction order issued on May 6, 2008.

Conclusion

For the foregoing reasons, the terms poly- [beta] -1-->4-acetylglucosamine and poly- [beta] -1-->4-glucosamine, as used in the asserted claims of the '245 patent, do not include a limitation requiring them to be free of protein.
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2. "Polyionic polymer"

Caliper proposes that the term "polyionic polymer" be construed as: "a polymer that has multiple electrical charges, is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a reagent or product, and binds to a reagent or product in a non-specific, charge-dependent manner." Caliper proposes that a "polymer is a relatively high molecular weight substance comprising relatively lower molecular weight repeating units." Caliper further contends that the "polyionic polymer may include, inter alia, large molecules having associated therewith multivalent metal ions that have a relatively high affinity for oxygen, nitrogen and sulfur groups and as a result impart a significant binding affinity to the large molecule towards, for example, phosphate groups in nucleic acids or phosphorylated substrates."

MDC proposes: "a polymer, meaning that is a large molecule made up of smaller repeating groups that are connected to each other (like links in a chain, for example). A polymer is polyionic when it has repeating groups that are ionic -- meaning that they have either positive or negative charges."

Both parties agree that in the context of the '774 patent, the term "polyionic compound" refers to a compound that binds to a smaller molecule in a non-specific, charge-dependent manner. However, Caliper contends that non-specific, charge-dependent should be construed to mean that the association does not require the presence of a specific recognition site and

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that the binding is at least partially driven by charge. MDC again contends that non-specific, charge-dependent means that the binding "depends on the fact that the polyionic polymer has a net charge that is opposite to that of the smaller molecule, and does not depend on their structures." Both parties agree that the polyionic polymer must be of sufficient size (large enough) to change the fluorescence polarization when it binds with (or associates with) a smaller molecule. 2

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2 Both parties agree that in the context of the '774 patent, the terms "polyionic polymer" and "polyion" are used interchangeably and mean the same thing.

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a. "Polymer"

Caliper proposes that a "polymer is a relatively high molecular weight substance comprising relatively lower molecular weight repeating units." MDC proposes: "a large molecule made up of smaller repeating groups that are connected to each other (like links in a chain, for example)." Finding no significant difference between the two proposals, the Court adopts Caliper's proposal and finds that a polymer is a relatively high molecular weight substance comprising relatively lower molecular weight repeating units.

b. "Polyionic"

Caliper proposes that polyionic means that the polymer has "multiple electrical charges." MDC proposes that "a polymer is polyionic when it has repeating groups that are ionic -- meaning that they have either positive or negative charges." MDC clarifies that its construction does not require that each repeating unit in the polymer be ionic, merely that "there are some repeating units in the polymer that are ionic." (MDC Opp. Br. at 9.) MDC only contends that some of the repeating groups have to be charged. (Markman Hearing 66:10-16.) The parties' central dispute is whether the polymer is itself charged, or polyionic, or whether "the polyionic polymer may be comprised of an uncharged polymeric material that becomes 'polyionic' due to the association of charged metal ions, which 'as a result' allows the large molecule to bind to charged compounds, such as phosphorylated substrates." (Caliper Br. at 12.)

The Court adopts the construction of the term "polyionic polymer" to mean: a relatively high molecular weight substance comprising relatively lower molecular weight repeating units that is of sufficient size to cause a change in the level of fluorescence polarization upon its association with a smaller molecule when it binds to it in a non-specific, charge-dependent manner.

The Court finds that the parties' two proposals are not inherently contradictory. Although on its face, the construction of the term "polyionic " does not necessarily require a definitive description of the types of compounds that qualify as polyionic polymers, the Court will address the parties' concerns regarding the specific potential embodiments. Caliper contends that the patent makes clear that the "polyionic polymer may be comprised of an uncharged polymeric material that becomes 'polyionic' due to the association of charged metal ions, which 'as a result' allows the large molecule to bind to charged compounds, such as phosphorylated substrates." (Caliper Br. at 12.) The '774 patent clearly indicates that the polyionic component "may alternatively comprise a large molecule, e.g., a protein or the like, that has associated therewith multivalent metal cations selected from, e.g., Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+> . . . . Specifically, these metal ions have relatively high affinity for oxygen, nitrogen and sulfur groups. As a result, they impart a significant binding affinity to a large molecule (as a polyion) towards, e.g., phosphate groups in nucleic acids or phosphorylated substrates and the like." ('774 Patent at 13:33-43.) This description of a preferred embodiment is explicitly contemplated by the patent. Therefore, the Court agrees with Caliper that the polyionic polymer may include, among other things, a large molecule, e.g., a protein, that has associated therewith multivalent metal cations selected from, e.g., Fe<3+>, Ca<2+>, Ni<2+>, and Zn<2+>.
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3. "a rubbery polymer comprising a blend of … and polyisobutylene"

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Carlisle argues that the term "polyisobutylene" should be construed to mean "high molecular weight polyisobutylene." Adco contends that the ordinary meaning of the claim language should apply, or that the phrase should be construed to mean "a rubbery polymer, wherein the blend is made up of (but is not limited to) the various constituent ingredients listed in the claim, and including either high molecular weight solid polyisobutylene, low molecular weight liquid polyisobutylene, or both."

The patent specification expressly discloses that the polyisobutylene component of the claimed invention may comprise low molecular weight polyisobutylene compounds. Col. 5, lines 1-9. Thus, the court finds that the claim term should not be restricted to high molecular weight polyisobutylene, as advocated by Carlisle. The court finds that the claim term is sufficiently clear that no additional construction is necessary.
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polymer

The Court and the parties agree that the term should be construed as "a molecule composed of repeating units."
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2. Polymeric Material

Claim 1 also includes "an elongate layer of flexible polymeric material." Barton Nelson submits that parchment paper is "polymeric material." 3M conversely argues that "polymeric material" specifically excludes paper. The language of the patent and the prosecution history support 3M's assertion that paper is not "polymeric material."

The patent itself explains that the '825 patent is an invention that was an improvement over, and different from, 3M's previous paper Post-It notes. Particularly, the prior art states:

> [3M paper Post-It notes] are not as suitable for marking portions of substrates as may be desired, however, because relatively small percentages of such sheets are coated with the repositionable pressure sensitive adhesive so that they are sometimes dislodged during handling; because the sheets are made of paper and easily become damaged; and because the sheets are opaque so that they obscure more of the document they are marking than may be desired.

(Truitt Aff. Ex. 2, '825 patent, col. 1, ll. 21-29.) Barton Nelson attempts to assert that only the combination of these factors, rather than each one individually, render the Post-It notes unsuitable for purposes of the '825 patent. The Court is unpersuaded. 3M distinguishes the '825 patent from the prior art and thus indicates that the '825 patent does not include paper.

The prosecution history also supports this construction. In the 1989 Amendment, 3M again distinguished the '825 patent from a similar British patent:

> Nor does [Great Britain Patent 345,066 ("GB '066")] teach or make obvious the structure of the present invention as described above and claimed in claim 1. GB '066 describes an elongate strip of "paper or fabric" or "thin metal or paper or fabric coated with metal foil" . . . . There is no teaching that such strips be of flexible polymeric material, nor that their uncoated end portions be visually distinctive, nor that their adhesive coated second end portion be generally transparent when adhered to a substrate. Thus the strip described in GB '066, which when made of paper is similar in structure to the 3M Post-It notes, does not provide the structure or advantages of the present invention as described above and claimed in claim 1, and does not make that structure obvious.

(Liro Decl. Ex. I at 4.) This further supports that the '825 patent specifically excludes paper.

Barton Nelson relies heavily on the dictionary definition of polymer. "Polymer" is defined as "a chemical compound or

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mixture of compounds formed by polymerization and consisting essentially of repeating structural units." Webster's New Collegiate Dictionary 912 (9th ed. 1984). Barton Nelson contends that cellulose, a primary component of paper, is a polymer, and therefore paper is "polymeric material" under the '825 patent. If the Court were persuaded by Barton Nelson's argument, then the '825 patent would encompass nearly all materials because almost everything is composed of polymers. Although paper may be composed of polymers, paper is not by itself a polymer. (Lucia Decl. P8 ("paper was comprised of approximately 87% natural polymeric material with 81% of this polymeric material being cellulose and the remainder of the polymeric material comprising low weight hemi-celluloses, which are low-molecular-weight natural polymeric materials")). The evidence submitted by Barton Nelson indicates that "polymeric material" is not interpreted as Barton Nelson submits by those arguably "skilled in the art." (See id.) Moreover, this construction is contrary to the plain language and history of the '825 patent. Therefore, the Court construes "polymeric material" to exclude paper.
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The parties dispute the proper interpretation of the phrase "polymerization catalyst species," which is contained in all claims of the '761 patent. Defendants contend that this phrase refers to metallocene catalyst compositions, the first component of which is a bis-cyclopentadienyl ("bis-Cp") derivative of a Group IV-B metal compound. Exxon asserts that the claims are not so limited, and that the phrase "polymerization catalyst species" should be construed to extend also to mono-Cp metallocenes, such as those used by defendants.

Because the claim language itself contains no further explication of the "polymerization catalyst species" to which the claimed method applies, the Court looks to the specification of the patent for guidance. Markman, 52 F.3d 967, 979-80. The Court finds that, when construed in light of the specification, the claims of the '761 patent are confined to polymerization catalyst species consisting of bis-Cp metallocenes. 4

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4 The specification of the '761 patent contains repeated and detailed descriptions of the "polymerization catalyst species" referenced in the patent claims. All of these descriptions state that the species is comprised of a bis-Cp metallocene.

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In light of the Court's finding of no infringement and the Court's determination that the claims of the '761 patent are confined to polymerization catalyst species, consisting of Bis-Cp metallocenes, the remaining independent grounds of noninfringement need not be addressed.
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(1) A nonnative polynucleotide construct comprising . . . The Court construes the term "polynucleotide construct" to mean any string of nucleotides, including DNA, as discussed in Claim 34 of the '931 Patent. "Nonnative" means something not originating in the cell, but instead introduced from an outside source.
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A. Claims 1, 17, 18: "Polynucleotide Sequence"

Plaintiffs would construe "polynucleotide sequence" in these claims by the dictionary definition, as simply "a sequence of two or more nucleotides." Such a broad construction would mean that the patent would cover methods where the probe is attached to a fixed support and the labelled analyte is washed over it ("reverse dot" or "microarray" techniques, see Kricka Report, Ex. 10 at 19-20, 29).

Defendants "certainly [do] not dispute that the dictionary definition of a 'polynucleotide' is 'two or more nucleotides'," but

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argue that this simplistic definition does not address the dispute between the parties, which is whether "said polynucleotide" refers to any polynucleotide or only the analyte, as opposed to the probe. See Def. Opening Br. at 35. They would construe the term in Claims 1, 17, and 18 as "the polynucleotide sequence to be detected (i.e., the analyte)." Defendants point out that the specification explains that it applies to "analytes to be detected by the detection processes of this invention..." '373 Pat. 5:22-23. The specification further describes "the hybridization of the probe to the single-stranded analyte," which has been affixed to the solid support. Id. at 5:67-68.

The plain language in Claim 1 compels the conclusion that the "polynucleotide sequence" refers to the analyte. The claim is a "method for detecting a polynucleotide sequence which comprises . . . fixing said polynucleotide" -- which obviously refers back to the polynucleotide sequence to be detected -- on a solid support and then hybridizing it with a "probe." Because the second step of the method requires hybridizing a probe with "said polynucleotide," that "said polynucleotide" must be the analyte to be "detected."

The Background of the Invention section defines "analyte" as a "substance or substances . . . whose presence is to be detected and, if desired, quantitated. . . . Among the common analytes are nucleic acids (DNA and RNA) or segments thereof, oligonucleotides, either single- or double-stranded, viruses, bacteria, cells in culture, and the like." '373 Pat. 1:27-36. "Probe" is defined as a "labelled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide sequence of a particular analyte and which hybridizes to said analyte sequence." Id. at 1:42-45. Thus, the definitions support the construction that the substance "whose presence is to be detected" is the analyte, i.e., the unknown substance. Moreover, the probe is defined as the sequence that hybridizes with the analyte, and therefore when Claim 1 states that "said polynucleotide sequence" is hybridized with the probe, "said polynucleotide sequence" must refer to the analyte.

Accordingly, "a polynucleotide sequence" and "said polynucleotide sequence" are construed to refer to the polynucleotide sequence to be detected, meaning the analyte.
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6. polynucleotides is construed to mean a polymer of nucleotides of length two or more.

Affymetrix contends that "polynucleotides" means a polymer of nucleotides of length two or more.

Incyte contends that "polynucleotides" means a strand of DNA longer than an oligonucleotide, and often naturally occurring or cloned from naturally occurring DNA.

Hyseq contends that "polynucleotides" means a polymer of nucleotides that is longer than twelve nucleotides in length.

The Court adopts the plain and ordinary meaning of the term. As with its construction of "oligonucleotides," the Court rejects the attempts by Incyte and Hyseq to import limitations into the meaning of the term without citing any portion of the specification or prosecution history to indicate that Affymetrix intended to use "polynucleotide" in a way other than the conventional meaning. For the reasons previously discussed, the Court will not limit the claim term based solely on putative non-enablement.
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B. The Isobutane Patents

With respect to the isobutane patents, AVI seeks the construction of the claim terms "polyolefin foam" in the '933 patent, "polymeric composition" in the '361 patent and "olefin polymer foam" in the '027 patent. As these terms are not meaningfully different for purposes of construction, I will follow the lead of the parties and refer to them collectively as "foam."

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According to AVI, foam should be construed to require foam that is "dimensionally stable." As support, AVI relies heavily on the prosecution history, in which it asserts that DOW narrowed its claims before the Patent Trade office ("PTO") to foam having dimensional stability to distinguish its claims from prior art. AVI asserts that Dow's test data submitted to the PTO emphasized this distinction and that without it, Dow's isobutane patents add nothing to the prior art and thus would be unpatentable. AVI also relies on the specification sections of the patents, which it asserts repeatedly emphasize the criticality of dimensional stability. Further, it cites to the claim language itself, which requires a stability control agent as a component of the claimed foam composition. This is significant, according to AVI, because the purpose of the stability control agent is to render the foam stable.

AVI's construction is flawed. The term "dimensional stability" appears in only four dependent claims of the '933 patent and in the preamble of the '027 patent; it does not appear in any of the claim terms that AVI now seeks to add it too. Simply put, while AVI seemingly requests the construction of the term foam, it is not attempting to define this commonly understood term. Rather, it seeks to interject into foam the requirement of dimensional stability. Essentially, AVI endeavors to add words--dimensionally stable--to all of the isobutane patents claims that use the claim terms foam but which do not contain this requirement. Thus properly understood, AVI is not attempting to construe existing claim language; it is attempting to limit the scope of the invention itself by adding a requirement not found there.

AVI's construction is contrary to existing precedent. As explained in Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 395-96 (Ct. Cl. 1967):

The claims of the patent provide the concise formal definition of the invention. They are the numbered paragraphs which particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention. It is to these wordings that one must look to determine whether there has been infringement. Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth. No matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them.

See also E.I. Du Pont de Nemours & Co. v. Philipps Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir.) (citing Autogiro), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988); McCarty v. Lehigh Valley R. Co., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240 (1895) ("We know of no principle of law which would authorize us to read into a claim an element which is not present . . . ."). Here, the plain language of the claims does not require dimensional stability. As such, to read this requirement into them would be error. See Du Pont, 849 F.2d at 1433 (discussed below); American Standard Inc. v. Pfizer Inc., 722 F. Supp. 86, 93 (D. Del. 1989) (refusing to read requirement of "bone growth" into patent); Proctor & Gamble Co. v. Nabisco Brands, Inc., 711 F. Supp. 759, 764-65 (D. Del. 1989).

Furthermore, the examiner in charge of prosecution of the isobutane patents specifically treated the term "dimensionally stable" numerous times and allowed claims both with and without this language. If the examiner wanted the requirement of dimensionally stable in the claims, he presumably would have ensured that it appeared there. AVI thus, in effect, asks the Court to hold the examiner incompetent to understand this distinction among Dow's claims. Additionally, it seeks to have this Court substitute its judgment for the PTO by having the claims limited by the language dimensionally stable. This is not appropriate. See Intervet, 887 F.2d at 1054 ("The presumption of validity under 35 U.S.C. § 282 carries with it a presumption the examiner did his duty and knew what claims he was allowing. In any event, the claims as allowed are what we have to deal with and it is not for the courts to say that they contain limitations which are not in them.") (citations omitted).

AVI's construction also is at odds with the doctrine of claim differentiation, which presumes that there is a difference in scope among the claims of a patent. See, e.g., United States v. Telectronics, Inc., 857 F.2d 778, 783-84 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046, 104 L. Ed. 2d 423, 109 S. Ct. 1954 (1989). Simply stated, by reading the requirement of dimensionally stable foam from the narrower dependent claims of the isobutane patents into the broader independent claims, AVI renders the dependent claims superfluous. 2 See id.; Beachcombers v. Wildewood Creative Prods., Inc., 31 F.3d 1154, 1162 (Fed. Cir. 1994) (stating that it is "presumptively unreasonable" to interpret different claims as having the same scope); Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988) ("Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or escape infringement.") (quoting Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 770, (Fed. Cir. 1983), cert. denied, 465 U.S. 1026, 79 L. Ed. 2d 687, 104 S. Ct. 1284 (1984)).

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2 The distinction between an independent and dependent claim is as follows: "An independent claim does not refer to any other claim of the patent and is read separately to determine its scope. A dependent claim refers to at least one other claim in the patent, includes all of the limitations of the claim to which it refers, and specifies a further limitation on that claim." Jeneric/Pentron, Inc. v. Dillon Co., Inc., 1999 WL 66537, at *9 (D. Conn. Feb. 3, 1999).

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AVI advances several arguments that merit discussion. First, AVI relies on the specifications of the isobutane patents, which speak of dimensional stabile foam. Its mistake here, however, is that while dimensional stability is undeniably an advantage of the isobutane patents as recited in the specifications, it is improper to read this advantage from the specification sections into the claims as a requirement of the inventions themselves. Comark Communications, Inc., 156 F.3d at 1186 (noting that Federal Circuit has repeatedly held "limitations from the specification are not to be read into the claims"); Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 141 F.3d 1084, 1096 (Fed. Cir. 1998) (Newman J., dissenting) ("Advantages described in the body of the specification, if not included in the claims, are not per se limitations to the claimed invention."); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed. Cir. 1993) (finding that district court erred in interpreting "'straw-shaped, channel-forming element' limitation to mean 'straw-sized' . . . because (the claim) does not impose any requirement as to size."); Du Pont, 849 F.2d at 1433 (Fed. Cir. 1988) ("It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim. But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.") (internal citation omitted).

Second, AVI relies on the prosecution history to support its construction. However, the preceding principle applies equally here; that is, while the prosecution history is relevant to interpreting the claim language, see Laitram Corp. v. Morehouse Ind., Inc., 143 F.3d 1456, 1463 (Fed. Cir. 1998), it cannot be used to rewrite claims to impose a requirement not found in the claim language. See Intervet, 887 F.2d at 1053 (stressing the "impropriety of injecting into claims limitations from the prosecution history"). At bottom, AVI is not using the prosecution history to aid in the interpretation of a term already in the claim--which would be entirely permissible. Rather, it is using the prosecution history to import an additional property into the claim--an entirely inappropriate tact. See id.

The Du Pont case is instructive in this regard. In that case, the district court interpreted the claims as including two properties or advantages of the claimed inventions--"superior environmental stress crack resistance and impact strength." 849 F.2d at 1433. The Federal Circuit reversed, holding that "courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth. No matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them." Id. (quoting Autogiro, 384 F.2d at 395-96). Like the Du Pont defendants, AVI seeks to add a property to claims that contain no such property. Du Pont teaches this would be error.

Third, AVI contends that the claim language itself supports its construction because the claim language includes the term "stability control agent," which has as its basic purpose to allow for dimensional stable foam. The flaw here, however, is that while dimensional stability is obviously an intended advantage or purpose of the patents as expressed by the stability control agent component, it is not a requirement contained in the claims themselves. In other words, the isobutane patent claims in question do not claim dimensionally stable foam. See, e.g., Du Pont, 849 F.2d at 1433; American Standard Inc., 722 F. Supp. at 93. This distinction between an advantage and a limitation is illustrated by an example offered by Dow. An engineer invents an electric car that can travel 100 miles per hour. The engineer files a patent application claiming an electric car traveling 100 miles per hour comprising an automobile with four wheels, a battery, an electric motor, and a widget connecting the battery to the electric motor that increases the motor's efficiency. The invention is the car--comprised of a body with four wheels, a battery, an electric motor and a widget--not that the car can travel 100 miles per hour. The speed of the car is an advantage of the invention, not a limitation to the claim. In this case, the invention is the use of a blowing agent in conjunction with a permeability modifier that allows for dimensionally stable foam; it is not the advantage of dimensionally stable foam.

Fourth, AVI points to the term "dimensional stability" in the preamble of the '027 patent, asserting that the preamble of the claim is a positively stated limitation of the claim. The Federal Circuit has held that:

A claim preamble has the import that the claim as a whole suggests for it. Where a patentee uses the claim preamble to

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recite structural limitations of his claimed invention, the PTO and courts give effect to that usage. Conversely, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation.

Rowe v. Dror, 112 F.3d 473, 478 (Fed. Cir. 1997) (internal quotations and citations omitted); see also Kropa v. Robie, 38 C.C.P.A. 858, 187 F.2d 150, 151-52 (Fed. Cir. 1951) (summarizing collection of cases). In this case, dimensional stability is not a structural limitation of the claims, but rather, an advantage or objective of the invention. Moreover, the claim body defines the structurally complete invention. As such, the preamble of the '027 patent does not support AVI's construction.

Finally, AVI suggests that without defining foam as dimensionally stable, the isobutane patents add nothing to the prior art and thus would be invalid. This stage of the proceeding, however, is addressed only to the construction phase of the isobutane patents. See, e.g., Stairmaster Sports/Med. Prods., Inc. v. Groupe Procycle, Inc., 1998 U.S. Dist. LEXIS 8228, *6 n.5, 1998 WL 290296, at *2 n.5 (D. Del. May 20, 1998); Rohm and Haas Co. v. Lonza Inc., 997 F. Supp. 635, 639-40 (E.D. Pa. 1998). Inasmuch as AVI relies on the "language in [prior] decisions [that] may have given the perception that claims are to be 'saved' from invalidity by reading extraneous limitations into them, [the Federal Circuit's] consistent approach in interpreting claims, and in rejecting resort to extraneous limitations from the specification, should have negated that perception by now." Du Pont, 849 F.2d at 1434 (internal citations omitted).

It also is significant that aside from being incorrect as a matter of patent interpretation, AVI's construction is incorrect as a factual matter. As noted by Dow, the isobutane patents do not always result in dimensionally stable foam as defined by AVI. Thus, to say foam means dimensionally stable foam is inaccurate, and does not reflect the invention as set forth in the claims.

For all these reasons, I cannot accept AVI's proposed construction that adds the requirement of "dimensionally stable" to the claim terms "polyolefin foam" in the '933 patent, "polymeric composition" in the '361 patent and "olefin polymer foam" in the '027 patent. 3

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3 As AVI's papers do not seek the construction of the claim term "dimensional stability" in the dependent claims 11-14 of the '933 patent, I will not address this issue.

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A.

This court first addresses whether the term "IFN-alpha " encompasses all IFN-alpha subtypes. The district court concluded that the IFN-alpha terminology was new matter added to Dr. Weissmann's patent application in violation of 35 U.S.C. § 132 (1994). Thus, the district court did not consider the references to IFN-alpha when construing the claims. See Schering I, 18 F. Supp. 2d at 389.

Section 132 of the Patent Act provides: "No amendment shall introduce new matter into the disclosure of the invention." 35 U.S.C. § 132. The fundamental inquiry is whether the material added by amendment was inherently contained in the original application. See Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1438, 221 U.S.P.Q. (BNA) 97, 106 (Fed. Cir. 1984). To make this judgment, this court has explained that the new matter prohibition is closely related to the adequate disclosure requirements of 35 U.S.C. § 112. See Pennwalt Corp. v. Akzona Inc., 740 F.2d 1573, 1578, 222 U.S.P.Q. (BNA) 833, 836 (Fed. Cir. 1984). Section 112, in turn, requires: "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112 (1994) (emphasis added). Thus, to avoid the new matter prohibition, an applicant must show that its original application supports the amended matter. See Kolmes v. World Fibers Corp., 107 F.3d 1534, 1539, 41 U.S.P.Q.2D (BNA) 1829, 1832 (Fed. Cir. 1997).

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When originally filed, the application that issued as the '901 patent ('901 application) referred to leukocyte interferon, not IFN-alpha . About six months after the filing of the patent application, however, a committee of scientists adopted new terminology to describe interferons. See Interferon Nomenclature, 286 Nature 110 (July 10, 1980). Because scientific experiments showed that the old terminology did not accurately differentiate between species of interferon, that committee abolished the term "leukocyte interferon" in favor of the term "IFN-alpha ." The term "leukocyte interferon" indicated the source of the interferon - leukocytes. The term "IFN-alpha " more specifically identified a particular polypeptide by its physical properties - molecular weight, binding affinity for highly specific antibodies, and amino acid sequence. The committee determined that leukocytes in fact produce other types of interferon beyond "leukocyte interferon," thus necessitating the nomenclature change. See id.

Because of the terminology change in the art, Dr. Weissmann amended the claims of his '901 application to substitute "IFN-alpha " for "leukocyte interferon." Dr. Weissmann also amended the written description to explain: "in this application the interferon nomenclature announced in Nature, 286, p. 110 (July 10, 1980) is used. E.g., leukocyte interferon is designated IFN-alpha ." '901 patent, col. 1, ll. 21-23.

The district court determined that this substitution of the term "IFN-alpha " in the '901 application did not merely replace the outdated term "leukocyte interferon." Rather, according to the trial court, the substitution imported years of scientific advance into the '901 patent's disclosure and claims. Following this reasoning, the district court found that the change in terminology actually advanced the patent's definition of interferons to include numerous polypeptides not discovered at the time of the patent application. Thus, the district court concluded that the terminology substitution violated the new matter prohibition.

This court does not discern a new matter violation in the substitution of the term "IFN-alpha for "leukocyte interferon". This court interprets the claim term "IFN-alpha " in light of the patent's written description. The written description clarifies that Dr. Weissmann made no attempt to broaden his invention to cover polypeptides not discovered at the time of his patent application. Rather, Dr. Weissman stated no more than: "leukocyte interferon is designated IFN-alpha ." In other words, Dr. Weissman's amendment explained that the leukocyte interferon he had isolated and produced now has a new scientific name. Indeed the scientific community had designated Dr. Weissman's interferon as IFN-alpha . The written description accompanying his new claim language specifies that the amendment merely renames his invention - whatever its scope may have been at the time of application - in accordance with accepted scientific norms. The amendment merely substitutes terminology.

This reasoning refocuses the question before this court on the scope of the claim term "polypeptide of the IFN-alpha type" at the time of application. As already noted, this court interprets the claim at issue to cover no more than what the specification supported at the time of filing. Thus, this court undertakes to discern the scope of the claim term IFN-alpha at the time of Dr. Weissman's application.

"The claim language, of course, defines the bounds of claim scope." York Prod., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572, 40 U.S.P.Q.2D (BNA) 1619, 1622 (Fed. Cir. 1996). "Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." Id. In this case, as explained above, the patentee expressly limited the meaning of the term "IFN-alpha " to define the leukocyte interferon Dr. Weissmann described in his original application.

The scientific meaning of "IFN-alpha " evolved with new discoveries. Specifically, the scientific community learned that leukocytes produce more than a single interferon polypeptide. The term as used in the '901 patent, however, did not and could not enlarge the scope of the patent to embrace technology arising after its filing. Rather the term "IFN-alpha " in the patent has a specialized meaning limited to the particular leukocyte interferon that Dr. Weissmann supported in his original application. In sum, this court must determine what the term meant at the time the patentee filed the '901 application. See Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1555, 42 U.S.P.Q.2D (BNA) 1737, 1742 (Fed. Cir. 1998) (abrogated by the en banc court on other grounds in Cybor v. FAS Technologies, Inc., 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1174 (Fed. Cir. 1998)) ("As a general rule, the construing court interprets words in a claim as one of skill in the art at the time of invention would understand them.").

In February of 1980, when Dr. Weissmann filed the '901 application, leukocyte interferon (and its later substitute, the term "IFN-alpha " in its limited application) defined what scientists thought was a specific single polypeptide. At the time of

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invention, the record shows that scientists in this field interpreted Dr. Weissmann's pioneering work to have produced a specific polypeptide produced by leukocytes, hence the term "leukocyte interferon." At that time, the record shows, the scientific community and Dr. Weissmann understood that this interferon was the sole interferon polypeptide produced by leukocytes. Therefore, those skilled in the art used the term "leukocyte interferon" to denote an interferon polypeptide that originates from leukocytes.

Only later did scientists learn that interferon has many subtypes. The Nature article, published more than five months after the '901 application filing, acknowledged the possibility of different IFN-alpha subtypes stating: "subtypes of IFNs based on specific amino acid sequence differences can be classified as Hu IFN-alpha [1], Hu IFN-beta [2], etc." Because, at the time of the '901 application, neither Dr. Weissmann nor others skilled in the art knew of the existence of, let alone the identity of, the specific polypeptides now identified as subtypes of IFN-alpha, those subtypes cannot be within the scope of the claims. The district court correctly concluded:

After perusing the specification of the '901 Patent, the Court found the specification did not differentiate between different subtypes of leukocyte interferon. It followed from this conclusion that only one subspecies of alpha interferon was described and enabled in the specification.

Schering Corp. v. Amgen, Inc., 25 F. Supp. 2d 293, 297, 50 U.S.P.Q.2D (BNA) 1125, 1128 (D. Del. 1998) (Schering III).

More to the point, because the specific identity of the polypeptide coded for by the DNA isolated by Dr. Weissmann was unknown (either by the polypeptide's amino acid sequence or the DNA sequence of Dr. Weissmann's inserts), the district court correctly limited the claim scope to cover only polypeptides coded for by the inserts deposited by Dr. Weissmann. Thus, because the record shows that when sequenced, the inserts were discovered to code for IFN-alpha-1, that is the only interferon subtype that Dr. Weissmann's patents describe and embrace. To grant broader coverage would reward Dr. Weissmann for inventions he did not make. Therefore, although this court disagrees with the rationale by which the district court reached its decision regarding the IFN-alpha subtypes, this court agrees with the district court's conclusion that the claims cover only IFN-alpha-1 polypeptides.

B.

Another issue affects the claim interpretation question. After the district court construed the claims, Schering for the first time proffered evidence that one of Dr. Weissmann's original deposits codes for IFN-alpha-14 - another interferon subtype. After possessing Dr. Weissmann's deposits for nearly 18 years, Schering nonetheless pled that recent tests had discerned that insert 4c (one of the samples deposited at the time of Dr. Weissmann's original application) codes for IFN-alpha-14. The district court denied Schering's motion to reopen the record and reinterpret the claims to account for the recent test results:

Given the availability to Schering of the 4c insert DNA for over 18 years, the fact that its researcher, Greenberg, determined the DNA sequence of the 4c insert at some unknown time, but in any event before June 9, 1998, and the fact that the necessary computer work to reveal the "newly discovered evidence" could have been done in two days all leads to the conclusion that the "newly discovered evidence" could have been easily discovered prior to the Markman hearing. Under these facts, it is impossible to conclude that Schering exercised due diligence to discover that the 4c insert DNA allegedly codes on IFN-alpha-14.

Schering III, 25 F. Supp. 2d at 299-300.

On appeal, Schering asks this court to interpret the claims to accommodate its recent information. This court interprets a claim without deference to the district court's interpretive efforts, solely on the basis of the record on review. See Curtis Publ'g Co. v. Butts, 388 U.S. 130, 144, 18 L. Ed. 2d 1094, 87 S. Ct. 1975 (1967). This appellate court does not possess authority to both make and review a record. The sequence evidence Schering asks this court to consider is not part of the record on appeal. The district court expressly excluded that evidence as untimely in its denial of Schering's motion for reargument. See Schering III, 25 F. Supp. 2d at 300.

This court reviews the district court's decision to exclude that evidence according to the evidentiary standards set by our sister circuit, the United States Court of Appeals for the Third Circuit. See Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1359, 50 U.S.P.Q.2D (BNA) 1672, 1675 (Fed. Cir. 1999) (en banc in relevant part). The Third Circuit will

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only reverse in this situation if the trial court abused its discretion. See Murray v. Commercial Union Ins. Co., 782 F.2d 432, 435 (3rd Cir. 1985). As the district court explained, Schering held Dr. Weissmann's DNA inserts in its possession for over eighteen years, before choosing to sequence the inserts. Schering then sought to use the sequence information obtained, even though Schering proffered that information only after the district court closed its proceedings to interpret the claims. This court discerns no abuse of discretion in the district court's exclusion of the 4c insert sequence data because Schering did not exercise due diligence in obtaining that data.

Schering further argues that, even though it did not timely analyze Dr. Weissmann's DNA inserts, the inserts were part of the public record by virtue of their public deposit. This court has held that, "such a deposit has been considered adequate to satisfy the enablement requirement of 35 U.S.C. § 112." Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1210, 18 U.S.P.Q.2D (BNA) 1016, 1024 (Fed. Cir. 1991). Indeed, if the evidence Schering now proffers at the appellate stage had been part of the record at trial, it might indeed support a claim construction that includes IFN-alpha-14. However, it is not part of the record either before the trial court or this court. Although a deposit may suffice for enablement purposes, it must be part of the record before it can provide evidence to support a particular claim construction. The party proffering evidence to the trial court must offer and explain that evidence in terms accessible to the court. A court has no scientific resources or expertise to derive a DNA sequence from a raw deposit and apply its legal reasoning to that result. Schering had the burden, which it did not meet, to supply evidence of the content and meaning of the deposit to the trial court in a timely fashion. Therefore, this court sustains the district court's ruling on the evidentiary value of Schering's proffer. Without Schering performing the appropriate sequencing analysis and presenting evidence to the district court under the applicable Federal Rules of Civil Procedure and Evidence, the deposit of the 4c insert is not before this court or the district court and cannot influence the scope of the '901 patent claims.

C.

Next, Schering argues that the claims of the '901 patent should be construed to cover the mature IFN-alpha polypeptide. Natural DNA sequences for human interferon (and many other proteins) include extra genetic code that, when translated into a nascent polypeptide, is used for locational targeting within the cell and perhaps for other purposes. In nature, post-translational processes inside the cell remove those sequences to create a mature protein. Scientists in the genetic engineering art often attempt to identify the DNA sequences coding for such extra parts of the polypeptide. They can then remove the genetic code for those extraneous sequences, thus producing a mature polypeptide that needs no further processing.

When Dr. Weissmann isolated the interferon DNA sequences that he claimed as the inserts in the '901 patent, he had not identified the extraneous sequences, nor the need to remove them. The record indicates that Dr. Weissmann's inserts cited in the claims of the '901 patent also contain the extraneous sequence that, when expressed, produce an immature polypeptide. For the same reasons as discussed above relating to IFN-alpha subtypes, this court concludes that the district court correctly construed the claims as covering only immature polypeptides. This court need not reach the question of whether one of skill in the art at the time of infringement would know to remove the extraneous sequence and thus would infringe under the doctrine of equivalents.

III.

Because this court finds that the district court correctly construed the claims of the '901 patent to embrace only the immature form of the polypeptide now known in the art as IFN-alpha-1, this court affirms the district court's grant of Schering's motion for summary judgment in Amgen's favor.

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"Porcelain Powder"

Ivoclar asks the Court to construe the claim "porcelain powder" as "porcelain matter in a finely divided particulate state." Def. Mem. at 3. PSN, on the other hand, seeks to construe the same claim as "a medium containing porcelain particles." Defendant's Local Rule 56.1 Statement of Facts, Ex. 14 (hereafter "Def. 56.1 Ex. "). The parties do not dispute that the '530 Patent describes applying a porcelain powder that has been mixed into an "opaque water slurry," while the Empress

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product uses a "ceramic ingot" that has been heated into a "flowable" state.

Ivoclar relies on several technical dictionary definitions of "powder" as "finely divided particles." See Def. 56.1 Exs. 15-17. Therefore, maintains Ivoclar, a hard ceramic ingot cannot be a powder. But the Phillips decision specifically cautions courts against using the analysis urged by Ivoclar- that is, reading the claimed term in insolation and relying upon a dictionary definition of that term that is at odds with the use of the term throughout the specification of the patent. See Phillips, 415 F.3d at 1321. A person of ordinary skill in the art is presumed to read the claimed term in the context of the entire patent. Phillips, 415 F.3d at 1313. Ivoclar maintains that only powder, and not a solid form of powder, can be a "powder" in the '530 Patent. But taking Ivoclar's proposed construction to its logical conclusion, the claimed step "applying porcelain powder to the surface of said statue" would mean that someone following the '530 Patent must apply powder, alone, to the surface of the statue to form the veneer. At no point in the '530 Patent summary, preferred embodiment, or example does the Patent describe use of the porcelain powder without a medium. To the contrary, the specification describes complimentary functions for the medium, such as adding pigment to the medium to render the porcelain opaque. See '530 Patent, col. 4, ll. 4-9.

The preferred embodiment and example in the '530 Patent describe applying the porcelain powder to the statue after mixing it with water. To read the term "porcelain powder" as excluding porcelain powder in a medium, as proposed by Ivoclar, would make it impossible to make the invention as described. See Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996) ("[I]t is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.") Therefore, the Court construes the claim "porcelain powder" as proposed by PSN: a porcelain powder is a medium containing porcelain particles.
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"Porcine Circovirus Type II"

The district court found that the claim term "porcine circovirus type II" was limited to the five sequences that were deposited with the PTO as part of the description of the invention. The district court was persuaded by Intervet's arguments that the patent specification defined the invention as being these five sequences, and contained no disclosure from which to infer that any other sequences were also part of the invention.

It is clear enough to us, however, that the patent states that the five deposited strainsand listed sequences are "representative of" a "type of porcine circovirus," and thus do not constitute the entire scope of the invention. '601 patent col.1 ll.60-61 (emphases added). HN3Go to this Headnote in the case.Sequences are representative of the scope of broader genus claims if they indicate that the patentee has invented species sufficient to constitute the genera. Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 967 (Fed. Cir. 2002); In re Smythe, 480 F.2d 1376, 1383 (C.C.P.A. 1973). Here, the deposited strains are representative species of the larger "type II" genus, where the genus is identified and claimed as the invention.

Claims properly directed to a genus may be adequately supported by the patent disclosure if a sufficient number of species is disclosed so as to properly identify the scope of the genus. Id.Here, the patentee has disclosed five species of PCV-2, provided the full sequences for four, and identified the potential coding portions of the sequences. The patentee also provided a counterexample, PCV-1, that by definition lies outside the scope of the claimed genus, as well as a representative species of the counterexample, its sequence, and potential coding portions for the representative.

Neither the claim itself nor the specification provides a homology threshold above or below which a particular PCV strain is properly considered PCV-2 rather than PCV-1. It refers instead to strains of the invention having "significant serological similarity" and stringent, selective cross-hybridization to the deposited strains over PK/15. The only quantitative boundaries disclosed in the patent are the 96% homology among representative PCV-2 sequences, and the 76% homology between those sequences and the representative of PCV-1.

The patent's stated conclusion that the disclosed PCV-2 sequences "thus" represent a new type of porcine circovirus is based on the pathogenicity of the isolated strains, as well as the observed homology patterns. See, e.g., '601 patent col.5 ll.59-61. This conclusioncomports with the way that viruses are typically classified in the relevant art. Cf. Universal Virus Database of the International Committee on Taxonomy of Viruses available at http://www.ictvdb.rothamsted.ac.uk/. The invention is

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then defined as being the type II porcine circovirus, which is in turn "as defined above." '601 patent col.5 ll.64. Thus, the pathogenicity and homology patterns are the defining properties of the new type of virus. The claim construction of "porcine circovirus type II" is therefore properly limited to porcine circoviruses that have these two defining properties.

We therefore construe the claim term "porcine circovirus type II" to be "a pathogenic pig virus having a circular genome that is at about 96% or more homologous with the four sequences disclosed in the present specification, and about 76% or less homologous with the PK/15 sequence." Strains that fit this definition would be expected to have strong serological similarity and cross-hybridize to the deposited strains under high stringency conditions. As such, limiting the claim scope according to these properties is not inconsistent with the other descriptive language in the specification.
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1. "pores"

The parties do not dispute that a pore is a hole or cavity in a magnetic particle which may be open or closed. (DX 60; Buxbaum 11/15/96 Dep. 447-448). An "open pore" is a "cavity or channel communicating with the surface of a particle." (DX 60; O'Grady Tr. 687). A "closed pore" is a "cavity or channel not communicating with the surface of a particle." (DX 60; O'Grady Tr. 687).

The parties' disagreement centers on the size of the pores contemplated by the Bayer patent. Pores can be classified into three size ranges: (1) micropores which are less than approximately 2nm, (2) mesopores which are between approximately 2nm and 50nm and (3) macropores which are above approximately 50nm. (DX 60; O'Grady Tr. 688). Bayer contends that the size of the pores is necessarily limited by their manner of detection and count as described in the '799 Patent. According to Bayer, this method is via bright field TEM analyses at approximately 120,000:1 magnification, i.e. the magnification present in Figures 1 through 3 of the '799 Patent. Individual pores appear as light-colored areas or spots in an otherwise darker TEM micrograph of the particle at the relevant magnification. According to Bayer one skilled in the art would realize that only mesopores would be detectable in the TEM analysis at the magnification of 120,000:1. Bayer contends that macropores would be excluded because their size exceeds the diameter of the particles, and micropores would be excluded because they cannot be seen, let alone counted and averaged at the 120,000:1 magnification. Thus, Bayer contends that it is only those pores visible in the TEM images at the relevant magnification that must be counted and averaged to determine the "on average" pore limitations of the '799 Patent.

In response, the Sony Defendants contend that the term "pore" should not include any size limitations. According to the Sony Defendants, one of ordinary skill in the art reading the '799 Patent would understand that the term "pore" refers to pores as commonly understood and that no size limitation or distinction between open and closed pores is stated or implied in the patent.

After reviewing the disputed term in light of the specification, the Court agrees with the Sony Defendants. The term pore is not limited to any size or distinction between open and closed pores. The specification contains no limitations about pore size whatsoever. If Bayer had wanted to limit the definition of pores to mesopores, it should have done so explicitly in the patent. See e.g. Beachcombers v. Wildewood Creative Products, Inc., 31 F.3d 1154, 1158 (Fed. Cir. 1994) ("[A] patentee can be his own lexicographer provided that patentee's definition, to the extent that it differs from the conventional definition, is clearly set forth in the specification."); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582. Absent clear language in the specification departing from the customary use of the term pore, the Court concludes that the word should be given its ordinary meaning as used by those skilled in the art, without the limitation Bayer seeks to impose. See Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Bayer contends that the patent should be limited by the illustrative figures, Fig. 1-3 of the patent, which both parties agree are at a magnification of 120,000:1. The Court disagrees. The inclusion of the TEMs in Bayer's patent does not inform someone of ordinary skill in the art how the TEMs should be used or that they should be used for counting pores. Although TEM analysis can be used for counting pores, other methods are available and are recommended by those skilled in the art to confirm the impressions one gains from TEM analysis. (O'Grady Tr. 846-847). Further, Dr. Buxbaum, one of the inventors of the patent testified that the figures in the '799 Patent were for illustrative purposes only and not for use in counting pores. (Buxbaum Tr. 339). Similarly, another inventor of the patent, Dr. Schroder, testified that he was not

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concerned about the size of the pores, because "the goal was to possibly have no pores because the recognition was prevailing with us that the fewer pores, the better." (Schroeder 9/27/96 Dep. at 127-128).

The Court's conclusion that the term "pore" is not limited by size is also supported by the understanding of the term by one skilled in the art. The parties agree that the literature recognizes three sizes of pores. (D.I. 476 at 25, P 42; D.I. 477 at 34-35, P 91). Further, Dr. Buxbaum, admitted that individuals researching magnetic particles were using high magnification TEMs to look for micropores in the late 1970s and 1980s. 1 (Buxbaum Tr. 201). Thus, in the Court's view, micropores were encompassed in the term "pores" as used by those skilled in the art, and Bayer has not persuaded the Court otherwise.

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1 Indeed, even Bayer's experts used TEMs at magnifications as high as 240,000:1 and 220,000:1 in connection with the proceedings related to Bayer's related Japanese patent. (Buxbaum Tr. 207-209, 213; DX 268E, PX 640). That Bayer's experts used TEMs at higher magnifications in a related patent further suggests that the '799 Patent is not limited by the TEM magnification in its examples.

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That one skilled in the art would not exclude micropores from the term "pores" is further evidenced by the expert testimony of Professor O'Grady, which the Court finds credible. As Professor O'Grady testified:

I have heard testimony in this court that says that micropores are of no significance. Personally, as an expert in the field, I don't agree with that testimony. But if someone wished to place that restriction upon one skilled in the art, that person would have to state that in my opinion quite explicitly, because it's contrary to the accepted International Union of Pure and Applied Chemistry definition of pores.

(O'Grady Tr. 829). Accordingly, the Court construes the "term" pore as a hole or cavity in a magnetic particle which may be open or closed, and the Court declines to impose any size limitation on the term "pore."
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DISCUSSION

I.

In the 1980s, Aronowitz and Louis Terminiello (Terminiello) began researching methods for testing heterogeneous bodily fluids for the presence of certain materials. Technical Chems. I, slip op. at 2-3. Such methods are useful in testing biological fluid samples, containing multiple components, for the presence of analytes such as glucose, cholesterol, and urea. Aronowitz's and Terminiello's research efforts resulted in the technology disclosed in the '192 and '580 patents.

The '192 patent, entitled "A Dry Reagent Delivery System With Membrane Having Porosity Gradient," discloses a system for detecting the presence of an analyte in a heterogeneous fluid sample. Claim 11, the only independent claim of the '192 patent at issue, provides:

A dry chemistry reagent system for detection of an analyte in a heterogenous [sic] fluid sample, said system comprising:

a porous membrane of essentially uniform composition and a porosity gradient from one planar surface thereof to the other, wherein said porous membrane's inherent fluid absorption and distribution characteristics have been modified by imbibing a conditioning agent, an indicator, flow control agent and reagent cocktail into its matrix, the effect of such absorption being to effect an essentially uniform distribution of indicator, flow control agent and reagent cocktail within the porous membrane thereby enhancing the uniformity of internal structure of said film so as to enhance the uniformity of absorption and modulate the rate of absorption of the fluid sample and its interaction with the reagent cocktail.

'192 patent; col. 22, ll. 56-68, to col. 23, ll. 1-5. This system is commercially embodied in products known as test strips.

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When a biological fluid sample, such as a drop of blood, containing the analyte for which a test is being conducted is placed on the reaction zone of the test strip, a chemical reaction occurs. The reaction produces a characteristic color change that indicates the presence of the analyte.

The '580 patent, entitled "Assay Kit Including An Analyte Test Strip And A Color Comparator," discloses a kit comprised of a test strip and a color comparator. The test strip functions in a manner similar to that disclosed in the '192 patent. The color comparator consists of a series of color fields which correlate color intensity to corresponding numerical values of the amount of analyte present. The color comparator contains apertures that allow a section of the reaction zone of the test strip, where the characteristic color change occurs, to be compared to the various colors on the comparator, while shielding the remainder of the reaction zone and the inert support medium of the test strip from view. The kit allows the user to compare the characteristic color intensity of the indicator in the reaction zone of the test strip to the color comparator and thereby determine the numerical amount of analyte present in the sample. Claims 1 and 8 of the '580 patent, the only claims of the '580 patent at issue, provide:

1. A test means comprising:

(a) a test strip which includes an inert support and a sample receptive medium comprising a dry chemistry reagent system specific for an analyte of interest which upon interaction with said analyte produces a characteristic color indicative of an assay value of said analyte of interest, said receptive medium being positioned on said test strip so as to be bordered on one or more sides by said inert support;

(b) a color comparator including a plurality of different color fields representing a range of assay values of said analyte physically arranged in a predetermined ordered succession for comparison with the color of the sample receptive medium of the test strip, each of said color fields having an aperture which permits viewing therethrough of at least a portion of a reaction zone of the sample receptive medium after said analyte has reacted to produce a color therein, and

2. means for positioning said test strip relative to the aperture of each of said color fields so as to mask from view the inert support which borders the reaction zone of the sample receptive medium.

8. A test means comprising an analyte test strip having an analyte reaction zone and a color comparator therefor, said color comparator comprising a plurality of color fields physically arranged in a linear succession, each successive field connoting a different numerical assay value of said analyte, characterized in that each color field has an aperture therethrough entirely framed by said color field, each aperture permitting at least a portion of said reaction zone to be viewed when said reaction zone is positioned behind the color field framing the aperture.

'580 patent; col. 4, ll. 60-68, to col. 5, ll. 1-14, 46-56.

II.

The '192 patent issued on September 27, 1988, and the '580 patent issued on October 31, 1989. Aronowitz and Terminiello assigned both patents to Technimed Corp. (Technimed), a Florida corporation formed by Aronowitz in the 1970s. Technical Chems. I, slip op. at 2-3. Aronowitz originally served as Technimed's President and later as its Executive Vice President and Technical Director. Id. at 2. Aronowitz claims that at the time he assigned his interest in the patents to Technimed, he also executed an additional agreement whereby the patents would revert to him if Technimed failed to successfully commercialize the inventions disclosed in the patents. Id. at 3.

Technimed attempted to commercialize the inventions claimed in the patents by entering into an agreement with HDI on April 15, 1988 (1988 agreement). Id. The agreement consisted of two parts: (1) a Supply Agreement, under which HDI was to purchase glucose and cholesterol test strips from Technimed, and (2) a Contingent Manufacturing Agreement, which allowed HDI to become licensed to make glucose and cholesterol test strips using Technimed's technology if Technimed was unable to meet HDI's demand for these products. The Contingent Manufacturing Agreement was conditioned on HDI having purchased specified minimum quantities of test strips from Technimed. Under the Contingent Manufacturing Agreement, HDI was assessed royalties based on the number of strips it produced, subject to a minimum annual royalty provision.

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On January 8, 1990, the parties entered into a second agreement (1990 agreement). The 1990 agreement invoked the Contingent Manufacturing Agreement and modified sections of the 1988 agreement. Technical Chems. I, slip op. at 3. Pursuant to the 1990 agreement, Technimed released certain technical information and "Know-How" to HDI, and HDI was licensed to manufacture glucose and cholesterol test strips. Id. at 3-4. As part of the 1990 agreement, HDI purchased a portion of Technimed's test strip manufacturing facilities and hired nine employees who were working in test strip manufacturing-related positions at Technimed. The district court found that almost simultaneously with the 1990 agreement, Technimed assigned the '192 and '580 patents to Pacific National Bank (Bank) as part of a refinancing agreement. 1

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1 The court noted that TCPI and Aronowitz failed to present any evidence to support their claim that the '580 patent had been assigned to the Bank. Technical Chems. I, slip op. at 4.

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Id. at 4. Shortly thereafter, Technimed defaulted on its obligations to the Bank. Id. at 4-5.

On September 24, 1992, Aronowitz obtained a Partial Final Judgment By Default against Technimed in the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida. The judgment was in a suit by Aronowitz against Technimed in which Aronowitz asserted that Technimed had failed to commercialize the inventions of the two patents, as required under an agreement which Aronowitz alleged existed between Technimed and himself. Technical Chems. I, slip op. at 5. This judgment purported to rescind the assignments from Aronowitz to Technimed and purported to give Aronowitz superior rights relative to Technimed in the '192 and '580 patents, as well as in U.S. Patent No. 4,790,979 (the '979 patent). On October 14, 1992, Aronowitz obtained a Final Judgment By Default against the Bank. Id. This judgment purported to give Aronowitz superior rights relative to the collateral claim of the Bank. 2

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2 It is unclear from the Judgment By Default and from the record evidence which patent or patents were covered by this judgment.

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On November 2, 1992, Aronowitz granted TCPI, the company of which he is President and Chief Executive Officer, a purportedly exclusive license under the '192 and '580 patents. Id.

As early as 1991, Technimed had attempted to terminate the 1988 and 1990 agreements, claiming that HDI had failed to pay the required royalties. In fact, Technimed and Aronowitz threatened to terminate the agreements on at least two occasions. Id. On November 22, 1993, TCPI and Aronowitz sued HDI, alleging willful infringement of the '192, '580, and '979 patents. 3

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3 At the close of plaintiffs' case, the court entered judgment as a matter of law, in favor of HDI, under Fed. R. Civ. P. 52(c), with respect to all claims under the '979 patent. Technical Chems. II, slip op. at 1. The '979 patent is not at issue in this appeal.

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TCPI alleged that the Ultra+ test strips manufactured by HDI infringed the '192 patent. Technical Chems. I, slip op. at 6. TCPI also alleged that HDI's LipoScan Total Color Cholesterol Chart and Ultra+ Blood Glucose Color Chart infringed the '580 patent. Id. After filing the action, TCPI and Aronowitz sent a letter to HDI dated October 18, 1994, entitled "Formal Notice of Termination of License." The letter purported to terminate, because of HDI's alleged failure to pay royalties, whatever rights HDI had by virtue of the 1988 and 1990 agreements. Id. at 5.

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III.

The case was tried to the bench from September 18-22, 1995. Id. at 1. After trial, the court determined that Aronowitz and TCPI had standing to assert the '192 and '580 patents against HDI, subject to any existing license HDI had previously been granted by Technimed. Technical Chems. I, slip op. at 9-10. The court also determined that HDI had not infringed independent claim 11 and dependent claims 14 and 15 of the '192 patent, either literally or under the doctrine of equivalents. 4

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4 With respect to the other claims of the '192 patent, the court stated: "Because of the absence of any evidence to support a finding of infringement on claims 1 through 10, 12, 13, 16 through 40, the Court concludes that such claims have not been infringed." Technical Chems. I, slip op. at 14.

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Id. at 17-18. The court further determined that HDI's LipoScan product and its Ultra+ Blood Glucose Color Chart, when used in conjunction with the Ultra+ test strips, were within the scope of the claims of the '580 patent. Id. at 20. The court concluded, however, that HDI had not infringed claims 1 and 8 of the '580 patent because it was validly licensed pursuant to the 1988 and 1990 agreements. Id. at 21-22. The court additionally concluded that HDI had not materially breached the agreements and that, therefore, the agreements could not have been terminated. Technical Chems. I, slip op. at 21-22. Finally, the court held that HDI was not required to pay royalties under the agreements because the contingencies giving rise to royalty payments had not occurred. Id. On August 30, 1996, the court entered final judgment in favor of HDI on all counts. Technical Chems. II, slip op. at 2-3.

IV.

A.

We address the arguments of the parties in turn, beginning with the infringement issues. .A determination of infringement requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1576, 27 U.S.P.Q.2D (BNA) 1836, 1839 (Fed. Cir. 1993). Claim construction is a question of law, which we review de novo. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995) (in banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577 (1996). Infringement, both literal and under the doctrine of equivalents, is a question of fact which we review for clear error when tried to the court. See SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1125, 227 U.S.P.Q. (BNA) 577, 589 (Fed. Cir. 1985) (in banc); Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1255, 43 U.S.P.Q.2D (BNA) 1666, 1668 (Fed. Cir. 1997). In interpreting the claims of a patent, the court first looks to the intrinsic evidence of record, including the claims of the patent, the specification, and the prosecution history. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 U.S.P.Q.2D (BNA) 1573, 1576 (Fed. Cir. 1996). When intrinsic evidence unambiguously delineates the scope of the patented invention, resort to extrinsic evidence, including expert testimony, is unnecessary. See id. at 1583, 39 U.S.P.Q.2D (BNA) at 1577.

B.

Claim 11 of the '192 patent requires "a porous membrane of essentially uniform composition and a porosity gradient from one planar surface thereof to the other." '192 patent; col. 22, ll. 59-61. The district court construed this limitation to mean "that the untreated membrane, to which the dry chemistry reagent system is added, must have a porosity gradient[,] . . . a gradual change in the porosity from one planar surface [of the membrane] to the other." Technical Chems. I, slip op. at 15-16. The court determined that the claimed membrane was "prior to conditioning, anisotropic, in that there existed a density gradient from one planar surface to the other." Id. at 16. The court rejected TCPI's and Aronowitz's argument that a "'porosity gradient' can also be characterized by differences in the density of the two planar surfaces [of the membrane], rather than a gradual, continuous change in the internal structure." Id. at 16-17.

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TCPI and Aronowitz argue that the court misconstrued claim 11 by limiting the term "porosity gradient" to gradual changes in porosity from one planar surface of the membrane to the other. They contend that "porosity gradient" means that one surface of the membrane or the area immediately contiguous thereto is denser than the other surface of the membrane or the area immediately contiguous thereto. We cannot agree.

The language of claim 11 requires that the porosity gradient run "from one planar surface [of the membrane] . . . to the other." '192 patent; col. 22, ll. 60-61. The specification provides that the membrane of the claimed invention "is, prior to conditioning, anisotropic, in that there exists a density gradient from one planar surface to the other." Id.; col. 11, ll. 32-34. Since the patentee did not express in the patent an intent to impart a novel meaning to the term "gradient," we give that term its ordinary meaning. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572, 40 U.S.P.Q.2D (BNA) 1619, 1622 (Fed. Cir. 1996). "Gradient" is defined as a "change in the value of a quantity . . . per unit distance in a specified direction." Webster's Third New International Dictionary 985 (1986). We agree with the district court that "porosity gradient", as used in the claims of the '192 patent, requires "a gradual change in the porosity from one planar surface [of the membrane] to the other." Technical Chems. I, slip op. at 16. The term "gradual" is used to describe the change in porosity in contrast to a discontinuity. Thus, moving from one surface of the membrane to the other, porosity changes continuously, rather than exhibiting two regions of uniform porosity separated by a plane of discontinuity. Under TCPI's and Aronowitz's proffered construction, the claimed membranes could consist of two layers joined at a single plane. Such a structure does not contain a gradient as the term is ordinarily defined, but rather a discontinuity. We reject this construction because it is inconsistent with the claims and the specification, which require that the porosity gradient run "from one planar surface [of the membrane] to the other" rather than existing at only a plane of discontinuity within the membrane.

The district court also construed claim 11 to require that "the untreated membrane, to which the dry chemistry reagent system is added, must have a porosity gradient." Id. at 15-16. While claim 1 of the '192 patent addresses the membrane prior to chemical conditioning, claim 11 is directed to a system in which the membrane has "been modified by imbibing a conditioning agent, an indicator, flow control agent and reagent cocktail into [the membrane's] matrix." '192 patent; col. 22, ll. 63-65. Claim 11 does not require the membrane to have a porosity gradient prior to chemical conditioning, but instead requires that the membrane of the chemically conditioned reagent system have a porosity gradient. In other words, the proper construction of claim 11 requires the membrane to have a porosity gradient, but does not require the gradient to be present prior to chemical conditioning. The court thus erred in reading the "prior to conditioning" limitation from the specification, see '192 patent; col. 11, ll. 31-34, into claim 11. See Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571, 7 U.S.P.Q.2D (BNA) 1057, 1064 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed language in the claims, particular embodiments and examples appearing in the specification will not generally be read into the claims."); E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 U.S.P.Q.2D (BNA) 1129, 1131 (Fed. Cir. 1988).
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E. Construction of Claims in Patents '192 and '580 and Comparison with Defendant's Accused Products

53. This case involves two patents: a) U.S. Patent 4,774,192 ('192), issued September 27, 1988, entitled: "A Dry Reagent Delivery System With Membrane Having Porosity Gradient"; b) U.S. Patent 4,877,580 ('580), issued October 1, 1989, entitled "Assay Kit Including an Analyte Test Strip and a Color Comparator."

1) Patent '192

54. Patent '192 describes a product used to test heterogenous bodily fluids such as blood, urine, or saliva. Such fluids are tested by placing a drop of fluid on a test strip containing a treated membrane and waiting for a color reaction. As the fluid flows through the membrane, the '192 system eliminates the interference of substances such as red blood cells, particles, and macromolecules from the heterogenous fluid prior to the color reaction.

55. Patent '192 contains forty (40) claims, but the allegations, evidence, and testimony presented at trial address only three of the forty claims. Because of the absence of any evidence to support a finding of infringement on claims 1 through 10, 12, 13, 16 through 40, the Court concludes that such claims have not been infringed.

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56. The claims at issue upon which the Court heard evidence are Claims 11, 14, and 15. 5 Claim 11 is the only independent claim. Claims 14 and 15 are dependent on Claim 11. The dry chemistry reagent system explained in Claim 11 6 of Patent '192 begins with "porous membrane of essentially uniform composition and a porosity gradient from one planar surface thereof to the other."

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5 Although the Court heard some limited testimony regarding the Defendant's method of applying various solutions to the untreated membrane, the patent claim addressing the method of application was not addressed during the trial, nor did the Plaintiff present sufficient evidence for the Court to determine whether the system of preparing the untreated membrane constituted infringement of Patent '192.6 Specifically, Claim 11 of the '192 patent claims a:

dry chemistry reagent system for detection of an analyte in a heterogenous, fluid sample, said system comprising: a porous membrane of essentially uniform composition and a porosity gradient from one planar surface to the other, wherein said porous membrane's inherent fluid absorption and distribution characteristics have been modified by imbibing a conditioning agent, an indicator, flow control agent, and reagent cocktail into its matrix, the effect of such absorption being to effect an essentially uniform distribution of indicator, flow control agent and reagent cocktail within the porous membrane thereby enhancing the uniformity of internal structure of said film so as to enhance the uniformity of absorption and modulate the rate of absorption of the fluid sample and its interaction with the reagent cocktail.

(Plaintiffs' Exh. 18).

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57. Having reviewed the patent claims in accordance with the law set forth herein, the Court concludes that Claim 11 contains the limitation that the untreated membrane, to which the dry chemistry reagent system is added, must have a porosity gradient. A porosity gradient is a gradual change in the porosity from one planar surface to the other.

58. The '192 Patent describes the membrane which is suitable as a repository of the dry chemistry reagent system as a membrane which is "prior to conditioning, anisotropic, in that there exists a density gradient from one planar surface to the other." (Patent '192, Col. 11, lines 31-33). Thus, an anisotropic membrane is one in which the membrane contains a porosity gradient (or slope) from one planar surface of the membrane, through the membrane, to the opposing planar surface.

59. The dry reagent chemistry system added to the membrane is described extensively in prior art and the '192 patent incorporates by reference numerous prior art patents concerning such dry reagent systems. (See Patent '192, Col. 1, lines 38-40). Aronowitz's patent, however, sought to improve the dry method of testing heterogenous bodily fluids by using a membrane with a porosity gradient.

60. The porosity density of the membrane may be enhanced by the use of various chemical solutions, including a flow control agent, that modulates the flow of fluid and permits the progressive absorption of the fluid in relation to the sequential enzymatic reaction.

61. An isotropic membrane, however, cannot be physically altered into an anisotropic membrane.

62. Plaintiffs argue that a "porosity gradient" can also be characterized by differences in the density of the two planar surfaces, rather than a gradual, continuous change in the internal structure. To do so, however, would require the Court to ignore the plain meaning of the term "gradient," as well as the meaning assigned to the term by the patent. (See Patent '192, Col. 11, lines 31-34).

63. The key feature upon which Defendant has distinguished its Ultra+ test strip is the porosity gradient.

64. HDI's Ultra+ test strip, which allegedly infringes on Plaintiffs' Patent '192, however, uses an isotropic membrane which does not have a porosity gradient prior to imbibing the conditioning agent, indicator, flow control agent, and reagent cocktail.

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65. Instead of using a membrane with a porosity gradient, HDI uses a nylon mesh screen to filter out the red blood cells, particles, etc. prior to the fluid mixing with chemicals to produce the color reaction.

66. Although both products serve the same function: to take fluid, pass it through the membrane to result in a color reaction which can be visually compared to a color comparator, or measured by a meter that reads the color reaction's reflectance, they accomplish their results by using different raw materials and methods. Whereas the '192 patent starts with an anisotropic, porous gradient membrane, it appears that Defendant's product starts with an isotropic, non-porous gradient membrane. Defendant's method of using a mesh screen rather than an anisotropic membrane to filter out red blood cells and other particles, is an entirely different means and method to achieve the filtration process.

67. Having duly considered the evidence presented at trial and having found that the Defendant's product uses an isotropic membrane without a porosity gradient, the Court concludes that the Defendant's product does not contain a clear limitation of the Claim 11 of Patent '192: a membrane with a porosity gradient.

68. Because the product does not use the same means to accomplish the goal of testing blood, the product does not infringe under the Doctrine of Equivalents.
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C. Construction of the Claim Terms in Dispute.

1. "The portion of open pores in the material forming said plate is 85 to 95% based on total pore volume." Technip invites this Court to construct this term to mean that the pores making up the remaining 5 to 15% of the total pore volume are closed pores. (Doc. 33, at 23) In other words, Technip requests this Court to read into this term the corollary that the remaining 5 to 15% of the total pore volume are closed pores. However, this Court agrees with plaintiff that this term does not require construction by the Court as it is sufficiently clear on its face to a person of ordinary skill in the art and, as well, is sufficiently clear on its face to the undersigned. See ITP, Inc. v. BP Corp. of North America, Inc., 2005 U.S. Dist. LEXIS 39078, 2005 WL 3542577, *8 ("This definition is subject to the more specific limitation of claim 9, in which the portion of open pores of the material 'is 85 to 95% based on total pore volume, with an average pore diameter less than or equal to 0.1 [mu] m.' The court finds this limitation sufficiently clear on its face.")), adopted by, 2005 U.S. Dist. LEXIS 39074, 2005 WL 3542575 (S.D. Tex. 2005). The cases set forth herein counsel courts to presume that a term means what it says; this Court, guided by that principle, finds that the above term needs no construction because it means what it says and is clear on its face.
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A Claim construction

As part of its claim construction, the district court instructed the jury that "[t]o infringe one of the claims of the '355 Patent, a bread must (a) contain ingredients in the proportions in claim 5, 6, 7, 8, or 10 and, (b) in that particular bread, the ingredients must act as a potassium bromate replacer, that is, the ingredients must perform essentially the same function in the production of that bread as would potassium bromate." J.A. at 113 (emphasis added). The court also provided the jury with the following definition: "Potassium Bromate is a slow acting oxidant once commonly used in the breadmaking process. Its function in the breadmaking process is to strengthen the dough, increase loaf volume, and contribute to fine crumb grain." J.A. at 147 (emphasis added). Kim objected to these jury instructions. On appeal, Kim concedes that "potassium bromate replacer" is a claim limitation, but argues that a "potassium bromate replacer" is simply a "potassium bromate substitute," which she in turns describes as a composition that is present when potassium bromate is not.

Upon review of the specification, we agree with the district court's claim construction. "[C]laims must be read in view of the specification, of which they are a part." Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). The specification "is the single best guide to the meaning of a disputed term." Id. (internal

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quotation marks omitted). Here, while the specification does not explicitly define the term "potassium bromate replacer," it does make clear that the claimed potassium bromate replacer is an oxidizing agent. In fact, the specification explicitly states that "the potassium bromate replacer provided in the present invention is a more effective oxidant than potassium bromate." '355 patent, col. 3, ll. 1-2. The specification also describes oxidants, or oxidizing agents, as follows:

Oxidizing agents provide strengthening of dough during the manufacturing process of yeast-leavening products. As a result, oxidizing agents are used to provide greater loaf volume, improve internal characteristics such as grain and texture, and enhance symmetry and keeping quality of yeast-leavening products.

'355 patent, col. 1, ll. 22-27.

Thus, the specification reveals that the claimed potassium bromate replacer functions as an oxidant and that oxidants strengthen dough, increase loaf volume, and contribute to fine crumb grain. The specification also states that, "the present invention is particularly useful [in] that it provides natural ascorbic acid as the only oxidizing agent in dough that is effective and functional throughout the entire manufacturing process." '355 patent, col. 1, ll. 57-60 (emphasis added). When the claim limitation is read against this backdrop, it is clear that the potassium bromate replacer must be functional. The district court's construction of "potassium bromate replacer" as a composition that performs essentially the same function in the production of bread as would potassium bromate (by strengthening the dough, increasing loaf volume, and contributing to fine crumb grain) is, therefore, supported by the specification. We thus find no error in the district court's construction of "potassium bromate replacer composition." 5

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5 Kim also argues that because dependent claims 7 and 8 add specific functionality limitations, independent claim 5 must not require functional attributes. Claim 7 requires that the ascorbic acid act as a "slow acting oxidant" and claim 8 requires that the ascorbic acid in the composition be a "more effective oxidant" than when used alone during the manufacturing process. However, under the district court's claim construction, claim 5 requires the potassium bromate replacer to have essentially the same function in the production of bread as would potassium bromate. As noted in the text below, this construction does not require the potassium bromate replacer to be a slow acting oxidant, nor does it require that the ascorbic acid be more effective in this composition than when used alone. The fact that the dependent claims may require additional functional attributes does not undermine the district court's claim construction.

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We also agree with the district court's determination that "there is no indication that the three [potassium bromate replacer ingredients] must first be combined together to form a stand-alone replacer composition and then be added as a whole to the bread mix or dough." J.A. at 206. We see nothing in the '355 patent which supports ConAgra's argument for a contrary claim construction.

Relying on various references in the specification and prosecution history which describe Kim's potassium bromate replacer as functioning as a slow acting oxidant, the dissent urges that "potassium bromate replacer" should be construed as "a slow acting oxidant that is functional throughout the entire manufacturing process." Diss. Op. at 2. Neither party urged this construction in the district court or in this court. While we may have the authority to adopt claim constructions which have not been proposed by either party, see Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1556 (Fed. Cir. 1995), we should be hesitant to do so. Considering the dissent's proposed construction on the merits, we find it to be incorrect. The mere fact that one object of the invention is to produce a slow acting oxidant which is functional throughout the entire manufacturing process does not mean that this particular feature was adopted as a limitation in each claim of the patent. The specification does not require that the potassium bromate replacer must necessarily be a slow acting oxidant, only that particular potassium bromate replacers perform that function. '355 patent, col. 2. ll. 25-33. Thus the fact that the patent here discloses the advantages of a slow acting oxidant does not mean that all the claims are directed to such an oxidant. See E-Pass Tech., Inc. v. 3Com Corp., 343 F.3d 1364, 1368-69 (Fed. Cir. 2003). Indeed, Kim chose to claim a "slow acting" oxidant in dependent claim 7, while her independent claims were directed to a more general potassium bromate replacer. The doctrine of claim differentiation suggests that the independent claims here should not include explicit limitations of a dependent claim. See Phillips, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."); Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004). The prosecution history does not compel a different construction.

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II.

Throughout the specification of the '355 patent, Kim consistently defines the term "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process." The first instance occurs in the Abstract, which states in relevant part, "The potassium bromate replacer essentially comprises ascorbic acid, food acid, and/or phosphate. It is a slow acting oxidant that is functional throughout the entire manufacturing process. It is also an effective oxidant that produces properly oxidized dough needed in the production of high quality, yeast-leavened products." '355 patent, abstract (emphasis added). The next instance occurs in the Background section, which provides, "It is a further object of the present invention to provide the ascorbic acid composition that acts as a slow acting oxidant that is functional throughout the entire manufacturing process." '355 patent, col. 2, ll. 45-49 (emphasis added). In describing how the claimed invention overcomes disadvantages of prior potassium bromate replacers, the Background section further provides:

The advantages of the potassium bromate replacer provided in the present invention are:

(a) It comprises all natural ingredients.

(b) It is a slow acting oxidant that is functional throughout the entire manufacturing process.

(c) It is an effective oxidant that produces properly oxidized dough needed in the production of high quality, yeast-leavened products.

(d) It is specifically adapted for various methods of the breadmaking process.

Furthermore, the potassium bromate replacer provided in the present invention is a more effective oxidant than potassium bromate because potassium bromate has little effect on oxidation of dough during mixing and the early stages of proofing.

'355 patent, col. 2, l. 57 to col. 3, l. 5 (emphasis added).

The Summary of the Invention is also insightful. It states in part:

The present invention relates to potassium bromate replacer comprising an ascorbic acid composition that replaces an oxidizing agent of potassium bromate. The potassium bromate replacer essentially comprises ascorbic acid, food acid, and/or phosphate.

In methods for preparing the ascorbic acid composition, it has been discovered that a food acid added in an effective amount slows down oxidation of ascorbic acid to dehydroascorbic acid in a dough and thus, ascorbic acid is changed to a slow acting oxidant that is functional throughout the entire manufacturing process.

'355 patent, col. 3, ll. 8-18 (emphasis added). These passages evince that Kim defined "potassium bromate replacer" to mean "a slow acting oxidant that is functional throughout the entire manufacturing process."

The Detailed Description is consistent with the passages cited above. It states:

[A] food acid slows down oxidation of ascorbic acid to dehydroascorbic acid in dough by forming metal ion-food acid complex during the mixing stage of dough and gradually dissociating into free metal ion and food acid during the later stages of the manufacturing process. Thereby, ascorbic acid is changed from a fast acting oxidant to a slow acting oxidant. Thus, ascorbic acid combined with a food acid acts as a slow acting oxidant that is functional throughout the entire manufacturing process.

'355 patent, col. 5, ll. 26-34 (emphasis added). The Detailed Description continues:

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As illustrated in the preparation of ascorbic acid composition, a food acid added in an effective amount allows ascorbic acid to oxidize at a slow rate in a dough. Thus, ascorbic acid acts as a slow acting oxidant that is functional throughout the entire manufacturing process. Now ascorbic acid and food acid replace an oxidizing agent of potassium bromate.

'355 patent, col. 6, ll. 3-9 (emphasis added). 1 Thus, from the beginning of the patent in the Abstract through the Detailed Description, Kim consistently defined "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process."

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1 Lastly, the Detailed Description concludes:

Summarizing, it has been discovered that a food acid added in an effective amount slows down oxidation of ascorbic acid to dehydroascorbic acid in a dough, thereby ascorbic acid is changed to a slow acting oxidant and a phosphate increases the amount of complex formation with food acid and metal ion. Thus, the ascorbic acid composition essentially comprises ascorbic acid, food acid, and phosphate and replaces an oxidizing agent of potassium bromate or other oxidizing agents. The potassium bromate replacer provided in the present invention is a more effective oxidant than [sic] potassium bromate because potassium bromate has little effect on oxidation of dough during mixing and the early stages of proofing.

'355 patent, col. 7, l. 62 to col. 8, l. 7.

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In my view, the prosecution history also is instructive. In a response to an office action, in which she amended her claims, Kim stated:

3 to 30 ppm ascorbic acid combined with 5 to 60 ppm dicarboxylic acids does not act as a slow acting oxidant due to insufficient amounts of ascorbic acid and dicarboxylic acids used; thus, it is not potassium bromate replacer. About 10-300 ppm ascorbic acid combined with about 150-2,000 ppm food acid acts as a slow acting oxidant; thus, it is potassium bromate replacer . . . .

Kim continued, "[T]he potassium bromate replacer composition developed is a new, slow acting oxidant that is effective during mixing, proofing, and baking." 2 These statements are consistent with statements made almost four years earlier in response to an office action in a related application. There, Kim wrote: "It has been discovered that a food acid added in an effective amount slows down oxidation of ascorbic acid to dehydroascorbic [sic] acid in dough. Thus, ascorbic acid is changed to a slow acting oxidant that is functional throughout the entire manufacturing process. Now ascorbic acid and food acid replace potassium bromate." It seems to me that these passages from the prosecution history, when combined with the statements in the specification, compel the conclusion that Kim was acting as her own lexicographer by defining a "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process."

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2 Furthermore, in an earlier response, Kim wrote:

The applicant's invention uses food acids to slow down oxidation of ascorbic acid to dehydroasorbic acid, resulting in the improvement in the role of ascorbic acid as an oxidant in the breadmaking process . . . . Phosphate is used to enhance the complexing power of food by increasing the pH value of the dough . . . . Accordingly, the ascorbic acid is changed from a fast acting oxidant to a slow acting oxidant that is effective and functional during mixing, proofing, and baking.

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The majority construes the term "potassium bromate replacer" as "a composition that performs essentially the same function in the production of bread as would potassium bromate (by strengthening the dough, increasing loaf volume, and contributing to fine crumb grain) . . . ." Majority Op. at 6. For me, the problem with the majority's claim construction is that it focuses almost exclusively on the Background section of the '355 patent and fails to take into account the remainder of the specification and the prosecution history. The majority quotes the Background as stating that "the potassium bromate

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replacer provided in the present invention is a more effective oxidant than potassium bromate . . . ." Majority op. at 6 (quoting '355 patent, col. 3, ll. 1-2). The majority then relies on the statement that

[o]xidizing agents provide strengthening of dough during the manufacturing process of yeast-leavened products. As a result, oxidizing agents are used to provide greater loaf volume, improve internal characteristics such as grain and texture, and enhance symmetry and keeping quality of yeast-leavened products.

'355 patent, col. 1, ll. 20-27. This passage appears at the beginning of the Background section. It discusses oxidizing agents generally--not the present invention specifically.

In sum, in my view, the intrinsic record's repeated defining of a "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process" overwhelms the portion of the specification upon which the majority relies for its claim construction. Thus, I would conclude that Kim acted as her own lexicographer in defining a "potassium bromate replacer" as "a slow acting oxidant that is functional throughout the entire manufacturing process." See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1370 (Fed. Cir. 2005) ("When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description."). Accordingly, I would vacate the judgment of the district court and remand the case for an infringement analysis under this claim construction.
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4. "powder"

The Sony Defendants contend that the term "powder" refers to an aggregation of loose, small, solid particles. According to the Sony Defendants, "powder" is a more limited term than "particles," and "powder" must be loose, free flowing and unaligned. Because "powder" must be loose and free flowing, the Sony Defendants contend that "powder" is different than magnetic tape, which is not loose or free flowing.

In response, Bayer contends that the '799 Patent places no such limitations on the term "powder." Bayer contends that the term "powder" refers to a conglomeration of individual particles, which may be loose, free flowing and unaligned, but which need not be. Thus, Bayer contends that the term "powder" describes metal particles both before and after they are embedded into magnetic tape.

The Court addressed the parties' respective arguments in its decision on the Sony Defendants' Motion For Summary Judgment That Tape Is Not Powder. (D.I. 217, 326). In denying the Sony Defendants' motion, the Court stated:

After a review of the intrinsic evidence, the Court concludes that the term 'powder' is not limited in the manner SEL contends. Powder is used to describe a conglomeration of individual particles. Powder may be loose, free flowing and unaligned, but it need not be.

(D.I. 326 at 19). The Court is not persuaded that its prior conclusion was erroneous, and therefore, for purposes of claim construction, the Court adheres to the above-stated definition of the term "powder."
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4. predefined region is construed to mean a localized area on a surface which is, was, or is intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface.

Affymetrix and Incyte assert that "predefined region" as used in the '305 patent has the same meaning as the parties respectively proffered for "discrete known regions" in the '934 patent.

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Hyseq contends that "Predefined regions" is a localized area on a surface which is, was, or is intended to be activated for the formation of a polymer.

The Court notes that Hyseq's arguments parallel Incyte's arguments and accordingly adopts the same construction for "predefined regions" as it did for "discrete known regions" in the '934 patent.
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G. Predetermined Time/Temperature

The parties agree that the word predetermined means "established in advance." (Sunny Fresh Opening Markman Br. at 39-40; Michael Foods Resp. at 33.) Yet the parties disagree on whether "predetermined" is based upon USDA preapproval requirements and/or is limited to commercial runs. 12 The patent states that "terms used herein have their standard meaning in accordance with industry and regulatory usage." (See Kempf Aff., Ex. 1, Col. 8, ll. 58-60). The patent also incorporates by reference USDA regulation 7 C.F.R. 59.570(b)(1985), which sets forth pasteurization requirements. (Kempf Aff., Ex. 1, Col. 8, ll. 58-60). Moreover, the patent does not indicate an intention to define the term "predetermined" other than according to industry and regulatory usage. The court therefore construes the term "predetermined" to be based upon relevant USDA requirements because the patent specifically incorporates USDA regulations. 13

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12 The parties disputes the construction of the term "predetermined" in the following claim terms: "predetermined holding temperature," "predetermined holding time," "heated to a predetermined real temperature," "the liquid whole egg product is heated to a predetermined real temperature by contacting said liquid whole egg product to a heated surface," and "wherein said predetermined temperature and predetermined time are selected to impart said predetermined shelf life."

13 In its initial Markman brief, Michael Foods correctly asserts that the court should look to the relevant Code of Federal Regulations to define "liquid egg product" and "sterilize." (See, e.g., Michael Foods Initial Markman Br. at 14, 39.) For the same reason that the Michael Foods asserts that the court should consider those regulations in defining those terms, Michael Foods errs in arguing that the court should not consider those regulations to define "predetermined."

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However, the court's construction of the term "predetermined" does not include the additional limitation of "commercial" as the Patent Office has previously stated that the claims are not limited to commercial process. (See, e.g., Kempf Aff., Ex. 46 at 45, 51, 77-78.) Moreover, the court's construction of "predetermined" in no way allows Sunny Fresh to let its process drift either intentionally or unintentionally. See Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1574 (Fed. Cir. 1995)("[A] finding of infringement is not dependent on a finding of negligence or culpable intent by the wrongdoer. An infringement, like a trespass, may be committed unknowingly."). The court therefore construes the term predetermined to mean established in advanced based upon USDA pre-approval requirements but not limited to commercial runs.
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H. A Preselected Refrigerated Shelf Life

The parties disagree upon the construction of the term "preselected." Michael Foods contends that a "preselected refrigerated shelf life" means a refrigerated shelf life known ahead of time, (Michael Foods' Initial Markman Br. at 25), while Sunny Fresh asserts that the term means a desired shelf life chosen by (1) selecting a point on a line or in a region of Figure 4 of the patents which will provide the desired shelf life, (2) specifying a total thermal treatment based on an equivalent time and equivalent temperature in advance of the start of the pasteurization process, (3) establishing the operating conditions of the particular pasteurizing apparatus being used that will provide the selected thermal treatment and

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(4) obtaining USDA pre-approval of a process for commercial use and product labeling. (See Kempf Aff. Ex. 26 at 2.)

Contrary to Sunny Fresh's assertion, the claims do not require use of Figure 4. For instance, Claim 15 of the '225 patent provides, in relevant part:

A method of making a packaged liquid whole egg product characterized by a preselected refrigerated shelf life of about four weeks to about 36 weeks…

Claim 15 does not even mention Figure 4.

The specification discusses Figure 4 and the term "preselected shelf life" as follows:

A liquid whole egg product having a preselected shelf life of from about 4-36 weeks is made by selecting a point on a line or in a region which will provide the desired shelf life, determining the equivalent time and equivalent temperature which correspond to the point selected, and - preferably through the use of the equivalent point method - establishing the operating conditions on the particular pasteurizing apparatus being used that will provide the selected thermal treatment. Products have shelf lives not depicted in FIG. 4 are made by extrapolating the teachings of the figure in light of the teachings above.

(Kempf Aff., Ex. 1, Col.6 l. 67; Col. 7 ll. 1-11.) While this portion of the specification provides a guide as to how to establish "preselected shelf life," the specification does not require use of Figure 4 to determine "preselected shelf life." The specification emphasizes that the patent does not require use of Figure 4 when stating that the graphs, including Figure 4, "are … not to be taken as limiting the present invention, as departures could be made therefrom while still capturing and benefitting from the teachings of the invention." (Kempf Aff., Ex. 1, Col. 7, ll. 32-35.) To read such a limitation into the claims would violate the cannon of claim construction that the court cannot import a limitation from the specification's general discussion. See, e.g., Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1278 (Fed. Cir. 1995)(finding the district court "erred by importing unnecessary functional limitations into the claim.").

The prosecution history supports the court's analysis. In Papetti's, Judge Barry found that "preselected shelf life" does not incorporate or refer to Figure 4 of the patents, using similar analysis:

Moreover, the claims do not require reference to Figure 4. For example, claim 15 of the '408 patent provides that what is claim is:

A method of making a package liquid whole egg product characterized by a preselected shelf life of about four weeks to about 36 weeks… wherein said holding temperature and holding time are selected to impart said preselected shelf life.

Clearly the language of this claim does not require one to use Figure 4, which is not even mentioned (only Figure 3 is mentioned here), to choose time and temperature operating conditions. The language merely requires that operating conditions be established so as to produce an extended shelf life product. Even if the claim language itself were unclear, the specification states that the graphs are not to be taken as limiting the invention. ('425 Patent, Col. 7, Lines 33-36; '425 Patent, Col. 15, Lines 39-43.) See Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 ("where a specification does not require a limitation, that limitation should not be read from the specification into the claims.")

Plaintiffs correctly argue that the "preselection methodology" Papetti's interprets the claim to require is not, in fact, required. The language "heated to a predetermined real temperature" of claim 4 of the '408 patent, for example, simply means that the temperature must be known ahead of time.

fn17 Neither Official Action issued by the PTO in the reissue proceeding, to be discussed infra, suggests that use of any of the graphs is required.

(Kempf Aff., Ex. 8 at 17-18.) Thus, based upon the intrinsic evidence, the court construes the term "preselected" to mean known ahead of time. 14

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14 In contrast to Sunny Food's discussion of the term "predetermined," Sunny Fresh has given no explanation of why the requirement of USDA pre-approval of a process for commercial use and product labeling should be incorporated into the patent. The court finds that an ordinary person skilled in the industry at the relevant time would not have understood the patent to include such a requirement.

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9. "pre-treated"

Plaintiff's proposed construction of "pre-treated" is: "refers to a condition of jojoba oil starting material indicating that the jojoba oil has been subjected to reaction, processing, conditioning, and/or the like, prior to saponification." Defendant's proposed construction is: "refers to jojoba oil as having been chemically modified prior to saponification."

Defendant did not provide a proposed construction of "pre-treated" in the claim construction briefing and provided no arguments in support of the construction it now proposes.2 Plaintiff's proposed construction will be adopted.

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2 Defendant only provided a proposed construction in the parties' joint statement of disputed terms, which was filed after the briefing and hearings were concluded.

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V. Disputed term in claim 10 of Patent '127 and claim 4 of Patent '717: "pre-treated"

The claims at issue here state: "The method as claimed in claim 1 wherein said sample is a blood, plasma or urine sample pre-treated with a disulphide bond cleaving reducing agent." (emphasis added.) Axis-Shield argues that "pre-treated" means "altered with one or more agents prior to with (sic) contacting the sample with the homocysteine converting agent." General Atomics' proposed construction is, "treated with a preparatory treatment prior to contacting the sample with the homocysteine converting agent. Pre-treated does not include the conversion of homocysteine in the sample by the homocysteine converting enzyme."

The patents teach only two methods of pretreatment. The first frees homocysteine in the sample from other proteins to which it may be bound. See Patent '127, 4:14-22. The second method removes naturally-occurring (endogenous) analyte molecules already present in the sample to prevent them from skewing the results. See Patent '127,6:63-7:19. Pretreatment does, therefore, as Axis-Shield argues, "alter" the blood, plasma, or urine sample prior to engaging in steps (i) and (ii) of claim 1.

There is no dispute that pretreatment must occur before steps (i) and (ii) of claim 1, and thus before the homocysteine in the sample is converted, during steps (i) and (ii) of claim 1, by the homocysteine converting enzyme. Logically, the homocysteine cannot also be converted by the same homocysteine converting enzyme during the pretreatment, so General Atomics is correct that "'[p]re-treated' does not include the conversion of homocysteine in the sample by the homocysteine converting enzyme." However, as this conclusion flows logically from the construction of claim 1, it need not be included in the construction of "pre-treated."

Accordingly, the proper construction of "pre-treated" is "altered, prior to steps (i) and (ii) of claim 1."

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Claim Construction

At issue is whether Baxter's sevoflurane product, containing no more than 130 ppm of water, falls within the claims of Abbott's '176 Patent. Claim 1 of the Patent states:

What is claimed is:

1. An anesthetic composition comprising:

a quantity of sevoflurane; and

a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol.

(PX 1, '176 Patent, Claim 1, Col. 11, Lines 21-28.)

In its review of this Court's construction of that claim, the Federal Circuit held that the phrase "in an effective amount" means "the amount of Lewis acid Inhibitor that will prevent the degradation of sevoflurane by a Lewis acid." Abbott, 334 F.3d at 1277-78. Thus, this Court is left with the task of construing the phrase "to prevent degradation" to determine whether the Baxter product has a sufficient amount of water to prevent degradation and, therefore, infringes Abbott's '176 patent.

When construing a claim, intrinsic evidence -- the language of the patent and its prosecution history -- is considered first. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention.") The Court gives the words of the claim the ordinary and customary meaning that they "would have to a person of ordinary skill in the art in question at the time of the invention," Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), unless it appears from the specification or the file history that they were used differently by the inventor. Carroll Touch, Inc. v. Electro. Mech. Sys. Inc., 15 F.3d 1573, 1577 (Fed. Cir. 1993).

Sometimes, "the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges." Phillips, 415 F.3d at 1314. In other cases, like this one, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." Id To divine the ordinary meaning of claim language in those cases, courts may use "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," including "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. (quotation omitted).

If the meaning of a disputed term is clear from the intrinsic evidence, as informed by evidence about the relevant technology, then no extrinsic evidence as to the proper claim construction may be used. Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 715 (Fed. Cir. 1998). If, however, intrinsic evidence does not fully illuminate the meaning of a claim, a trial court may rely on extrinsic evidence, including expert testimony. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996).

The phrase "to prevent degradation" is not defined in the Patent. Thus, we must determine what a person of ordinary skill in the art would have understood that term to mean at the time the application for the '176 Patent was filed.

It is clear that the word prevent, as used in the phrase "to prevent degradation" is a term of art. In laymen's terms, "to prevent" means "to keep from happening." See WEBSTER'S NEW WORLD DICTIONARY 1067 (3rd College ed. 1988). But Drs. Loffredo and Jung, both of whom are skilled in the art, agree that it is impossible to stop all degradation of sevoflurane. Dr. Loffredo testified:
Q. When you did your analysis and concluded that Claim 1 of the Abbott water patent covered the Baxter product with 130 parts per million of water, did you assume that the use of the word "prevent" meant that all degradation must be prevented in

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order for the amount of water to be effective?

A. In this context, the word "prevent," you can never prevent all degradation. There will always be some level of degradation in any product.

(Tr. at 435, Dr. Loffredo.) Similarly, Dr. Jung testified:
[To] slow down, essentially, and inhibit, make it slower. You never get zero degradation. The likelihood of having something which is 99.999 percent pure is extremely low. There's always some degradation. And so what "prevent degradation" means is to slow it down so that the material is not very degraded. That is, it is inhibited the degradation process... [I]t's very had to get any compound with no degradation. It's essentially impossible.

(Id. at 239.) If it is not possible to prevent all degradation, then the term "prevent degradation" as used in the patent must mean to prevent degradation past a certain point.

The next step then, must be to determine what that point is. In other words at what level is degradation so great that the amount of Lewis acid inhibitor has not been sufficient to "prevent degradation." Or to put it another way, when, according to the teachings of the patent to one of ordinary skill in the art is sevoflurane deemed to be degraded. Dr. Jung says the term is illuminated by the experiments described in examples 1-6 in the Patent. Those experiments were performed by Abbott during its investigation to determine if sevoflurane degraded after being exposed to a Lewis acid.

Abbott used activated alumina in its tests. Activated alumina is made using a chemical called aluminum oxide. If you take aluminum oxide and heat it or treat it with hydrochloric acid, you can activate the Lewis acid by driving off the water molecules that are normally present. Thus activated, the alumina will cause the sevoflurane to degrade. Abbott chose alumina as the Lewis acid with which to conduct its tests because it was what Abbott's scientists thought would be present in many circumstances and was certainly present in the glass container itself.

The test described in example 1 of the Patent involved sprinkling alumina into a container of sevoflurane and then incubating it to accelerate the reaction which, without incubation, would take six to nine months to occur. After heating the mixture, Abbott looked for degradation. Next, Abbott added water to the mix and did the same experiment to see if the water was effective in preventing degradation. In this first example, Abbott took 20, 10 and 50 milligrams, respectively, of the Lewis acid and added it to sevoflurane, incubated the mixtures and then analyzed them. The results, according to Dr. Loffredo, demonstrated the Lewis acid-inhibiting quality of water:
You could put a certain amount of water in and cut off the degradation process, and this was -- I think the significance of this was to show that if you had an inadvertent introduction of Lewis acids, this idea of sprinkling in, okay, that certainly the water present at an appropriate level would stop that from causing a reaction to proceed.

(Id. at 116, Dr. Loffredo.)

Another experiment, reflected in example 2 of the Patent, involved putting sevoflurane into a glass ampule that was flame-sealed to cause the formation of Lewis acid sites. Once formed, the Lewis acid sites caused the sevoflurane to degrade. Abbott did the same thing with another flame-sealed glass ampule, but the sevoflurane in this ampule was saturated with water. Abbott then heated both of the ampules at a high temperature. The results: the non-saturated sevoflurane degraded while the sevoflurane saturated with water did not. Dr. Loffredo referred to this as "sort of an on-and-off mechanism . . . . You've introduced an active Lewis acid site, and you've stopped that site from degrading sevoflurane by the addition of the inhibitor." (Id. at 118, Dr. Loffredo.)

Abbott expanded on its second experiment in the test described in example 3. Instead of using one ampule, it used multiple ampules with varying levels of water and varying levels of heat. The results showed that a water level of 595 ppm produced a pH of 5 and very low levels of degradation. With water levels of 303 ppm, 206 ppm, and 109 ppm, respectively, the results showed high levels of degradation.

Example 4 of the Patent describes additional ampule experiments at what Dr. Loffredo testified was a more reasonable temperature range, i.e., 60 degrees for 144 hours and 40 degrees for 200 hours, as depicted in Table 3. Under these conditions, sevoflurane with 109 ppm of water had a pH of zero, indicating a high acid concentration, and large quantities of degradants. The degradation was minimized when more water was added. Example 4 suggests that as the temperature

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increases, the amount of water required to inhibit the degradation of sevoflurane will also increase.

The experiment described in example 5 is similar to the first experiment. It was designed to assess what happened in an actual bottle that Abbott used to package its sevoflurane. Abbott took glass containers that had been previously etched, so the surface was known to be Lewis acid activated, and added sevoflurane with water to them to demonstrate that a Lewis acid inhibitor would inhibit the degradation that had occurred in the glass bottles of sevoflurane that Abbott had previously recalled. The tests showed that sevoflurane in previously etched bottles would degrade, but the degradation was inhibited by adding 400 ppm of water.

In example 7, Abbott rolled a previously etched glass container in saturated sevoflurane and then tested it in the same way as in example 5. The idea was to coat the etched glass with water to see if the coating would prevent degradation. The result was that the sevoflurane experienced virtually no degradation. Dr. Jung says that this example demonstrates not only that coating a container with a Lewis acid inhibitor decreases degradation, but that the container itself can be a Lewis acid inhibitor. (Tr. at 247.)

According to Dr. Jung, a person of ordinary skill in the art would conclude from the patent examples that degradation as it is used in Claim 1 means sevoflurane with total impurities of 4000 ppm or more. (Id. at 287.) Conversely, a person of ordinary skill in the art would understand that sevoflurane with less than 4000 ppm of degradants is not degraded. (Id. at 241.)

Dr. Jung based this conclusion primarily on his reading of example 6 of the patent. When asked how the '176 patent defines degradation, Dr. Jung replied by referencing Table 6 (columns 9 and 10), which reflects the results of example 6. (Id at 239-40.) Dr. Jung said that Table 6 shows that when only 20 ppm of water is added to sevoflurane that had been introduced to Lewis acid, large amounts of degradation -- from 4100 to 6500 ppm of impurities -- resulted. (Id.) However, when 400 ppm of water was added to the sevoflurane, the number of degradants was reduced to a range of approximately 100 to 600 ppm. (Id.)

According to Dr. Jung, Figures 4 and 5 of the Patent, which are bar graphs of the impurity levels in the sevoflurane tested in examples 5 and 6, also demonstrate that degradation of sevoflurane is inhibited by the addition of water at 400 ppm. (Id. at 240.) Dr. Jung says the graphs in Figures 4 and 5 show no impurities in the sevoflurane with 400 ppm of water tested in example 6 and at least 4100 ppm of impurities in the sevoflurane with only 20 ppm of water. (Id.) From these graphs, Dr. Jung concludes that a person of ordinary skill in the art would interpret the word degraded as it is used in the '176 Patent to mean sevoflurane with no less than 4000 ppm of degradants. (Id. at 239-40, Dr. Jung.)

But the Patent does not say that the study group with 400 ppm of water is not degraded. Rather, it says that Figures 4 and 5 "demonstrate that the degradation of sevoflurane is inhibited by the addition of water at 400 ppm." (PX 1, Col. 10, Lines 38-40.) In fact, at column 10, line 25, the Patent states that the HFIP concentration, which indicates the presence of hydrofluoric acid, of that study group is "quite high and suggests that the glass surfaces were still somewhat active." This language directly contradicts Dr. Jung's contention that the study group is not degraded.

Moreover, even a cursory examination of the graphs in Figures 4 and 5 reveals that they cannot bear the weight that Dr. Jung ascribes to them. Based on the visual representations of the bar graphs in Figures 4 and 5, Dr. Jung equates "inhibited," as it is used to describe those Figures, with eliminated: "[I]f you look at those bar graphs and you see bar graphs going off scale for the control group and you see zero bar graph for the other, that tells me this is undegraded." (Tr. at 290, Dr. Jung.) The visual representations, however, are clearly imprecise. They are extremely small -- occupying no more than a few inches in the center of an 8 1/2 x 11 inch page -- and measure impurities by the thousands of parts per millions. It is impossible to tell from these tiny, summary graphs precisely what level of impurities was found in any bottle tested.

Moreover, the conclusion that Dr. Jung draws from these graphs contradicts other portions of testimony. At one point, Dr. Jung testified that a person skilled in the art would understand the word degradation to refer to the pH level of the sevoflurane. (Id. at 243.) In his view, sevoflurane with a pH level of 1.5 is highly degraded. (Id.) Dr. Loffredo, who performed the tests described in the Patent, said that bottle 1 in Example 6, had a pH level of 1.5. (Id. at 500.) Yet, according to Dr. Jung, Figures 4 and 5 of the Patent show that bottle 1 of example 6 was not degraded. (Id. at 240-41.)

Like his reading of Figures 4 and 5, Dr. Jung's pH theory does not hold up to scrutiny. According to Dr. Jung, Table 2, column 7, of the patent differentiates between a pH reading of 0, which is extremely acidic, and a pH readings of 5 and

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above, which are described in the language below the table as reflecting the inhibition of degradation of the sevoflurane. (Id. at 243.) In Dr. Jung's view, Table 2 demonstrates that a pH reading of 5 or higher is non-degraded. (Id.) Table 3, Dr. Jung said, narrows the pH range further, by teaching that a pH level of 3.5 is degraded while a level of 5.0 is not degraded. (Id. at 243-44.)

Dr. Jung admits that the Patent does not explicitly define as degraded sevoflurane with a pH level between 3.5 and 5.0. (Id. at 244-45.) But, he said, a person of ordinary skill in the art would know that sevoflurane with a pH level of 4 and above is not degraded because that is the pH level of many foods people commonly consume. (Id.) Because vinegar, Coca-Cola and orange juice, for instance, have pH levels as low as 3.5 and they do not harm us, the use of sevoflurane with a pH level of 4.0 should not harm us either. (Id.)

Dr. Jung's conclusion rests on the assumption that lung and mucous tissue have the same ability to tolerate inhaled, acidic sevoflurane as the stomach has to tolerate acidic foods in solid or liquid form. This seems a highly dubious assumption and, at any rate, one for which there is no support in the record. n2

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n2 During cross examination regarding another matter, Dr. Jung volunteered that he is not an expert on patient safety. (Tr. at 281, 283, 294.) He seems to forget this self-proclaimed limitation on his expertise when he offers this opinion, which amounts to nothing less than an opinion as to how acidic sevoflurane can still be safe for patient use.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Moreover, Dr. Loffredo, who is also skilled in the art, contradicted Dr. Jung's testimony. According to Dr. Loffredo, a trained scientist would conclude from the patent examples that there is no single pH cutoff point below which sevoflurane is considered degraded. (Id. at 484-87.) Rather, Dr.Loffredo said a person skilled in the art would understand that no conclusion about the pH level dividing line can be drawn from any single experiment, but must be drawn from the entire data set, that is, all of the examples in the patent. (See id. at 505, Dr. Loffredo ("[The pH] value is subjective and depends upon the nature of the experiment that you're doing.").)

Given the contradictory testimony of Drs. Jung and Loffredo, the Court concludes that intrinsic evidence is insufficient to determine the ordinary meaning of the term "degradation" to persons skilled in the art. Thus, The Court will turn to extrinsic evidence for guidance.

Sources of extrinsic evidence are the specifications for various sevoflurane products. According to Dr. Loffredo, those specifications provide a practical measure of degradation: the amount of chemical change that renders the product useless during its announced shelf life. (See id. at 375-76, 435-37, Dr. Loffredo.) After all, the purpose of producing sevoflurane is to provide a product that dispensers of medical services can use safely. If the Lewis acid inhibitor prevents the product from becoming so chemically decomposed or altered that it cannot be used during its shelf life, then it can be said to be sufficient to prevent degradation.

Dr. Cromack, one of the Patent's inventors, testified in a similar vein. In his view, if medical-grade sevoflurane becomes unusable because of exposure to Lewis acid, the sevoflurane would be considered degraded within the meaning of the Patent. (Id. at 1217-18, Dr. Cromack.) Moreover, he said, the sevoflurane is degraded if it falls outside the product specification. (Id. at 1308, Dr. Cromack.)

Baxter, Abbott, the FDA and the U.S. Pharmacopeia all have specifications that require sevoflurane to have less than 300 ppm of total impurities. (Id. at 437, 1506-07, 1576, Dr. Lessor; 376-77, Dr. Loffredo.) The Court, therefore, finds that for purposes of the Patent, sevoflurane is degraded if it contains degradants in amounts greater than 300 ppm.

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B. "Prevention of cerebral ischemia"

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The next term in dispute is "prevention of cerebral ischemia." The proper construction follows from the construction of "cerebral ischemia." I recommend that this term be construed as "prevention of an imbalance of neuronal stimulation mechanisms."

Plaintiffs propose that "prevention of cerebral ischemia" be construed as "prevention of impairment or further impairment, i.e., degeneration and loss of nerve cells, after cerebral ischemia," with "cerebral ischemia" defined as I have recommended above. Plaintiffs contend that the patentee defined this term. Id. For support, they point to the following specification statement: "It has been found unexpectedly that the use of these compounds prevents an impairment or further impairment, i.e., degeneration and loss of nerve cells, after ischemia." (JA3 at col. 3 lines 7-10) I do not agree with Plaintiffs that this specification statement clearly, deliberately, and precisely defines "prevention of cerebral ischemia." If this statement is defining anything, it seems to be defining "impairment" -- as "degeneration and loss of nerve cells, after ischemia" -- and not defining "prevention of cerebral ischemia." Moreover, the specification statement on which Plaintiffs rely references "ischemia," not "cerebral ischemia."

The Defendants' proposed constructions, however, are no more persuasive. The Majority Defendants propose that "prevention of cerebral ischemia" be construed as "prevention of the destruction of brain cells that results from an acute interruption of blood supply to the brain." Having rejected the Majority Defendants' proposed construction of "cerebral ischemia," there is nothing to recommend adopting their construction of "prevention of cerebral ischemia." Even the Majority Defendants concede that they have not proposed the plain and ordinary meaning of the term, which would be something like the "prevention of an acute interruption of blood flow to the brain." See Tr. at 199-200.

Apotex, by contrast, does propose to construe "prevention of cerebral ischemia" consistent with its plain and ordinary meaning, as "prevention of an acute interruption of blood supply to the brain." (D.I. 222 at 12 n.5) However, for the same reasons I recommend rejecting Apotex's proposed construction of "cerebral ischemia," I likewise recommend rejecting Apotex's proposed construction of "prevention of cerebral ischemia." Fundamentally, the '703 patent discloses an invention that works on neuronal activity, not on blood flow. Thus, one of ordinary skill in the art would not read "prevention of cerebral ischemia" in the context of the '703 patent to refer to "prevention of an acute interruption of blood supply to the brain."

Therefore, I recommend that "prevention of cerebral ischemia" be construed as "prevention of an imbalance of neuronal stimulation mechanisms."
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B. "Prevention of cerebral ischemia" and "treatment of cerebral ischemia"

The Magistrate Judge recommends that the term "prevention of cerebral ischemia" in claim 1 be construed to mean "prevention of an imbalance of neuronal stimulation mechanisms." (D.I. 373 at 32.) This construction follows from the construction of "cerebral ischemia." The Magistrate Judge recommends that the term "treatment of cerebral ischemia" in claims 1 and 14 be construed to mean "an antagonistic intervention with regard to the N-methyl-D-aspartate [NMDA] receptor channels." (Id. at 32.)

The defendants' objections to both of these constructions stems from their insistence that "cerebral ischemia" should be construed as an interruption of blood supply to the brain. As described above such a construction is contrary to the specification, which defines cerebral ischemia with reference to an imbalance in neuronal stimulation mechanisms and states that "in order to treat this pathological situation, an antagonistic intervention is required with regard to the NMDA receptor channels." (D.I. 243 at JA2, col. 2 lines 53-55.) Thus, for the reasons set forth in the Report and Recommendation, the court will adopt the Magistrate Judge's construction for these terms.
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1. Primer

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In defendants' invention, fluorescent tags are attached to primers in order to facilitate analysis of DNA fragments. Defendants argue that the term "primer" should be defined broadly as "a short nucleic acid of defined sequence that serves as a locus for initiation of polymerization at a predetermined site on a template." On the other hand, plaintiff argues that "primer" is more particularly defined in the '748 patent's specification at column 4, lines 29 through 36 and this definition is controlling. I conclude that plaintiff is correct in arguing that the more specific definition of "primer" in the specification should be applied to that term as it is used in the '748 patent's claims.

"As a general rule, all terms in a patent claim are to be given their plain, ordinary and accustomed meaning to one of ordinary skill in the relevant art" and "unless compelled to do otherwise, a court will give a claim term the full range of its ordinary meaning as understood by an artisan of ordinary skill." Rexnord Corp., 274 F.3d 1336, 2001 WL 1456191 at *3 However, "patent law permits the patentee to choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." Id. 274 F.3d 1336, [Wl] at *4. When a patent applicant chooses to wear the lexicographer hat, "the definition selected by the patent applicant controls." Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

In the case of the '748 patent, the applicants chose to be their own lexicographers. In the first paragraph under the specification heading "detailed description of the invention," the applicants explain that use of a radioactive label was necessary "in previous methods of DNA sequencing, including those based on Sanger," but that "this problem is overcome in the present invention" by the use of fluorescent labels attached to primers. The second paragraph proceeds to set out the specific characteristics the primers must have for purposes of the invention disclosed in the '748 patent.

The primers must have the following characteristics: 1) They must have a free 3' hydroxyl group to allow chain extension by the polymerase. 2) They must be complementary to a unique region 3' of the cloned insert. 3) They must be sufficiently long to hybridize to form a unique, stable duplex. 4) The chromophore or fluorophore must not interfere with the hybridization or prevent 3'-end extension by the polymerase.

'748 Patent at Col. 4, lines 29-36. This definition describes clearly four distinct characteristics that "the primers must have," repeatedly using the word "must" before each of the four characteristics, apparently to emphasize their essential nature. Defendants argue strenuously that the enumeration of the primers' required characteristics and the repeated references to DNA sequencing amount to no more than a discussion of a preferred embodiment or an example of one possible application of the invention. I disagree. Defendants are correct that "an attribute of [a] preferred embodiment cannot be read into [a] claim as a limitation," Burke, Inc. v. Bruno Independent Living Aids, Inc., 183 F.3d 1334, 1341 (Fed. Cir. 1999), but this is not a case of limiting broad claims to a narrower preferred embodiment. Indeed, the definition of primers in the specification is followed three paragraphs later, in the fifth paragraph of the "detailed description of the invention," by the first mention of a preferred embodiment. The preferred embodiment involves coupling "a set of four fluorophores with different emission spectra, respectively" to the primers. '748 Patent at Col. 4, lines 45-46. The term "primers" is clearly defined before the preferred embodiment of the invention is discussed and well before any examples are given. There is no indication that the specification's copious references to DNA sequencing are merely part of a discussion of a preferred application or that the specification's definition of primers is merely a component of a preferred embodiment. Rather, it is the use of four different emission spectra (presumably one for each of the four nucleotides that make up nucleic acid molecules) that constitutes the preferred embodiment.

This conclusion is bolstered by a reading of other sections of the specification, which are replete with discussions of sequencing analysis. The section titled "background of the invention" closes by noting that "the invention of the present patent application addresses problems associated with DNA sequencing procedures and is believed to represent a significant advance in the art." '748 Patent at Col. 3. lines 1-4. The section titled "summary of the invention" opens by noting that "this invention comprises, a novel process for the elctrophoetic [sic] analysis of DNA fragments produced in DNA sequencing operations wherein chromophores or fluorophores are used to tag the DNA fragments produced by the sequencing chemistry." '748 Patent at Col. 3, lines 8-12. It goes on to note that "it is an object of this invention to provide a novel process for the sequence analysis of DNA." '748 Patent at Col. 3, lines 41-42. And, as noted, before any discussion of examples or a preferred embodiment appears, the term "primers" is defined unequivocally. '748 Patent at Col. 4, lines 29-36. This defeats defendants' argument that plaintiff is attempting to improperly import into the claims a definition of "primers" from a mere preferred embodiment dealing with DNA sequencing.

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The prosecution history also supports this construction, as defendants relied on the definition of "primers" in the specification for a variety of purposes, including support of the claim language when it was originally submitted. For instance, on March 19, 1996, defendants submitted a second preliminary amendment adding new claims that eventually matured into the issued claims of the '748 patent. In order to demonstrate that these new claims found support in the specification, defendants pointed the examiner to the definition of "primers" that now appears at column 4, lines 29 through 36 of the '748 patent.

Claims 75, 76, 81, 82, 92, 98 and 101 recite primers, oligonucleotides, oligonucleotide fragments, or portions of oligonucleotides that have been base-paired or hybridized to a template or a complementary sequence. Support is found in the specification on [Col. 4, lines 31-32] ('They [the primers] must be complementary to a unique region …') and at [Col. 4, lines 34-36] ('The chromophore or fluorophore must not interfere with the hybridization…').

Thus, in seeking approval of their claims, defendants relied on the very definition of "primers" that they now seek to disavow.

Defendants also relied on the definition of "primers" to overcome objections by the patent examiner. On March 23, 1998, the examiner rejected certain claims "as indefinite over the recitation 'said chromophore and fluorophore attached' because it is unclear as to where, how and to what the label is attached." In response, defendants submitted amendments dated June 23, 1998, to make clear that the primers and the chromophores or fluorophores of the invention are chemically coupled. Citing again to the definition of "primers" in the specification, defendants

noted that [Col. 4, lines 34-36] recites that 'the chromophore or fluorophore must not interfere with the hybridization or prevent 3'-end extension by the polymerase' which is consistent with the Examiner's interpretation of the claim. Accordingly, one of skill in the art, upon reading the claim and the specification would known [sic] how and where the chromophore or fluorophore should be attached to the primer, i.e., so that it would not interfere with 3'-end extension.

Here again, defendants pointed to the definition of "primers" in the specification, and observed that by reading the definition of primers in the specification in conjunction with the claims, one of skill in the art would be able to understand how the invention functions.

Defendants point also to the special requirements of the "primers" outlined in the specification to distinguish the primers of the '748 patent from those of the prior art. On May 1, 1997, defendants responded to the examiner's rejection of certain claims as anticipated by Draper, arguing that the primers of the claimed invention differed from the primers taught by the Draper reference. According to defendants, "Draper et al. does not teach a primer as defined herein and therefore, also does not teach a primer hybridized to a template. … The polynucleotides of Draper et al. are not always capable of forming stable duplexes with the template." On the other hand, the primers defined in the '748 patent's specification "must be sufficiently long to hybridize to form a unique, stable duplex." '748 Patent at Col. 4, lines 32-34. Therefore, defendants relied on the unique requirements of the primers defined in the specification to escape the reach of the prior art.

In summary, a review of the intrinsic evidence, including the claims, specification and prosecution history, makes clear that the primers of the '748 patent are defined expressly in the specification. '748 Patent at Col. 4, lines 29-36. "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics, 90 F.3d at 1582. The '748 patent's specification expressly defines "primers" at column 4, lines 29 through 36 in the "detailed description of the invention." Further, the prosecution history, which "is often of critical significance in determining the meaning of the claims " id reveals that the defendants relied on the express definition of "primers" in the specification to support the claim language it submitted to the Patent and Trademark Office, to overcome objections by the patent examiner and to escape the constraints of the prior art. "Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." Southwall, 54 F.3d at 1576. I conclude that plaintiff's construction of the term "primer" is correct.

Defendants put much emphasis on the fact that one of ordinary skill in the art would understand "primer" to be a broad term meaning "a short nucleic acid of defined sequence that serves as a locus for initiation of polymerization at a predetermined site on a template," and argue that this definition is borne out by technical dictionaries, the declaration of its expert, Dr. Peter Gilham, and even a glossary of terms on plaintiff's own website. This argument is unpersuasive for several reasons. First, as plaintiff argued at the December 7 hearing, the dictionary definitions defendants point to differ from the proposed

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construction of the term "primer" offered by defendants and their expert. For instance, defendants point to the definition of "primer" in the Concise Dictionary of Biomedicine and Molecular Biology 752 (1996): "A short sequence of RNA or DNA that serves as a starting point for DNA synthesis," and to the definition in the Dictionary of Biochemistry and Molecular Biology, 381 (2d ed. 1989): "In nucleic acid chemistry, a primer is a short, single-stranded RNA or DNA segment that functions as the starting point for the polymerization of nucleotides." Unlike defendants' proposed construction, these definitions do not require that the requisite segment or sequence of DNA be "defined" or that the starting point for polymerization be a "predetermined site on a template." As plaintiff points out, these additional limitations appear only in the defendants' proposed construction of "primers" and would exclude classes of primers that fall within the dictionary definitions, including random primers and primers that are extended by non-template dependent polymerases. Decl. of David A. Casimir in Supp. of Plt.'s Rebuttal of Defs.' Claim Construction Submission Regarding U.S. Patent No. 6,200,748, Ex. 1 at 6. This indicates that defendants are not seeking to adopt the general meaning of the term "primer" as found in the technical dictionaries they cite. It also calls into question whether one skilled in the art would understand the term "primer" in the '748 patent's claims to be consistent with the defendants' proposed construction.

Defendants argue also that plaintiff's proposed construction of "primers" cannot be correct because the invention claimed in the '748 patent is not limited to DNA sequencing. In support of this argument, defendants point to the "summary of the invention" section of the specification and highlight the following passage:

> It is an object of this invention to provide a novel process for the sequence analysis of DNA.
>
> It is another object of our invention to provide a novel system for the analysis of DNA fragments.

Accordingly, defendants argue, the invention is not limited to use in DNA sequencing but applies more broadly to a wide range of nucleic analysis. I am not persuaded by this argument. The first cited sentence refers to a "novel process" for DNA sequence analysis, while the second sentence refers to a "novel system" for analyzing DNA fragments. Plaintiff argues persuasively that the "novel system" referred to in the second sentence is the "automated DNA sequencer gel electrophoretic system," a device that is illustrated in Figure 2 of the patent and is identified in the specification in the section titled "brief description of the drawings." Therefore, the novel system referred to in the second sentence is a DNA sequencer and the DNA fragments referred to are fragments from a sequencing reaction. Accordingly, the specification's "summary of the invention" does not support defendants' argument that the invention of the '748 patent applies broadly to a wide range of nucleic analysis. Indeed, the specification is replete with references to DNA sequencing. As noted above, there is no indication that these references to sequencing are intended as a discussion of a mere preferred embodiment. Accordingly, I conclude that the "primers" of the 748 patent's claims

> must have the following characteristics: 1) They must have a free 3' hydroxyl group to allow chain extension by the polymerase. 2) They must be complementary to a unique region 3' of the cloned insert. 3) They must be sufficiently long to hybridize to form a unique, stable duplex. 4) The chromophore or fluorophore must not interfere with the hybridization or prevent 3'-end extension by the polymerase.

'748 Patent at Col. 4, lines 29-36.
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C. "Principal Protein Source"

We decline the parties' invitation to "construe" this phrase except so far as to note that Patent 728 teaches rennet casein as the majority source (i.e. more than 50%) of the product's protein. We will not determine when the measurement is to be taken because we cannot. Even the parties' arguments regarding the issue demonstrate the impossibility of deciding that issue in a vacuum. At the Markman hearing, Schreiber argued that "later added sources of protein do not count." Later than what? Saputo's argument is no clearer absent some context: "[A] product [that] possesses a greater percentage of protein derived from some source other than rennet casein does not fall within this claim limitation." Saputo's statement begs the question of when to measure the protein source; when does the batter (for lack of a better word) become "a product." We invite the parties to revisit the issue in their summary judgment briefs.
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II

Teva challenges the district court's construction of the claim limitation requiring the composition to be administered "prior to the onset of [a woman's] menstrual period." The district court construed that phrase to mean treatments administered "prior to the onset of a woman's menstrual period, including those that go on continuously thereafter." Teva argues that the district court erred by construing the claim to include dosing regimens "that go on continuously thereafter." Instead, Teva contends, the district court should have construed the term to refer to dosing "limited to administration during part or all of the 14 days prior to her menstrual period and up to 3 days after," i. e., dosing limited essentially to the luteal phase only.

We disagree with Teva's proposed claim construction. The district court's interpretation is consistent with both the claim and the specification, which do not limit the dosing to the luteal phase. The claim language does not provide that dosing should take place within a certain time frame. Rather, the claim simply states that the recited composition should be administered "prior to the onset of [the woman's] menstrual period." '998 patent, col. 7, line 10. The specification also does not suggest a discrete time period for dosing, but states only that dosing should begin "prior to the expected onset of [a woman's] menstrual period." Id., col. 5, ll. 14-15; see id., col. 6, ll. 51-52 (providing, as an example, the administration of fluoxetine "starting two weeks prior to the expected onset of a subject's menstrual period").

In support of its argument that the dosing period is limited to the luteal phase. Teva relies on language from the specification stating that the dosing period for fluoxetine "will generally begin 1 to 14 days prior to menstruation and may continue for several days (e. g., 3 days) after onset of menstruation." Id., col. 2, ll. 47-49; see id., col. 5, ll. 17-19. That statement, however, is preceded by the statement that "the length of time during which [fluoxetine] will be given varies on an individual basis." Id., col. 2, ll. 45-46; see id., col. 5, ll. 15-16. Hence, the specification is not as restrictive as Teva suggests and does not support limiting the dosing scheme to exclude any regimen that includes administration of the drug outside the luteal phrase.

Teva argues that the prosecution history supports construing the claim to permit dosing only during the luteal phase. Teva points to the prosecution history of a parent patent application, U.S. Patent Serial No. 111,771 ("the '771 application"), and asserts that the applicants added a luteal phase dosing limitation to the claims in that application in order to overcome a rejection. Teva's argument lacks merit because the prosecution history merely reflects the applicant's statement that dosing should occur "prior to and during the late luteal phase." That characterization of the timing requirement indicates that dosing should take place during the luteal phase, but it does not suggest that administration of the drug must terminate at any time. Hence, the prosecution history does not carry the weight Teva attributes to it.

Finally, Teva argues that the district court's claim construction is incorrect because in the case of continuous dosing no monthly treatment regime can be said to "begin prior to the onset of [a woman's] menstrual period." The claim language is broad, and we agree with the district court that it does not exclude a regime of continuous dosing. The language of the claim would plainly cover a treatment regime that began, for example, 20 days before the onset of the woman's menstrual period and continued for eight days after the end of the period, with a two-day hiatus before the beginning of the next treatment cycle. That being so, it would be highly artificial to hold that the claim would cease to apply if the treatment regime were extended to include administration of the composition during the two-day hiatus period. Although it is awkward to characterize a continuous treatment regime as having a beginning point each month, the claim by its terms merely requires that the treatment occur "prior to" the onset of menses, and that plainly occurs in the case of continuous treatment. We therefore affirm the district court's construction of the disputed claim term, at least insofar as it applies to a regime of continuous coverage. Teva does not contest a finding of literal infringement under the district court's claim construction. Accordingly, we affirm the judgment of infringement.

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1. Construction Of "Probe Array"

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Affymetrix's proposed construction of "probe array" is "a collection of surface-immobilized molecules, at least two of which are different, that can be recognized by a particular target." (D.I. 243 at 21.) Illumina's proposed construction is "a collection of probes, at least two of which are different, that are surface-immobilized (chemically linked) to a single surface." (D.I. 240 at 21.) The parties agree that the Court's construction should incorporate the express definitions of "probe" and "array" provided in the '531 patent's glossary. (D.I. 250 at 16; D.I. 240 at 21.) The parties' dispute is over Illumina's contention that the construction should be further limited to require that the molecules be attached via a chemical linkage and that they be attached to a single surface.

The term "probe array" is explicitly defined in claim 1 of the '531 patent: "each probe array comprising a collection of probes, at least two of which are different, arranged in a spacially defined and physically addressable manner . . . ." ('531 patent, col. 12, ll. 46-49.) Furthermore, this definition is identical to the '531 patent's glossary definition of "array." (Id., col. 4, ll. 1-3.) For the same reasons discussed in section II.B.1. supra, the Court concludes that this definition, chosen by the inventors acting as their own lexicographers, governs here.

The further limitations Illumina seeks are not required. Illumina contends that the language of claim 1 supports its position that a "probe array" must be on a single surface. The language Illumina relies upon reads: "a wafer comprising on its surface a plurality of probe arrays . . . ." (D.I. 240 at 21.) However, while this language arguably might limit the wafer to a single surface, it says nothing about the surfaces of the probe arrays.

Illumina also points to various embodiments in support of the claim limitations it urges. (Id. at 22-23.) The Court concludes that importation of limitations from those embodiments into the claims would be improper. See JVW Enterprises, 424 F.3d at 1335.

Finally, Illumina cites language from the prosecution history. (D.I. 240 at 24.) Like the claim language, however, the cited language refers to the surface of the wafer, not the surfaces of the probe arrays. For the reasons discussed above, the Court construes "probe array" to mean "a collection of probes, at least two of which are different, arranged in a spacially defined and physically addressable manner."

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2. Construction Of "Probe Intensity"

Affymetrix's proposed construction of "probe intensity" is "a detectable signal, e.g. fluorescence." (Id.) Illumina's proposed construction is "intensity from a labeled sample nucleic acid hybridized to a probe location." (D.I. 240 at 32.) The dispute here is whether the Court should construe "probe intensity" to require that the intensity come from a labeled sample nucleic acid and that the intensity be associated with a particular probe location. The Court concludes that Illumina's construction is appropriate.

Affymetrix contends that there are many ways to generate a signal indicating the extent of hybridization other than by labeling the sample sequence that hybridizes to a probe. (D.I. 243 at 32.) While not disputing that all of the embodiments and examples in the '716 patent's specification describe "probe intensities" as coming from labeled sample nucleic acids, Affymetrix argues that imposing such a limitation on the claims would be an improper importation from the specification. (Id. at 33.) However, this is not a case of improperly importing a limitation from the specification into the claims, but of reading a claim in light of the specification. See Phillips, 415 F.3d at 1323 (stating that "there is sometimes a fine line between reading a claim in light of the specification and reading a limitation into the claim from the specification"). It may be true, as Affymetrix argues, that there are other methods of generating signals indicating the extent of hybridization. It is clear, however, from the specification's consistent descriptions of "probe intensities" as arising from labeled sample sequences, and its lack of discussion of any alternative method, that "what the inventors actually invented and intended to envelop with [their claims]," Phillips, 415 F.3d at 1316, is a system in which "probe intensities" are generated by labeled sample nucleic acids hybridized to probes.

Similarly, all of the embodiments and examples in the specification indicate that the "probe intensities" must be associated with known probe locations. Moreover, during patent prosecution, the inventors clearly and unmistakably limited the scope of their claims to require that the location of the hybridized probes be known. (See D.I. 244, Ex. DD at 14 (distinguishing

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prior art references on the grounds that "[i]n the present invention, the locations of the hybridized probes are known . . . .").) Therefore, the Court construes "probe intensity" to mean "intensity from a labeled sample nucleic acid hybridized to a probe location."

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5. "A Process for Stabilizing"

The next term to construe is from claim 16, "a process for stabilizing." Pejic Decl. 3d Ex. 1, col. 6:54-56. Schwarz Pharma alleges that there is no dispute regarding the meaning of this claim term because Paddock admits that it will practice "a process for stabilizing," and Paddock fails to challenge the validity of the claim. Paddock construes the language to mean "a method of making a pharmaceutical dosage form of an ACE inhibitor in which cyclization has been inhibited." Paddock asserts that its claim construction is consistent with that used in the related litigation, and Schwarz Pharma should be bound by the previous construction. n10

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n10 In the related litigation, the New Jersey District Court found that "a process for stabilizing" means "a method of making a pharmaceutical dosage form of an ACE inhibitor in which cyclization has been inhibited." Warner-Lambert II, No. 99-922, at 2. Teva did not appeal the district court's grant of summary judgment of infringement with respect to claim 16. Warner-Lambert III, 418 F.3d at 1339 n.12.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

As discussed with regard to the first claim term, Paddock's agreement that it will practice "a process for stabilizing" does not mean that the parties agree as to what the term means, or that the Court can not construe it. The parties failed to agree to the meaning of the term in the Joint Claim Construction Statement. The purpose of the '450 patent is ultimately to create an effective dosage form of an ACE inhibitor in which cyclization and hydrolysis are inhibited. However, the "Description of the Invention" section of the specification distinguishes the "pharmaceutical composition," the "process for stabilizing," and the "method of making a pharmaceutical dosage form:"

The invention deals with:
I. A pharmaceutical composition which contains:
(a) a drug component which comprises an ACE inhibitor which is susceptible to retard cyclization, hydrolysis, and/or discoloration, and
(b) an amount of a stabilizer component or components suitable to retard cyclization, hydrolysis, and/or discoloration, and
II. A process for stabilizing an ACE inhibitor drug which comprises the step of contacting the drug with:
(a) an amount of stabilizer(s) suitable to retard cyclization and/or hydrolysis.
III. A method of making a pharmaceutical dosage form which comprises the step of including in the formulation suitable amounts of:
(a) an ACE inhibitor, and
(b) stabilizers which contain alkaline agents alone or alkaline agents in combination with saccharides (i.e., sugars) as one or more cyclization, hydrolysis, and discoloration inhibitor(s).

Pejic Decl. 3d Ex. 1, col. 1:44-63. Claim 16 does not appear to be directed toward making a particular dosage form. Therefore, there is no need to import a limitation regarding "a pharmaceutical dosage form" into claim 16. The term "a process for stabilizing" is construed as "a method of making a drug product containing an ACE inhibitor in which cyclization has been inhibited."

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a. "processing"

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The first dispute involves whether or not the term "processing" should be defined. Defendants propose a definition that "processing means producing fractions of sufficient purity that they are at least ready for refinement to commercial products." (Joint Stmt. p. 15). Plaintiff asserts that no definition is needed. Although the court agrees with Defendants that a definition may be necessary because Claim 14 describes "a method for processing," the court finds Defendants' interpretation unnecessarily restrictive. (DTX 3, Col. 14). The court construes the term "processing" to mean "producing fractions from a beet-derived sucrose-containing material utilizing the steps described in the claim." This definition describes the term as it is used in the language of the claim.
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1. "produce a greater anabolic state"

Plaintiffs contend that this term means "promoting a greater gain of total body weight or statural growth." According to Plaintiffs, here, Plaintiff Genentech acted as its own lexicographer; the patent's specification contains an explicit definition of producing an anabolic state, and that definition must be followed. Defendants disagree, arguing that the term should be given its common and ordinary meaning. Defendants state the term means "characterized by or promoting constructive metabolism." Defendants contend that the intrinsic evidence, including the specification, is consistent with the common and ordinary meaning of the term.

The specification provides,

As used herein, the words "producing an anabolic state" refer to promoting total body weight gain as well as the dynamics of statural growth experienced by an individual during infancy, childhood, and adolescence as depicted by a normal growth curve, i.e., growth of linear-producing bone plate driven by chondrocytes, as well as growth of osteoblast cells, derived from a different part of the bone. Restoration of normal growth patterns would allow the patient to approach a more satisfactory growth curve. Examples of patients that are relatively resistant to GH but require treatment to induce an anabolic effect include those with Turner's Syndrome, GH-deficient children who grow poorly in response to GH treatment, children who experience a slowing or retardation in their normal growth curve about 2-3 years before their growth plate closes, so that GH administered alone would no longer increase growth of the children, so-called short normal children, and patients where the IGF-I response to GH has been blocked chemically (i.e., by glucocorticoid treatment) or by a natural condition such as in adult patients where the IGF-I response to GH is naturally reduced. In addition, the method herein is useful for treating pregnant women who are in a catabolic state and/or experience loss of bone mass, for treating women with osteoporosis, and for repairing bone.

'151 patent, col. 6:38-68.

Plaintiffs focus on the first sentence of the above paragraph; Defendants focus on the last sentence. Defendants also highlight other parts of the specification that they contend support their definition. As they note, the Field of the Invention states, "This invention relates to a method for producing an anabolic or growth promoting state in a mammal. More specifically, this invention is directed to the use of a complex of IGF-I and one or more of its binding proteins to produce an anabolic state, including enhancing whole body and bone growth." '151 patent, col. 1:7-12. The specification also states, "Efficacious results are measured by increases in body weight gain, lean body mass, bone growth, or statutory [sic] growth approximating the normal range, or by other criteria for measuring the anabolic state of a mammal, as defined herein, as are deemed appropriate by the practitioner." '151 patent, col. 8:2-7. These statements and the last sentence in the paragraph quoted above, however, do not support Defendants1 definition. The patent and its history do not contain the term "constructive metabolism." The last sentence of the quoted paragraph, stating that the method described is useful for treating pregnant women and for repairing bone, is not part of the definition; it does not broaden the definition beyond what the patent explicitly states that it is. Rather, that sentence provides examples of patients and conditions that can also benefit from the method for producing an anabolic state as claimed in the patent.

Plaintiffs are correct that the specification's definition of "produce a greater anabolic state" controls. Therefore, the Court construes the term "produce a greater anabolic state" to mean promoting greater total body weight gain as well as statural growth.

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(2) Defendants propose that the phrase "a thermal fogging mist is produced" be construed as "a thermal fogging mist is produced at the outlet of the thermal fogger." Plaintiffs argue that the phrase need not be construed, that defendants have admitted infringement, and that the proposed definition violates the doctrine of claim differentiation.

Despite the fact that defendants' proposed definition mentions a "thermal fogger" that has an "outlet," defendants are not attempting to impose a limitation related to the device from which the fogging mist emanates. Rather, they are attempting to identify the point at which the composition, temperature, and velocity of the fogging mist are measured in order to determine whether the elements of claim 1 are satisfied. The intrinsic and extrinsic evidence support a finding that the characteristics of the fogging mist must be evaluated at the point where the mist is released from the mist-generating device for the treatment of fruit and/or vegetables, not at some point within the fogging device.

Claim 1 requires that a thermal fogging mist be produced from the specified components and that the droplets comprising the mist have a temperature of 200 to 280 [degrees] and a linear velocity of between 110 and 140 m/s. The natural and unstrained understanding of the claim is that all of the elements must be satisfied at the same time. Because there is no temporal distinction between the production of the mist and the existence of the required composition, temperature, and velocity elements, the mist must have the specified characteristics at the time it is produced.

The question then becomes when is the mist "produced?" The invention, as set forth in claim 1, establishes a process for thermal fogging for the treatment of fruits and vegetables. In particular, the inventors claimed to have discovered that the release of a hotter, faster, non-aqueous mist is beneficial because it increases the stability of the mist formed and creates a thin and homogeneous coating on the fruits and vegetables. See Col. 1, ll. 11-61. Creating a thermal fogging mist with the specified characteristics somewhere inside a machine or canister simply is not the invention: the mist is not "produced" until it is discharged from the fogging apparatus to perform its stated purpose. Measurements taken within the fogging device would not accurately reflect the mist that is ultimately generated because the droplets would slow, cool, and agglomerate to the point where the resulting mist might be no better than the mists generated using the prior art.

Given that the mist is produced at the time it is released or discharged from the fogging device, the composition, temperature, and velocity elements of claim 1 must be satisfied at that point. This understanding is further supported by the specification and the prosecution history. The inventors discuss temperature and velocity measurements that are taken at the point where the fogging mist is released, or discharged, from the fogging device. No other measurement site is mentioned or suggested. When explaining the benefits of the invention, the inventors differentiate prior art based on the lower temperatures and/or velocities produced "at the outlet of the thermal fogging device." See, e.g., Col. 1, ll. 38-41; Decl. of Edgar R. Cataxinos (Dkt. # 56), Ex. 2. The comparisons drawn and claims made by the inventors would make no sense if the point of measurement were to vary widely: the claimed benefits of the invention would not result if the specified temperature and velocity were reached at some point within the apparatus but were allowed to dissipate by the time the mist was released from the fogging device. Thus, the language of the claim, the specification, and the prosecution history all support a finding that the mist is "produced" when it is released or discharged from the fogging device and must at that time satisfy the other elements of claim 1.

Extrinsic evidence from John Forsythe and Dr. Hyde supports this conclusion. Both gentlemen are skilled in the art and understand that measurements related to temperature and velocity of fogging mist occur at the point of discharge. Nothing in the patent suggests that the inventors intended to utilize some other, undisclosed measuring point. In fact, whenever a measuring point is mentioned in the specification or prosecution history, it comports with the industry standard as presented by defendants' witnesses. Mr. Forsythe further testified that it would be extremely difficult, if not impossible, to measure temperatures and velocities prior to discharge because the insertion of measuring devices would affect the characteristics that were being measured. Counsel's acknowledgment that, if plaintiffs' proposed construction were adopted, he might have a difficult time getting accurate readings from within the misting apparatus also suggests that an internal measurement point is simply not the industry norm. Because one skilled in the art would understand that the specified characteristics of the mist must be measured where the fogging mist is released or discharged from the fogging device, both the extrinsic and intrinsic evidence support the Court's analysis.

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Plaintiffs' admission and claim differentiation arguments are unpersuasive. Defendants admit that the accused product produces a thermal fog. Whether the fog has the proper composition or is "produced" as that term is defined above is not established. Plaintiffs' claim differentiation argument is based on the fact that claims 5 and 6 of the '364 patent refer to a cylindrical channel as the source of the fogging mist. Because claim 1 is silent regarding how or where the mist originates, plaintiffs argue that claim 1 should not be construed to include reference to "the outlet of the thermal fogger." See Phillips, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."). The Court agrees only to the extent that the doctrine of claim differentiation suggests that claim 1 is not limited to a particular type of fogging device or outlet. As long as a thermal fogging mist is produced with the specified composition, temperature, and velocity, claim 1 is satisfied. It does not matter how the mist is generated or whether the device utilizes a cylindrical channel. As discussed above, however, the specified attributes of the fogging mist must exist at the time the mist is released or discharged from the fogging device for the treatment of fruits or vegetables.

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DISCUSSION

On appeal, SmithKline argues that the district court improperly "ignored the process limitations of the two product-by-process claims in the '944 patent" when it determined validity. SmithKline's Br. at 17, 23-24, 27. In other words, if the district court had treated the process steps recited in the '944 patent as claim limitations, it would have found that the '723 patent did not anticipate the '944 patent, or that there was a genuine issue of fact over whether the '723 patent disclosed those process limitations.

SmithKline misunderstands the nature of anticipation. As set forth below, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

I

A product-by-process claim is "one in which the product is defined at least in part in terms of the method or process by which it is made." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158, 109 S. Ct. 971, 103 L. Ed. 2d 118 n. (1989) (quoting D. Chisum, Patents § 8.05, at 8-67 (1988)). While the patent statute does not provide for product-by-process claims, the courts have long recognized the appropriateness of such claims. See, e.g., In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985); In re Brown, 59 C.C.P.A. 1036, 459 F.2d 531, 535 (C.C.P.A. 1972); In re Steppan, 55 C.C.P.A. 791, 394 F.2d 1013, 1018 (C.C.P.A. 1967). The purpose of product-by-process claims is to allow inventors to claim "an otherwise patentable product that resists definition by other than the process by which it is made." In re Thorpe, 777 F.2d at 697. Thus, an inventor will not be foreclosed from the benefits of the patent system simply because a product is difficult to describe in words, or its structure is insufficiently understood. Today, however, product-by-process claims are used by inventors even if the invention could have been described independent of the process. 2

2 See 3 Chisum on Patents § 8.05[2][c] (2003 ed.) (explaining that the Patent and Trademark Office ("PTO") has rejected the "necessity rule" which permitted product-by-process claims only in cases where the product was otherwise undefinable; instead, the PTO has opted to allow product-by-process claims so long as the definiteness requirement is met).

This court has previously considered the scope of product-by-process claims. In Scripps, we held that the product-by-process claims at issue were not limited by the process steps within those claims. 927 F.2d at 1583. There, the patent concerned a protein, Factor VIII: C, essential to blood clotting. Id. at 1568. The patent contained product-by-process claims directed at the product made in accordance with a particular process, also claimed in the patent. Id. at 1570. The court found that Factor VIII:C that was produced by a different process would nonetheless infringe the product-by-process claims because:

In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of the product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.

Id. at 1583.

A year later this court decided Atlantic Thermoplastics. There, we held that the process steps in a product-by-process claim do serve as claim limitations. 970 F.2d at 846-47. The patent in Atlantic Thermoplastics concerned shock absorbing shoe innersoles. Id. at 835. The patentee argued that the defendant had infringed its product-by-process claim. Id. at 836. Finding

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that the accused products were made by a different process than that claimed in the patent's product-by-process claim, the court determined that the patent did not extend to cover the product as made by any process. Id. At 846-47. This court stated that "in light of Supreme Court caselaw and the history of product-by-process claims, this court acknowledges that infringement analysis proceeds with reference to the patent claims. Thus, process terms in product-by-process claims serve as limitations in determining infringement." Id.

A sharply divided court denied rehearing en banc of Atlantic Thermoplastics, with four judges dissenting in four separate opinions. See 970 F.2d 834, rehearing en banc denied, 974 F.2d 1299 (concurring opinion), 974 F.2d 1279 (dissenting opinions). Judge Newman, joined by Judges Rich and Lourie, urged that the panel in Atlantic Thermoplastics had incorrectly adopted a blanket rule that the process steps of a product-by-process claim should be automatically treated as claim limitations. 974 F.2d at 1282-83. In their view, the process steps should sometimes be treated as claim limitations and sometimes not, depending on the "class of claim" at issue. Id. at 1284.

Some commentators, like the district court here, have perceived a conflict between Scripps, where the court construed the product-by-process claims without reference to the process steps, and Atlantic Thermosplastics, where the court read the process steps as claim limitations. 3 We need not address this controversy here. The issue here does not turn on how broadly or narrowly we construe the '944 patent's claims, for it is undisputed that the product that is the subject of the patent's claims is paroxetine. Rather the issue is whether the '723 patent anticipated the '944 product-by-process patent, when the '723 patent broadly claimed paroxetine without regard to the process by which it was made. 4 Thus, the ultimate issue is simply whether the prior art disclosure of a product precludes a future claim to that same product when it is made by an allegedly novel process. 5

3 See Trs. of Columbia Univ. v. Roche Diagnostics GMBH, 126 F. Supp. 2d 16, 31 (D. Mass. 2000) (noting that after Scripps and Atlantic Thermoplastics, the district court is left in the unenviable position of choosing the better rule); DeKalb Genetics Corp. v. Northrup King Co., 1997 U.S. Dist. LEXIS 14275, No. 96 C 50169, 1997 WL 587492, *2 (N. D. Ill. Aug. 14, 1997) (finding that Scripps and Atlantic Thermoplastics are "in seeming conflict"); Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7, 8 (D. Mass. 1993) (noting the "disagreement" between Scripps and Atlantic Thermoplastics); see also 3 Chisum on Patents § 8.05[1][b] ("Federal Circuit panel decisions in 1991 and 1992 differed over whether a product-by-process claim can be infringed by a product not made by a specified process."); Conflicts in Federal Circuit Patent Law Decisions, 11 Fed. Cir. B.J. 723, 765 (2002) (describing controversy).

4 The '723 patent also contained a separate process claim for the preparation of the paroxetine; however, this claim has not been implicated here. See '723 patent, col. 10, ll. 36-38.

5 Although we have previously held the '723 patent invalid, SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1346 (Fed. Cir. 2005), it can still, of course, anticipate a later product patent. By virtue of publication, the '723 patent has become prior art. 1 Chisum on Patents § 3.06 (2003 ed.) ("A United States patent is published on the date it is issued and thereby becomes a printed publication within the meaning of Section 102(a) as well as a patent.").

II

Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process. It has long been established that one cannot avoid anticipation by an earlier product disclosure by claiming the same product more narrowly, that is, by claiming the product as produced by a particular process. This was the exact issue in In re Thorpe. There, the patent concerned a composition that was used in carbonless copy paper systems. 777 F.2d at 696. The composition was know n in the prior art, but was previously made using zinc dibenzoate. In a product-by-process claim, Thorpe claimed the same composition made by a process that used zinc oxide and benzoic acid, rather than zinc dibenzoate. The court upheld the PTO's rejection of the claim. Id. at 698. It held that "if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Id. at 697. In re Thorpe has never been overruled and has been followed for many years by the 6 PTO. The current MPEP states:

[Even] though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

MPEP § 2113 (8th ed., Rev. 2, May 2004) (quoting In re Thorpe, 777 F.2d at 698).

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6 The 1987 revision of the PTO's Manual of Patent Examining Procedure ("MPEP") stated the rule for product-by-process claims as follows: "When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection . . . is appropriate." Atlantic Thermoplastics Co., Inc., 974 F.2d at 1288 (denial of rehearing en banc) (quoting MPEP § 706.03(e) (5th ed., Rev. 6, Oct. 1987)) (Newman, J., dissenting). Later revisions of the MPEP contain the identical quote. See, e.g., MPEP § 2113 (6th ed., Rev. 3, July 1997); MPEP § 2113 (7th ed., Rev. 1, Feb. 2000); MPEP § 2113 (8th ed., Rev. 1, Feb. 2003).

At the time of In re Thorpe, the rule as articulated was hardly new. Long before In re Thorpe, our predecessor court, the Court of Customs and Patent Appeals, consistently held that product-by-process claims could not validly claim products already known in the art. See In re Fessmann, 489 F.2d 742, 744-45 (C.C.P.A. 1975); In re Johnson, 55 C.C.P.A. 1463, 394 F.2d 591, 594-95 (C.C.P.A. 1968); In re Stephens, 52 C.C.P.A. 1409, 345 F.2d 1020, 1023, 1965 Dec. Comm'r Pat. 707 (C.C.P.A. 1965) ("We think it well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product."); In re Dilnot 49 C.C.P.A. 1015, 300 F.2d 945, 950, 1962 Dec. Comm'r Pat. 217 (C.C.P.A. 1962) ("The addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product."); In re Moeller, 28 C.C.P.A. 932, 117 F.2d 565, 567, 1941 Dec. Comm'r Pat. 316 (C.C.P.A. 1941) ("The article itself must be inventive and patentably distinct from such articles disclosed in the prior art."); In re Ewert, 22 C.C.P.A. 1262, 77 F.2d 498, 499, 1935 Dec. Comm'r Pat. 626 (C.C.P.A. 1935); In re Brawn, 22 C.C.P.A. 1239, 77 F.2d 362, 363, 1935 Dec. Comm'r Pat. 603 (C.C.P.A. 1935); In re Harvey, 21 C.C.P.A. 1155, 71 F.2d 200, 201, 1934 Dec. Comm'r Pat. 544 (C.C.P.A. 1934). This rule is also supported by earlier Supreme Court cases. For example, in Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) ("BASF"), natural alizarine was already known in the art. Id. at 311. However, BASF obtained a patent covering artificial alizarine, as produced by a bromine reaction process. Id. at 296. The accused infringer, Cochrane, then sold artificial alizarine made by a different, sulfuric acid reaction process. Id. at 309. The Court reasoned that if the BASF patent were construed to cover the product itself, it would be invalid because the product was old. Id. at 311-12. The Court stated that "while a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time. . . ." Id. at 311. As the Atlantic Thermoplastics panel recognized, the BASF court thus held that "a patent applicant could not obtain exclusive rights to a product in the prior art by adding a process limitation to the product claim." Atlantic Thermoplastics, 970 F.2d at 841 (citing BASF, 111 U.S. at 311); see also Tri-Wall Containers, Inc. v. United States, 187 Ct. Cl. 326, 408 F.2d 748, 750-51 (Ct. Cl. 1969), cert. denied, 396 U.S. 828, 90 S. Ct. 78, 24 L. Ed. 2d 79 (1969) (following BASF, and stating that "the addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product"). This understanding of BASF has been recognized by leading commentators. See, e.g., 3 Chisum on Patents § 8.05[3] (2003 ed.) (citing BASF for the proposition that "even through a product may be claimed in terms of the process of making it, the product still must be new in structural terms in order to meet the novelty requirement."). Other Supreme Court cases have reached the same conclusion. See Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 373, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938) ("Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced."); Wood-Paper Patent, 90 U.S. 566, 596, 23 L. Ed. 31 (1874).
As this history of cases from the Supreme Court, our court, and our predecessor court make clear, anticipation by an earlier product patent cannot be avoided by claiming the same product more narrowly in a product-process claim. It makes no difference here whether the '944 patent's product-by-process claims are construed broadly to cover the product made by any process or narrowly to cover only the product made by a dry admixing process. Either way, anticipation by an earlier product disclosure (which disclosed the product itself) cannot be avoided. While the process set forth in the product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. We agree with the district court's conclusion that the '723 patent disclosure anticipated the identical product claimed by the '944 patent even though that product was produced by an allegedly novel 7 process.

7 Contrary to the dissent's suggestion, the court does not hold that a claim to a product is never limited by process limitations. We simply hold that a prior art disclosure of a product precludes a future claim to that same product, even if it is made by an allegedly novel process. We take no position on whether a product-by-process claim is construed with reference to the process steps.

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III

In the district court, the parties differed on a second issue, that is, whether the product produced by the process claimed in the '944 patent was, in fact, a different product than that disclosed in the '723 patent. If those product-by-process claims produced a different product than that disclosed by the '723 patent, there would be an argument that the '723 patent disclosure did not anticipate. In re Luck, 476 F.2d 650, 653 (C.C.P.A. 1973). On this appeal, in response to Apotex's argument that the issue had been waived by failure to include it in the opening brief, SmithKline did not point out in its reply brief where the issue had been presented in its opening brief. Questioned by this court at oral argument as to whether this second issue has been properly preserved on appeal, SmithKline urged that it had raised this issue on appeal and was challenging the district court's finding regarding the novelty of the product claimed by the '944 patent. We conclude that this issue has been waived for failure to brief it on appeal.

Our law is well established that arguments not raised in the opening brief are waived. See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1320-21 n.3 (Fed. Cir. 2005). SmithKline's opening brief focused on the perceived conflict between Scripps and Atlantic Thermoplastics to the exclusion of arguments that the product produced by the allegedly novel process was novel. Indeed, SmithKline argued that "this Court should address only the issue that provided the basis for the district court--its incorrect interpretation of the product-by-process claims of the '944 patent." SmithKline's Br. at 30. SmithKline failed to include in the Argument section of its opening brief an argument that, contrary to the district court's finding, the product claimed in the '944 patent is it self different from that disclosed in the '723 patent. To be sure, there are various places in its opening brief where SmithKline alluded that the paroxetine tablets claimed in the '944 patent were different from tablets disclosed in the prior art and expressed its disagreement with the district court's determination that the product produced by the '944 patent was not new. In its Argument section, SmithKline stated "there were numerous factual disputes between the parties, including the scope and content of the prior art, and the unexpected improvement of the claimed invention over the prior art." SmithKline's Br. at 19. Similarly, on page 27 of its brief, SmithKline stated:

Here, the district court held that "the product of the '944 Patent cannot be distinguished from the paroxetine tablets in the prior art . . . ." (A64.) Accordingly, although SB's disagrees with that determination, if the district court was determined to follow Scripps, it should have then considered the process limitations of the product-by-process claims of the '944 patent as essential limitations in determining validity.

SmithKline's Br. at 27 (emphasis added). 8 In a footnote to this sentence, SmithKline further noted that the '944 patent's tablets have a "significantly reduced tendency to pink, and have a different 'finger print' than tablets made by a [prior art] wet granulation process. The district court erroneously believed it did not need to consider such differences because they were not literally recited in the claim. This was an error of law." Id. at n.8. This footnote is the only statement that even approaches a substantive argument on novelty in the entire Argument section of SmithKline's opening brief.

8 In various other places, SmithKline noted its disagreement with the district court's decision and stated in conclusory fashion that factual disputes "should have precluded the district court from entering summary judgment." See, e.g., SmithKline's Br. at 2, 13-14.

We find that these mere statements of disagreement with the district court as to the existence of factual disputes do not amount to a developed argument. See, e.g., Anderson v. City of Boston, 375 F.3d 71, 91 (1st Cir. 2004) ("When a party includes no developed argumentation on a point . . . we treat the argument as waived under our well established rule."); Tolbert v. Queens Coll., 242 F.3d 58, 75 (2d Cir. 2001) ("It is a settled appellate rule that issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.") (internal quotation marks omitted); United States v. Elder, 90 F.3d 1110, 1118 (6th Cir. 1996) (same); Laborers' Int'l Union of N. Am. v. Foster Wheeler Corp., 26 F.3d 375, 398 (3d Cir. 1994), cert denied, 513 U.S. 946, 115 S. Ct. 356, 115 S. Ct. 357, 130 L. Ed. 2d 311 (1994) ("An issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue . . . will not suffice to bring that issue before this '") court. (quoting Simmons v. City of Philadelphia, 947 F.2d 1042, 1066 (3d Cir. 1991), cert. denied, 503 U.S. 985, 112 S. Ct. 1671, 118 L. Ed. 2d 391 (1992)); United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991) ("A skeletal 'argument', really nothing more than an assertion, does not preserve a claim. . . . Especially not when the brief presents a passel of other arguments . . . . Judges are not like pigs, hunting for truffles buried in briefs.").

Further, arguments raised in footnotes are not preserved. See Cross Med. Prods., Inc., 424 F.3d at 1320-21 n.3 (holding that an argument raised in a footnote in an opening brief was waived as not properly raised); Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368, 1375 n.4 (Fed. Cir. 2005) (finding that an argument raised in a footnote in an opening cross-appeal

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brief and then more fully in the reply brief, was not properly raised); Graphic Controls Corp. v. Utah Med. Prods., 149 F.3d 1382, 1385 (Fed. Cir. 1998) (finding that an argument raised in a footnote which in turn referenced the full argument in the appendix was not preserved) (citing Fed. R. of App. P. 28(a)(6) which then stated that "the argument [in the appellant's brief] must contain the contentions of the appellant on the issues presented, and the reasons therefor, with citations to the authorities . . . and parts of the record relied on . . . ."). 9

9 As we held in Becton Dickinson and Co. v. C.R. Bard, Inc., 922 F.2d 792, 800 (Fed. Cir. 1990), this court nonetheless has discretion to consider arguments that are not properly raised in the opening brief. But here, as in Becton, we see no reason to exercise that discretion.

Therefore, SmithKline has not established that the district court erred in its ultimate judgment holding the '944 patent anticipated by the '723 patent.
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In this case the district court found "anticipation" based on a claim construction that erased critical limitations of the claim. At issue are claims that require the use of a specified process for the commercial production of tablets of the known pharmaceutical product paroxetine (Paxil(R)). The claims are simple and straightforward, and state the processing steps that produce the stabilized tableted product, as follows:

1. A pharmaceutical composition in tablet form containing paroxetine, produced on a commercial scale by a process which comprises the steps of:
a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
c) compressing the mixture into tablets.
2. A pharmaceutical composition in tablet form according to claim 1 containing an amount of paroxetine selected from 10 mg, 20 mg, 30 mg, 40 mg and 50 mg, wherein the amount of paroxetine is expressed as the free base, produced on a commercial scale by a process which comprises the steps of:
a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
c) compressing the mixture into tablets using a single punch or rotary tablet machine.

The general rule of infringement is that every claim limitation or its equivalent must be represented in the accused activity. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997) (" Each element contained in a patent claim is deemed material in defining the scope of the patented invention.") That which infringes if later, anticipates if earlier. Peters v. Active Manufacturing Co., 129 U.S. 530, 537, 9 S. Ct. 389, 32 L. Ed. 738, 1889 Dec. Comm'r Pat. 453 (1889); Door-Master Corp. v. Yorktowne, Inc., 256 F.3d 1308, 1312 (Fed. Cir. 2001) ("'that which infringes, if later, would anticipate, if earlier'") (quoting Peters). These rules, like all rules, have generated exceptions, but the exceptions in connection with "anticipation" of claim content are rare, and represent a pragmatic adjustment to the needs of science, not law.
Such an exception exists for inventions directed to a novel product that, although patentable as a product, cannot be adequately described other than by the way it was made; the process may or may not itself be novel, but that aspect is deemed irrelevant to the claim to the new product. This exception was created to accommodate the rare circumstances to which it has been applied, as illustrated in In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985) and Scripps Clinic & Re search Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991). Yet the courts, including my colleagues on this panel, do not appear to have understood the role of the exception, as illustrated in the holding in this case. Thus my colleagues today adopt a one-rule-fits-all rule for claims with process limitations, a rule that is seriously flawed. Instead of taking this opportunity to clarify the confusion surrounding this issue, the court exacerbates it. I must, respectfully, dissent.
I
CLAIM CONSTRUCTION
The SmithKline inventors in the '944 patent describe the production of a stabilized paroxetine tablet by a specified process that reduces or eliminates the formation of a pink-colored catechol-based impurity. They claim the commercial paroxetine

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tablets produced by and limited to the specified process. That is their invention. They do not assert that the claims cover every form of paroxetine however it is produced, and they report that paroxetine is well known. The district court, citing the confusion of conflicting Federal Circuit precedent, held that the process steps in the '944 claims are not claim limitations, whereby the court held the claim invalid because paroxetine itself is a known compound.

It is not the law that process limitations in product claims are not claim limitations. It is not the law that process limitations are ignored in construing claims, whatever the nature of the invention. Claims state the invention for which a patent is sought. See 35 U.S.C. § 112 P2 (claims state "the subject matter which the applicant regards as his invention"). All claims are construed in light of the specification: the observer looks to the specification to ascertain what has been invented, and understands the claim accordingly. See Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc). This rule is not suspended when product and process limitations appear in the same claim. No precedent so requires, and no policy is served by this creative new rule.

Claim construction is a fact-dependent, invention-oriented exercise in logic and law. It requires judicial awareness that patent claims are directed to inventions which come in great variety. There is no need for judges to create one-type-fits-all pigeonholes for claims, even for claims containing process limitations.

When product and process limitation appear in the same claim it is generally because these limitations serve to define and distinguish the invention. Practitioners well understand the variety of types of claims that may contain both product and process limitations. As discussed by E.P. Mirabel, Product-by-Process Claims: A Practical Perspective, 68 J. Pat. & Trademark Off. Soc'y 3 (1986), the most prevalent types are (1) claims where the product is defined by the way it is made; (2) claims to a product that is limited by process steps, and (3) claims where a process limitation is a "structural" part of the product (e.g., a molded plastic). Failure to understand such distinctions led this court into debate at the time of Scripps Clinic, supra, and Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992), a debate that remains of concern to practitioners and courts, see notes 3 and 6 in the majority opinion. The panel majority, apparently itself misunderstanding the distinctions debated in those cases, both prolongs the confusion and misapplies the law to the facts of this case.

This court has sharpened the principles of claim construction, in fulfilling its assignment to bring national uniformity to patent principles. Thus the court reaffirmed en banc in Phillips that claims are construed in light of the specification, recognizing that the claims reflect the invention that is set forth in the specification. That is how we, our predecessor courts, and the Supreme Court, have always construed claims. For example, in Cochrane v. Badische Anilin & Soda Fabrik., 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884), the Court explained that claims to a new method of producing a known compound are limited to the new method, and do not cover the known compound however it is produced. In the case of General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364, 373, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938), the Court indicated that process limitations limit the claims to products produced by those processes unless the product itself is patentable, stating: "Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." And in Merrill v. Yeomans, 94 U.S. 568, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1877), the Court explained that the principal consideration is whether the invention is the product itself, or the product made by a particular method. The Court recognized the diversity of situations in which product claims can contain process limitations, stating that:

If the product is meant, the words "by treating them substantially as hereinbefore described" are useless. They are not only useless, but embarrassing; for, by the well-settled rules of construing all instruments, some importance must be attached to them; and, if they are to be regarded at all, they must either refer to the process of making the oils for which the applicant is claiming a patent, or they are intended to limit his claim for a patent for the product to that product only, when produced by treating the oils in the manner before described.

Merrill, 94 U.S. at 571.

These early cases nicely illustrate the fundamentals of modern-day claim construction in light of the specification; they are not a pronouncement that it is proper to ignore process limitations in product claims. To the contrary, all of these cases state the obverse of the panel majority's view. These long-standing rules of claim construction have had many iterations, such as summarized by our predecessor court in In re Luck, 476 F.2d 650, 653 (CCPA 1973), that "to the extent these process limitations distinguish the product over the prior art, they must be given the same consideration as traditional product characteristics." That is, the process limitations cannot be ignored.

While a patentee can choose how to claim his invention, the choice must be commensurate with the nature of the invention. Perhaps this is where the court lost its focus in the debate on Scripps and Atlantic Thermoplastics. When correctly viewed,

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these two decisions are not in conflict; they simply deal with different situations, as I have previously advised. See Id., 974 F.2d at 1282-84 (Newman, Rich and Lourie, JJ., dissenting from the denial of rehearing en banc). To the extent that these differences remain unclear, it is time for clarity.

In Scripps the invention was a novel protein (the blood clotting factor VIII: C) of unknown structure based on the science as it then existed. Applying precedent, this court held that the product claims characterized by the specific activity of the product were not limited to the method of production, and remanded for determination of infringement. Although advances of science have diminished the reason for such claims, this recognition of the complexity of this important new science filled a pragmatic need. I will not reprise the old debate. What is important, now that the issue is again before us, is that it be correctly resolved.

The district court held that the process limitations in claims 1 and 2 do not limit the claims, such that the claims are simply directed to paroxetine, a known product, in the belief that Federal Circuit precedent so required. The court stated: "separated from the process limitations, claim 1 of the '944 Patent is a 'pharmaceutical composition in tablet form containing '" paroxetine, a product of the prior art, and held the claims invalid on the ground of anticipation. My colleagues repeat this error.

The fundamentals of claim analysis require that all of the claim limitations limit the claim. We have so held in myriad decisions. The panel majority's holding that a claim to a product is never limited by the process limitations in the claim is an extraordinarily mischievous holding, for there are thousands of patents with such claims. It is for the inventor, not the judge, to state what has been invented and to choose how to claim it. Our system of patents absorbs a glorious variety of human ingenuity, and each year well over a hundred thousand patents are granted, each claiming a different invention, each including claim limitations that the patentee is entitled to rely upon to distinguish the invention and avert "anticipation." Although my colleagues state that "both the district court and SmithKline misunderstand the nature of anticipation," maj. op. at 5, I fear that the misunderstanding is on the part of others.

The term "anticipation" in patent usage means that the invention was previously known to the public; that is, that it previously existed in the precise form in which it is claimed, including all of the limitations in the claim. It is not correct that, as a rule of claim construction, a claim that contains product and process limitations is free of the process limitations, whatever the nature of the invention. The district court felt constrained to apply the holding in Scripps to the quite different facts of this case, a constraint for which this court must take responsibility by refusing to clarify the growing uncertainty. When the process limitations in a claim distinguish the invention as a whole from the prior art, when they are material to the invention as set forth by the inventor, the claim cannot be "anticipated" by prior art that does not have all of the limitations in the claim. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000) (anticipating reference must disclose "each and every limitation of the claimed invention"); General Electric Co. v. Nintendo Co., 179 F.3d 1350, 1356-57 (Fed. Cir. 1999) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). Applying the law correctly, the claims here at issue cannot be found on summary judgment to be anticipated.

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1. "Progeny cells"

Monsanto argues that the term "progeny cells" is limited to the daughter cells of the specific plant cell produced in claim 1, and no other cells later produced. Mycogen claims that the term refers to all descendants of that cell, including cells many generations removed from the original cell.

The patent specification makes clear that the invention is intended to cover the newly-created plant cells, and also the cells that will eventually make up the plants that will be insecticidal. The specification explains that "once plant cells expressing a synthetic insecticidal structural gene under control of a plant expressible promoter are obtained, plant tissues and whole plants can be regenerated therefrom using methods and techniques well-known in the art." (Col. 14, lines 9-13). The court thus finds that the term "progeny cells" refers to multiple generations of cells.

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2. "Progeny plant"

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Similarly, Monsanto argues that "progeny plant" only refers to the single plant that is directly regenerated from the cells described in the preceding claims. For the same reasons as above, the court finds that this phrase refers to all descendant plants, even those many generations removed.

Monsanto also argues that these claims can include plants that do not express the Bt insecticidal protein, because only a portion of progeny plants will inherit the synthetic gene. Thus, Monsanto argues that the claims are indefinite.

Dr. Bogorad testified for Mycogen that the wording of the claims makes clear that they are referring only to those progeny cells and plants that contain a pesticidal protein toxin, as described in the claim upon which each of the subsequent claims depend. The specification, as indicated above, indicates that the patent covers not only the original cell, but also the resulting plants and seeds that will be necessary to utilize the invention commercially. Thus, the court finds that the term "progeny plant" refers to plants that encode a pesticidal protein toxin.
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2. "Promoter"

DeKalb argues that "promoter" means, a DNA construct that tells the cell to start a process that results in the production of the EPSP synthase. DeKalb specifically asserts that this is a general claim, and includes all species of promoter. 9 Syngenta presents an alternate construction, asserting that the term promoter should be construed to exclude actin and rice actin promoters. 10 Syngenta basis this proposed construction on the specification language and the patent prosecution history. Syngenta also argues that DeKalb specifically disclaimed the actin promoter in a later patent application, and therefore, cannot now assert that it is covered by the patent at issue.

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -
9 Both Parties make arguments based on genus claims verses species claims. Within the context of promoters, reference can be made to all promoters, which would be the broadest genus claim; reference could be made to a group of promoters, for example bacterial promoters or biological promoters, or there could also be reference to a specific species of promoter, for example actin promoter, which is the promoter used by Syngenta in its production of GA21 corn.10 The Parties refer alternately to a rice actin promoter, or simply an actin promoter. A rice actin promoter is a type of actin promoter, therefore the Court will simply refer to an actin promoter.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Before the Court addresses the specific arguments, the Court will briefly describe the roll of the promoter. The term "promoter" refers to a DNA sequence that instructs the cells to start a process which results in the production of EPSP synthase. This DNA sequence is key to being able to modify the corn plants so that they are resistant to glyphosate. 11

- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -
11 DeKalb does not dispute that at the time of the patent application, the named inventors, Lundquist and Walters, had only conducted research with hygromycin resistance, not glyphosate resistance. However, DeKalb argues that it is the ability to transform the cells and create a fertile plant that is the key invention, and that any type of transformation can be conducted through the process described in the patent. See DeKalb's Claim Construction Brief, 4 ("Lundquist and Walters demonstrated that their fertile transgenic corn plants were able to pass onto progeny corn plants the hygromycin resistance trait provided by the hygromycin phosphotransferase gene they inserted. However, with the availability of their process for transforming corn scientists had the ability to insert any gene of interest into corn to provide a new or enhanced trait, including the glyphosate resistance trait that is the subject of the '798 patent claims.").

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

DeKalb's principal argument is that by reading the claim terms to exclude an actin promoter, Syngenta is improperly reading a limitation into the claim. In the case of Hoganas AB v. Dresser Industries, Inc., the Federal Circuit held that "[it] is improper for a court to add 'extraneous' limitations to a claim, that is limitations added 'wholly apart from any need to

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interpret what the patentee meant by particular words or phrases in the claim.'" 9 F.3d 948, 950 (Fed.Cir. 1993) (citing E.I.Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988)). Syngenta argues that it is not reading a limitation into the claim, but rather is interpreting the claim in light of the specification. Specifically, says Syngenta, DeKalb cannot teach narrowly but claim broadly. Syngenta argues that the only reference to a promoter encoding for EPSP synthase, is a bacterial promoter, and that this cannot be construed to cover an actin promoter, which is a mutated biological promoter.

DeKalb's argument, that Syngenta's construction improperly limits the claim, and Syngenta's argument, that the claim must be construed in light of the specification, are two sides of the same coin. That is, using the specification as guidance as to the meaning of the claimed terms, without using the specification to impose limitations not found in the claim itself. The Federal Circuit case law is clear that a district court cannot impermissibly read limitations into a claim. See E.I. du Pont de Nemours & Co, 849 F.2d at 1433. The Federal Circuit held that "[c]ourts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth." Id; see also Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 867 (Fed.Cir. 1985) ("Generally, particular limitations or embodiments appearing in the specification will not be read into the claims."). However, "it is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim." E.I. du Pont de Nemours & Co, 849 F.2d at 1433. "But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." Id.

The rules cited above, dictated to the district court by the Federal Circuit, are easy to state, however they are very difficult to apply. By DeKalb's own admission, at the time the patent at issue was prosecuted, the named inventors had not used an actin promoter to create glyphosate resistance. However, DeKalb argues that the patent is aimed at the process by which fertile corn plant is created, the specific promoter that is used is not part of the claimed invention. The Court agrees with DeKalb's interpretation. Syngenta makes a number of strong arguments regarding enablement, and fraud, which will appropriately be addressed later in the litigation, relating to the inability of the inventors, at the time of the invention, to perform the claimed invention. However, this is not the appropriate time to address those questions. The Court's obligation is to interpret the terms of the claim, in accordance with the claim language, the specification, and the prosecution history. Nothing in the specification defines the term promoter as referring only to bacterial promoter, nor does it limit the type of promoter in anyway. Syngenta is correct that the only examples cited in the specification reference a bacterial promoter, however, examples do not serve to limit the claim construction. Loctite Corp., 781 F.2d at 867.

While the Court does not believe that the term promoter, as used in the patent, excludes an actin promoter, the Court must address Syngenta's disclaimer argument, which if correct, would serve to limit DeKalb's claim construction. Syngenta points to the prosecution history of the '545 and '713 patents to support their position that DeKalb disclaimed coverage of the actin promoter in the '798 patent. DeKalb disputes this position, arguing that in an attempt to overcome the rejection of the '545 and '713 patents on the basis of obviousness-type double patenting, DeKalb represented to the patent office that the '798 patent contained a genus claim, encompassing all promoters, whereas the '545 and '713 patents were species claims; at no point did they disclaim coverage of the actin promoter from coverage of the '798 patent.

The prosecution history of the patents at issue in these arguments is somewhat convoluted, and therefore the Court will review it in detail. All three patents, the '545 patent, the '713 patent, and the '798 patent, claim priority back to the '983 patent application, which is the parent application for the '798 patent. 12 One of the claims of the '545 patent, was rejected by the patent office based on obviousness-type double patenting. 13 Syngenta's Opening Claim Construction Brief, Ex. 19. 14 This rejected claim specified a "heterologous DNA construct encoding EPSP synthase operably linked to an actin promoter." Syngenta's Opening Claim Construction Brief, Ex. 17. DeKalb appealed this rejection. A similar series of events occurred in the prosecution of the '713 patent.

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12 In Microsoft Corporation v. Multi-Tech Systems, Inc., the Federal Circuit held that "the prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stepping from the same parent application." 357 F.3d 1340, 1349 (Fed.Cir. 2004). Therefore, the Court will look at the prosecution history of all three patent applications in determining whether DeKalb disclaimed the use of an actin promoter.13 35 U.S.C. § 154(a)(2) limits the duration of a patentee's right to exclude others from practicing a claimed invention. "The judicially-created doctrine of obviousness-type double patenting cements that legislative limitation by prohibiting a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." Eli Lilly and Co. v. Barr Laboratories, Inc., 251 F.3d 955, 967 (Fed. Cir. 2001). "A later claim that is not patentably

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distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting." Id. at 968.14 This rejection stated in full:

Claims 82-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. patent No. 5,554,789 [sic 798]. Although the conflicting claims are not identical, they are not patentably distinct from each other because the prior US patent is drawn to a fertile transgenic Zea mays plant containing an isolated heterologous chimeric DNA construct encoding EPSP synthase operably a promoter wherein said heterologous chimeric DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said tolerance or resistance is not present in Zea mays plants not containing said chimeric DNA and wherein said heterologous chimeric DNA construct is transmitted through a normal sexual cycle of the transgenic plant. The instant application is considered an obvious variation on the prior patent by the addition of claims directed to the plant expressing EPSP synthase in which the promoter is either an actin or histone promoter. In the absence of evidence to the contrary, the person having ordinary skill in the art would view the use of prior art promoters, such as actin or histone, to be art recognized equivalents to plant active promoters per se. Accordingly the prior art patent and the instant comprise but a single inventive concept and thus one invention.

Syngenta's Opening Claim Construction Brief, Ex. 19, 5, lines 7-20.

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Claim terms are generally given their "full ordinary and customary meaning, unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." Omega Engineering, Inc., 334 F.3d at 1323. "As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." Id. at 1324. However, this doctrine is to be approached cautiously, as only a clear and unambiguous disclaimer is sufficient to limit the ordinary meaning of a claim term. Id.

Syngenta relies upon DeKalb's brief in support of their appeal of the PTO's denial of DeKalb's '545 patent. It is helpful to quote at length the portion of DeKalb's brief relied upon by Syngenta.

While independent claim 82 of the present application is similar in terminology to claim 1 [of the '798 patent], it recites that the DNA encoding EPSP synthase is operably linked to an actin promoter, i.e. as if the promoter recited by claim 2 of the '798 patent is the actin promoter. Thus, claim 82 can be considered a species of claims 1-2.

The only reason given for the Examiner's conclusion that claims 82-87 are obvious over the claims of the '798 patent in the Office Action mailed April 30, 1997 is that "the person having ordinary skill in the art would view the use of prior art promoters, such as actin or histone, to be art recognized equivalents to plant active promoters per se." (Appendix II).

While claim 2 of the '798 patent, which depends on claim 1, recites that the DNA construct in the transgenic maize plant comprises a promoter, none of the claims in the '798 patent recite a transgenic maize plant containing a DNA construct comprising an actin or a histone promoter. Nor is there mention of an actin promoter in the '798 specification. Although several promoters are disclosed at Col 9, lines 39-57, neither the text nor the cited Weising et al. paper discloses the use of actin promoters to express heterologous genes in plants. Thus, claims 1-6 of the '798 patent do not render Applicants' invention obvious.

To support his argument that the '798 patent suggests the use of the actin promoter with the EPSPS gene, the Examiner argues that the Wang et al. paper is "cited and incorporated by reference" into the '798 patent. This is not the case.

The Wang et al. paper (Appendix III) is not listed in the publications incorporated by reference at Col. 3, lines 9-54 of the '798 patent. It is listed among eight pages of references cited during the prosecution of the patent, i.e., on information disclosure statements, but this list is not incorporated by reference into the application. Therefore, the specification of the '798 patent would not per se suggest using the actin promoter with an EPSPS gene, to impart glyphosate resistance to maize.

Syngenta's Opening Claim Construction Brief, Ex. 21, 5-6 (emphasis in original). Syngenta further argues DeKalb's disclosure by pointing out that the title of the section from which the above quoted material is taken, states "The '798 Patent

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Does Not Disclose or Suggest the Actin Promoter." Syngenta's Opening Claim Construction Brief, Ex. 21, 5. The only mention of an actin promoter in relation to the '798 patent was in a single reference listed in the patent. However, DeKalb expressly denied the significance of this reference when they stated that it was one reference, in a list of eight pages of references. Syngenta's Opening Claim Construction Brief, Ex. 21, 6. DeKalb further argued in their appeal brief before the PTO, that even if the Wang paper were incorporated by reference, it "Would Not Give Rise to a Reasonable Expectation that the Actin Promoter Would Express Useful Levels of Resistant EPSPS in Maize." Syngenta's Opening Claim Construction Brief, Ex. 21, 6. DeKalb stated that "there is no mention or suggestion in Wang et al. of the EPSPS gene. Moreover, the Wang paper did not show that regenerable Zea mays cells transformed with a construct having the actin promoter linked to a gene resulted in a fertile transgenic plant, or seed or progeny of such a plant, which expressed that gene at any level. . . . Thus, Wang et al. do not disclose or suggest Applicants' invention." Syngenta's Opening Claim Construction Brief, Ex. 21, 7 (emphasis in original).

Prior to DeKalb appealing the rejection of their '545 patent application, DeKalb responded to the rejection in a July 15, 1997 amendment, in which they stated

The Examiner is respectfully requested to note that this is a situation of Applicants claiming a small number of species falling somewhere within the broad generic disclosure of the '789 [sic '798] Lundquist et al. patent . . . . The fact that a claimed species may be encompassed by a prior generic description does not by itself render the species obvious.

Def. Syngenta's Opening Claim Construction Brief, Ex. 20, 3. Following this response, the Examiner concurred with DeKalb's assertion that the '545 patent was a species claim, and the '798 patent was a genus claim, but continued to deny the patent application on the basis of obviousness-type double patenting. DeKalb eventually overcame this dismissal on the basis of unexpected results. See Pl. DeKalb's Responsive Claim Constructive Br., Ex. 24, 2).

DeKalb made numerous statements, as asserted by them in their claim construction briefs, that their '545 patent application was a species claim. However, DeKalb also made numerous representations, far more than those relating to genus verses species, stating that the '798 patent did not disclose an actin promoter. When a court is determining whether a patent is unenforceable based on obviousness-type double patenting, a two-part test is employed. "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." Eli Lilly and Company, 251 F.3d at 968. In this case, the patent office made the determination, rather than a court, but the analysis was the same. In rejecting the second patent application, the PTO determined that the '545 patent was not patentably distinct, because the '798 patent disclosed an actin promoter. See Syngenta's Opening Claim Construction Brief, Ex. 22, 3. The key difference in the Parties' arguments, is how DeKalb overcame this rejection. If as Syngenta argues, DeKalb overcame the rejection by asserting that the '798 patent did not recite the actin promoter, then, Syngenta would be correct that the '798 patent excludes the actin promoter from the definition of promoter. If however, DeKalb's assertion is correct, that they overcame the rejection by showing an unexpected use, then the general meaning of the term promoter would remain valid.

For two reasons, the Court concurs with DeKalb, that they did not disclaim the recitation of an actin promoter in their application for the '545 patent. First, the Court notes that claim terms are generally given their "full ordinary and customary meaning, unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." Omega Engineering, Inc., 334 F.3d at 1323 (emphasis added). The Court has reviewed the numerous references to the prosecution history cited by the Parties, and concludes that it is inconclusive. DeKalb, in an effort to overcome the PTO's rejection of its '545 patent did state, numerous times, that the '798 patent did not disclose an actin promoter. However, DeKalb also made statements that while the '798 patent recited promoters generally, the '545 patent referenced a specific type of promoter. These statements do not constitute a clear and unambiguous statement of disclaimer. Secondly, the Court concurs with DeKalb, that DeKalb overcame the obviousness-type double patenting rejection by asserting that the actin promoter showed unexpected results. See DeKalb's Responsive Claim Construction Brief, Ex. 24, 2 ("The claimed invention is considered patentable in view of the establishment of unexpected results, as set forth in the declaration of Dr. T. Michael Spencer, establishing the criticality of an actin promoter in the expression of the gene of interest in Zea mays plants."). The case law is clear that a patentee may overcome a finding of obviousness, for a later patent which falls within the range of an earlier patent, if the patentee can show unexpected results. Iron Grip Barbell Company, Inc. v. USA Sports, Inc., 392 F.3d 1317 (Fed.Cir. 2005) ("When 'the difference between the claimed invention and the prior art is some range or other variable within the claims . . ., the [patentee] must show that the particular range is critical,

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generally by showing that the claimed range achieves unexpected results.'" (citing In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (alterations in original).).

The Court concludes that the plain meaning of the term promoter includes all promoters, and specifically includes the actin promoter. The Court further finds that while DeKalb made a number of statements suggestive of disclaimer, these statements were not unambiguous, and therefore insufficient to change the plain meaning of the claim terms.
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(5) A transcriptional promoter segment . . . The Court concludes that the promoter is the portion of the DNA construct which facilitates the start of the transcription of the RNA. (Green Tr. at 114). This promoter must be the starting point for the RNA polymerase to begin reading the information necessary for transcription. (Falkinham. Tr. at 1413).
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C. "Prophylactic Treatment of PHN"

Novartis proposes the following construction of the term "prophylactic treatment of PHN" as used in Claim 15:

Achieving, by preventative measures (i.e., before PHN manifests itself), a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

(Novartis's Resp. Br., at 4.) Roxane, on the other hand, defines "prophylactic treatment of PHN" as used in Claim 15 to mean:

Preventing PHN in humans who would otherwise develop PHN when compared to a control.

(Id.) In addition to the two differences discussed above for the term "treatment of PHN" in Claim 1, the parties also differ on whether prophylactic in this term means "by preventative measure" or "preventing PHN." Roxane argues that the plain meaning of prophylactic,as defined using extrinsic evidence, is something that is preventative. It also argues that Novartis's construction of the term "prophylactic treatment of PHN" is inappropriate because it would render the word "prophylactic" superfluous, resulting in Claims 1 and 15 having the same scope. See Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1381 (Fed. Cir. 2006) (noting that a claim generally should not be construed in a way that "would render additional, or different, language in another independent claim superfluous"). As the Court noted above, there is no support in the specification or other intrinsic evidence that the claimed methods are aimed at preventing PHN. The specification expressly states that there is no proven therapy for preventing PHN. Thus, the term prophylactic as used in Claim 15 should not be so construed. In fact, Roxane's expert, Dr. Gilden, testified that "prophylactic treatment" could mean "anything that would impact on the disease in advance," such as a treatment that would lessen "the severity or duration" of a disease. (Gilden Dep. Tr. 130:2-11.) The Court also disagrees with Roxane that Novartis's construction renders Claims 1 and 15 ofidentical scope. While Claim 1 encompasses preventative measures, its scope is not limited to such measures. Claim 1 is broad enough also to encompass treatment after PHN manifests itself, subject to the limitations identified below with regard to the other disputed terms. For these reasons, the Court construes the term "prophylactic treatment" in Claim 15 to mean: Achieving, by preventative measures (i.e., before PHN manifests itself), a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.
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B. Propofol

The second disputed claim term is "propofol." Defendant argues that the correct construction of propofol includes "the additional features of (i) being present in any amount where not expressly limited; and (ii) being a phenol known to have

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anesthetic and antimicrobial activity." (Def. Mem. at 23.) Plaintiffs do not dispute that the claimed propofol must be a phenol known to have anesthetic and antimicrobial activity. However, arguing that the amount of propofol must not be construed such that the claimed invention is rendered inoperative (Pl. Reply Mem. at 16-18), they contend that propofol should be construed as "2,6-diisopropylphenol" (Tr. at 35). n8

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n8 Plaintiffs had earlier argued that propofol should be construed as "2,6-diisopropylphenol in an amount up to about 2%, unless expressly limited in the claim." (Goldberg Decl. Ex. P.) They no longer suggest this definition. (Tr. at 32-33.)

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The claim language requires that the claimed composition include propofol as one of its components, but does not mention any specific amount of propofol. In particular, Claim 1 requires the propofol amount be such that the "sterile pharmaceutical composition [is suitable] for parenteral administration." There is no dispute, however, that the ordinary and customary meaning of propofol is "2,6-diisopropylphenol." (Tr. at 35, 76; see also Col. 1, lines 4-5.)

Because the claim language does not require any specific amount of propofol, this Court declines to read that limitation into the claim term. See Texas Digital, 308 F.3d at 1204; Advanced Cardiovascular, 261 F.3d at 1338-39; Johnson Worldwide, 175 F.3d at 992; Advanced Micro-Devices, 848 F.2d at 1572. Accordingly, this Court gives propofol its ordinary and customary meaning of "2,6-diisopropylphenol."
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10. "Wherein the proportion of hydroxy acrylic monomer units to silicon units in said tear-wettable surface layer is greater than that of said lens body"

The plaintiff proposes "the proportion of hydroxy acrylic monomer units to silicon units is higher in the tear-wettable surface layer than in the lens body." The plaintiff also proposes that "silicon units" means "silicon atoms that are part of a polymer." The defendants propose "a ratio of HAM units to silicon atoms in the tear wettable surface layer greater than the ratio of HAM units to silicon units in the lens body which converts a clinically unacceptable lens to a lens having a high degree of clinical acceptability. The ratio of HAM units to silicon units in the tear wettable surface layer must be sufficient to convert a clinically acceptable lens to a lens having a high degree of clinical acceptability."

The defendants contend that the proper construction must recognize the relationship between the proportion and the high degree of clinical acceptability. The defendants also contend that the specification states what proportion is acceptable (e.g., 0.5) and what is not acceptable (e.g., 0.15). '327 Patent, 6:30-50. The defendants argue that their construction simply excludes subject matter that does not work.

The defendants attempt to limit the construction to a preferred embodiment. Accordingly, the Court adopts the plaintiff's proposed construction.
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As to Gore's third objection, Gore states that the parties and the Special Master have agreed that an identical construction should be given to each of the introductory terms in each of the claims, that is, "prosthetic vascular structure," "prosthetic vascular graft", and "artificial vascular prosthesis". (Doc.315, at p. 11). The Special Master has recommended that these terms be defined as "a structure used to replace, repair, augment, or bypass blood vessels." (Report, para. 26). Gore contends that the proposed construction is improper to the extent that it includes "augment" or "repair." Gore contends that the operative word is "prosthesis" or its adjective form "prosthetic" as referring to "an artificial device to replace a missing part of the body." In support of this definition, Gore refers to the definition set forth in Webster's Third New International Dictionary (1972 ed.), noting that medical dictionaries published in 1981, 1985 and 1993 were in accord. Gore challenges

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Bard's reference in its opening Markman brief that the meaning of the term "prosthesis" has been expanded in or about 2003 to include "an artificial device to replace or augment a missing or impaired part of the body." (emphasis supplied). (Doc. 315, at p. 12).

As part of its objection, Gore contends that the Special Master was incorrect when he stated at paragraph 13 of his Report that "Gore does not dispute that these terms' generally understood meaning in the art would extend to structures used to repair or augment blood vessels . . ." Gore contends that it has expressly denied that "augment" was part of a 1974 definition of prosthesis and that it has never asserted any argument about "repair" in the proceedings. (Doc. 315, at p. 12).

At paragraph 14 of the Report, the Special Master noted that Gore had disagreed that it had conceded that any relevant dictionary definition of prosthesis, prosthetic structure or graft includes devices used to repair or augment blood vessels. The Special Master went on to note in paragraph 14 that at the claims construction hearing, Gore had specifically acknowledged that there are such things as "patch grafts" or "patch prostheses" but had argued that the claims could not cover such structures because "there is no disclosure of a flat patch . . . [and] [t]he only description is tubular", citing the hearing transcript. The Special Master further observed that Gore had stressed that the claims cover structures used to "replace and bypass but not repair" "because of the specification", again citing the hearing transcript.

As part of this present objection, Gore further argues that there is nothing in the intrinsic record, or the 1974 extrinsic record, which supports the Special Master's recommended conclusion that his construction "reflects the understanding of the meaning of these phrases to one skilled in the art based on the patent and the rest of the intrinsic record", as set forth at paragraph 25 of the Report. Gore therefore contends that there is no support in the intrinsic record, or in the 1974 extrinsic record, for "prosthesis" to be construed to include devices which "repair" or "augment."

In paragraph 14, the Special Master recommended that, despite whether Gore's statements at the hearing can be considered concessions, "intrinsic evidence from the patent's prosecution history contains references that indicate that one skilled in the art of the invention at the time of the application would understand the terms 'graft' and 'prosthesis' to include devices used to patch, and thus repair or augment, a blood vessel." The Special Master in support of the recommended finding cited four scientific articles which were prior art references listed on the first few pages of the patent. These articles indicated that patches or patch grafts were known in the prior art by 1974.

The Special Master analyzed the issue based on a thorough discussion set forth in several paragraphs of his Report. (Report, paras. 16-25). The Special Master considered whether the words should be accorded their ordinary meaning in the art or whether this meaning should be narrowed by the disclosure of the patent specification. (Report, para. 16). As part of his proposed findings, the Special Master, after citing relevant case law, recommended that the embodiments are exemplary and not restrictive. (Report, para. 21). The Special Master also found in part that "there was no disclaimer of non-tubular or non-sutured embodiments, or of embodiments used to repair or augment a blood vessel." (Report, para. 23). The Special Master specifically noted that "[t]he patent also expressly states that the claimed prosthesis 'may assume many embodiments and configurations other than those specifically set forth and described' in the specification, providing examples," referring to Col. 9, lines 20-28. (Report, para. 21). The Special Master supported his recommended conclusion with a thorough analysis of the issue and case law. The Special Master has recommended that the phrases be construed as "a structure used to replace, repair, augment or bypass blood vessels" (Report, para. 26), stating that he has "articulated the construction using language that he believes more simply reflects the understanding of the meaning of these phrases to one skilled in the art based on the patent and the rest of the intrinsic record." (Report, para. 25).

The Court has considered Gore's objection based on a recitation in the specification that "a principle objective of the invention" is to "provide a prosthetic vascular structure capable of replacing or bypassing natural blood vessels . . .", citing Col. 1, lines 25-27, as well as Gore's objection based on the absence of any pre-1974 dictionary definition that included "repair" or "augment." The Court also has considered Gore's objection regarding the Special Master's consideration of pre-1974 scientific articles as indicating that the devices could be used "to patch" and "thus repair or augment" a blood vessel. The Special Master set forth his legal conclusions in part at paragraph 17, including that "[c]laims may cover such after-arising technology, which logically can never be described in the patent specification. (citation omitted)." See also the Report at paras. 18, 21-22 & 25. The Special Master gave the terms their ordinary meanings to persons of skill in the art at the time of the invention based on the patent and the rest of the intrinsic record. This recommended construction is consistent with Phillips, 415 F.3d at 1313 ("the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing

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date of the patent application."). The Court is in agreement with the recommendation of the Special Master. Gore's objection is overruled.
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1. "Protected From Light"

We are not persuaded by the minor distinction between the parties' proposed constructions of the expression "protected from light." The specification indicates that the phrase "protected from light" is no more than a direction for care. It states that the inventors stored the platinum complex in the dark until testing. '925 patent, col. 2, ll. 20-23. No other reference is made to protecting cisplatin from light in the patent. Although the applicants asserted during prosecution that "the compounds per se must be protected from light" and that "the claims of the present application are thus patentably distinguished from the claims in the [method] patents," J.A. at 9490, we are not persuaded that this direction for care adds any limitation to the structure of the composition, which is the subject of the claim.

We are not construing a composition claim that contains a material that in fact protects it from light. No brown bottle appears as part of the claim, nor is there any ingredient in the composition that protects the composition from light. The only apparent distinction between the claimed composition protected from light and that not protected from light is how it is treated; that is not a structural or otherwise meaningful claim limitation. If anything, the inventors discovered only a property -- light sensitivity in the context of TCAP formation -- of the composition recited in the method patents. A direction for care that does no more than reflect the inventor's recognition of a newly discovered property does not itself impart patentability to that composition. See, e.g., In re Spada, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed. Cir. 1990) (holding that the discovery of a new property of an old product does not render the old product patentable); Ex parte Masham, 2 U.S.P.Q.2D (BNA) 1647, 1648 (Bd. Pat. App. & Int. 1987) (holding that a claimed apparatus was anticipated because it did not "undergo a metamorphosis to a new apparatus merely by affixing instructions thereto" that it be completely submerged, which the prior art device was also capable of). Thus, the "protected from light" language provides no distinguishing structure to the claim. There is simply "no there there." n4 We therefore construe the expression "protected from light" to be non-limiting.

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n4 Gertrude Stein, Everybody's Autobiography, ch. 4, in Chambers, Dictionary of Quotations 965 (Alison Jones ed., 1998).

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e. "protect the immunoglobulin from degradation and thus stabilize the IgG 1 composition" and "so that said stabilization (sic) composition is made"

Genentech argues that the phrases "protect the immunoglobulin from degradation and thus stabilize the IgG 1 composition" of the '403-S patent (Claim 1) and "so that said stabilization (sic) composition is made" of the '838 patent (Claim 1) require copper-mediated degradation that is significantly reduced by the addition of chelator. Genentech contends that in order for the immunoglobulin composition to be stabilized, the copper mediated degradation that would otherwise have occurred absent a chelator of copper ions must be substantially prevented. In support of its construction, Genentech refers the court to the specification, the file history and the inventors' testimony as evidence that the terms "protect" and "stabilize" require nearly complete prevention of the degradation.

Glaxo argues in response that the phrases convey their plain and ordinary meaning to one of skill in the art in that they require a reduction, elimination or retardation of copper ion-mediated degradation. Therefore, the essence of the dispute over these phrases is whether the terms "stabilize" and "protect" require that the chelator substantially prevent degradation of the composition, or simply reduce such degradation.

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In support of its construction, Genentech first refers the court to an excerpt from Example 1 of the '403-S specification. In describing the results of the experiment, the excerpt states that "these results demonstrate that copper enhances the degree of degradation of the antibody relative to the control. The addition of EDTA virtually eliminates degradation whilst the other metal ion chelator 1,10-phenanthroline reduces degradation to a considerable extent." The excerpt makes clear that two chelators, EDTA and 1,10-phenanthroline, nearly prevent degradation, but the invention is not limited to EDTA and 1,10-phenanthroline. Such results cannot be presumed for all chelators of copper ions. Thus, Example 1 does not create a limitation that the chelators virtually prevent degradation.

Genentech also relies on deposition statements made by Dr. Riveros, one of the Smith inventors, in support of its construction. In describing decreases resulting from the addition of a protease inhibitor to the composition, Dr. Riveros stated that "it's not something that is drastic like it is the effect of EDTA and copper." Genentech argues that Dr. Riveros' characterization of the stabilizing effect of EDTA on copper as drastic shows that such effect is required by the patent claims. Again, the Smith patents are not limited to the chelator EDTA. Therefore, the statement does not reveal a requirement that chelators substantially prevent degradation of the composition.

Genentech next points to Dr. Riveros' answer to a question by opposing counsel, in which opposing counsel asked "so it's your understanding that when it's less than one percent change in degradation or showing one percent degradation that that is because of the detection method?" Dr. Riveros responded, "I understand the method has variations which are in-built in the method and one-percent is really insignificant. You can see the increase produced by copper can be over a hundred percent degradation." Genentech contends that this testimony distinguishes the stabilization and protection required by Smith patents from "insignificant" protection. After reviewing the context of that statement, the court finds that Dr. Riveros responded to the second part of a compound question. That is, he was speaking to degradation rates, not reduction rates. This is evident in the second part of Dr. Riveros' response where he refers only to "one hundred percent" degradation. As such, the response does not reveal a limitation that chelators substantially prevent degradation of the composition.

After reviewing the parties' proposed constructions, the court concludes that the phrases should be construed according to their plain meaning. The term "stabilizer" is defined as "any substance that tends to keep a compound, mixture or solution from changing form or chemical nature. Stabilizers may retard a reaction rate or . . . preserve a chemical equilibrium . . . ." Richard J. Lewis Sr., Hawley's Condensed Chemical Dictionary 1042 (13th ed. 1997). The specification and the examples therein show dramatic reductions in degradation, but they do not modify the plain meaning of "stabilize" or "protect," and they certainly do not establish a required amount of stabilization or protection. As such, the court construes the phrases "protect the immunoglobulin from degradation and thus stabilize the IgG 1 composition" of the '403-S patent and "so that said stabilization (sic) composition is made" of the '838 patent to require that the chelator reduce degradation.
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D. "Protein Sparing"

The Court is of the opinion that the phrase "protein sparing" in claim 1 is capable of a similarly straightforward construction. As previously discussed, the patent specification discloses a direct link between protein and nitrogen loss in the body; namely, accelerated protein breakdown is manifested by increased nitrogen loss. '979 patent, col. 1, lines 42-43. "Protein wasting, " which is defined as "excessive breakdown of tissue proteins," is equated with "excessive loss of body nitrogen." '979 patent, col. 1, lines 16-20; see also '979 patent, col. 1, lines 51-52. "Protein sparing" is described as an antidote to protein wasting, or the breakdown of tissue proteins, with the specification indicating that "protein sparing therapy may be indicated" for elderly patients who are experiencing loss of muscle protein due to aging. '979 patent, col. 1, lines 45-48.

The structure of claim 1 demonstrates that "protein sparing" is the result that is achieved by the process described therein. '979 patent, col. 6, lines 7 ("The method of protein sparing, comprising . . ."). The process comprises administering HMB in one of a variety of forms "until the amount of nitrogen in the patient's urine has substantially decreased." Thus, an inference is created by the claim language that protein sparing is achieved when nitrogen retention occurs. The only method that is disclosed in the patent for measuring the fluctuation of protein in the body is the measurement of the nitrogen excreted in an individual's urine. See '979 patent, col. 1, lines 16-20; '979 patent, col. 5, lines 64-68, col. 6, lines 1-3.

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Viewing the intrinsic evidence as a whole, protein sparing in claim 1 means the retention of protein in the body sufficient to trigger a decrease in the level of nitrogen excreted by the body, as measured by urinary nitrogen levels.
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A. The '430 Patent

The language of Claim 1 states:

"A process for recovering betaine from molasses which comprises:

(a) diluting the molasses to provide a diluted molasses having a solids content within the approximate range of 25-50%,

(b) providing a chromatographic column of a salt of a polystryrene sulfonate cation exchange resin cross-coupled with from about 2 to about 12 weight percent of divinylbenzene, the resin being of uniform particle size and having a mean particle size within the range of about 20 to 400 U.S. mesh,

(c) submerging the column of resin in water,

(d) introducing the diluted molasses in uniform supply to the resin surface at the top of the column,

(e) eluting the molasses from the column with water to provide an eluate, and

(f) recovering from the downstream side of the resin bed a fraction which consists principally of betaine."

(Dft's Ex. DTX 1, Col. 12 ('430 Patent)). (Emphasis added to highlight the terms in dispute).

1. "to provide an eluate"

The first phrase disputed by the parties in their Joint Statement is "to provide an eluate." (Joint Stmt. p. 2). Plaintiff advocates a dictionary definition of "eluate," which means the "washings obtained by eluting." (Joint Stmt. p. 2). Thus, "to provide an eluate" means to provide the washings obtained by eluting. (Joint Stmt. p. 2). On the other hand, Defendants interpret the phrase to mean "to provide several fractions from the column, including at least a non-sugar fraction, a sugar fraction, and a betaine fraction." (Joint Stmt. p. 2). For support of their interpretation, Defendants refer to the specification. The relevant language states:

"On elution with water, there is recovered from the column as eluate, a first nonsugar fraction, a second sugar-containing fraction, and a third fraction consisting principally of betaine." (DTX 1, col. 2/ln. 63-66).

Plaintiff is mainly concerned that adopting Defendants' proposed jury instruction on the meaning of this phrase would suggest to the jury that there is a requirement of recovering three fractions. (Markman Hearing Tpt. p. 186). However, Defendants' construction does not impose this requirement. Rather, "to provide an eluate" only means "to provide several fractions…;" the fractions do not necessarily have to be recovered. (Joint Stmt. p. 2) (emphasis added). The claim language only requires that the resultant eluate from the "eluting of the molasses from the column with water…" in step (e) consists of several fractions. (DTX 1, Col. 12/ln. 38-40). The specification describes these fractions as a nonsugar fraction, a sugar-containing fraction, and a betaine fraction. (DTX, Col. 2/ln. 63-66). As consistent with the claim language and the specification, the court construes the phrase "to provide an eluate" to mean "to provide several fractions from the column, including at least a nonsugar fraction, a sugar fraction, and a betaine fraction." (Joint Stmt. p. 2).
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Background

Purdue and Roxane are pharmaceutical companies that each have developed controlled release oxycodone medications for the treatment of moderate to severe pain. Purdue is the owner of the '912, '042, and '295 patents, which are respectively a continuation-in-part, divisional application and continuation-in-part of United States Patent No. 5,266,331 (the '331 parent). The asserted claims of the patents-in-suit are similar, and their specifications are virtually identical. Claim 2 of the '912 patent is representative of the asserted claims and reads as follows:

A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 to about 40 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

'912 patent, col. 20, ll. 45-54.

During the prosecution of the '912 patent, the applicants filed a terminal disclaimer with respect to the '331 parent to overcome a rejection based on the parent. At the examiner's suggestion, the applicants amended the specification of the '912 patent to claim priority of the filing date of the '331 parent.

On May 18, 1999, Purdue filed suit against Roxane alleging that its oxycodone controlled-release product, Roxycodone TM SR, infringed claims of the '912, '042 and '295 patents. Roxane filed counterclaims of invalidity (based on anticipation of the patents-in-suit) and inequitable conduct. On October 1, 1999, Purdue moved for a preliminary injunction. By stipulated order, the parties conducted expedited discovery, and on November 15-18, 1999, the district court held an evidentiary hearing that included live fact witness testimony and submitted expert declarations. Purdue's and Roxane's respective economics experts submitted written testimony concerning the likelihood of price erosion, loss of market share, and market expansion.

Following the hearing, on February 3, 2000, the Food and Drug Administration independently stayed its approval of Roxane's oxycodone pain relief product in response to a Citizen's Petition brought by Purdue. Roxane's accused product has therefore never been marketed in the United States. In contrast, Purdue's controlled release oxycodone product, OxyContin, accounted for approximately 63% of Purdue's 1999 sales and a projected 79% of Purdue's 2000 sales. Purdue has chosen not to license its patent portfolio.

On May 16, 2000, the district court issued its order granting Purdue's motion for preliminary injunctive relief, holding that: (1) Purdue was likely to prove infringement under a claim construction of the term "administration" encompassing values for the time of maximum oxycodone blood plasma concentration ("Tmax") determined in a multiple dose steady-state study; (2) Roxane's defense that the '331 parent anticipates and renders invalid the patents-in-suit lacks substantial merit; (3) Roxane's inequitable conduct defense that applicants made an improper claim of priority to the '331 parent lacks substantial merit; and (4) Purdue would suffer irreparable harm if no preliminary injunction were to issue. The district court entered the injunction on May 25, 2000.

Discussion

As the moving party, Purdue was required to establish its right to a preliminary injunction in light of four factors: "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships and (4) the impact of the injunction on the public interest." Polymer Techs. v. Bridwell, 103 F.3d 970, 973; 41 U.S.P.Q.2D (BNA) 1185, 1188 (Fed. Cir. 1996) (citing Nutrition 21 v. United States, 930 F.2d 867, 869, 18 U.S.P.Q.2D (BNA) 1347, 1348-49 (Fed. Cir. 1991)). If Purdue as the moving party "clearly establishes the first factor (by making a 'clear showing' of both validity and infringement), it is entitled to a rebuttable presumption" of irreparable harm. Id. The only issues Roxane argues on appeal are the district court's determination of factors one and two.

The decision to grant a preliminary injunction is within the discretion of the district court. See 35 U.S.C. § 283 (1994); Polymer Techs., 103 F.3d at 973, 41 U.S.P.Q.2D (BNA) at 1188. An abuse of discretion may be shown if the district court made a clear error of judgment, or based its decision on an erroneous legal conclusion or clearly erroneous factual findings.

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Canon Computer Sys. Inc. v. Nu-Kote Int'l, Inc., 134 F.3d 1085, 1087-88, 45 U.S.P.Q.2D (BNA) 1355, 1358 (Fed. Cir. 1998). We are also mindful that all findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits. See Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 681, 15 U.S.P.Q.2D (BNA) 1307, 1308-09 (Fed. Cir. 1990) (citations omitted).

With respect to the first factor of reasonable likelihood of success on the merits, Purdue was required to show that "in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove infringement and (2) its infringement claim will likely withstand Roxane's challenges to the validity and enforceability of the . . . patents." Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1364, 42 U.S.P.Q.2D (BNA) 1001, 1003 (Fed. Cir. 1997) (quoting New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882-83, 23 U.S.P.Q.2D (BNA) 1622, 1625-26 (Fed. Cir. 1992)). If Roxane defends with evidence raising a "substantial question" concerning validity, enforceability, or infringement, Purdue was required to produce countervailing evidence demonstrating that these defenses "lack substantial merit." Genentech, Inc., 108 F.3d at 1364, 42 U.S.P.Q.2D (BNA) at 1001.

An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995) (en banc). Claim construction is a question of law that we review de novo. Cybor v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1174 (Fed. Cir. 1998) (en banc). Infringement, both literal and under the doctrine of equivalents, is a question of fact. Insituform Techs., Inc. v. Cat Contracting, Inc., 161 F.3d 688, 692, 48 U.S.P.Q.2d (BNA) 1610, 1614 (Fed. Cir. 1998).

The claim language at issue concerns the type of administration (single dose, or multiple dose, steady-state) used to determine the mean time "after administration" at which the maximum mean plasma level of oxycodone in human patients is reached. Roxane contends that the claim language limits the determination of Tmax to single dose studies, while Purdue contends that the language encompasses both single dose and multiple dose, steady-state studies.

Finding the language of the claim ambiguous, and ultimately relying on the specification and the "'fundamental purpose and significance' of the invention," the district court held that the range of values for Tmax "after administration" encompasses values obtained from multiple dose, steady-state studies. Purdue Pharma L.P., slip op. at 20. Roxane argues that this claim construction is erroneous because the plain language of the claim shows that when the drafters wanted to require multiple dose administrations (as for mean minimum plasma concentration values), they so specified, while specification examples and language and the '331 parent refer to single dose administration to determine Tmax.

We see no error in the district court's initial conclusion and reasoning. The bare language of the claim is unclear as to the type of administration to determine Tmax. The specification includes examples of single and multiple dose administrations, and the district court's refusal to read in a single dose limitation from the specification and thereby ignore its references to multiple dose, steady-state examples is not improper. See Burke v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340-41, 51 U.S.P.Q.2D (BNA) 1295, 1299-1300 (Fed. Cir. 1999). Moreover, the construction is "consistent with and furthers the purpose of the invention," which the court determined to be to administer steady-state dosages to a patient "to facilitate the titration process by reducing the range of daily dosages needed to provide effective pain relief across the spectrum of patients." See CVI/BETA Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1160, 42 U.S.P.Q.2D (BNA) 1577, 1587 (Fed. Cir. 1997); Purdue Pharma L.P., slip op. at 20.

In arguing that the patents teach that Tmax is determined in a single dose study, Roxane cites the following paragraph from the specifications of the patents:

In order to obtain a controlled release drug dosage form having at least a 12 hour therapeutic effect, it is usual in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between about 4-8 hours after administration (in a single dose study). The present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2-4.5 hours after administration gives at least 12 hours pain relief and, most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma levels (of oxycodone) in the normal period of up to 2 hours after administration.

'912 patent, col. 5, II. 5-16; '042 patent, col. 5, II. 7-18; '295 patent, col. 5, II. 5-16. Roxane contends that the parenthetical

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reference to a single dose study defines "administration" within the context of the invention. The district court, however, determined that the reference to a single dose study merely explains prior art. Although there was testimony that supports the court's interpretation, its interpretation is a reasonable one independent of that testimony. We therefore cannot say that the court impermissibly relied on extrinsic evidence when construing the claims.

Moreover, the court did not err in rejecting Roxane's argument that the '331 parent's patent prosecution history limits the claim to values obtained in single dose administrations. The '331 parent, which uses the bare term "administration," also discloses values obtained in multiple dose, steady-state studies. Finally, although the specifications of the patents-in-suit refer to the use of "methods" set forth in United States Patent No. 4,990,341 (a Purdue patent on a hydromorphone-based controlled release pain medication that relied specifically on Tmax determinations in a single dose study), this language is narrower than the reading urged by Roxane, and refers to the preparation of the oxycodone medication formulation itself.

There appears to be no real dispute that Roxane's accused product infringes under the above claim construction. The district court thus did not err in finding that Purdue made a strong showing of a reasonable likelihood that it would succeed on the merits of its infringement claim.
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1. "pure"

This term is found in claims 1, 6 and 7. Plaintiff proposes the following construction: "essentially free from chemical impurities to permit use in a pharmaceutical formulation." Astra's construction goes on to state that "essentially free from chemical impurities to permit use in a pharmaceutical formulation" means 98% chemically pure. DRL contends that the disputed claim term should be construed as "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation." 2

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2 This was the construction originally offered by Teva, one of the settling defendants in this case. In its letter to the Court of January 21, 2010, DRL stated that its claim construction briefing was coordinated with Teva and directed the Court to those portions of Teva's briefs relevant to DRL's arguments in support of its proposed constructions. The Court considered those materials in rendering this decision.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Both parties agree that the term "pure" as used in the aforementioned claims of the '504 patent limits the claims to a chemically pure alkaline salt of the (-)-enantiomer of omeprazole. The difference in the two constructions is that Astra's provides a quantitative limitation of 98% chemically pure, apparently derived from its proposed construction of the term "optically pure," which is discussed further below. However, such reliance is misplaced, as the disputed claim term "pure" relates to chemical purity, not optical purity. Indeed, Astra itself concedes that "pure" does not refer to optical purity. See, e.g., Pl. Brf. at 5 ("'pure' in claim 1 should mean something other than … 'optically pure.'") Moreover, where the term "essentially free" is used in the specification, the term is used to described optical purity, not chemical purity. '504 patent, col. 3, lines 31-35 ("With the expression 'optically pure Na+ salts of omeprazole" is meant the (+)-enantiomer of omeprazole Na-salt essentially free of the (-)-enantiomer and the (-)-enantiomer of omeprazole Na-salt essentially free of the (+)-enantiomer."). The testimony of Astra's expert, Dr. Davies, cited to by Astra in support of its construction (see Attachment 9 to Joint Statement), where Dr. Davies refers to levels of purity "98 percent and above," also is a reference to optical, and not chemical, purity. Astra simply has not established that there is any basis for reading the quantitative limitation of 98% into the disputed claim term. Without this limitation, the "essentially free" language proposed by Astra is ambiguous.

DRL's proposed construction, on the other hand, provides an unambiguous definition that would be understood by one of ordinary skill in the art. Plaintiff's expert, for example, states that "a skilled person would know that certain impurities … are tolerated at only very low levels or not at all. In another instance the overall impurity level may be higher, if there is less risk associated with those particular impurities. Byrn Decl. at P 42. Under DRL's proposed construction -- "sufficiently free

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from chemical impurities to permit its use in a pharmaceutical formulation" -- it would be clear whether a sample is one where, for example, "the overall impurity level may be higher." Consequently, the Court shall adopt DRL's proposed construction, and construe "pure" in the '504 patent to mean "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation."
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6. X% Pure is construed to mean that X percentage of polymers within a predefined region have identical sequences.

Affymetrix contends that this term means polymers within a localized region wherein a given percentage of said polymers exhibit characteristics which distinguish them from other localized regions. Typically, purity will be measured in terms of biological activity or functions as a result of uniform sequence. Such characteristics typically will be measured by way of binding with a selected ligand or receptor.

Incyte contends "pure" means polymers within a predefined region have uniform monomer sequence and length.

The '934 specification presents a definition of "substantially pure:"

A polymer is considered to be "substantially pure" within a predefined region of a substrate when it exhibits characteristics that distinguish it from other predefined regions. Typically, purity will be measured in terms of biological activity or functions as a result of uniform sequence. Such characteristics will typically be measured by way of binding with a selected ligand or receptor.

('934 patent at col. 8:12-19). Although the Court ordinarily would accept this express definition of "pure," the Examiner determined that this meaning was indefinite, unclear and confusing. (Livornese Decl., Exh. 41 (6/2/93 Office Action) at 4). In response, Affymetrix amended the claims to recite specific percentages of purity, and characterized the claims as "now referring to a purity (i.e., identical sequences) of greater than 50%." Given the clear prosecution history that modifies the definition presented in the specification, the Court adopts the modified definition as recited above.
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A. What does "purified" mean in the context of the patents in suit?

There can be no question as to the critical importance of this limitation which appears in each of the claims of the '052 and '120 patents. All the application claims were repeatedly rejected as unpatentable over the prior art references (especially the Dahlstrom patent) over some seven years of prosecution and through many continuation and divisional applications until, in response to the Examiner's repeated suggestion, the claims were finally amended to limit them to a "purified" 69k antigen. However, the parties hotly dispute the meaning of this limitation.

Plaintiffs contend that it means only that the desired material has been at least partially separated or isolated from an unwanted material -- in other words, that any degree of purification suffices. Defendants urge a construction at the opposite end of the spectrum, one requiring that the extracted proteinaceous material be put through all of the purification steps described in the specification, including the final immunopurification step of "Example 3." On the basis of the intrinsic evidence alone, it is difficult to conclude that either of these extreme positions is the correct one, although that of defendants seems closer to the mark.

Our analysis begins of course with the patent specification, which discloses a vaccine wherein the only active ingredient mentioned is "an antigenic preparation derived from B. pertussis comprising ACAP, optionally toxoided e.g. using formalin, glutaraldehyde or [beta] -propiolactone, together with a pharmaceutically acceptable carrier therefor." ('052, 2/54-59.) All the specific examples of vaccine formulations given include "antigen according to the invention" as the only active ingredient. ('052, 9/36-10/26.)

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The specification, after discussing the prior research in "isolating and purifying the 20 or more surface antigens of the B. pertussis organism and characterizing their ability to induce immune reactions," states that among the antigens suggested for such investigation is adenylate cyclase. ('052, 1/54-64.) The specification then discusses several prior methods of reducing the toxicity of the extracted proteinaceous material, including that of defendant Takeda's U.K. Patent Specification 2 047 358 A, which discloses production of a B. pertussis extract vaccine "involving removal of endotoxin from culture supernatants." ('052, 2/6-9.)

The specification initiates its discussion of the patented invention by stating:

It has now been discovered that certain proteinaceous material, associated with adenylate cyclase activity, as hereinafter described, found in the cultures of B. pertussis, is capable of providing protection against challenge by B. pertussis when administered to experimental animals. This discovery that the proteinaceous material usually associated with adenylate cyclase activity is a major protective antigen against B. pertussis permits the preparation of vaccine formulations comprising antigenic preparations which are free from, or contain reduced amounts of, other known B. pertussis components which may be responsible for the toxic side-effects demonstrated by whole cell vaccines.

('052 2/28-40; emphasis added.) The specification later adds that although the patented antigenic preparations may have "minor quantities of other antigenic compounds, in addition to the ACAP," they are "preferably substantially free from other antigenic compounds." ('052, 3/34-42; emphasis added.) Then, after describing the disadvantages of prior methods of extracting ACAP from the outer membrane of B. pertussis organisms, the specification states:

We have now discovered that . . . extraction of B. pertussis organisms using regulated, mildly acidic conditions results in the extraction of substantially increased yields (about 40x better than previously reported techniques) of adenylate cyclase from the outer membrane in a form which is water-soluble.

('052, 4/6-12.) The specification then more specifically describes the extraction process, including incubation of the B. pertussis cells with an amino acid buffer and centrifuging to separate the cells from the ACAP-containing supernatant. ('052, 4/13-37.) It continues to describe use of the supernatant extract in the Kendrick test on mice, from which it was learned that

. . . control vaccines containing no adenylate cyclase activity were found to provide little or no protection against challenge with B. pertussis, suggesting that ACAP may, in fact, be the most important factor in immunity. Analysis of batches of non-protective whole-cell vaccine has also shown that non-protection tends to be associated with a lack of adenylate cyclase activity, further suggesting that ACAP may be the key antigen necessary for eliciting an immune response against B. pertussis.

('052, 4/41-50; emphasis added.)

The specification then teaches a multi-step purification process for producing the "purified" ACAP antigen, commencing with the "Crude Outer Membrane Proteins" extracted in the first step, which is described in "Example 1." ('052, 5/54-55.) Plaintiffs have admitted that this "crude" mixture is not a "purified" material. (Exh. 30, Interrog. # 9.)

In support of their contention that the ACAP is "purified" only after it has been put through all the steps of the purification process described in the specification, including the immunopurification step of "Example 3," defendants point out that "Example 3" is entitled "Purification of ACAP Using a Monoclonal Immunosorbent Column," ('052, 7/26-28), and that none of the products of the earlier steps in the process is described as a "purified" material. On the other hand, plaintiffs lay principal stress on the fact that in its initial, summary description of the purification process, the specification states:

The supernatant extract [from "Example 1"] . . . may . . . contain the ACAP in small quantities complexed with other proteins including fragments of LPS [lipopolysaccharide, which is suspected as the cause of toxic side effects], in which case it may be desirable to purify further the material for use in the vaccine formulations according to the invention. Thus, for example, further purification may be effected by ion exchange chromatography and/or by preparative isoelectro-focussing to eliminate complexed material. . . . After the above-described purification steps the ACAP may, if desired, be further purified, for example by passing the material through an immunosorbent column containing an appropriate monoclonal antibody against the ACAP.

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('052, 4/51-68; emphasis added.) Since the process steps denominated "Example 2(a)" and "Example 2(b)" are referred to as "purification" of the extract, plaintiffs argue that the product of those steps must be deemed to have been "purified" in the lexicography of the patent. However, this argument proves too much: because these steps are described as "further purification," carrying plaintiffs' argument to its logical conclusion would mean that the crude extract resulting from "Example 1" would likewise have to be deemed "purified." But, as already noted, plaintiffs have admitted that that product is not purified, as indeed they must in view of the prior art and the prosecution history of the applications for the '052 and '120 patents.

The limitation of the broadest claims of those applications to a "purified" ACAP material was added during prosecution to overcome the rejection of the claims as unpatentable over the cited references, particularly the Dahlstrom patent. Dahlstrom discloses the preparation of a B. pertussis antigen by extraction of proteinaceous material from B. pertussis cells in a saline solution (pH 8.5-10.5), which is later neutralized by the addition of sterile acid and centrifuged to separate the cells. The extracted antigen was tested for immunogenic potency by injection into mice and challenge by B. pertussis organisms introduced intracerebrally. Because Dahlstrom's antigen provided excellent immunity, with a 100% survival rate at a dosage of 0.015ml, it must have included a significant amount of ACAP, if we are to believe the teaching of the patents in suit that "vaccines containing no adenylate cyclase activity were found to provide little or no protection against challenge with B. pertussis" and that ACAP "may be the key antigen necessary for eliciting an immune response against B. pertussis." ('052, 4/41-50.) Thus there was ample support for the PTO Examiner's conclusion that the Dahlstrom process "inherently . . . would result in the extraction of Applicant's claimed protein. Note that Applicant's claims 28-32 do not require the antigen to be purified." (Exh. 41 P 5.) Novotny acquiesced in that conclusion by amending all of the claims of the application for the '052 patent so that they cover only a "purified" 69k antigen.

Nevertheless, in his co-pending application for the '120 patent, Novotny made another effort to obtain the coverage which he had thus relinquished, asserting claims similar to those of the '052 patent except that the word "purified" was replaced with the word "acellular" (See Exh. 31 at 3.) These broader claims were rejected as unpatentable over an article by Novotny and K. Cownley -- "Effect of Growth Conditions on the Composition and Stability of the Outer Membrane of Bordetella pertussis" -- published in 1978 as part of the Proceedings of the Third International Symposium on Pertussis (the "Novotny & Cownley article"). In rejecting the claims, the Examiner stated that "the rejected claims do not contain any limitations which would distinguish the claimed products from the isolated outer membrane of the [Novotny & Cownley] article on the basis of purity." (Exh. 32 P 6.) Novotny thereafter amended all the claims to limit them to "purified" 69k. (See Exh. 34.)

Therefore, there can be no dispute that the claim limitation to a "purified" material requires, at the least, sufficient purification to distinguish it from the extracted ACAP-containing material of the prior art, including the Dahlstrom patent and the Novotny & Cownley article, which was cited in rejecting the claims. It is clear that a "purified" ACAP is one that results from subjecting the mixture of proteins extracted from the outer membrane of B. pertussis bacteria to one or more purification steps which, to a substantial degree, isolate ACAP and eliminate the other antigens in the mixture. The only remaining question is how much purification is required for the material to be deemed "purified" within the meaning of the claims?

Defendants' argument that the third step (immunopurification), "Example 3," is necessary to achieve a "purified" material runs contrary to the specification's statement that the final step is optional:

After the above-described purification steps ["Example 2(a)" and "Example 2(b)"] the ACAP may, if desired, be further purified by passing the material through an immunosorbent column containing an appropriated monoclonal antibody against the ACAP ["Example 3"].

('052, 4/64-68; emphasis added.)

In opposition, plaintiffs argue that, because the limitation to a "purified" 69k was added to the broadest claims of the '052 and '120 patents to overcome their rejection as anticipated by or obvious in view of the prior Dahlstrom patent, the limitation should be construed as narrowing the claims only to the minimum extent necessary to overcome the rejection based on Dahlstrom. At the oral argument of the motions, plaintiffs' counsel conceded that the extraction and centrifugation steps of Dahlstrom constitute "purification." (Transcript of May 26, 1998 Oral Argument at 27.) Yet he argued that the claims of the '052 and '120 patents must be construed so as to cover antigens which have undergone any degree of

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purification beyond that performed by Dahlstrom.

However, that argument considers only one type of intrinsic evidence -- the prosecution history -- and ignores the equally important intrinsic evidence of the specification itself, which contains strong indications as to the meaning of the term "purified." The specification teaches that ACAP may be the "key antigen" for immunization against B. pertussis, that "the vaccine formulations according to the invention may, if desired, contain minor quantities of other antigenic compounds, in addition to the ACAP . . . . [but are] . . . preferably substantially free from other antigenic components." ('052, 3/33-42; emphasis added.)

Moreover, the only antigen that is described in the specification as "purified" is the product of the immunopurification step of "Example 3." At the oral argument, plaintiffs' counsel contended, with impressive ingenuity, that this step is unnecessary to produce a safe and effective antigen and was disclosed only so that Novotny "could characterize and identify [69k] as part of his teaching." (Tr. at 26-27.) But Novotny's specification taught immunopurification as the final step in producing an "antigen according to the invention." There is not the slightest suggestion that it was disclosed only as a means of identifying the new antigen which Novotny claims to have discovered.

After thorough consideration of all the intrinsic evidence, the Court concludes that the term "purified" in the claims of the '052 and '120 patents means that the mixture of proteins extracted from the outer membrane of B. pertussis has been treated to reduce the concentration of antigens other than 69k at least to the point where they are "minor" ingredients and 69k is the major remaining antigen. In other words, 69k must constitute, at the minimum, more than half of the extracted proteinaceous material present in the mixture.

If there were any doubt about this conclusion, resort to the most persuasive extrinsic evidence -- the testimony of the patentee Novotny against his own interest -- would only narrow the definition further in favor of the defendants. In pretrial depositions, Novotny stated unequivocally that the extracted material is not "purified" even after it has been subjected to the preliminary purification steps of "Example 2(a)" and "Example 2(b)" and not until it has gone through the final immunopurification step of "Example 3":

Q: At the end of Example 2(a), after you have performed that procedure, do you have something that is purified, as you understand the meaning of that term?

A: No, it was crude separation of some components which we weren't interested in, and some components which we wanted to proceed further, which was made, at that time, electrofocusing.

Q: What about the procedure of Example 2(b), which is: "Preparative flat bed isoelectrofocusing [in] granulated gel" . . . . At the end of that procedure, do you have something that was purified, as you understand that term?

A: No, it was still complex.

Q: Turning to Example 3 in column 7, that example is entitled: "Purification of ACAP using a monoclonal immunosorbent column."

A: That's correct.

Q: What were you trying to achieve in that procedure?

A: No, that's the final step of the purification which started in column 5, because [the] immunosorbent column was specific for the protein. So, it stuck to the column and was then eluted from the immunosorbent and you obtained a variety of a very pure preparation.

Q: So, according to your understanding, it is only after someone completes the procedure of Example 3, with monoclonal antibodies, that you have a purified substance, as you understand that term?

A: Yes.

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Q: Turning back then to column 10, where you see the claim, am I right that you understand the term, "a purified Bordetella pertussis antigen," that refers to the product that you get after you complete Example 3?

A: Yes, sir. You have to finish all of it.

(Novotny Dep., June 2, 1997, Exh. 49 at 65-67.) It would be difficult to envision a clearer and more positive statement from the patentee himself that the position advanced by defendants as to the meaning of the term "purified" in the claims of his patents is absolutely correct, and that the construction for which plaintiffs contend is plainly wrong.

In light of this testimony, it is not surprising that plaintiffs urge the Court of follow the rule that where the intrinsic evidence permits an unambiguous construction of the meaning of the claim terms, reliance on extrinsic evidence is improper. However, plaintiffs themselves invite the Court to violate the rule by offering the declaration of Dr. Carine Capiau, an employee of plaintiff SmithKline, as to the meaning of the claims. She states: "In my opinion, the term 'purified' as used in the claims of the '052 patent and the '120 patent means that the desired material has been at least partially separated or isolated from an unwanted material." However, that opinion is pure ipse dixit, Capiau's declaration cites absolutely no evidence, intrinsic or extrinsic, in support of her opinion. She merely adds: "It is my further opinion that those skilled in the art would define 'purified' in such a manner." Such conclusory statements by an employee of one of the parties carry little if any probative weight, especially when they contradict clear and positive statements against interest by the patentee himself.

Thus, the best and most reliable extrinsic evidence strongly supports the Court's conclusion that the word "purified" in the claims of the '052 and '120 patents means that the proteinaceous material extracted from the outer membrane of B. pertussis bacteria must be purified at least to the extent that 69k is its major antigenic component. Indeed, if the intrinsic evidence left any doubt as to the meaning of the term "purified," resort to the patentee's own testimony would lead only to a further narrowing of the claim coverage to require completion of the entire purification process disclosed, including immunopurification in a chromatographic column charged with a monoclonal antibody which selectively binds 69k.
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III

We turn first to the infringement issue. Any infringement inquiry entails a two-step process. "First, the claims must be correctly construed to determine the scope of the claims. Second, the claims must be compared" to the accused product. Enercon GmbH v. International Trade Comm'n, 151 F.3d 1376, 1384, 47 U.S.P.Q.2D (BNA) 1725, 1731 (Fed. Cir. 1988).

The claim construction inquiry "begins with the language of the claim itself." National Recovery, 166 F.3d at 1194, 49 U.S.P.Q.2D (BNA) at 1675. The parties dispute the meaning of "purified" as recited in the '052 and '120 patent claims. Plaintiffs assert that the term limits their claims no more than required by the extraction step taught by Dahlstrom. Defendants take the far more Draconian view that the term imputes to the claims the requirement that the 69kD antigen be "purified" through the monoclonal antibody isolation step of the written description's Example 3. The district court afforded the term an intermediate scope based on Novotny's disclosure that only "minor components" may be present in the "purified" antigen isolate.

As a term of degree, "purified" inherently requires an evaluation of that degree in order to be defined precisely. Our independent review of the record convinces us that no consensus has emerged on the plain meaning of the term to one of ordinary skill in the art. See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990, 50 U.S.P.Q.2D (BNA) 1607, 1610 (Fed. Cir. 1999) (claim term given ordinary meaning unless "the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used"). In view of the lack of consensus, we conclude that the term as used in the claims requires clarification. For such clarification we turn to the written description. See Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1248, 48 U.S.P.Q.2D (BNA) 1117, 1120 (Fed. Cir. 1998) ("[A] claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description.").

We agree with the district court that the written description compels a construction of "purified" requiring that the claimed antigen comprise greater than fifty percent 69kD antigen. The written description states that the 69kD antigen preparation

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contemplated as the invention for use in vaccines "may, if desired, contain minor quantities of other antigenic compounds." We think it clear that this statement, by its own terms, clearly does not permit "other components" to comprise more than fifty percent of the contemplated 69kD antigenic preparation as used in a vaccine--thus setting a lower bound on the amount of 69kD antigen required by the claims.

Of course, the statement does not necessarily set a higher, upper bound on the degree of purity required. In contrast to the absolute requirement that no more than "minor quantities" of other components be present in the 69kD antigen preparation, the statement in the written description that "the antigenic preparations are, however, preferably substantially free from other antigenic components"--the degree of purity that would be expected upon completing the monoclonal antibody isolation step of Example 3--is but a permissive, not obligatory, condition. Further, we are mindful that the particular isolation steps provided in the examples may merely represent the best mode known to Novotny, and as such, ought not in and of themselves further limit his claims that do not recite these steps. See, e.g., Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533, 3 U.S.P.Q.2D (BNA) 1737, 1743 (Fed. Cir. 1987) (applicant may in principle claim more broadly than a single disclosed embodiment).

At the same time, we nevertheless read the purification steps through Example 3 as making clear that Novotny's invention is directed to procedures having the aim of enriching for the 69kD antigen, a notion corroborated by the written description's statement that only "minor quantities" of other components may be present in the final 69kD antigen preparation used in a vaccine. Thus, while our construction of "purified" does not require that the claimed antigen be "substantially free" of other components--as would be the result of employing all of the purification steps described--that the aim of the invention, as conveyed by the written description, is to enrich for the 69kD antigen, further supports our construction of "purified" as being limited to antigen preparations that are greater than fifty percent pure. Such a degree of purity clearly meshes with a requirement for a degree of enrichment that could not be achieved by happenstance alone, as, for example, a by-product of procedures not specifically aimed at enriching for 69kD antigen. See Renishaw, 158 F.3d at 1250, 48 U.S.P.Q.2D (BNA) at 1122 ("Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. . . . The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.").

We therefore agree with the district court that the proper construction of "purified" in the '052 and '120 patent claims requires that the 69kD antigen be present in an amount greater than fifty percent of the antigen isolate.
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B. The Court Adopts the Plaintiff's Construction of Claim 1

Claim 1 of the LeMaire patent states that the subject of the patent is:

[a] purified and isolated TNF [alpha]-binding protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence

Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Set Thr Cys Arg Leu Arg Glu where Xaa is hydrogen, a phenylalanine residue (Phe) or the amino acid sequences Ala Phe, Val Ala Phe, Gln Val Ala Phe, Ala Gln Val Ala Phe, Pro Ala Gln Val Ala Phe, or Leu Pro Ala Gln Val Ala Phe.

Def.'s Br. Ex. A ("LeMaire Patent") at Col. 6, lines 38-46. The parties agree that the construction of claim 1 turns on whether the LeMaire patent covers only the TBP-II protein (as the plaintiff maintains), Pl.'s Br. at 3; Pl.'s Resp. to Def.'s Br. ("Pl.'s Resp.") at 1, or if the patent covers the TBP-II protein, as well as the naturally occurring muteins of the TBP-II protein (as the defendant argues), Def.'s Br. at 31, 32; Def.'s Resp. To Pl.'s Br. ("Def.'s Resp") at 4. 9 Based on the intrinsic evidence (the plain language of the claim, the patent specification, and the prosecution history) the court concludes that the LeMarie patent covers only the TBP-II protein.

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9 According to the plaintiff, the "normal" form of the TBP-II protein is the form that is most prevalent in the population.

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Pl.'s Br. at 4.

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1. The Language of Claim 1

The defendant argues that the court should construe claim 1 to cover: "a purified and isolated TNF [alpha]-binding protein [and its naturally-occurring mutations]." Def.'s Resp. at 9. Although the defendant argues that claim 1 encompasses muteins, the language of claim 1 does not include any reference to the term mutein. Because neither side claims that the term protein automatically includes the term mutein, it is unreasonable to alter the scope of the plain meaning of the term chosen by the plaintiff and include muteins in the definition of a protein. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting McCarty v. Lehigh Valley R.R. Co., 160 U.S. 110, 116, 16 S. Ct. 240, 40 L. Ed. 358, 1895 Dec. Comm'r Pat. 721 (1895), for the proposition that "if we once begin to include elements not mentioned in the claim, in order to limit such claim . . . we should never know where to stop").

Assuming arguendo that a person skilled in the art would use the term protein to refer not only to a protein but also to a mutated form of a protein, the court's conclusion would not change because claim 1 refers to proteins in the singular, not the plural. In short, it is unnatural to read the phrase "a purified and isolated TNF [alpha]-binding protein" in claim 1 to mean "a TNF [alpha]-binding protein and its naturally-occurring muteins," or "TNF [alpha]-binding proteins." 10

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10 The defendant also argues that the LeMaire patent should be construed to cover many proteins instead of just one because the indefinite article "a" in claim 1 should be construed to mean "one or more." Def.'s Claim Construction Br. at 24-25. Despite the defendant's arguments regarding the interpretation of the indefinite article, the plain and ordinary meaning of "a purified and isolated TNF [alpha]-binding protein" is a singular protein which is characterized by the binding properties, weight, and amino acid sequence described in the claim. While the court could read the indefinite article "a" as "one or many," "there is no indication in the patent specification that the inventors here intended it to have other than its normal singular meaning." North Am. Vaccine v. Am. Cyanamid, 7 F.3d 1571, 1576 (Fed. Cir. 1993).

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2. The Patent Specification

The patent specification also undermines the defendant's argument that claim 1 encompasses "a TNF [alpha]-binding protein and its naturally-occurring muteins." The LeMarie patent specification distinguishes muteins from the TBP-II protein by stating that muteins "are produced by the suitable exchange, deletion, or addition of amino acids of peptides in the protein chain without this leading to a large reduction in the action of the novel protein." LeMarie Patent, Col. 1, lines 31-35. According to the defendant, the definition of muteins in the specification refers only to man-made mutations of a protein. Def.'s Resp. at 10. Thus, under the defendant's theory of the case, it is of no moment that the claim language does not include the word mutein. In other words, the defendant bases its argument that claim 1 includes the TBP-II protein as well as its naturally occurring mutations on the assumption that the plaintiff restricted the meaning of the term mutein, as used in the specification, to man-made mutations. Def.'s Resp. at 11-12.

The term mutein, as used in the specification, however, is not limited to man-made mutations. For example, the specification describes how TBP-II and its muteins are "isolated" from a naturally occurring substance and not "created" from the substance, indicating that at least some muteins must have natural origins. LeMarie Patent, Col. 1, lines 41-46. Also, the specification states that the "proteins [and muteins] described herein are present in urine and ascites fluid," further indicating that muteins can be naturally occurring products. Id., Col. 1 lines 61-62.

The defendant also argues that because the specification states that "muteins . . . are preferably prepared by genetic engineering methods," LeMarie Patent, Col. 2, lines 27-30, the word muteins only includes man-made mutations, Def.'s Resp. at 11-12. "In the course of construing the disputed claim terms, a court should not ordinarily rely on the preferred embodiments alone as representing the entire scope of the claimed invention." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1370 (Fed. Cir. 2002). Accordingly, the plaintiff's statement that muteins are preferably prepared by genetic engineering methods does not automatically serve to limit the meaning of the word to man-made mutations. The court therefore concludes that the specification does not limit the definition of the term mutein to man-made mutations.
3. The Prosecution History

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The prosecution history provides the strongest support for the court's conclusion that the LeMarie patent does not encompass the naturally-occurring mutations of the TBP-II protein. The LeMaire patent originally included the phrase "and the muteins thereof" at the end of claim 1. After the patent examiner objected to this term because it potentially included an unlimited number of mutated proteins, Def.'s Br. Ex. F at 2, the plaintiff narrowed the scope of the claim by removing the objectionable phrase. Pl.'s Resp. at 5. Because the plaintiff removed the term mutein from the claim, the court cannot replace it to expand or reduce the claim's scope. United States v. Telectronics, Inc., 857 F.2d 778, 783 (Fed. Cir. 1988). That is, because the plaintiff expressly disavowed that its patent covered the muteins during prosecution stage, the court cannot reintroduce the term into the patent by construing claim 1 to include muteins. Id. (citing Kistler Instrumente AG v. United States, 628 F.2d 1303, 1308, 224 Ct. Cl. 370 (1980) for the proposition that "courts are not permitted to read 'back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office'"). Accordingly, the court rules that in conjunction with the language of the claim and the specification, the prosecution history shows that claim 1 encompasses the TBP-II protein but not its naturally-occurring muteins.
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2. "Purified from mammalian cells grown in culture"('422 claim 1)

Amgen	Roche/Hoffmann	This Court (earlier case)
Wherein the protein is obtained in substantially homogeneous form from mammalian cells grown in culture, such that it originates in mammalian cells, but need not be taken directly out of the interior of the cells	Obtained in substantially homogeneous form from mammalian cells, using the word "from" in the sense that it originates in mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture	"obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture". Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (D. Mass. 2001), aff'd in part, rev. in part 457 F.3d 1293 (Fed. Cir. 2006).

This Court previously interpreted "purified from mammalian cells grown in culture" to mean purified to substantial homogeneity. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 89 (D. Mass. 2001), aff'd in part, rev. in part 457 F.3d 1293 (Fed. Cir. 2006). Further, the Federal Circuit stated: "the [district] court read the phrase 'mammalian cells grown in culture' as a whole to encompass purification techniques from the cells or the cell culture medium." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1347-48 (Fed. Cir. 2003) (citing Amgen, Inc., 126 F. Supp. 2d at 88-89). In fact,

As to the '422 patent, the limitation "purified from mammalian cells grown in culture" in claim 1 clearly limits the source of the EPO used in the claimed "pharmaceutical composition." The limitation only speaks to the source of the EPO and does not limit the process by which the EPO is expressed. Rather, the claim is broadly drawn to a "pharmaceutical composition" having certain elements, one of those being EPO "purified from mammalian cells in culture." This reading is in line with the district court's construction ….

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Id. at 1329-30. The Federal Circuit further explained, "[w]e do not hold that these limitations lack meaning, only that they mean just what they say. Accordingly, they limit only the source from which the EPO is obtained, not the method by which it is produced." Id. at 1330 n.5.

Taking as a starting point this settled construction, that the claim only limits the source from which the EPO is obtained, Roche/Hoffmann asks this Court to revise its previous interpretation. The argument is based on SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312 (Fed. Cir. 2006), where the Federal Circuit affirmed the invalidation of a patent to a pharmaceutical composition that recited process steps as the only distinguishing feature over a prior art tablet, id. at 1321. The Federal Circuit stated:

It makes no difference here whether the '944 patent's product-by-process claims are construed broadly to cover the product made by any process or narrowly to cover only the product made by a dry admixing process. Either way, anticipation by an earlier product disclosure (which disclosed the product itself) cannot be avoided. While the process set forth in the product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. We agree with the district court's conclusion that the 1723 patent disclosure anticipated the identical product claimed by the '944 patent even though that product was produced by an allegedly novel process.

Id. at 1318-19.

As Amgen correctly states, however, and as has long been recognized by the Federal Circuit, source or process limitations can and do serve to define the structure of a claimed product where such limitations are the best means to distinguish a claimed product over prior art. In re Luck, 476 F.2d 650, 653 (C.C.P.A. 1973)("[P]roduct claims may include process steps to wholly or partially define the claimed product …. To the extent that these process limitations distinguish the product over the prior art, they must be given the same consideration as traditional product characteristics.") (internal citation omitted). In this context, Roche/Hoffmann's citation to SmithKline Beecham Corp. is misplaced since it omits the next passage, which recognizes that process limitations may impart novel structure to a product claim: "If those product-by-process claims produced a different product than that disclosed by the '723 patent, there would be an argument that the '723 patent disclosure did not anticipate." SmithKline Beecham Corp., 439 F.3d at 1319 (citing In re Luck, 476 F.2d at 653).

In this case, Dr. Lin has testified that at the time, "the only way [to] characterize [his claimed] product is by the way they were making . . ." Def.'s Mem. Opp'n Amgen's Claim Construction. [Doc. 322] at 11-12 (citing Trial Transcript at 965:8-14, Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293 (Fed. Cir. 2006)). Accordingly, the Court deems it appropriate to include the "source limitation" in a product claim. Thus, Roche/Hoffmann's petition that the Court change the previous construction is denied. This Court's construction will stand as follows:

Purified from mammalian cells grown in culture: obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture.

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E. Purified from Mammalian Cells Grown in Culture

The phrase "purified from mammalian cells grown in culture" is contained only in Claim 1 of the '422 patent, for which the Court subsequently granted summary judgment on literal infringement grounds. The parties presented strikingly different constructions of this phrase during the Markman hearing. Amgen contended it means "purified from the in vitro culture in which the mammalian cells have been grown," Pl.'s Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. Amgen's '422 Patent Claim 1, whereas TKT argued that it means "obtained in a substantially homogeneous state from the mammalian cells in which it was produced and not from the cell culture media," Defs.' Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. 50. TKT admitted that the specification taught three different methods of obtaining EPO: extraction (1) from the cell cytoplasm; (2) from the cell membrane; and (3) from the cell culture medium. TKT nonetheless contended that the plain and ordinary meaning of the phrase meant that the EPO had to be purified from the cells. Thus, argued TKT, Amgen only claimed one of the three methods it taught in the patent. Because TKT obtains its EPO from the cell culture media and not directly from its cells, the parties' positions are not surprising.

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The Court, however, disagreed with TKT's interpretation of the claim with respect to both the plain and ordinary meaning of the terms and the consistency of its interpretation with the other claims. First, TKT's construction would exclude the patent's preferred embodiment: Example 10. Constructions that exclude the patent's preferred embodiment should rarely be adopted. Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996); MediaCom, 4 F. Supp. 2d at 28. Example 10 extensively describes techniques for obtaining substantially purified erythropoietin from cell culture media. Trial Ex. 1 at 27:15-50, 28:29-32. TKT's claim construction would exclude the method taught in the patent's preferred embodiment and hence is suspect.

Second, from the Court's perspective, TKT's construction ignored the language "grown in culture" and focused solely on the immediately preceding language, "purified from mammalian cells." If the claim merely read "purified from mammalian cells," then TKT's argument that the human erythropoietin must be extracted from the cell itself would indeed have held more sway. Yet all of the terms of the claim must be given effect. Consequently, the Court read the phrase "mammalian cells grown in culture" as a whole and, therefore, as not specifying a particular method, but rather encompassing purification techniques from the cells or the cell culture medium. Thus, the Court held that "purified from mammalian cells grown in culture" means "obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture." Tr. of Markman Hr'g, Vol. III at 16:15-19.
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I

Apotex argues that the district court erred in construing claim 1 of the '181 patent as covering CA having no more than 5% degrading, unwanted impurities not including excipients, such as the sorbitol and zinc chloride added by Apotex to its CA product. Apotex asserts that "a purity of at least 95%" means at least 95% of a sample has to be CA regardless of what the remaining 5% is.

The district court did not commit legal error in claim construction in its preliminary injunction decision. First, to read the CA of claim 1 as containing less than 5% of anything other than CA would read preferred embodiments of the invention out of the scope of the claim. For example, the product disclosed in Example 26 contains 60% of CA and 40% of additives. '181 patent, col. 11, II. 42-55. It is well established that claims are generally construed so as to not exclude a preferred embodiment. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1578 (Fed. Cir. 1996) (stating that a claim interpretation that excluded a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support, which is wholly absent in this case"). Second, the specification describes impurities and that the typical impurities are degrading, unwanted isomers of CA. '181 patent, col. 2, II. 27-38. The description of the typical impurities in the specification is consistent with the patentee's early attempt during the prosecution history to define the invention using a percentage of impurities.

We thus conclude that, in the context for the preliminary injunction, the district court did not err in construing claim 1 so that excipients would not be counted as impurities to affect the purity of CA as claimed by the '181 patent. Although GSK and Apotex also dispute various dictionary definitions of "purity," we find the district court's construction correct at least for purposes of a preliminary injunction in view of the claims, specification, and prosecution history of the '181 patent.
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B. Infringement of the '181 Patent 2

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2 The dissent argues that we should not address Apotex's infringement and invalidity arguments before turning to the issue of willful infringement because there are no past damages awarded for the infringement and because the patents have

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expired. We disagree. Willful infringement requires that the defendant infringe a valid patent without a reasonable belief that its actions would avoid infringement. Vulcan Eng'g Co. v. FATA Aluminium, Inc., 278 F.3d 1366, 1378-79 (Fed. Cir. 2002). We thus find it appropriate to speak to the threshold issues of infringement and validity before turning our attention to willful infringement.

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On appeal, Apotex argues that the district court erred in construing the phrase "having a purity of at least 95%" of Claim 1 of the '181 patent to cover formulations with more than 5% of other ingredients. Apotex argues that Claim 1 covers only pure CA and that any other compounds added to CA render the CA impure for purposes of meeting the 95% purity limitation of Claim 1. Under this definition, Apotex's formulation, which contains only 90% amorphous CA, would not infringe the '181 patent.

To properly construe a claim term, a court first considers the intrinsic evidence, starting with the language of the claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claim terms should be construed consistently with their ordinary and customary meanings, as determined by those of ordinary skill in the art. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). In construing the terms of a patent, the court must also examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term. See, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1988); Brookhill-Wilk, 334 F.3d at 1299.

In the present case, Apotex's construction of the phrase "having a purity of at least 95%" is both contrary to the ordinary meaning of such a phrase in the pharmaceutical arts and belied by the specification of the '181 patent. The specification describes in detail the types of molecules that are considered impurities, including among the "typical impurities" compounds related to CA such as the 2-isomer and E-isomer of CA. '181 patent, col. 2, ll. 36-38. The patent therefore uses the term impurities in a manner similar to its ordinary usage, where impurity is considered as an unwanted reaction product formed during synthesis. Glaxo, 268 F. Supp. 2d at 1026. In contrast, excipients are inactive ingredients that are routinely and purposefully added to the active ingredient to enhance the performance of the active ingredient. Id. at 1023. To one of ordinary skill in the art, excipients are almost universally used with the active ingredient, and therefore do not act to affect the purity of the drug. Id. at 1026. This common understanding of purity is aptly demonstrated by Apotex's patent application for its co-precipitate, which stated that, "In the case of pure amorphous cefuroxime axetil, the process of manufacture will preferably be to dissolve the zinc salt along with the cefuroxime axetil in suitable solvent and then evaporate the solvent . . . ." Apotex's statement strongly suggests that the purity of CA remains unaffected by the addition of excipients such as the zinc chloride used by Apotex in its generic product.

Apotex's construction also violates the principle that claims should rarely, if ever, be construed to exclude a preferred embodiment. Vitronics, 90 F.3d at 1583. Were we to count excipients as impurities for purposes of Claim 1, we would be forced to limit Claim 8 to pharmaceutical formulations in which CA composed at least 95% of the formula. The specification of the '181 patent provides, however, that "compositions may contain between 0.1 - 99 % of the active ingredient . . . ." '181 patent, col. 5, ll. 17-37, 59-61; col. 6, ll. 1-5. The specification also provides a list of pharmaceutical examples related to Claim 1, all of which contain less than 95% amorphous CA.

Because Apotex's construction (1) conflicts with the ordinary understanding of the phrase "having a purity of at least 95%," (2) would exclude all preferred embodiments of Claim 8, and (3) is in conflict with the specification of the '181 patents, this Court affirms the district court's construction of the '181 patent. Based on this construction, Apotex's ANDA admission that its generic CA products contain less than 2% by weight impurities of CA supports the district court's finding of infringement of the '181 patent.

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1. Quantity

The term "quantity" appears in Claims 1, 2, 4, and 5 of the '311 Patent. Plaintiffs argue that quantity means "a measurable amount" whereas defendant argues it means "a specific, objective, non-arbitrary amount, an amount which is neither

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subjective nor relative." The court is in agreement with plaintiffs.

In Claim 1, the patent method requires the examiner to obtain bodily fluid from the patient in question and analyze "to determine the quantity therein" (Col. 17, line 1) of at least one of the ten listed compounds. Claims 2 and 4 refer to the "said quantity" (Col. 17, lines 11, 17), and Claim 5 refers to the claim term in plural, instructing that there should be a determination of "the quantities of the plurality of said compounds." (Col 18, lines 19-20).

Based on the claim language, the term "quantity" should be straightforward. However, Metametrix's definition is problematic for several reasons. First, if quantity is a specific, objective, non-arbitrary amount, as Metametrix proposes, then a simpler formation is to describe the "quantity" as measurable. Next, Metametrix's description of "quantity" as "neither subjective nor relative," blurs the line between defining the term "quantity" and describing a process of measuring quantity. On its face, defendant's definition creates a contradiction between the definition of "quantity," and the process of measuring and comparing quantities. For example, if "quantity" cannot be subjective or relative, then the process of measuring and comparing the amount of a particular organic acid in a patient as compared to a non-autistic individual defies Metametrix's definition of "quantity." Such an approach appears contrary to the claim language and the specification. Therefore, the court adopts plaintiffs' definition and defines quantity as simply "a measurable amount."
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that at least one of the halogens CI, Br or I is present in a quantity

The '181 Patent's "Summary of the Invention" describes the potential for tungsten evaporated from the electrodes to be deposited on the wall of the envelope (bulb), thereby causing blackening of the walls which would lead to higher wall temperatures and a shorter life of the lamp. It further describes how the presence of a small quantity of a halogen (chlorine, bromine or iodine) creates a cycle by which the evaporated tungsten is transported back to the electrodes, thereby lessening the blackening. (col. 2, ll. 30-34)

The parties dispute the interpretation of the phrase "that at least one of the halogens Cl, Br or I is present in a quantity between 10<-6> and 10<-4> [mu] mol/mm<3>." Neither party disputes that "Cl," "Br" and "I" are the abbreviations for the halogens chlorine, bromine and iodine. I construe "quantity" to mean a concentration--the amount per unit volume.

Philips reads the phrase "is present in a quantity" to mean only such of the halogen that is "participating, supporting and keeping in existence the tungsten transport cycle during lamp operation." (Philips Br. at 14-18; Philips Reply Br. at 4-5.) Philips relies upon the preamble language--"a halogen for maintaining a tungsten transport cycle during lamp operation"--preceding the transitional phrase "characterized in that:" 1 I conclude that the phrase "a halogen for maintaining a tungsten transport cycle during lamp operation" identifies a filling material and describes the function of that material and nothing more. The phrase, fairly read, does not qualify or limit the halogen that "is present in a quantity".

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1 As Philips urges me to do, I read the claim language as a whole and consider the preamble language to be relevant to claim interpretation. I note that a Jepson-type claim is one in which the existing art is described in a preamble followed by a transitional phrase such as the "improvement comprising" or "wherein the improvement comprises" after which the claimed elements are stated. See U.S. Pat. Off. Rule 75(e), 37 C.F.R. § 1.75(e). Ex Parte Jepson, 243 O.G. 525 (1917). Iwasaki asserts that the "characterized in that" language (common in certain European applications) should be given a similar construction, thereby rendering everything prior to the transitional phrase admitted prior art. I need not and do not decide the issue at this time. See generally Landis on Mechanics of Patent Claim Drafting at § 6:8 (R. C. Faber ed., PLI 2004).

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Reading the claim as a whole, one of ordinary skill in the art would conclude that the quantity that is stated following the transitional phrase "characterized in that:" means the quantity of halogen in the bulb or envelope. It would be a strained construction to interpret the language to mean an amount of halogen less than the total quantity of halogen present in the envelope, i.e. only such of the quantity of halogen that is necessary "for participating, supporting and keeping in existence

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the tungsten transport cycle during lamp operation." 2 I also have considered the extrinsic evidence and do not find it persuasive in Philips' favor.

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2 "I would say that the quantity being added, when we look to measure this quantity, it is this quantity has to be there that is for the tungsten transport cycle. Any quantities that are there that are not used for the tungsten transport cycle are irrelevant. We're only claiming the quantities in the bulb for maintaining a tungsten transport cycle." (Counsel for Philips, Nov. 22 Hr'g at 38)

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a quantity between 10<-6> and 10<-4> [mu] mol/mm<3>

The parties also dispute the meaning of the phrase "a quantity between 10<-6> and 10<-4> [mu] mol/mm<3>." There is no dispute that the phrase "[mu] mol/mm<3>" means micromoles per cubic millimeter. Iwasaki contends that "10<-6> and 10<-4>" is intended to express a specific numerical range between 1 x 10<-6> and 1x 10<-4> while Philips argues that the phrase refers to a range between two orders of magnitude. Philips points out that there is no multiplier preceding the values "between 10<-6> and 10<-4> [mu] mol/mm<3>." Iwasaki points out that there are no words used such as "on the order of" or "approximately" or "of a magnitude of" that would give a person of ordinary skill in the art an awareness that the number that followed was not a specific numerical value.

I have examined other uses of scientific notation in the specification. There are references to quantities of methyl bromine in quantities of "5.10<-6>". (col. 3, l. 53) Elsewhere there is a reference to "5.10<-4> to 5.10<-2> g atoms of at least one of the halogens per cubic millimeter are fed into the envelope." (col. 1, l. 22.) While the use of a numerical multiplier is of some significance, it is also true that a numerical multiplier is not universally used when the multiplier is 1. 3 For example, to one skilled in the art, 10<5> means 100,000 and it may also be expressed as 1 x 10<5>. But, depending upon how it is used, it could also mean an order of magnitude of 10<5>, i.e. any numerical value in the hundreds of thousands. The specific context becomes critical to understanding. Here, I conclude that the use of two numbers in the phrase "a quantity between ___and ___" implies a specific range, as argued by Iwasaki. It does not imply a range between two values which are themselves ranges.

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3 I have considered the reference to "10<-5> [mu] mol of Br/mm<3>" (col. 3, l. 54) and conclude it to be ambiguous for the reasons discussed at the hearing. (Nov. 22 Hr'g, compare 25-27 with 56-59.)

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Philips disclaims inexactitude in its interpretation. (Nov. 22 Hr'g at 78) To bring precision, Philips urges that, utilizing rounding principles, "10<-6> and 10<-4> [mu] mol/mm<3>" represent a specific numerical range and that the concentration of the halogen "could be as low as 5 x 10<-7> [mu] mol/mm<3> and as high as 5 x 10<-4> [mu] mol/mm<3>." (Expert Report of Dr. David R. Lide at 9) 4 I am reluctant to read more into the claim language than is written. 5 A more natural interpretation is that the phrase "between 10<-6> and 10<-4> [mu] mol/mm<3>" means a quantity between 1 x 10<-6> and 1 x 10<-4> [mu] mol/mm<3>. If the claim language were intended to refer to orders of magnitude, it likely would have used a modifier or qualifier and not have expressed the quantity in the seemingly absolute terms implied by the form "present in a quantity between ___and ___". 6

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4 Another of Philips experts states as follows: "in my opinion, one skilled in the art would interpret the lower limit of halogen concentration in the '181 Patent Claims as extending downwards to 10.<-6.5> and the upper limit extends upwards

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to 10.<-3.5> [mu] mol/mm<3>." (Expert Report of Dr. Robin Devonshire at 15)

5 Philips relies upon Holmes, et al. (U.S. Patent No. 3,382,396). In that patent in this field of art, quantities of iodine are displayed in a one single table in the form "1x 10<-5>" and also in the form "10<-4>". For the reasons discussed at the November 22 hearing, these references are ambiguous.

6 I note that Claim 5 employees the language "that the mercury vapor pressure is about 400 bar." (emphasis added).

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I conclude that the phrase "a quantity between 10<-6> and 10<-4> [mu] mol/mm<3>" means that the halogen is present in the envelope or bulb in a quantity between 1 divided by 1,000,000 and 1 divided by 10,000 micromoles per cubic millimeter.
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C. Claim Construction

We next turn to the question of claim construction. U.S. Philips argues that the term "between 10 -6 and 10 -4 [mu] mol/mm 3" expresses a range of orders of magnitude, not a range of more-precise numbers, and that it was therefore error for the district court to construe the claim to mean "between 1 x 10 -6 and 1 x 10 -4 [mu] mol/mm 3." According to U.S. Philips, one of ordinary skill in the art of lamp chemistry would understand "10 -4" to mean something different and less precise than "1 x 10 -4"; i.e., the absence of a coefficient ("1") means that the term encompasses all values that are closer on a logarithmic scale to 10 -4 than to 10 -5 or 10 -3, or a range of approximately 3.2 x 10 -5 to 3.2 x 10 -4. 1 Thus, according to U.S. Philips, the full range should be construed as approximately 3.2 x 10 -7 to 3.2 x 10 -4 [mu] mol/mm 3, and Iwasaki's lamps with admitted halogen concentrations of 1.2 x 10 -4 to 2.0 x 10 -4 [mu] mol/mm 3 literally infringe.

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1 In other words, under U.S. Philips's proffered construction, the term "10 -4," as an order of magnitude, encompasses a range of values from 10 -4.5 and 10 -3.5--the set of numbers with base-10 logarithms that round to -4. This range is approximately 3.2 x 10 -5 to 3.2 x 10 -4. Mathematically, 10 -4.5 = 10 0.5 x 10 -5 = [square root] 10 x 10 -5, and 10 -3.5 = 10 0.5 x 10 -4 = [square root] 10 x 10 -4; the square root of 10 is approximately 3.2.

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We disagree with U.S. Philips and, like the district court, conclude that the claim limitation is properly construed to mean "between 1 x 10 -6 and 1 x 10 -4 [mu] mol/mm 3." Although the upper and lower bounds of the claimed range are expressed as powers of ten, this alone is no reason for treating them as anything other than the ordinary numbers that they are. As the district court observed, the overall phrase--"a quantity between and "--is a construction that "implies a specific range . . . . It does not imply a range between two values which are themselves ranges." Claim Construction Opinion at 8. The limitation does not refer to either bound as a range, an order of magnitude, or an approximation.

The specification fully supports this construction. In the LAMP 1 embodiment, under the heading "halogen," the '181 patent refers to "5 x 10 -6 [mu] mol of CH[2]Br[2][/mm 3] (10 -5 [mu] mol of Br/mm 3)." '181 patent, col. 3, ll. 53-54. The parenthetical expression apparently refers to the fact that one molecule of CH[2]Br[2] contains two bromine atoms, so the concentration of atomic bromine (Br) should be double the concentration of CH[2]Br[2]--two times 5 x 10 -6, or 1 x 10 -5. See Tr. of 11/22/2005 motion hearing at 57, ll. 10-11 (Dist Ct. Dckt. No. 64; Fed. Cir. J.A. 1233) ("You simply multiply the number on the first line by 2 because there are two bromines in every mole."). This suggests that "10 -5" is used as a synonym for "1 x 10 -5." Moreover, the LAMP 1 example specifies particular quantities for a number of attributes of the embodiment: e.g., an envelope volume of 23 mm 3, filling mercury at a concentration of 0.261 mg/mm 3, and power of 50W. It would be odd to infer in this context that "10 -5 [mu] mol of Br/mm 3," alone among the specified quantities, refers to a range or order of magnitude, solely because it uses a power of ten. Indeed, there is no use of a power-of-ten quantity such as 10 -5 anywhere in the specification that requires the broader construction that U.S. Philips advocates. We therefore affirm the district court's claim construction of the halogen range "between 10 -6 and 10 -4 [mu] mol/mm 3" as meaning

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"between 1 x 10 -6 and 1 x 10 -4 [mu] mol/mm 3."

However, there remains the question of how this construction is to be applied to the accused lamps. Before the district court, U.S. Philips argued that even under a claim construction of "between 1 x 10 -6 and 1 x 10 -4 [mu] mol/mm 3," a lamp with a halogen concentration toward the lower end of Iwasaki's admitted range--for instance, with a concentration of 1.2 x 10 -4 [mu] mol/mm 3--might still literally infringe due to rounding. The question of whether and how to apply rounding, it argued, is a question of fact that should have been left for the jury rather than decided as part of the claim construction or at summary judgment. See Summary Judgment Opinion, 2006 U.S. Dist. LEXIS 71276 at *18-19. The district court disagreed and held that the question of whether to apply rounding should be treated solely as a claim construction issue that did not present any factual questions for a jury. 2006 U.S. Dist. LEXIS 71276 at *20. U.S. Philips declined to argue its position as to rounding as a matter of claim construction, instead limiting its claim construction argument to its contentions regarding the meaning of the phrase "between 10 -6 and 10 -4 [mu] mol/mm 3," as discussed supra. 2006 U.S. Dist. LEXIS 71276 at *21.

In its opening brief on appeal, U.S. Philips does not challenge the district court's decision to treat the question of rounding as an issue of claim construction, nor does it challenge the district court's entry of summary judgment of no literal infringement under the district court's claim construction. Its sole infringement arguments on appeal are that the bounds of the claimed range refer to orders of magnitude rather than ordinary numbers--the claim construction argument we reject above--and that the doctrine of equivalents should have been available, an argument we address below. Accordingly, we deem the argument based on rounding to have been waived as to the Iwasaki products that the district court considered. See SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1319 (Fed. Cir. 2006) ("[A]rguments not raised in the opening brief are waived."). We therefore affirm the entry of summary judgment of no literal infringement as to Iwasaki's alleged acts of infringement after the filing of the complaint. 2 We do not reach U.S. Philips's argument that the question of rounding should have been presented to a jury, nor do we determine in this case where the process of claim construction ends and the literal infringement analysis begins.

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2 In so doing, we do not decide whether and to what extent this waiver applies to further proceedings in this case on remand with respect to alleged literal infringement occurring between the Rolfes letter and the filing of the complaint.

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We emphasize that the claim construction we affirm today should not be read to state the endpoints of the claimed range with greater precision than the claim language warrants. In some scientific contexts, "1" represents a less precise quantity than "1.0," and "1" may encompass values such as 1.1 that "1.0" may not. See Viskase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1320-21 (Fed. Cir. 2001) (discussing distinction between "0.91 g/cm 3" and "0.910 g/cm 3"). In other words, "1.0" may be said to have more significant digits than "1" with no decimal point. Because "10 -6" and "10 -4" are simply the numbers 0.000001 and 0.0001 expressed as powers of ten, the claim language provides no basis for inferring any level of precision beyond the single digit "1." The way that power-of-ten quantities are used in the specification, discussed supra, confirms that the quantities of halogen described by the claims are not intended to be more precise. Thus, it is technically incorrect to assert, as Iwasaki does in its brief before this court, e.g., Br. for Appellee at 35, that "10 -x" should be construed to mean "1.0 x 10 -x." It means, simply, "1 x 10 -x." "1.0 x 10 -x" expresses a quantity with greater precision, reflected in the recitation of a significant digit following the decimal point.

The claim construction that we affirm today is "between 1 x 10 -6 and 1 x 10 -4 [mu] mol/mm 3," not "between 1.0 x 10 -6 and 1.0 x 10 -4 [mu] mol/mm 3." We leave for another day the question of whether this claim construction is sufficient to answer the infringement questions presented by a future record. See E-Pass Techs., Inc. v. 3Com Corp., 473 F.3d 1213, 1219 (Fed. Cir. 2007) ("[A]ny articulated definition of a claim term ultimately must relate to the infringement questions that it is intended to answer.").
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B. Quantity of Aloe Vera

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For the reasons set forth below, this court interprets the claim term "quantity of Aloe Vera" in the '328 patent to mean:

an indefinite amount of aloe vera.

Ansell has asked this court to read into this term the same limitations it requested for "coat of Aloe Vera." As before, Ansell first argues that "quantity of Aloe Vera" should be interpreted to mean a quantity consisting entirely of aloe vera and no other substance, and second, that if substances other than aloe vera are present along with the aloe vera, then the percentage of aloe vera must be greater than 0.5% of the entire quantity.

In support of its first proposed limitation, Ansell relies on the same arguments it makes regarding the term "coat of Aloe Vera"; that Shen Wei has disclaimed the use of ingredients other than aloe vera and that Robie requires constructing "quantity" to exclude the use of other ingredients. As explained, this court finds no prosecution disclaimer of this scope. Furthermore, Ansell's reliance on Robie is misplaced. In Robie, the court explained that a "reference . . . to a coat of paint . . . ordinarily [means] that the coat consists entirely of the specified material." Robie, 36 C.C.P.A. 739, 171 F.2d 310, 311, 1949 Dec. Comm'r Pat. 25 (C.C.P.A. 1948) (emphasis added). This case is inapposite given that the court in Robie never considered the term "quantity," and the fact that Ansell (in response to Shen Wei's objection that Ansell was not considering "quantity" and "coat" as distinct terms) argued to this court that it "has never suggested that the terms 'coat' and 'quantity' have the same meaning." (Def.'s Reply at 3.) Finally, while Ansell asserts that Shen Wei has not used the terms "comprising" or "including" in conjunction with the term "quantity," Ansell has pointed to no case law, rule of construction, or other reason showing that not using these open terms requires the conclusion that a "quantity of Aloe Vera" cannot be aloe vera mixed with other ingredients. Therefore, this court refuses to limit the term "quantity of Aloe Vera" to substances consisting entirely of aloe vera.

Ansell apparently supports its second proposed limitation -- that "quantity of Aloe Vera" should not include substances with 0.5% or less of aloe vera -- with the same prosecution history citation in which Shen Wei disclaims a coat of aloe vera containing 0.5% or less of aloe vera. As with Ansell's attempt to apply Robie to the term "quantity," Ansell's attempt to apply Shen Wei's disclaimer regarding "coat of Aloe Vera" is hard to understand in light of Ansell's admission that the terms "coat" and "quantity" do not share the same meaning. Because the terms are not the same, Ansell cannot impose a limitation which applies to the term "coat" to the term "quantity" in the '328 patent.

Shen Wei argues that this court should construe "quantity" to mean an "amount." In support it cites to a general dictionary defining "'quantity' as, among other things, an 'indefinite . . . amount.'" (Pl.'s 56.1(a) Stmt., P24.) While Ansell has argued in favor of its proposed limitations on the term "quantity," it has not objected to construing "quantity" according to its dictionary definition. 6 This court concludes that the term "quantity" should be defined to mean an "indefinite amount."

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6 "Dictionaries . . ., which are extrinsic evidence, hold a 'special place' and may sometimes be considered along with intrinsic evidence when determining the ordinary meaning of claim terms." Bell Atlantic Serv., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001) (citation omitted). Furthermore, this court is aware of the Federal Circuit's admonishments regarding general purpose dictionaries. Id. ("We have previously against the use of non-scientific dictionaries 'lest dictionary definitions . . . be controverted into technical terms of art having legal, not linguistic significance.") (citation omitted); AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1247-48 (Fed. Cir. 2001) ("This court has repeatedly cautioned against using non-scientific dictionaries for defining technical words.") (citation omitted). The definition utilized by this court is not contradicted by Ansell. (Def.'s 56.1(b) Stmt., P24.) Nor does Ansell object to its use, except to argue that its proposed limitations should be adopted. Finally, this court concludes that the adopted definition of "quantity" is not inconsistent with the specification or the prosecution history.

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quaternized ammonium polymer

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The parties and the Court agree that the term should be construed as "a polymer compromising a quaternized nitrogen moiety, wherein said quaternized nitrogen moiety compromises a nitrogen atom, wherein all four atomic orbitals of said nitrogen atom are filled with an organic group."
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Claim Interpretation

2. The formula set out in claim one of each of the patents describes the same hydroxy-terminated urethane compound, with two components identified as "R" and "R<1>." The patents are distinguished primarily by the different applications for which the urethane compound is claimed. In addition, the '260 patent claims a method for using the patented compound in a topical composition.

3. Claim interpretation is a matter of law, solely within the province of the Court. Markman v. Westview Instruments, 52 F.3d 967, 978 (Fed. Cir.), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The Court interprets the meaning of the claim terms as would one skilled in the art. Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 867 (Fed. Cir. 1985). Because the inventor may be his or her own lexicographer, Autogiro Co. of American v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 397 (Ct. Cl. 1967), the Court may also determine whether a word or term used in the claims was intended to have a meaning which differs from the meaning used in the art.

4. Where there is question about the meaning that those skilled in an art give a term used in the claim, the specification and prosecution history (which contains the patent application as filed and the official record of the proceedings before the Patent and Trademark Office ("PTO")) can provide relevant information about the scope and meaning of the claim. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988). To ascertain the meaning of the claims, the Court considers these three sources: the claims, the specification, and the prosecution history. Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991). The patent specification, in particular, is the principal source for determining the meaning of ambiguous terms used in a patent claim. Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452-53 (Fed. Cir. 1985); see also Specialty Composites, 845 F.2d at 987.

5. It is inappropriate to read limitations into the claims from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim. E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir.), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).

6. Because the terms "linear" and "branched" do not appear in, nor are they required by, the language of the claims-in-suit, the claims do not contain any limitation based on the "linear" or "branched" nature of the claimed composition, or of its ingredients.

7. The claims also do not require the claimed urethane molecule to have been created by synthesizing an isocyanate with a diol, as opposed to a triol.

8. Thus, a person of ordinary skill in the art at the time the invention was made would understand that "R," as used in the claims, can be an alkylene or alkenylene radical containing from one to about 20 carbon atoms, or a cycloalkylene or cycloalkenylene radical containing from about 5 to about 10 carbon atoms, or a mononuclear or fused ring arylene radical containing from about 6 to about 10 carbon atoms, all of which may be unsubstituted or substituted with one or more lower alkyl, lower alkoxy, lower alkoxy-substituted lower alkyl, nitro or amino groups or halogen atoms.

9. Such person would also understand that "R<1>," as used in the claims, can be any alkylene or alkenylene radical, which may be the same or different alkylene or alkenylene radical as "R," and which may also be unsubstituted or substituted in various ways, including but not limited to substitutions with one or more lower alkyl, lower alkoxy, lower alkoxy-substituted lower alkyl, nitro or amino groups or halogen atoms. The patent does not limit the number of carbon atoms in "R<1>."
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Disputed Claim Language	ASM's construction	Genus's construction
A gaseous second reactant of radicals	A second reactant gas that includes radical atoms or molecules, which are highly reactive gas fragments (for example, atoms or molecules produced as a result of a glow discharge) that allow or encourage the desired reaction.	Free radicals, which are highly reactive gas fragments. Genus' expert, Dr. Oldham, defines "free radicals" as "molecules that possess one unpaired valence electron."

The dispute here is over the definition of "radicals." ASM argues that no definition is necessary, but that if the Court chooses to construe the term, it should construe it with reference to the mentions of "radicals" in the specification. ASM argues that Genus' proposed definition of free radicals as "molecules that possess one unpaired valence electron" is clearly wrong, as it is not based on anything in the specification, and would exclude substances that are unquestionably considered "radicals" by persons of ordinary skill in the art. The essence of the argument appears to be whether "radical" means any reactive gas fragment, including ions, or whether "radicals" are only electrically neutral reactive gas fragments.

The '365 patent contains several explanations of the term "radicals." The background portion of the specification provides:

In the 1960's it was realized that we could lower the temperature required for thin film

deposition at acceptable rates by creating a low pressure glow discharge in the reactive gas mixture. The glow discharge produces many high energy electrons that partially decompose the reactive gases, and these gas fragments (radicals) are very reactive when they impinge on a surface area even at moderate temperatures.

(Id. 1:38-45.) The summary of the invention provides that "the second reactant passes through a radical generator which partially decomposes or activates the second reactant into a gaseous radical before it impinges on the monolayer." (Id. 5:13-16.) The summary of the invention concludes: "It is an object of the invention to facilitate the growth of thin films of any element by using a radical generator to make available highly reactive gases (radicals)." (Id. 5:34-36.)

The only relevant portion of the file history that the parties have cited discusses the '365 patent in relation to United States Patent No. 5,693,139 ("Nishizawa"):

Nishizawa fails to recognize the necessity for the second reactant to contain free radicals …. The present invention recognizes the value of using a second reactant containing free radicals which react to remove the undesired elements of the first reactant adsorbed to the part, at low temperature, without also desorbing the desired elements of the first reactant monolayer.

(Sarboraria Decl., Ex. D ('365 patent file history) at 58.) This discussion is unhelpful in defining the term "radical," however, as it appears to be undisputed that "free radical" and "radical" are interchangeable terms. For example, the definition of "free radical" in the McGraw-Hill Dictionary of Scientific and Technical Terms states: "Also known as a radical." (Sarboraria Decl., Ex. L.)

ASM's expert, Alexander Glew, attests that:

The Genus construction of radicals, as free radicals with unpaired electrons, is incorrect and does not cover many known radicals. The '365 patent specification makes mention of methods, such as a glow discharge or plasma, of producing these radicals that would not be covered under the Genus construction. For example, the halogens cited in the '365 patent such as chlorine, bromine, fluorine, iodine, and astatine acquire an extra electron and fill their valence shell. The resulting radical is a negatively charged ion with a completed valence shell and no unpaired electrons. Other atoms and molecules may be

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stripped of electrons, resulting in no unpaired electrons in their valence shell, yet still be encompassed within the definition of radicals as known by those skilled in the art and as described in the '365 patent.

(Glew Expert Report at 13.) It is unclear to the Court, however, where Glew believes the '365 patent cites to halogens such as chlorine, bromine, fluorine, iodine, and astatine.

A patent assigned to Genus, United States Patent No. 6,305,314 ("the '314 patent") defines "radical" as follows:

The term radicals is well-known and understood in the art, but will be qualified again here to avoid confusion. By a radical is meant an unstable species. For example, oxygen is stable in diatomic form, and exists principally in nature in this form. Diatomic oxygen may, however, be caused to split to monoatomic form, or to combine with another atom to produce ozone, a molecule with three atoms. Both monotonic oxygen and ozone are radical forms of oxygen, and are more reactive than diatomic oxygen.

(Gasner Decl., Ex. 3, '314 patent 6:5-13 (emphasis added).) The patent also explains that:

Radical species, as introduced above, are reactive atoms or molecular fragments that are chemically unstable and therefore are extremely reactive …. Radicals may be created in a number of ways, and plasma generation has been found to be an efficient and compatible means of preparation.

(Id. 7:14-20.) Sneh, one of the inventors of the '314 patent, testified at deposition that radicals are electrically neutral. (Sun Decl., Ex. 6, Sneh Dep. 174:16-18.)

Galewski, the other inventor of the '314 patent testified that the ordinary meaning of "radical" in the semiconductor industry is atoms or clusters of atoms with unpaired electrons. (Sun Decl., Ex. 5, Galewski Dep. 74:12-75:4.; Sarboraria Supp. Decl., Ex. C, Galewski Dep. at 243:10-16.) Galewski also testified, however, that in the real world, "if I have something that generates something that's reactive, I may look at that as a radical, in a simple explanation." (Sun Decl., Ex. 5, Galewski Dep. 76:8-11.) According to Galewski, there is no need to know whether the reactive element was a radical, "because the end result is what we care about." (Id. 77:3-4.) Galewski also testified that ions are not reactive by themselves, and "are actually quite stable and happy because the electronic shell's structure is satisfied." (Id. 82:9-20.)

Genus' expert, William Oldham, does not actually dispute Glew's statement that radicals need not have an unpaired valence electron. In his expert report, he defines "radicals" as "highly reactive gas fragments," and explains that they are highly reactive because "they typically contain one or more unpaired electrons." (Oldham '365 Expert Report at 9 (emphasis added).) Although Oldham's rebuttal expert report omits the word "typically," he does not expressly dispute Glew's conclusion that certain radicals may not have an unpaired electron.

At least one treatise, in addition to Galewski's testimony, supports Oldham's conclusion that a radical has an unpaired valence electron, however. The McGraw-Hill Dictionary of Scientific and Technical Terms provides two definitions of "free radical":

[CHEM] An atom or a diatomic or polyatomic molecule which possesses at least one unpaired electron. [ORG CHEM] A species which is uncharged and possesses one or more unpaired electrons. Also known as a radical.

(Sarboraria Decl., Ex. L.) Another treatise states that "[a] radical is a molecular fragment with an odd number of unshared electrons." (Oldham Expert Report, Ex. H, Hart, H., Organic Chemistry, 8th edition(1991) at 13.)

Oldham disputes Glew's conclusion that a negatively charged ion can be considered a radical. "It is well known in the semiconductor art that the word radical is used specifically to identify those atoms or molecular fragments which are highly reactive and which are uncharged: In other words, the term "radicals" specifically distinguishes against ions." (Oldham '365 Rebuttal Expert Report at 5.) Oldham cites several treatises which distinguish ions, which are charged particles, from radicals, which are uncharged. (Id. at 5 (citing Wolf, S. and Tauber, R.N., Silicon Processing for the VLSI Era, Volume I: Process Technology, at 543-44; and Stephan A. Campbell, The Science and Engineering of Microelectronic Fabrication, 2d edition, at 249).)

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The Wolf and Tauber treatise defines radicals as "an atom, or collection of atoms, which is electrically neutral, but which also exists in a state of incomplete chemical bonding, making it very reactive." (Sarboraria Decl., Ex. M at 544.) It distinguishes radicals from "charged species, including positive ions, electrons, and negative ions[.]" (Id.)

The Campbell treatise states:

> Dissociated atoms or molecular fragments are called radicals. Radicals have an incomplete bonding state and are extremely reactive.

(Id. Ex. N at 249.) It defines ions as "charged atoms or molecules" which "may have more than one positive charge or may even be negatively charged." (Id.) It also distinguishes radicals from "charged species." (Id.) Both treatises also discuss radicals as components of a plasma or glow discharge, which comports with the specification's explanation that radicals are highly reactive components of a gas that have been created or triggered by a glow discharge.

Sherman, the inventor of the '365 patent, testified at deposition that a radical is:

> either an atom which is an unstable atom -- excuse me, oxygen atoms, nitrogen atoms, hydrogen atoms, for example. It could be a molecular fragment such as HN, which you would undoubtedly see if you made a discharge in ammonia, and any other number of molecular fragments. In reality, it could be a metastable atom and could possibly even be an ion.

(Kwun Decl., Ex. 1, Sherman Dep. 122:17-24.) On the other hand, Genus points to a pending patent application in which ASM's Chief Technical Officer, Raaijmakers, distinguishes radicals from ions. (Sarboraria Decl., Ex. I, at ASM 26068.)

Glew provides no independent support for his contention that radicals can include negatively charged ions. In fact, at his deposition, Glew stated that one could identify which atoms in a plasma are radicals and which are ions, because the ions are charged particles. (Sarboraria Decl., Ex. E, Glew Dep. 218:2-6.) Glew also testified that the chemistry textbook definition of "radical" is that radicals are uncharged, although he also stated that that definition would be slightly different than that to which one practicing in the field would subscribe. (Id. 215:6-12.) Glew also acknowledged that Wolf and Tauber is a semiconductor-oriented publication, and that under the Wolf and Tauber definition, ions are not radicals. (Id 215:13-15, 218:7-12.) It appears that Glew is not disputing that, to a person of ordinary skill in the art, radicals are uncharged particles. His deposition testimony suggests that his concern with the Wolf and Tauber definition in the context of the '365 patent is that the reactive gas fragments that are produced in a glow discharge include both radicals and ions. (Id. 217:12-218:25.) From this testimony, it appears to the Court that Glew believes the '365 patent is defining "radical" broadly to include all reactive gas fragments produced in a glow discharge or radical generator. (See, e.g., '365 patent 1:41-44.) This definition would include ions within the definition of "radical." That definition is different from the standard meaning of "radical" to a person of ordinary skill in the art, however. Oldham argues in his rebuttal expert report that "it would be absurd to suggest[] that everything produced by such generators is a 'radical' because it would mean, for instance, that an electron is a radical." (Oldham '365 Rebuttal Expert Report at 6.)

Because the language of the '365 patent does not clearly redefine the ordinary meaning of "radical" to include ions, the Court does not accept Glew's definition. As Genus has provided several treatises which agree with Oldham that radicals are uncharged, and it appears to be undisputed that the person of ordinary skill in the art would consider radicals typically to be uncharged, the Court agrees with Genus that a radical must typically be electrically neutral and possess at least one unpaired electron. The Court does not find that "radicals" must always be electrically neutral, however, because it appears that persons of ordinary skill in the art may use the term somewhat more loosely than the textbook definition. (See, e.g., Oldham '365 Expert Report at 9; Kwun Decl., Ex. 1, Sherman Dep. 122:17-24; Sun Decl., Ex. 5, Galewski Dep. 76:8-11.)

The parties are in general agreement that a radical is a highly reactive gas fragment. The Court also concludes that a radical is typically electrically neutral and contains one or more unpaired valence electrons. Should it be necessary to decide whether a particular gas fragment that does not contain an unpaired valence electron may nonetheless be properly referred to as a "radical," the Court will consider that issue at a later date. It was apparent at the claim construction hearing that whether ozone is a radical is an issue in this case, and that ozone may have properties that may make it difficult to categorize as a radical or an ion in this context. As ASM notes, the issue may be unimportant, as the ordinary by-product of a plasma discharge includes both radicals and ions. For now, the Court construes radical as "highly reactive gas fragments that typically possess at least one unpaired valence electron (including certain atoms or molecules produced as a result of a

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glow discharge) that allow or encourage the desired reaction."
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1. "Rapamycin"

This disputed term is found in claims 1 and 2 of the '781 patent, claim 1 of the '146 patent and claim 2 of the '728 patent. Claim 1 of the '781 is representative of how the term appears in the asserted claims:

A method of treating restenosis in a mammal resulting from said mammal undergoing a percutaneous transluminal coronary angioplasty procedure which comprises administering an antirestenosis effective amount of rapamycin to said mammal orally, parenterally, intravascularly, intranasally, intrabronchially,transdermally, rectally, or via a vascular stent impregnated with rapamycin.

'781 patent, Claim 1.

Cordis contends that this term means "a compound containing a macrocyclic triene ring structure produced by Streptomyces hygroscopicus, having immunosuppressive and antirestenotic effects." Defendants argue that this disputed term should be defined to mean "the chemical compound produced by Streptomyces hygroscopicus which has the following structure:

[SEE FIGURE IN ORIGINAL]

The difference in the two constructions is significant--under the Plaintiff's proposed construction, "rapamycin" refers to a family of compounds, each compound in the class having a macrocyclic triene ring structure and each having immunosuppressive and antirestenotic effects. Defendants construction, on the other hand, limits "rapamycin" to a single compound known as sirolimus.

Cordis bases its proposed construction primarily upon the language of the specification of the Morris patents, 1 which describes rapamycin as follows:

Rapamycin, a macrocyclic triene antibiotic produced by Streptomyces hygroscopicus [U.S. patent No. 3,929,992] has been shown to prevent the formation of humoral (IgE-like) antibodies in responseto albumin allergic challenge [Martel, R., Can. J. Physiol. Pharm. 55:48 (1977)], inhibit murine T-cell activation [Staruch, M. FASEB 3:3411 (1989)], prolong survival time of organ gratis in histoincompatible rodents [Morris, R., Med Sci. Res. 17:877 (1989)], and inhibit transplantation rejection in mammals [Calne, R., European Patent Application 401,747]. Rapamycin blocks calcium-dependent, calcium independent, cytokine-independent and consitutive T and B cell division at the G1-s interface. Rapamycin inhibits gamma-interferon production induced by n-1 and also inhibits the gamma-interferon induced expression of membrane antigen [Morris, R. E., Transplantation Rev. 6:39 (1992)].

'781 patent, col. 3, lines 1-24. According to Plaintiff, its construction is basically "succinct shorthand" for what someone skilled in the art would understand rapamycin to be based upon this detailed description in the specification. Danishefsky Dec. P 32.

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1 The three patents-in-suit share the same specification.

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Plaintiff also contends that extrinsic evidence supports its proposed construction. In January 1992, about the time the initial patent application was filed, the inventor of the Morris patents publishedan article in the Journal Transplantation entitled "Rapamycins: Antifungal, Antitumor, Antiproliferative, Immunosuppressive Macrolides." Danishefsky Decl. Ex. 14 (emphasis added). Cordis points to several other more recent articles that describe various different compounds as "rapamycin." Danishefsky Decl. Exs. 9, 11, 12, 13.

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Last, Cordis points to the prosecution history in support of its proposed construction. During prosecution, the examiner rejected pending claims for obviousness-type double patenting based on two other Wyeth patents. Those two other patents, U.S. Patent Nos. 5,252,579 and 5,256,790 involved changes to the macrocyclic triene ring of rapamycin. In response to the rejection, the applicant explained that the compounds in these two patents had an intentionally modified macrocyclic triene ring where the "rapamycin" in the pending application did not have these kind of changes to the ring structure.

As noted, under the Defendants proposed construction, rapamycin refers to a single chemical compound. In support of their proposed construction, they argue first that the language of the claims themselves use the word in its singular form. Second, Defendants argue that thespecification similarly refers to "rapamycin" in a singular form. Further, Defendants argue that the various test results in the specification are for a single compound and cannot be for a broad class of compounds because each compound in the alleged class would not produce the same test results.

Turning to the prosecution history, Defendants argue again that the applicant, in communications with the PTO, used the term rapamycin in its singular form. Defendants also refer to the same portion of the prosecution history relied upon by Cordis as described above. In that regard, Defendants argue that because the applicant allegedly convinced the PTO that the Morris patents' "rapamycin" claims are limited to a specific rapamycin compound and do not cover rapamycin derivatives either literally or under the doctrine of equivalents (including derivatives with only one point of structural difference), Plaintiffs are legally barred from taking a contrary position. Last, Defendants point to deposition testimony from Dr. Gregory Kopia, a former Cordis employee who, several years prior to this lawsuit, conducted a review of the Morris patents and concluded they covered only a single compound andnot a class of compounds.

Having carefully examined the claim language, the specifications, the prosecution history and the extrinsic evidence cited to by the parties, the Court finds Defendants' arguments unpersuasive. First, the Court rejects the notion that because the claims and specification refers to, for example, "rapamycin" instead of "rapamycins," the patents must encompass a single compound. As Plaintiff points out, many words can be used in the singular form to refer to a group. For example, BSC's expert testified that the term "penicillin" may be used to refer to a group of antibiotics. (Weiner Decl. Ex. 19, Dorland's Illustrated Medical Dictionary (28th Ed. 1994) 1252; Weiner Decl. Ex. 4, Wandless Dep. 24:10-13.).

Second, given express definition of rapamycin in the specification, the Court declines Abbott's invitation to limit construction of the term to only the compound used in the experiments. Third, the Court is not persuaded by Defendants' prosecution history arguments and finds no clear disclaimer of additional compounds in the prosecution history. An "argument made to an examiner constitutes a disclaimer only if it is clear and unmistakable," and an "ambiguous disavowalwill not suffice." Schindler Elevator Corp. v. Otis Elevator Co., 593 F.3d 1275, 1286 (Fed. Cir. 2010). Last, the Court finds the extrinsic evidence relied upon by Defendants to be of little help. Dr. Kopia, for example, does not appear to have had any involvement with the invention or prosecuting the patents-in-suit. Consequently, the Court adopts Plaintiff's proposed construction, which is derived from and is consistent with the language in the specification, and shall construe "rapamycin" to mean "a compound containing a macrocyclic triene ring structure produced by Streptomyces hygroscopicus, having immunosuppressive and antirestenotic effects."
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A. Rapid, Large Scale Screening.

The preamble of the representative claim begins with the phrase "[a] method for rapid, large scale screening to identify a ligand that binds to a . . . target protein . . . ."

3-DP argues that because this language merely recites the intended purpose of the claimed invention, it does not serve as a claim limitation. See, e.g., Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1350 (Fed. Cir. 1998). In response, Scriptgen contends that this language "give[s] life, meaning, and vitality" to the claim and, therefore, should be interpreted as a limitation. See, e.g., Pitney Bowes, 182 F.3d at 1306; Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

For example, both specifications explain that "large scale screening approaches can be complicated by a number of factors."

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For this reason, the specification from the '582 patent continues, "there is a need in the art for a rapid, cost-effective, high throughput assay that enables the screening of large numbers of compounds for their ability to bind [to] . . . relevant proteins." And, as the specification from the '277 patents states, the claimed "method provides an inexpensive, quick, and efficient means to determine the ability of a large array of ligands to bind [to] their respective target protein or proteins." Furthermore, Scriptgen notes, the "rapid, large scale screening" phrase was introduced during the prosecution history of the '277 patent in order to overcome several prior art rejections. As the inventors explained, "nowhere in the cited references was there any suggestion of a broadly applicable, high-throughput method to search for protein-binding compounds that did not rely on known biologically significant interactions." In other words, unlike the prior methods, "the present invention provide[s] a rapid, high-throughput screening method for detecting any compound that has the capability of binding anywhere on the target protein . . . ."

In this respect, the phrase "rapid, large scale screening" gives life or meaning to the asserted claims which contain this language in their preamble. In short, these claims are not directed to any screening method which identifies a ligand that binds to a target protein. Instead, these claims address only those methods which are rapid and large scale.

Of course, interpreting the term "rapid, large scale screening" as a limitation only begs the question: What is "rapid" and "large scale"? On this point, the parties go to great length to dispute whether "rapid, large scale screening" is synonymous with "high throughput screening." The court, however, need not resolve that question here because even if the two terms were synonymous, neither one of them is defined within the patent specifications. Therefore, their "ordinary meaning to one skilled in the art controls." See, e.g., Ekchian v. The Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997) (citing Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1564 (Fed. Cir. 1996); Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1580 (Fed. Cir. 1995)). In this case, the court believes that it may safely presume that the inventors are skilled in the art.

During the prosecution history of the '277 patent, one of the inventors submitted a declaration to the U.S. Patent and Trademark Office in support of the amendments which were made to overcome the prior art references. The declaration explained that "the methods of the present invention were used to screen several thousand test ligands for their ability to bind to . . . target proteins." It appears that 5,000 compounds were tested in this particular instance. Moreover, the specification of the '582 patent discloses two embodiments where 3,600 and 4,000 compounds were tested, respectively. Thus, it seems as if, by "large scale," the inventors meant that the method would be used to test thousands of compounds. This interpretation is supported by the following language from the specification for the '582 patent: "The present invention can be applied to large-scale, systematic high-throughput procedures that allow a cost-effective screening of many thousands of test ligands.") (emphasis added).

As far as the term "rapid" is concerned, the court notes that the inventor's declaration continues by explaining that, after an appropriate incubation period, the compounds were tested through various methods known to those skilled in the art. This incubation period could last for a number of hours or, in some instances, upwards to an entire day, depending upon the technique used. Thus, the rapidity of the screening method would appear to depend upon not only the speed of the available technology but also type of incubation process employed in addition to, logically, the number of compounds tested.

Therefore, after considering the intrinsic evidence, the court concludes that the phrase "rapid, large scale screening" means that several thousand test ligands are to be screened through a process which can be completed within a number of hours or a number of days, depending upon the technology employed and the number of compounds tested.

In adopting this interpretation, the court has attempted to walk a fine line. As the Federal Circuit has explained, "ordinarily, a claim element that is claimed in general, descriptive words. . . is not limited to the numbers [set forth] in the specification or the other claims." See Modine Mfg. Co. v. United States Intn'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996). For this reason, "it is usually incorrect to read numerical precision into a claim from which it is absent . . . ." See id.; cf. Ekchian v. The Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997) (cautioning against limiting a claim to only those specific embodiments which were disclosed in the patent specification) (citing Latriam Corp. v. Cambridge Wire & Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988); Texas Instruments, Inc. v. United States Intn'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986)). Thus, the court is understandably hesitant to assign a fixed numerical value or range of values to either "rapid" or "large scale."

Nevertheless, the court also believes that failing to provide any range of values would run a different risk. In particular, it

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would seem to turn the issue of claim interpretation over to the "experts" since only those who were skilled in the art could explain how quick and voluminous this "rapid, large scale screening" had to be. The Federal Circuit, however, has discouraged this type of approach since it generally results in a series of post hoc rationalizations, by "individuals who played no part in the creation and prosecution of the patent," that are made in an attempt to "inject a new meaning into terms [which] is inconsistent with what the inventor set forth in his . . . patent." See Bell & Howell, 132 F.3d at 706.

For these reasons, the court has turned to the patent specifications and the prosecution histories in order to discern what the inventors meant when they used the term "rapid, large scale screening." As previously discussed, they described tests which screened thousands of test ligands, not dozens or hundreds. Consequently, the court believes that interpreting the term "large scale" as meaning that several thousand compounds are to be screened is appropriate. Likewise, in light of the examples set forth in both the specifications and the prosecutions histories, it appears as if these screening methods could be completed within a number of hours or, at most, a number of days, depending upon the technology employed and the number of compounds tested. The court will, therefore, assign these meanings to the phrase "rapid, large scale screening" so that the asserted claims which contain this language in their preamble may possess this particular life and vitality.
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J. "Rapid thermal anneal process" (claims 3, 4, and 5)

Much to this court's dismay, neither party has been terribly helpful with regard to the construction of this claim term. The phrase "rapid thermal anneal" appears only once within the specifications: "Second, an additional dose of Pt atoms is applied to a selected surface of the device and is diffused at a higher temperature, e.g., 950 [degrees] -1100 [degrees] C. for 5-20 seconds (rapid thermal anneal)." '202 patent, 24:17-20. Ixys seizes upon this specification language and attempts to construct claim limitations from it, despite the fact that not only is this language almost surely a preferred embodiment (which cannot be read into the claims), see Intervet, 887 F.2d at 1053, but it is explicitly non-exclusive, since it contains the signal "e.g." Ixys might be able to construct an argument that the "e.g." is denominating one of the "higher temperatures" at which Pt may be diffused, and that therefore the parenthetical "(rapid thermal anneal)" is in fact defining this process, but they have not attempted to do so--the lack of any justification for such a brazen disregard for the typical canons of claim construction is one of the most striking aspects of this section of Ixys' brief.

Regardless, this limitation cannot possibly be valid. First, it refers only to platinum, while the claims in no way limit the scope of possible metals. Second, if the temperature range is to be read into the claims as a limitation there is no reason to believe that the temporal range should not similarly be included; however, to do so would render Claims 4 and 5 redundant in violation of the principle of presumed claim differentiation. See, e.g., Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed. Cir. 1999). APT's proposal to read the 1 minute limitation from Claim 5 into the definition of "rapid thermal anneal" is similarly wrong-headed. See id. at 972 ("limitations stated in dependent claims are not to be read into the independent claim from which they depend").

By contrast, APT proposes that a rapid thermal anneal process be construed to involve a system "able to handle very short thermal cycles over very large thermal excursions," without giving any indication of what a "cycle" or "excursion" is in this context (neither term is used in either the claims or the specifications) or trying to define "very short" or "very large" in any meaningful manner. If ever there were ever a moment to employ a modicum of that much-maligned "extrinsic evidence," this is it. However, APT writes that "What is important is that the system that implements the process be capable of short thermal cycles over large thermal excursions, such that the metal dopant profile can be created in a short time at that temperature and immediately frozen in the substance." without any citation whatsoever.

This places the court essentially in the position of guessing at the meaning of this term, or of defining it broadly and unspecifically (as APT seems to request). Since Ixys has given this court no cognizable reason to deviate substantially from APT's generalized construction, the court construes this claim term to mean: "A process that employs high temperatures for short periods of time."
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7. What is the Proper Construction for the Phrase "rapidly cooling" in the '311 Patent?

Claim 1 and claim 94 of the '311 patent contain the phrase "substantially immediately after formation of said continuous binder structure, rapidly cooling said mixture to below the softening point of the binder material to retain said converter binder material in its continuous webbing structure condition to produce the composite material." KXI contends "rapidly cooling" requires cooling the mixture to below the softening temperature of the binder material in a sufficiently short enough time to prevent wetting of the carbon by the binder and deterioration of the bonds. Culligan contends "rapidly cooling" means cooling as rapidly as practicable to retain the composite material's structure. Culligan contends "rapidly cooling" includes cooling by ordinary methods to a temperature below the softening temperature of the binder, including by allowing the part to cool naturally in ambient air.

The term "wetting" never appears in the '311 patent. KXI contends wetting means the softened binder particles penetrate the primary particles or completely surround the primary particles. KXI alleges that wetting of carbon particles by softened binder particles can cause the bonds between carbon and a binder to break down, causing deterioration of the bonds.

KXI argues the inventors recognized that wetting is a problem, and that it may be solved by rapid cooling. KXI relies on column 14, lines 8-16 of the '311 patent's specification, which reads in relevant part:

> It has been shown that, if the product of the [continuous web matrix] or [forced point-bonding] processes is held for an extended period at the elevated temperature, there is a rapid deterioration of the product and loss of the continuous web or binding points. Therefore, following the formation of continuous binder resin structure in the [continuous web matrix] product or bonding points in the [forced point-bonding] product, the material should be cooled rapidly, preferably as rapidly as possible.

KXI contends the inventors developed "rapid cooling" to solve the wetting problem. KXI argues, "rapidly cooling" requires cooling the mixture to below the binder's softening temperature in a sufficiently short enough time to prevent wetting of carbon by binder. KXI therefore construes "rapidly" to mean sufficiently quickly to prevent wetting or deterioration of the bonds.

Culligan argues its interpretation is supported by the '311 patent's specification. Culligan cites column 13, lines 4-8. This reads in relevant part: "the resulting immobilized material is relatively quickly cooled to a temperature below the melting point of the binder to 'freeze' the unstable structure once it is formed." Culligan cites column 14, lines 22-23. This states that "water sprays or air blasts may be used to hasten cooling." Culligan also cites example 1, at column 26, lines 34-35, which discloses utilizing air cooling to cool pellets that were made in a 0.5 inch diameter cylindrical compression molding die.

KXI responds that Culligan's construction of the phrase containing "rapidly cooling" would allow air cooling in any situation. According to KXI, air cooling may not be appropriate in certain circumstances to "rapidly cool" the product. KXI argues that:

> because the type of cooling depends on many factors, including the temperature and size of the article and the thermal mass of the mold surrounding the article, it would be improper to define 'rapidly cooling' as allowing any type of cooling. . . . Instead . . . the cooling must be sufficiently fast to prevent wetting of the carbon and deterioration of the bonds."

The court finds that preventing "wetting" never appears in the '311 patent, and is not required by the claim. Otherwise, the court agrees with KXI's interpretation. The court construes "rapidly cooling" to mean cooling the mixture to below the softening temperature of the binder material in a sufficiently short enough time to prevent deterioration of the bonds.

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III. "(3) a rate of consumption of the catalyst by the FCC unit" '236 patent, col. 15, ll. 58-59.

Plaintiff contends that this phrase means "a fixed proportion or (approximate) relationship or ratio of the average loss of catalyst additive by the FCC unit (including, for example, a ratio of loss of catalyst additive relative to loss of fresh catalyst)." 41 Defendants assert that it means "the total weight of catalyst lost in a given period divided by the duration of the period." 42 The key words are "consumption" and "rate."

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41 (Pl.'s Claim Construction Br. at 25.)

42 (Defs.' Opening Claim Construction Br. at 21.)

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The parties agree that "consumption" means "loss" or "lost." 43 But they pointedly disagree on the meaning of "rate." 44 Defendants view "rate" as only a change in quantity over time. Relying on the McGraw-Hill Dictionary of Scientific and Technical Terms, they define "rate" as "the amount of change of some quantity during a time interval divided by the length of the time interval." 45 Plaintiff views "rate" not only as a change in quantity over time, but also as the ratio of one material to another, such as the ratio of catalyst additive to fresh catalyst. 46 Relying on Webster's Third New International Dictionary, it defines "rate" as, among other things, "a fixed relation (as a quantity, amount or degree) between two things: ratio." 47 At oral argument, Plaintiff's counsel illustrated how catalyst loss can be depicted on a relative basis of one catalyst to another: If catalyst "X" is lost over time "t" and catalyst "Y" is also lost over time "t," the equation would be X/t/Y/t. If the "t's" are cancelled out, then a relative ratio of X/Y remains. 48

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43 (Pl.'s Claim Construction Br. at 27; Defs.' Opening Claim Construction Br. at 20.)

44 (Pl.'s Claim Construction Br. at 25-27; Defs.' Opening Claim Construction Br. at 20-21.)

45 (Defs.' Opening Claim Construction Br. at 20, Ex. 6 at WRG-51913.)

46 (See Pl.'s Claim Construction Br. at 25-27; Markman Hr'g Tr. at 100.)

47 (Pl.'s Claim Construction Br. at 25, Ex. E at I-31090.)

48 (Markman Hr'g Tr. at 101.)

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The Court finds that neither of the proposed definitions is inconsistent with the intrinsic record and will construe "rate" to encompass both. See Nystrom, 374 F.3d at 1112 n.2; Texas Digital, 308 F.3d at 1203. While the claim does not express "rate" in any terms whatsoever, the examples in the specification and prosecution history express "rate" as quantity over time--i.e., "tons/hr," "1 ton/hr," "one ton per hour." See '236 patent, col. 8, ll. 19, col. 10, ll. 16-17; (Defs.' Opening Claim Construction Br. Ex. 4 at I-3151). But neither the specification nor the prosecution history clearly disavows other expressions of "rate," such as the ratio of catalyst additive over fresh catalyst. See Texas Digital, 308 F.3d at 1204. Absent a clear disclaimer disavowing other expressions of "rate," the fact that the patentee anticipated that "rate" may be expressed as a change in weight over time does not limit the claim's scope to that narrow context. See Brookhill-Wilk 1, 334 F.3d at 1301. As such, the Court is "constrained to follow the language of the claims . . . and to give the claim term its full breadth of ordinary meaning as understood by persons skilled in the relevant art." Id. at 1301-02 (citations and internal quotations omitted).

Defendants assert that the full breadth of dictionary definitions are rejected "even though they are not expressly disavowed where the term is unvaryingly used in the specification according to a narrow definition," relying on Searfoss v. Pioneer

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Consol. Corp., 374 F.3d 1142 (Fed. Cir. 2004). 49

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49 (Defs.' Reply Br. at 2-3.)

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Defendants' reliance on Searfoss is misplaced. In Searfoss, the court was called upon to construe the meaning of "connecting" in a patent for movable truck bed cover systems. 374 F.3d at 1144, 1149. The plaintiffs argued that the dictionary definitions they cited defined "connecting" as encompassing both direct and indirect connections. Id. at 1149. But the court determined that "connecting" meant only a direct connection because the patent referred to "connecting" as synonymous with "attaching" and because a contrary construction would lead to a problematic reading of the claim "such that the cover . . . is exerting a downward force upon itself." Id. at 1150. In reaching this construction, the court looked to the specification to determine which dictionary definition was consistent with the use of the claim term. However, the court did not hold that the "unvarying use" of a term in the specification narrowed the claim's scope. Nor did it overrule, sub silentio, the longstanding rule that when the specification and prosecution history fail to manifestly exclude or restrict a claim term, the claim is given the "full breadth" of its ordinary meaning. See, e.g., NTP, - - F.3d - - -, 2004 U.S. App. LEXIS 25767, 2004 WL 2861370, at *6; Ferguson, 350 F.3d at 1338; Brookhill-Wilk 1, 334 F.3d at 1302.

Defendants also assert that the specification and prosecution history express "rate" in no terms other than weight over time. 50 This may be so, 51 but as the Federal Circuit has observed: "That a specification describes only one embodiment does not require that each claim be limited to that one embodiment." SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) (en banc); see Superguide, 358 F.3d at 875; Texas Digital, 308 F.3d at 1204. While claims must be construed in light of the specification, "limitations from the specification are not to be read into the claims . . . for' it is the claims that measure the invention.'" Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004) (emphasis in original) (citations omitted).

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50 (See Defs.' Opening Claim Construction Br. at 21; Defs.' Reply Br. at 8-9.)

51 It is arguable, however, that the specification does teach that "rate" may be expressed on a relative basis. For example, it notes that the consumption rate can be determined by analyzing samples taken from the FCC unit's total bulk catalyst "on the basis of changes in their weight percentages or concentrations over time with respect to the weight of the FCC unit's bulk catalyst." '236 patent, col. 8, ll. 13-16.

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Accordingly, the Court concludes that the phrase "(3) a rate of consumption of the catalyst by the FCC unit" means "(3) a ratio of the catalyst lost by the FCC unit over time, or a ratio of the catalyst additive lost by the FCC unit over the fresh catalyst lost."
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3. Independent Claim 1

Claim 1 describes a specific ratio of HPMC to bupropion hydrochloride for each tablet. The tablets must contain between . 19 to 1.1 parts HPMC to 1 part bupropion hydrochloride. Reading this claim in context of the specification, the court construes this claim as describing a specific polymer, HPMC, blended with bupropion hydrochloride in a specific ratio to form an admixture. The presence of HPMC within the admixture serves to retard the release of bupropion hydrochloride into the bloodstream.
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The parties and the Court agree that the term should be construed as "pretreatment; before any chemicals have been added, before any processes have been applied."

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12. "Reacting said lens body with a member selected from the group consisting of"

The plaintiff proposes "the lens body undergoes a chemical reaction that involves one of the molecules in the defined group." The defendants propose "allowing the lens body and the member to interact in a manner to combine the member with the lens body, for example by chemical bonding to create a tear wettable surface layer on the lens body."

The plaintiff contends that the specification discloses a chemical reaction to alter the surface of the lens, and does not simply involve "combining" with the lens body. Therefore, according to the plaintiff, the defendants' construction excludes a preferred method. The defendants argue that "combining" encompasses all the preferred embodiments.

In the Court's view, the defendants' proposed construction would exclude a preferred embodiment. See '327 Patent, 4:46-64. It is therefore rejected. "Reacting said lens body with a member selected from the group consisting of means "the lens body undergoes a chemical reaction with a member selected from the group consisting of"

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9) "Reactive Gas"

MKS contends that the term "reactive gas" used in claims 13, 36, 37, 42, and 44 means "a gas that can rapidly take part in chemical reactions." (D.I. 103 at 36). Advanced Energy contends that the term "reactive gas" means "a gas having an ability to combine chemically with another substance." (D.I. 110 at 30).

With regard to the term "reactive gas," the parties' dispute centers on MKS' inclusion of the adverb "rapidly" to describe the rate at which a reactive gas can take part in a chemical reaction. In construing the term "reactive gas" the Court has considered the patent specification and prosecution history. (D.I. 104, Ex. A col. 8, ln. 3-5, col. 8 ln. 26-28). Based upon a review of these sources, the Court concludes that there is neither a definition of the term, nor a suggestion that the term should be assigned a meaning other than its ordinary and accustomed meaning. The Court concludes that the ordinary and accustomed meaning does not include a description of the rate at which the reactive gas takes part in a chemical reaction. Accordingly, the Court construes the term "reactive gas" to mean a gas having an ability to combine chemically with another substance.

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Claim Construction -- Claim At Issue

The threshold requirement in claim construction is an examination of the claim at issue. In the instant case, McGill argues that the phrase "recovered liquid hydrocarbon absorbent" in the claim at issue means an undefined absorbent that is capable of recovering a substance called "recovered liquid hydrocarbon". Zink, on the other hand, argues that the phrase means that the recovered liquid hydrocarbon is being used as an absorbent. Thus, Zink's use of fresh gasoline in the absorption step would be an infringing use under McGill's interpretation and not an infringing use under Zink's.

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To support its interpretation, McGill first contends that "recovered liquid hydrocarbon absorbent" and "recovered liquid hydrocarbon" cannot be the same substance due to the following passage in the fifth paragraph of claim 2: "a recovered liquid hydrocarbon mixed with said absorbent". It seems to argue that mixing requires the presence of two different substances. Zink, however, counters with the contention that the overall language of claim 2 is consistent with its interpretation. In addition, Zink argues that the use of the words "said absorbent" merely refers to previously defined "recovered liquid hydrocarbon absorbent" and does not mean that the recovered liquid hydrocarbon is not being used as the absorbent.

Thus, the language of the claim at issue is in dispute, 5 and Zink contends that other tools of claim construction must be used to interpret the claim.

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5 It is interesting to note that the district court could determine in the first instance, as a matter of law, whether or not the language of the claim at issue was disputed and would require extrinsic evidence for interpreting that claim. Cf. Seitz v. Brewers' Refrigerating Mach. Co., 141 U.S. 510, 517, 35 L. Ed. 837, 12 S. Ct. 46 (1891); Motor Carriers Council of St. Louis, Inc. v. Local Union No. 600, 486 F.2d 650, 653 (8th Cir. 1973).

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Claim Construction--File History

In construing or interpreting claims, a whole host of factors may be considered. Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 219 U.S.P.Q. (BNA) 1137 (Fed. Cir. 1983); Autogiro, 384 F.2d at 401, 155 U.S.P.Q. (BNA) at 705. One such factor is the prosecution history of the patent. The Court, in Graham v.
John Deere Co., 383 U.S. 1, 33, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966), stated that "an invention is construed not only in light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office."

In the instant case, McGill contends that prosecution history estoppel is inapplicable since the claim at issue and in particular, the phrase "recovered liquid hydrocarbon absorbent," was not amended or distinguished in response to a prior art rejection, citing Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1362, 219 U.S.P.Q. (BNA) 473, 481 (Fed.Cir.1983). It argues that the amendments to the predecessor claims of the claim at issue were made only in response to a section 112 rejection for original claim 9 and in response to a rejection regarding the vacuum pump for original claim 7. Since there were neither amendments nor arguments in the file history regarding "recovered liquid hydrocarbon absorbent," McGill contends that there was no surrender by amendment that could support a finding of estoppel, citing Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1115, 219 U.S.P.Q. (BNA) 185, 187-88 (Fed.Cir.1983). In addition, McGill argues that whether or not the absorbent was "recovered" was not a pivotal issue during prosecution because the examiner twice rejected both claims 7 and 8 on the basis of the same prior art without differentiating the only difference between these claims -- "recovered." If this issue had been pivotal, McGill contends, the examiner would have allowed claim 8 and rejected claim 7. McGill concludes that the phrase "recovered liquid hydrocarbon absorbent" means an undefined absorbent that is capable of recovering a substance called "recovered liquid hydrocarbon." Zink's use of fresh gasoline as the absorbent in the absorption step is, therefore, an infringing use. We disagree.

Prosecution history may be used not only in an estoppel context but also as a claim construction tool. Fromson, supra. Where, as here, an unambiguous limitation such as the one that was present in original claim 8 was voluntarily added to a subsequent claim during prosecution, it may be used to construe the claim. In the instant case, the examiner twice remarked that original claim 9 would be allowed if it were rewritten in an independent form and included all the limitations present through dependency. The phrase "recovered liquid hydrocarbon absorbent" in original claim 8 was clearly a limitation, a limitation having the meaning: recovered liquid hydrocarbon being used as an absorbent. Since this condition for allowance was clear and the limitation of original claim 8 was clear on its face, the appearance of the phrase in new claim 14 was an indication, as interpreted by Zink, that the limitation of original claim 8 had been incorporated into the new claim.

Claim Construction -- Specification

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Another factor in claim construction is the use of the patent specification. McClain v. Ortmayer, 141 U.S. 419, 35 L. Ed. 800, 12 S. Ct. 76 (1891); Fromson, 720 F.2d at 1569-70, 219 U.S.P.Q. (BNA) at 1140. Words which were defined in the specification must be given the same meaning when used in a claim. General Electric Co. v. United States, 215 Ct. Cl. 636, 572 F.2d 745, 753, 198 U.S.P.Q. (BNA) 65, 71 (Ct. Cl. 1978). In Autogiro, 348 F.2d at 397-98, 155 U.S.P.Q. (BNA) at 702-3, the Court of Claims stated:

In serving its statutory purpose, the specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification. U.S.Pat.Off. Rule 75(d). The use of the specification as a concordance for the claims is accepted by almost every court, and is a basic concept of patent law. [Footnotes omitted.]

In the specification of the patent at issue, the phrase "recovered liquid hydrocarbon absorbent" is not defined. However, the phrase "recovered liquid hydrocarbon" and the word "absorbent" are defined. For example, the specification states that the "recovered liquid hydrocarbon overflowing the weir 54 is withdrawn from separator 52 through line 62 connected between the lower portion of separator 52 and line 74 for use as a liquid adsorbent [sic]." The specification then describes the direct countercurrent contact of the vapor hydrocarbon component and the recovered liquid hydrocarbon "introduced in the upper portion of the absorber via line 72." In addition, the specification discloses that a portion of the recovered liquid hydrocarbon discharged from absorber 70 is first cooled by cooler 82 and then pumped via line 72 to the top of absorber 70 "for use as absorbent." Thus, the specification discloses a process in which the absorbent is created internally within the system and not a process that utilizes an external liquid as its absorbent.

It is clear from the specification that the recovered liquid hydrocarbon functions as the absorbent in absorber 70. Contrary to McGill's construction, the phrase "recovered liquid hydrocarbon absorbent" does not mean an undefined absorbent that is capable of recovering a substance called "recovered liquid hydrocarbon." In addition, all of the drawings of the patent show only the use of internally-created recovered liquid hydrocarbon as the absorbent. Dominion Magnesium Ltd. v. United States, 162 Ct. Cl. 240, 320 F.2d 388, 394, 138 U.S.P.Q. (BNA) 306, 310 (Ct. Cl. 1963). Thus, the phrase "recovered liquid hydrocarbon absorbent" in claim 2, as urged by Zink, has the meaning that was defined in the specification which is internally-created recovered liquid hydrocarbon being used as an absorbent.

Claim Construction -- Other Claims

A third factor in claim construction is the use of other claims in the patent to determine the scope of the claim at issue. Fromson, 720 F.2d at 1570, 219 U.S.P.Q. (BNA) at 1140-41; General Electric , 572 F.2d at 751, 198 U.S.P.Q. (BNA) at 70.

In dependent claim 3, 6 the steps of cooling the recovered liquid hydrocarbon discharged by absorber 70 and the recycling of the cooled liquid to the absorber are claimed. The cooled recovered liquid hydrocarbon are recycled to absorber 70 "for use as absorbent in the absorption step." McGill contends that if independent claim 2 is interpreted to include an absorption step carried out with "recovered liquid hydrocarbon," then the second step of dependent claim 3 would be redundant. As such, it would be an improper reading of a limitation explicitly set forth in a dependent claim into an independent claim, citing Environmental Designs, Ltd. v. Union Oil Co. of California, 713 F.2d 693, 699, 218 U.S.P.Q. (BNA) 865, 871 (Fed. Cir. 1983). We disagree.

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6 Claim 3 states:

3. A process, as recited in claim 2, the further steps comprising:

cooling a portion of the recovered liquid by hydrocarbon; and

recycling the cooled recovered liquid hydrocarbon for use as absorbent in the absorption step.

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McGill is misconstruing claims 2 and 3. It seems to be reading claim 2 to mean that something other than internally-

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created, recovered liquid hydrocarbon was used as the absorbent in the initial or first absorption step. Then, in light of claim 3, only the cooled recovered liquid hydrocarbon is being recycled as the absorbent. Since the specification and drawings fail to show the use of anything but the internally-created, recovered liquid hydrocarbon as the absorbent, Zink contends that this is a tortured reading. It interprets claim 3 to mean that the "recovered liquid hydrocarbon" of claim 2, already being used as the absorbent, is further cooled and recycled for the same use.

Claim Construction -- Expert Testimony

In addition to tools of claim construction such as file history, patent specification, and other claims in the patent, testimony by expert witnesses may be used to construe claims. See Control Components, Inc. v. Valtek, Inc., 609 F.2d 763, 770, 204 U.S.P.Q. (BNA) 785, 791 (5th Cir.), cert. denied, 449 U.S. 1022, 66 L. Ed. 2d 484, 101 S. Ct. 589 (1980). Such testimony is evidence of construction of the claims as they would be construed by those skilled in the art. Fromson, 720 F.2d at 1571, 219 U.S.P.Q. (BNA) at 1142. In this regard, experts for both sides testified as to their interpretation of the phrase "recovered liquid hydrocarbon absorbent."

McGill contends that the testimony of two of its experts, a co-inventor of the '423 patent and its patent law expert, supports its interpretation of claim 2. The co-inventor stated that recovered liquid hydrocarbon was not the same thing as recovered liquid hydrocarbon absorbent. The patent law expert interpreted the phrase "recovered liquid hydrocarbon absorbent" to mean an undefined absorbent that is capable of recovery a substance called "recovered liquid hydrocarbon." McGill also contends that U.S. Patent No. 3,770,622, cited in the '423 patent, confirms the interpretation it urges.

Zink, however, disputes the interpretation of McGill's experts. Its own patent law expert equated recovered liquid hydrocarbon with recovered liquid hydrocarbon absorbent. Zink also argues that even a Dr. Garwin, another one of McGill's experts, testified that the absorbent and the recovered liquid hydrocarbon were the same substance. In particular, Zink contends that its cross-examination of McGill's patent law expert raised questions regarding that expert's interpretation of claim 2.

Claim Construction -- Conclusion

After considering the record taken as a whole, including the experts' testimony, Hayes v. Department of the Navy, 727 F.2d 1535, slip op. at 5 (Fed.Cir.1984); see Control Components, supra; cf. Moraine Products v. ICI America, Inc., 538 F.2d 134, 146, 191 U.S.P.Q. (BNA) 65, 75 (7th Cir.), cert. denied, 429 U.S. 941, 50 L. Ed. 2d 310, 97 S. Ct. 357 (1976), we are convinced that there is no set of facts, consistent with McGill's interpretation, that is supported by substantial evidence. Thus, McGill's interpretation of claim 2, a legal conclusion implied from the jury's finding of infringement, cannot be upheld, premised as it must be on facts which are not supported by substantial evidence.

In regard to possible infringement under the doctrine of equivalents, we are similarly convinced that there is no set of facts, consistent with McGill's interpretation, that is supported by substantial evidence. As discussed above, there is no substantial evidence to support McGill's interpretation that its process uses an absorbent that is not the internally-created, recovered liquid hydrocarbon. In light of the fact that Zink's process utilizes an absorbent that is composed of an external fluid, McGill's and Zink's processes are not equivalents in that different ways are used to perform the desired function. Graver Tank & Manufacturing Co. v. Linde Air Products Co., 339 U.S. 605, 608-9, 94 L. Ed. 1097, 70 S. Ct. 854 (1950); Carman Industries, Inc. v. Wahl, 724 F.2d 932, 942, 220 U.S.P.Q. 481, 488-89 (Fed.Cir.1983). Thus, any finding regarding equivalence is not supported by substantial evidence.

McGill's claim 2 is limited, instead, to an absorbent which consisted of internally-created, recovered liquid hydrocarbon. It is undisputed that fresh gasoline, as used by Zink to recover liquid hydrocarbon, is not "recovered liquid hydrocarbon" as that term is used in the '423 patent. As such, Zink's use of fresh gasoline as the absorbent is noninfringing. Accordingly, the district court should have granted Zink's motion for JNOV in relation to infringement and the district court's denial is reversed.

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"Reducing"

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Neither party addresses this term in its briefs. In the Joint Claim Construction Chart, Nutrition 21 identifies "reducing" as a distinct term in certain claims from the '623 and '624 Patents and argues that for both patents the term "should be given its plain and ordinary meaning, i.e., lowering." GNC does not ask the Court to construe this term. Construction is unnecessary to aid the jury in understanding the term, and therefore the Court does not construe the term.
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B. "reducing agent"

This term is easily construed without looking beyond the plain text of the immediate claim. The reducing agent is designed "to produce... activated SAH-hydrolase" when combined with inactive SAH-hydrolase. In the context of these "kit" claims, therefore, "reducing agent" is "a substance that can restore the catalytic activity of the inactive SAH-hydrolase."
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Reducing Ambient

The Court adopts Motorola's proposed construction and construes the term "reducing ambient" as "a gaseous atmosphere that adds an electron to an element or compound." The parties agree that a "reducing ambient" is a gaseous atmosphere that "adds" or "donates" electrons. The only discrepancy between the parties' constructions is ST's assertion that in a "reducing ambient," the "principal reactant gas" must be a "chemical" and that the electrons must be donated in a "chemical reaction." The Court finds that specification and claims do not so limit the definition of "reducing ambient." See Sunrace Roots Enter. Co., LTD v. SRAM Corp., 336 F.3d 1298, 1303-1304 (Fed. Cir. 2003). In the Tobin Patent, a "reducing ambient," as Motorola proposes, is simply a gaseous atmosphere that adds electrons to some element or compound. Whether, in a particular circumstance, a chemical reaction is or is not the means by which those electrons are added is a question of infringement properly for a jury to decide. See Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361, 1367 (Fed. Cir. 2004) (holding that infringement is a two-step analysis where the court first interprets claims' scope and meaning and the factfinder then compares properly construed claims to the allegedly infringing device).
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B.

The second disputed phrase of the '125 patent is "an apolipoprotein reducing amount." SourceOne proposes to construe that phrase to mean "an amount that reduces apolipoprotein B" (SourceOne's Br. at 20). KGK proposes to construe the phrase to mean "an amount that is sufficient to reduce the production of apolipoprotein B" (KGK's Br. at 10). For the reasons discussed below, the Court finds that KGK's proposal is the proper construction of the phrase.

In aid of its proposed construction, SourceOne cites the portion of the specification which states that administering the compound "results in a reduction in the amount of substances in the blood," such as apoB (J.A. at 670, '125 patent, Col. 5, lines 2-7; SourceOne's Br. at 21). SourceOnecontends that this portion of the specification implies that the compound is designed to "eliminate quantities of apolipoprotein B that are already present in the blood" (SourceOne's Br. at 21). SourceOne further contends that because the word "production" is already present in the preceding phrase of the claim, it is inappropriate to add that term to the current phrase at issue (SourceOne's Reply at 5).

We disagree. The phrase "an apolipoprotein B reducing amount" is a limitation of claims that includes the previously construed preamble, "a composition for reducing apolipoprotein B production." SourceOne argued in favor of construing the preamble to mean that the composition is intended for reducing production of apoB, which the Court adopted. It would be internally inconsistent for the Court to construe the first limitation following that preamble to mean that the composition is intended to reduce not production but rather quantities of apolipoprotein B already present in the blood.

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We also note that statements in the specification explicitly describe the claimed compositions as having a reducing effect on the production of apoB. For example, several compounds were "found to be activeas inhibitors of apolipoprotein B (apo-B) 14 production . . . ." (J.A. at 669, '125 patent, Col. 4, lines 61-63), and the compounds tested "have a dose-response inhibitory effect on apo-B production" (J.A. at 672, '125 patent, Col. 9, lines 37-38). Thus, the phrase should be construed as reducing production of apoB, rather than simply reducing apoB.

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14 The parties refer to apolipoprotein B as "apoB," while the patent itself lists it as "apo-B."

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The rest of KGK's proposed construction, however, is not supported by the language of the patent and is not necessary to give meaning to the claim limitation. KGK proposed construing the phrase "an apolipoprotein reducing amount" as "an amount that is sufficient to reduce the production of apolipoprotein B." The words "is sufficient" are unnecessary to give meaning to the phrase, and thus, we construe the phrase as: "an amount that reduces the production of apolipoprotein B."
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Abbott claims that the '616 patent invention provides a "method of reducing gastrointestinal adverse side effects". In a memorandum filed by Abbott on March 20, 2006, Abbott took the following position regarding construction of claim 1 of the '616 patent:

"[R]educing gastrointestinal adverse side effects," as used in claim 1 of the '616 patent, should be construed to mean a reduced incidence of gastrointestinal adverse side effects following ingestion of the ER clarithromycin formulation compared to an immediate release formulation, including reduced incidence of severe gastrointestinal adverse side effects and/or a reduced incidence of gastrointestinal side effects severe enough to cause patient or subject discontinuance of treatment. "Gastrointestinal adverse side effects" means those physiological effects to the gastrointestinal system which cause pain and discomfort to the individual subject.

The parties do not dispute the meaning of "gastrointestinal adverse side effects." As Ranbaxy, Teva, Andrx, and Sandoz all note, examples of such effects include abdominal pain, constipation, diarrhea, dyspepsia, flatulence and nausea, all of which are listed in Table VI of the '616 patent.

Abbott Laboratories' Memorandum in Support of Its Proposed Claim Construction, p. 26 (emphasis added). Sandoz's own proposed construction did not differ very much from Abbott's.

One of ordinary skill in the art would understand the term "gastrointestinal adverse side effects" to include adverse events in the digestive system, abdominal pain, constipation, diarrhea, dyspepsia, flatulence and nausea. (Ex. D at P 15.) These are the adverse side effects listed in Table VI of the patent specification.

Memorandum of Law in Support of Defendant Sandoz, Inc.'s Construction of Claim Terms of the Patents In Suit, p. 10-11.

This Court declines to find that the term "reducing gastrointestinal adverse side effects" only refers to the most severe GI side effects and the patient discontinuations due to GI side effects. However, it is clear from both Table VI and Table VIII that some data demonstrating no change in the subcategories of GI adverse side effects of abdominal pain, constipation, diarrhea, dyspepsia, flatulence and nausea were in fact disclosed to the PTO. The data Sandoz claims was withheld demonstrates the exact same conclusion as the data that was disclosed. Therefore, such data was cumulative under 37 C.F.R. § 1.56, Abbott was not under a duty to disclose it and Sandoz's argument fails.
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6. "said modification comprising"

Claims 1, 2, 7, and 8 of the '600 patent contain the phrase "said modification comprising reducing the number of codons having CG in codon positions II and III in a region between plant polyadenylation signals."

DeKalb claims that the phrase "said modification comprising" requires that the reduction in the number of these codons ("XCG codons") must simultaneously either increase the number of preferred codons (when the phrase is located in a claim using the "greater number" limitation) or make the frequency more closely resemble the frequency of the plant host (when the phrase is located in a claim using the "frequency" limitation). In other words, each replacement of an XCG codon must be with a preferred codon, or a codon that makes the frequency of the gene more plant-like.

For example, DeKalb points out that the frequency of GCG codons in the native Bt gene is 12%, for those codons specifying alanine, while it is only 6% in dicot plant genes. DeKalb argues that the removal of a GCG codon from the native Bt gene only satisfies the claim because that removal will simultaneously make the frequency of the new synthetic gene lower, and thus more like the intended plant host. DeKalb goes on to point out that the frequency of GCG codons in monocot genes is 22%, higher than the frequency in the native Bt gene. Thus, according to DeKalb, if a monocot plant is the intended plant host, a reduction in the amount of GCG codons makes their frequency less like that of the intended plant host (going from 12% to something less than 12%), and does not satisfy the claim language.

Mycogen argues, however, that the phrase "said modification comprising" only requires that the overall sequence resulting from the modification step include fewer XCG codons, while still satisfying the limitation of the first half of the step. Mycogen argues that the satisfaction of these two limitations do not have to be simultaneously satisfied each time an XCG codon is removed. In other words, even if a reduction of XCG codons by itself makes the frequency of the synthetic gene less like the intended plant host, the other changes made to the native gene can make up for it, so that overall the frequency is more plant-like, and the claim language would then be satisfied.

DeKalb focuses on the plain language of the claims to support its position. Step (b) of claim 1 of the '600 patent, which is representative of the claims at issue here, provides for the step of:

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said modification comprising reducing the number [of XCG codons].

DeKalb argues that "said modification comprising" must refer to the word "modification" in the immediately preceding text. DeKalb offers the testimony of several Mycogen witnesses to support this position. DeKalb then points out that "comprising" has a specific meaning in patent law, meaning including at least the enumerated elements, but not excluding others. Ex parte Schaefer, 171 U.S.P.Q. 110 (Pat. Bd. App. 1970).

DeKalb also points out that the only reason offered in the patent specification for the reduction of XCG codons is that "the CG dinucleotide is strongly avoided in plants." (Col. 10, lines 63-64). DeKalb argues that this is further evidence that the patent is only claiming a reduction of XCG codons because it makes the synthetic gene more plant-like.

However, the "modification" referred to in the first portion of these claims is not restricted to a series of codon changes, each of which individually results in a satisfaction of the "greater number" or "frequency" limitation. The example given in the specification shows a synthetic gene in which many changes were made to codons, not all of which led to a satisfaction of these two limitations. The patent claims a resulting sequence which is more plant-like, not a series of changes, each of which individually makes the gene more plant-like. This is demonstrated by the formula set out in the patent specification, which calculates the percent deviation of preferred codon usage. The formula takes into account all codon changes, and indicates whether the changes to a frequency closer to that of plants outweighs the changes to a frequency further away from that of plants. The specification thus assumes that not all changes to codons will individually make the synthetic gene more plant-like.

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Accordingly, it is inconsistent to interpret "said modification comprising" to require that every change involving an XCG codon be a change that either increases the number of preferred codons (in the claims involving the "greater number" limitation) or causes the frequency to more closely resemble that of plants (in the claims involving the "frequency" limitation). The court finds that the language "said modification comprising reducing the number [of XCG codons]" means only that the overall modification must include a reduction in the number of XCG codons, not that each change of an XCG codon to a non-XCG codon must satisfy the "greater number" or "frequency" limitation.
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reduction of color

The Court and the parties agree that the term should be construed as "a lowering in the amount of measurable Pt Color Units (as defined in Standard Methods for the Examination of Water and Wastewater 20th Edition) present in water, which are often caused by the presence of tannins, lignins, and other humic substances."
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reduction of turbidity

The Court and the parties agree that the term should be construed as "improving clarity, measured as reducing reported NTUs."
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(3) Which construct produces an RNA which regulates the function of a gene . . . The Court concludes that the nonnative DNA construct must carry out normal cellular functions, including transcription and translation. Thus, upon transcription, the DNA construct must split its double helix, an RNA polymerase must then synthesize with one of the DNA strands according to base-pairing rules, and the RNA polymerase ultimately must produce an mRNA. Finally, the Court concludes that this non-naturally occurring mRNA must "regulate the function of a gene" by binding with a naturally-occurring mRNA from the gene targeted, and preventing the naturally-occurring mRNA from functioning.
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3. "relatively low level" or "relatively low value"

As noted above, AB/Sciex contends that the "relatively low" level or value of kinetic energy at which the ions must be maintained is such that the ions will avoid significant fragmentation caused by collision induced dissociation.

Micromass argues that the term "relatively low," as used in the claims, is indefinite and therefore all of the claims of the 736 patent should be held invalid as indefinite under paragraph 2 of 35 U.S.C. § 112. It also argues that AB/Sciex's proposed construction of "relatively low" is similarly indefinite, because it would require understanding how much fragmentation is "significant." Micromass does not, however, offer an alternative construction of "relatively low." Rather, it simply criticizes AB/Sciex's proposed construction by arguing it has no basis in the words of the claims.

The claims themselves provide no support for AB/Sciex's proposed construction of "relatively low." Nor is it apparent, from the face of the claims themselves, what meaning should be ascribed to that term.

The only discussion of "relatively low" is in the claim specification's discussion of the relationship between kinetic energy and the dissociation of ions.

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It appears that a large number of relatively low energy collisions are effective in damping both the radial and axial velocities of the ions and in forcing the ions by collisional damping closer to the centre line of the AC-only rod set 32. It appears that more energetic collisions, which occur when the offset voltage is higher, do not have a similar effect and in fact for some reason reduce the ion signal. Further, a high ion energy can lead to collision induced dissociation, resulting in further ion loss."

736 Patent, Col. 12, ln. 39-49 (emphasis added). Furthermore, in the patent reexamination proceedings, MDS made several comments in distinguishing tandem mass spectrometers on the basis that they use a high pressure to fragment ions. MDS stated, "the use of high pressure gas and high kinetic energy parent ions to cause fragmentation is in contrast to the invention which maintains the kinetic energy of ions at a relatively low level and uses an increased pressure to improve ion transmission." Request for Reexamination, at 18.

On the basis of the statements made in the specification and reexamination, the court concludes that the relationship of high kinetic energies and collision induced dissociation is clear from the patent's intrinsic evidence. It is therefore appropriate to construe "relatively low" by resort to what the patent specification and prosecution history state will occur when the kinetic energy is not relatively low -- fragmentation caused by collision induced dissociation. Whether the fragmentation needs to be "significant," however, is not supported by the specification or prosecution history. The specification only indicates "relatively low energy collisions" improve the operation of the mass spectometer, that "energetic collisions" reduce the ion signal and that "high ion energy" results in further ion loss. Thus, the specification supports construing "relatively low" to mean that further increases would "reduce the ion signal."

Thus, the court will construe "relatively low level" and "relatively low value" to mean "the level or value of kinetic energy below the level at which the ion signal is reduced by further increases of the kinetic energy." This construction is consistent with the whereby clause in claims 1(k) and 14(h) discussed next.

4. "whereby to provide improved transmission of ions through said interchamber orifice"

Micromass argues at length that the two "whereby clauses" at the end of claims 1(k) and 14, are claim limitations because they describe the "necessary result" or "critical property" of the claimed invention. See KX Indus., L.P. v. Culligan Water Techs., Inc., 90 F. Supp. 2d 461, 487-88 (D. Del. 1999) (holding that a whereby clause that was substantially amended to overcome prior art was sufficiently definite to constitute a claim limitation and did not simply announce the invention's result). This is in contrast to the general rule that "a whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim" and is therefore not a claim limitation. Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1172 (Fed. Cir. 1993). Thus, Micromass proposes construing the whereby clause to mean that one practicing the invention must realize improved ion transmission through the interchamber orifice relative to the number of ions that would be transmitted without practicing the invention.

AB/Sciex agrees that the whereby clause is a claim limitation, but argues that Micromass's proposed construction is too broad because it defines "improved" as "relative to the number of ions that would be transmitted without practicing the invention." According to AB/Sciex, Micromass's proposed construction would foster a comparison between the ion transmission rates of any other method of ion transmittal and the claimed invention. It is difficult to understand AB/Sciex's concern. Assuming the whereby clause is a claim limitation, it is only meaningful to the extent that a potential infringer might practice all of the other claims and somehow not realize improved ion transmission through the interchamber orifice. Thus, AB/Sciex's concern that Micromass might try to avoid infringement by comparing any other method of ion transmission to the claimed invention is unfounded.

Nonetheless, the court agrees with AB/Sciex that the "whereby" clause requires no further construction. The proper construction of the whereby clause is self-evident from the face of the claims, which state "to provide improved transmission of ions through said interchamber orifice." The court will therefore decline to provide further construction of the claim.

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The court heard oral argument on the issue of claim construction in order to better understand the extent of the parties' disagreement about the construction of the claims. During oral argument, both parties focused primarily on the '273 patent. Since neither party has distinguished the facestock claims of the '273 patent from the facestocks claimed as part of the process patents, the court's reasoning in this opinion regarding construction of the '273 patent should be considered applicable to the '532 and '669 patents.

When considering the claims, the "terms of a claim will be given their ordinary meaning, unless it appears that the inventor used them differently." ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579 (Fed. Cir. 1988) (citation omitted). Claim 19 of the '273 patent provides:

19. A multilayer facestock for use in pressure-sensitive label, tape or sign applications comprising a coextrudate of cojoined layers comprising a relatively thick core or base layer of polymeric film material of a stiffness of between 10 and 100 Gurley and which contributes the majority of the dimensional stability and stiffness of labels or signs cut or formed from the facestock, and at least one relatively thin skin layer, said skin layer being on the face side of the coextrudate and having an ink-printable surface, and a pressure-sensitive adhesive layer combined at the side of said coextrudate opposite said face side.

Claims 20 and 21 are dependant on claim 19 and necessarily incorporate by reference all the elements of claim 19. Claims 19-21 cover a plastic multilayer facestock or film. Claim 1 of the '532 patent provides:

1. A method of economically manufacturing die-cut labels or signs using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate comprising a relatively thick core layer and at least one relatively thin skin layer, the former layer providing the majority of the dimensional stability and stiffness of the construction, preselecting the charge for said core layer, as by selection of density or flex modulus, to provide a degree of stiffness suitable for the label or sign application, preselecting the charge for said skin layer to provide a skin adapted to the intended decorating process, such as printability, or surface performance characteristics, such as weatherability of the facestock, and combining said extrudate with a pressure-sensitive adhesive layer to form label or sign facestock, combining said facestock with a liner, die-cutting said facestock to form a label or sign releasably adhered to said liner and surrounded by a matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away from the die-cut label or sign.

Claims 3 and 8 are dependent on claim 1 and claim 9 is dependent on claim 8. Claim 14 of the '532 patent provides:

14. A method of economically manufacturing die-cut labels or signs using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate having a face side and a back side, said multilayer extrudate including stiffening layer means which contributes the majority of the stiffness of the construction, preselecting at least one of the charges, as by selection of density or flex modulus, to provide said stiffening layers means with a degree of stiffness suitable for the label or sign application, and combining said multilayer extrudate with a pressure-sensitive adhesive layer and release liner to form linered label or sign facestock, die-cutting said facestock to form a label or sign releasably adhered to said liner and surrounded by a matrix of excess facestock material, and stripping said matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away form the die-cut label or sign.

Claim 16 is dependent on claim 14. Claim 1 of the '669 patent provides:

1. A method of economically manufacturing die-cut labels using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate comprising a relatively thick core layer and at least one relatively thin skin layer, preselecting the charge for said core layer, as by selection of density or flex modulus, to provide said facestock with a degree of stiffness suitable for the label application, preselecting the charge for said skin layer to provide a skin adapted to the intended decorating process, or surface performance characteristics, of the facestock and combining said extrudate with a pressure-sensitive adhesive layer to form label facestock, combining said facestock with a liner, die-cutting said facestock to form a label releasably adhered to said liner and surrounded by a matrix of excess facestock material, and stripping said matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away from the

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die-cut label.

Claims 2, 3, 7, 8 and 9 are dependent on claim 1. Claim 11 of the '669 patent provides:

11. A method of economically manufacturing die-cut labels using roll or sheet facestock, comprising the steps of providing a plurality of at least two charges of film-forming resin, coextruding said charges to thereby form a construction in the form of a multilayer extrudate comprising a relatively thick core layer and at least one relatively thin skin layer, preselecting the charge for said core layer, as by selection of density or flex modulus, to provide said facestock with a suitable degree of stiffness and sufficient body and strength for the label application, preselecting the charge for said skin layer to provide a skin adapted to the intended decorating process, or surface performance characteristics, of the facestock, hot-stretching and combining said extrudate with a pressure-sensitive adhesive layer to form label facestock, combining said facestock with a liner, die-cutting said facestock to form a label, releasably adhered to said liner and surrounded by a matrix of excess facestock material, and stripping said matrix of excess facestock material to utilize non-tearing self-supporting properties of said material to pull said matrix away from the die-cut label.

The construction of the facestock claims' terms and phrases desired by the parties, especially "coextrudate of cojoined layers" and "comprising a relatively thick core or base layer," require the court to look beyond the language of the claims. To aid in construction of the claims, the court must look at the patent specifications. "The specification acts as a dictionary when it defines terms used in the claims or when it defines terms by implication." Vitronics at 1582. The patent inventor is his or her own "lexicographer." ZMI at 1580. Therefore, "the specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification." Id. (citation omitted).

The patent specifications for the '273 patent offer several illuminating claim descriptions. The specifications for the facestock offer two prototypical examples in Figures 5 and 6. The coextrudates in these examples "comprise polymeric film materials, are formed by simultaneous extrusion from a suitable know type of coextrusion die, and are adhered to each other in a permanently combined state to provide a unitary coextrudate." Patent '273, Column 9, Lines 21-26. The elements of the facestock, as described in the specifications, are as follows: "a relatively thick core layer of polymeric film material . . . having a cojoined, relatively thin, ink-printable skin layer at least at the face side of the construction, and having a pressure-sensitive adhesive layer combined at the sides of the construction opposite the face side." Patent '273, Column 10, Lines 59-66. The facestock is produced "by coextruding a plurality of at least two charges of film-forming resin to form a coextrudate having a relatively thick core layer and at least one relatively thin skin layer . . . and combining the coextrudate with a pressure-sensitive adhesive layer." Patent '273, Column 10, Lines 67-68; Column 11, Lines 1-8.

The prosecution history of the patents provides similarly helpful evidence for this court. A patent's "prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985). The prosecution history reveals that in the application for the '273 patent, Serial No. 06/853,772, the inventor, Melvin S. Freedman, distinguished his facestock from a product which is "formed by adhering preformed layers." The patent examiner issued a restriction requirement on October 17, 1986 stating: "the product as claimed can be made by a materially different process such as by adhering pre-formed layers." Def's Resp. Ex. W. In an amendment filed October 27, 1986, Freedman responded: "The process pointed out by the Examiner, namely adhering preformed layers, cannot be used to form the claimed coextrudate, since if the layers were preformed they would not have been coextruded and would not constitute a coextrudate as called for in [the] independent product claims." Def's Resp. Ex. X.

Based upon a review of the entirety of the patent, including the claim language, specifications and prosecution history, the court concludes that claims 19-21 of the '273 patent should be plainly construed to cover a coextrudate which is a facestock, or plastic film, formed solely by simultaneous, or joint, extrusion of several materials through a die. The immediate result of this simultaneous extrusion, or coextrusion, is a multilayer film wherein the layers are firmly adhered to one another in a permanently combined state, i.e., the patented coextrudate. A facestock formed by adhering preformed layers is not within the scope of claims 19-21 of the '273 patent. Further, in claim 19, the coextruded product must have (1) a thick core or base layer (with a stiffness of between 10 and 100 Gurley); (2) at least one thin ink-printable skin layer on the face side of the product; and (3) a pressure-sensitive adhesive layer on the side opposite the face side. In claim 20, the product is the same as in claim 19 with the addition of a second skin layer between the core or base layer and the adhesive layer. In claim 21, the product is the same as in claim 19 with the addition of a releasable liner on the adhesive.

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The parties, especially UCB Films, have also devoted substantial time to arguing that the phrase "core or base layer" in the claims must mean "core layer or base layer" (meaning the core must be made up of only one layer) and not, as Avery argues, "core" (which could have one or more layers) or "base layer." However, the court finds that the patent specifications, on which UCB Films primarily relies, use both the term "core" (e.g. '273 Patent; Column 10, Line 46) and the phrase "core layer" (e.g. '273 Patent, Column 10, Line 60). This court is thus unwilling to apply UCB Films' reading to the claims and cannot find on the basis of this argument that the claims are limited to a core composed of a single layer.

As stated previously in this opinion, the court's construction of the claims of the '273 patent is largely applicable to the facestock portions of the process patents. In light of the above claim construction, this court finds that there are disputed issues of material fact as to whether UCB Films infringed the patents and that infringement remains a question of fact to be submitted to a jury. The motions for summary judgment [154-1, 250-1] are therefore denied.
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remove algae

The Court modifies Plaintiffs' proposed construction and construes the term as "a reduction in the amount of a biological organism capable of absorbing chlorophyll A to an appreciable extent." Defendants argue that the term should be construed as "to eliminate, take away, or do away with all biological organisms capable of absorbing chlorophyll A." Defendants' arguments in support of their proposed construction are almost identical to those urged with regard to "remove turbidity." One of the few difference being that here, Defendants point to example 15 in the specification, which describes a "complete algal kill[]" in the treated water. See Col. 14:32-35.

For the same reasons discussed above with regard to "remove turbidity," the term "remove" is used synonymously with the term "reduce" in the '690 patent and the patent does not require the complete elimination of algae. Even in light of example 15, Defendants' proposed construction would limit the claim terms so as to exclude certain preferred embodiments discussed in the specification that do not require the complete elimination of all amounts of color or turbidity. As mentioned above, claim terms should not be construed to exclude a preferred embodiment found in the specification, while at the same time "particular embodiments and examples appearing in the specification will not generally be read into the claims." Comark Communs., 156 F.3d at 1187; see also Phillips, 415 F.3d at 1323. Accordingly, the Court construes the term "remove algae" in a way that does not exclude a preferred embodiment found in the specification and so that no particular embodiment from the specification is improperly read into the claim.
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B. Ocean Spray Does Not Treat Dried Fruit With An Acidulant In A Manner Intended to Substantially Remove the Natural Flavor Of The Dried Fruit

Although the court's construction of "dried fruit" as used in Claim 1 of the Mazin patent is alone sufficient to grant Ocean Spray's motion for summary judgment, that motion is also meritorious on another ground. In addition to not using dried fruit, Ocean Spray's manufacturing process does not use an acidulant to remove flavor from cranberries.

Step (a) of Claim 1 requires "treating a dried fruit with an acidulant . . . in an amount and for a period of time which is sufficient to substantially remove the natural flavor of the dried fruit." See Mazin patent at 10:3-8 (emphasis added). Although Ocean Spray stipulates that it uses citric acid, an acidulant, as part of its infusion process, the parties disagree on the meaning of the word "remove" as used in Claim 1. Ocean Spray asserts the claim language plainly requires the use of an acidulant to remove natural flavor, and not to add flavor as occurs in its infusion process. Amazin' Raisins argues that Ocean Spray in fact uses citric acid to remove flavor.

The court construes Claim 1 to require the use of an acidulant to remove the fruit's flavor and also finds that using an acidulant to add flavor back to the fruit is not within the scope of Claim 1. The express claim language indicates that

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Amazin' Raisin's process requires the use of an acidulant to remove the natural flavor of the dried fruit. Id. at 10:7-8. The specification is consistent with this language, repeatedly stating that the purpose of the acidulant is to remove the flavor from the dried fruit. Id. at 2:58-66, 4:38-66, 5:56-64, 6:13-17. Indeed, the specification distinguishes the use of citric acid to remove flavor and the use of citric acid to add flavor. Id. at 5:37-41. As explained earlier, Amazin' Raisins made similar distinctions during prosecution to overcome the use of citric acid as a food additive in the prior art following the patent examiner's rejection of their initial claims. See Woodford Decl. Ex. 4, at 6.

As with the term "dried fruit," the word "remove" as explicitly used in Claim 1, and as repeatedly and consistently used in the specification and the prosecution history, cannot be properly construed to include the act of addition. See Phillips, 415 F.3d at 1317-19. Moreover, any extrinsic evidence on the meaning of "remove" is being disregarded, as it directly contradicts the clear and unambiguous intrinsic record, specifically the claim language, the specification, and the prosecution history. Id. The act of removal is necessarily different than the act of addition. See Asyst, 402 F.3d at 1195; Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 1106 (Fed. Cir. 2000).

It is undisputed that Ocean Spray uses water or cranberry juice permeate to remove flavor from its cranberry pieces during the CCE extraction process. No acidulant is added to the water or permeate in the CCE phase of the process. Ocean Spray only uses citric acid to add the tart flavor characteristic of cranberries during the CCI infusion process. Ocean Spray closely monitors the acidity of the cranberry pieces, first reducing it from 2.4% to .25%, and then, during infusion, increasing the acid content to a range of 1.2% to 1.8%. Based on the foregoing, Ocean Spray does not literally infringe Claim 1 by using an acidulant to substantially remove flavor.

Nor does Ocean Spray infringe Claim 1 under the doctrine of equivalents. First, Amazin' Raisins expressly acknowledged the use of citric acid as a food additive existed in the prior art and distinguished its claim on the grounds that the prior art did not suggest the use of acid to remove flavor. Woodford Decl. Ex. 4, at 6. Second, even if Amazin' Raisins did not evince a clear and unmistakable intention to disclaim the use of citric acid as a flavor additive, it cannot use the doctrine of equivalents to encompass subject matter already existing in the prior art, see K-2 Corp., 191 F.3d 1356, 1367, or to reclaim by equivalents what the express language of the patent disclaims--the act of adding flavor, as opposed to removing it. See Warner-Jenkinson, 520 U.S. at 29; Asyst, 402 F.3d at 1195; Moore, 229 F.3d at 1106.

Therefore, the court is also granting Ocean Spray's motion for summary judgment on the ground that its process does not use an acidulant to remove flavor from cranberries as required by Claim 1.
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remove turbidity

The Court modifies Plaintiffs' proposed construction and construes the term as "increase clarity, reduce reported NTU to an appreciable extent." Defendants argue that the term should be construed as "to eliminate, take away, or do away with all measurable NTUs." Plaintiffs argue that the term "remove turbidity" should be construed as "increase clarity, reduce reported NTU."

Defendants contend that the ordinary meaning of "remove" is "to eliminate, or do away with." Defendants urge that Plaintiffs' proposed construction attempts to define "remove" synonymously with "reduce," meaning essentially, a lowering by any amount. Defendants contend that such a construction would expand the scope of the claims "to cover the practice of the claimed technology where any amount of turbidity or algae was reduced." Defendants rely on the examples found in the specification of the '690 patent to support their contention that the patent claims an invention with a purpose of virtual, if not total, removal of all measurable amounts of turbidity.

A patentee may give a claim term a different meaning than the term might otherwise have, and in these situations, the inventor's lexicography controls. Phillips, 415 F.3d at 1316. Contrary to Defendants' argument, the claims and specification of the '690 patent appear to use the terms remove and reduce interchangeably. Claim 10 of the '690 patent is an independent claim that states, "A process for clarification of water and reduction of color and turbidity of water by chemical treatment of said water, said process comprising." Col. 17:1-3. The claim then describes the process and indicates it as "to remove color and turbidity from the water." See Col. 17:4-10. Claim 17 follows a similar pattern. See Cols. 17:44-18:21. In these

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examples, each of the claims use the words "remove" and "reduce" interchangeably while discussing the same process.

Similarly, the specification of the '690 patent appears to use the terms "reduce" and "remove" interchangeably and does not indicate that a complete elimination of turbidity is required under the patent. The specification uses the term "remove" in conjunction with turbidity. See Col. 2:46-48 ("such that removal of color units, turbidity units, oil and grease are enhanced and simplified."). Additionally, the specification uses the term "reduction" in conjunction with turbidity. See Col. 3:11-13 ("The present invention further provides a process for turbidity reduction. . . ."); see also Col. 7:40-44 (using reduction and removed synonymously).

A term that is construed to exclude a preferred embodiment found in the specification '"is rarely, if ever correct.'" SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1285 (Fed. Cir.2005) (quoting Vitronics, 90 F.3d at 1583). None of the examples in the specification, all of which are preferred embodiments of the patent, indicate a complete elimination of all measurable NTUs of turbidity or units of color. n4 See Cols. 8:25-15:26. Instead, the examples demonstrate that the invention "reduces" turbidity and color to minimal but measurable amounts. See id. Example 10 in the specification explains that test results showed the patented chemicals to "significantly remove more color" than other chemicals. Col. 12:30-32. Example 10 goes on to explain that the color reduction was from 120 color units to 14 color units under the patented process. See Col. 12:32-36. Fourteen color units is clearly a measurable amount of color and does not represent a complete elimination of color. A construction of "remove turbidity" that required the elimination of all measurable turbidity or color would exclude a preferred embodiment found in the specification.

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n4 Turbidity is measured in units referred to as NTUs. The term "remove" is used with regard to color and turbidity throughout the patent and the parties do not dispute that the same meaning should apply with regard to "remove" irregardless of which of these terms it is used in conjunction with.

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The claim language and the specification indicate that the applicant used the terms "remove" and "reduce" interchangeably. Furthermore, neither the specification nor the claims themselves indicate that all measurable NTUs of turbidity, units of color, or algae must be removed from the treated water. Accordingly, Defendants' proposed construction of "remove turbidity" is rejected.

As mentioned above, Plaintiffs argue that the term "remove turbidity" should be construed as "increase clarity, reduce reported NTU." Defendants contend that this definition improperly broadens the scope of the claim term because it allows any reduction in turbidity, even a minimal one, to be within the claims of the patent.

The specification clearly demonstrates that the patent discloses a process that improves upon previous water treatment technology. See Col. 8:25-15:26. The examples in the specification demonstrate that previous technologies removed turbidity to levels at least as low as 0.3 NTU in most cases. See id. Plaintiffs' proposed construction would broaden the scope of the claims such that any increase in clarity or reduction of NTUs would fall within the claims of the '690 patent. The specification clearly indicates that the scope of the claimed invention is not this broad. Accordingly, the Court construes the term "remove turbidity" as "increase clarity, reduce reported NTU to an appreciable extent."
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(b) "and wherein the sum of [corresponding peptide sequences] [claim 24] [said corresponding epitopic peptide sequences] [claim 34] [encoded by said oligonucleotide population] [claim 24] represents at least about 10% of all possible peptide sequences of said length"

While written slightly differently in the two claims, this limitation refers to the size of the peptide library needed to make the invention work. Plaintiffs offer no consistent construction of what is meant by "about 10% of all possible peptide sequences," but suggest that "10%" can consist of: (1) 300,000 (or perhaps 30,000) distinct members for any coded library of random peptides with a length in the range of 5 to 13 amino acid residues; (2) 16,000 (or perhaps 1,600) distinct

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members for any coded library of random peptides with a length of 4 amino acid residues; and (3) 80 (or perhaps 800) distinct members for any coded library of random peptides with a length of 3 amino acid residues. 5 Plaintiffs' Brief, at 11, 16. The limitation "all possible peptide sequences of said length" plaintiffs construe to mean "the complete range of possible epitopic peptide sequences … within the range of 3 to 13 L-amino acid residues consistent with the means by which the 'oligonucleotide population' was generated." Id., at 11.

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5 The suggested population figure of 80 tripeptides may be a mathematical error. It is possible that plaintiffs meant 800 rather than 80 as 20<3>/10 = 800. Plaintiffs' calculations for populations of tetrapeptides and pentapeptides are largely faithful to the formula 0.10 x L = 20<L>/10), reporting the accurate result of 20<4>/10 = 16,000 for tetrapeptides, and the approximately accurate result of 20<5>/10 = 300,000 for pentapeptides. Nonetheless, the parentheticals following the two calculations (suggesting the figures of 1,600 and 30,000 respectively) are consistent with the assertion that 10% in fact means 1%.

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According to Dyax, the 10% limitation requires that the total of the peptide sequences encoded by the oligonucleotide population encompass at least 10% of the possible peptide sequences of a single given length within the range of from 4 to 12 L-amino acids. "All possible peptide sequences of said length," Dyax construes to mean the number of sequences derived by the formula L = 20<L> where <L> represents the given length within the specified range of L-amino acid residues and 20 signifies the number of genetically encodeable amino acids. Thus, if L is 12, the possible number of sequences is 20<12> or 4.096 x 10<15>, which when divided by 10 yields a library of 4.096 x 10<14> members. Dyax Brief, at 13-14.

Analysis

The parties' dispute boils down to a basic difference in interpretation that plaintiffs accurately summarize as follows: "Dyax argues that [infringement] should be determined from the perspective of the size of the peptide library made, whereas plaintiffs' position is that infringement is determined by the size of the peptide library necessary to bind the desired target." Plaintiffs' Response, at 2. Plaintiffs, in other words, maintain that as Dr. Pieczenik refined his invention, he realized that "five amino acids [the pentapeptide] is a representative length of peptide sequences which can bind with differential specificity to an antibody." Plaintiffs' Brief, at 14 (emphasis in original). Moreover, "antibodies are now known to have specificities which can be competed by peptides in the range of 5-7 amino acids, with a mean in the range of around 5 amino acids." Plaintiffs' Response, at 10 (emphasis added). Thus, "the entire universe of antibodies is equivalent to the entire universe of epitopic peptides that are 5 amino acids long on average or 3.2 x 10<6> possible antibodies." Plaintiffs' Brief, at 15. Because "many of the encoded peptides will present sufficiently similar binding surfaces that a single antibody will react with any of them …. it is not necessary to have all, or even most, of the possible coding sequences represented." Id., at 15 (quoting from File History, at 202). In fact, "all possible antibodies will be found to bind specifically with one of the mixture of random peptides provided a) the peptides are 5-7 amino acid residues in length, and b) the mixture contains at least about 10% of all possible peptide sequences." Id. (quoting File History, at 200). Therefore a library of "about" 300,000 members is all that is required to identify the "universe" of possible antibody binding sites. Id.

This assertion is the crux of the dispute about the necessary size of the specified library because, as a matter of undisputed scientific fact, there are 20 naturally occurring amino acids. Thus, where the peptide length consists of 5 amino acid residues, the possible number of peptides is 20<5>, or more conventionally stated, 3.2 x 10<6>. Where, however, the length is 12 amino acid residues, the possible number of peptides is 20<12> or 4.096 x 10<15>. It follows that a library containing 10% of all possible peptide sequences where the length is 12 would contain 4.096 x 10<14> members, as Dr. Pieczenik himself pointed out to the PTO in correcting the examiner's assumption that the correct formula for calculating the possible number of peptide sequences where L is 12 is the inverse of 20<12>, or 12<20>. In traversing the examiner's rejection, Dr. Pieczenik gave the following example. "For a peptide having a sequence length of 12 (L = 12), each position having an equal probability of being one of the 20 natural amino acids (N = 20), the number of possible sequences is N<L> = 20<12>, which can be converted to 4.1 x 10<15>." Dyax Brief, at 21 (quoting File History, at 734). He went on to point out that the examiner's method resulted in a million-fold error on the high side. Id. (quoting File History, at 735). 6 The point is crucial because, as Dyax points out, "the peptides in [its] libraries are longer than 12 amino acids -- indeed, some are longer than 60 amino acids. And, Dyax's phage display libraries include far fewer than 10% of the possible peptide sequences for a selected

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peptide length." Dyax Brief, at 9. A library of 300,000 members would represent but 0.0000000073% of the possible number of sequences where L is 12, when the formula advocated by Dyax and used by Dr. Pieczenik in his illustration to the PTO is applied. See Table, Dyax Reply, at 5. None of the corresponding percentages for lengths 6 to 13, which range from 0.47% (6) to 0.00000000037% (13), could ever reasonably thought to be "about 10%," no matter how flexibly the limitation is to be read. It is therefore critical to an understanding of plaintiffs' position to trace the elements of the argument that the "said" in the phrase "all possible peptide sequences of said length," refers to pentapeptides.

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6 Plaintiffs maintain that Dr. Pieczenik was taken out of context and was referring to the correct method of calculating the number of theoretically possible sequences and not the number of sequences that are biochemically possible. Plaintiffs' Response, at 13-14. This distinction, however, appears nowhere in the exchange with the examiner.

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To the extent that plaintiffs' argument is based on the actual language of claims 24 and 34, it rests on the supposed difference between the meaning of "selected length" (the term used in the antecedent application) and the term "said length" (the term ultimately chosen). "Whereas selected refers to the random length selected a priori, said refers to the length of the random peptide sequence that, for example, binds to an antibody." 7 Plaintiffs' Response, at 8 (emphasis in original). This semantic change, plaintiffs argue, would have alerted an attentive reader of ordinary skill in the art, familiar with the "scientific presumption" that "antibodies are now known to have specificities which can be competed by peptides in the range of 5-7 amino acids, with a mean in the range of around 5 amino acids," to the fact that a pentapeptide library is sufficient to define all peptide sequences with lengths from 6 to 13 amino acid residues. Id., at 10. In other words, a library of 300,000 distinct figures (roughly 10% of 3.2 x 10<6>) would completely satisfy the 10% limitation in the claims. "Said" is a term used by patent drafters who (like many lawyers) are unexplainably uncomfortable with using the more colloquial "the" when referring back to previously recited claim elements. See Landis on Mechanics of Patent Claim Drafting (2001) § 23. Neither claim 24 nor claim 34 makes any antecedent reference to pentapeptides as the sequence defining the "said" length. The element referenced is rather "a length from about 4 to about 12 nucleotide triplets," that is, one of 9 (or 10) designated lengths with its corresponding peptide sequence. Pentapeptides are certainly one of these lengths, but not the only length referenced. The claims language, in other words, simply will not support the load bearing weight plaintiffs attempt to assign to the word "said."

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7 As Dyax points out, this assertion contradicts the specification of the patent, which teaches that "the invention features a discrete recombinant vector population of substantially identical autonomously replicating nucleic acid sequences including a structural gene and a population of oligonucleotide inserts therein, each insert containing a uniform length selected from between about 4 to about 12 nucleic acid coding triplets, preferably between 4 and 7, and most preferably five. '393 patent, Col. 4, Ins. 19-27 (emphasis added).

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Plaintiffs' prosecution file history and prior art arguments fare no better. Much emphasis is placed on the qualified disclosure in the original 1985 application that

> the size of the antibody recognition site corresponds to a peptide sequence in the range of between about 4 and about 12 amino acid residues … [and that] there are about three million (20<5>) different possible sequences of the twenty amino acid residues taken five at a time and about sixty million if the amino acid residues are taken six at a time. This finite number of peptide sequences may represent the full range of possible antibody recognition sites. Production and maintenance of a representative sample of the peptide sequences of the appropriate length provides the means (1) to screen any antibody of interest in order to determine the precise peptide sequence it binds to ….

Plaintiffs' Brief, at 12 (quoting File History, at 14-15). 8 From this, plaintiffs deduce that it would have been "clear" to one skilled in the art that the inventor had "recognized that random pentapeptides can adequately represent any random 12 amino acid sequence in terms of competitive binding to antibodies." Id., at 12-13. Why this is so is not explained in any

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meaningful way, other than by random citations to the discussion of the prior art in the original 1985 patent application, which when read in context, offer no support for plaintiffs' late blooming theory that the '363 patent teaches a universe of antibody binding sites bounded by pentapeptides. The citation to Geyson, et al., in the file history is a good example. It is clear in context that Geyson was cited to explain to the PTO why degeneracy (the phenomenon by which an antibody may recognize more than one peptide sequence) made it possible to construct a working population consisting of only 10% of the peptides of a given length rather than, as the examiner thought would be necessary, the entire peptide population associated with that length. It does not follow from the discussion of Geyson (or Dame, et al., the other principal prior art source cited) that the "prosecution file history make[s] clear to one skilled in the art that any coded library of random peptides with [a] length in the range of 5-13 amino acid residues and containing at least about 300,000 (e.g. 30,000 = 1%) distinct members is understood to mean an oligonucleotides population that represents at least about 10% of all possible peptide sequences of said length." Plaintiffs' Brief, at 15-16 (emphasis in original).

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8 As Dyax argues, the assertion that the range of 3 to 60 million peptides represents the universe of possible antibody recognition sites ignores antibodies that bind conformationally dependent epitopes "for which pentapeptides and hexapeptides cannot successfully compete in many circumstances." Dyax Brief, at 25 n*. According to Dyax, when these are considered the number of possible antibody recognition sites "far exceeds" the 3 to million figure posited by Dr. Pieczenik. Even if the 3 to 60 million figure is correct, plaintiffs do not explain why the absolute bottom of that range represents the operative number of desired peptides.

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Conclusion

The limitation establishing a library of peptide sequences representing "at least about 10% of all possible peptide sequences" of "from about 4 to about 12 L-amino acid residues" has one definite term -- "all possible" -- and two indefinite terms -- "at least about 10%" and "from about 4 to about 12." There is no indication in the patent specification that Dr. Pieczenik intended these phrases to convey any meaning other than their ordinary English connotation. Thus, "all possible" can only be understood to mean the universe of peptide sequences associated with L-amino acid lengths of "from about 4 to about 12." While I agree with plaintiffs that the term "about" is a term of deliberate imprecision that might fairly capture the integers 3 and 13 at the boundaries of "from about 4 to about 12," the term "all possible" can only mean in context the entire universe of what could occur, that is, the total number of naturally occurring sequences that can possibly be associated with the selected length, whether 20<3> or 20<13> or some other specified length within the asserted range of 3 to 13 amino acid residues. In similar fashion, in the interest of lexicographic consistency, "at least about 10%" can be understood to perhaps capture 9%, or given the qualification of "at least about 10%," perhaps a number substantially above 10%, but certainly not 1%, as plaintiffs' expert, Dr. Makowski, maintains. 9

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9 That the phrase "at least about 10%" means "more than at least 1%" was the position taken by Dr. Makowski in his deposition. It is not clear from the briefs whether plaintiffs continue to support Dr. Makowski on this point, or whether even Dr. Makowski believes that the 1% figure is supported by the patent. See Dyax Brief, at 29; Plaintiffs' Response, at 14.

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As Dyax points out, plaintiffs' redefinition of the universe of antibody binding diversity as corresponding with a population of pentapeptide sequences "reads out" of the claims the range of peptides of from 6 to 12 amino acids in length "by making them synonymous with the 5 amino acid member of the range." Dyax Brief, at 27. Like Dyax, I am puzzled why, if the point of the invention was to provide a population of peptide sequences representing the "universe of possible antibody binding sites," the claims would have been written "to specify lengths of peptides that admittedly cannot do so," or why it is not simply made clear that pentapeptide sequences define the intended universe. Dyax Response, at 8. Indeed, there is nothing said at all in the claims (or the specification) about this universe, nor is any meaningful suggestion made that longer peptides can be expressed as representative lengths of pentapeptides. Like Dyax, I can only conclude that plaintiffs' "pentapeptide universe" theory is an attempt to expand on the claims of the patent to broaden their coverage for purposes of

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this litigation. 10

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10 While it is true that the '393 patent identifies populations of 5 amino acid length sequences as a preferred embodiment of the invention, it is only one of four such preferred embodiments (the others being populations of sequences 4, 6, and 7 amino acids long). Moreover, as plaintiffs acknowledge, "references to a preferred embodiment, such as those often present in a specification, are not claim limitations." Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988).

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* * *

ORDER

For the foregoing reasons, the court for Markman purposes will construe the disputed terms as follows. The limitation "from about 4 to about 12 nucleotide triplets," as used in claims 24 and 34 of the '363 patent, is sufficiently indefinite to include a range whose boundaries are delimited by 3 and 13. Similarly, the limitation "from about 4 to about 12 L-amino acid residues" means a range of from 3 to 13 of such residues. The limitation "represents at least about 10% of all possible peptide sequences" means approximately 10% or more of the possible peptide sequences of a given length within the range of 3 to 13 L-amino acids where the number of possible peptide sequences is equal to 20<L>. "Oligonucleotide" means a compound created by the condensation of typically fewer than 20 nucleotides.
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2. "A Resin"

Magistrate Judge Smith has recommended that this Court construe "a resin" to mean "a thermoplastic solid or semi-solid substance." (Id. at 12.) Medtech has narrowly objected to this definition, insisting only that the correct definition must also include the word "thermosetting," so that the definition reads, "a thermosetting or thermoplastic solid or semi-solid substance." (Pl.'s Objection to R&R ("Medtech Obj.") 7-10.) Medtech claims that Magistrate Judge Smith's decision to exclude "thermosetting" from the definition of "a resin" is erroneous for the following reasons: (1) the accepted dictionary definition of "resin" includes thermosetting and thermoplastic materials; (2) consistent with Federal Circuit precedent, a preferred embodiment in the specification should not be used to limit the claim, but should instead be seen as "at least one embodiment of the invention that falls within the scope of the claims"; (3) the patent specifically states that it is not limited by the embodiments described in the specification; and (4) even Dentek's expert acknowledged that the base of the invention could be made from thermosetting resins. (Medtech Obj. 9-10.) The Court agrees with Medtech.

It does not follow from the fact that "the word 'thermosetting' is not mentioned anywhere in the patent" (R&R 13) that the term "a resin" must be limited to thermoplastic resins. Dentek did not request such a limitation in its initial briefing before Magistrate Judge Smith (Mem. of Def. Dentek Oral Care, Inc. on Construction of Claim 17 of the '051 Patent ("Dentek Mem.") 16-17), and agreed to accept a definition stating that a resin "may include thermoplastic or thermosetting materials." (Pl. Medtech Prods. Inc.'s Claim Construction Br. ("Medtech Mem.") 15; Reply of Def. Dentek Oral Care, Inc. to Pl.'s Br. ("Dentek Reply Mem.") 5 n.1.) Dentek provides no reason for changing its view that "a resin" may include a thermosetting material, and merely states that the R&R "properly and consistently circumscribed the definition of 'resin' to thermoplastic resins." (Dentek Resp. to Medtech Obj. ("Dentek Resp.") 5.)

Magistrate Judge Smith acknowledged that thermosetting materials are embraced by her accepted dictionary definition of "resin" and that Dentek and Medtech previously agreed that the term was not limited to only thermoplastic materials (R&R 13), but nevertheless concluded that "the inventor impliedly defined the term 'a resin' . . . as a thermoplastic material" (id. at 14). She based this conclusion on the patent's description of the functionality of the preform (id.), but the preform is only one of the two parts of the appliance made of a resin, and it is clear that the other part -- the base -- has a functionality that does not require a thermoplastic material. (Medtech Obj. 8.) Magistrate Judge Smith also relied on the fact that the word

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"thermoplastic" "is used either in place of or to modify the word 'resin' numerous times throughout the patent." (R&R 13.) However, the repeated use of the word "thermoplastic" in describing the preferred embodiments of the appliance does not limit the term "a resin" in Claim 17. See Phillips, 415 F.3d at 1323-24 (cautioning against importing restrictions from statements designed to "teach and enable those of skill in the art to make and use the invention"); Interactive Gift Exp., 256 F.3d at 1331 (same). And while the statement in Claim 7 that "the base resin comprises a[] . . . copolymer blended with a thermoplastic" limits that claim, it says nothing about the meaning of the term "a resin" in Claim 17.

Accordingly, the Court construes "a resin" to mean "a thermoplastic or thermosetting solid or semi-solid substance."
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The first disagreement by the parties centers around the meaning of the word "resistance". RPA argues that "resistance" means something like immunity; that a non-transgenic plant would die from application of a normally lethal amount of glyphosate while the transgenic plant would remain unharmed (the construction given the advisory jury). DeKalb, on the other hand, contends that "resistance" is inherently comparative; that a plant exhibits "resistance" to glyphosate if it suffers even slightly less harm from an application of glyphosate than do normal corn plants.

The starting point, then, is an examination of the intrinsic evidence, here the patent claim language, the specification, and the prosecution history. RPA points to the prosecution history where the terms "resistance" and "partial resistance" each appear. (Pros. Hist. '798 Patent at 804 n29, 812 n30.) RPA argues that the concept of "partial resistance" would have no meaning unless "resistance" were interpreted as complete or absolute resistance. See Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005)(explaining that the term "steel baffles" strongly implies that the term "baffles" does not inherently mean objects made of steel); Minebea Co. v. Think Outside, Inc., 159 Fed. Appx. 197, 202 (Fed. Cir. 2006)(explaining that because the claim provides that certain structures will "slide in addition to pivot" sliding motion should not be subsumed into pivoting motion).

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n29 In an Interview Summary dated May 24, 1996, the patent examiner states: "The declaration clearly evidences that a person of ordinary skill in the art, employing the methods disclosed in the specification, would have obtained a transgenic corn plant expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at leaves that would normally kill corn." (Pros. Hist. '798 Patent at 804 (emphasis added).)

n30 T. Michael Spencer, a DeKalb scientist, filed a Declaration dated August 12, 1993 in which he provided information about two examples of experiments. (See Pros. Hist. '798 Patent at 807-15.) Example One discussed experiments with versions of the aroA gene in which Spencer concluded that "a low level of expression of the aroA gene had been attained which provides partial resistance to herbicide application." (Pros. Hist. '798 Patent at 812 (emphasis added).) In contrast, Example Two, which discussed experiments with the mutant maize ESPS gene, concluded that glyphosate resistance had been conferred. (Pros. Hist. '798 Patent at 815 (emphasis added).)

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However, after reviewing the specification, the prosecution history, and the arguments of counsel, it is determined that the intrinsic evidence substantially supports DeKalb's view that, as used in claim 1, "resistance" should be accorded its broader meaning, i.e. that a transgenic plant is "herbicide resistant" even if it is severely harmed by herbicides, so long as it is less harmed than the non-transgenic version of the plant would be at the same applied level of glyphosate.

For example, the specification -- which does not describe a transformation in which glyphosate resistance was the trait being conferred -- does describe a transformation which used the process claimed in the original application for conferring a trait for hygromycin resistance and also describes the testing for evidence that the DNA encoding hygromycin resistance had been inserted and passed to the R1 generation. In the test, the tissue was subjected to hygromycin and then scored from 0 to 6; 0 being all brown and 6 being all green. ('798 Patent, col.21, II.6-12.) Those scoring from 3 to 6 were classified as "hygromycin resistant". ('798 Patent, col.21, II.6-12.) Significantly, the tissue scored at 3, 4, and 5 -- each being classified as "resistant" -- would be less than all green with a 3 being more brown than green. Thus, the specification itself ascribes a

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meaning to the term "resistance" much broader than total resistance or immunity.

Additionally, the prosecution history contains several statements by DeKalb through its attorneys which suggest the understanding of "resistance" intended in the application. First, the prosecution history contains a reference by DeKalb's patent attorney to a declaration by T. Michael Spencer, one of DeKalb's scientists. (Pros. Hist. '798 Patent at 416.) The attorney contends that the declaration shows that "resistance to glyphosate" has been imparted to corn plants. Read together with the declaration itself which discusses the production of transgenic corn plants that are severely harmed by glyphosate, though somewhat less so that normal corn plants, it is clear that the attorney is using the term "resistance" in a broad sense. n31 (Pros. Hist. '798 Patent at 807-15.)

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N31 The same sense in which clothing that is not waterproof is sometimes called "water resistant."

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Second, the Amendment filed by DeKalb's attorneys on February 22, 1996 n32, contains a description of resistance that strongly suggests inclusion of more than just immunity. That Amendment states: "The DNA construct is expressed so that the transgenic plant exhibits tolerance or resistance to glyphosate at levels that render it identifiable over the corresponding untransformed corn plant which does not comprise the heterologous DNA." (Pros. Hist. '798 Patent at 748-49.) The DeKalb attorney's statement conveys an understanding of resistance that includes the transgenic plant being harmed, but less so than the non-transgenic corn, and not that of immunity.

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n32 The Amendment was sent February 19, 1996, but does not appear to have been filed until several days later.

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Such statements, made by the patent applicant himself, are strong evidence of the meaning intended in the claim language. See Markman, 52 F.3d at 980 ("Th[e] construction of the patent is confirmed by the avowed understanding of the patentee, expressed by him, or on his behalf, when his application for the original patent was pending . . . . [W]hen a patent bears on its face a particular construction, inasmuch as the specification and claim are in the words of the patentee, . . . such construction may be confirmed by what the patentee said when he was making his application. ")(citing Goodyear Dental, 102 U.S. at 227).

There is no suggestion in the prosecution history that DeKalb, in its communications with the Patent Office, ever agreed to or was asked to limit the meaning of resistance to full or total resistance. In this context, it is interesting to note that the cited use of the phrase "resistance or partial resistance" was that of the patent examiner who at the time was necessarily using both as fulfilling the limitation of "resistance" in claim 1. The patent examiner's Interview Summary dated May 24, 1996 contains the following statement:
The specification does not clearly evidence the effects of the expression of EPSP synthase in transgenic corn plants in the absence of [sic] Spencer declaration, the orginal [sic] filed in parent application 07/508,045, of the instant continuation application. Applicants' attorney submitted said declaration for review in this interview. The declaration clearly evidences that a person of ordinary skill in the art, employing the methods disclosed in the specification, would have obtained a transgenic corn plan expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at levels that would normally kill corn . . . . Actual reduction to practice is viewed as the completion of the conception of the invention (Fiers v. Sugano 984 F.2d 1164, 25 U.S.P.Q.2d (BNA) 1601 (Fed Cir. 1993)).

(Pros. Hist. '798 Patent at 804 (emphasis added).) As is evident from this statement, the patent examiner put great weight in the information contained in the Spencer declaration. The Spencer declaration described one example of a transformation in which Comai's CT7, aroA bacterial gene, was biolistically implanted into embryonic cells, a plant regenerated and crossed with a non-transgenic plant. Plants of the R1 generation were then subjected to applications of 2, 4, 8 and 16 ounces of glyphosate. At the two ounce level, all lived; at the eight and sixteen ounce levels all died. At the four ounce level some died and those that lived were stunted. The example was cited in the declaration as illustrating that "a low level of expression of

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the aroA gene had been attained which provides partial resistance to herbicide application." (Pros. Hist. '798 Patent at 811-12 (emphasis added).) Example Two described transformation using RPA's construct of the DMMG and the OTP constructs, but only through the in vitro stage. Following microprojectile bombardment and a selection process in which glyphosate was used in the growth medium as a selectable marker, Southern blot hybridization showed that both callus lines tested had incorporated the new DNA. This was cited in the Spencer Declaration as a clear demonstration of the "introduction and expression in cultured maize cells and plants of an ESPS gene which confers glyphosate resistance." (Pros. Hist. '798 Patent at 815 (emphasis added).) The use of the term "glyphosate resistance" in the second example describing the in vitro analysis of a cell line and not a plant was not inconsistent with the use of the term "partial resistance" as it was applied to the testing of a fertile, transgenic plant of the R1 generation in the first example. Both were consistent with the use accorded the term "resistant" in the specification when "hygromycin resistant" tissue was defined to include all shoots scoring from 3 to 6 after being exposed to hygromycin. ('798 Patent, col.21, II.5-13.)
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D. "Resistance to normally toxic levels of glyphosate"

The next claim term for this Court to construe is "resistance to normally toxic levels of glyphosate." This phrase can be broken down into two distinct terms, "resistance" and "normally toxic levels of glyphosate." DeKalb argues that resistance means any level of resistance above that observed in a non-transformed plant, and normally toxic levels of glyphosate means any level of glyphosate which will damage a normal plant. Syngenta proposes that the phrase means "that as a result of the expression of the DNA construct, the corn plant will not be significantly injured when glyphosate is applied to it at a rate that will typically kill a non-transgenic corn plant of the same variety growing under similar conditions." Syngenta's Opening Claim Construction Br., 26-27. The Court notes that it is necessary to address the terms of this phase independently, as the phrase itself is not found in the patent specification. 16

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16 This is where DeKalb petitions the Court to rely upon the North Carolina decision, which defined the term as partial resistance to low levels of glyphosate. However, as the Court discussed above, the Court is not bound by that opinion, and will therefore conduct it's own analysis.

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The Court first looks at the available intrinsic evidence in determining the meaning of resistance to normally toxic levels of glyphosate. See Phillips, 415 F.3d at 1315. The applicable language of Claim 1, for the purposes of construing these terms states, "wherein said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a Zea mays plant not containing said DNA construct. . ." This claim language is significant because it compares resistance between the fertile transgenic plant and the non-transgenic plant. The claim language expresses a comparison of resistance, not an exact result or absolute value. DeKalb's definition of "resistance" presents a comparative definition. There is no absolute value described in the claims, in the Specification, or in the Prosecution History.

The Court looks next to the specification. As correctly noted by Syngenta, the specification does not reference "resistance to normally toxic levels of glyphosate." The specification does address the purpose of the patent in general, which is to enhance beneficial features in corn, through the use of the process outlined in the patent. The specification states that "[t]he transgenic plants produced herein are expected to be useful for a variety of commercial and research purposes." United States Patent 5,554,798, column 14, lines 11-12. The specification then spends the next four paragraphs describing potential uses of the invention, almost entirely discussing commercial applications. Id. at column 14, lines 13-49. The reference to research is expounded in the fourth paragraph of the section entitled "Uses of Transgenic Plants," and states as follows:

The transgenic plants may have many uses in research or breeding, including creation of new mutant plants through insertional mutagenesis, in order to identify beneficial mutants that might later be created by traditional mutation and selection. The methods of the invention may also be used to create plants having unique "signature sequences" or other marker sequences which can be used to identify proprietary lines or varieties.

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United States Patent, 5,554,798, column 14, lines 42-49. DeKalb argues that this reference to research value allows a less stringent interpretation of resistance, as any level of resistance would be beneficial for research purposes. However, the portions of the patent which reference research, as quoted above, anticipate research beyond the original enhanced trait, in this case glyphosate resistance. These portions of the specification do not support DeKalb's argument, as they do not suggest that the invention is useful for providing a basis for future research that might produce corn with the desired enhanced trait. However, this conclusion does not conclusively support Syngenta's position either, as this portion of the specification does not specifically address the level of resistance necessary to fall within the scope of the invention.

Looking to how the inventors view their invention, under Example 1, set forth in the specification, the patent describes an experiment performed with hygromycin. The experiment tested the resistance to hygromycin in plant shoots, not full grown plants. The specification states that, following the application of either 0 or 100 mg/l 17 hygromycin, each plate contained duplicate sections of each shoot, and was incubated in the dark for 18 hours.

They were then incubated in a light regimen of 14 hrs light 10 hrs dark at 26 [degrees] C. for 48 hrs, and rated on a scale of from [sic] 0 (all brown) to 6 (all green) for the percent of green color in the leaf tissue. Shoots were classified as untransformed (hygromycin sensitive) if they had a rating of zero and classified as transformed (hygromycin resistant) if they had a rating of 3 or greater.

United States Patent 5,554,798, column 21, lines 6-12. While it is correct that this section does not reference glyphosate resistance, it does reference resistance in general and therefore is instructive on the meaning of that term. The intention of the inventors was to create resistance to glyphosate, the inventors stated that they had created resistance in an experiment where there was some resistance. While the Court finds this evidence strongly supportive of DeKalb's position, it is not conclusive. The experiment was in the context of small portions of plant roots, not the plant themselves, and involved hygromycin, not glyphosate.

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17 Milligrams per liter.

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Syngenta argues that exposure to toxic levels of glyphosate means that the non-transgenic plant would be killed. DeKalb complains that Syngenta relies on the extrinsic evidence of Dr. Ward who disregards the first stage of the selection process in the specification to refer to the second stage of that process. The Court is not relying on the extrinsic evidence of Dr. Ward, but notes from reading the specification on page 12 at columns 22-24, the inventors say that "once the few individual transformed cells have grown sufficiently, the same may be shifted to media containing a higher concentration of the toxic agent to kill essentially all untransformed cells." Referring to the first stage, the specification language states, "[p]referably, the concentration of the agent is initially such that about a 5 to 40 percent level of growth inhibition will occur." This passage talks about harm to plants, not killing, and its talking about the effect caused by a toxic agent. Reference to resistance to toxic levels of glyphosate includes both harming and killing the non-transformed plant.

DeKalb's definition of resistance is further supported by the patent prosecution history. In an amendment filed by DeKalb in the prosecution of the '798 patent, it states that "the DNA construct is expressed so that the transgenic plant exhibits tolerance or resistance to glyphosate at levels that render it identifiable over the corresponding untransformed corn plant which does not comprise the heterologous DNA." Pros. Hist. United States Patent 5,554,798, 748-749. Furthermore, the patent officer, in the course of prosecution, stated that:

The specification does not clearly evidence the effects of the expression of EPSP synthase in transgenic corn plants in the absence of Spencer declaration, the original filed in parent application 07/508,045, of the instant continuation application. Applicants' attorney submitted said declaration for review in this interview. The declaration clearly evidences that a person of ordinary skill in the art, employing the methods disclosed in the specification, would have obtained a transgenic corn plant expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at levels that would normally kill corn.

United States Patent 5,554,798, Pros. Hist. Joint Submission, 6372 (emphasis added). These statements made during the prosecution of the '798 patent, taken in conjunction with the specification, lead the Court to conclude that "resistance"

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means any level of resistance above that observed in a non-transformed plant.

However, this does not conclude the Court's analysis, as it is also necessary to define "normally toxic levels of glyphosate." 18 The specification does not define the term normally toxic levels of glyphosate, and therefore the Court again turns to the prosecution history. The portion of the prosecution history cited above will again be restated with emphasis supplied by this Court to different language in the Examiner's conclusions. The Patent examiner states in the parties joint stipulation:

The specification does not clearly evidence the effects of the expression of EPSP synthase in transgenic corn plants in the absence of the Spencer declaration, the original filed in parent application 07/508,045, of the instant continuation application. Applicants attorney submitted said declaration for review in this interview. The declaration clearly evidences that a person of ordinary skill in the art, employing the methods discussed in the specification, would have obtained a transgenic corn plant expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at levels that would normally kill corn. . ..

United States Patent 5,554,798, Pros. Hist. Joint Submission, 6372 (emphasis added). This language supports Syngenta's proposed construction. DeKalb attorneys represented to the patent examiner that a fertile transgenic corn plant with the EPSP gene would obtain resistance or partial resistance to glyphosate at levels that would normally kill corn.

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18 The North Carolina Court reached the same conclusion regarding the definition of resistance, however, the North Carolina Court reached a different conclusion regarding the definition of "normally toxic levels of glyphosate." However, this Court notes that the North Carolina Court relied on Webster's dictionary definition of the term toxic. Pl. DeKalb's Opening Claim Construction Brief, Ex. 3, 49. Using such definitions is cautioned against by the Federal Circuit in Phillips. 415 F.3d at 1321 ("The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.").

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The Court emphasizes that the purpose of the patent, as articulated in the introduction of the specification, is to create transgenic corn, which can then be bred with existing corn lines, to create a desired characteristic, in this case resistance to glyphosate. The Court notes that while even partial resistance would be beneficial, such resistance would not be beneficial if the levels at which the glyphosate were applied were so low that the glyphosate would not effectively kill the weeds, without killing the corn, as glyphosate's function is as a weed-killer. This Court does not find, and nor does Syngenta argue, that the words, "normally toxic levels of glyphosate " must be at a commercial level, because the Federal Circuit cautions against trial judges making claim construction determinations on the basis of the commercial embodiment of the invention. ACS Hosp. Systems Inc. v. Montefiore Hosp., 732 F.2d 1572, 1578 (Fed. Cir. 1984) (Finding error by the District Court in comparing the accused device with the commercial embodiment of the patent, rather than to the claims of the patent); see also Unique Functional Products, Inc. v. Mastercraft Boat Co., Inc., 82 Fed.Appx. 683, 689 (Fed. Cir. 2003) ("It is of no consequence that those extraneous features are present in [Plaintiff's] commercial embodiment."). However, the court believes that the language in the specification supports Syngenta's argument and the Court's conclusion, that the level of glypohsate applied must be at levels sufficient to kill non- transformed corn.

Syngenta further submits extrinsic evidence, in the form of expert testimony on the ordinary meaning of "normally toxic levels of glyphosate," however, it is unnecessary for the Court to look to extrinsic evidence. The intrinsic evidence, which includes the prosecution history, supports Syngenta's proposed construction. Contrary to DeKalb's argument, the definition of resistance, as including partial resistance, does not necessitate that the term "normally toxic levels of glyphosate " be defined as something less than a lethal dose.
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(2) Retain
The use of the term "retain" in claim 1 is essentially the same in both the '096 and the '187 patents. In claim 1 of '096, the process or method patent, the red blood cells are altered by the salt so that their "ability . . . to pass through filter media" is "decreased" and thereafter a filter "retains the altered red blood cells but allows passage therethrough of a sample filtrate."

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'096 Patent, col. 3, 49-53. In claim 1 of '187, the apparatus patent, provision is made, first, for the blood to be mixed with the hypertonic solution, and, next, for a "filter having a porosity to permit said mixture of said sample and said hypertonic solution to pass . . . through said filter, said filter being capable of retaining the red blood cells in said sample." '187 Patent, col. 4, 6-10. There really can be little doubt about what "retain" means; in claim 1 of both patents, it means hold back. Therefore under either patent, filter media must hold back red blood cells.

What the parties disagree over is whether all the red blood cells must be held back. SAS/Abaxis say yes; IDEXX says no. The actual claim 1 language is not dispositive in either patent. In '096 the red cells' ability to pass is said to be decreased, the filter is said to retain altered red blood cells (no reference is made to rate of retention or to red blood cells that may remain unaltered) and a sample filtrate does pass through. '096 Patent, col. 3, 49-53. In '187, we are told simply that the filter is "capable of retaining the red blood cells" in the sample. '187 Patent, col. 4, 9.

Since the language of claim 1 does not answer the dispute in either patent, I turn to the specifications. According to the abstract, the invention alters red blood cells "to decrease their ability to pass through filter media," and the "filter . . . retains the red blood cells, but allows the passage therethrough of filtrate. . . ." '096 Patent, p. 1; '187 Patent, p. 1. According to the summary, the invention alters the red blood cells "to decrease their ability to pass through filter media, exposing the resultant sample to a filter which retains the red blood cells but allows the passage therethrough of filtrate containing the member of the specific binding pair being assayed. . . ." '096 Patent, col. 1, 24-29; '187 Patent, col. 1, 27-32. "It is believed that the salt causes the red blood cells in the sample to exhibit a change in physical properties, e.g., deformability, so that they are unable to pass through filter media which would have permitted their passage prior to treatment with the salt. A filter having an average pore size small enough to retain untreated red blood cells would become clogged and prevent passage of liquid as well. According to the invention, a filter can be used which has an average pore size . . . large enough to prevent clogging, but which still retains the treated red blood cells." '096 Patent, col. 1, 35-45; '187 Patent, col. 1, 39-49. In other words, there still is no indication whether every single red cell must be retained in the filter.

SAS/Abaxis point to the use of apparently more restrictive language--"red blood-cell free"--when the inventor describes the embodiments. According to the description of the structure of the preferred embodiment, the filter "is capable of retaining red blood cells in a mixture of whole blood and salt while allowing passage therethrough of red blood cell-free liquid." '096 Patent, col. 2, 39-41; '187 Patent, col. 2, 42-44. According to the description of the assay of the preferred embodiment, "the red blood cells in the blood are retained by the filter, and the red cell-free liquid containing the component to be detected passes through the filter to the assay membrane." '096 Patent, col. 2, 66-68 & col. 3, 1; '187 Patent, col. 3, 1-4. In the example, the claim describes other embodiments, stating that it is "preferred that the red cell-free liquid be collected on a solid support. . . ." '096 Patent, col. 3, 33-34; '187 Patent, col. 3, 36-37. But the Federal Circuit has made clear that Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998). 4

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4 Even in the preferred embodiment, one skilled in the art would recognize that the chosen filter (the Gelman A/E) would not retain every single one of the red blood cells. Toone Decl. at 11.

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SAS/Abaxis also seek support for the restrictive meaning in the prosecution history. During the application process, the IDEXX inventor undertook to distinguish the already existing Fetter patent. 5 The Fetter patent described an invention for testing whole blood that used salt to get rid of the red. IDEXX's inventor distinguished Fetter by saying that Fetter's technique involved (1) chromatographic separation of colored portions of the blood through exposure to a dried salt; (2) differential migration rates for the resulting separated parts. Toone Decl., Ex. 5 at 3-4 (Freeman letter, July 3, 1989). According to the IDEXX inventor, Fetter reported that he did not completely understand the chemical/physical action of the salt, but surmised that the chromatographic separation occurred either by lysing of the red blood cells, which removed the red color from the cells in whole or in part; or by removal of the entire red cell. Id. at 3. The differential migration rate then allowed the red portion of the blood to move along the testing medium more slowly than the other portions and testing could be conducted during this separation. According to the IDEXX inventor, his invention was different from Fetter's because IDEXX's "hypertonic aqueous solution reduces red blood cell deformability sufficiently to alter passage of the red cells through a filter," so that they have "reduced ability to pass through a critically sized filter," 6 thus achieving "clean filtration" or "clean separation" as opposed to Fetter's "chromatographic separation . . . by differential migration rates." Id. at

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3-4. But this language distinguishing Fetter's differential migration process does not mean that IDEXX's filtration process holds back every single red cell. "Clean" filtration or separation need not mean 100%. Instead, in another part of the prosecution history, the inventor claimed that in his invention the filtrate contained "substantially no red blood cells." Toone Decl., Ex. 3 at 1 (Clark letter, July 11, 1989). Finally, it is apparent that the IDEXX inventor did not claim that any red blood cells that remained unaltered after application of the hypertonic solution would be stopped. Instead he distinguished Fetter on that ground as well, saying that Fetter's chromatographic medium was not "designed to pass most components (including unaltered red cells) and to retain altered components." Toone Decl., Ex. 5 at 4-5 (Freeman letter, July 3, 1989).

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5 The question on this motion is not whether Fetter is invalidating prior art, but whether statements the IDEXX inventor made in distinguishing Fetter thereby narrow the scope of IDEXX's claim.

6 Before the invention, any filter small enough to remove the red cells would quickly clog and become unusable. Toone Decl., Ex. 5 at 4 (Freeman letter, July 3, 1989).

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From the claim, the specification and the prosecution history, I conclude that retain means hold back, not merely delay, the movement of the red blood cells. But neither the term "retain" nor the references to how the Fetter patent differs from IDEXX's and its "clean" filtrate suggests that every single red cell must be removed in the filtering media; indeed, the prosecution history's reference to the filtrate having "substantially no red blood cells" negates such a conclusion. The problem the invention overcame was the clogging of filters by red blood cells. What was important was that filters could be used permitting portions of the blood with the suspect antigen to pass through the filter for testing, but holding back the redness so that the resulting filtrate could be tested by colorimetric methods or their equivalents. Science does not often presume absolutes at this level; that would require assurance that the hypertonic solution reaches every single red blood cell, that each red blood cell is affected in the same manner and that the filter is a perfect blockade.
Therefore, I conclude, retain means hold back, not merely delay, but does not require that every red cell be held back.
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C. "Retention of Nitrogen"

Read in the context of claim 1, the phrase "retention of nitrogen" does not appear to pose a great interpretive challenge to the Court. Although Plaintiffs argue that "retention of nitrogen," along with "protein sparing," should be construed to mean building lean muscle mass, the Court does not believe that such an interpretation is warranted based on the language of the claim considered in conjunction with the specification. The respective meanings of the terms "retention of nitrogen" and "protein sparing" are clear upon examination of the claim language and specification. The Court finds that a construction of these terms that reaches further to include a description of the secondary effects in the body when "retention of nitrogen" or "protein sparing" takes place is not warranted. The Federal Circuit has cautioned that a district court should not

> under the rubric of claim construction . . . give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after a court has defined the claim with whatever specificity is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact."

PPG Industries v. Guardian Industries Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998).

The language of claim 1 indicates that retention of nitrogen refers to retaining nitrogen in the body. The claim describes a method that is undertaken by administering an effective amount of HMB for increasing the "retention of nitrogen." The last clause of the claim indicates that the administration of HMB should be continued "until the amount of nitrogen in the patient's urine has substantially decreased." This indicates that determining whether retention of nitrogen has occurred is accomplished by measuring the amount of nitrogen excreted in the patient's urine.

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The specification as well offers a very clear picture of what nitrogen retention means in the context of the claims. In summarizing their invention, the inventors noted that in experiments leading to the invention, "nitrogen retention was increased [due to HMB supplementation] by an average of 18%." '979 patent, col. 2, line 66. Later in the patent document, the inventors detail the results of the experiment to which they referred in citing an increase in nitrogen retention. In that experiment, the authors reported an 18% decrease in the average amount of urine nitrogen in the subjects. '979 patent, col. 5, lines 62-64. Thus, retention of nitrogen refers to a decrease in the excretion of nitrogen from the body, as measured by the amount of nitrogen in a subject or patient's urine.
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Genentech argues on appeal that the term "ribosome binding site" in claim 1 of the '013 patent encompasses only the S-D sequence and the start site because they are the only sequences that bind the ribosome to initiate translation. Thus, according to Genentech, the RBS, and consequently the "control region" of claims 1 in the '362 and '619 patents, do not include the "non-functional" linking nucleotides that do not directly bind the ribosome. This assertion is important to Genentech's assertion of literal infringement because Amgen's plasmid regulatory region (P, O, and RBS) differs from the endogenous lambda regulatory region only in the RBS linker sequence. If "ribosome binding site" includes only the S-D sequence and the start codon, then Amgen's regulatory region is homologous to the lambda regulatory region, and is potentially derived from a single operon, as required under the district court's claim construction of "homologous" and "control region."

The specification does not explicitly define "ribosome binding site." Claim 1 of the '013 patent uses the term without explanation. The specification mentions the term once when referring to the regulatory element derived from lambda DNA. '013 patent, col. 9, ll. 2-8. Figure 5A in the '362 and '013 patents refers to the "Ribosome Protected RNA," which shows the area where the ribosome protects the RNA from degradation. This "Ribosome Protected RNA" does not necessarily equate to the RBS, however, because the ribosome may protect more RNA than is actually involved in transcription initiation, such as nucleotides close to the RBS.

The prosecution history sheds some light on the meaning of RBS. As stated in an amendment submitted by the patentee to the PTO on December 16, 1986:

Shine and Dalgarno showed that nucleotides within a ribosome binding site can form base pairs with complementary nucleotides within 16S ribosomal RNA, thereby suggesting an explanation for how ribosome binding sites participate in the initiation of translation. See for example the following publications []: [citations omitted]. These early papers, the latest of which was published almost two years before applicants' filing date, certainly demonstrate that by the time of the filing of the present application [the '362 patent, filed Nov. 5, 1979] the art was well aware of the fact that a S-D sequence was one of the necessary elements of the control region that directs the expression of structural genes.

* * * *

Both Figures [5A and 5B] clearly show the . . . AGGA . . . sequence, 8-11 nucleotides before the ATG start codon, which is the Shine-Dalgarno sequence of the lac control region. It is one of the "control elements" of the lac operon and one of the "key portion(s)" of the plasmids shown.

* * * *

The quoted section [from the section entitled "Plasmid Construction Generally"] unequivocally demonstrates the presence in the specification of an explicit teaching of the ribosome binding site, which includes the S-D sequence, as a necessary element in regulating expression.

Amendment submitted to U.S. Patent and Trademark Office, U.S. Application Serial No. 06/090,979, at 11, 14, 15 (Dec. 16, 1986) (Amendment) (emphasis added).

Thus, in the prosecution history, the inventors defined the S-D sequence as a necessary element of the ribosome binding site. Id. at 11, 14. Because the ribosome binding site "includes the S-D sequence," however, the ribosome binding site clearly includes something else. The prosecution history suggests that the ATG start site also is part of the ribosome binding

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site. As stated by the patentee during prosecution:

The thrust of [a prior art] patent is the introduction of an alleged "hybrid" ribosome binding site in which the ATG codon is brought in with the heterologous DNA rather than being present in the homologous control region. Since "ATG" is "ATG" regardless of its origins, this is a distinction without a difference.

Id. at 18. In addition to the S-D sequence, therefore, the ribosome binding site also must include at least the start codon. The start codon binds directly to the ribosome (via complementary nucleotides within the 16S ribosome RNA), and is a "necessary element[] of the control region that directs the expression of structural genes." Id. at 11.

The patent and its prosecution history, however, do not suggest whether the ribosome binding site also encompasses the linker sequence. Moreover, extrinsic evidence, such as testimony from Amgen's expert, Dr. Alexander Johnson, and Genentech's expert, Dr. Jeffrey Ravetch, does not speak directly to this issue. In his declaration submitted to the district court, Dr. Johnson states:

In bacteria, ribosomes differentiate by initially binding with specific sequences, up to six nucleotides long, located upstream from the initiation codon, and then through a complex reaction, interact with the start codon to initiate translation. Collectively, these regions of nucleotides are known as the "ribosome binding site" and include all sequences necessary to initiate translation.

Johnson Decl., P 32. Although Dr. Johnson appears to suggest that the S-D sequence and the start codon "are known as the 'ribosome binding site,'" he also asserts that the RBS "includes all sequences necessary to initiate translation." Thus, Dr. Johnson's declaration leaves open the question of whether the linker sequences might be among those necessary to initiate translation. Dr. Ravetch, on the other hand, expressly states in a declaration: "There are two components which make up the ribosome binding site: the Shine Dalgarno sequence and the initiation codon ATG. . . . A ribosome binding site is a sequence of DNA that when transcribed into RNA is capable of binding a ribosome and initiating translation." Ravetch Decl., P 9.

In sum, the entire record -- both intrinsic and extrinsic evidence of claim meaning -- does not establish that the linker DNA sequence is a required functional element of the RBS. To the contrary, the record adequately supports the district court's original claim construction of "RBS" -- "a DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome, and is thus required for the initiation of translation." Order at 50. The record shows that Judge Alsup's later interpretation of Judge Smith's claim construction order (requiring the RBS to include the linker DNA sequence between the S-D sequence and the start codon) is incorrect. Amended Summary Judgment Order at 13.

While Judge Smith's construction correctly specifies that the ribosome binding site, when transcribed into mRNA, is bound by the ribosome and is required for translation, it may unintentionally suggest that a sequence that is necessary but not sufficient for the initiation of translation satisfies this claim limitation. Such an interpretation would include within the ambit of a ribosome binding site a single base pair that is bound by the ribosome and is necessary for the initiation of translation, irrespective of whether that base pair alone (along with the promoter and operator) can perform the desired function of initiating translation. Judge Smith doubtlessly did not intend such a result. Therefore this court clarifies Judge Smith's interpretation. The claim term "ribosome binding site" is properly construed according to its function of being bound by the ribosome and initiating translation, irrespective of whether, as a general proposition outside of this context, the linker DNA between the Shine-Dalgarno site and ATG start codon is included within the scope of the claim term. This court therefore adopts Judge Smith's original construction of "ribosome binding site" with slight modification and interprets it to mean a "DNA sequence that is an irreducible constituent of the expression control region that, when transcribed into mRNA, is bound by the ribosome and is thus necessary and sufficient to initiate translation."
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I.

Brassica contends that the district court erroneously construed the claims by failing to treat the preamble of claim 1 of the '895 patent as a limitation of the claims. In addition, Brassica argues that the district court failed to construe the limitations

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"rich in glucosinolates" (appearing in claims 1 and 9 of the '895 patent) and "high Phase 2 enzyme-inducing potential" (appearing in claim 1 of the '567 patent and claims 1 and 16 of the '505 patent).

No litmus test defines when a preamble limits claim scope. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257, 9 U.S.P.Q.2D (BNA) 1962, 1966 (Fed. Cir. 1989). Whether to treat a preamble as a limitation is a determination "resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Id.; Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 U.S.P.Q.2D (BNA) 1781, 1785 (Fed. Cir. 2002). In general, a preamble limits the claimed invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Catalina Mktg., 289 F.3d at 808, 62 U.S.P.Q.2D (BNA) at 1784 (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 U.S.P.Q.2D (BNA) 1161, 1165 (Fed. Cir. 1999)). Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention. Catalina Mktg., 289 F.3d at 808, 62 U.S.P.Q.2D (BNA) at 1785; Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 U.S.P.Q.2D (BNA) 1508, 1513 (Fed. Cir. 2001).

In this case, both the specification and prosecution history indicate that the phrase "rich in glucosinolates" helps to define the claimed invention and is, therefore, a limitation of claim 1 of the '895 patent. The specification, for example, states that "this invention relates to the production and consumption of foods which are rich in cancer chemoprotective compounds." '895 patent, col. 1, ll. 18-19. A stated object of the invention is "to provide food products and food additives that are rich in cancer chemoprotective compounds." Id. at col. 2, ll. 38-39. The specification therefore indicates that the inventors believed their invention to be making food products that are rich in chemoprotective compounds, or, in other words, food products "rich in glucosinolates."

1 In addition, during reexamination 2 of the '895 patent the patentee argued as follows:

Claim 1 of the patent, for example, is directed to "[a] method of preparing a food product rich in glucosinolates, . . . and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts." . . . Although "rich in glucosinolates" is recited in the preamble of the claim, the pertinent case law holds that the preamble is given weight if it breathes life and meaning into the claim. . . . Accordingly, the cited prior art does not anticipate the claims because it does not explicitly teach a method of preparing a food product comprising cruciferous sprouts that are rich in glucosinolates or contain high levels of Phase 2 inducer activity.

This language shows a clear reliance by the patentee on the preamble to persuade the Patent Office that the claimed invention is not anticipated by the prior art. As such, the preamble is a limitation of the claims. See Bristol-Myers Squibb, 246 F.3d at 1375, 58 U.S.P.Q.2D (BNA) at 1513.

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1 Phase 2 enzymes are part of the human body's mechanism for detoxifying potential carcinogens. These enzymes therefore have a chemoprotective effect against cancer. According to the '895 patent, "most of the [Phase 2 enzyme] inducer potential of crucifer plants is due to their content of isothiocyanates and their biogenic precursors, glucosinolates." '895 patent, col. 8, ll. 14-16.

2 On December 6, 1999, the Patent Office granted a request for reexamination of the '895 patent. Claims 1-6 and 9-13 were rejected as anticipated by or obvious in light of many of the same prior art references relied on by the defendants in this case. After considering the patentee's arguments and declarations in support of patentability, the Patent Office issued a reexamination certificate and gave the following examiner's statement of reasons for patentability: "a method of preparing a food product wherein cruciferous sprouts, with the exception of cabbage, cress, mustard, and radish sprouts, that are rich in glucosinolates or contain high levels of phase 2 inducer activity are harvested prior to the 2-leaf stage is not taught or fairly suggested by the prior art or any combination thereof."

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Brassica also asks this court to construe the phrases "rich in glucosinolates" and "high Phase 2 enzyme-inducing potential" to require "at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential at 3-days following

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incubation under conditions in which cruciferous seeds germinate and grow." '895 patent, col. 7, ll. 47-53.

"The words of a claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor." Carroll Touch, Inc. v. Electro Mech. Sys., Inc., 15 F.3d 1573, 1577, 27 U.S.P.Q.2D (BNA) 1836, 1840 (Fed. Cir. 1993). However, "limitations appearing in the specification will not be read into claims, and . . . interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'" Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053, 12 U.S.P.Q.2D (BNA) 1474, 1476 (Fed. Cir. 1989). Brassica's proposed construction violates this rule by improperly importing limitations from the specification into the claims. True, the specification states that "suitable sprouts will have at least 200,000 units per gram of fresh weight of Phase 2 enzyme-inducing potential following 3-days incubation of seeds under conditions in which the seeds germinate and grow." '895 patent, col. 10, l. 66 - col. 11, l. 2. The specification does not, however, indicate that the phrases "rich in glucosinolates" or "high in Phase 2 enzyme-inducing potential" are limited to these precise conditions. Rather, the specification uses the term "high" in its ordinary, comparative sense to mean "not low". For example, the specification states that "the cruciferous sprouts of the instant invention have higher Phase 2 enzyme-inducer potential than market stage plants," id. at col. 14, ll. 5-7, and the "Phase 2 enzyme-inducing potential of such sprouts may be as much as several hundred times higher than that observed in adult, market stage vegetables obtained from the same seeds," id. at col. 8, ll. 6-9; see also Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1332, 59 U.S.P.Q.2D (BNA) 1676, 1680 (Fed. Cir. 2001) (construing the term "small volume" based in part on the specification's use of the phrase in its general sense to mean "not large"). Likewise, the term "rich" is not specifically defined or limited by the specification, but instead is used in its ordinary, relative sense. See, e.g., id. at col. 11, ll. 15-17 ("Mature Brussels sprouts and rapeseed are rich in these undesirable glucosinolates."); col. 11, ll. 37-39 ("Seeds, as well as sprouts have been found to be extremely rich in inducer potential.").

Brassica's proposed construction is also inconsistent with the language of the dependent claims. Claim 19 of the '567 patent recites: "The method according to claim 1, wherein said seeds produce cruciferous sprouts containing at least 200,000 units per gram fresh weight of Phase 2 enzyme-inducing potential measured after 3-days of growth." '567 patent, col. 22, ll. 62-65. Brassica's proposed construction would render this claim meaningless. See Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187, 48 U.S.P.Q.2D (BNA) 1001, 1005-06 (Fed. Cir. 1998) (finding a violation of the doctrine of claim differentiation when a proposed construction would render another claim superfluous). We therefore reject Brassica's proposed claim construction for the phrases "rich in glucosinolates" and "high in Phase 2 enzyme-inducing potential."
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4. "Ring-stabilizing amount" (all asserted claims) -- means that the amount of soluble metal nitrate salt is sufficient to stabilize the 3-isothiazolone and deter decomposition. See Joint Markman Hearing Statement, at 29.

Defendants' view -- an amount of metal nitrate sufficient to inhibit opening of the 3-isothiazolone ring, see Joint Markman Hearing Statement, at 30 -- is similar. Their argument is that this claim term is indefinite because the amount of metal nitrate salt is not specified. See Tr. at 86, Apr. 7, 1997. The rebuttal is found in prior art: "Of course, the amount of metal nitrate or nitrite needed to stabilize the solution will be partly dependent on the solvent, the isothiazolone and its concentration, the nitrate or nitrite used, the length of time the solution is to be kept, and other related factors." 795 patent, at 3:33-38; 878 patent, at 3:39-44; see also supra note 4. To the extent that this may be a vagueness invalidity issue, 35 U.S.C. § 112-P 2, it is inappropriate in a Markman proceeding. See Intervet Am. v. Kee-vet Laboratories, 887 F.2d 1050, 1053 (Fed. Cir. 1989).
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1. The parties at bar argue that the phrase "ripe human growth hormone" requires a protein having the same amino acid sequence as hGH produced by the pituitary gland. (D.I. 202 at 5) Plaintiffs argue that the phrase also requires that the hGH be biologically active and substantially pure. In response, defendants assert that neither the intrinsic nor extrinsic evidence imposes either of the latter two limitations.

2. Claim construction is question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en

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banc).

3. In interpreting the claims, a court should begin with the intrinsic evidence of record (i.e., the patent itself, including the claims, the specification, and the prosecution history). Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Id.

4. First, a court should look to words of the claims themselves to define the scope of the patented invention. Id. There is a heavy presumption that the claim terms carry their ordinary and customary meanings as would be understood by one of ordinary skill in the art. Markman, 52 F.3d at 986. Put differently, the court must determine how a person of experience in the field of this invention would, upon reading the patent documents, understand the words used to define the invention. Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Dictionaries and scientific treatises may help to supply the pertinent context and usage for claim construction. Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201, 1202 (Fed. Cir. 2002).

5. Second, because a patentee may choose to be his own lexicographer and use a term in a manner either more or less expansive than its general usage in the relevant art, the court also should review the specification to determine whether an inventor has used any term in a manner other than its ordinary meaning. Vitronics, 90 F.3d at 1582. The specification may act as a dictionary when it either expressly defines terms used in the claims or when it defines terms by implication. Id.

6. Third, a court may consider the prosecution history of a patent, if in evidence. Id. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id. (quoting Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)). That is, a court must look to the prosecution history to determine if the patentee has limited the scope of the claims by disclaiming a particular interpretation during prosecution. Biodex Corp. v. Loredan Biomed, Inc., 946 F.2d 850, 862 (Fed. Cir. 1991).

7. Additionally, if the meaning of a term is not clear from the intrinsic evidence, then a court may consult extrinsic evidence, such as expert testimony, in construing claim terms as they would be understood in the relevant art. Markman, 52 F.3d at 980-81.

8. When construing the claims, courts must take great care to avoid importing unnecessary limitations into the claims from the specification. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003). "If we once begin to include elements not mentioned in the claim in order to limit such claim . . . we should never know where to stop." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (quoting McCarty v. Lehigh Val. R.R., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240, 1895 Dec. Comm'r Pat. 721 (1895)). Nevertheless, a court should look to the specification to determine whether it refers to a limitation only as a part of less than all possible embodiments or whether it suggests that the very character of the invention requires the limitation be a part of every embodiment. It is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002). On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1345 (Fed. Cir. 2001).

9. After reviewing the language of claim 1 (i.e., biosynthetic ripe human growth hormone free of contaminants from pituitary derived human growth hormone) in accordance with the above principles of claim construction, the court construes this claim to mean a protein produced by recombinant DNA techniques composed of a 191 amino acid sequence identical to that of hGH produced by the human pituitary gland with the full biological activity of hGH produced by the human pituitary gland, and free of the contaminants present in hGH produced by the human pituitary gland.

10. One of skill in the art at the time the '352 patent application was filed would have understood the term "biosynthetic" to mean that the human growth hormone must be made by recombinant DNA techniques, consistent with its ordinary meaning.

11. In contrast, the term "ripe" did not have a widely-understood meaning to those of skill in the art at the time the '352 patent application was filed. The court, consequently, turns to the intrinsic evidence to ascertain the meaning of this term.

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12. The specification implies that the term "ripe" refers to hGH with an amino acid sequence identical to that of hGH produced by the human pituitary gland. The specification states: "However, this known process results in hGH whose N terminus has attached to it the amino acid methionine which is not present in ripe hGH." (352 patent, col. 1 at ll. 23-25) In so contrasting the hGH produced by the "known process" with "ripe hGH," the specification suggests that "ripe hGH" consists only of the 191 amino acid residues present in the hGH produced by the human pituitary gland and does not have any additional amino acid residues (e.g., methionine) attached to its N-terminus. Similarly, the specification also refers to ripe hGH as "ripe hGH, i.e. with a correct amino acid sequence." ('352 patent, col. 1 at ll. 47) This language virtually defines "ripe hGH" to mean hGH having the same amino acid sequence as the hGH produced by the human pituitary gland.

13. The prosecution history of the '352 patent supports this definition for the term "ripe." In four instances, plaintiffs argued that "ripe" hGH was human growth hormone of 191 amino acids having the identical amino acid sequence to human growth hormone produced from the pituitary gland. The PTO examiner also adopted this meaning and referred to it in deciding plaintiffs' request for reexamination of the '352 patent. The Board likewise used this definition in characterizing the technology in dispute during the interference proceeding.

14. Besides imparting a sequence identity limitation, the term "ripe" also relates to the biological activity of the claimed product. If the claimed hGH has the same amino acid sequence as the hGH produced by the human pituitary gland, the court reasons that it implicitly has the same biological activity as hGH produced by the human pituitary gland.

15. The specification supports this interpretation. In all examples, the tibia test results show that the hGH product is equipotent with the hGH produced by the human pituitary gland.

16. The prosecution history also affirms this construction. During the interference proceeding, plaintiffs claimed as a fact and defendants agreed that the biosynthetically-produced ripe hGH has the full biological activity of pituitary-derived hGH. The Board also described the invention of the '352 patent as having the same biological activity as hGH secreted by the pituitary gland.

17. Contrary to plaintiffs' argument, the term "ripe" does not impart a purity limitation. First, if the term "ripe" meant "substantially pure" as suggested by plaintiffs, there would be no need for the language "free of contaminants from pituitary derived human growth hormone" because, by definition, "ripe hGH" would not be contaminated in any way.

18. Additionally, in submitting dependent claims 5, 6, and 7 via preliminary amendment during the prosecution of the '352 patent, plaintiffs attempted to narrow the scope of claim 4, which is identical in scope to claim 1 of the '352 patent, by way of various purity limitations. The juxtaposition of independent claim 4 without any reference to a purity with dependent claims 5, 6, and 7 that add a purity limitation suggests that independent claim 4 was not intended to contain a purity limitation. Indeed, the Federal Circuit has stated that the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim. See Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001) ("Claim differentiation . . . is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims."); see also Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302-03 (Fed. Cir. 2003) (the presumption that an independent claim does not have a limitation that is introduced for the first time in a dependent claim "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim."). Given this presumption and the absence of evidence to rebut it, claim 1 of the '352 patent cannot be construed as having a purity limitation.

19. Furthermore, in attempting to amend claim 1 of the '352 patent to include a 99% purity limitation and add a new claim 3 to recite a "sufficient purity to be administrable to humans" limitation during reexamination, plaintiffs established that the term "ripe" does not implicate a purity limitation. If it did, then both the proposed amendment and the new claim would have been unnecessary and redundant.

20. Lastly, the court is not persuaded that construing the term "ripe" as having a purity limitation is required based upon the purity disclosure contained within the examples and the abstract. The court finds that these discussions of purity are directed to the "free from hGH contaminants" limitation already expressly recited in claim 1. Indeed, the abstract nearly mirrors the language of claim 1 stating "hGH without content of Met-hGH may be produced by the process." ('352 patent, abstract)

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Accordingly, the court concludes that it would be improper to construe the term "ripe" as imparting a purity limitation.
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C.

Clontech challenges the district court's claim construction, defining claims 3, 4, 12, and 13 by reference to gel assay results. Instead, Clontech argues, under a proper construction each claim must be limited to the results of a solubilization assay. We disagree.

Claim construction requires the court to determine the meaning of disputed claim terms to one of ordinary skill in the art at the time of the invention. See 35 U.S.C. § 112; Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc); Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1360 (Fed. Cir. 2004); Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1332 (Fed. Cir. 2001). The court determines this meaning by examining the claim language, as it relates to the invention set forth in the written description, the drawings, and where relevant the prosecution history. See Phillips, 415 F.3d at 1313-17; Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

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The court necessarily begins with the language of the asserted claims. See Phillips, 415 F.3d at 1312; Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp., 55 F.3d 615, 619-20 (Fed. Cir. 1995). Clontech does not challenge the trial court's conclusion that "no detectable RNase H activity" and "lacks RNase H activity" mean "a complete absence of RNase H activity" to one of skill in the art. Although Invitrogen suggests, inter alia, that "no detectable" and "lacks" might have different meanings, Invitrogen does not provide any cogent argument explaining why there is error in this trial court ruling. Thus, notwithstanding the presumption that "no detectable" in claim 3 and "lacks" in claim 4 have different scopes, see Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998), we take the parties as conceding claims 3 and 4 both mean "a complete absence of RNase H activity."

Focusing on the terms "no detectable" and "lacks," neither can be understood without reference to the written description because each limitation begs the question of how one of skill in the art would understand the patent specification as describing how to measure RNase H activity for claims 3 and 4. See Phillips, 415 F.3d at 1332. Although the '608 patent specification does not expressly define either term, it unmistakably teaches how one skilled in the art would determine that a mutant RT "completely lacks" RNase H activity. See '608 patent, col. 16, ll. 33-49.

The specification explains that "to confirm" that a claimed mutant RT "completely lacked" RNase H activity, the inventors undertook a specific gel assay. The specification describes the assay in detail, and provides the results in Fig. 5. Id., ll. 33-45. Fig. 5 compares the RNase H activity of the mutant RT (Fig. 5A) to unaltered MMLV RT (Fig. 5B). n20 The written description further notes that, "in addition," the same mutant RT showed no RNase H activity under a solubilization assay. Id., col. 16, ll. 45-49. With this primacy placed on the gel assay results, the patent unmistakably instructs one skilled in the art to measure RNase H activity, for purposes of claims 3 and 4, by using a gel assay. This establishes the gel assay as being both necessary and sufficient to measure RNase H activity for claims 3 and 4.

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n20 See '608 patent, col. 12, ll. 50-60 (describing pRT601 as encoding MMLV RT); id., col. 15, l. 29 - col. 16, l. 32 (describing creation of deletion plasmid pRTdEcoRV-C from pRT601); id., col. 16, ll. 33-45 (explaining comparison, shown in Fig. 5, of RNase H activity from mutated RT and wild RT).

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Although the written description might teach a different mix of gel assay and solubilization results as sufficient to show different levels of RNase H activity, as explained above the parties concede that the claims speak only to a "complete absence" of such activity. This points the court directly to the passage discussed above, and establishes the gel assay as determinative of the claimed behavior.

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For the same reasons, the specification even more strongly indicates that the gel assay is the proper means for determining compliance with claims 12 and 13, each of which expressly references Fig. 5 in the patent and points the person of skill in the art to this discussion in the specification. n21 Clontech's contrary reading simply cannot be squared with either the plain language of claims 12 or 13, or the relevant portions of the '608 patent specification.

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N21 In its opening brief to this court, Clontech did not set forth a separate argument for reading claims 12 or 13 to require a solubilization assay, to the exclusion of a gel assay. Instead, Clontech lumps claims 12 and 13 into the argument discussed above with regard to claims 3 and 4. In its reply, Clontech raises a new argument in support of its contention that a gel assay was foreclosed by the stipulated definition of "substantially no RNase H activity."

This reply argument renews Clontech's earlier argument to the Special Master, with specific reference to claims 12 and 13. Invitrogen did not seek permission to file a supplemental brief responding to this new contention, and the issue was not reached at oral argument. Nevertheless, we view this belated argument by Clontech as improper and do not consider it. See Novosteel SA v. United States, 284 F.3d 1261, 1274 (Fed. Cir. 2002) (litigant waives argument not presented in opening brief). Clontech waived this argument by failing to raise it in its opening brief on the cross-appeal.

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Clontech's arguments to the contrary are without merit. Clontech attempts to link the meaning of "no detectable" and "lacks" to the stipulated definition of "substantially no RNase H activity". n22 Clontech argues that these terms must mean less RNase H activity than the amount satisfying the stipulated definition of "substantially no RNase H activity" in the '797 and '005 patents. We disagree.

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n22 On June 22, 1999, the district court signed a stipulated order, defining an RT with "substantially no RNase H activity" as

a reverse transcriptase purified to near homogeneity and having an RNase H activity of less than 0.001 pmoles [3 H](A)n solubilized in 20 minutes per g protein in a reaction volume of 50 l wherein the [3 H](A)n is solubilized from a [3 H](A)n . (dT)n substrate in which the [3 H](A)n has a specific radioactivity of 2,200 cpm/pmole.

Life Techs., Inc. v. Clontech Labs., Inc., slip op., No. AW-96-4080 (D. Md. June 22, 1999) (stipulation and order). The parties agree that by its terms, testing RT RNase H activity against this stipulated definition requires using a solubilization assay.

This stipulated definition corresponds, not surprisingly, verbatim to the definition of "substantially no RNase H activity" in the common written description of the patents-in-suit. See, e. g., '608 patent, col. 9, ll. 21-26.

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First, Clontech points to the '608 patent prosecution history. The court examines the prosecution history, when pointed out and placed in evidence, to ascertain if a proffered claim construction has been disclaimed. See 415 F.3d 1303, 1317; 415 F.3d 1278, 1286-87; Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term ...in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history."); Vitronics, 90 F.3d at 1582. Clontech argues that claim 1 of the '608 patent (and thus the dependent claims 3 and 4), as originally filed, required "substantially no" instead of "substantially reduced" RNase H activity. But as Clontech further notes, Invitrogen canceled those originally-filed claims and added new claims drawn to the "substantially reduced RNase H activity" limitation in the issued claim 1. Indeed, as Invitrogen observes, it canceled those original limitations by preliminary amendment with its continuation application, meaning the "substantially no RNase H activity" limitation was never presented to the PTO for examination as part of the '608 patent. Nonetheless, because Invitrogen sought, in the prosecution, to distinguish prior art having "reduced" RNase H activity, Clontech concludes

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"substantially reduced" must mean less RNase H activity than the failed "substantially no" limitation in the original claim.

To the extent that this represents a prosecution disclaimer or prosecution history estoppel argument, it falters on the principle that the prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application. See ResQNet. com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1383 (Fed. Cir. 2003); Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1322 (Fed. Cir. 1999); cf. Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1141 (Fed. Cir. 2003) ("When an applicant is seeking different claims in a divisional application, estoppel generally does not arise from the prosecution of the parent."). Although the court recognizes an exception where an amendment to a related limitation in the parent application distinguishes prior art and thereby specifically disclaims a later (though differently worded) limitation in the continuation application, see, e. g., Elkay Mfg. Co. v. EBCO Mfg. Co., 192 F.3d 973, 978-79 (Fed. Cir. 1999), Clontech nowhere explains how that exception would apply in this case. Nor does Clontech explain how any prior art distinguished in the '797, '005, or '608 patent prosecutions operates to disclaim use of a gel assay to show "complete absence" of RNase H activity in claims 3 and 4 of the '608 patent. The prosecution history presented to the court does not impose such a limitation. The fact that the parties stipulated to a definition of "substantially no RNase H activity," drawn verbatim from the wording of an express definition in the written description, does not mandate that the different limitations at issue here be given the same construction. To the contrary, the use of the distinct terms "substantially reduced" and "no detectable" and "lacks" canonically suggests that these limitations be given a different scope than the limitation to which the parties stipulated. See Comark, 156 F.3d at 1187.

Second, Clontech argues that the district court's "complete absence" definition, by its plain meaning, requires construing claims 3 and 4 consistent with the stipulated definition of "substantially no RNase H activity" in the '797 and '005 patents. Nothing in the notion of "complete absence of RNase H activity" in the '608 patent requires consideration in view of the "substantially no RNase H activity" limitation set forth in the '797 and '005 patents and defined by the stipulated order. Nor is it proper to read provisions in the '608 patent written description, pertaining to the "substantially no RNase H activity" limitation in the parent applications, into the meaning of claims 3 and 4 in the '608 patent. See id., 156 F.3d at 1186-87 (discussing the prohibition against reading limitations from the specification into the claims). These are not, as Clontech presupposes, isolated terms with abstract meanings amenable to easy comparison such as by referencing a thesaurus; rather, these are claim terms with defined meanings rooted in the particular context of different patents and patent claims.

Thus, the court finds no error in the district court's analysis, under which the complete absence of RNase H activity for claims 3, 4, 12, and 13 must be shown by the gel assay as set forth in the written description of the '608 patent.
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"At Room Temperature"

Plaintiffs assert that the term "at room temperature" does not require construction, or, alternatively, that it means "an ambient temperature of between 20 to 25[degrees]C (68 to 77[degrees]F)." Defendants propose that we read the term "at room temperature" to mean "the junction is about 72[degrees]F (295 K 9)." Neither the claims nor the specification provides a specific definition for the term "at room temperature." However, some insight can be gleanedfrom the patent's description of the prior art.

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9 The symbol "K" stands for "Kelvin." Named in honor of Lord Kelvin, it is "the basic scale used for temperature definition." McGraw Hill Dictionary of Scientific and Technical Terms 1147 (6th ed. 2003). Kelvin is converted to Celsius by the formula C = K - 273.15. Id. at 352. Celsius can then be converted to Fahrenheit by the formula F = (C x 9/5) + 32. Id. at 774.

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The Background section discusses the changes in resistance achieved by researchers using FM-I-FM tunnel junction devices 10 similar to the present invention. It states that "in most of these cases, the change in the tunnel resistance [DELTA]R/R was 2-6% at 4.2 K, and only fractions of a percent at room temperature." '922 patent at 1:62-64. This means that in some

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cases the researchers actively manipulated the temperature of the device to achieve extremely cold conditions, whereas in other cases the temperature of the device was not intentionally cooled but rather was allowed to remain consistent with the ambient environment in which it was tested. Although prior researchers were able to achieve only "fractions of a percent" of resistance change at room temperatures, the patenthere proclaims that "[i]n the present invention, some of the problems leading to low values of resistance change ([DELTA]R/R) in spin-polarized tunneling of FM-I-FM trilayer have been solved." Id. at 2:44-46.

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10 A FM-I-FM tunnel junction is defined as a three layer system consisting of a ferromagnet electrode, an insulator, and a second ferromagnet electrode. '922 patent at 1:20-24.

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With this context in mind, we find that a person of ordinary skill in the art at the time of the invention would understand that a device which causes a change in resistance of at least 10% "at room temperature" is a device capable of achieving such resistance without actively manipulating the temperature of the device, that is, that the device is capable of achieving a 10% change in resistance while operating within a room-temperature environment.

As for the exact range of temperatures which can be considered "room temperature," we again turn to the intrinsic evidence provided in the specification. In column 5, lines 23-49, the patent discusses a number of tests in which the resistance generated by a device embodying the invention was measured at various temperatures: 295 K (71.6[degrees]F), 77 K (-320.8[degrees]F),and 4.2 K (-451.84[degrees]F). It reports that "[t]he change in the junction resistance with respect to the absolute value at the peak, [DELTA]R/R, for this junction is 10.6% at 295 K [71.6[degrees]F]. In several tens of junctions, over a 10% effect has been consistently observed at room temperature …." Id. at 5:32-36 (emphasis added). This suggests that when the device was tested under "room temperature" conditions, it was tested in an environment which was approximately 72[degrees]F. By contrast, the specification reports that "[i]n general, a percentage change of junction resistance nearly doubled at 77 K compared to a value taken at 295 K. A further increase in resistive change occurred upon cooling the junction to 4.2 K …." Id. at 5:39-42; Fig. 4. This description clarifies that resistance measurements taken at "room temperature" are in contrast to those taken under conditions in which the device is actively cooled to cryogenic temperatures.

Accordingly, we believe the ordinary meaning of "room temperature" to a person skilled in the art would be understood as an ambient temperature of approximately 72[degrees]F. However, because the term "room temperature" as used within the contextof the patent is placed in contrast to extremely cold conditions exceeding -450[degrees]F, some reasonable deviation up or down from 72[degrees]F would still fall within the scope of the claim. 11 Unlike some of the other claim terms under dispute, we believe a jury is capable of grasping the concept of "room temperature" to include a reasonable deviation up or down from 72[degrees]F.

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11 For example, there was discussion during the Markman hearing that the heat generated in the process of applying a small magnitude of electromagnetic force to a junction, along with the other motions and frictions inherent in the normal operation of a computer hard drive (an anticipated application of the invention), would cause the device to experience a relatively minor increase in temperature. Such a change in temperature would not be beyond the scope of the claims.

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Step A -- "room temperature"

(1) Claim construction

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A patent claim is to be construed as it would be understood by a person of ordinary skill in the art at the time of the invention. Markman I, 52 F.3d 967 at 986. The construing court must look first to "intrinsic evidence," Vitronics Corp. v. Conceptronic Inc., 90
F.3d 1576, 1584 (Fed. Cir. 1996) comprising the specification, claims, drawings, and file history, Markman I, 52 F.3d at 979. "Extrinsic evidence" should not be used unless intrinsic evidence alone is insufficient to resolve ambiguity, and is to be used in any event only to assist the trial court's understanding of the patent, and not to vary or contradict the terms of the claims. Vitronics, 90 F.3d at 1583-1584.

The '179 patent does not explicitly define the term "room temperature." AMI asserts on the basis of a dictionary definition that "room temperature" is a technical term with a precise meaning of 20 [degrees] - 25 [degrees] C (68 [degrees] - 77 [degrees] F). Pltf. Mot. at 17-18, Tr. at 20. Clement asserts on the basis of an expert's declaration that "room temperature" is "approximately . . . the range of temperatures found in a pulping room but below the melting point of the 'stickies'." 1 Def. Opp'n. at 39; Forester Decl. at P10.

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1 Stickies are non-ink contaminants that have low melting points, such as binders and plastics. Kamyr I, 952 F. Supp. 12 at 13 n.2.

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The specification, claims, drawings and file history of the '179 patent contain no probative intrinsic evidence as to the meaning of "room temperature." It is true, as Clement asserts, that the claim specification does not specify a hard numerical range, instructing only that pulping be accomplished at temperatures below the melting point of the non-ink contaminants. But Clement has cited no doctrine providing that a claim limitation is to be construed by the broadest terms in its specifications.

Nor does the prosecution history support Clement's argument that "room temperature" should be construed to include temperatures as high as 45 [degrees] C (113 [degrees] F). 2 The argument is that (a) during the prosecution of the '179 patent, Clement described Ortner's process as performing at room temperature; (b) there is evidence that Ortner's process operates at 45 [degrees] C (113 [degrees] F); and therefore (c) "room temperature" includes 45 [degrees] C (113 [degrees] F). Def. Opp'n. at 41; Tr. at 49-50 (Citing Ex. 2-64, 2-112). That syllogism, of course, is faulty. Clement was attempting to distinguish his process from Ortner. See text accompanying note 3, infra. Moreover, he does not allege that his description of Ortner's process was accepted or even considered by an examiner or a court. His characterization of a process of prior art as occurring at "room temperature" cannot be allowed to define the term.

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2 Prosecution history is evaluated twice during the infringement analysis. During the claim construction stage, the prosecution history is evaluated to see if the prosecution history indicates how ambiguous terms were meant to be used, Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995), although at this stage its use is limited to "excluding any interpretation that was disclaimed during prosecution." Id., at 1576. Once the claim has been construed, prosecution history is again evaluated to consider whether and how the range of equivalents has been limited. Id. at 1578.

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The extrinsic evidence is not powerful either. The only expert testimony is the declaration of Mr. Forester. The court has broad discretion to use expert testimony, Markman I, 52 F.3d at 983, but may not use it to contradict or vary terms that have been unambiguously defined by the intrinsic evidence. Id. at 981. Mr. Forester's declaration does not establish the ordinary meaning of the term "room temperature" to one skilled in the art. See Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996). Indeed, Mr. Forester states that he is not aware of any "specific technical meaning in the pulping and paper industry." His own view that the term means the temperature of the room in which pulping or de-inking occurs, Forester Decl. at P10, is not persuasive. See Southwall Tech. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1577 (Fed. Cir. 1995).

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Dictionary definitions are usually considered "extrinsic evidence"; judges may rely on them when construing claim terms, "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics, 90 F.3d at 1584 n.6; see also, Universal Oil Products Co. v. Globe Oil & Refining Co., 40 F. Supp. 575, 582 (N.D. Ill. 1941). AMI's dictionary definition is the best of the weak evidence in this record as to the meaning of "room temperature." Clement asserts that AMI's citation to a chemical dictionary is inappropriate because the '179 patent is industrial rather than chemical, Def. Opp'n. at 40; Tr. at 46, but Clement presents no alternative dictionary definition (industrial or otherwise) that more suitably interprets the '179 patent.

The term "room temperature" is construed to mean 20 [degrees] - 25 [degrees] C (68 [degrees] - 77 [degrees] F).
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3. Claim Nine

Claim 9, clause 2 reads as follows: "wherein said gripping structures comprise elongate rubber members having transverse grooves formed therein to facilitate manual handling of said calculator."

The parties dispute whether the term "rubber" refers to natural rubber or includes synthetic rubber. There is no clear intrinsic evidence to aid in this determination. Similarly, neither party has put forth any evidence on what a person skilled in the art might consider to be the ordinary construction of the word "rubber."

Webster's Third International Dictionary defines "rubber" as: "a: a substance that is obtained from the latex of many tropical plants… b: Any various rubber-like substances that like natural rubber can be vulcanized. c: natural or synthetic rubber that has been modified to increase its useful properties[.]"

Because in common parlance rubber includes not only natural rubber but also various forms of synthetic rubber-like substances, we construe the term "rubber" to mean the elastic substance derived from tropical plants and any of various similar synthetic substances.
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a. Optical Activity Limitation

The Court has already concluded that "S(-)" in the claims indicates that the claimed substance is the levorotatory enantiomer. The S describes the configuration in space. The parties dispute whether the (-) in the claim language limits the claim. The Court must, therefore, determine how one of ordinary skill in the art would read the (-). Dr. Klibanov testified that the (-) indicates that the compound is "optically active," i.e., it will rotate a plane of polarized light counterclockwise. (Klibanov Tr. at 1881.) Dr. Mitscher neither disputed nor conceded that actual optical activity was required to merit the S(-) designation, but admitted that each molecule of S(-) will contribute to the optical activity of a solution of S(-) molecules. (Mitscher Tr. at 6117.) n10

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n10 Mylan accuses Daiichi/Ortho of "asking the Court to impermissibly inject" the "optically active" limitation into the claims. The (-), however, is contained within the claim. The specification confirms that the claim is referring to an optically active compound by specifically employing that language; to find otherwise would be to refuse to give full effect to the language of the claim.

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Because the parties dispute the significance of the S(-), the Court must consult a dictionary. See International Union of Pure and Applied Chemistry ("IUPAC"), Basic Terminology of Stereochemistry (IUPAC Recommendations 1996), at

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http://www.chem.qmul.ac.uk/iupac/stereo/NQ.html. n11 IUPAC, one of the principal authorities on stereochemistry, defines "optical activity" as follows:

Optical Activity
A sample of material able to rotate the plane of polarization of a beam of transmitted plane-polarized light is said to possess optical activity (or to be optically active). This optical rotation is the classical distinguishing characteristic (sufficient but not necessary) of systems containing unequal amounts of corresponding enantiomers. An enantiomer causing rotation in a clockwise direction (when viewed in the direction facing the oncoming light beam) under specified conditions is called dextrorotatory and its chemical name or formula is designated by the prefix (+)-; one causing rotation in the opposite sense is laevorotatory and designated by the prefix (-)-.

Id.

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n11 IUPAC is the International Union of Pure and Applied Chemistry. (Mitscher Tr. at 747.) Dr. Mitscher employed a definition from the same document during his trial testimony, relying on it as an authoritative source for the proper method of calculating optical purity. (Id.)

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This definition comports with Dr. Klibanov's testimony. According to IUPAC, "an enantiomer . . . causing rotation" in a counterclockwise direction is "laevorotatory and designated by the prefix (-)-." Thus, the (-) indicates that the claims refer to an "optically active" compound.

This reading of S(-) is confirmed by the specification. The specification repeatedly refers to the invention as "optically active." '407 patent, col. 1:6-11 ("[The] invention relates to optically active pyridobenzoxazine derivatives" and "optically active compounds of Ofloxacin and its analogs"); id. at col 1:25-26 ("The present inventors obtained optically active compounds of the racemic Ofloxacin . . . . "); id. at col. 2:29-40 ("to provide optically active Ofloxacin and its analogs"; "to provide a novel intermediate . . . useful for synthesizing optically active Ofloxacin"; "to provide a novel process for preparing optically active Ofloxacin and its analogs by the use of [that] intermediate"); id. at 2:65-67 (noting three methods for preparing "optically active Ofloxacin")). Thus, the specification accords with the meaning that a person of ordinary skill in the art would have attributed to the (-) designation.

It is undisputed that more than a single molecule is required to manifest optical activity. (Klibanov. Summ. J. at 42). Not only was Dr. Klibanov's testimony on this point unimpeached and uncontradicted, but Mylan's expert, Dr. Mitscher, also admitted that a collection of levofloxacin molecules is required to exhibit optical activity, because a "single molecule would be too small" to measure its optical rotation. (Mitscher Tr. at 991.) Thus, on their face, the claims require at least enough levofloxacin molecules to rotate polarized light.
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"(S)-(-)-1-propyl-2',6'-pipecoloxylidide hydrochloride."

65. This disputed term in claim 1 shall be construed to mean a compound with an (s)-enantiomer with an optical purity of more than 99.0%.

66. "Optical purity" is a function of how much more of one enantiomer there is than of another enantiomer. In the (S)-(-)-1-propyl-2',6'-pipecoloxylidide hydrochloride compound recited in claim 1 of the '086 Patent, the "(S)" denotes that the compound is the "S" enantiomer. The "(-)" denotes that the compound has some level of optical purity. (Atwood Testimony, 7/20/09 Tr. at 68:18-69:3; Atwood Testimony, 7/21/09 Tr. at 231:17-20.) See also Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 348 F. Supp. 2d 713, 725-26, 729 (N.D. W. Va. 2004) (where claim referred to "S(-)" enantiomer of levofloxacin but intrinsic record did not claim or identify a minimum level of optical purity, court construed claim to cover substantially optically pure levofloxacin and held that person skilled in the art would understand "S(-)" to require substantial optical

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purity).

67. A construction that "the compound" of claim 1 has an optical purity of more than 99.0% is consistent with other claims of the '086 Patent. For example, Claim 3 states that "the compound" contains "less than 0.5% by weight of the corresponding (R)-(+)-enantiomer." This indicates that greater than 99.5% of the (S)-(--) enantiomer is present, giving the compound an enantiomeric purity of greater than 99.5%. This translates into an optical purity of more than 99%.

68. The '086 patent specification indicates that the patent achieves multiple and different objectives, one being a compound that is optically pure, another being the compound in the form of its monohydrate. '086 Patent, PLT 1 at col. l, lines 32-35.

69. The '086 applicant emphasized the optical purity of the claimed compound during the prosecution history of the '086 patent. The applicant pointed out to the Patent Office Examiner that WO 085/00599 to Thuresson disclosed a compound that is "neither hydrated nor optically pure," while further noting that "the claimed compound [i.e., the (S)-enantiomer] was the only compound prepared having an optical purity of over 99.0%." (PLT 4 at p. 72; Atwood Testimony, 7/20/09 Tr. at 31:22-32:3, 78:3-6.)

70. The originally filed application for the '086 Patent describes (S)-(-)-1-propyl-0.2',6'-pipecoloxylidide hydrochloride as having an optical purity of greater than 99%. Original claim 3 stated: "Compound according to claim 1 characterized in that it contains less than 0.5% by weight of the corresponding D-enantiomer." This also translates into an enantiomeric purity of greater than 99.5% and an optical purity of greater than 99.0%. (PLT 4-0020.)
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The parties continue to dispute the proper construction of the terms "an S(-)-pyridobenzoxazine compound" and "S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2, 3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid."

An examination of the plain meaning of the claim language as understood by persons skilled in the art at the time of invention, the specification and the prosecution history indicates that "an S(-)-pyridobenzoxazine compound" and "S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid" refer to the levorotatory enantiomer of racemic ofloxacin, levofloxacin. These terms do not refer to racemic ofloxacin.

Before addressing the dispute, the Court notes that the parties agree that, to one skilled in the art, claims 2 and 5 of the '407 patent plainly refer to the "S(-)" optical isomer (enantiomer) of ofloxacin, levofloxacin.

Despite this agreement, Mylan argues that the chemical name in claims 1 and 4 needs a plain-English "purity" qualification to avoid a breadth of coverage that would include the prior art racemic ofloxacin. There are a number of problems with this position, however.

First, Mylan's argument directly conflicts with its position that the plain language of the claim refers to levofloxacin. As discussed above, chemists skilled in the art regard levorotatory enantiomers as distinct from racemic compounds or the dextrorotatory enantiomer. Additionally, each type of compound has its own unique nomenclature. "S(-)" clearly designates the levorotatory enantiomer in this case. Had the inventor meant to designate the racemic compound, he would have used the designation "(+/-)" or "RS." Even Mylan's own expert testified at his deposition that it "would be an error" to use only the (-) symbol to designate a racemic compound, (Jordis Dep. at 22), and a chemist would not use a lone "S" to designate a racemic compound. (Id. at 176.)

Mylan also asserts that In re Williams, 171 F.2d 319, 36 C.C.P.A. 756, 1949 Dec. Comm'r Pat. 42 (C.C.P.A. 1948), requires a plain-English "purity" limitation in claims for enantiomers. In Williams, the court was faced with an inventor seeking to patent an enantiomer. The claim language "call[ed] for the laevo rotary form 'substantially free from the dextro rotary form.'" Id. at 319. The Court did not construe the patent claims; indeed, aside from the preceding quotation, the claim language does not appear in the opinion at all. Thus, it is impossible to determine if the Williams court required the "substantially free" language as Mylan urges. The "substantially free" language certainly distinguishes the levorotatory enantiomer from the racemic compound. However, there is no indication that such a plain-English purity limitation is the only way to distinguish the prior art.

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The case of In re May, 574 F.2d 1082 (C.C.P.A. 1978), suggests otherwise. May, too, involved the patentability of an enantiomer. The claims at issue in that case stated:

1. A method of affecting analgesic and morphine antagonistic activity without producing physical dependence in animals which comprises administering to an animal an effective dosage of an acid addition salt of the levo isomer of a compound of the structure where R is a lower alkyl group and R 1 is hydrogen or a lower alkyl group.
2. The method of claim 1 wherein said compound is -(-)-5,9-diethyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
3. The method of claim 1 wherein said compound is (-)-5-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
4. The method of claim 1 wherein said compound is (-)-5-ethyl-2'-hydroxy-2- methyl-6,7-benzomorphan.
5. The method of claim 1 wherein said compound is -(-)-5-propyl-9-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
6. The method of claim 1 wherein said salt is the hydrochloride.
7. The method of claim 6 wherein said compound is -(-)-5,9-diethyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
8. The method of claim 6 wherein said compound is (-)-5-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
9. The method of claim 6 wherein said compound is (-)-5-ethyl-2'-hydroxy-2- methyl-6,7-benzomorphan.
10. The method of claim 6 wherein said compound is -(-)-5-propyl-9-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
11. A pharmaceutical composition for internal administration having an analgesic, non-addictive, morphine-antagonistic effect which comprises a pharmaceutical carrier and an effective amount of an acid addition salt of - (-)-5,9-diethyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
12. The composition of claim 11 wherein said salt is the hydrochloride.
13. The composition of claim 11 wherein said salt is the acetate.

Id. at 1084-85.

Claims 1 and 6 were rejected because they were specifically described in the prior art. Id. at 1089-90. The remaining claims were upheld. Notably, these claims contain no plain-English purity limitations whatsoever. Instead, they distinguish the enantiomer from the racemic compound with the symbol "(-)."

Mylan argues that the distinguishing language is not "(-)" but rather the phrase "without producing physical dependence in animals," which describes a chemical attribute unique to the levorotatory enantiomer. There are two problems with this analysis, however. First, the language emphasized by Mylan modifies the method for which claim 1 sought patent protection, not the compound through which that method was effected. The compound itself is simply described as "an acid addition salt of the levo isomer of a compound [with the following structure . . .]." Thus, the description of the compound contains no plain-English purity limitation. Most importantly, the May court stated that, under common nomenclature, a chemical compound designated as "(-)" is "limited to the levo enantiomer." 574 F.2d at 1085.

Thus, while it is certainly necessary to distinguish a new invention over the prior art, there is no indication that an inventor must use a plain-English purity limitation, as Mylan contends. Instead, an inventor may use anything that a person skilled in the relevant art would understand to limit the claim. In this case, the term "S(-)" clearly and plainly limits the claim language to the levorotatory enantiomer. Those skilled in the art clearly understand the term "S(-)" to affirmatively denote only the levorotatory enantiomer of a racemic compound, and not the racemic compound itself. Furthermore, those skilled in the art clearly understand the terms "RS" or "(+/-)" to affirmatively denote a racemic compound. The inclusion of "S(-)" in the claim language, coupled with the obvious exclusion of "RS" or "(+/-)," militates against Mylan's assertion that an additional plain-English purity limitation is necessary to distinguish the patented invention over the prior art racemic ofloxacin.

This interpretation is not contradicted by the specification or the prosecution history. Indeed, it is directly confirmed by the prosecution history. As the Court observed in its March 31, 2003, Order:

The prosecution history is replete with instances where the inventor distinguishes levofloxacin from the prior-art racemic ofloxacin. The first three claims of the '407 patent were rejected by the patent examiner twice on the grounds that they were obvious in light of the prior art disclosure of racemic ofloxacin. Daiichi presented evidence of the differences between levofloxacin and ofloxacin until the examiner approved the patent as written.
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A.

We begin with claim construction, a question of law reviewed de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). When interpreting claims, we inquire into how a person of ordinary skill in the art would have understood claim terms at the time of the invention. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

Ranbaxy contests the district court's construction of "saccharide" and "saccharides" as those terms are used in independent claims 1 and 16. According to Ranbaxy, the district court should have construed "saccharides" to mean "sugars." In Ranbaxy's view "sugars" would include polysaccharides with up to ten monosaccharide units but would not include polysaccharides, such as microcrystalline cellulose, with more than ten monosaccharide units.

The claim language itself does not support Ranbaxy's proposed construction. "The claims themselves provide substantial guidance as to the meaning of particular claim terms." Id. at 1314. Claim 1 includes "a suitable amount of a saccharide to inhibit hydrolysis," and claim 16 includes "one or more saccharides. " It is important to note that the claims do not include the terms "sugar" or "sugars." Neither do the claims distinguish between polysaccharides having ten or less monosaccharide units and polysaccharides having more than ten monosaccharide units.

Ranbaxy argues, however, that the district court erred by not adopting an explicit, narrow definition of "saccharides" set forth in the '450 patent. It points to the following language in the '450 patent: "saccharides (i.e., sugars)." '450 patent, col. 1, II. 61 - 62. This language is located in a part of the '450 patent discussing what the "invention deals with." Id. at col. 1, I. 44.

This court has previously construed a disputed claim term by referencing use of "i.e." in a patent specification. See Abbott Labs. v. Novopharm Ltd., 323 F.3d 1324, 1327, 1330 (Fed. Cir. 2003). In that case, however, the court did not identify any support in the intrinsic evidence for a construction of the disputed claim term other than the construction linked to "i.e." Id. at 1330. Indeed, the problem with Ranbaxy's argument is that it ignores the fact that the person of ordinary skill in the art is deemed to have read the claim term in the context of the entire patent. Phillips, 415 F.3d at 1313. See also SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1285 (Fed. Cir. 2005) ("The court must always read the claims in view of the full specification." (emphasis added)). "It is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent." Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1379-80 (Fed. Cir. 2001).

Notably, the '450 patent includes the following discussion in a section entitled "SACCHARIDES":

The saccharide components to be used in the pharmaceutical products and methods of the invention are substances which are compatible with the alkali or alkaline earth metal-containing stabilizers. Generally, they are substances which do not contain groups which could significantly interfere with the function of either the metal-containing component or the drug component. Mannitol, lactose, and other sugars are preferred. Mixtures are operable.

'450 patent, col. 3, II. 46-55. By using the label "SACCHARIDES," the patentee clearly intended for this section to address the meaning of the same term.

As a preliminary matter, the first two sentences of this section indicate that a broad construction of "saccharides" may be appropriate. The first sentence explains that "saccharides" are "substances which are compatible with the alkali or alkaline earth metal-containing stabilizers." Id. at col. 3, II. 49-50. The second explains that "saccharides" are "substances which do not contain groups which could significantly interfere with the function of either the metal-containing component or the drug component." Id. at col. 3, II. 51-54. Particularly when compared to the parallel section labeled "EXCIPIENTS," it is clear that these sentences do not affirmatively define what "saccharides" are, but instead negatively define what "saccharides" are not. The section addressing "excipients" similarly states that excipients are "substances which must be

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compatible with the alkali or alkaline earth metal-containing stabilizers so that it [sic] does not interfere with its [sic] function in the composition." Id. at col. 3, II. 60-65. Properly understood, then, these sections do not define the exact meaning of "saccharides" and "excipients." Nevertheless, by only indicating what substances should not be considered "saccharides" or "excipients," the patentee has left open a vast array of substances that may be considered to be "saccharides" and "excipients."

Moreover, the section labeled "SACCHARIDES" indicates that the term "saccharides" should not be limited to sugars. The third sentence in this section states that "Mannitol, lactose, and other sugars are preferred." Id. at col. 3, I. 54. Since mannitol is a sugar derivative and not a sugar, were we to accept Ranbaxy's proposed construction of "sugars," we would exclude mannitol from the scope of the '450 patent's use of "saccharides." This would be improper. "A claim construction that excludes a preferred embodiment . . . is 'rarely, if ever, correct.'" SanDisk Corp., 415 F.3d at 1285 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)).

Ranbaxy admits that mannitol is not a sugar. It nevertheless argues that the patentee labeled mannitol as a sugar, and that we should respect the patentees' decision to do so. Thus, according to Ranbaxy, "Mannitol, lactose, and other sugars are preferred" is, for the purpose of the patent, a list of like ingredients, "sugars."

We are not convinced that one of ordinary skill in the art would understand the patentee to have classified mannitol as a sugar in this sentence. As the district court found and Ranbaxy does not dispute on appeal, mannitol is not actually a sugar. On the other hand, lactose is a sugar. The reference to "other sugars" therefore appears to relate to the disclosure of lactose only. In short, the reference to "other sugars" does not mean that mannitol is a sugar or should be considered to be a sugar for purposes of the '450 patent.

Even if we concluded that Ranbaxy's reading of "Mannitol, lactose, and other sugars are preferred" is correct and that mannitol, a sugar derivative, should be considered to be a sugar for the purpose of the '450 patent, this sentence would only identify sugars as being preferred embodiments of "saccharides." We hesitate to adopt a construction of "saccharides" that would be limited to disclosed preferred embodiments. See Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 907-08 (Fed. Cir. 2005). Indeed, identifying sugars as preferred saccharides seems to indicate that there is a broader, albeit less preferred class of substances that are still "saccharides."

Extrinsic evidence in the form of technical dictionaries, treatises, and expert testimony supports the conclusion drawn from the '450 patent that one of skill in the art would understand "saccharides" to encompass more than sugars. The district court reviewed the extrinsic evidence presented by the parties and found that one of skill in the art would understand "saccharides" to include polysaccharides. Ranbaxy, however, points to specific examples of references and testimony that allegedly support its view that "saccharides" means sugars.

Based on our review of the preliminary record, we do not disagree with the district court's conclusion that a person of ordinary skill in the art would understand "saccharides" to encompass polysaccharides. The district court weighed the disclosures of the competing references and testimony and concluded that the "general view" is that the saccharides include polysaccharides. Contrary to Ranbaxy's assertions, the district court did not err by referencing dictionary definitions of "saccharides." As this court has held, judges may "'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" Phillips, 415 F.3d at 1322-23 (quoting Vitronics, 90 F.3d at 1584 n.6). And as discussed above, when read in the context of the entire '450 patent, the reference to "saccharides (i.e., sugars)" does not constitute a definition of "saccharides."

Furthermore, the district court's conclusion that the "general view" is that the group of substances called saccharides includes polysaccharides appears to be well supported. As Warner-Lambert notes, many of the references cited by Ranbaxy do not actually address the scope of the term "saccharides." Rather, they clarify that sugars and polysaccharides are both subclasses of the larger class of substances called carbohydrates. For example, one reference submitted by Ranbaxy states that "carbohydrates" include both sugars and polysaccharides. As the district court noted, however, even that reference stated that "the carbohydrates are sometimes referred to as the saccharides." Edward Staunton West et al., Textbook of Biochemistry 174 (MacMillan 4th ed. 1966) (1951).

Ranbaxy faults the district court for relying on this text in view of its use of the word "sometimes." Ranbaxy also alleges that to reach its conclusion the district court was forced to ignore the next sentence in the reference, which explains that

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"'saccharide' comes from the Greek word sakcharon, meaning sugar." Id.

We do not believe that the district court erred in its analysis. First, evidence that "saccharides" is sometimes used to refer to "carbohydrates" does support the conclusion that the '450 patent in particular may be understood to have used "saccharides" to mean "carbohydrates." Thus, reliance on this disclosure to support the district court's construction is not improper. Second, understanding the historical origin of the term "saccharides" does not exactly answer the question of how one of ordinary skill in the art would interpret the term on the filing date of the '450 patent. "The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. " Phillips, 415 F.3d at 1313. We therefore do not fault the district court for not considering the historical origin of "saccharides" to be dispositive of the term's meaning to those skilled in the art.

To support its proposed construction, Ranbaxy also points us to the construction of "saccharides" previously agreed upon by two of the parties to this case in separate litigation:

The word "saccharide" in Claims 1 and 16 of the '450 patent means "a sugar, and specifically includes only lower weight carbohydrates, specifically, mono- and disaccharides and their simple derivatives, including such substances as lactose, sucrose, mannitol and sorbitol."

Ranbaxy asks us to adopt this construction in this appeal.

Ranbaxy has not identified any legal doctrines that would compel us to adopt the stipulated construction. And to the extent Ranbaxy's argument addresses issue preclusion, we conclude that issue preclusion does not apply in this case. The district court noted that the stipulation presented to the court in the earlier litigation specifically stated that it was for the purposes of that litigation only. Bench Decision, slip op. at 13. Because Ranbaxy does not dispute this finding, issue preclusion cannot apply to this case. "The scope of a consent decree must be discerned within its four corners" and the conditions upon which a party has consented to waive its right to litigate particular issues "must be respected." United States v. Armour & Co., 402 U.S. 673, 682, 91 S. Ct. 1752, 29 L. Ed. 2d 256 (1971). See also In re Graham, 973 F.2d 1089, 1097 (3rd Cir. 1992) (noting that the Third Circuit defers to the intent of parties concerning the preclusive effect of agreed facts or claims in consent decrees and stipulations). While we do not fault Ranbaxy to the extent it may have adopted or relied upon the stipulated construction of "saccharide," that stipulation does not define the scope of the invention claimed in the '450 patent for purposes of this case.

Ranbaxy additionally contends that the district court's claim construction would render the claims invalid for lack of enablement under 35 U.S.C. § 112, P1. In Phillips, this court stated:

While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction. Instead, we have limited the maxim to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous. In such cases, we have looked to whether it is reasonable to infer that the PTO would not have issued an invalid patent, and that the ambiguity in the claim language should therefore be resolved in a manner that would preserve the patent's validity.

415 F.3d at 1327 (citations and quotation marks omitted). Both Ranbaxy and Warner-Lambert were able to find at least some extrinsic evidence supporting their proposed constructions of "saccharides." Nevertheless, Ranbaxy has not presented sufficient evidence for us reasonably to infer that, unless "saccharides" means "sugars" or at least does not encompass polysaccharides, claim 1 and 16 would have been considered by the Patent and Trademark Office ("PTO") to be invalid. We therefore decline to apply the maxim in this case.

For the reasons discussed, we conclude that the district court did not err in construing "saccharides" to include polysaccharides.

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C.

Next, the parties seek construction of the term "saccharides" as used in Claim 1 of the '431 Patent and Claim 1 of the '220 Patent The parties agree that the term, which is defined in the specification, should be construed to at least mean "carbohydrates or sugars which can be in the form of mono-, oligo-, and/or polysaccharides." (See Plf. Cl. Constr. App. at 28, col. 8, ll. 63-64; see also id. at 61, col. 8, ll. 63-64). However, plaintiff argues that the phrase "e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose" -- which also appears in the specification -- should be part of the definition. (Plf. Cl. Constr. Br. at 16). Defendants oppose expanding the definition to include the additional language proposed by plaintiff.

The argument made by plaintiff is based on the recent decision in Sinorgchem Co. Shandong v. Int'l Trade Commission, 511 F.3d 1132 (Fed. Cir. 2007). In Sinorgchem, the Federal Circuit construed the term "controlled amount" used in two patents claiming a method of producing the chemical compounds 6PPD and 4-ADPA. The specification included the following language:

A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g. up to about 4% H[2]O based on the volume of the reaction mixture when aniline is used as a solvent.

Sinorgchem, 511 F.3d at 1136. Although the term "controlled amount" was defined in the specification, the parties disagreed as to whether the language "e.g. up to about 4% H[2]O based on the volume of the reaction mixture when aniline is used as a solvent" should be included as part of the definition. Id. at 1137. The Federal Circuit construed the term to include the disputed language because "the drafter clearly, deliberately, and precisely defined the term 'controlled amount' of protic material as 'an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H[2]O based on the volume of the reaction mixture when aniline is utilized as the solvent.'" Id. at 1136.

By contrast, the specification in the '431 Patent and the '220 Patent does not define "saccharide" to expressly include the phrase "e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose." Rather, the specification reads:

As used herein, the term "carbohydrate" is used interchangeably with the terms "saccharide", "polysaccharide", "oligosaccharide" and "sugar" the definitions of which are well known in the art of carbohydrate chemistry. Although the compositions of the invention are intended to include at least one of the eleven essential saccharides, it should be noted that the saccharides can be in the form of mono-, oligo-, and/or polysaccharides, e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose. Therefore, by controlling the amount of particular gums in a given dietary supplement, one can control the amount of the respective saccharides in said dietary supplement.

(Plf. Cl. Constr. App. at 28-29, col. 8, ll. 57-67 & col. 9, ll. 1-3; see also id. at 61-62, col. 8, ll. 57-67 & col. 9, ll. 1-3). The definition states that, for purposes of the claimed invention, the term "saccharide" means the same thing as "carbohydrate," "polysaccharide," "oligosaccharide," and "sugar." (Id. at 28, col. 8, ll. 57-59; see also id. at 61, col. 8, ll. 57-59). See Sinorgchem, 511 F.3d at 1136, citing Cultor Corp. v. A.E. Staley Manufacturing Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) (where a term in the specification is set off by quotation marks, it is often a strong indication that what follows is a definition). The sentence that follows reiterates that a saccharide can be in the form of monosaccharide, an oligosaccharide, or a polysaccharide. (Plf. Cl. Constr. App. at 28, col. 8, ll. 63-64; see also id. at 61, col. 8, ll. 63-64). The same sentence elaborates, by way of example, that a composition containing gum tragacanth and guar gum will be considered as containing seven specific saccharides. (Id. at 28, col. 8, ll. 64-67; see also id. at 6l, col. 8, ll. 64-67). This example is repeated throughout the specification. (See id. at 28-30, col. 8, ll. 19-22 & 26-46, col. 12, ll. 34-50 see also id. at 61-63, col. 8, ll. 19-22 & 26-46, col. 12, ll. 34-50).

When read in the context of the specification as a whole, it is clear that the language plaintiff seeks to incorporate into the definition of "saccharide" is not part of the definition. Rather, the language "e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose" is an example directed to a preferred embodiment. Generally, particular embodiments and examples appearing in the specification will not be read into the claims. See Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986). Thus, the court should construe the term "saccharides" to mean "carbohydrates or sugars which

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can be in the form of mono-, oligo-, and/or polysaccharides."
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7. "One or More Saccharides"

The final term to construe is found in subsection (b) of claim 16, "one or more saccharides." Pejic Decl. 3d Ex. 1, col.6:59. Schwarz Pharma construes this term to mean "the process must involve the use of at least one saccharide. There is no requirement that the saccharide perform any particular function in the process or formulation." Paddock's construction is "a saccharide or saccharides which are a component of a dosage form of an ACE inhibitor in which cyclization has been inhibited." Paddock again avers its construction is consistent with that used in the prior litigation. n12

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n12 In the related litigation, the New Jersey District Court found that "one or more saccharides" means "a saccharide or saccharides which are a component of a dosage form of an ACE inhibitor in which cyclization has been inhibited." Warner-Lambert II, No. 99-922, at 2. Teva did not appeal the district court's grant of summary judgment of infringement with respect to claim 16. Warner-Lambert III, 418 F.3d at 1339 n.12.

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This Court agrees with New Jersey District Court Judge Debevoise's construction and analysis of the instant claim term. See Warner-Lambert II, No. 99-922, at 17. The plain language of the claim terms, read in conjunction with the entire specification, make clear that the function of the saccharide in the pharmaceutical composition is to inhibit hydrolysis. Claim 16 does not speak to the functioning of the saccharide. Pejic Decl. 3d Ex. 1, col 6:54-59. This does not mean, however, that the saccharide performs no function with respect to the pharmaceutical composition, as claim 1 and the specification state that the saccharide performs the function of inhibiting hydrolysis. It simply means that claim 16 does not speak to the function of the saccharide, and therefore the claim construction propounded by the New Jersey District Court and proposed by Paddock is adopted, with the exception that "drug product" is substituted for "dosage form:" "a saccharide or saccharides which are a component of a drug product containing an ACE inhibitor in which cyclization has been inhibited."
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18. Where subsequent uses of a claim term within a claim make reference to the first usage as an antecedent (through the use of introductory definite articles such as "said" or "the"), the claim term must be interpreted consistently across all such uses. See Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1356-57 (Fed. Cir. 1999).
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IV. Disputed terms in claims 8 and 9 of Patent '127: "said analyte"

Claims eight and nine of Patent '127 state: "8. The method as claimed in claim 1 wherein said analyte is a said conversion product. 9. The method as claimed in claim 8 wherein said enzyme is[SAH-hydrolase] and said analyte is [SAH]." (emphasis added).

Construction of this term requires resolution of the Jepson issue discussed at length in the Court's Order Granting Summary Judgment of Non-infringement. See Order 5-8 (Docket No 83). Specifically, construction of "said analyte" requires the Court to determine whether the analyte must be a "substrate for [the homocysteine converting] enzyme," as stated in the preamble of claim 1. Axis-Shield suggests that "[s]ince the only current infringement contentions relate to SAH-hydrolase, it is not clear that the Court needs to resolve this issue." However, claim construction requires that the Court define disputed

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terms, and "said analyte" is clearly a disputed term.

To review, the Jepson issue arises because of an apparent conflict between the definition of "analyte" in the preamble of claim 1, and its definition in the description of improvements, later in claim 1. The preamble to claim 1 of Patent '127 describes the second step of the invention as "assessing an analyte which is a substrate for said enzyme." The "improvement" half of claim 1 describes the second step of the invention as "assessing a non-labelled analyte selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." Taking the preamble and improvements together, the analyte must be (1) a substrate for the enzyme; (2) non-labelled; and either (3) a homocysteine co-substrate or (4) "the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." The last possibility may create an inconsistency, if the preamble is treated as a claim limitation. n3

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n3 The parties agree that the term "substrate" means "the substance on which an enzyme acts to form a product." See Joint Claim Construction and Prehearing Statement, Exh. A. Except with respect to "reversible" or "inhibition" reactions, it is not logically possible for the analyte to be both (1) a substrate for the enzyme and (4) the product of the enzymic conversion of that substrate. Put another way, as "homocysteine conversion products" are the products of, not the reagents used in, the reaction, in most cases it appears that "homocysteine conversion products" will not be substrates of the enzyme used in the reaction. Thus, the inclusion of "substrate" may create an inconsistency with the 'improvement" portion of the patents' claims, except when "reversible" reactions are involved.

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General Atomics argues that while ordinarily a claim preamble does not limit the scope of the claimed invention, the preamble in a Jepson claim is a claim limitation that helps define the scope of the claimed invention. Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997) ("When [the Jepson] form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope."); see also Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029 (Fed. Cir. 2002) ("[T]he fact that the patentee has chosen the Jepson form of the claim evidences the intention 'to use the preamble to define, in part, the structural elements of his claimed invention.' Thus, the preamble is a limitation in a Jepson-type claim."); Manual of Patent Examining Procedure § 608.01(m) ("The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination."). Especially given the "public notice" function of a patent, it seems fairest to read any contradiction in a patent's claims against the patent holder. Cf Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("[W]here there is an equal choice between a broader and a narrower meaning of a claim... the notice function of the claim [is] best served by adopting the narrower meaning."). Further, the "substrate" limitation does not appear in the '717 patent, suggesting that the language plays some role in the '127 patent.

It is true that none of the cases cited by General Atomics involved preambles that were inconsistent with the improvements disclosed in a Jepson claim. See Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997) (finding that "balloon angioplasty catheter" in preamble to claim was structural limitation); Epcon Gas Sys, Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029 (Fed. Cir. 2002) (finding that preamble that described method for "providing gas assistance to a resin injection molding process" did not restrict claim to "apparatuses and methods that perform complete injection molding processes"). Moreover, the federal regulations only require the preamble to contain a "general description" of the prior art, not the type of detailed limitations that are ordinarily found in patent claims. See 37 C.F.R. § 1.75(e). However, where the preamble does contain specific "elements or steps," the MEPE and the case law seem to require that they be treated as limitations, along with the improvements. (MPEP § 608.01(m): preamble "is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination.")

Accordingly, the Court construes "said analyte" in claim 8 of the '127 Patent to be "an analyte which is both the 'analyte which is a substrate for said enzyme' and the 'non-labelled analyte' described in claim 1." The balance of claim 8 requires that the said analyte be a said conversion product.

Further, the Court construes "said analyte" in claim 9 of the '127 Patent to be "an analyte which is both the 'analyte which is a substrate for said enzyme' and the 'non-labelled analyte' described in claim 1, and is a said conversion product." The

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balance of claim 9 requires that the said analyte be SAH.
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A. Claim Construction

The '783 patent, entitled "Thiazolylacetamido Cephalosporin Compounds," was issued on May 26, 1987. It has six claims; only claim 1 is independent:

1. A compound of the formula:

[SEE DIAGRAM IN ORIGINAL]

wherein R4 is a residue of a nucleophilic compound selected from hydroxyl, mercapto, cyano, azido, amino, carbamoyloxy, carbamoylthio and thiocarbamoyloxy, said group being unsubstituted or substituted by alkyl of up to three carbons, and R5 is hydroxyl or lower alkoxy.

'783 patent, col. 39, l. 26 to col. 40, l. 14 (emphasis added). The emphasized limitation, defining the R4 substituent, is at issue.

5 Specifically, Ranbaxy contends that a methoxy (-OCH[3]) residue, which occupies the R4 position in both Pharmacia's VANTIN (R) products and the accused products, is not encompassed by the phrase "hydroxyl . . . substituted by alkyl of up to three carbons." More specifically, Ranbaxy argues that one of ordinary skill in the art would not read "substituted" in claim 1 to modify "hydroxyl."

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5 According to Pharmacia, claim 2 of the '783 patent, directed to "[a] pharmaceutically acceptable ester of the compound of claim 1," covers its VANTIN (R) product (and, correspondingly, the accused products), as marketed, while claim 1 recites the chemical form of the antibiotic as it exists in the body after the drug has been metabolized.

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As support for its position, Ranbaxy notes (and Pharmacia agrees) that "substituted or unsubstituted" in claim 1 cannot modify every residue recited in the R4 Markush group because, as a matter of chemistry, two of the recited residues -- cyano and azido -- cannot be "substituted" with an "alkyl of up to three carbons" because they lack substitutable hydrogen atoms. It argues that the recitation of "alkoxy," a conventional reference to the genus including methoxy, in the claim's definition for the R5 substituent (but not for R4) shows that R4 and R5 have different meanings, and that the patentee knew how to include "alkoxy" substituents had it meant to.

Similarly, Ranbaxy points to the written description's definition of R4: "-W-R wherein W represents oxygen or sulfur atom and R represents hydrogen, carbamoyl, N-alkylcarbamoyl, thiocarbamoyl, N-alkylthiocarbamoyl, an acyl, sulfamoyl, alkylsulfonyl or hetero ring," '783 patent, col. 4, l. 67 to col. 5, l. 4, and argues that there, the patentee "could easily have defined 'R' to include alkyl, the most elementary of residues, and thereby define R4 as alkoxy." Ranbaxy further relies on the absence of an example in the '783 patent's lengthy written description of a compound in which R4 is methoxy or alkoxy, and its use of the terms "methoxy" and "alkoxy" when referring to other substituents, including R5, in the claimed structure.

Ranbaxy cites further to the declaration of its expert, who testified that in accordance with the "naming convention" used by organic chemists, (1) a "methoxy residue . . . would not be referred to as a 'methyl-substituted hydroxyl'" because "chemists would . . . not ordinarily refer to a residue as a 'substituted' version of the 'original' residue if the residue were so altered by the substitution that its basic chemical and physical characteristics were fundamentally changed," and a methoxy residue "does not have the general physical and chemical properties of a hydroxyl residue"; (2) "compounds having hydroxyl residues are known as alcohols" whereas "compounds having alkoxy residues are known as ethers"; and (3) a methoxy residue in the R4 position is not a "substituted hydroxyl residue" because no "hydroxyl residue" remains.

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Pharmacia responds that the "substituted or unsubstituted" clause of the R4 limitation, as a matter of grammar, modifies every residue recited in the Markush group. Therefore, with a nod to the fact that two of the recited residues cannot be "substituted" as recited therein, it contends that the language of claim 1 supports the construction adopted by the district court, namely:

The words "said group being unsubstituted or substituted by alkyl of up to three carbons" means that (1) all of the structures named in the Markush group may be used in their unsubstituted form; and (2) all of the structures named in the Markush group that can be chemically "substituted" by replacing a hydrogen atom with "alkyl of up to three carbons," may be so substituted within the meaning of the R4 limitation. This leads to the conclusion that an alkoxy residue such as methoxy (-OCH[3]) may be substituted for the hydroxyl residue (-OH) within the meaning of the R4 limitation of Claim 1.

Pharmacia & Upjohn, 274 F. Supp. 2d at 609 (emphasis in original). It notes that the written description's definition of R4, quoted in part above, continues as follows:

The typical residue of nucleophilic compound may be exemplified by hydroxyl, mercapto, cyano, azido, amino, carbamoyloxy, carbamoylthio, or thiocarbamoyloxy group, or those substituted with alkyl (e.g., methyl, ethyl, propyl, etc.). . . . Furthermore, the symbol R4 may preferably represent a mercapto group substituted with a hetero ring which may be 5- or 6-membered one [sic] . . . .

'783 patent, col. 5, ll. 4-15 (emphasis added). Thus, says Pharmacia, not only does the written description specifically define R4 as including "hydroxyl . . . substituted with alkyl . . . e.g., methyl"; it also undermines Ranbaxy's nomenclature argument, as Ranbaxy's expert asserted (and Pharmacia agrees) that a mercapto (-SH) group is comparable for purposes of the present inquiry to a hydroxyl (-OH) group. Furthermore, Pharmacia's expert declared that he is unaware of any nomenclature convention a methoxy-including construction would violate, and that chemical substitutions, including those Ranbaxy acknowledges fall within the scope of the R4 limitation, "virtually always change the physical and chemical properties of the starting compound to some degree." He further cited Morrison & Boyd, Organic Chemistry, 518 (3d Ed. Allyn and Bacon 1973), a "highly respected Organic Chemistry textbook," which states: "Reaction of an alcohol involves the breaking of either of two bonds: the C-OH bond with the removal of the -OH group; or the O-H bond, with the removal of -H. Either kind of reaction can involve substitution, in which a group replaces the -OH or -H. . . ."

We conclude that the district court's construction, on this record, is correct. It is consistent with the language of claim 1 and the definition of R4 in the written description, and at odds with nothing in the claims, written description, or prosecution history. 6 Pharmacia correctly notes that the R4 limitation cannot properly be construed to exclude methoxy simply because the written description lacks such an example. E.g., Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988) ("What is patented is not restricted to the examples, but is defined by the words in the claims if those claims are supported by the specification in the manner required by 35 U.S.C. § 112."). And the express disclosure of a "mercapto group substituted with a hetero ring" in the R4 position bolsters the adopted construction, particularly in view of the parties' agreement that persons of ordinary skill in the art would regard mercapto and hydroxyl groups as comparable in this context.

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6 Ranbaxy contends that during prosecution of an ancestor application, the patentee "acquiesced" to the examiner's assertion that a claim limitation reciting "groups convertible to a methoxy group" was "broader than the disclosure." That assertion, however, concerned the patent's disclosure as to a different R substituent -- one not even recited in the claims of the '783 patent -- and any "acquiescence" thereto is irrelevant to the construction of the R4 limitation.

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The district court also carefully considered the parties' extrinsic evidence and regarded Pharmacia's "more responsive to the issue of interpreting the R4 limitation[,] based upon the applicable scientific authority and reasoning" and "more persuasive." Pharmacia & Upjohn, 274 F. Supp. 2d at 609. It specifically noted that it had "not found in the extrinsic evidence any reason to deviate from the claim construction that appears appropriate based upon the intrinsic evidence discussed above." Id. On the record developed before the district court, we see no basis to question either conclusion, and,

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as noted above, we agree that the relevant intrinsic evidence supports its construction. Accordingly, since Ranbaxy acknowledges that its products fall within the scope of the claims as construed by the district court, we uphold the district court's finding that Pharmacia has met its burden of showing a reasonable likelihood of success on its claim of literal infringement.
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D. "Whereby a Substantially Tasteless Super-Purified Smoke Is Created; and "Treating Meat Having Freezing Point with Said Tasteless Super-Purified Smoke."

Finally, HISI and TPI dispute the meaning and use of "said tasteless" in relation to "substantially tasteless" in Claim 1. TPI argues that the simultaneous use of "substantially tasteless" and "said tasteless" is "an improper double inclusion of the element." (TPI Response 22.) TPI believes that a person of reasonable skill in the art would not be able to distinguish between "substantially tasteless" and "said tasteless." On this basis, TPI argues, Claim 1 should be ruled indefinite. HISI, on the other hand, that "substantially tasteless smoke" is not a limitation, but a label for what results at the end of the process, and that "said tasteless smoke" is merely an obvious shorthand reference for that product.

The Court agrees with HISI's analysis, and finds neither ambiguity nor indefiniteness in this portion of Claim 1. The use of "said" makes it clear that "said tasteless super-purified smoke" refers to the "substantially tasteless super-purified smoke" that is a result of the processes previously described in the Kowalski Patent.
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(1) A Salt

Claim 1 of the '096 patent uses the term "a salt." Specifically, the invention involves "treating the [whole blood] sample with a salt to alter the red blood cells." Patent '096, col. 3, 48-49. IDEXX contends that the term "a salt" includes a salt in solution. SAS/Abaxis argue that "a salt" can refer only to a chemical compound, not to a solution in which the compound's component elements exist unbound.

I turn first to the dictionary, to see if a salt in solution is among the generally accepted definitions of a salt. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 & n.6 (Fed. Cir. 1996). The dictionaries cited by Drs. Toone and McDermott, respectively IDEXX's and SAS/Abaxis's expert, show that a salt is commonly understood to exist both as a solid and in solution. Webster's Third International Dictionary 2005 (1993) (describing the properties of salt compounds "in solution"); American Heritage Dictionary of Science 572-73 2 ("'salts [are] usually defined as ionic compounds which in water solution'" yield a positive and a negative ion (quoting Jones, Inorganic Chemistry)). Having examined the patent claim, the specification and the prosecution history, I conclude that a person of ordinary skill in the art would understand the '096 patent to embrace that definition.

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2 SAS/Abaxis do not provide information sufficient for a complete citation.

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According to the summary of the invention, "in preferred embodiments of this method, the step of treating the sample with a salt involves mixing the sample with a hypertonic solution to form a dilute solution. . . . Preferably, the hypertonic solution contains a salt of ionic strength of at least 0.5M." Patent '096, col. 1, 47-48. The structure of the patent's preferred embodiment explicitly recommends treatment of the blood sample by a salt in a salt solution. Patent '096, col. 2, 47-50 (teaching that a salt should be provided "in any suitable container, e.g. a cylindrical PVC container, preferably as a buffer solution"). That should be sufficient. The Federal Circuit says that "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics

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Corp., 90 F.3d at 1582. Additionally, both the applicant and the patent examiner refer to salt solutions in the prosecution history. See, e.g., Toone Decl., Ex. 2 at 2 (Nucker letter, Jan. 25, 1988); Toone Decl., Ex. 3 at 2 (Clark letter, July 11, 1988); Toone Decl., Ex. 11 at 2 (Freeman letter, Feb. 13, 1989); see also Toone Decl., Ex. 5 at 3, 5 (Freeman letter, July 3, 1989) (distinguishing the Fetter patent's use of a dry salt from IDEXX's use of a salt in solution).

But despite all those references to "solution" in the patent documents, SAS/Abaxis argue that, as a matter of law, a salt cannot mean a salt in solution. When dissolved in liquid, they say, a salt molecule separates into its component elements. Thus, a salt solution contains no salt molecules, only a collection of its component elements. It is therefore no longer a salt. For support, they cite a product patent case, Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed. Cir. 1995), and Judge Newman's dissent from the denial of rehearing en banc. Exxon Chemical Patents, Inc. v. Lubrizol Corp., 77 F.3d 450, 452 (Fed. Cir. 1996). There, Judge Newman argued that the majority's holding meant that a hypothetical product patent for salt water could no longer simply list salt and water, but would have to describe the product's chemical composition: water, sodium and chlorine. Exxon Chemical Patents, 77 F.3d at 452. This dispute about product patents among the judges of the Federal Circuit, as reflected by Judge Newman's effort to demonstrate the wrongheadedness of the majority's approach, does not help SAS/Abaxis. Exxon Chemical Patents's claim explicitly was not a process claim like '096; instead, it was a patent of a particular composition: a product patent claim. The court held that a product patent claim, describing the chemical composition as "containing" a list of particularly defined ingredients, protects only a composition that in fact contains the listed chemicals exactly as stated; a product patent is not a patent for a recipe, such that any composition that results from combining the listed chemicals is also covered. Exxon Chemical Patents, 64 F.3d at 1557-58. The Exxon Chemical Patents court was very careful to distinguish between product patent claims and process or product-by-process patent claims. Exxon Chemical Patents, 64 F.3d at 1556-57. The Federal Circuit did not implicitly or explicitly rule that solutions cited in process patents must be described in molecular detail. '096 is a process patent, and I conclude that the ordinary meaning of a salt to a person of ordinary skill in the art of the '096 patent is not precluded by Exxon Chemical Patents. The intrinsic evidence of the patent makes clear that a salt includes a salt in solution. 3

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3 I observe that claim 1 of the apparatus patent, the '187 patent, does not use the term "a salt." Instead it describes use of a "hypertonic solution." '187 Patent, col. 4, 3-7. There is no dispute over this term.

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1. Claim Construction

Prior to trial, the court only defined one disputed claim term -- "salt." The court defined salt as, "a compound that contains a positively charged component (cation) and a negatively charged component (anion), other than a hydrogen or hydroxyl ion, and is not an oxide." (D.I. 360 at 3319-20) Although the parties asked the court throughout trial to further refine the definition, neither party is challenging the final claim construction.

For purposes of simplification, the claims of the '343 and '481 patents can be broken into a few limitations. Claim 1 of the '343 patent, the broadest claim, requires a catalyst that contains an efficiency-enhancing amount of (1) a cesium oxyanion salt and (2) an alkali metal salt. Claim 1 of the '481 patent, the broadest claim, requires a catalyst that contains an efficiency-enhancing amount of at least two cesium salts wherein at least one of the cesium salts has an anion selected from a particular group of elements.

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2. Construction of "Sanitize"

The '676 patent claims are directed to a "method for sanitizing fowl," '676 Patent col.10 l.15, and the patent explicitly states

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that the term "sanitize" "denote[s] a bacterial population reduction to a level that is safe for human handling and consumption," id. at col.2 ll.10-12. Thus, Ecolab argues that Inspexx cannot infringe the '676 patent claims because it does not and cannot make raw poultry safe for human consumption; cooking is required. The district court instructed the jury that, in the context of the '676 patent, the "sanitized" meat was not necessarily safe for human consumption immediately after treatment with PAA; the "sanitized" meat was not safe for consumption until it was cooked. Thus, Ecolab argues that "[b]y incorporating a subsequent 'cooking' element into the term 'sanitize,' the district court overrode the express definition of 'sanitize' set forth in the '676 patent." Appellant's Br. at 41. We review the district court's claim construction determination de novo, Cybor Corp., 138 F.3d at 1456, and we find Ecolab's argument unpersuasive.

It is well-settled that an inventor may act as his own lexicographer to define a patent term, Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc), as FMC clearly chose to do here--notably failing to state that the invention can make poultry safe for consumption only after it is cooked. It is likewise well-settled that courts generally may not re-draft claims; we must construe the claims as written. Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004). Ecolab relies heavily on Chef America in asserting that the district court erred when it construed "sanitize." In that case, the claim at issue regarded a method for baking cookies and required "heating the resulting batter-coated dough to a temperature in the range of about 400 [degrees] F. to 850 [degrees] F." Id. Clearly, the patentee meant that the user should set the oven so as to heat the dough at 400-850 [degrees], rather than to 400-850 [degrees]; otherwise, the dough would be burned to a crisp and the claims would be nonsensical. Still, this court held that "in accord with our settled practice we construe the claim as written, not as the patentees wish they had written it. As written, the claim unambiguously requires that the dough be heated to a temperature range of 400 [degrees] F. to 850 [degrees] F." Id. (emphasis added).

Because the claim language at issue in Chef America was unambiguous, that case is distinguishable from the present case. In the present case, the definition of "sanitize" is ambiguous in that it does not indicate when consumption is to take place--the definition does not indicate whether the consumption would occur immediately after application of PAA or, for example, at a later time after the meat is cooked. The testimony of Ecolab's expert, Dr. Tompkin, helps to resolve that ambiguity, albeit in FMC's favor. Specifically, Dr. Tompkin admitted that in-plant inspectors examine poultry that has been treated with PAA to determine if it is "fit for human consumption." J.A. at 5785. Surely, the inspectors do not require the poultry to be "fit for human consumption" in its uncooked state. Thus, Chef America is distinguishable, and the district court did not err when it construed the term "sanitize" to mean that the treated meat has become safe for human handling and post-cooking consumption.

In summary, FMC did not, via an explicit or implicit disclaimer, limit the claims to the use of compositions containing PAA as the only antimicrobial agent, and FMC's claims do not require that PAA-treated fowl be safe for immediate raw consumption. Thus, we affirm the district court's denial of Ecolab's motion for JMOL of noninfringement.
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10. "saponification"

Plaintiff's proposed constructionof "saponification" is: "the hydrolysis reaction of jojoba oil starting material with an alkali metal or alkaline earth metal hydroxide to form jojoba-oil starting material." Defendant's proposed construction is: "the hydrolysis reaction of a wax, oil or fat with an alkali metal or alkaline earth metal hydroxide."

Defendant did not provide a proposed construction of "saponification" in the claim construction briefing and provided no arguments in support of the construction it now proposes. Plaintiff's proposed construction will be adopted.
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2. Saturate and Saturation

Poseidon argues that the terms "saturate" and "saturation" have a specific meaning to those skilled in the art of Diffused Air Flotation that is different from the common understanding of those terms. "Saturate" is commonly defined as "to cause (a

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substance) to unite with the greatest possible amount of another substance, through solution, chemical combination, or the like." RANDOM HOUSE UNABRIDGED DICTIONARY 1705 (2d ed. 1993). Poseidon argues that those skilled in the art of diffused air flotation would have used the term to indicate "the condition in which at least a portion of the liquid to be fed to the tank contains enough dissolved air such that bubbles begin to form upon a decrease in pressure."

Poseidon is correct that the terms have a specific meaning to those skilled in the art of DAF, but the terms should be construed slightly differently from Poseidon's suggestion.

Claim terms are construed through the eyes of a person of ordinary skill in the field. See, The Toro Co. v. White Consolidated Indus., 199 F.3d 1295, 1299 (Fed. Cir. 1999). Where a claim term has a specialized meaning to those skilled in the art, that meaning controls unless the evidence indicates that the patentee used the words in a different manner. See, Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971 (Fed. Cir. 1999). Under these circumstances, extrinsic evidence may be considered, if needed, to assist in determining the meaning of technical terms in the claim. See, Vitronics Corp., 90 F.3d at 1583.

Poseidon has provided sufficient evidence to suggest that the terms "saturate" and "saturation" have a particular meaning to those skilled in DAF. The affidavit of Harri K. Kytomaa indicates that those skilled in DAF do not use these terms to indicate 100% saturation. Instead, the terms are used to suggest that liquid infused with air can have "multiple saturation levels" expressed as a percent of the maximum air concentration of the liquid. Kytomaa bases his interpretation on his own experience as well as several texts dedicated to DAF. What is more, it does not appear as if the claims use these terms in a manner other than that which someone skilled in the art would understand.

The texts cited by Kytomaa, and his own statements, however, do not support the broad definition provided by Poseidon. Kytomaa asserts that the DAF field employs saturation levels that range from 60% to 90%. See Docket 90, Ex. D P 10. In addition, each of the treatises Kytomaa refers to indicate that saturation levels in the DAF field range from 60% to 90%. Accordingly, the terms saturate and saturation will be construed as meaning "dissolving sufficient air or gas into the liquid so that the liquid contains 60% to 90% of its maximum air concentration."
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3. "sealed"/"sealed container"

a. The Parties' Proposed Constructions

Pharmacia asserts that "sealed container" means "[a] closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed[.]" (D.I. 232 at 28.) In support of its proposed construction, Pharmacia cites the specification of the patent, which describes both "closing" and "sealing" the container, as well as the prosecution history of the patent and the statements of witnesses. (Id. at 28-31.) Sicor, on the other hand, argues that the term "sealed" means "closed in some fashion such that it does not allow the passage of the solution." (D.I. 234 at 18.) Sicor cites to the language of the specification in support of its construction, and argues that Pharmacia is improperly attempting to import a limitation from the preferred embodiment into the claims by its definition. (Id. at 18-19.) Sicor also cites to the prosecution history of the patent and to what it asserts is the ordinary meaning of the term "sealed." (Id. at 19-21.)

b. The Court's Construction

The ordinary meaning of the term "sealed" is different from, and encompasses something more than, the ordinary meaning of the term "closed." For example, the definitions of "sealed" cited by Sicor in its claim construction brief define "sealed" to mean "anything that tightly or completely closes or secures a thing ... to close by any form of fastening that must be broken before access can be gained" (D.I. 235, Ex. M (Random House Dictionary of the English Language 1286 (1983))), and "an airtight closure ... to close hermetically" (id. at Ex. O (The American Heritage Dictionary 1105 (2d College ed. 1982))). Thus, based on the ordinary meaning of the term "sealed," even accepting Sicor's authorities, Sicor's definition must fail, since Sicor essentially equates "sealed" with "closed."

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That "sealed" means something more than "closed" is confirmed by the specification of the patent, which repeatedly states that "[t]he vials were then closed with ... rubber stoppers and sealed with aluminum caps." ('285 patent at 6:8-10; see also id. at 7:1-3; id. at 8:32-34; id. at 9:27-29; id. at 10: 30-32.) In fact, the patent uses language like this fourteen times, which contrasts something "closed" with something "sealed." The prosecution history further supports Pharmacia's definition of "sealed," as it states on at least four separate occasions the significance of the container being sealed. (See D.I. 232, Ex. 5 at PI 844; id., Ex. 6 at PI 877; id., Ex. 7 at PI 928; id., Ex. 31 at PU 15057.)

Thus, I will construe the term "sealed container," as Pharmacia proposes, to mean "a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed."
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c. "The Seeds"

AnazaoHealth also seeks construction of the term "seeds" in Claims 3 and 10, which it contends means "radioactive sources." The World Wide Plaintiffs respond that "seeds" should be construed in the same manner as "elements."

In the Field of the Invention section of the specification, the patentees state that the "invention relates to a needle assembly for implanting therapeutic elements." ('760 Patent col. 1, ll. 7-8.) More specifically, it allows the user to load and place "radioactive 'seeds' in the body for the purpose of treating cancer." Id. at col. 1, ll. 8-11 (emphasis added). In the Background of the Invention section, the patentees refer to "radioactive sources or 'seeds'," id. at col. 1, ll. 18 (emphasis added), and describe two principal types of radioactive seeds: "free" seeds, which are individual radioactive seeds that are loaded in the cannula with small cylindrical spacers stacked in between the radioactive seeds, and pre-manufactured strands, where the radioactive seeds are encapsulated in a biodegradable material that spaces the radioactive seeds apart from one another. Id. at col. 1, ll. 61-67. The Description of the Preferred and Other Embodiments section describes Figure 1 as showing radioactive seeds as a type of therapeutic element, id. at col. 3, ll. 56-57, which alternate with spacers. In explaining the operation of the needle assembly, the description refers to depositing in the tissue the line of seeds and spacers, which leaves the seeds in the exact desired position in the body. Id. at col. 4, ll. 32-33. Figures 3 and 4 show an encapsulated line of seeds 128 connected by spacing webs 131. Id. at col. 4, ll. 45-46. In addition to Claims 3 and 10, Claim 17 references "radiation seeds." Id. at col. 6, ll. 44. Thus, the specification draws a clear distinction between seeds and spacers.

It is true, as the World Wide Plaintiffs point out, that the prosecution history indicates that they substituted "line of elements" for "line of seeds" in Claim 3 after the Examiner had objected to this Claim as anticipated by combining Mercereau and Langton (Patent No. 5,460,592) (W0470), which teaches a seed train that uses encapsulation to eliminate the need for spacers. 24 In explaining why their invention was not anticipated by Mercereau and Langton, however, the patentees did not rely on the distinction between "elements" and "seeds." 25 Instead, they relied on the distinction between their needle assembly and that of Mercereau. "[T]he needle assembly as recited in base Claim 1 distinguishes over the needle assembly of Mercereau, and hence Claim 3 is not rendered obvious by combining Mercereau and Langton." (W0482.) The Court is not persuaded by Plaintiffs' argument that the prosecution history supports a finding that the term "seeds" should be construed as "elements."

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24 The Examiner stated that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to use the encapsulation with the seeds of Mercereau et al. to eliminate the need for spacers as taught by Langton et al." (W0470.)25 "Applicant admits that Langton discloses seeds spaced at pre-determined intervals in a bio-absorbable material, this construction being known in the art." (W0482.)

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The Court also notes that, while the patentees changed "line of seeds" to "line of elements" in Claim 3, they did not substitute "elements" for the second reference to "seeds" in Claim 3. (W0485.) Additionally, Claim 10 contains this same distinction. (W0486.)

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To construe "seeds" as "elements," as suggested by the World Wide Plaintiffs, would render the term "seeds" as encompassing "anything intended for use in brachytherapy, including radioactive seeds and/or spacers." This does not make sense. "Seeds" are just one form of an "element."

The Court finds that the patentees have acted as their own lexicographers and have defined "seeds" as "radioactive sources." Additionally, it is clear from an examination of the specification that "seeds" are one form of "elements" and, thus, are intended for use in brachytherapy." While at times this construction will import redundancy into the claims, to use the definition of "elements" would suffer from the same infirmity. Where the claim speaks of "radioactive seeds," the term "seeds" should be construed simply as "sources intended for use in brachytherapy."
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c. "segments of DNA from different genomes"

The crux of the dispute concerning this claim language, and which underlies many of the ensuing claim disputes between the parties, is whether the DNA segments that form the recombinant DNA molecule have to be from naturally-occurring genomes or may also be from non-naturally occurring genomes. Amgen argues this phrase must be construed narrowly such that the segments of DNA that make up the recombinant DNA molecule must be taken from the DNA of different naturally-occurring cells or viruses, e.g., segments of DNA from human beings and bacteria. Schering, on the other hand, maintains that the term "genome" should be interpreted broadly to mean the recombinant DNA molecules may be taken from both naturally occurring DNA sequences and from non-naturally occurring DNA sequences, such as those DNA sequences found in the engineered plasmids described in the specification.

The term "genome" is defined in the specification:

Genome - The entire DNA of a cell or a virus. It includes inter alia the structural genes coding for the polypeptides of the substance, as well as operator, promoter and ribosome binding and interaction sequences, including sequences such as the Shine-Dalgarno sequences.

See Col. 6, lines 57-62. It is unclear from this definition whether a genome is limited to DNA that originated in nature. Schering argues that the recombinant DNA molecules described in the '901 Patent specification include DNA sequences that did not originate in nature; specifically, the pBR322 and pKT287 engineered plasmids that were used as cloning vehicles. See Col 27, lines 8-27; Col. 30, line 42. Because Schering asserts it is well-settled patent law that claims should be interpreted to encompass the embodiments of the specification, see Vitronics, 90 F.3d at 1583, it contends this claim language must be construed to include the engineered plasmids which did not originally occur in nature. Further, Schering finds support in the specification which states:

A wide variety of host/cloning vehicle combinations may be employed in cloning the double stranded cDNA prepared in accordance with this invention. For example, useful cloning vehicles may consist of segments of chromosomal, non-chromosomal and synthetic DNA sequences, such as . . . vectors derived from combinations of plasmids and phage DNAs such as plasmids which have been modified.

See Col. 12, lines 3-14.

The Court agrees with Schering that the examples disclosed in the specification take DNA segments from the genome of both naturally occurring and non-naturally occurring cells. Not only does a recombinant DNA molecule's genome not occur in nature, but at least one of the segments of DNA that make up this recombinant molecule may not come from nature. Specifically, the recombinant DNA molecules synthesized in the specification include either the pBR322 or pKT287 bacterial plasmids, which both parties agree, were engineered in the laboratory. See also D.I. 186 at 3, 6. Amgen argues, however, that even though the plasmid product is engineered in the laboratory, the plasmids consist of natural DNA, with the exception of one synthetic nucleotide in pKT287.

Significantly, it is the bacterial genome as a whole, which is not naturally-occurring, and the desired interferon-type DNA

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sequence which are spliced together to form the recombinant DNA molecule. See Col. 36, lines 4-5. The combination of natural DNA with other non-natural constituents to form the pKT287 and pBR322 plasmids is not part of the '901 invention, but existed previously in the art. See Col. 13, lines 61-68 (pBR322); Col. 30, lines 42-43 (pKT287). Accordingly, regardless of whether the patent permits the splicing together of more than two segments of DNA from different genomes, as Amgen urges, the fact of the matter is that the preferred embodiment contemplates splicing an alpha interferon type segment with an engineered plasmid. The preferred embodiment must be covered by any interpretation of this claim language as an interpretation of a claim term which excludes a preferred embodiment is to be avoided. See Vitronics, 90 F.3d at 1582. The Court thus construes "segments of DNA from different genome" as permitting segments of DNA from genome of both naturally occurring cells or viruses and non-naturally occurring cells and viruses.

The prosecution history further strengthens this conclusion. Under the doctrine of prosecution history estoppel, the prosecution history may limit the interpretation of the disputed language to meanings not expressly disclaimed by the inventor during the prosecution of the patents. See CVI/Beta Ventures, 112 F.3d at 1155 (quoting Southwall, 54 F.3d at 1579). This estoppel "may arise either from matters surrendered as a result of amendments to overcome patentability rejections . . . or as a result of argument to secure allowance of a claim." See Cybor, 138 F.3d at 1460. However, the reason for offering an amendment or an argument remains relevant to the application of an estoppel. See Litton Systems, Inc. v. Honeywell, Inc., 140 F.3d 1449, 1456 (Fed.Cir. 1998). It is thus important for the Court to determine the reason a patentee submitted an argument or amendment during the prosecution of the patent. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 117 S. Ct. 1040, 1051, 137 L. Ed. 2d 146 (1997).

The originally filed claims recited: "DNA from whatever source obtained, including natural, synthetic, or semi-synthetic sources, related by mutation, including single or multiple, base substitutions, deletions, insertions, and inversions to any of the foregoing DNA sequences or inserts." D.I. 172, Tab 1 at 64 (February 4, 1980). Amgen argues that because Biogen was forced to eliminate this language by the patent examiner, Biogen is now estopped from claiming synthetic and semi-synthetic sources for the DNA segments from different genomes. In rejecting this initial claim language, however, the examiner found over broad the use of the terms "related by mutation," "multiple base substitutions," "deletions," "insertions," and "inversions," but significantly did not question the validity of the terms "synthetic" or "semi-synthetic." See id., Tab 17 at 3 (November 29, 1982). Accordingly, the Court finds prosecution history estoppel does not bar an interpretation of "segments of DNA from different genomes" which includes both naturally occurring and non-naturally occurring DNA segments. 19

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19 Amgen points to another part of the prosecution history in which Biogen explained the use of human and bacterial DNA:

As defined in the art and in this application, a recombinant DNA molecule consists of segments of DNA from different genomes (the entire DNA of a cell or virus) . . . . The specific recombinant DNA molecules of claims 1-9 consist of particular DNA that codes for human leukocyte interferon . . . joined end-to-end with a segment of DNA from another genome [e.g., E. coli]. It could not be plainer that such a combination is not naturally occurring.

D.I. 172, Tab 11 at 7 (January 27, 1982). Amgen infers from this statement that although the resulting combination of two genomes is not itself naturally occurring, the individual constituents must be naturally occurring. The Court is not persuaded. Prosecution history may only inform the Court's understanding of the specification and the claim, it cannot add limitations to a claim that directly contradict a preferred embodiment. See Markman, 52 F.3d at 980. Therefore, the Court declines to make such an inference from this prosecution history language.

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For all of these reasons, the Court holds the claim language "segments of DNA from different genomes" refer to DNA segments or DNA sequences in genomes of cells or viruses which may be both naturally occurring and non-naturally occurring. Combining the above construed elements, the Court finds the claim language "[a] recombinant DNA molecule consisting of segments of DNA from different genomes" refers to a molecule which may consist of segments of DNA in genomes from both naturally occurring or non-naturally occurring cells or viruses.
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B. The Parties' Positions on the Issue of a Dominant Selectable Phenotype, and Their Evidence and Arguments in Support of Those Positions

The major claim construction dispute involves the language in claim 54 of the '216 patent. Claim 54 states:

A process for generating a multiplicity of foreign DNA I molecules corresponding to multiple copies of a gene in a eucaryotic cell which comprises transforming said eucaryotic cell with a molecule which is formed by linking one of said foreign DNA I molecules to a DNA II molecule corresponding to an amplifiable gene for a dominant selectable phenotype not expressed by said eucaryotic cell, and culturing the transformed eucaryotic cells in the presence of successively elevated concentrations of an agent permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene, said transformation and culturing being carried out under suitable conditions.

(emphasis added). Specifically, the parties contest the meaning of the phrase "an amplifiable gene for a dominant selectable phenotype," and by implication, the meaning of "eucaryotic cell" (at least as referred to in claim 54 of the '216 patent).

Roche argues that a dominant selectable phenotype must mean something different than a selectable phenotype, since "dominant" is modifying the word "selectable." That difference, according to Roche, is this: The "amplified" gene that codes for the dominant selectable phenotype is always used in the patent in connection with the transformation of a wild-type host cell, never the transformation of a mutant cell. 23 A dominant selectable phenotype, it argues, has to be inserted into a wild-type host cell so that it has a wild-type genome to "dominate."

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23 Roche's proposed definition of "dominant selectable phenotype" reads as follows: "A property of a cell which allows that cell to survive under conditions lethal to a wild-type cell."

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Columbia claims that a "dominant selectable phenotype" should simply be read as a phenotype involving an amplifiable gene. The claims, it suggests, refer to "dominant selectable phenotypes" only in the context of processes utilizing amplification. 24 And in that setting, both mutant and wild-type host cells would qualify. In any event, Columbia argues that it would make no sense to define the eucaryotic host cells described in claim 54 as limited to only wild-type cells while interpreting eucaryotic cells without regard to mutant/wild form in all other claims.

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24 Columbia's definition links the concept of a dominant selectable phenotype to the use of an amplifiable gene by linking the survival of a cell to having acquired sufficient copy number of the gene: "A selectable phenotype which allows an organism or a cell of a defined genotype that acquires such phenotype, e.g. as a result of introducing a gene at a suitable copy number, to survive while other organisms or cells of the same defined genotype which have not acquired such phenotype will not survive or proliferate."

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Roche advances a series of arguments in support of its interpretation:

1) The claims "expressly distinguish" between "selectable" and "dominant selectable" as claims 1-53 of the '216 patent and all of the claims of '665 patent exclusively use the term "selectable," whereas claims 54-73 of the '216 patent exclusively use the term "dominant selectable."

2) In the specification, "dominant selectable" always describes transformation of wild-type cells and never describes the transformation of mutant cells.

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3) The experiments described in the patent that used mutant host cells never refer to the foreign DNA as coding for a "dominant" selectable phenotype or as a dominant acting marker, whereas the experiments involving wild-type cells refer to the foreign DNA as a dominant-acting gene.

4) The inventor's publications (incorporated by reference into the patents) describe experiments using mutant host cells where the markers are described as selectable and/or recessive, and further state that these markers can only be used in mutant host cells.

5) The prosecution history of the '216 patent shows that the inventors distinguished their claim from prior art involving the cotransfer of two linked human genes in eucaryotic cells by indicating that the prior art did not "teach or suggest transforming eucaryotic cells with a DNA molecule that is formed by linking a foreign DNA I molecule, containing a gene encoding a protein, to a DNA II molecule which corresponds to an amplifiable gene for a dominant selectable phenotype . . ."

6) Interpreting the claims as Columbia proposes would render some claims invalid in light of prior art that successfully incorporated multiple copies of linked genes in transformed eucaryotic cells as early as 1975.

Roche's first four arguments are inferences from the coincidence of certain words. Roche asks the Court to infer a limitation on the type of eucaryotic cell that can be used as host cells in claim 54 because the words "dominant selectable" or "dominant acting" are always used when discussing cotransformation processes involving wild-type host cells in the claims, the specification, the descriptions of the experiments in the specification, and, the publications of the inventors (incorporated by reference into the specification).

At the same time, Roche concedes that no intrinsic evidence explicitly announces that limitation -- that a dominant selectable phenotype cannot be used with a mutant host cell. Indeed, nowhere in the claim language do the words "wild-type cell" even appear. Rather, Roche argues that such consistent usage of the term with wild-type cells is not an accident, but reflects a de facto limitation inherent in the word "dominant."

Columbia's approach is the same but its conclusions are different. Because the phrase "dominant selectable phenotype" is invariably used in conjunction with the phrase "amplifiable gene," it is that trait that defines the phrase. Here again, nothing in the intrinsic evidence explicitly states that a dominant selectable phenotype must be associated with a process using an amplifiable gene. Like Roche, Columbia asks the Court to infer this from the juxtaposition of the two phrases.

As described below, Columbia has the better of the argument.

1. Claim Language

The claim language specifically describes in great detail a process of selection which requires the amplification, or increased copy number of, the amplifiable gene. Indeed, amplification is a central part of the patent's innovation.

In contrast, there is no mention in the claim language of the distinction Roche presses, between eucaryotic mutant host cells and eucaryotic wild-type host cells. Moreover, as described below, such an interpretation seems to unreasonably convert what was described as the innovative capability of the process -- that it would work on wild-type host cells -- into a limitation. The more logical inference is that the patentees associated a dominant selectable phenotype with the use of an amplifiable gene, whether it be with a mutant or wild-type host cell.

2. The Specification

Roche seeks out further support from the patent specification of the '216 patent. It relies primarily on this paragraph:

Cotransformation with dominant-acting markers should in principle permit the introduction of virtually any cloned genetic element into wild-type cultured eucaryotic cells. To this end, a dominant-acting methotrexate resistant, dihydrofolate reductase gene from CHO A29 cells was transferred to wild-type cultured mouse cells. . . . The use of this gene as a dominant-acting vector in eucaryotic cells will expand the repetoire [sic] of potentially transformable cells, no longer

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restricting these sort of studies to available mutants. (emphasis added).

Focusing on the language of this paragraph, Roche argues:

The distinction that the phenotype, or the gene that encodes the phenotype, is variously described in the patent as either selectable or dominant selectable is clearly related to the phenotypic background, i.e., mutant versus wild-type, of the cells into which the DNA is being incorporated. It is only where the foreign gene is inserted into a wild-type background with respect to the phenotype being assayed for that the foreign gene is referred to as a dominant-acting selectable marker or encoding a dominant selectable phenotype. (emphasis in original).

I do not find that this language, especially when considered in the context of the remainder of the specification, demonstrates what Roche proposes, and hardly demonstrates it "clearly."

The final sentence states that use of the marker expands the range of potential host cells, no longer restricting them to mutant cells. This suggests that the dominant marker technique includes a range of host cells beyond, yet including, mutant cells. It does not suggest a restriction at all.

Moreover, the specific mention of wild-type cells in conjunction with the linked cotransformation process is not surprising because (1) it trumpets an advance of the patents, and (2) it references an experiment that is discussed later in the patent. As Webb, Roche's expert, testified:

the problem with [an older] system is it limits you somewhat in the utility of the procedure. You have to have this very unusual condition of a mutated cell. What people clearly wanted to do was to use this technique of transformation in any cell type, and so the utility of the procedure would be greatly enhanced were that possible. (emphasis added).

That was precisely the market, if you will, to which this invention was directed. It was directed towards having an essentially unlimited, an unrestricted supply of the type of cells into which one could make the transfer carry out the selection in a normal cell, not a specialized cell that one had to hunt high and low for. You could just take any cell, so-called primary cells, the normal cells from normal tissues of human beings, for that matter, and to carry out the selection. 25

Simply because the "market" demands a process with a particular capability does not mean that the process should, by definition, be limited to only that capability and no other -- especially without any explicit statement suggesting that it be so limited. 26

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25 My recitation of Webb's expert testimony should not be taken as a retreat to extrinsic evidence. I merely note it to show that neither party contests this position. The very same information is articulated in the patent itself: "Cellular genes coding for selectable biochemical functions have previously been introducted [sic] into mutant cultured cells . . . In the present study, a dominant acting, methotrexate resistant dhfr gene has been transferred to wild-type cultured cells. The use of this gene as a vector in cotransformation systems may now permit the introduction of virtually any genetic element into a host of new cellular environments."

26 Indeed, in discussing the claims of the '216 patent generally, there are over thirty references to the host cells being eucaryotic cells without ever suggesting that certain claims cover different types of eucaryotic cells than other claims. If such a distinction existed in the minds of the patentees, it surely would have been expressed explicitly.

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The remainder of Roche's argument with respect to the specifications relies on the same type of inference argument that Roche made with respect to the claim language. The argument is equally unavailing for similar reasons.

In any event, Roche's inference argument is significantly weakened when considering it in the context of the entire specification. In describing the linked cotransformation claims, the term wild-type cells only appears in the two instances cited by Roche - one of which merely refers to an experiment that is described later in the patent. In every other instance

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(the Court counts nine other instances) in which the linked cotransformation claims are discussed, the host cells are invariably described as eucaryotic cells with no reference to wild or mutant form -- just as in the actual language of the claims.

In fact, the specification suggests the very opposite of what Roche proposes. The patentees clearly intended the term eucaryotic cell to cover the broadest range of cells possible without regard to: (1) which of the individual claims were involved, (2) the experiments discussed in the patent, and (3) the form, i.e. mutant or wild, of the eucaryotic cell:

Although the experiments discussed hereinafter concern cultured eucaryotic cells of mammalian origin such as human blood cells, mouse fibroblast cells, chinese hamster ovary cells and mouse teratocarcinoma cells, it is clear that the process described is generally applicable to all eucaryotic cells including, for example, cells from birds such as chickens, cells from yeast and fungi, and cells from plants including grains and flowers. Therefore, it is to be understood that the invention encompasses all eucaryotic cells even though the invention may ultimately be most useful in cotransforming mammalian cells.

If the patentees intended certain claims to cover certain types of eucaryotic cells and not others, such a limitation would surely have been included in the above paragraph defining the scope of eucaryotic cell. Instead, the quoted text suggests that eucaryotic cell means all eucaryotic cells, and, significantly, regardless of whatever types of cells are used in the experiments discussed later in the patent. Again, this paragraph, which is the only paragraph dedicated to describing what types of host cells are covered by the term eucaryotic cell, does not even hint of a distinction with respect to mutant vs. wild-type form.

Moreover, adopting a more limited definition of eucaryotic cell than the ordinary meaning (which would make no distinction with respect to mutant or wild form) for some of the patent claims would also be inconsistent with the rules of patent construction. There is a heavy presumption in favor of the ordinary meaning of a term. See Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999)(two situations permit deviation from the ordinary meaning of a term: (1) "the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term"; and, (2) "where the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used.")(citations omitted).

In this case, the patentees do not offer a definition for eucaryotic cell different from its ordinary meaning. Nor does use of the terms "amplifiable gene for a dominant selectable phenotype" in any way deprive the claim of clarity. On the contrary, the most logical inference is Columbia's: that dominant selectable phenotype is associated with an amplifiable gene, and its use in connection with eucaryotic cells does not alter its common meaning.

Finally, one need only look to the patentees' treatment of the term "selectable phenotype" for further support.

First, "selectable phenotype" like "dominant selectable phenotype" is defined in the claims without reference to whether the host cell in question is wild-type or mutant. Roche, however, agrees that the former can be used with either while in the case of the latter, it maintains only wild-type host cells are contemplated.

Second, the experiments described in connection with a "selectable phenotype" use only mutant host cells. Nevertheless, Roche agrees that the claim language pertaining to "selectable phenotypes" should not be so limited. Again, it takes a different position with respect to "dominant selectable phenotypes."

Third, at one point in the specification the patentees describe mutant DHFR (which everyone agrees is also a "dominant selectable phenotype") as an example of a selectable phenotype. This cannot be reconciled with Roche's position -- that selectable phenotypes can be used with both types of host cells while dominant selectable phenotypes are more limited.

The definition of "selectable phenotype" found in the specification states:

selectable phenotype is a phenotype which confers resistance upon an organism [sic] ability to exist under conditions which kill off all organisms not possessing the phenotype. . . . (italics in original).

In addition, the specification notes:

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a DNA II which includes a gene coding for a selectable phenotype associated with drug resistance, e.g., a mutant dihydrofolate reductase gene which renders cells resistant to methotrexate greatly extends the applicability of the process. (emphasis added).

In short, Roche's definitions are inconsistent with the rules of claim construction, "varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition." Zebco Corp., 175 F.3d at 991 (citations omitted). Here, a gene coding for a dominant selectable phenotype is also referred to as a gene coding for a selectable phenotype. The word dominant cannot impose a limitation, but rather, must demonstrate the breadth of the term, i.e., genes coding for a dominant selectable phenotype, such as a mutant DHFR gene, can also code for a selectable phenotype.

Reading the specification in its entirety, several things are clear: (a) When discussing the claims of the '216 patent generally, the specification uniformly discusses eucaryotic host cells without regard to whether they are in mutant or wild form. Indeed, the language suggests that the patentees intended to include the broadest possible range of host cells permitted by the term eucaryotic cell, without differentiating between the various claims of the patent. (b) There is simply nothing in the specification which suggests that the patentees intended eucaryotic cells to mean anything other than its ordinary definition. (c) Nor is there any support for Roche's attempt to limit the meaning of eucaryotic host cells by use of the term dominant selectable phenotype. The patentees clearly did not define selectable phenotype with reference to the type of host cell, and there is no reason to think the patentees would have defined dominant selectable phenotype in that manner either.

For all these reasons, the language of the specification favors Columbia's proposed claim construction.

3. The Experiments Described in the Patents

Roche's argument with respect to the descriptions of the experiments repeats the same themes:

There are a total of five series of experiments in the '216 patent. In four out of those 5 . . ., there is transfer of foreign DNA (the TK gene) into a mutant cell line . . . This foreign DNA is never referred to as a dominant acting marker or encoding a dominant acting marker or encoding a dominant selectable phenotype. It is always referred to as a selectable marker or encoding a selectable phenotype. In stark contrast, in the remaining series of experiments . . . where the co-transformation of wild-type, non-mutant cells is described, the foreign gene responsible for encoding a selectable phenotype 27 is referred to as a dominant acting gene.

Once again, the consistent use of the term "dominant" with cotransformation using wild-type cells can just as easily be explained by its consistent association with an amplifiable gene, which Columbia emphasizes. The TK gene, or gene for thymidine kinase, which is the gene used in the four experiments where the term dominant is not used, is not an amplifiable gene. The remaining series of experiments, which did use the term dominant, used a mutant DHFR gene, which is an amplifiable gene. However, there is additional language in this section which favors Columbia's interpretation.

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27 While attorney argument is certainly not evidence, I should note for the record that counsel for Roche has argued that the "dominant-acting" gene mentioned in the experiments using wild-type cells encoded for only a "selectable phenotype." Under Roche's definition of the term, however, a dominant-acting gene could never code for a "selectable phenotype" because selectable phenotypes may be used with mutant host cells (unlike dominant selectable phenotypes). Roche's counsel actually makes this error twice in the section of its brief discussing the experiments.

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In the section entitled "THE dhfr GENE AS A GENERALIZED TRANSFORMATION VECTOR," the mutant DHFR gene (which Roche argues is a dominant acting gene, or marker, rather than a selectable marker like the TK gene) is twice referred to as merely "selectable":

The generality of this approach was tested for the selectable marker, the mutant dhfr gene.

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An alternate approach to generalized transformation involves ligation of a nonselectable DNA sequence to a selectable gene. Since the muant [sic] dhfr gene is a dominant acting drug resistance [sic] factor, this gene is an ideal vector. (emphasis added).

There simply is no way to reconcile this language with Roche's proposed claim construction that the term dominant, unlike the term selectable, must go hand in hand with wild-type cells (and consequently, never mutant cells). In short, "dominant-acting gene" and "selectable gene" are used interchangeably.

There are additional passages in this section of the patent which suggest that the term dominant does not impose any limitation on the type of host cells that may be used in cotransformation:

Furthermore, the use of dominant acting mutant genes which can confer drug resistance will extend the host range for cotransformation to virtually any cultured cell.

In this way it is possible to transfer and amplify virtually any genetic element in cultured mammalian cells.

Nevertheless, it appears that the mutant dhfr gene can be used as a vector for the introduction and amplification of defined DNA sequences into cultured animal cells.

The use of this gene as a vector in cotransformation systems may now permit the introduction of virtually any genetic element into a host of new cellular environments.

None of these selections even hint of a limitation on using dominant selectable phenotypes with wild-type host cells.

Finally, at two points in the specification, the patentees stress that the experiments should be taken as examples only, and not as limitations on the broader claim language. The first is one which I mentioned with respect to the scope of the eucaryotic cell, where the patentees clearly state, "although the experiments discussed hereinafter concern cultured eucaryotic cells of mammalian origin such as . . . , it is clear that the process described is generally applicable to all eucaryotic cells . . ." The second occasion references experiments using mouse fibroblast cells:

Cotransformation in accordance with this invention may be carried out in any suitable medium limited only in that cotransformed cells be capable of survival and/or identification on the medium. Merely by way of example, a suitable medium for mouse fibroblast cells which acquired the thymidine kinase gene in HAT is described more fully hereinafter. (emphasis added).

The experiments were not meant to provide limitations on the broader language used in the claims.

4. The Inventors' Publications

Roche makes a similar argument with respect to two of the inventor's publications, both of which are incorporated by reference into the patent. Roche begins by noting that the gene coding for TK, or thymidine kinase, is never associated with the term dominant, and in fact, on one occasion, is referred to as a recessive marker -- requiring that it be used with mutant host cells. Still it acknowledges that the unlinked cotransformation claims using selectable phenotypes cover processes using both mutant and wild-type host cells.

And in the very same article referring to these markers as recessive, in fact, in the very next sentence, the inventors make clear that dominant markers are capable of using, but not restricted to using, non-mutant host cells:

The ability to transfer dominant-markers is not restricted to specific mutant cells and would greatly extend the usefulness of the transformation technology.

(emphasis added). Nothing in this article suggests any reason to limit dominant-markers to cotransformation processes using only wild-type cells.

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In the other article to which Roche appeals, a similar sentence follows the one quoted by Roche:

> The use of such dominant acting mutant genes which confer drug resistance may extend the host range for co-transformation to virtually any cultured cell.

While these articles might provide some support for a position that neither party adopts (that selectable markers must only be used with mutant cells), they certainly provide no support for the position that dominant genes or dominant markers must only be used with wild-type host cells.

5. Prosecution History and Prior Art

Roche's final attempt to bolster the evidence in support of its claim construction looks to the prosecution history and prior art arguing that (1) the term dominant selectable phenotype was needed to overcome a prior art objection by the Patent and Trademark Office, and (2) that Columbia's proposed interpretation of dominant selectable phenotype would render some of the claims invalid in view of the prior art.

Roche argues that the patentees were able to overcome the Patent and Trademark Office's objection based on prior art by Willecke, et. al., by pointing to the use of a dominant selectable phenotype. This is simply unsupported by the prosecution history. The objection based on Willecke, et. al. reads in its entirety:

> Willecke et al [sic] teach the cotransfer of two linked genes into cultured mouse cells using one gene coding for a selectable trait and producing proteins from each gene.

The patentees' full response reads:

> Willecke et [sic] al. teach the cotransfer in eucaryotic cells of a segment of chromosomal DNA from human lymphoblastoid cells which contains two linked human genes. Willecke et [sic] al. do not teach or suggest transforming eucaryotic cells with a DNA molecule that is formed by linking a foreign DNAI molecule, containing a gene encoding a protein, to a DNAII molecule which corresponds to an amplifiable gene for a dominant selectable phenotype which is not expressed by the eucaryotic cell, as in applicants claim 153. Furthermore, Willecke et [sic] al. do not teach or suggest culturing elevated concentrations of an agent permitting identification of eucaryotic cells which have acquired multiple copies of the amplifiable gene and thereby multiple copies of foreign DNAI, as in applicants' claim 153. Willecke et [sic] al. do not teach or suggest the use of a DNA II which encodes an amplifiable gene for a dominant selectable phenotype as a means of identifying eucaryotic cells which have been amplified to contain multiple copies of a foreign DNAI.

The patentees raise numerous distinctions other than the use of the term "dominant selectable phenotype": (1) the prior art did not link the two genes, (2) the prior art did not use an amplifiable gene for a dominant selectable phenotype, (3) the prior art did not involve culturing the transformed cells in successively elevated concentrations of an agent that permits the selection of cells which have acquired multiple copies of both the amplifiable gene and the DNAI, and, somewhat related, (4) the prior art did not use an amplifiable gene for a dominant selectable phenotype as a means of identifying eucaryotic cells which have been amplified to contain multiple copies of a foreign DNAI. Again, while the term dominant selectable phenotype appears in the patentees' response to the objection, it never appears apart from the term amplifiable gene.

More significantly, there is a conspicuous absence of any reference to either wild-type host cells in the Axel invention, or mutant host cells in the prior art. In fact, the prior art is described by the patentees in their objection as involving eucaryotic cells, generally. Roche's prosecution history argument is simply without merit.

Roche's final argument is an invalidity argument based on the prior art. Roche relies on Webb's expert report to argue that the claims in question would be invalid if the term dominant selectable phenotype were defined without regard to the phenotypic background of the host cell. In support of this position, Webb identified prior art by Kraiselburd and colleagues which he reports involved the transformation of TK- (mutant) cells with the gene for TK that resulted in multiple copies of the TK gene and other genetic information, when using the "kinetics of hybridization between radioactively tagged HSV DNA and cellular DNA isolated from TK+ transformants." Though the specifics of the prior art by Kraiselburd are difficult to glean from the scant information provided by Webb, it is clear that (1) Kraiselburd did not utilize an amplifiable gene, and (2) the multiple copies of the genetic information were not the result of using an amplifiable gene which increases its

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copy number upon exposure to successively elevated concentrations of an agent permitting survival or identification of those cells which have acquired multiple copies of the amplifiable gene. This argument is also without merit.

After a thorough review of the arguments made by both sides, and an extensive examination of the intrinsic evidence, I conclude that Columbia's position (which links dominant selectable phenotype to the use of an amplifiable gene) is the most proper way to define the term, and that Roche's proposed construction is unsupported by the intrinsic evidence, including the prosecution history. The Court's definition of the term appears in the claim construction chart appearing at the close of this opinion. 28

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28 While the Court feels that reliance on the extrinsic evidence presented is not necessary to define the term at issue, I note that nothing in that testimony would alter the conclusion or even cast doubt upon the Court's conclusion. The testimony of Webb and Weinberg was not only inconsistent vis-a-vis each other, but was inconsistent with both parties' proposed claim construction. Moreover, each recognized that scientists' understanding of the terms at issue were not uniform. Given that ambiguity, strict adherence to the intrinsic evidence would have been even more appropriate.

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* * *

III. CLAIM CONSTRUCTION CHART ADOPTED BY THE COURT DEFINING DISPUTED CLAIM LANGUAGE

TERM	COURT'S CONSTRUCTION
* * *	
Selectable Phenotype	A phenotype which confers upon an organism or a cell the ability to exist under conditions which kill off all organisms or cells not possessing the phenotype. Examples include drug resistance or the ability to synthesize some molecule necessary to cell metabolism in a given growth medium. Selectable phenotypes also include identifiable phenotypes such as the production of materials which pass from or are secreted by the cell and can be detected as new phenotypes either by functional, immunologic or biochemical assays

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I. Background

Ecolochem combined the Houghton process with an ion exchange resin to remove excess hydrazine and carbon contaminants and was awarded two patents based on this invention, the '492 patent and the '411 patent (a continuation of the '492 patent application). As prior art, the examiner cited references to applications of the Houghton process and the known

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use of hydrazine to deoxygenate liquid. In addition, with respect to the '411 patent, the examiner cited references, including Akol'zin, that teach the use of filters and ion exchange resins to remove liquid contaminants. Claim 1 of the '492 patent reads:

1. a deoxygenation process comprising a first step of adding hydrazine to a liquid containing dissolved oxygen, a second step of passing said liquid through a bed of activated carbon to catalyze a reaction between said dissolved oxygen and said hydrazine whereby an amount of dissolved carbon contaminants are added to said liquid, and a third step of passing said liquid through an ion exchange resin selected from the group consisting of mixed bed resin and cation resin to remove at least said dissolved contaminants.

(Claims 2, 5, and 6 are dependent on independent claim 1; claim 7 is dependent on claim 6; claim 10 is dependent on claim 9 which is dependent on independent claim 8.) Claim 1 recites three basic steps: 1) adding hydrazine to a liquid containing dissolved oxygen, 2) catalyzing the reaction between the dissolved oxygen and the hydrazine using activated carbon, and 3) removing dissolved carbon contaminants with an ion exchange resin. Claim 2 adds a filtration step to remove undissolved carbon contaminants; claim 5 recites the additional removal of unreacted hydrazine through the ion exchange resin; claim 6 limits the liquid of claim 1 to water; claim 8 is similar to claim 1 but requires the removal of excess hydrazine in the third step, not the dissolved carbon contaminants; and claims 7 and 10 add a final step of circulating the deoxygenated water at elevated temperature conditions in a power generating apparatus. Claim 20 of the '411 patent is similar to claim 1 of the '492 patent but omits the first step of the process, taking into account that hydrazine may already be present, and claims the removal of dissolved carbon contaminants with both cation and anion exchange resins in series. On Southern California Edison Co.'s (Edison) motion for summary judgment, the district court found that claims 1, 2, 5 and 6 of the '492 patent are anticipated by Demmitt, a reference not considered by the examiner during prosection of the application leading to the issuance of the patents in suit, and held that, in light of Demmitt, claims 7 and 10 of the '492 patent and claim 20 of the '411 patent are obvious under 35 U.S.C. § 103. 1 Ecolochem appeals from the judgment based on these findings and conclusions which it challenges.

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1 Claims 8 and 9 of the '492 patent and claim 21 of the '411 patent were also held anticipated, but these findings are not being appealed.

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II. Standard of Review

We review the district court's grant of summary judgment de novo, resolving all doubts respecting the presence or absence of genuine factual issues in the nonmovant's favor. Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 619, 34 U.S.P.Q.2D (BNA) 1816, 1819 (Fed. Cir. 1995). Proper claim construction is a question of law which we review de novo. Markman v. Westview Instruments, Inc. 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995) (in banc), aff'd, 116 S. Ct. 1384 (1996).

III. Anticipation

It is undisputed that the Demmitt reference discloses an application of the Houghton process followed by the use of a cation exchange resin to remove hydrazine from the liquid. The reference does not disclose that carbon contaminants are added to the liquid by the Houghton process, nor does it indicate the desirability of removing those dissolved carbon contaminants. By its very nature, however, the cation resin removes cationic dissolved carbon contaminants. Furthermore, it is agreed by the parties that most, if not all, carbon sources used in the Houghton process would leach anionic as well as cationic contaminants. Since anticipation is shown where each and every limitation of the claimed invention is found in a single prior art reference, In re Donohue, 766 F.2d 531, 534, 226 U.S.P.Q. (BNA) 619, 621 (Fed. Cir. 1985), Demmitt anticipates claim 1 if that claim requires only the removal of dissolved cationic carbon contaminants, rather than all of the dissolved carbon contaminants, both cationic and anionic.

A claim is construed by looking at the language of the claim, other claims in the patent, the specification and, where in evidence, the prosecution history. Markman, 52 F.3d at 979, 34 U.S.P.Q.2D (BNA) at 1329. Claim 1 recites a "deoxygenation process comprising a first step of adding hydrazine . . . a second step . . . [where] carbon contaminants are added . . . and a third step of passing said liquid through an ion exchange resin selected from the group consisting of mixed

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bed resin and cation resin to remove at least said dissolved contaminants." Ecolochem argues that it is clear from the language of the claim itself, the specification, and the prosecution history of the patent that claim 1 recites a process including a limitation that all dissolved carbon contaminants are to be removed by the ion exchange resin.

Analyzing the language of the claim, we observe that step three of claim 1 is written in the alternative using the Markush format. By claiming a Markush group, Ecolochem has indicated that, for the purpose of claim validity, the members of the claimed group are functionally equivalent. Thus, if utilizing one element of the group is anticipated or obvious, the patentee is precluded from arguing that the claim is valid. See In re Skoll, 523 F.2d 1392, 1397, 187 U.S.P.Q. (BNA) 481, 484-85 (CCPA 1975). Accordingly, if either alternative in the Markush group of step three, i.e., employing a cation resin or a mixed bed resin, is anticipated, the entire claim is anticipated.

Demmitt clearly discloses the use of the Houghton process on oxygenated water followed by use of a cation exchange resin. As discussed above, Demmitt meets all the limitations of one of the claimed alternatives in claim 1 of the '492 patent (i.e., using a cation exchange resin to remove dissolved contaminants). Accordingly, it would appear that claim 1 is anticipated by Demmitt.

Ecolochem argues, however, that, despite the recitation of a cation exchange resin as an element of the Markush group, there is a limitation in the claim requiring that all dissolved carbon contaminants be removed. This result can be accomplished, Ecolochem claims, by the use of a mixed bed resin or by the use of a cation resin in combination with an anion resin, and since claim 1 is written using the open-ended term "comprising," the claim should be construed to include the use of additional elements, i.e., addition of an anion resin to follow the cation resin of the second alternative. Placement of "comprising" before recitation of steps, however, results in a "comprising" claim that would cover a process that includes additional steps, not one that uses an additional unrecited element for accomplishing a claimed step. See Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271, 229 U.S.P.Q. (BNA) 805, 812 (Fed. Cir. 1986), cert. denied, 479 U.S. 1030, 93 L. Ed. 2d 829, 107 S. Ct. 875 (1987) ("While a transitional term such as 'comprising' or, as in the present case, 'which comprises,' does not exclude additional unrecited . . . steps . . . we conclude that the transitional phrase does not . . . affect the scope of the particular structure recited within the method claim's steps.") Thus, all the claim requires, in step three, is that either a mixed bed resin or a cation exchange resin be used exclusively to achieve the stated goal of removing dissolved carbon contaminants added in step two. In sum, a patentee may not import additional limitations into the steps of a process claim merely by using the word "comprising" in the claim preamble. Accordingly, claim 1 is anticipated by Demmitt. 2

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2 The dissent asserts that "anticipation requires that the patented invention was previously known and is described in a single reference." Dissent at 1. The test for anticipation, however, is not a literal word for word comparison between the prior art and the commercial embodiment of the patentee's invention; the test is whether "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1570, 7 U.S.P.Q.2D (BNA) 1057, 1064 (Fed. Cir. 1988) (emphasis added); Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1554, 33 U.S.P.Q.2D (BNA) 1496, 1498 (Fed. Cir. 1995) ("the claimed process, including each step thereof, must have been described or embodied, either expressly or inherently, in a single reference.") (Newman, J.) (emphasis added); Standard Havens Prods., Inc. v. Gencor Indus., Inc.,953 F.2d 1360, 1369, 21 U.S.P.Q.2D (BNA) 1321, 1328 (Fed. Cir. 1991) ("An anticipation reference, however, need not duplicate word for word what is in the claims. Anticipation can occur when a claimed limitation is 'inherent' or otherwise implicit in the relevant reference."). As previously discussed, the cation exchange resin disclosed by Demmitt would inherently remove cationic dissolved contaminants, and the claim, as written, requires no more than the removal of those cationic dissolved contaminants.

Although there is support in the '492 patent specification for a claim that would require the removal of all dissolved contaminants, including anionic contaminants, the applicant did not draft such a claim for the '492 patent. In fact, he did with claim 20 of the '411 patent. See discussion on obviousness infra. Although we construe limitations narrowly to save the validity of patents, we are precluded from rewriting the patent claim to include unclaimed limitations even where the specification contains adequate support thereof. See, e.g., Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 n.6, 17 U.S.P.Q.2D (BNA) 1097, 1102 n.6 (Fed. Cir. 1990) ("Nothing in any precedent permits judicial redrafting of claims.").

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Because Demmitt clearly discloses the use of water as the liquid to deoxygenate and that the cation exchange resin can be used to remove excess hydrazine, claims 5 and 6 of the '492 patent are anticipated by Demmitt as well. It is unclear why claim 2, which also calls for the removal of undissolved contaminants, was found to be anticipated by Demmitt. In any event, because Ecolochem fails to distinguish claim 2 from claim 1 for purposes of anticipation, we also affirm the finding on summary judgment that, on the undisputed facts, Demmitt anticipates claim 2. 3

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3 The dissent states that Ecolochem distinguishes claim 2 from claim 1 of the '492 patent for purposes of anticipation by stating that "'claim 2 requires the presence of a fourth filtration step to remove undissolved active carbon contaminants.'" Dissent at 2 (emphasis in original). This statement was made in the background section of Ecolochem's brief for the purpose of listing the claims in suit. In the argument section of its brief, however, Ecolochem asserts that "the anticipation issues center on the interpretation of claim 1 of the '492 patent" and does not distinguish claim 2 as being patentably distinct from claim 1.

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A. Markush Groups

Plaintiff Green Edge acknowledges that the patent contains three "Markush groups" in the '514 patent using the phrase "consisting of." These groups are:

1. "rubber selected from the group consisting of natural polymers and synthetic high polymers;"

2. which looks like natural mulch "selected from the group consisting of pea gravel, wood chips, and tree bark;" and

3. "rubber particles are preferably selected from the group consisting of waste rubber buffings and ground tires."

"A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1280 (Fed. Cir. 2003). Further, "[i]t is well known that 'members of the Markush group are … alternatively usable for the purposes of the invention.'" Id. (quoting In re Driscoll, 562 F.2d 1245, 1249 (CCPA 1977)). "Proper claim drafting requires the Markush group to be closed; therefore, the group must be characterized with the transitional phrase 'consisting of' rather than 'comprising' or 'including.'" Maxma v. ConocoPhillips, Inc., 2005 U.S. Dist. LEXIS 34020, 2005 WL 1690611 at *5 (E.D. Tex. July 19, 2005) (citation omitted). Therefore, "members of the Markush group are used singly." Abbott Labs., 334 F.3d at 1281 (quotation omitted). Moreover, "the transitional phrase 'consisting of' closes the group of alternatives, not the claim." Maxma, 2005 U.S. Dist. LEXIS 34020, 2005 WL 1690611 at *5 (emphasis in original). In Abbot Labs., the Federal Circuit held:

If a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim . . . Thus, without expressly indicating the selection of multiple members of a Markush grouping, a patentee does not claim anything other than the plain reading of the closed claim language.

334 F.3d at 1281.

Plaintiff Green Edge maintains that the members contained in the Markush groups are not mutually exclusive, allowing Green Edge to select more than one alternative. Defendants, on the other hand, assert that the plain meaning of the Markush groups contained in the '514 patent limits the Markush claim element to only one of the group's members because the claim does not include qualifying language expanding the nature of the group.

The undersigned agrees with the Defendants that the Markush groups are closed and that they do not contain any qualifying language which would allow mixtures or combinations. Indeed, the unpublished cases cited by Green Edge do not hold

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otherwise. Both Maxma v. ConocoPhillips, Inc., No. Civ. A. 2:03CV421, 2005 U.S. Dist. LEXIS 34020, 2005 WL 1690611 (E.D. Tex. July 19, 2005) and Dow Agrosciences LLC v. Crompton Corp., No. 1:03-CV-0654-SEB-JPG, 2004 U.S. Dist. LEXIS 8532, 2004 WL 1087362 (S.D. Ind. May 12, 2004) relied on the Abbott Labs. case in construing the Markush groups. The Maxma court noted that a Markush group closes the group of alternatives, not the claim. Maxma, 2005 U.S. Dist. LEXIS 34020, 2005 WL 1690611 at *5. Thus, the court held that, because the claim was open-ended, the presence of any of the alternatives in the Markush group satisfies the claim limitation "even if other structures or ingredients are also present." Id. The Maxma court further cited Abbott Labs. with approval, stating:

Abbott Laboratories is not to the contrary. The Markush group in that case required the presence of an "amount effective of a Lewis acid inhibitor selected from a group. Abbott Laboratories, 334 F.3d at 1276. The patentee attempted to prove infringement by combining two Lewis acid inhibitors to prove that the combination of those substances in the accused product was an "amount effective." Id. at 1282-1283. The Federal Circuit noted, however, that the Markush group at issue did not permit mixtures of the individual members of the group. Id. at 1283. Therefore, the court concluded that the patentee, to prove literal infringement, would need to show that only one member of the group was present in an "amount effective" to meet the claim limitation. Id. at 1282. "Thus, the plain meaning of asserted claims 1 and 6 limits them to a single Lewis acid inhibitor selected from the recited Markush group, and present in an amount effective to prevent degradation of sevoflurane by Lewis acids." Id. at 1281. Abbott Laboratories did not hold that the presence of any Lewis acid inhibitor, together with an "amount effective" of a listed Lewis acid inhibitor, would defeat a claim of literal infringement.

Maxma, 2005 U.S. Dist. LEXIS 34020, 2005 WL 1690611 at *5 (quoting Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274 (Fed. Cir. 2003)).

Similarly, the court in Dow Agrosciences relied on Abbott Labs. to set forth the legal standards for Markush groups. Dow Agrosciences LLC v. Crompton Corp., No. 1:03-CV-0654-SEB-JPG, 2004 U.S. Dist. LEXIS 8532, 2004 WL 1087362 at *7 (S.D. Ind. May 12, 2004). Specifically, the Dow Agrosciences court noted that "[i]f a patentee desires to use or to combine multiple members of the Markush group, then he or she must add qualifying language to the claim." Id. (citing Abbott Labs. v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1281 (Fed. Cir. 2003)). In Dow Agrosciences, the patentee used the language "contains at least one substituent chosen from the group consisting of." Id. The court held that this qualifying language "modifies the word substituent, allowing the patentee to select more than one substituent from among the Markush group." Id.

Patent '514, however, contains no such qualifying language. Claims 1(a) and 8(a) contain the language "with the rubber selected from the group consisting of natural polymers and synthetic high polymers." Claim 1(a) also contains the language "with said rubber particles having an outer surface designed and dimensioned to look like natural mulch selected from the group consisting of pea gravel, wood chips, and tree bark . . ." The language of Claims 2 and 6 reads, "said rubber particles are preferably selected from the group consisting of waste rubber buffings and ground tires." (Pl. Exh. 1) (emphasis added). Like the patent in Abbott Labs., "the claims do not clearly embrace more than one member of the Markush group." Abbott Labs., 334 F.3d at 1281. Therefore, the plain meaning of the claims asserted in 1, 2, 6 and 8 "limits them to a single [alternative] selected from the recited Markush group." Id.
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5. "Selected Technique"

GTG proposes the construction "any analytical method chosen to detect haplotypic patterns," while Applera proposes "a method that produces patterns of DNA fragments that have been separated according to mobility and visualized, meaning RFLP analysis, primer defined length polymorphism and allele- and haplotype-specific amplification analysis."

The court adopts GTG's proposed construction. As previously discussed in the context of the term "haplotypic patterns," the prosecution history does not support Applera's interpretation of the claim as limiting the patent to two specific analytic methods. The term "selected technique" is construed as: any analytical method chosen to detect haplotypic patterns.
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Scantibodies argues that it is likely to succeed on the merits of its appeal because, inter alia, the district court erred in adding a claim limitation to claim 17 of Nichols' patent that the antibody must distinguish between biologically active hPTH and biologically inactive hPTH. Scantibodies argues that while claims 1 and 9 refer to active hPTH, claim 17 does not and that by adding such a limitation the district court improperly determined that the patent was not invalid as anticipated by the 1994 abstract. Nichols responds that the district court properly construed claim 17 to distinguish between biologically active and inactive hPTH.
We determine that Scantibodies has shown in the motion papers that the district court likely erred by interpreting claim 17 as distinguishing between biologically active and inactive hPTH. As Scantibodies points out, while certain claims of Nichols' patent expressly refer to active hPTH, claim 17 does not. * Without prejudicing the ultimate disposition of this case by the merits panel, we determine that Scantibodies has shown the requisite likelihood of success to obtain a stay of the injunction pending appeal.

* Claim 17 reads: "A composition comprising an antibody or antibody fragment and a suitable carrier, wherein the antibody or antibody fragment selectively binds a peptide of human parathyroid hormone (hPTH) selected from the group consisting of peptides having SEQ. ID. Nos. 1-6." In contrast, claim 1 reads: "A kit for detecting active human parathyroid hormone . . ." (emphasis added).
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a. "separating"

First, the parties dispute whether or not the term "separating" should be defined. (Joint Stmt. p. 12). Plaintiff asserts that no definition is needed. Alternatively, Plaintiff would accept the ordinary meaning of "separating" to mean "to isolate from a mixture, to divide into constituent parts." (Joint Stmt. p. 12 (quoting from Webster's Dictionary)). Defendants argues that a definition is needed and would accept Plaintiff's proposed definition. Since this particular patent, as is the other two patents, involve processes used to separate the components of beet molasses, the court finds it helpful to provide a definition of the term "separating" to the jury. Both parties agree to the dictionary definition of the term, and the court adopts this proposed instruction.
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2. The Term "Separating Layer"

Andrx argues that the terms "subcoating" and "separating layer" are used interchangeably throughout the '505, '230 and '281 patents, so that both terms should be accorded the same definition throughout. (See Andrx Cl. Constr. Mem. of 11/5/01, at 22.) In fact, the terms "subcoating" and "separating layer" are not used interchangeably in the '505 and '230 patents. The court has analyzed the ordinary meaning of the terms "subcoating" and "separating layer" in detail in the context of construing the term "subcoating" as used in the claims of the '505 and '230 patents. See Omeprazole I, at 464-68. The court defined the term "subcoating" to mean "a layer that is physically on and conforms to the contours of a core and is underneath another layer--the enteric coating." Id. at 464. The court also found that the specifications of the '505 and '230 patents make clear that the subcoating required by the claims of the '505 and '230 patent is a type of separating layer, as that term is used in the specifications of the '505 and '230 patents. Id. at 465. Thus, the subcoating required by the claims of the '505 and '230 patents is a species of the more generic term "separating layer" as used in the '505 and '230 patents, id., and the terms "subcoating" and "separating layer" do not have the same definition in the '505 and '230 patents.

Like its use in the '505 and '230 patents, the term "separating layer" as used in the '281 patent is a generic term, which includes different species like subcoatings and capsules. As the '281 patent explains, there are different kinds of separating layers:

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The discoloration can be avoided by applying some type of separating layer between the core material ….

Thus, there are a lot of patent applications describing such a separating layer between a core material comprising the pharmaceutically active substance and an enteric coating layer. See for instance, U.S. Pat. No. 4,786, 505 ….

(P3, col. 5:18-25 (emphasis added).) The '505 patent identifies gelatin capsules as one kind of separating layer and subcoatings as another. See Omeprazole I, at 465-66. (See also Pl, col. 4:8-11.) The difference then, is not the definition that the patents ascribe to the term "separating layer," which has the same meaning in all three patents. Rather, the difference is in the choice of claim language. The '505 and '230 patents claim only the species of separating layer that is a subcoating, while the '281 patent contains broader claim language that covers not only subcoatings but all species of separating layers. 3

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3 Defendant Andrx argues that the '281 patent specifically adopts for the term "separating layer" the same meaning ascribed to the term "subcoating" in the '505 and '230 patents. (See Andrx Cl. Constr. Reply Mem. of 11/13/01, at 9-10.) The court is unpersuaded by this argument. The inventors of the '281 patent did not define the term "separating layer" in the '281 patent to have the same meaning as the term "subcoating" in the '505 and '230 patents. The language in the '281 patent abstract and specification pointed to by Andrx in support of this argument (see id.) is far from a definition rendered by inventors acting as their own lexicographers. Since the patentees have not "clearly and explicitly defined the claim term" "separating layer" to have a meaning equivalent to that of the term "subcoating" as used in the '505 and '230 patents, the court rejects Andrx's argument and defines the term in accordance with "the ordinary meaning of claim language as understood by one of ordinary skill in the art." Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001) (quotations omitted).

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Like the definition Andrx proposed for the term "subcoating" in the claims of the '505 and '230 patents, the definition Andrx proposes for the term "separating layer" in the claims of the '281 patent would impose numerous additional requirements on the separating layer that are not stated in the claims. See Omeprazole I, at 470-71. For example, Andrx's construction of the term "separating layer" would require that the layer be continuous so that the core and the enteric coat do not come into contact with each other. (See Andrx Cl. Constr. Mem. of 11/5/01, at 21-22; Andrx Cl. Constr. Reply Mem. of 11/12/01, at 8.) Andrx argues that if the separating layer is not continuous, then it cannot perform its intended function, which is to keep the omeprazole in the core from coming into contact with the enteric coating. (Andrx Cl. Constr. Mem. of 11/5/01, at 22.) The court has already decided that, as understood by a person of ordinary skill, a "sub-coating" need not exhibit these qualities that are not stated in the claims. See Omeprazole I, at 539-40. Similarly, the "separating layer" of the '281 patent, as understood by those of ordinary skill, may have imperfections.

Andrx also argues that evidence presented during Phase II of the trial demonstrated that the "separating layer" claimed by the '281 patent cannot contain that which it is "separating." (See Andrx Updated Proposed Findings of 5/30/03, at 5.) However, it is clear that the separating layer required by the claims of the '281 patent can contain components other than the enteric-coating polymer salt product itself. For instance, Example 1 of the '281 patent, which is one of the preferred embodiments of the invention and has the highest concentration of ARC in any exemplified core, employs an enteric-coating layer that contains HPMCAS as well as triethylcitrate, sodium laurylsulphate and talc. (P3, col. 8:65 - col. 9:51.) Persons skilled in the art would understand that each of those components are also present in the in situ layer generated by the claimed process, as well as in the enteric-coating layer. See Dow Chemical Co. v. Sumitomo Chemical Co., 257 F.3d 1364, 1378 (Fed. Cir. 2001) ("It is unlikely that an inventor would define the invention in a way that excludes the preferred embodiment, or that persons of skill in this field would read the specification in such a way."). The court cannot ignore this preferred embodiment when construing the term "separating layer;" therefore, the court finds that Andrx's proposed construction cannot be adopted. See id. ("It is axiomatic that claims, not the specification embodiments, define the scope of the protection … However, it is also well established that a claim construction that excludes a preferred embodiment is rarely, if ever, correct.") (internal quotations and citations omitted); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996).

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"Regulatory Sequence"

The district court construed "regulatory sequence" in the first occurrence to mean "any and all sequences required for gene expression of the human alpha-galactosidase A gene, consisting of at least one sequence which promotes gene expression." Column 14, ll. 9-14, of the '804 patent discloses several examples of regulatory sequences that are appropriate expression control elements. While the specification teaches a process requiring one or more of these elements to transform cells with alpha-Gal A DNA, it does not teach that all of them are required. The district court erred in this regard, but the error is harmless in view of the trial court's proper construction of the claim term "chromosomally integrated."
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2. "Sequentially Adding."

The "preamble clauses" of claim 20 make clear that the claimed process for accelerating the hardening of hydraulic cement mixes involves, first, the "sequential adding" of cement, aggregate, and water. The "admixture clause" of claim 20 then recites "incorporating" an admixture into the cement mix, without reciting when in the overall mixing process the admixture should be added. MBT asserts that the phrase "sequentially adding" should take its ordinary meaning, and needs no special construction by the Court. Euclid asserts this phrase should be construed to mean adding the ingredients in a specific order: "hydraulic cement, followed by aggregate, followed by sufficient water to effect hydraulic setting of the cement." MBT responds that, while the ingredients must be added one after the other, the claim language does not insist on a particular order.

The Court concludes that MBT is correct. Neither the claim language itself nor the specification modify or define the term "sequentially adding," or indicate the term is used in a special manner. The Court, therefore, concludes that the term must be used in its ordinary and customary manner. Importantly, the claim language itself states that the patented process involves sequential adding of cement, aggregate, and water, and "incorporating" into this process an admixture. The claim language is silent as to when in the process the incorporation of the admixture must occur -- it could be, for example, before or after addition of the water. Given that there is no necessary order in the claimed process for incorporation of the admixture, an ordinary and straightforward reading of the term "sequentially adding" indicates there is no necessary order for combining the other ingredients, either. That is, the ordinary and customary meaning of the term "sequentially adding," as used in the context of the claim language, is that the ingredients be added one at a time; "sequentially adding" does not mean, as Euclid urges, "in the following sequence." The patent specification also supports this construction. While the specification does not provide any explicit discussion of the term "sequentially adding," it does state that the admixture may be added "before, after, or during addition of water." '194 patent at col. 2, line 67 ("summary of the invention"). That is, the admixture may be added either preceding or following another ingredient, but it is still being added sequentially. The patent does not claim any specific ordering of the ingredients in the process.

The Court's reading of the claim language is also supported by extrinsic evidence. It is true, as Euclid notes, that the dictionary definition of the word "sequence" means "a following of one thing after another." But this definition is ultimately unhelpful, because the claim language does not state the sequence must be a particular one, as opposed to "any sequence." And the experts who testified at the Markman hearing, as well as the treatises to which they point, made it very clear that a person of ordinary skill in the art would not understand that the concrete ingredients listed in the preamble clause of claim 20 must follow one another into the mixer only in the order listed. Rather, the ordinary and accustomed meaning of the claim language is merely that the ingredients are not added simultaneously. Further, this same extrinsic evidence makes clear that one of ordinary skill in the art would understand that "sequentially adding" hydraulic cement, aggregate, and water simply means these ingredients are not all added into the mixer at the same time. 8 Simultaneous adding of concrete ingredients into a mixer is rarely practiced "in the field," because doing so does not lead to accurate mixes or efficient mixing. Rather, cement, aggregate, and water are added one at a time. The order of adding is usually cement, then aggregate, then water, but this order is not "set in stone."

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8 Similarly, prior art cited in the '194 patent makes clear that a person skilled in the art would understand that cement admixtures can be incorporated in any number of ways: "The admixture … can be incorporated into the cementitious mixture as desired, e.g. during the grinding of the cement clinker at the cement plant, separately during mixing with aggregate, … together with one of the main ingredients of the wet cementitious mixture, … added to [the fine aggregate], … or mixed with a small part of the cement to produce a pre-packaged concentrated mixture …." Patent 3,536,507 at col. 4, lines 34-50.

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Put simply, Euclid's proposed construction of the term "sequentially adding" is different from that term's ordinary and accustomed meaning, which works perfectly well in the context of the claim language. This conclusion does not end the inquiry, however, because MBT's suggestion -- that is, that the phrase "sequentially adding" needs no special construction -- is likely to leave a jury confused. The meaning of "sequentially adding" ingredients may be clear to one skilled in the art, but, "in the end, claim construction must result in a phraseology that can be taught to a jury of lay people. It is not enough simply to construe the claims so that one skilled in the art will have a definitive meaning." Control Resources, Inc. v. Delta Electronics, Inc., 133 F. Supp. 2d 121, 127 (D. Mass. 2001); see MacNeill Engineering Co., Inc. v. Trisport, Ltd., 126 F. Supp. 2d 51, 56 (D. Mass. 2001), dismissed on appeal; 15 Fed. Appx. 835, 2001 U.S. App. LEXIS 17014, 2001 WL 838410 (Fed. Cir. 2001) ("The Court's "claim construction obligation … involves not only properly construing the claim language so that the litigants (for the most part skilled in the particular art) will understand it, but also teaching the chosen construction to the jury in language that will inform the jury in plain English the legal framework it must apply in order to do justice.").

The Court concludes that the term "sequentially adding" must be construed to remove any risk of ambiguity to the jury at the time of trial. Accordingly, the Court construes this term to mean "adding one after the other, but in no particular order." This construction ensures that the jury will not mistakenly believe that the ingredients recited in the claim language must be mixed together in a particular order.
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Claims 11 and 12 of the '275 patent protect:

11. An assay method for determining the presence of circulating parasite antigens of Dirofilaria immitis [heartworm] in the serum or plasma of D. immitis-infected dogs which comprises combining a sample of serum or plasma from a dog infected with Dirofilaria immitis and to which no parasite antigen or extract derived from D. immitis is added with a first monoclonal antibody which specifically binds to determinants present on said circulating parasite antigens, and detecting the presence of said antigens by means of a label on said first antibody or by means of a label on second antibody added to said first monoclonal antibody, said second antibody specifically binding to said circulating parasite antigens.

12. An assay method as set forth in claim 11 wherein said label is selected from the group consisting of radioactive labels, fluorescent compounds, enzymes, biotin and ferromagnetic labels.

CONFIRMATORY VS. DIAGNOSTIC TESTING

I summarily reject IDEXX's argument that claims 11 and 12 are devoted to confirmatory testing rather than to diagnostic testing. It is apparent from the claims and from the patent as a whole that the subject at issue is diagnosis. IDEXX's position on this issue is frivolous.

HOMOGENEOUS VS. HETEROGENEOUS ASSAY

Nothing in claims 11 and 12 limits their scope to a "homogeneous" test. IDEXX's expert, Dr. Hamilton, would like to interpret them as precluding a "heterogeneous" test (i.e., including a separate step such as IDEXX uses), but such a limitation is simply not supported by the patent. Dr. Hamilton's interpretation narrows the patented language and reads

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limitations into the patent that do not exist. There is no word or phrase in claim 11 or 12 that requires the test to be homogeneous, and IDEXX cannot avoid literal infringement by imposing limitations not present in the claim as patented. See E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433-34 (Fed. Cir.) ("'We know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not mentioned in the claim in order to limit such claim and avoid a defense or anticipation, we should never know where to stop.'") (quoting McCarty v. Lehigh Valley R.R. Co., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240 (1895)), cert. denied, 488 U.S. 986 (1988). IDEXX has pointed to no portion of the claim, specification, or file wrapper that demonstrates that the patent examiner awarded the patent only for homogeneous tests, and therefore has failed to create a genuine issue of material fact with respect to this issue.

"SPECIFICALLY BIND"

At an earlier stage, in seeking summary judgment on claims 7 through 14 for the line of SNAP(R) PF and PETCHEK(R) PF, IDEXX's Vice-President of Business Development (also its 30(b)(6) designee) stated by affidavit that "all of IDEXX's nine heartworm antigen diagnostic products" use ELISA technology by which "both the bound antibody and the labeled antibody specifically bind the antigen to be detected." Tonelli Aff. PP 10, 12 (emphasis added) (Docket Item 40). This affidavit is dispositive of IDEXX's new argument that Jewish Hospital has not provided evidence that the IDEXX antibodies "specifically bind." 2

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2 I therefore need not deal with IDEXX's experts' opinion that the tests do not specifically bind because they may also detect human virlarial antigens.

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WHOLE BLOOD VS. SERUM OR PLASMA

All of the IDEXX products in question except for SNAP(R) Whole Blood perform their tests on serum or plasma just as the specific requirement of claims 11 and 12 provides. I therefore GRANT summary judgment on literal infringement to Jewish Hospital on the CITE(R) SemiQuant, Cite(R) SemiQuant (revised), PETCHEK(R), PETCHEK(R) (revised), and SNAP(R) products. The issue remaining is whether the SNAP(R) Whole Blood test, which purports to conduct its test on whole blood rather than serum or plasma alone, also literally infringes claims 11 and 12.

The parties agree that serum and plasma are components of whole blood, and that heartworm antigens are found in serum and plasma. IDEXX maintains, however, that claims 11 and 12 are limited to tests on serum and plasma and do not cover tests that detect heartworm in whole blood. Indeed, the language of the claim speaks of "serum or plasma" (although part of the description talks about using blood or bodily fluid). IDEXX maintains that it made the first effective use of whole blood detection and that this novel method of detection resulted in its Patent No. 4,939,096 ('096). If effective, heartworm detection on whole blood would beneficially eliminate the serum/plasma extraction step. 3 Jewish Hospital, however, argues that IDEXX's '096 patent simply removes the red blood cells as part of the testing process so that in fact SNAP(R) Whole Blood's antigen testing is carried on in serum or plasma as Jewish Hospital's '275 patent describes.

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3 Although IDEXX concedes that its SNAP(R) Whole Blood test could work on either on serum or plasma or on whole blood samples, see Letter from IDEXX to Clerk of Court (Mar. 19, 1997) (Docket Item 193), Jewish Hospital has offered no evidence of any use of IDEXX's test on serum or plasma. Therefore, IDEXX is correct that Jewish Hospital does not argue that the IDEXX products are used on serum or plasma, but rather only notes that the products could be used that way. See id.; Jewish Hospital's Br. in Supp. Summ. J. at 8 n.6 (Docket Item 96). Consequently, I do not consider Jewish Hospital to be arguing that using the SNAP(R) Whole Blood test on serum and plasma infringes, but rather that the test's use on whole blood infringes.

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Because the '275 patent claim language includes only language about "serum or plasma," a test solely on whole blood, without first extracting serum or plasma, would not literally infringe. Jewish Hospital claims that SNAP(R) Whole Blood's test with whole blood is a distinction without a difference, however since the detection process requires that the serum or plasma be extracted from the whole blood as part of the process. The result, claims Jewish Hospital, is de facto infringement since the SNAP(R) Whole Blood test eventually detects heartworm "in the serum or plasma" as the claims describe. In support of its argument, Jewish Hospital offers the declaration of Dr. Kate Murashige, see Hospital's Reply Br., Ex. 3 P. 4 (Docket Item 195), which states that "assuming that the method set forth in ['096] is employed, it is apparent that the assay itself is conducted on plasma rather than whole blood." Dr. Murashige goes on to explain that '096 elaborates on how to separate the red blood cells from the whole blood, but concludes that "whole blood is always the starting material prior to its separation into the red blood cell and serum components. . . . It could not be more clear that the assay itself is being conducted on the . . . plasma." Id. P 5. IDEXX does not dispute that serum or plasma are extracted from the whole blood as part of the process, arguing only that starting with whole blood is a "distinction [that] is not immaterial," Opp. to Mot. for Summ. J. at 3 (Docket Item 188). Nor does IDEXX dispute Jewish Hospital's characterization of its process other than to assert that its '096 patent is proof of the novelty of the test. Therefore, I find that although the IDEXX test begins with whole blood, the de facto result is that its detection works on extracted serum or plasma. Consequently, the IDEXX test literally infringes claims 11 and 12, leaving IDEXX to rely on an affirmative defense to avoid summary judgment.
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6. "Serum Sample"

The parties agree that the term "serum sample" (claims 7, 8) refers to a component of blood, but they disagree about whether it includes dried samples. PerkinElmer and NTD argue that the word means "the clear fluid obtained from whole blood by removing blood cells, platelets, and fibrinogen." In contrast, Intema contends that it may refer to a component of a fluid or a dried blood sample. The specification refers to drawing a blood sample and refrigerating a "separated serum," which is consistent with either construction. '103 Patent Specification at 11:50-52.

Turning to extrinsic evidence, some technical dictionaries refer to serum as a "fluid" or "liquid." Physician's Desk Reference Medical Dictionary 1603 (1995) (document # 44-12); Dorland's Illustrated Medical Dictionary, supra, at 1512. However, at least one study cited by both parties refers to "serum" analyzed "from whole blood collected as a dried dot onto card." Hyett & Thilaganathan, supra, at 565. Moreover, Intema's expert states that scientists in the field would interpret "serum sample" to include dried blood, a common substitute for fluids. Second Canick Declaration P 32.

I adopt Intema's definition because the more specific extrinsic evidence suggests that individuals in the field understand "serum sample" to include dried blood.
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The final remaining dispute with respect to the '716 patent concerns the meaning of the term "set." Affymetrix contends that "set" means a collection or group. Hyseq contends that "set" has a particular meaning when used in reference to nucleic acid probes. Hyseq argues that "a set of probes" must include four probes which are coextensive. Consequently, Hyseq argues that "set of signals" indicating the extent of hybridization of the probes and reference nucleic acid sequence is the set of signals from the four probes. Hyseq further asserts that the probes used to obtain the "second set of signals" must be identical in length and sequence to the probes in the first set of signals.

The Court adopts the plain and ordinary meaning of the term, "set," as meaning a collection or group. Hyseq attempts to alter the plain meaning of this term by importing extraneous limitations from embodiments described in the specification. For the reasons already discussed, the Court rejects this approach.
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IV.

TorPharm advances several claim constructions that, if resolved in its favor, would provide an adequate and independent basis to affirm the summary judgment of non-infringement. Because these issues involve questions of law, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995) (in banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577 (1996), over which we exercise plenary review, see Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 46 U.S.P.Q.2D (BNA) 1169, 1171 (Fed. Cir. 1998) (in banc), and that were adequately developed before the district court, we will consider them, see Fireman's Fund, 909 F.2d at 499.

Claim 1 of the '431 patent recites "Form 2 ranitidine hydrochloride characterized by an infra-red spectrum as a mull in mineral oil showing the following main peaks: [table listing 29 frequencies]." (emphasis added). TorPharm argues that when "showing" and "main" are properly interpreted, there is no infringement. TorPharm contends that the word "main" should be interpreted to mean "chief in size, extent, or importance; principal; leading," quoting a dictionary definition. According to TorPharm, this definition is not only supported by the plain language but is also supported by the prosecution history. TorPharm argues that because the peaks of the Form 2 component of the accused product are overwhelmed by the predominant peaks of the Form 1 component in the overall spectrum, the 29 peaks of Form 2, even if present, could not be "main peaks." The problem with TorPharm's argument is that it fails to recognize that "main" is a relative term. In order to be "chief in size," the peaks must be measured relative to something. We think it is clear from the intrinsic record, including the prosecution history, that all the word "main" requires is that the peaks be "chief in size" relative to the baseline of the pure Form 2 compound. TorPharm's definition would require us to define "main" relative to the overall compound, which is not the subject of the claim.

TorPharm also contends that the word "showing" requires the 29 main peaks to be visually identifiable, again citing a dictionary definition, which defines "show" as "to cause or allow to be seen." We disagree. The word "show" is broader than that. All that "show" requires is that Glaxo demonstrate with an acceptable degree of certainty, visually or by other appropriate means of data display, that the accused product contains the 29 main peaks. The district court so held, and we agree. When the facts are construed in a light most favorable to Glaxo, Glaxo's calibration model does "show" that the accused product contains the 29 main peaks. Accordingly, we cannot affirm the grant of summary judgment on either of these alternative grounds.
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B. "Shows the Peaks"

The parties have taken considerable pains to define "shows the peaks," in part because of the Court's repeated inquiries. The parties' have, at various times, focused both on the phrase as a whole and on the individual words which comprise it. Because each of the individual words has received special attention from the parties, they will be addressed separately below.

1. "Shows"

According to Lupin, "shows" requires a graphical PXRD display, like the one found in Figure 1 of the '507 patent, that would render peaks visible to the human eye. (See Lupin Br. at 13.) Abbott and Astellas, on the other hand, argue that "shows" is not limited to the graphical display of a PXRD pattern and, instead, includes any data display that demonstrates the existence of peaks in PXRD pattern. (See Abbott and Astellas Response Br. at 15.) The '507 patent's specification confirms that the definition of "shows" offered by Abbott and Astellas is the most correct one.

To begin, the language of Claim 1 limits "shows" to some display of a "powder X-ray diffraction pattern." See '507 Patent col.16 ll.15-17. However, the patent's specification "shows" those PXRD patterns in two different ways. For example, the specification displays two charts which list the numerical values of PXRD angles and relative intensity figures that correspond to Crystal A. Id. col.12 ll.48-69, col.13 l.66-col.14 l.17. In those charts, the "powder X-ray diffraction pattern of . . . Crystal A was shown," even though no graphically-depicted peaks were visible. Id. col.12 l.49, col.13 l.67 (emphasis added). Such peaks are visible, however, in Figure 1, where Crystal A's peaks are also "shown" in a graphical display. Id. col. 1 ll.64-66. Thus, because the '507 patent's specification "shows" PXRD peaks in two different ways, the Court cannot

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justify construing "shows," as used in Claim 1, to require any single method of "showing." 15

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15 This reading of "shows" is fully consistent with the plain meaning of the word "show" as defined by Webster's Third New International Dictionary (2002). None of the many definitions of the word requires visibility to the eye alone.

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In Glaxo, Inc. v. TorPharm, Inc., 153 F.3d 1366 (Fed. Cir. 1998), the Federal Circuit addressed the meaning of the word "showing" in a somewhat similar factual situation. There, the court required that the relevant peaks be demonstrated to "an acceptable degree of certainty" either "visually or by other appropriate means of data display." Glaxo, 153 F.3d at 1374. Given the uses of "show" in the '507 patent's specification, the same definition can be adopted here. 16 Therefore, the Court holds that "shows" requires the display of a PXRD pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display.

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16 Glaxo involved an infrared spectrum, not PXRD, but the definition of "showing" used by the Federal Circuit in that case is appropriate on these facts as well. See Glaxo, 153 F.3d at 1374.

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II. Ward Patents
A. '767 and '824 Patents, Claim 1: "A comprises at least three carbon atoms and represents at least one component of a signalling moiety capable of producing a detectable signal" and "signalling moiety"

The '767 and '824 patents claim: "A method of detecting the presence or absence of a nucleic acid in sample which comprises the steps of (a) contacting under hybridizable conditions said sample with at least one compound comprising the structure [DIAGRAM] . . . wherein A comprises at least three carbon atoms and represents at least one component of a signalling moiety capable of producing a detectable signal. . . ." '824 Pat. 30:49 - 31:29. Plaintiffs construe this term such that A may constitute, in some instances, the whole signaling moiety (a chemical entity) capable of direct and indirect detection. See Expert Report of Richard Sinden, Def. Ex. 12, at 25 ("I understand the claims of the '824 and '767 Patents as requiring that the A moiety (i) have at least three carbon atoms and (ii) form one or more parts of a signalling moiety capable of producing a detectable signal.").

Plaintiffs argue that "at least one component" can mean "from one to all of the component parts of the signalling moiety," because scientists recognize the existence of single-component systems. (See Pls.' Claim Constr. Mem. at 16.) Further, they point out that dependent Claims 67, 68 and 70 of the '767 patent and Claims 18, 19 and 21 of the '824 patent specifically provide that "A comprises an indicator molecule," n4 and argue that it would be impermissible to construe the independent claim more narrowly than the dependent claims.

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n4 '767 Patent, Claim 67: "An oligo- or polynucleotide of claim 1 or 48 wherein A comprises an indicator molecule."

'767 Patent, Claim 68: "An oligo- or polynucleotide of claim 67 wherein said indicator molecule is fluorescent, electron a dense, or an enzyme capable or depositing insoluble reaction products."

'767 Patent, Claim 70: "An oligo- or polynucleotide of claim 68 wherein fluorescent indicator molecule is selected from the group consisting of fluorescein and rhodamine."

'824 Patent, Claim 18: "The method of claim 1 wherein the moiety A comprises an indicator molecule."

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'824 Patent, Claim 19: "The method of claim 18 wherein said indicator molecule is fluorescent, electron dense, or is an enzyme capable of depositing insoluble reaction products."

'824 Patent, Claim 21: "The method of claim 19 wherein fluorescent indicator molecule is selected from the group consisting of fluorescein and rhodamine."

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Additionally, plaintiff's expert, Dr. Richard R. Sinden, testified at the Markman hearing that the specification includes an example of direct detection. Examples 1-6 of the patents describe indirect detection, where biotin or iminobiotin is complexed with detectable polypeptide, and Examples 7 and 8 merely suggest the use of a NAGE linker arm between the nucleic acid and A, which was well known in the art. However, Example 9 describes use of successive chemical reactions, involving covalent bonds, that would only function using direct detection with fluorescent labels.

Defendants construe Claim 1 as precluding the possibility of A being the whole signalling moiety. They primarily rely on the specification, which states several times in each patent that "A represents a moiety consisting of at least three carbon atoms which is capable of forming a detectable complex with polypeptide when the compound is incorporated into" DNA or RNA. Defendants argue that because this specification does not teach a directly detectable moiety, Claim 1 must not do so. Defendants also argue that because the specification states that A is "formed," A must have multiple components and cannot itself be the directly detectable complex. Additionally, they rely on competing dictionary definitions that differ from plaintiffs', as well as that the six articulated "essential criteria" for A listed in the specifications, which, they argue, require that, among other properties, A be able to "react specifically with chemical or biological reagents to provide a sensitive detection system," '824 Pat. 6:35-37, and that the "detection system" be able to react with A, '824 Pat. 6:55-57, suggesting that A itself is not directly detectable.

The Court finds that the plain language and structure of the '824 and '767 Patents indicate that these patents cover both direct and indirect detection. Plaintiffs acknowledge that dependent claims 2-11 of the '824 Patent, and dependent claims 3, 54-59 and 61 of the '767 Patent, teach indirect detection. They teach that A is a "ligand" that is capable of binding with a detectable polypeptide, and therefore that A is not itself detectable. However, another chain of dependent claims in each patent teaches direct detection, with A comprising an indicator molecule." '767 Patent, Claims 67, 68, 70; '824 Patent, Claims 18, 19, 21; see also supra note 4.

"[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. Thus, the presence of dependent claims in both patents that teach both direct and indirect detection creates a presumption that Claim 1, the independent claim, is not limited to either. The specifications do not alter this conclusion. While "claims must be read in view of the specification," Phillips, 415 F.3d at 1315, and the specification is "the best source for understanding a technical term," id., courts are also to "avoid importing limitations from the specification into the claims." Id. at 1323. It is true that in the two Ward patents at issue, the specifications largely focus on indirect detection. However, the expert evidence indicates that Example 9 could involve direct detection. See Reply Expert Report of Richard R. Sinden, Def. Ex. 13, 56, 57 (citing Kricka Report, Def. Ex. 10, 30). Thus, importing into Claim 1 only the examples of indirect detection from the specification would skew the full illustrative range of all examples, resulting in utilization of the specifications as "limitations" on Claim 1 rather than as aids for understanding technical terms.

Defendants argue that the term "comprise" in the dependent claims asserted to teach direct detection implies that the indicator molecule is only a part of a multi-component system. The dependent claims, however, utilize "is" and "comprises" interchangeably. For example, Claim 67 of the '767 Patent teaches that " A comprises an indicator molecule," and Claims 68 and 70 teach that "An oligo- or polynucleotide of claim 67 wherein said indicator molecule is fluorescent, electron dense, or an enzyme capable or depositing insoluble reaction products," or "is selected from the group consisting of fluorescein and rhodamine." The drafting of this claim language is less than clear, but in the context of all the dependent claims taken together, the Court sees no basis for inferring from the word "comprise" in certain claims that A must have more than one component, as opposed to suggesting that A may have more than one component. See infra § I.F.

The Court therefore finds that A may be a part of or the entire signalling moiety. For this reason, it declines to limit Claim 1 only to indirect detection, and adopts plaintiffs' construction of the disputed Claim 1 language in the '824 and '767 Patents:

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"A comprises at least three carbon atoms and is one or more parts of a signalling moiety, which includes, in some instances, the whole signalling moiety."

Accordingly, the Court also construes the term "signalling moiety," as including, but not limited to, "a chemical entity capable of producing a detectable signal."
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D. "Significant increase in HDL cholesterol"

Term/Phrase (Claim Nos.)	Abbott's Proposed Construction	Lupin's Proposed Construction
"significant increase in HDL cholesterol" ('848 patent, claim 1)	No construction needed. If construed, then: "substantial increase in the level of HDL cholesterol in the patient's blood."	A 20% increase or greater in a patient's HDL profile.

i. The Parties' Positions

The dispute over the meaning of "significant increase" in claim 1 of the '848 patent again revolves around whether the Court should import a specific numerical limitation found in the portion of the '848 patent's specification describing the results of Niaspan(R) clinical trials.

Abbott argues that no construction is needed for this phrase because courts have repeatedly recognized that "terms of degree such as 'significant' or 'substantial' are descriptive terms not susceptible to precise numerical limitations." (D.I. 55 at 38 (citing Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 907 (Fed. Cir. 2005); Anchor Wall Sys. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310-11 (Fed. Cir. 2003);Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp., 540 F. Supp. 2d 1233, 1269 (M.D. Fla. 2008))) Abbott also argues that the specification offers no support for Lupin's proposed numerical limits, which appear to be based on a mean increase in HDL levels of 23% and 25.3%, respectively. (Id. at 39) According to Abbott, there is no evidence that the inventor intended to claim a particular percentage that the HDL levels must exceed to be "significant;" indeed, David Bova rejected any rigid numerical threshold. (Id.; see also D.I. 58 at 35; D.I. 61, LA000467-68, Bova Dep. at 147-48) Additionally, Abbott notes that original claim 1 of the '848 patent contained this term ("significant increase") and it issued without amendment. (D.I. 58 at 35) Finally, Abbott asserts that its expert, Dr. Sacks, confirms that a person of ordinary skill in the art would understand that "whether a particular increase in HDL cholesterol is 'significant' is patient specific," and that "[i]n some patients an increase of considerably less than 20% would be deemed 'significant' if it contributes to a lowering of the individual's risk of developing cardiovascular disease." (Id. (citing Sacks Decl. P 40))

Lupin,on the other hand, observes that the specification states that dosing with a sustained release product once a day in the evening or at night achieves a "significant" reduction in LDL cholesterol and triglycerides along with a "significant increase" in the desired HDL cholesterol. (D.I. 54 at 22 (citing '848 patent, col. 3 lines 35-40)) To Lupin, the meaning of "significant" is set forth in the Niaspan(R) clinical trial results listed in Table II; specifically, the specification notes that 13 out of 25 patients who had increases of HDL cholesterol of over 20% had "significant" "increases" in HDL cholesterol. (Id. (citing '848 patent, col. 9 lines 59-60)) Lupin's proposed 20% threshold for "significant" is lower than the increases actually referred to in the supporting study, and is roughly the average from the study discussed in the patent's Background section. (Id. (citing '848 patent, col. 2 lines 5-18)) Lupin insists that its construction avoids the vagueness inherent in Abbott's proposal, fulfilling the specification's express goal of providing SR products with "balanced lipid alteration" between prior art IR and SR products. (Id. at 23)

ii. Recommended Construction

I recommend thatthe Court construe "significant increase in HDL cholesterol" as "an increase in HDL cholesterol that results in a meaningful decrease in an individual's risk of developing cardiovascular disease."

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As an initial matter, the word "significant," as used in the disputed claim term, does require construction. The '848 patent's specification implicitly links "significant" to average increases in HDL cholesterol of 23% and 25.3%, but it gives no guidance regarding which number should determine the meaning of "significant." ('848 patent, col. 9 lines 53-60) I agree with Abbott that the inventor wanted to avoid limiting this claim to a specific numerical threshold. (See generally D.I. 61, LA000467-68, Bova Dep. at 147-48.) The inventor, Bova, testified that the disputed phrase would mean a "clinically significant or statistically significant increase" compared to the baseline/placebo, and that "[c]linically significant would mean have a positive effect on cardiovascular risk." (Id.) The inventor's testimony is consistent with Dr. Sacks' discussion of how a person ordinarily skilled in the art would understand the term. 25 (Sacks Decl. PP 39-40) Additionally, I am persuaded that, as Dr. Sacksnotes, the meaning of "significant increase in HDL cholesterol" will vary from patient to patient, in large part because patients have individual baseline levels of HDL cholesterol and individual medical histories and conditions that must be taken into account. Also, I am unpersuaded by the specific numerical requirement that Lupin would impose -- for the same reasons already described in reference to the treatment-limiting claim terms.

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25 With respect to Lupin's criticism of Dr. Sacks' declaration for not citing the patents' specifications, I note that none of the four expert affidavits submitted by Lupin do so either. See D.I. 61, LA000670-78, LA000679-84, LA000964-67, LA000968-72.

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As Dr. Sacks and Bova point out, an increase in HDL cholesterol is considered significant because it reduces a patient's risk for cardiovascular disease. (See id.; D.I. 61, LA000467-68, Bova Dep. at 147-48) Thus, I conclude that a person ordinarily skilled in the art would understand the disputed term to mean "an increase in HDL cholesterol that results in a meaningful decrease in an individual's risk of developing cardiovascular disease."
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1. "Silica particles." Consistent with the ordinary meaning and the intrinsic evidence of the '150 patent, the term "silica particles" shall mean "particles of SiO[2], which may include other elements, compounds or substances picked up as impurities during the synthesis of silica sols, but not including any elements, compounds or substances that are intentionally added during the synthesis process." 1

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1 The court finds the above construction consistent with the Federal Circuit's recent decision in Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002). Pursuant to the directive in Texas Digital, this court must "give a claim term the full range of its ordinary meaning as understood by persons skilled in the relevant art," unless compelled otherwise. Id. at 1202. The plain meaning of silica particles is undisputed, particles consisting of SiO[2]. However, both parties acknowledge that in the papermaking field, persons of ordinary skill in the art recognize that silica particles may include other elements, compounds or substances as impurities that are unintentionally picked up during the process of synthesizing silica sols. The court thus concludes that this is the ordinary meaning of the term "silica particles" to a person skilled in the art.

Eka asks the court to depart from this ordinary meaning and include intentionally added elements in the definition of silica particles. As the Federal Circuit has stated in Texas Digital, once an ordinary meaning is established, a district court must then turn to the intrinsic record to determine whether the "presumption of ordinary and customary meaning is rebutted." Id. at 1204. In this case, Eka points to no evidence in the intrinsic record warranting deviation from the ordinary meaning. Because neither the specification nor the claims of the '150 patent mention intentional modifications to the silica particles, the court declines to broaden the scope of the claim by embracing Eka's construction.

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II. SILICONE ESTER WAX

In accordance with these principles, the Court is called upon to construe the meaning of "silicone ester wax" as found in the '937 patent. Specifically, as found in claims 1 and 16, a composition is claimed comprising:
0.1-15% of a silicone ester wax comprising moieties of the general formula:

R[a]

SiO4-(a+b)/2

R[b]<1>

Wherein R is hydrogen or methyl, R<1> is a carboxylic ester containing radical having 12 or more carbon atoms and comprising a carboxylic acid moiety esterified with an aliphatic alcohol moiety, a is an integer of 0 to 3 inclusive, b is an integer from 1 to 3 inclusive, and the sum of a+b has an average value of from about 1.0 to 3.0 with the proviso that there is present at least one R<1> radical.

'937 patent, Col. 7, lines 31-45; Col. 8, lines 43-50 (emphasis added) n3.

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n3 This formula will be referred to as the "chemical formula." Claim 33 recites a chemical formula which differs only lightly. Col. 10, lines 12 - 29. The differences are not relevant to the issue of claim construction put before the Court. Therefore claims 1, 16 and 33 will be analyzed as a group. The remainder of the claims are dependant on claims 1, 16 and 33.

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Revlon asserts the ordinary and customary meaning of the term silicone ester wax "includes silicone polymers with attached ester groups and waxlike physical properties including linear silicone esters." Transcript of Markman Hearing ("Transcript") at 51. Defendants on the other hand urge "the term silicone ester wax as understood by those who have read the patent specification means that silicone ester wax is a resin and does not include linear silicone esters." Id.

The parties agree one of ordinary skill in the art has the following background: (1) a Bachelor's Degree, (2) a Master's Degree in Chemistry (3) three to five years experience developing makeup products, and (4) possible attendance of specialty courses in makeup formulation. Id. Thus the task before the Court is whether one with such experience would interpret the claims of the '937 patent to cover linear silicone ester waxes.

The significance of whether the claims include linear silicone esters -- the crux of the dispute between the parties -- is as follows. The product used by defendants L'Oreal and Cosmair in their allegedly infringing lipsticks is "behenic ester dimethicone." Transcript at 11. Defendants admit behenic ester dimethicone is a silicone ester, but note it has a "linear" chemical structure. Id. at 13. Defendants assert there is a distinction between a linear chemical structure and one that is "branched." Defendants argue Revlon's '937 patent would be read by one of ordinary skill in the art only to claim silicone esters that are branched as opposed to linear. n4

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n4 Although defendants originally asserted Revlon's claimed silicone ester waxes were cyclic, see D.I. 93, at 2, at the hearing on claim construction they urged Revlon's claimed silicone ester waxes were in fact branched. In a cyclic silicone structure, a sequence of silicones would form a circle. Transcript at 37; D.I. 139, at 5. The parties disagreed as to whether a cyclic structure was limited to one circle or multiple circles within the structure. See Transcript at 55-56. The resolution of that disagreement is not necessary to the Court's decision on claim construction. The Court considers defendants' position to

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be Revlon's claim did not cover silicone ester waxes with linear chemical structures.

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A. The Claim Language

As required by the Federal Circuit, construction of the term "silicone ester wax" begins with an examination of the words of the claim. See Vitronics, 90 F.3d at 1582. The word "wax" does not illuminate the question of whether Revlon's silicone ester waxes could have a linear chemical structure. Defendants preferred not to use the word "wax", finding it confusing; plaintiff asserted that "wax" described the substance's physical properties as opposed to chemical structure. n5 Transcript at 7-8, 68. Further, according to the parties' Stipulated Glossary of Terms, an "ester" is "a functional derivative of carboxylic acid in which the -OH of the carboxyl group has been replaced by -OR<1>. The structure is RCO-OR<1> where RCO- represents the carboxylic acid radical and where -OR<1> is the alcohol residue." D.I. 95, at 1-2. Nothing in that definition helps the Court determine whether the chemical structure of the silicone ester waxes is to be considered linear, branched, both, or neither. Finally, the parties do not seem to dispute that silicone is merely the combination of a silicon atom and an oxygen atom, see Transcript at 11, 65, but that does not inform the Court's decision either. In summary, the Court finds nothing easily discernable about the words silicone ester wax to aid in determining the chemical structure of the resulting compound.

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n5 In post-Markman hearing briefing, defendants assert Revlon's use of the word "wax" in the claim is inconsistent with the use of the word "resin" in the specification. According to defendants, wax is a solid at room temperature while Revlon's '937 patent specification's use of the word resin indicates the silicone esters can be liquids. See D.I. 142, at 2-3. This argument is not materially different than defendants' main argument in this case, that is, that the use of the word "resin" in the '937 patent specification defines the claimed silicone ester wax.

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The chemical formula found in the claim represents another possible source of information as to whether the structure of this silicone ester wax can only be branched, or if it can be linear as well. In this determination, the Court, lacking the necessary background in polymer chemistry, relies in part on "extrinsic evidence," specifically, expert testimony presented at the Markman hearing. In evaluating conflicting expert testimony the Court considers not only the spoken word but also non-verbal testimony. Non-exhaustive examples of non-verbal testimony are: the witnesses' body language, the inability to maintain eye contact, the long pause following a question challenging the expert's opinion where it is apparent the delay was not caused by the content of the ensuing answer, or the tone of voice or facial expression that indicates the expert is not convinced by his or her own testimony. The Court evaluates conflicting experts' testimony based on which spoken word makes more sense combined with some or all of the nontranscribable events described above.

After reviewing the prosecution history and the expert testimony, the Court is persuaded the chemical formula depicted in claims 1, 16 and 33 does not indicate the silicone ester waxes are limited to compounds with branched chemical structures. As explained by defendant's expert, Professor James McGrath, silicon atoms have a valence of four, requiring the formation of four bonds to other atoms. Transcript at 152. If one or two of those four silicon bonds is connected to an oxygen atom, the result is likely to be a linear polymer. Id. If three or four of the silicon's bonds are connected to oxygen atoms, however, the result can be a branched polymer. Id. At its most basic level, the question is whether the chemical formula in claims 1, 16, and 33 could define a silicone ester wax in which only one or two of the silicon's four bonds is connected to an oxygen.

Once again, the information given in the claims to interpret the formula is:
0.1-1.5% of a silicone ester wax comprising moieties of the general formula:

R[a]

SiO4-(a+b)/2

R[b]<1>

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Wherein R is hydrogen or methyl, R<1> is a carboxylic ester containing radical having 12 or more carbon atoms and comprising a carboxylic acid moiety esterified with an aliphatic alcohol moiety, a is an integer of 0 to 3 inclusive, b is an integer from 1 to 3 inclusive, and the sum of a+b has an average value of from about 1.0 to 3.0 with the proviso that there is present at least one R<1> radical.

A moiety, according to Webster's Third International Dictionary, is either "one of two equal portions of a whole" or, "one of the portions into which something is divided; component, part." The Court accepts the parties' positions in this context a moiety is a component -- not necessarily an equal half -- of the whole. See Transcript at 11; D.I. 141, at 5 n.2.

It will be recalled the silicon must have four bonds to other atoms. The value given to "a" in the above formula signifies how many R groups will be bonded to the silicon. The explanation following the formula indicates there can be between zero and three R groups bonded to the silicon. The value given to "b" signifies how many R<1> groups are bonded to the silicon. It is indicated there will be between one and three R<1> groups bonded to the silicon. Depending on the value assigned to "a" and to "b", with the caveat that there always will be one "b", the result of the mathematical equation connected to the O, "[(4-(a+b)]/2," controls how many oxygen bonds there will be. n6

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n6 If read literally, the mathematical equation means 4 - [(a+b)/2]. However, that literal reading may lead to results which are absurd because the silicon atom only has four valences. Stated differently, if a = 1 and b = 1, the result of the equation is 3 1/2 -- meaning 3 1/2 oxygens are to be bonded to the silicon. This is impossible because if a = 1 and b = 1, the silicon atom has only two remaining valences for the formation of two more bonds. Formation of 3 1/2 bonds, i.e., a value greater than two, is thus chemically impossible.

Revlon used the mathematically correct equation in the specifications. See Col. 2, lines 32-37. Moreover, Revlon consistently used this impossible equation in its prosecution history, although it was apparent it actually meant the entire [4-(a+b)] to be divided by 2, leading to results that are not impossible. See Defendants' Markman Hearing Exhibit 44 ("Exh. 44") at 73-75. With that in mind, the equation 4-(a+b)/2 will be considered a hasty shorthand for the equation [4-(a+b)]/2.

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Contrary to what might be expected, the equation is not an impossibility if the mathematical equation results in a fraction of a whole number. This is because 0.5 of an oxygen atom can be bonded to one silicon if the other 0.5 is bonded to another silicon. In other words, one oxygen can be shared by two silicons, resulting in the following chemical equation: Si - O - Si.

Accordingly, if a = 0 and b = 1, there will be 1.5 oxygen atoms bonded to the silicon atom, leading to a silicone ester wax that is likely to be branched because three oxygen atoms are bonded to a silicon atom. As is demonstrated by the figure below, the presence of the third oxygen bonded to another silicon creates two axes of silicon atoms -- one horizontal and one vertical -- giving rise to the "branched" structure:

Si

O[0.5]

- Si - O[0.5] - Si - O[0.5] - Si -

R<1>

On the other hand, if a = 1 and b = 1, which is clearly possible under the formula, only one oxygen atom remains to be bonded to the silicon, and the resulting silicone ester wax has only a horizontal axis along which the silicons can be found. Thus, the structure would be considered linear:

R

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- Si - O[0.5] - Si - O[0.5] - Si -

R<1>

This compound would likely possess a linear chemical structure, because as explained above, at least three oxygen atoms are needed to form branches. n7

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n7 The deposition testimony of Bianca Thayer, the developer of these silicone ester waxes, is seemingly contradictory. Although she agrees a branched formula usually contains more than two oxygens, she also says if a = 1 and b = 1, the result is branched. It appears there were follow-up questions which possibly clarified this testimony; unfortunately those pages of the deposition were not included in the record before the Court. See D.I. 140, Exh. I.

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A patent examiner requested Revlon map out all the possible combinations of the formula, giving "a" and "b" their range of possible values. See Exh. 44, at 73-75. Revlon's response, consistent with what has been explained above, indicates that when a = 1 and b = 1, only two bonds remain to be connected to oxygen atoms. Id. As the Court understands the expert testimony, the resulting silicone ester wax will possess a linear structure. This is true when a = 0 and b = 2 as well. Id. Therefore the Court does not find anything in the chemical equation contained in the claims 1, 16 and 33 indicating Revlon's patent only covers silicone ester waxes with branched structures as opposed to linear ones.

B. The Specifications

Having decided there is nothing in the words "silicone ester wax" or in the chemical formula in the claim that necessarily limits Revlon's claim to a non-linear chemical structure, the focus of the inquiry becomes the specifications. It is here defendants vigorously assert the use of the word "resin" in conjunction with silicone ester wax would indicate to one skilled in the art that Revlon's patent only claimed a branched, as opposed to linear, compound. See Col. 1, line 41; Col. 2, line 28. Defendants also argue both preferred embodiments of the silicone ester waxes contained in the specifications are branched, thus adding to their belief one skilled in the art would believe Revlon's patent only covered silicone ester waxes with branched structures. See Col. 2, line 49 - Col. 3, line 10.

i. Resin

The focus of defendants' "resin" argument is language found in Column 2, lines 28 - 31, of the '937 patent. It is stated: "The silicone resins used in the composition of the invention of the invention are silicone ester waxes comprising moieties of the general formula:

R[a]

SiO4-(a+b)/2

R[b]<1>
Wherein R is hydrogen or methyl, R<1> is a carboxylic ester containing radical having 12 or more carbon atoms and comprising a carboxylic acid moiety esterified with an aliphatic alcohol moiety, a is an integer of 0 to 3 inclusive, b is an integer from 1 to 3 inclusive, and the sum of a+b has an average value of from about 1.0 to 3.0 with the proviso that there is present at least one R<1> radical. n8

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n8 The mathematical equation is set out correctly here, as opposed to the claim. See supra note 6.

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Defendants assert this sentence means the silicone ester waxes are defined as, or limited to, certain silicone resins. And, according to defendants, the word resin has a meaning in the world of chemistry that denotes a branched chemical compound. Defendants then reason the use of "resin" would inform one of ordinary skill in the art that the structure of the silicone ester wax claimed in the '937 patent is not linear. Revlon on the other hand, argues the word resin as read by cosmetic chemists merely refers to certain physical properties of the compound and not any particular chemical structure. Once again lacking expertise on this subject, the Court is forced to rely on extrinsic evidence.

Defendants have put sufficient evidence in the record to support their proposition that distinctions exist in the field of chemistry between linear and resinous compounds, wherein resinous compounds are branched. Defendants' expert Professor McGrath testified to this. n9 Transcript at 170-71. The linear - resinous distinction can be found in the patent literature as well. See D.I. 101, Exh. 14 ("Thimineur patent"). Moreover, defendants proffered deposition testimony to the same effect. See D.I. 142, Exh. E, at 63 (deposition of Myriam Mellul, head of L'Oreal's cosmetic research laboratory).

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n9 Professor McGrath was offered as an expert in silicon polymer chemistry. He is a professor of chemistry at Virginia Polytechnic Institute and State University, and directs a center on polymeric adhesives and composites there. He has a Masters Degree in Chemistry and a Ph.D. in Polymer Science. Transcript at 145; 148.

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The position advanced by defendants is similar to that of an examiner in the European Patent Office, who, with regard to Revlon's patent for transfer resistant lipstick filed there, stated:
It should be mentioned . . . the silicone esters of the invention are always referred to in the description as filed as silicone resins, which implies a branched structure, preferably selected from the resinous silicone ester waxes described [within] . . . [A] skilled person would be unable to decide from the contradictory information given what characteristics should have the silicone esters of the invention (solid or not, resinous or not).

Defendants' Markman Hearing Exh. 43.

Yet there is ample support for Revlon's position as well. Revlon's expert, Dr. Robert Lochhead testified the term resin is "a broad and probably an indefinite term. If I think of a resin, I think of everything from something like a -- the sticky liquid you get from Christmas trees, all the way up to plastic. That would be the general definition, or definition of a resin, where you define it by physical properties." Transcript at 84. n10 Dr. Lochhead posited a possible explanation for the discrepancy between his testimony and the testimony of Professor McGrath:

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n10 Dr. Lochhead was offered as an expert in cosmetic chemistry and silicon chemistry. He is the Chair of the Department of Polymer Science at the University of Southern Mississippi. He has a Bachelor's Degree in pure chemistry and a Ph.D. in polymer solution. Transcript at 60-61; 63.

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When silicone chemists started to try to get resinous properties, and the way to get resinous properties was to take the SIO [sic] unit and create branching, and that gives you the resinous, the properties that you normally associate with a resin. Now we know that those physical properties can be achieved by other means . . . . The term specifically in silicone chemistry, resinous began to mean branch compounds. . . . Cosmetic chemists would not normally think of the structure that way.

Transcript at 100. n11

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n11 As admitted at the Markman hearing, defendants' expert Professor McGrath does not work in the cosmetics industry, and thus may be considered in the category of silicon chemists referred to by Dr. Lochhead. See Transcript at 149-152. It is

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possible Professor McGrath does not meet the stipulated definition of one of ordinary skill in the art, as he does not have 3-5 years experience developing makeup. Although the Court is not inclined to entirely disregard Professor McGrath's testimony, Dr. Lochhead's testimony as to the word resin, as understood by one skilled in the art, was left largely unrebutted.

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Dr. Lochhead's explanation of the discrepancy is corroborated by the definition of a resin in a chemical dictionary. The general definition states:
Flammable, amorphous, vegetable products of secretion or disintegration, usually formed in special cavities of plants. . . . They are the oxidation or polymerization products of the terpenes, and are mixtures of aromatic acids and esters.

J. Grant, Hackh's Chemical Dictionary 578 (4th ed. 1969).

Within that definition is included a definition of "synthetic" resins, where it is stated:
A heterogeneous group of compounds produced synthetically from simpler compounds by polymerization and/or condensation. . . . The term was originally used to describe such synthetic substances having the properties of resin, but is now used in a wider sense.

Id. at 579 (emphasis added).

Dr. Lochhead's testimony that the word resin merely describes physical properties is corroborated by deposition testimony. See D.I. 140, Exh. D, at 100 (deposition of Jean-Claude Ser, formerly head of L'Oreal's Formulation Laboratory); D.I. 141, Exh. A, at 304 (deposition of Terry Jacks, formerly a Maybelline cosmetic chemist). Moreover, the record contains evidence of patent literature in which the term resin is used as a description of physical properties. See Defendants' Markman Hearing Exh. 19 (Mellul patent) (describing "three classes of silicones (oils, waxes, and resins) . . .").

Finally, even defendants have stated: "defendants have never contested that the term resin may include linear compounds, but have consistently stated that the term 'silicone ester wax' as used in the '937 patent refers to a non-linear (cyclic) silicone resin compound." D.I. 128, at 10 (reply memorandum in support of defendants' motion to amend by supplemental responses their responses to plaintiff's requests for admissions).

On balance then, both parties have advanced credible evidence their definition of resin is accepted in the chemical community. n12 The Court's opinion that Revlon's position is correct is, in the end, derived from accepting the testimony of Dr. Lochhead over that of Dr. McGrath in this critical area. Further, aided by the experts' testimony, the Court concludes the internal structure and language of the patent favors Revlon's position. See Markman, 116 S. Ct. at 1395 (indicating preference for a construction comporting with patent's internal "logic" and "coherence").

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n12 U.S. Patent No. 7,725,685 (the "Thayer patent") was the first patent involving silicone ester wax. This patent contains language that is helpful to both parties. It states: "Those of ordinary skill in the art will appreciate that the siloxane chain [comprising the silicone ester wax] can be substantially linear or resinous (i.e. highly branched)." Defendants' Markman Hearing Exh. 30. This language supports defendants' position that a distinction exists between a linear compound and one that is resinous, or branched. However, the passage also lends strong support to plaintiff's position that silicone ester wax, as it was viewed originally, could have either a linear or branched structure.

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In so finding, the Court is unable to adopt defendants' interpretation of that crucial sentence found in the specification: "The silicone resins used in the composition of the invention of the invention are silicone ester waxes comprising moieties of the general formula . . . ." '937 patent, Col. 2, lines 28-31. Defendants urge this means the silicone resins are a subset of silicone ester waxes. Close study of the patent leads to the conclusion, in fact, the term silicone resin is used in a broad sense, and defined as certain silicone ester waxes.

The patent begins with a "Summary of the Invention," Col. 1, line 36. In that summary, Revlon indicates the claimed

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composition comprises: a) 1-70% of a volatile solvent; b) 0.1-15% silicone resin; c) 10-45% wax; d) 5-50% powder; e) 1-30% oil. See Col. 1, lines 40-45. Significantly, the other components of the composition are all described here by their physical properties, as opposed to their chemical structures. Therefore, Revlon's assertion that "silicone resin" refers to the component's physical properties is consistent with how the patent defines all of the components of the invention.

Following the Summary of Invention is a "Detailed Description," describing and defining each component of the summary. Col. 1, line 50 - Col. 4, line 51. For example, in the first paragraph of the description, the terms "volatile" and "volatile solvents" are defined and described. Col. 1, line 51- Col. 2, line 27. It is the second paragraph that begins: "The silicone resins used in the composition of the invention of the invention are silicone ester waxes comprising moieties of the general formula . . . ." See Col. 2, lines 28-31. The third paragraph describes "the waxes or wax-like materials" and the next paragraph begins, "The powder component of the invention can be generally defined . . . ." Col. 3, lines 12, 20. Given that each paragraph is devoted to defining a component of the original Summary of the Invention, it is likely that silicone resins are defined as certain silicone ester waxes, instead of vice versa.

ii. Preferred Embodiments

The Court also cannot agree with defendants' further contention that because both preferred embodiments contained in the specifications employ silicone ester waxes which are branched, the patent does not cover linear structures. See Col. 2, line 49 - Col. 3, line 10. Examples given in a patent specification do not necessarily limit the claims. Ekchian v. The Home Depot, Inc., 104 F.3d 1299, 1997 WL 9979, at *4 (Fed. Cir. 1997). As noted above, the '937 claim itself does not in any way limit the silicone ester waxes to those that are non-linear.

Although not dispositive, the Revlon patent does contain the following language introducing its claims: "While the invention has been described in connection with the preferred embodiment, it is not intended to limit the scope of the invention to the particular form set forth, but, on the contrary, it is intended to cover such alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims." Col. 7, lines 17-23. The preferred embodiments do not act as limitations on the claim.

Defendants also argue the preferred embodiments are impossible under the chemical formula found in the claims, as interpreted by Revlon. If true, Revlon's claim construction would almost certainly be wrong. See Vitronics, 90 F.3d at 1583 (noting if the claim, as interpreted, does not cover the preferred embodiments, construction not likely to be considered correct). Defendants' argument is based on the fact the preferred embodiments of the silicone ester waxes both contain units where all four of the silicon's bonds are connected to oxygens. Such units are called "Q units" by chemists. Transcript at 152-53. These Q units are impossible under the chemical formula contained in the '937 claims because of the requirement that at least one R<1> be bonded to the silicon. If one R<1> is present, there is not room to bond four oxygen atoms to the silicon.

Defendants' argument ignores the language of the claims, however, which state the silicone ester wax "comprises moieties" of the general chemical formula. As noted above, the word moiety refers to a component of a whole, indicating there may be other units in the composition. Similarly, the word "comprising" or "comprises" indicates the silicone ester wax may contain other units in addition to units of the general chemical formula. n13 Azoplate Corp. v. Silverlith, Inc., 367 F. Supp. 711, 732 (D. Del. 1973), aff'd 506 F.2d 1050 (3d Cir. 1974), cert. denied, 421 U.S. 914, 43 L. Ed. 2d 780, 95 S. Ct. 1572 (1975); see also Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1555 (Fed. Cir. 1995), cert. denied 135 L. Ed. 2d 1073, 116 S. Ct. 2554 (1996) ("The claimed composition is defined as comprising -- meaning containing at least -- five specific ingredients).

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n13 In post-Markman hearing submissions, defendants argued if the chemical equation found in the claims does cover the preferred embodiments, Revlon has impermissibly introduced "new matter" into the claim. This Court's opinion on claim construction will not address defendants' new matter argument, as the Court does not have the benefit of full briefing and oral argument on the subject.

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C. The Patent Prosecution History

The patent prosecution history is relevant insofar as it documents the applicant's representations to the patent office concerning the scope of the claims. Vitronics Corp., 90 F.3d at 1582. Revlon made an assertion as to the chemical structure of the silicone ester waxes used in its lipsticks that is consistent with its argument here that silicone ester waxes can include compounds with linear chemical structures. On December 15, 1992, in response to questions by the patent officer as to chemical structure of the silicone ester waxes, Revlon asserted: "The silicone resin doesn't have a cyclic formula. . . . U.S. Patent No. 4,725,658 to Thayer discloses and claims the silicone ester waxes used in the invention. . . . Thayer states that the siloxane chain in the silicone ester waxes is substantially linear or resinous . . . ." Exh. 44, at 69. Although the Thayer patent clearly distinguished between linear and resinous structures, it also indicated silicone ester waxes could possess either type of structure. Thus Revlon's position in the patent prosecution history is consistent with its current position before the Court, that, by using the term silicone ester wax, it did not intend to limit its claim to a compound with a branched structure. n14

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n14 In a later amendment, dated June 27, 1995, Revlon states, "It is . . . clear from Applicant's disclosure as originally filed that the two preferred silicone ester waxes set forth in their examples [in the patent specification] are both 'siloxy silicates.' That is an art-recognized term referring to a 'branched resinous siloxane structure . . . surrounded by ester functionality.'" Exh. 44, at 214. This statement does not compel a different result, however, because the preferred embodiment does not limit the claims in this case. See supra, pp. 10-20.

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D. Conclusion

After analysis of the claims, specification and prosecution history of the '937 patent, as well as the expert testimony presented at the Markman hearing, the Court finds the term "silicone ester wax" in the patent claims includes substances with linear chemical structures. The Court, recognizing its responsibility to independently construe the claim under Exxon Chemical Patents, Inc., 64 F.3d 1553, believes Revlon's proffered definition is correct. Accordingly silicone ester waxes are "silicone polymers with attached ester groups and waxlike physical properties including linear silicone esters."
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Steps C and D -- "simultaneous actions" of high temperature, intense mechanical energy, and chemical agent.

(1) Claim construction

Construction of this claim requires that the term "simultaneous actions" be defined. Markman I, 52 F.3d at 797. Clement's undisputed suggestion is that "simultaneous" be construed according to its plain meaning: "happening, existing or done at the same time." Def. Opp'n. at 29 (citing The American Heritage Dictionary, 2nd College Ed.). The disputed question is what must happen or be done at the same time. AMI argues that the "simultaneous action" limitation requires all three type of energy to be added at the same time. Tr. at 27. Clement responds that the limitation requires only that the pulp be subjected simultaneously to the three types of energy at some point during dispersal. Tr. at 59-60.

Clement's interpretation is the proper one, because it is consistent with the plain meaning of the words. Step D instructs "detaching of the ink particles from the surface of the fibers . . . by submitting the second fibrous suspension to the simultaneous actions of (A) high temperatures between 85 [degrees] and 130 [degrees] C, (B) high shear forces substantially corresponding to a specific mechanical energy of more than 50 K.W.H/Ton . . . and (C) at least one chemical dispersing agent . . ." Ex. Q, Col. 13, 11. 24-41. That language is silent as to when each energy element must be added to the mix. If, as Clement suggests, an active dispersing agent is present in the frotopulper at the same time the threshold heat and mechanical energy levels are also met, "simultaneous action" has been achieved.
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5. Dispute claim term "size distribution" means: volume distribution, based on particle size as represented by the diameter of a sphere having the same volume as measured by conventional methods known to those of skill in the art, including sieving and laser diffraction particle size analysis.
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B. "Skin"

Plaintiffs' Construction	Defendants' Construction
Normal, healthy skin.	The external limiting tissue layer of an animal body; especially: the 2-layered covering of a vertebrate body consisting of an outer epidermis and an inner dermis.

Defendants' contend that the term "skin" is used throughout the patent "as it is generally understood" and that it should thus be construed according to a definition from the Merriam-Webster Online Dictionary. (See D.I. 174 at 8.) This definition requires "skin" to be, among other things, the outer two-layer tissue of a "vertebrate body." The Court will not adopt this definition. For one thing, there is no indication that the Merriam-Webster Online Dictionary is a resource that someone of skill in the relevant art would rely upon. More importantly, the Merriam-Webster definition does not appear well supported by the specification. Indeed, in describing "skin," the specification explains that "three major tissue layers are identified," while the Merriam-Webster definition describes "skin" as only a "2-layered covering." ('516 patent at 3:51-57.) In these circumstances, the Court concludes that it would be inappropriate to rely on the Merriam-Webster Online Dictionary. Phillips v. AWH Corp., 415 F.3d 1303, 1322-1323 (Fed. Cir. 2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1585 (Fed. Cir. 1996)) (explaining that judges may consult dictionaries "so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents").

However, Defendants do not appear to contend that the limitations present in the Merriam-Webster definition are critical. (See D.I. 192 at 59:4-60:5.) Rather, Defendants appear to take issue only with Plaintiffs' position that the term "skin" be limited to "normal, healthy" skin. Indeed, on reviewing the parties' briefing, the Court concludes that this is the only meaningful dispute regarding the claim term "skin." To resolve this dispute, the Court has reviewed the intrinsic evidence. Having done so, the Court concludes that the claims should not be limited to "normal, healthy" skin. As Defendants note, the specification explains that "the instant skin care composition not only helps to maintain treated skin in a healthy condition, but also promotes healing of dry, cracked, sore, or damaged skin." ('516 patent at 10:5-9.) Likewise, the specification explains that "a skin moisturizing composition, under the invention, may be applied specifically or preferentially to the point or area of a minor cut, crack, or abrasion of the skin." (Id. at 3:26-31.) Describing the use of the invention with cut, cracked, abraded, dry, sore, and/or damaged skin, the Court finds that the specification confirms that the claims are not limited to "normal, healthy" skin.

Having resolved the essential dispute among the parties, the Court sees no reason to offer any additional construction for the term "skin."
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1. "Skin cleaning composition for external use on human tissues / cleaning composition for use on human skin": A composition for removing unwanted non-water soluble substances from the skin.

Plaintiff argues for a broad construction of this limitation to cover any composition that has "an effect of treating unwanted

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substances so that the unwanted substance is easier to remove from the skin." (D.I. 229) Of course, such a broad construction encompasses rinsing your skin with water and, thereby, making it easier to remove dead skin cells. The court declines to give this patent such a broad expanse.

The specification of the '062 patent describes the invention as relating to "cleaning compositions suitable for external application to human skin tissue in order to remove unwanted substances such as tar, caulking compounds, sealants, adhesives and the like." ('062 patent, col. 1, ll. 6-9; col. 2, ll. 13-15 and 22-24) The specification goes on to describe that "it has not been readily apparent that orange oil alone or in combination with other substances could prove effective in cleaning compounds otherwise difficult to remove from the tissues of the skin." ('062 patent, col. 1, ll. 58-61) In investigating cleaning compositions "according to the present invention," the inventors tested "industrial type substances" that were "regarded as difficult to remove from the human hands." ('062 patent, col. 4, ll. 3-8); col. 5, ll. 17-19; col 6, ll. 36-55) In the prosecution history, the inventors hailed the superior cleaning properties of orange oil as being effective in removing "substances such as urethane caulking, paint and tar that resist d-limonene cleaning compositions." (D.I. 254, ex. B at LPM 000185) There is absolutely no indication in the claims, the specification or the prosecution history that the invention was directed to a compound that simply lubricates the skin, making it easier to remove such substances as dead skin cells.
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A. Claim Construction

This Court issued an Opinion and Order on August 14, 2003 in which it construed seven terms or phrases that were disputed by the parties: 1) "inducing and maintaining analgesia;" 2) "analgetically effective rate;" 3) "area of intact skin;" 4) "steady state administration rate;" 5) "a substantial portion of said extended period of time;" 6) "reservoir;" and 7) "means for maintaining." Alza Corp. v. Mylan Labs., Inc., No. 02-cv-20 (D. Vt. Aug. 14, 2003) (order granting in part, denying in part motion for interpretation of patent claims). The Court did not address the definition of "skin permeable form" in its opinion, because the parties had agreed on a definition: "fentanyl that is in a form that can pass through the skin."

At trial it became evident that the definition agreed to by the parties was not sufficiently precise to answer the question critical to this litigation: does "skin permeable form of fentanyl base" as used in the '580 patent include solutions of fentanyl at pHs of 7.0 or lower? As one of Mylan's scientific experts, Dr. Jonathan Hadgraft, stressed: "I find just describing something as skin permeable is an ambiguous statement." (Hadgraft 9/4/03, II at 112.) "You have to read [permeable] in the context in which it's written." Id. at 109.

Claim construction is an issue of law. Markman v. Westview Instruments, Inc., 517 U.S. 370, 391, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). In determining the meaning of disputed claim language, a court looks first to "'the intrinsic evidence of record,'" examining, in order, the claim language itself, the specification, and the prosecution history. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). On the rare occasion that intrinsic evidence does not settle the meaning of a claim limitation, then extrinsic evidence may be considered. Id. at 1332.

The words used in claim language are presumed to have "the ordinary and customary meanings attributed to them by those of ordinary skill in the art," unless an express intent appears otherwise. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). This presumption is a heavy one, Amgen Inc. v Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1327 (Fed. Cir. 2003), but may be overcome where the patentee has specifically set forth a definition of the term different from its ordinary and customary meaning, or where the patentee has clearly disavowed the apparent scope of coverage. Brookhill-Wilk, 334 F.3d at 1299.

A construing court must be careful not to read into the claims limitations that appear in the specification. See Interactive Gift, 256 F.3d at 1331-32 (recognizing a fine line between reading claim in light of specification and reading limitation into claim from specification, quoting Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998)); see also Amgen, 314 F.3d at 1325; Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1348 (Fed. Cir. 1998) (interpreting what is meant by word in claim must not be confused with adding extraneous limitation appearing in specification, which is improper, quoting Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989)). "'Advantages described in the body of the specification, if not included in the claims, are not per se limitations to the claimed invention.'" Brookhill-

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Wilk, 334 F.3d at 1301 (quoting Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc., 141 F.3d 1084, 1096 (Fed. Cir. 1998) (Newman, J., dissenting)).

Claims are construed the same for both invalidity and infringement. Amgen, 314 F.3d at 1330. Terms that appear in multiple claims should be construed consistently for each claim. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001).

"Skin permeable form" appears in each of the asserted claims. The term is used in all of the claims of the '580 patent. As was demonstrated at trial, from the point of view of one skilled in the art, the phrase "skin permeable form" is ambiguous, and must be interpreted in context. The base form of fentanyl has been generally described as the skin permeable form of the drug. See Samir D. Roy & Gordon L. Flynn, Transdermal Delivery of Narcotic Analgesics, 7 Pharmaceutical Research 842, 847 (1990) (PX 28). The asserted claims however specify the use of a skin permeable form of fentanyl base. If "skin permeable form" means merely "the base form of the drug," the term is redundant.

Where terms chosen by the patentee are sufficiently unclear that one cannot determine the scope of the claim from the language used, statements in the specification or prosecution history may be used to define the scope of the claim. See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999). The Court therefore looks to the specification to see if the meaning of skin permeable form is found there.

In column 3 the inventors state:

> we have discovered that fentanyl citrate, the form in which fentanyl is presently administered, has such a low skin permeability that it is not at all suitable for transdermal delivery even with the use of permeation enhancers. Instead we have found that, in order to obtain the delivery rates noted above, the drug should be incorporated in the transdermal therapeutic system in the form of the base.

'580 patent at 3:10-17. For purposes of the '580 patent, fentanyl citrate is considered by the inventors not to be a skin permeable form of the drug. The specification is usually dispositive as to the meaning of a disputed term. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002) (quoting Vitronics, 90 F.3d at 1582).

Even if the term were clear on its face, the intrinsic evidence must be examined to determine whether "a deviation from the clear language of the claims is specified," if for example, a patentee has relinquished a particular claim construction in an argument to overcome or distinguish a reference. Interactive Gift, 256 F.3d at 1331. The Gale Declaration, submitted during the second reexamination, specifically disclaims fentanyl citrate: "we specifically stated in the '580 patent [fentanyl citrate] was unsuitable for transdermal delivery." (Gale Decl. (PX 10) P 11; see also id. P 10 ("The '580 patent . . . discloses that the only form of fentanyl that was then being used for medical purposes, fentanyl citrate, is unsuitable for transdermal administration because of its low transdermal flux").) In disclaiming fentanyl citrate as a skin permeable form, Gale referred to the fentanyl solution contemplated by the Keith matrix as having a pH of 6.5 to 7.0, and noted that the fentanyl in this solution "would exist virtually completely in the form of fentanyl citrate." Id. PP 7-9.

"Where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Read in light of the specification, and the file wrapper's specific disclaimer, the "skin permeable form" that is claimed excludes fentanyl citrate.

Mylan points out, accurately, that the fentanyl that actually passes through the skin is in the form of the base, no matter what the pH of the fentanyl solution is. From this point it argues that the claim language cannot be construed to exclude solutions of fentanyl citrate, because citrate is not what is transdermally administered. But referring to the permeability of fentanyl means referring to its permeability in solution, because undissolved fentanyl will not pass through the skin. See, e.g., Hadgraft 9/5/03, I at 101. A skin permeable form cannot be undissolved fentanyl base, but must be fentanyl base in solution, even if what actually passes through the skin are molecules of fentanyl base. According to the intrinsic evidence, in the '580 patent's claims that solution is limited by the exclusion of solutions of pH 7.0 or lower.

Alza has urged the Court to construe "skin permeable form" as including the concept of minimizing residual drug. Although the patent specification clearly iterates drug minimization as a goal of the invention ('580 patent at 1:58-60; 2:23-26), the

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claims contain no limitation requiring minimization of drug loading. Indeed, claim 61.31 contains a limitation specifying that the drug reservoir contain between 0.1 and 50% by weight of a skin permeable form of fentanyl base, hardly an indication of minimal drug loading. There is no suggestion in the specification that "skin permeable form" means a form of fentanyl base in which adequate flux is achieved with the minimum amount of drug. Nor does the prosecution history supply such a definition. To read the asserted claims of the '580 patent as including a drug minimization limitation would be a classic example of '"adding an extraneous limitation appearing in the specification, which is improper.'" Laitram, 163 F.3d at 1348 (quoting Intervet Am., 887 F.2d at 1053).

The Court construes "skin permeable form" as fentanyl that is in a form that can pass through the skin, excluding solutions of fentanyl citrate. 4

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4 Because the claim language can be construed from an examination of the intrinsic evidence, consideration of extrinsic evidence is unnecessary. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) (improper to rely on extrinsic evidence where analysis of intrinsic evidence resolves ambiguity in disputed claim term); see also CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1368 (Fed. Cir. 2002) (unnecessary to examine expert testimony if ordinary meaning of term can be resolved by resort to intrinsic evidence and dictionary definitions). The Court notes that Mylan's expert Dr. Hadgraft interpreted the '580 patent's use of "skin permeable form" in the patent's claims as referring to the skin permeability coefficient, that value derived from flux and concentration. (Hadgraft 9/4/03, II at 114.) Dr. Hadgraft further interpreted the patent as excluding fentanyl citrate from the definition of skin permeable. Id. at 121. Dr. Hadgraft's interpretation of the phrase as used in the patent is consistent with the Court's claim construction. See Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999) (entirely appropriate for court to consult trustworthy extrinsic evidence to ensure claim construction is not inconsistent with understanding in pertinent technical field); accord Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1346 (Fed. Cir. 2003).

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III

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In determining the meaning of disputed claim language, a court looks first to the intrinsic evidence of record, examining, in order, the claim language itself, the specification, and the prosecution history. Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The parties had agreed upon the construction of the term "skin permeable form": "fentanyl that is in a form that can pass through the skin." However, in its claim construction following trial, the district court modified this construction by adding the phrase "excluding solutions of fentanyl citrate."

Here, the term "skin permeable form" when referring to fentanyl base is not plain on its face to one of ordinary skill in the art. As the district court explained, "the base form of fentanyl has been generally described as the skin permeable form of the drug." As such, if "skin permeable form of fentanyl" simply means "the base form of fentanyl," the inclusion of the word "base" in the claims would be redundant. Additionally, "skin permeable" is sometimes used by scientists to refer to flux, the rate at which a drug passes through the skin, and sometimes used to refer to the permeability coefficient, the relationship between flux and the concentration of the drug. Accordingly, the claim term "skin permeable form" is not plain on its face. We, therefore, must look to the specification and prosecution history to see if they shed any light on what is meant by the term "skin permeable form" in the '580 patent.

The specification states

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We have discovered that fentanyl citrate, the form in which fentanyl is presently administered, has such a low skin permeability that it is not at all suitable for transdermal delivery even with the use of permeation enhancers. Instead we have found that, in order to obtain the delivery rates noted above, the drug should be incorporated in the transdermal therapeutic system in the form of the base.

'580 patent, col. 33, II. 10-17. This clearly demonstrates to one of ordinary skill in the art that fentanyl citrate (the acidic form of the drug) is not a skin permeable form of fentanyl in the context of the invention of the '580 patent.

The prosecution history confirms that fentanyl citrate is not a skin permeable form of fentanyl as used in the claims. When the Keith reference was before the examiner during the second reexamination proceeding, Gale submitted a declaration detailing the differences between the reference and the claimed invention. Gale explained that Keith taught the production of a diffusion matrix containing fentanyl citrate, which the inventors of the '580 patent had expressly disclaimed:

[In describing possible diffusion matrices, the Keith patent] teaches that an "appropriate" amount of fentanyl, which is a basic substance, could be either (1) an amount of fentanyl that would not cause the pH of the matrix to increase above 7 or (2) any amount of fentanyl as long as the pH of the matrix is adjusted to 6.5 to 7 with citric acid. Thus, without trying to ascertain a specific quantity of fentanyl that would constitute an "appropriate" amount, I believe it is clear that the disclosure of the Keith patent requires that the fentanyl be present in the matrix at a pH no greater than 7. . . . Because fentanyl has a pK of 8.3, the fentanyl present in the Keith et al. matrix would exist virtually completely in the form of fentanyl citrate. As a result, to the extent that the Keith patent could be considered to disclose making a transdermal fentanyl delivery system by including fentanyl in the diffusion matrices of the Keith patent, such a system would be unsuitable for administering fentanvl at analgetically effective rates. . . . The '580 patent at col. 3, lines 6-14 and col. 1, lines 22-25 discloses that the only form of fentanyl that was then being used for medical purposes, fentanyl citrate, is unsuitable for transdermal administration because of its low transdermal flux. . . . Thus, in contrast to our disclosure and claims in the '580 patent, the Keith patent suggests the production of a diffusion matrix containing fentanyl citrate, which we specifically stated in the '580 patent was unsuitable for transdermal delivery, even with permeation enhancers.

Gale Declaration, PP 8-11 (emphasis added).

Both the prosecution history and the specification disclaimed fentanyl citrate because it was unsuitable for transdermal administration and therefore not a "skin permeable form" of fentanyl. For this reason, we agree with the district court's claim construction of "skin permeable form" as "fentanyl that is in a form that can pass through the skin, excluding solutions of fentanyl citrate."

Mylan and Alza argue this case as if the district court had construed the term "skin permeable form" to mean a fentanyl solution with a pH higher than 7.5. However, it did not. The court simply stated that the skin permeable form excluded fentanyl citrate without restricting that term to any particular. range of pH values.

All of Mylan's arguments on claim construction are directed to a purported pH level determined by the district court. However, as we just explained, the district court placed no pH limitation on its construction of "skin permeable form." Mylan contends that the district court's claim construction is contrary to the plain meaning of the term "skin permeable form" and asserts that the proper construction of the term is "fentanyl that is in a form that can pass through the skin," which could include fentanyl citrate solutions. 5 However, as demonstrated above, such a construction is contrary to the '580 patent's specification and prosecution history's clear disavowal of fentanyl citrate.

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5 This is based on the premise that regardless of whether a fentanyl solution contains primarily fentanyl in the base form or primarily fentanyl in the acidic form, it is the base form of the drug that will actually permeate the skin.

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Finally, we are not persuaded by Mylan's argument that the district court's construction is inconsistent with the specification. Mylan asserts that because Alza's own data shows adequate flux is obtainable from fentanyl citrate solutions, this somehow disproves the discussion in the specification about the low skin permeability of fentanyl citrate. Alza points out, however,

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that this argument assumes that "skin permeability" in the specification refers to the flux, which is the rate at which a product flows through the skin, and not to the relationship between that flux and concentration (the "permeability coefficient"). 6 The record supports Alza's contention that the discussion of skin permeability in the specification is not about the flux at which the product flows through the skin, but rather the permeability coefficient. Mylan also asserts that this claim construction excludes preferred embodiments disclosed in the patent. Mylan cites no evidence to support its assertion and only speculates based on the Keith matrix which was buffered. 7 Thus, we are unpersuaded by this argument.

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6 Flux describes the rate at which a drug will pass the skin, whereas permeability coefficient describes that rate in proportion to concentration. ("Flux, which is the amount that would go through the skin, . . . equals the permeability coefficient times the concentration." Trial Transcript, August 29, 2003, at 85.)7 A buffered solution is one that resists a change in pH upon addition of a small amount of acid or base. As such, when adding small amounts of fentanyl base to a solution buffered to remain around pH 7.0, as in the Keith patent, the pH would not be expected to change much, if at all. Such an addition would, however, likely have an effect on an unbuffered solution, such as that taught in the '580 patent.

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A. "Slope Of Strain Hardening Coefficient Of Greater Than Or Equal To 1.3"

Dow's Construction	NOVA's Construction
The slope of strain hardening multiplied by the melt index raised to the 0.25 power must be greater than or equal to 1.3.	This claim term is indefinite.

The dispute between the parties has two parts. Not only do the parties dispute whether this claim term is indefinite, but the parties dispute the law and procedure that the Court should apply in addressing the indefiniteness dispute.
1. The Law And Procedure For Addressing Indefiniteness

Dow contends that indefiniteness cases fall into two categories: those that raise issues of fact and those that do not. 1 (See D.I. 197 at 2-5.) Along these lines, Dow notes that the Federal Circuit has confirmed that fact issues can indeed permeate an inquiry into indefiniteness. Specifically, the Federal Circuit recently explained as follows:

A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims. To the extent there are any factual findings upon which a trial court's indefiniteness conclusion depends, they must be proven by the challenger by clear and convincing evidence.

Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1338 (Fed. Cir. 2008) (internal citations omitted).

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1 The latter category of cases, Dow contends, break down into two general sub-classes. First, there are cases where the intrinsic evidence demonstrates the definiteness of the claims. In these cases, no amount of extrinsic evidence can be used to "inject ambiguity where none exists." (See id. at 3 (citing Personalized Media Communications, LLC v. ITC, 161 F.3d 696, 706 (Fed. Cir. 1998)).) Second, there are cases "where an irreconcilable contradiction exists within the patent itself." (D.I. 197 at 3.) Presumably, Dow contends that in these cases, the intrinsic evidence demonstrates the indefiniteness of the claims conclusively, and no amount of extrinsic evidence can rescue the claims.

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Though acknowledging that "the determination of indefiniteness is ultimately a question of law," (D.I. 197 at 2), Dow further contends that "the Federal Circuit treats indefiniteness differently from claim construction." (D.I. 214 at 3.) Most importantly, Dow contends that Federal Circuit precedent calls for any fact issues surrounding indefiniteness to be submitted to the jury. (See D.I. 197 at 2, 6 (citing BJ Services Co. v. Halliburton Energy Services, Inc., 338 F.3d 1368, 1372 (Fed. Cir. 2003) ("Like enablement, definiteness, too, is amenable to resolution by the jury where the issues are factual in nature.")).) Furthermore, Dow takes the position that the trier of fact should consider the evidence pertaining to indefiniteness "as a whole." (D.I. 214 at 2.) Thus, Dow appears to be of the view that in considering indefiniteness, the Court should not necessarily adopt a preference for the intrinsic evidence over the extrinsic evidence, as is normally done during the claim construction process. See Phillips v. AWH, 415 F.3d 1303, 1317 (Fed. Cir. 2005).

NOVA responds, first and foremost, that "claim construction [is] a purely legal issue," which the Federal Circuit reviews de novo "including any allegedly fact-based questions relating to claim construction." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1451, 1454-56 (Fed. Cir. 1998). NOVA further notes the long-standing and often-repeated principle that "[a] determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Personalized Media Communs., L.L.C. v. ITC, 161 F.3d 696, 706 (Fed. Cir. 1998). In other words, NOVA emphasizes the link between claim construction and indefiniteness, arguing that to the extent the Federal Circuit admits the existence of fact issues underlying indefiniteness, they should be handled by the Court within the context of the claim construction process. Thus, NOVA does not envision a role for the jury when it comes to indefiniteness. Likewise, NOVA maintains that the Court should evaluate evidence pertaining to indefiniteness in accordance with Supreme Court and Federal Circuit authority on claim construction. See generally Markman v. Westview Instruments, Inc., 52 F.3d 967, 981 (Fed. Cir. 1995); Phillips, 415 F.3d at 1303. Accordingly, NOVA contends that in deciding indefiniteness the Court has the "authority to wholly dismiss . . . extrinsic evidence," such as expert witness testimony, in favor of more reliable intrinsic evidence. (See D.I. 204, Exh. 1 at 2-3, 6.)

On reviewing the authority on this topic, the Court concludes, first, that it is indeed authorized, where appropriate, to address indefiniteness within the context of claim construction using the machinery normally used to handle claim construction. See Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) ("Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction."); Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1348 (Fed. Cir. 2005) ("In the face of an allegation of indefiniteness, general principles of claim construction apply."). Furthermore, the Court should perhaps even endeavor to adopt this route when possible. See, e.g., Enzo Life Scis., Inc. v. Digene Corp., 305 F. Supp. 2d 406, 408 (D. Del. 2004) ("The claims at issue do not have technical or relational terms that may be understood differently by one of ordinary skill in the art. Instead, Digene's arguments of indefiniteness involve allegations of internal contradiction based upon the wording of the claims. Thus, as the construer of patent claims, the Court may reach the merits of the indefiniteness question.").

Nevertheless, the Court understands the authority on this issue as allowing, in appropriate circumstances, for the submission an indefiniteness dispute to the jury. Indeed, the Federal Circuit's statement in BJ Services that "definiteness . . . is amenable to resolution by a jury" has not, to the Court's knowledge, been explicitly overruled. BJ Services, 338 F.3d at 1372-73. Likewise, the Federal Circuit's recent statement in Technology Licensing admitting the potentiality for fact questions in an indefiniteness inquiry cannot, in the Court's view, be easily squared with the rigid view advanced by NOVA that the Court must always address indefiniteness within the context of claim construction as a pure legal issue. See Technology Licensing, 545 F.3d at 1316. Along these lines, thr Court noted long ago that "[t]he Federal Circuit has repeatedly stated that indefiniteness is a legal question, and, at the same time, held that in certain circumstances, 'evidence beyond the claims and written description may be reviewed.' Derived from such statements is an inherent tension as to the appropriateness of resolving indefiniteness questions as a matter of law." Enzo, 305 F. Supp. 2d at 408 (quoting Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379 n.4 (Fed. Cir. 2000)).

In fact, numerous other district courts have acknowledged that an indefiniteness inquiry cannot always be strictly equated with or incorporated into the claim construction inquiry. In the Court's view, the most notable district court opinion on this issue is the Southern District of New York's opinion in System Mgmt. Arts, Inc. v. Avesta Techs., Inc., 137 F. Supp. 2d 382, 399-400 (S.D.N.Y. 2001). There, the Southern District of New York noted conflicting expert testimony in denying a motion for summary judgment on indefiniteness. In so doing, the Court explained as follows:

> [W]hile the Federal Circuit has often stated that the indefiniteness inquiry is "drawn from" the district court's role as a

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construer of patent claims, see, e.g., Personalized Media, 161 F.3d at 705, the circuit court has not expressly held that these inquiries are one and the same, nor that the indefiniteness inquiry can not involve underlying questions of fact. Moreover, to state that the indefiniteness inquiry is a question of law or "legal conclusion," id., does not answer the question. The Federal Circuit has recognized that some questions of law involve underlying issues of fact. See Union Pacific Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 57 U.S.P.Q.2D (BNA) 1293, 1296 (Fed. Cir. 2001) (patent enablement is "question of law" but "as is often true of legal questions . . . the ultimate legal conclusion of enablement rests on factual underpinnings . . . .").

The reasoning of those courts holding that the indefiniteness inquiry may involve underlying issues of fact is persuasive. Indeed, to hold otherwise would seem to mask the actual role being played by the district court.

System Mgmt., 137 F. Supp. 2d at 400. Numerous district courts - both before and after System Mgmt. -- appear to have followed this or similar reasoning. See, e.g., A.K. Stamping Co. v. Instrument Specialties Co., 106 F. Supp. 2d 627, 644-45 (D.N.J. 2000) (denying a motion for summary judgment of indefiniteness when a "trier of fact" could conclude based on "the testimony of three engineers" that the claims were not indefinite); TC Mfg. Co. v. Polyguard Prods., Inc., No. 06 C 8392, 1999 U.S. Dist. LEXIS 14730 (N.D. Ill. Sept. 14, 1999) (denying a motion for summary judgment of indefiniteness where there was "support in the record presented for the dispute of a material fact" and concluding that the "issue must await for a resolution at trial where the facts can be evaluated and found . . . ."); Hako-Med USA, Inc. v. Axiom Worldwide, Inc., No. 8:06-cv-1790, 2008 U.S. Dist. LEXIS 64953, at *6 (M.D. Fla. July 29, 2008) (affirming a magistrate judge's recommendation denying summary judgment of indefiniteness where the magistrate was unable to determine indefiniteness as a matter of law because questions of fact remained); Presidio Components, Inc. v. Am. Tech. Ceramics Corp., No. 08-cv-355, 2008 U.S. Dist. LEXIS 65149, at *9 (S.D. Cal. Aug. 22, 2008) ("As several district courts have observed, however, while the Federal Circuit has described the indefiniteness inquiry as a question of law, where evidence beyond the claims and written description may be reviewed, factual issues are likely to arise.").

In light of the above persuasive authority, the Court concludes that the law on indefiniteness is not as rigid as NOVA contends. Although it may generally behoove the Court to address indefiniteness as a legal matter in the context of claim construction, there may arise cases where genuine issues of fact simply preclude such a treatment. In these circumstances, the question of indefiniteness must be addressed by the trier of fact.

2. Decision

The slope of strain hardening coefficient ("SHC") is calculated as follows:

SHC=(slope of strain hardening) (I[2])<0.25>

where I[2] is the melt index in grams/10 minutes. ('053 patent at 6:45-50.) NOVA raises two arguments in support of the position that the claim term "slope of strain hardening coefficient of greater than or equal to 1.3" is indefinite. First, NOVA contends that this claim term is indefinite because the units for the slope of strain hardening are indeterminable, thus making it impossible to determine the proper units for SHC. Second, NOVA contends that the claim term is indefinite because neither the claims nor specification adequately set forth the methodology for determining the slope of strain hardening. The Court will address each of these arguments in turn.

As to the issue of units, the Court notes that the specification includes a section directed specifically to the determination of the slope of strain hardening coefficient. See '053 patent at 6:8-43. This passage describes the preparation of the test sample to be used in determining the slope of strain hardening strictly in units of pounds and inches. See, e.g., '053 patent at 6:13-15 ("The plaque is . . . then pressed under pressure of about 200 psi."); id. at 6:6:17-18 ("The test piece is 0.315 inches wide and 1.063 inches long."). Based on this, Dow contends, one of skill in the art could determine that the slope of strain hardening is also to be determined using English units (i.e, pounds and inches). In support of this position, Dow submits the declaration of its expert witness, Dr. Benjamin S. Hsiao. (See D.I. 149 P 13.) The specification further explains that the actual test for determining the slope of strain hardening should be done using an Instron Tensile Tester at a "crosshead speed of 1 inch/minute." See '053 patent at 6:25-26. Describing the test parameters for determining the slope of strain hardening in units of inches, Dow contends that this further confirms that the slope of strain hardening should also be understood as being in English units. (See D.I. 148 at 13; D.I. 149 P 13.)

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In addition, Dow contends that an understanding of English units for the strain hardening coefficient would follow from the patent's explicit reference to the use of an Instron testing instrument because this instrument operates by default in terms of "US Customary" units, which, like English units, use inches for length and pounds for force. (D.I. 148 at 13.) The parties have each submitted copies of manuals for the Instron instrument, and, on reviewing the manual submitted by NOVA, the Court concludes that Dow's argument regarding the Instron instrument has some force. Indeed, although the Instron manual explains that the instrument may be operated using multiple unit systems, the manual explains that "the raw data file is stored in US Customary units." (D.I. 205, Exh. AL at 10-3.) Likewise, when referring to the display of raw data, the manual notes for emphasis that "[s]ince all raw data is stored in US Customary units, all displayed data is in US Customary units also (i.e., lbs., in., etc.)." (Id. at 11-2.) In addition, the Instron manual appears to explicitly confirm that US Customary units are the default units, instructing that a particular menu option "allows you to edit the raw data in either SI, Metric, or Mixed units instead of the default US Customary units." (Id. at 11-13 (emphasis added).) Thus, in the Court's view, one of skill in the art could easily conclude that the native units used in connection with the Instron device are pounds and inches and that the slope of strain hardening should thus be computed in such units. This conclusion is made all the more likely by the fact, noted above, that the patent describes the test to determine the slope of strain hardening in terms of English units. In light of this evidence - and the presumption of validity afforded issued patents - the Court is unable to conclude, as a matter of law, that the claims of the '053 and '023 patents are invalid as indefinite for failure to adequately specify the units for the slope of strain hardening.

With regard to the methodology for determining the "slope of strain hardening," the Court again looks to the specification, which explains as follows:

The slope of strain hardening is calculated from the resulting tensile curve by drawing a line parallel to the strain hardening region of the resulting stress/strain curve. The strain hardening region occurs after the sample has pulled its initial load ((i.e., stress) usually with little or no elongation during the initial load) and after the sample has gone through a slight drawing stage (usually with little or no increase in load, but with increasing elongation (i.e., strain)). In the strain hardening region, the load and the elongation of the sample both continue to increase. The load increases in the strain hardening region at a much lower rate than during the initial load region and the elongation also increase, again at a rate lower than that experienced in the drawing region. FIG. 1 shows the various stages of the stress/strain curve used to calculate the slope of strain hardening. The slope of the parallel line in the strain hardening region is then determined.

'053 patent at 6:27-43. NOVA contends that the above description is fatally deficient. First, NOVA contends that the passage fails to adequately explain how to draw a "line parallel to the strain hardening region" because the "strain hardening region" can, rather than being linear, actually be curved. (See D.I. 129, Exh. G PP 14-15 (NOVA's expert, Dr. Charles Stanley Speed, opines on the curvature of the strain hardening region).) In these circumstances, NOVA contends, there are multiple methods of drawing a line that may be regarded as being "parallel" to the curved "strain hardening region." (Id.) For instance, NOVA contends that one could draw a line "having the greatest slope in the strain hardening region" or, as another option, a 10% secant line, which corresponds to the "line between the failure or break point and the point at 10 percent extension back from the break point." (Id.) To the extent the patentee intended to set forth a single, definitive manner for drawing the line parallel to the strain hardening region, NOVA contends that this was to be in "FIG. 1" of the patent, but that this Figure is missing from the patent, a fact that Dow does not dispute. (See D.I. 141 at 2.) Given this uncertainty as to how the slope of strain hardening should be determined, NOVA contends that the claims must now be held indefinite as a matter of law.

The Court does not agree. Although, a figure is indeed missing from the specification, the text describing how to draw the line parallel to the strain hardening region is rather detailed. Indeed, the passage first instructs that the line should be drawn "parallel" to the strain hardening "region." Based on this guidance, one of skill in the art would be dissuaded from drawing secant lines or tangents that are not substantially parallel to the true strain hardening "region." As to how one of skill in the art could identify the true strain hardening region, the specification includes numerous details. To wit, the specification explains that the strain hardening region is the region where (1) the sample has pulled its initial load, (2) the sample has already gone through a slight drawing stage, (3) the load and elongation both continue to increase, (4) the load increases at a much lower rate than during the initial load region, and (5) the elongation also increases at a rate lower than experienced in the drawing region. See '053 patent at 6:25-44. NOVA's expert, Dr. Hsiao, explains that based on this description one of skill in the art would be able to identify this strain hardening region as a true linear "region" that occurs after the slope of the tensile curve stops arcing upwards but before it possibly begins to decrease again. (See D.I. 149 at 30-31.) To the extent the tensile curve begins to decrease after the true strain hardening region, Dr. Hsiao explains that one of skill in the art would

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not confuse this with the strain hardening region, but would instead attribute this to either a rupture of the sample or slippage of the sample in the test apparatus. (Id.) On reviewing NOVA's claim construction briefing and the supporting declaration of its expert, Dr. Speed, the Court concludes that NOVA has not effectively refuted this understanding of how one of skill in the art would identify the strain hardening region. Accordingly, the Court declines to find the claims indefinite as a matter of law.

However, the Court also cannot, at this stage, eliminate the possibility that the claims will ultimately be found indefinite. Indeed, the patent's failure to explicitly set forth the units for the slope of strain hardening coefficient and include a figure exemplifying the manner for computing the slope of strain hardening is, in the Court's view, troubling. And NOVA has presented a wide range of compelling evidence and arguments that, in light of this, one of skill in the art would be unable to determine the proper scope of this claim limitation. As just one example, NOVA has elicited testimony from numerous Dow engineers who, after reviewing the patents-in-suit, expressed an inability to calculate the slope of strain hardening. (See, e.g., D.I. 142, Exh. Q at 153:19-154:3; id., Exh. R at 161:7-162:16.) A named inventor on the patents-in-suit was even unable to explain how to carry out this calculation after reviewing the relevant portions of the specification. (See D.I. 130, Exh. I at 209-212 (excerpts of deposition transcript of inventor Pak-Wing Steve Chum).) In these circumstances, a trier of fact would, in the Court's view, be entitled to conclude that the claims are indefinite.

Accordingly, the Court shall construe the term "slope of strain hardening coefficient of greater than or equal to 1.3" to mean, as Dow contends, "the slope of strain hardening multiplied by the melt index raised to the 0.25 power must be greater than or equal to 1.3." However, although the Court has provided a construction for this term, NOVA may still present its indefiniteness theory to the jury. Halliburton Energy Services, Inc. v M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008) ("[E]ven if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.").
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a. "softening or melting temperature"

The Court tentatively construed the term "softening or melting temperature" in its Preliminary Injunction Opinion "as referring to any temperature at whichthe viscosity of the binder contained in the photopolymerizable layer will be reduced to such a point that the thermally removable layer, or portions thereof, may be removed by absorbing material." (Prelim. Inj. Op. at 44-45.) The Court, in reaching this conclusion, expressly considered and rejected MacDermid's contention that the term itself is indefinite. (Id. at 42-45.)

At the subsequent Markman hearing, MacDermid attacked the tentative construction and asserted that the term at issue is irreparably indefinite. (Tr. at 157-71.) Evidently accepting the validity of the melting temperature component, it contends that "we have a critically fatal indefiniteness problem with respect to the softening part." (Id. at 157.) MacDermid argues:

> We believe that the binder in this part of the claim needs to be directed to the binder of the thermally removable layer[,] not the photopolymerizable layer. Secondly, we don't believe that it can be any temperature. It needs to be a particular temperature in order to be definite. And then third, and I think probably most important is Your Honor's construction is functional. It doesn't define the class of binders by what they are. It defines them by howthey operate in this particular process, and, therefore, they're functional.

(Id. at 158.) MacDermid contends that the specification (1) does not define the notion of "softening temperature", leaving no way to know exactly what softening is, when it happens, and how to measure it, and (2) creates further uncertainty by "say[ing] some of the above materials do not have an actual softening or melting point." (Id. at 159-60.) As to the extrinsic evidence, MacDermid notes that "softening temperature" is defined as "the temperature at which material transforms a specific amount when measured under specific examination conditions, i.e., depends on how you measure it and under what circumstances you measure it." (Id. at 160.) Citing Halliburton Energy Services v. M-I LLC, 514 F.3d 1244 (Fed. Cir. 2008), Datamize, LLC v. Plumtree Software, 417 F.3d 1342 (Fed. Cir. 2005), and Honeywell Int'l v. Int'l Trade Comm'n, 341 F.3d 1332 (Fed. Cir. 2003), MacDermid argues that (1) the term is indefinite, (2) the applicant could have adopted an "ISO-known standard", or another objective method or standard, to measure softening, and (3) the Court's functional approach thus does not provide a meaningfullydefinite boundary because external circumstances affect the softening of different

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materials, thereby causing the boundary to shift impermissibly. (Id. at 161-67; see Mahanna Decl. Exs. 4-5.)

DuPont defends the Court's tentative construction, with some minor modifications. (Tr. at 44-47, 179-82.) It proposes the following construction: "Any temperature at which the viscosity of the binder will be reduced to such a point that the thermally removable layer, or portions thereof, may be removed." (Tr. at 44 (referring to slide).) It suggests the removal of the statement that the binder is contained in the photopolymerizable layer because "the binder is actually in the actinic radiation opaque layer." (Id. at 45.) It then recommends the removal of the phrase "by absorbing material" because such a process is addressed in claim 36. (Id.) As to MacDermid's assertions of indefiniteness, DuPont argues that MacDermid's position is inconsistent with language contained in the specification and its own expert's declaration. (Id. at 46-47.) DuPont explains that:

[T]heir expert had no problem construing it. Their expert said, "It's the temperature at which the material becomes inviscid enough to flow,and the purpose of specifying a softening temperature or melting temperature is to insure the flow and, therefore, thermal development -" he's talking about this patent "- can occur at a reasonable processing and developing temperature."

(Id. at 46 (quoting D.I. 44-6 at 6-7).)

MacDermid's contentions are reasonable, but the Court is not persuaded to find the term "softening or melting temperature" indefinite. The Court continues to adhere to the finding in the Preliminary Injunction Opinion that "the intrinsic evidence, including the specification and the context in which the term is used in limitation 1(a) of claim 1, provides a sufficient basis for construing 'softening or melting temperature.'" (Prelim. Inj. Op. at 44 (quoting Phillips, 415 F.3d at 1314-15).) After summarizing MacDermid's indefiniteness assertions, the Court explained:

The specification contains the following statements, which reference the "softening" or "melting" of the thermally removal layer:

Thermally treating the element includes heating the exposed photopolymerizable layer and the thermally removable layer at a temperature sufficient to cause the unexposed (uncured) portions of the element to soften or melt orflow, and contacting the layer to an absorbent surface to absorb the melt or flow portions. The polymerized areas of the photopolymerizable layer have a higher melting temperature than the unpolymerized areas and therefore do not melt, soften, or flow at the development temperatures. The term "melt" is used to describe the behavior of the unirradiated portions of the photopolymerizable elastomeric layer subjected to an elevated temperature that softens and reduces the viscosity to permit flow and absorption by the absorbent material. (Taylor Decl., Ex. 1, '859 patent, at col. 20, lines 47-60.)

[S]o the process functions to absorb the heated composition layer at any temperature above some threshold for absorption in the absorbent material. A wide temperature range may be utilized to "melt" the composition layer for the purposes of this invention. (Id. at col. 20, lines 63-67.)

The photopolymerizable layer and the thermally removable layer/s are heated by conduction, convection, radiation, or other heating methods to a temperature sufficient to effect melting of the uncured portions but not so high as to effect distortion of the cured portions of the layer. The photosensitive element isheated to a surface temperature above about 40[degree]sC.; preferably from about 40[degree]sC. to about 230[degree]sC. (104-446[degree]s.F.), more preferably from about 100 to 200[degree]sC., and most preferably from 100 to 160[degree]sC. in order to effect melting or flowing of the uncured portions of the photopolymerizable layer and the thermally removable layer. The absorbent material contacts the surface of the heated photosensitive element, and absorbs the softened or molten or flowing portions of the elastomeric layer from the unirradiated portions, forming a flexographic printing plate in which the uncured portions are removed to form a relief pattern or surface. The thermally removable layer disposed above the photopolymerizable layer may soften or melt or flow and be absorbed as well by the absorbent material. (Id. at col. 21, lines 8-27.)

Thus, there are multiple references in the specification establishing that the "softening or melting temperature" refers only to the temperature necessary to sufficiently reduce the viscosity of the binder contained in the thermally removable layer so that such layer may be absorbed by the absorbent material.

(Id. at 43-44.) This reasoning, made in the context of the Preliminary Injunction Opinion, is re-affirmed and adopted for

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claim construction purposes. But the Court accepts the seemingly minor and evidently uncontested changes suggested by DuPont. Accordingly, "softening or melting temperature" means "any temperature at which the viscosity of the binder will be reduced to such a point that the thermally removable layer, or portions thereof, may be removed."
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C. "solid"

1. The Parties' Proposed Constructions

Rhodia maintains that the word "solid" needs no construction. (D.I. 167 at 5.) If I do construe the word, however, Rhodia asserts it should be construed to mean "not a hollow body. Solid does not exclude porous solid forms." (Id.) In support of its proposed construction, Rhodia refers to statements made during prosecution of the '234 patent in which the inventors distinguish their invention over prior art on the basis that the prior art consisted of hollow silica spheres as opposed to the solid silica spheres of the '234 patented invention. (Id.)

PPG suggests that I construe "solid" "to mean that the spray-dried silica particulates have the form of a densely filled particle having no intervening air spaces or pockets. This definition would specifically exclude particles that are porous or spongy, as these … have interior spaces or voids making them akin to a hollow-type particle …." (D.I. 106 at 14; but see D.I. 167 at 15 (modifying proposed construction to read "the silica particulates have the physical form of a densely filled particle having few or no intervening air spaces or pockets.") (emphasis added).) PPG relies on similar statements the inventors made during patent prosecution to distinguish their invention over prior art with hollow silica spheres, but PPG draws a contrary inference. (Id. at 12-14.) PPG asserts that in distinguishing the patented invention over the hollow silica spheres of the prior art during patent prosecution, the inventors "drew a distinct line between … [their] dense silica spheres and any particles having hollow spaces or cavities in their interior." (Id. at 14.) Moreover, argues PPG, its proposed construction is consistent with the plain meaning of the word "solid", as evidenced by the definition of the word provided in a standard dictionary. (Id. at 14; D.I. 169, Ex. 22.)

2. The Court's Construction

The word "solid" carries an ordinary and not particularly technical meaning in the asserted claims, permitting construction by reference to a dictionary definition. I construe "solid" to mean an object having a definite shape that offers resistance to a deforming force. DICTIONARY OF SCIENCE AND TECHNOLOGY 1089 (T.C. Collocott M.A., ed., Barnes & Noble 1971). The word "solid" excludes a hollow body, but is broad enough to encompass porous material. Excluded from the definition is a hollow body, since the inventors distinguished their invention over prior art hollow bodies during patent prosecution, but a porous solid material is included within my construction.
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The disputed claim language in claim 3 is "solid dosage form." The parties stipulated to the meaning of these terms, defining "dosage form" as "a pharmaceutical preparation in which doses of medicine are included" and "solid dosage form" as "a dosage form that is neither liquid nor gaseous." (JCCR at 2.) Despite its agreement with these definitions, Mylan now asserts that the '355 patent implicitly limits the definition of "solid dosage form" to "osmotic dosage form." It maintains that "every time the 'dosage form provided by the invention' is referenced in the patent specification, it describes only an osmotic pump release mechanism." (Mylan's Opening CC Br. at 15) (citing several examples). n1

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n1 The credibility of Mylan's position on this issue is questionable. Nine months after filing its answer in this case, Mylan stipulated to the definition of "solid dosage form." It could not have been prepared to reach such an agreement without having read the specification thoroughly. Nonetheless, Mylan now posits a different definition of "solid dosage form" based primarily on the specification.

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As used in the '355 Patent, however, the term "dosage form" comports with its broad stipulated definition. In the section entitled "Objects of the Invention," the patent qualifies the term in numerous ways: "sustained-release dosage form," "solid-oral dosage pharmaceutical form," "drug delivery dosage form," "controlled-release dosage form," and, most notably, "an osmotic dosage form." '355 Patent, cols. 2-3. The examples in the written description also indicate that the invention encompasses more than one dosage form. See generally id. at 10:66-15:23 (referring to the manufacture of "a dosage form" or "dosage forms"); see Johnson Worldwide Assocs. v. Zebco Corp., 175 F.3d 985, 991 (Fed. Cir. 1999) ("Varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition.") (citation omitted). Moreover, the patent refers to both osmotic and non-osmotic dosage forms. See, e.g., id. at 4:2-5, 38-52; id. at 5:25-40; id. at 6:6-20. Thus, in the examples cited by Mylan, the osmotic dosage form is merely a preferred embodiment, which, by itself, cannot limit claim 3. Johnson Worldwide, 175 F.3d at 992.

Although "dosage form" is used in describing an osmotic pump delivery system, the specification does not manifestly or consistently equate "dosage form" with "osmotic dosage form." See Bell Atl. Network Servs., Inc. v. Covad Comm. Group, Inc., 262 F.3d 1258, 1271 (Fed. Cir. 2001). The patent also does not criticize or affirmatively exclude non-osmotic dosage forms. See SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems. Inc., 242 F.3d 1337, 1343-44 (Fed. Cir. 2001). Therefore, Mylan fails to persuade the Court that the specification unequivocally limits the term "solid dosage form" to mean "osmotic dosage form."

The March 1999 CIP/'115 patent also broadly defines "dosage form." Indeed, the '115 patent expressly states that "[d]osage form denotes a drug delivery system for administering a therapeutically effective dose of drug, for example oxybutynin to a patient in need of therapy." n2 '115 patent, col. 2:57-60. By inclusively defining "dosage form" while adding other examples of non-osmotic dosage forms, the '115 patent confirms that the term "dosage form" should not be limited to only osmotic dosage forms. Moreover, insofar as the March 1999 CIP/'115 patent suggests that the '355 patent specification describes only osmotic dosage forms, as Mylan argues, the CIP cannot restrict claim 3 in the '355 patent to osmotic dosage forms. Such a construction would indirectly and erroneously import a limitation from the specification. Accordingly, since neither the specification nor the March 1999 CIP clearly narrows the scope of claim 3's coverage to osmotic dosage forms, the Court broadly construes "solid dosage form" pursuant to the parties' stipulated definitions.

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n2 This definition differs from the parties' stipulated definition of "dosage form," i.e., "a pharmaceutical preparation in which doses of medicine are included." Accordingly, the two meanings appear to embrace discrete structures. As used in the '355 patent, "dosage form" is a pharmaceutical preparation that contains a drug. In the '115 patent, the term is defined as a drug delivery system. To the extent that this distinction is relevant to the claim construction at hand, it supports a broad reading of "dosage form."

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II. Construction Of The Disputed Phrases

The parties dispute the construction of four phrases: "substantially powdered form," "mixing the drug and the carbohydrate material," "solid integral mass," and "drug-containing matrix." The four disputed phrases appear in independent Claims 1, 6, 18, and 37 of the '737 patent. Claims 1 and 18 are method claims and Claims 6 and 37 are article of manufacture claims. The language of Claims 1 and 6 are representative of the disputed phrases. In full, Claim 1 provides (emphasis added):

1. A method for producing a drug-containing lollipop for use in transmucosal delivery of the drug to a patient, the method comprising the steps of:

(a) obtaining a pharmacologically effective dose of the drug in a substantially powdered form, the drug being capable of

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absorption through mucosal tissues of the mouth, pharynx, and esophagus;

(b) obtaining a soluble carbohydrate material capable of forming a compressible confectionary matrix and capable of dissolving in the mouth of the patient;

(c) mixing the drug and the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material to form a drug-containing matrix such that the drug is dispersed substantially throughout the matrix, the drug-containing matrix being capable of releasing the drug for absorption through the mucosal tissues upon dissolution of the matrix in the mouth of the patient;

(d) compressing the drug-containing matrix in a mold to form an integral mass such that, when the integral mass dissolves in the mouth of the patient, the drug is released for absorption through the mucosal tissues; and

(e) incorporating a holder as part of the integral mass in order to form the drug-containing lollipop.

('737 patent, col. 26, 11. 35-60).

In full, Claim 6 provides (emphasis added):

6. A drug-containing lollipop for use in transmucosal delivery of the drug to a patient comprising:

a soluble, compressible carbohydrate material;

a pharmacologically effective dose of a drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus and being dispersed substantially uniformly throughout the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material and compressed with the carbohydrate material into a solid integral mass which is capable of dissolving in the mouth of the patient so that the drug is released for absorption through mucosal tissues of the mouth, pharynx, and esophagus upon dissolution of the integral mass in the mouth of the patient;

holder means secured to the integral mass so as to form a drug-containing lollipop, the holder means being configured so as to permit convenient insertion and removal of the drug-containing integral mass into and out of the mouth of a patient.

('737 patent, col. 27, 11. 12-33).

The essence of the dispute with regard to all four disputed phrases is whether they should be construed to require the absence of "free liquid." "Free liquid" is defined by Barr as "any liquid that is not incorporated chemically into the fine particles, beyond that which may be sorbed naturally." (D.I. 41 at 15 n.8.) Cephalon takes no position with regard to whether Barr's definition of "free liquid" is correct. (D.I. 50 at 7 n.17.) The Court construes "free liquid" in accordance with Barr's definition.

Cephalon contends that the disputed claim phrases should not be limited by requiring the absence of free liquid, first, because the plain and ordinary meaning of the phrases does not require it, and second, because neither the specification nor the prosecution history shows any clear disclaimer of the use or presence of free liquid. In response, Barr contends that statements in the specification that describe the "present invention" limit the scope of the claims to preclude free liquid. Barr further contends that the prosecution history shows an effective disclaimer of the use of free liquid in the methods and articles of manufacture claimed by the '737 patent.

The Federal Circuit's recent decision in Phillips v. AWH Corp. clarified the approach that a court should take in construing disputed terms of a patent claim. 415 F.3d 1303 (Fed. Cir. 2005) . Rather than beginning with a broad, dictionary definition and then limiting it in accordance with the specification and the prosecution history, the preferred approach is to focus "at the outset on how the patentee used the claim term in the claims, specification, and prosecution history . . . ." Id. at 1321. Here, both the specification and the prosecution history demonstrate that the inventions actually described and claimed by the '737 patent are a method of producing drug-containing lollipops using the compression of dry, powdered ingredients, and the products resulting from the use of that method. Nowhere in the claims, the specification, or the prosecution history

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do the inventors ever discuss the possibility of using a liquid as part of their invention. In addition, and more significant, many of their statements indicate that the inventors viewed their invention as enveloping only the dry mixing and compression of powders to form the drug-containing lollipops.

The following are illustrative examples. In the Summary of the Invention section, the '737 patent states that "the present invention teaches the combination of dry powdered ingredients by geometric dilution," ('737 patent, col. 5, 11. 43-45); and "flavorings, drugs, and other components (which may be insoluble in liquid form) are easily mixed when they exist as a dry powder," (Id. at col. 6, 11. 6-8). In the General Discussion of the Preferred Embodiments section, the '737 patent states that "the present invention teaches the mixing of solid powders at room temperature, as opposed to liquid components at elevated temperatures," (Id. at col. 7, 11. 62-65); and "because solid powders are combined together, constituents which may be chemically incompatible when in a heated solution or suspension can be mixed," (Id. at col. 8, 11. 3-6). In the Methods of Manufacture of the Preferred Embodiments section, the '737 patent states that "each of the components is mixed with the other components in dry form to produce the compositions of the present invention." (Id. at col. 11, 11. 47-49).

Cephalon argues that these examples do not amount to a clear disclaimer of the use of liquid in the claimed manufacturing method (D.I. 50 at 12-13), but that argument is misplaced. Whether or not there was an explicit disclaimer, the consistent use of a claim term by the inventor in the specification may serve to limit the scope of a claim. Nystrom v. Trex Co., 424 F.3d 1136, 2005 U.S. App. LEXIS 19748, 2005 WL 2218632, 6-7 (Fed. Cir. 2005).

"What Phillips now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to . . . those of ordinary skill in the art . . . that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."

Id. 2005 U.S. App. LEXIS 19748, at 7 (citing Phillips, 415 F.3d at 1321). Here, the inventors consistently referred to the "present invention" as teaching the formation of drug-containing lollipops through the compression of "dry" or "solid" powders. There is nothing in the written description or the prosecution history to suggest that they intended the disputed phrases to cover methods or articles using free liquid. Therefore, it would be improper for this Court to broaden the inventors' use of the disputed phrases and construe them to encompass the use of free liquid.

This result is not, as Cephalon argues (D.I. 50 at 12-13), the improper importation of limitations from the specification into a claim. This is a case where "the specification read as a whole suggests that the very character of the invention requires the limitations to be a part of every embodiment." Alloc, Inc. v. ITC, 342 F.3d 1361, 1369 (Fed. Cir. 2003).

For the reasons discussed above, the Court construes the disputed claim phrases as follows:

A. "Substantially powdered form" means "largely in the form of fine particles absent the presence of free liquid."

B. "Mixing the drug and the carbohydrate material" means "combining or blending the drug from step (a), the drug being largely in the form of fine particles absent the presence of free liquid, with the carbohydrate material from step (b), without the use of free liquids."

C. "Solid integral mass" means "a drug, largely in the form of fine particles absent the presence of free liquid, pressed or squeezed together with the carbohydrate material, without the use of free liquids, into a unitary mass that is not liquid or gaseous."

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Claim 1

In a process of ladle refining of steel comprising the steps of disposing in a ladle a quantity of molten steel to be refined, adding a material which forms a covering of a molten protective ladle metallurgy slag on the steel in the lade and refining the steel in the ladle to the desired metallurgical condition, the improvement comprising: adding as the ladle metallurgy

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furnace additive a solid material comprising from about 10% to about 90% of a solid recycled ladle metallurgy furnace slag and from about 10% to about 90% of a raw material selected from the group consisting of: a calcium oxide source; soda ash; fluorspar; borax; calcium aluminate; an aluminum source; an alumina source; calcium carbonate; metallic calcium, magnesium, and sodium and their oxides, fluorides and carbides; and mixtures of all the foregoing. (emphasis added)

This claim describes the process "of ladle refining" -- that is, the method and steps. The key phrase in dispute here is "a solid material comprising." 1 Defendant argues this means a mixed solid material of two components -- recycled LMF slag and a raw material. Plaintiff's position is that Claim 1 never mentions a mixture of those two components and that Defendant is improperly attempting to limit the claim to mixtures. The specifications of the patent discuss three methods by which slag and raw materials may be added during the steeling refining process. Those three methods are: (1) solid granular mix; (2) briquetted mixtures; and (3) LMF slag ground separately from raw materials and added separately in at least two steps (Tr. 21).

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1 Claims 21-24 are dependent on Claim 1 and also dependent upon the definition of "a solid material."

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Defendant claims the last method does not apply to Claim 1 but is only directed to Claim 24. Plaintiff argues the three examples in the specification entitled "summary of the invention" do not limit the invention.

The Court agrees that solid material means something that is not liquid or gas, a point now conceded by Defendant (Amended Post Hearing Brief at p. 4). This meaning is supported by the history of the patent designed to improve upon the prior art using a liquid. Defendant would have the Court limit the phrase to mean a "mixed" solid material (Tr. 27). But that is not what its says, and the word "mixed" is used elsewhere in the patent. Also, as used in this phrase, solid material means something more than a single substance because the phrase discusses a solid material "comprising . . . slag and . . . raw material . . .". And the raw material may be a "mixture" made up of itemized items ("selected from a group"). But the claim does not define the raw material mixture as being mixed with the slag material -- the two materials could be added separately.
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6. "solid state"

This term appears in claims 1-7 and 10. Astra asserts that this term means "a solid form rather than liquid, such as, a syrup or oil." DRL contends that no construction of this term is necessary and the ordinary meaning as understood by those skilled in the art should apply. Alternatively, DRL proposes that the term be construed as "a solid form."

With respect to its proposed construction, Astra provides no justification for the language that distinguishes a "solid form" from a "liquid, such as, a syrup or oil." Moreover, the Court agrees with DRL that no construction of this term is necessary finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.
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Ultimax argues that the district court erred in construing "soluble CaSO[4] anhydride" to refer to a compound derived from an acid. According to Ultimax, the court erroneously used the stand-alone definition of "anhydride," without context. Ultimax asserts that the dictionary definition treats "anhydride" as a stand-alone compound, but in the context of the claim, it is a modifier, modifying the compound "calcium sulfate." Ultimax further argues that the court found its own definition inconsistent with the specification and unknown in the art, and that the neutral expert's finding also refuted the court's construction. According to Ultimax, even CTS's documents use "anhydride" and "anhydrite" interchangeably. Thus, Ultimax argues, the court should have adopted a definition consistent with the specification and the art.

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CTS responds that the district court correctly gave "anhydride" its ordinary meaning, which is different from the meaning of "anhydrite" and refers to an acid from which water has been removed. CTS's product does not contain such a material. According to CTS, the court correctly based its decision on the specification's lack of use of the term "anhydrite" and neutral expert testimony.

We agree with Ultimax that the district court erroneously construed "soluble CaSO[4] anhydride" to mean "a compound formed from an acid by removal of water" and hold that the term should be construed as "soluble anhydrous CaSO[4]," or "soluble anhydrous calcium sulfate." We review claim construction de novo on appeal. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). We begin a claim construction analysis by considering the language of the claims themselves. See Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). However, "claims must be read in view of the specification, of which they are a part." Id. at 1315 (quotation marks omitted). "[A] court should also consider the patent's prosecution history, if it is in evidence. . . . Like the specification, the prosecution history provides evidence of how the [Patent Office] and the inventor understood the patent." Id. at 1317 (citations and quotation marks omitted).

Furthermore, courts may "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Id. at 1322-23 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996)). However, "[a] claim should not rise or fall based upon the preferences of a particular dictionary editor, or the court's independent decision, uninformed by the specification, to rely on one dictionary rather than another." Id. at 1322. Indeed, "the authors of dictionaries or treatises may simplify ideas to communicate them most effectively to the public and may thus choose a meaning that is not pertinent to the understanding of particular claim language. The resulting definitions therefore do not necessarily reflect the inventor's goal of distinctly setting forth his invention as a person of ordinary skill in that particular art would understand it." Id. (internal citation omitted).

Here, without the benefit of our opinion in Phillips, which was issued after the district court's opinion in this case, the court erroneously relied on expert testimony and a single dictionary definition to the exclusion of other dictionary definitions and, most importantly, the context in which the term was used within the claim and the specification. Although the word "anhydride" appears in the term "soluble CaSO[4] anhydride," its proper construction requires consideration of the context of the rest of the term. "Anhydride," when placed next to "CaSO[4]," is intended as a modifier, modifying "CaSO[4]," or "calcium sulfate." In other words, the term refers to calcium sulfate from which any associated water has been removed. Indeed, dictionaries other than that relied on by the court allow "anhydride" to refer to a compound other than one obtained by removing water from an acid, based on context. For example, the definition that Plaintiffs proffered defines "anhydride" as "[a] chemical compound formed from another, often an acid, by the removal of water." J.A. 3749 (emphasis added) (citing definition from The American Heritage Dictionary of the English Language (2000)). Thus, especially in light of the ambiguity of the proffered dictionary definitions, the context must define what compound has had water removed. Here it is calcium sulfate, not an acid.

The context of the entire specification further supports the conclusion that "soluble calcium sulfate anhydride" means "soluble anhydrous calcium sulfate." First, the word "anhydride" never appears alone in the specification, but only as a modifier of "calcium sulfate." See '556 patent Abstract, col.3 l.51, col.3 l.55, col.8 l.6, col.8 ll.8-9, col.9 l.43, col.10 l.19, col.10 l.21, col.10 l.43, col.10 l.50 (referring to the same compound as "soluble CS anhydride"), col.5 l.16 (referring to "soluble calcium sulfate anhydride"), col.9 ll.40-41 (referring to the same compound as "soluble c--S anhydride"), col.9 ll.45-46 (referring to "CS anhydride"), claims (referring to both "soluble CaSO[4] anhydride" and "soluble CS anhydride"). As the court recognized, "[n]owhere in the teachings of patent '556 is there a discussion of forming a compound from an acid by removal of its water." '684 Indefiniteness and '556 Noninfringement and Laches Opinion, 2004 U.S. Dist. LEXIS 29580, at *41. There is no evidence shown of any acid from which water is removed to yield CaSO[4], as there is for acetic acid or maleic acid, which, when water is removed, yield acetic anhydride and maleic anhydride, respectively. Any water removed here is that associated with the method of obtaining calcium sulfate, such as mining, not water originally associated with an acid. As a result, contrary to the district court's conclusion, the context of the specification requires that "soluble calcium sulfate anhydride" be construed as anhydrous calcium sulfate.

Furthermore, contrary to the district court's conclusion, interpreting the claim term to mean "soluble anhydrous calcium sulfate" is not rewriting the claim or correcting a typographical error. The drafters could not have intended to claim "soluble

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calcium sulfate anhydrite," as that would have been redundant because the word "anhydrite" itself means "anhydrous calcium sulfate." See, e.g., Webster's Third New International Dictionary of the English Language Unabridged (1986) (defining "anhydrite" as "a mineral consisting of an anhydrous calcium sulfate CaSO[4] . . ."). Instead, the term "soluble calcium sulfate anhydride" simply means, in the context of the '556 patent, the same thing as "soluble anhydrous calcium sulfate." The neutral expert, Dr. Seible, agreed that the context of the specification led to the conclusion that the patent drafter likely meant "anhydrite and not anhydride," referring to the entire claim term. 2004 U.S. Dist. LEXIS 29580 at *41-42. As Ultimax points out, CTS and Rice himself, a person of at least ordinary skill in the art, use the word "anhydride" when they mean "anhydrite," with no resulting confusion. Ultimax Br. at 13-14. Thus, interpreting the claim in that way merely restates its plain meaning.

We therefore disagree with the district court's interpretation of "soluble CaSO[4] anhydride" to require derivation from an acid, and we instead construe the term to mean "soluble anhydrous CaSO[4]," or "soluble anhydrous calcium sulfate." Because we have reversed the court's claim construction, we vacate its holding of noninfringement and remand to the district court the issue of infringement of the '556 patent.
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F. 5% Soluble Protein Loss ("SPL") and 5% SPL Lines of Figure 3

Michael Foods contends that "heated for a predetermined time and to a predetermined temperature insufficient to cause more than a 5% soluble protein loss from said product means testing the product to determine the difference in SPL pre- vs. post-pasteurization." (Michael Foods' Initial Markman Br. at 30.) Sunny Fresh claims that "soluble protein loss" includes the cumulative losses of natural proteins in an egg product caused by thermal treatment and mechanical effects during the pasteurization and packaging of the product. (Kempf Aff., Ex. 26 at 7.) Sunny Fresh argues that the "loss" is measured from raw egg to packaged egg product. (Id.) The court therefore must construe the term "5% SPL."

The specification makes clear that "5% SPL" refers to an actual measurement calculated "by determining the loss of soluble protein as described by Hammid-Samimi et al., supra." (Kempf Aff., Col. 10, ll. 28-29.) The patent provides various industry-recognized tests for measuring the SPL in Table 3 of the patent. The court therefore construes the term "5% SPL" to refer to actual test results on product based on the test methods referenced in the patent.

While the parties appear to agree that the measurement begins from the raw product, (Michael Foods' Initial Markman Br. at 30; Kempf Aff., Ex. 26 at 7), the parties disagree on the measurement's ending point. The claim element refers to heating, not packaging. (See, e.g., Kempf Aff., Ex. 3, Col. 15 43-67; Col. 16 ll. 1-8.) If the court were to adopt Sunny Fresh's suggestion that the SPL is the difference between raw product and post-packaging, the court would erroneously read the requirement of packaging into the claim. See Markman, 52 F.3d at 980 (stating that it is the "function and purpose of the claims" to "delimit the right to exclude."). Instead, because the patent expressly mentions heating, the court construes the term "5% SPL" to mean testing the product to determine the difference in the SPL pre- and post-pasteurization based upon the methods described in the patent.

The court notes that certain claim elements also discuss whether the equivalent point calculation results in a point about the "5% SPL (Batch) line of Figure 3." For instance, Claim 1 of the '225 patent states that "the total thermal treatment received by the liquid whole egg product is defined by an equivalent temperature and an equivalent time defining a point about the 5% SPL (Batch) line of Fig. 3…." (Kempf Aff., Ex. 1, Col. 15, ll. 59-62.) The total thermal treatment a product receives in a continuous processing system includes any impact on product constituents caused by the heating, holding and cooling steps of the process. (Id., Col. 4, ll. 4-23.) In continuous flow processing equipment, the thermal treatment is described by a point in Figure 3 of the '225 patent defining an equivalent time and an equivalent temperature. Under the desired processing conditions, the equivalent point is above the 5% SPL (Batch) line shown in Figure 3. 11

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11 The court notes that the 5% SPL (Batch) line was mislabeled in Figure 3 as the 15% SPL (Batch) and is the lower of the 15% SPL (Batch) lines in Figure 3.

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B. Claim 1: "A Chemical Label Further Comprising a Signalling Moiety Capable of Generating a Soluble Signal"

The more complex dispute concerning the Stavrianopoulos Patent is whether a "chemical label further comprising a signalling moiety capable of generating a soluble signal" describes light itself (plaintiffs' position) or the soluble compounds resulting from the action of the enzyme label on a soluble substrate that can be measured by use of light, i.e., a spectrophotometer (defendants' position).

Plaintiffs would construe "soluble signal" in Claim 1 as "a signal which does not precipitate and is thus detectable by spectrophotometric and/or colormetric assay techniques, such as for instance, colormetric, photometric and fluorescent signals." They derive support for their construction from several dependent claims. Claims 2 and 13 claim a "detecting step [that] comprises spectrophotometric techniques." '373 Pat. 13:48-49. Claims 3 and 15 claim that the "soluble signal is selected from the group consisting of a colored product, a chemiluminescent product and a fluorescent product," while claim 19, which depends from an experiment "kit" claimed in 18, states that the "soluble signal is a colored product or a fluorescent product." Additionally, the specification teaches that "the method of the present invention involving the colorimetric or photometric determination of the hybridized probes employs as the signalling moiety reagents which are capable of generating a soluble signal, e.g., a color change in a substrate in solution." Id. at 6:9-13. Plaintiffs argue that because these dependent claims suggest that the soluble signal is a color or a fluorescence or can be detected with spectrophotometer, the soluble signal can include light.

Defendants construe "soluble signal" as a "soluble compound dissolved in solution," and would require that "the label includes a portion capable of producing a detectable compound." They emphasize the scientific definition of "soluble" as "capable of being dissolved," and argue that Enzo's construction is scientifically illogical because light cannot be dissolved. They would define the signal as the color change of a "compound in solution," not a property of the signalling moiety itself. Defendants' expert explains that Table 1 in the specification of the '373 patent, which lists "exemplary components" for the label and substrate, lists combinations that react to form water-soluble colored or fluorescent molecules. See Kricka Report at 37. Finally, defendants criticize plaintiffs for impermissibly reading the term "soluble" out of the phrase "soluble signal," and argue that the inventors would not have distinguished between soluble and insoluble signals (i.e., precipitates) if any signalling moiety were covered by the claims.

It is evident from the parties' arguments and expert reports that the term "soluble signal" would have no established meaning to one skilled in the art. See Krika Report at 35 ("In my opinion, a skilled person in 1983 would not have readily understood the term 'soluble signal.' Solubility is not a characteristic that is normally associated with a signal in general.") In this instance the inventors were their own lexicographers. The term they invented, however, is ambiguous given applicable scientific principles which, as defendants point out, instruct that the signal the inventors had in mind -- light (including color) -- is not "soluble" because it does not dissolve in solution. On the other hand, defendants' definition of "soluble signal" as "a detectable compound dissolved in solution" finds no basis in the claims or specification, which do not use the term "compound" and in fact suggest that the inventors intended "signal" to refer to light, which is not a compound. The Court's task therefore is to construe the term "soluble signal" giving effect to both of the words in that phrase.

The background of the invention defines "Signal" as "The characteristic of a label or signalling moiety that permits it to be detected from sequences that do not carry the label or signalling moiety." '373 Pat. 1:66-68. The technique for determining the presence and quantity of the signalling moiety is consistently referred to in the specification as "colorimetric or photometric determination," see, e.g., id. at 6: 10; 7:15; 8:56, and one example of "a soluble signal" consistently given in the specification is "a color change in a substrate in solution." Id. at 6:13. The advantage of the inventors' techniques, they claimed, was that previous techniques using "insoluble 'signals', i.e., precipitates, certain fluorescers, and the like. . . , only provide detection not quantitation." Id. at 4:43-44. Thus it appears that they did not intend to limit the "signal" to simply a "detectable compound," but were concerned with the characteristics of the signal that would allow it to be used to quantify the amount of probe that had hybridized with the analyte. While defendants may be correct that the exemplary components for the signalling moiety listed in Table 1 (col. 6) of the patent all involve compounds that would dissolve in solution, these were given only as examples, and the inventors clearly believed that the primary aspect of their invention was "the

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colorimetric or photometric determination of the hybridized probes. . . which are capable of generating a soluble signal, e.g., a color change in a substrate in solution." '373 Pat. 6:9-13 (emphasis supplied). Thus, the Court concludes: (1) the inventors wanted to distinguish their invention from previous methods utilizing insoluble signals such as precipitates; but (2) they were less concerned with the solubility of the signal than the method of detection, including colorimetric and photometric techniques.

Therefore, although neither party's proposed construction of the term "soluble signal" is entirely satisfying -- because the term itself has no inherent meaning outside of this patent -- the Court adopts plaintiffs' definition of "soluble signal" as "a signal that does not precipitate and is thus detectable by spectrophotometric and/or colormetric assay techniques, such as colormetric, photometric and fluorescent signals."
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Plaintiff has asserted claims 1, 17, 18, and 25 of this patent. n21 Claim 1 provides:
A method for detecting a polynucleotide sequence which comprises:

fixing said polynucleotide sequence to a solid support which comprises or is contained within a transparent or translucent, non-porous system, such that a single-strand of the polynucleotide is capable of hybridizing to complementary nucleic acid sequences;

forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, said probe having attached thereto a chemical label further comprising a signalling moiety capable of generating a soluble signal; and

generating and detecting said soluble signal.

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n21 Claims 17, 18, and 25 require no claim constructions independent of that given to claim 1.

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In brief, the technology at issue in this patent involves the determination of whether substances, described as "analytes," are present in biological or non-biological samples, such as "blood[,] urine, feces, saliva, pus, semen, serum, other tissue samples, fermentation broths, culture media, and the like." '373 patent col. 5, 11. 22-27. Detection of these substances is accomplished by "denaturing" strands of DNA or RNA found in the sample, such that these normally two-stranded molecules are separated into single-stranded form. See id. at col. 5, 11. 37-41. The single-stranded DNA or RNA of the sample is then attached to a solid surface, and a probe, which is single-stranded DNA or RNA sequence complementary to the analyte, is introduced. If the analyte is present in the sample, then the probe will bind, or hybridize, to the sample. Detection is accomplished by washing away unhybridized probes and then searching for the presence of the labeled probe using a variety of techniques. See id. at col. 5, ll. 58-68, col. 6, ll. 1-8.

All parties agree that it is possible for the test just described to be conducted by attaching unlabeled single-stranded probes to the solid surface and then introducing labeled strands of the sample. If the sample contains DNA or RNA complementary to the probe (that is, if the analyte is present in the sample), then hybridization will occur and the same steps will be taken to detect the presence of the label. See, e.g., Hr'g Tr. at 308, 520-21.

The question before the Court is whether claim 1 of the '373 patent contemplates conducting the test using the latter process described, i.e., attaching the probe to the solid surface. This Court finds that it does not.

The language of claim 1 indicates that "a polynucleotide sequence" is fixed to a "solid support" and "hybridized to a polynucleotide or oligonucleotide probe." Although plaintiff is correct that this language is theoretically broad enough to encompass conducting the test in either of the above fashions, n22 the patent specification contains definitions which necessarily limit the claim to the method whereby the sample, and not the analyte's complementary sequence, is fixed to the

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solid support. The patent defines "probe" as "[a] labelled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide sequence of a particular analyte and which hybridizes to said analyte sequence." '373 patent col. 1, ll. 42-45 (emphasis added). "Analyte," which is defined as "[a] substance or substances, either alone or in admixtures, whose presence is to be detected," id. at col. 1, ll. 28-30, is described as possibly being present in "any biological or non-biological sample" including blood, urine, and saliva, id. at col. 5, ll. 22-26. It is thus clear from these descriptions that the "probe" in claim 1 cannot be the sample, but, rather, is the sequence complementary to the analyte. In addition, because the patent requires that the probe be labeled, it would be impossible to conduct this test with the probe fixed to the solid support, since to do so would result in false positives. See, e.g., Hr'g Tr. at 520, 539-40. Therefore, this Court finds that claim 1 of the '373 patent requires that the sample, which is the substance within which one is looking for the presence of the analyte, must be fixed to the solid support, and that the probe, which is a labeled sequence complementary to the analyte, is not so fixed. n23

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n22 The reason for this is, quite simply, that the labeled sample could be thought of as acting as a "probe" when the sequence complementary to the analyte is fixed to the solid support. In effect, the labeled sample would look for its complementary sequence and hybridization (and later detection) would reveal the analyte's presence.

n23 Plaintiff's argument that example 5 compels a contrary construction is unpersuasive. Although that example indicates that "[t]he advantages of this invention are also obtainable when the probe is immobilized on a non-porous plastic surface," as explained above, the language of the patent places that setup for the test outside the scope of claim 1.

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The second dispute regarding this claim is the meaning of the term "soluble signal." Plaintiff claims that the patent's description of "insoluble 'signals'" as "precipitates, certain fluorescers, and the like," '373 patent col. 4, ll. 40-42, as well as its references to prior art, see id. at col. 4, ll. 45-64, compel the conclusion that the term "soluble signal," as used in claim 1 of the '373 patent, "is any signal, including light, that does not form a precipitate," Pl.'s Proposed Order at 24.

This Court cannot agree. First, the definition relied on by plaintiff is ambiguous, since it defines "insoluble signals" to include "certain fluorescers, and the like." '373 patent col. 4, ll. 40-42 (emphasis added); see Hr'g Tr. at 340-43. Second, even if this definition provided definitive guidance as to the scope of the term "insoluble signal" as used in the patent, it is nonetheless not a definition of what the patentee meant by the term at issue in this case--"soluble signal." Given that the patent does not provide a unique definition for "soluble signal," the Court must look to the patent as a whole, which supports the conclusion that this term was meant to have its ordinary meaning to a person skilled in the art. n24

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n24 As Dr. Stark pointed out, the term itself is something of a non sequitur, because "solubility is a property of compounds, and a signal, particularly in the context of this patent, is light, and it does not make any sense whatsoever to talk about whether light is soluble." Hr'g Tr. at 541-42.

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"Soluble" is generally understood to mean dissolved, or uniformly dispersed, in solution. See, e.g., Hr'g Tr. at 542; Merriam-Webster Dictionary 655 (1974). The language of the '373 patent embraces this definition, as it describes a system whereby an enzyme or other reagent reacts with a chromogen or substrate to produce a product dissolved in solution that makes its presence known by fluorescing or creating a color change which can be "measured by a spectrophotometer or the like." See '373 patent col. 6, ll. 4-65, col. 7, ll. 7-36, col. 8, ll. 50-56. Contrary to the position of plaintiff and its expert, a fluorescent signal that originated from a tethered molecule within the solution simply would not meet this definition. n25 Such a signal would not result from a soluble product, as the origin of the signal would not be uniformly dispersed throughout the solution. n26

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N25 The prior art references cited in the patent do not teach to the contrary. See, e.g., Hr'g Tr. at 335-36, 553-57.

n26 The Court found particularly unpersuasive Dr. Hammes' testimony stating that a tethered signal could be considered uniformly distributed if one re-defined the "solution" to include only that area directly surrounding the tethered molecule. See Hr'g Tr. at 367-69. Such a definition finds no support in the patent, and it is certainly inconsistent with the ordinary understanding of "solubility."

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The Court's conclusion finds further support in representations made to the Patent and Trademark Office by plaintiff while prosecuting a patent with the same specification as the '373 patent. At that time, plaintiff represented that "[w]ith soluble signals as set forth in the instant invention, the signal is not localized. . . .Indeed, with the generation of a soluble signal, a dispersed or scattered signal is obtained." Decl. of Sandy Choi, dated June 17, 2005, Ex. O at 36-37. As discussed above, such representations are relevant to the construction of the claim at issue, see Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349-50 (Fed. Cir. 2004), and they further support this Court's construction. n27 Therefore, as discussed above, this Court finds that "soluble signal" as used in claim 1 of the '373 patent requires a soluble product which generates a detectable signal. As such, tethered fluorescent molecules and other signals generated by non-dissolved molecules are outside the scope of this claim.

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n27 Contrary to defendants' repeated representations to this Court that plaintiff's statements on related patents are "binding," see Defs.' Post-Hr'g Brief at 10; Defs.' Post-Hr'g Reply at 3, the Court in Microsoft Corp. clearly held that such statements are "relevant" but are not binding, see Microsoft Corp., 357 F.3d at 1349-50.

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The claim construction dispute centers on the term "solubilizer," which is common to all asserted claims. The parties agree that as a general matter, artisans would understand the term "solubilizer" to embrace three distinct types of chemicals: (1) surface active agents (also known as "surfactants"), (2) co-solvents, and (3) complexation agents. n1 But Mutual has contended that in the context of the '081 patent's specification and prosecution history, "solubilizer" comprehends only surfactants. Because it is undisputed that Mutual's ANDA sought approval for extended-release felodipine tablets that use a co-solvent, not a surfactant, as a solubilizer, Mutual has argued that filing its ANDA was not an act of infringement under § 271(e)(2). The district court rejected Mutual's argument. Relying on the parties' agreement as to artisans' general understanding of "solubilizer," and on certain general-usage dictionary definitions of "solubilizer" and "solubility," the district court held that the "ordinary meaning" of "solubilizer" embraced the three types of chemicals noted above. See Astrazeneca, 221 F. Supp. 2d at 543-44. The district court held that the evidence intrinsic to the patent did not curtail this ordinary meaning. See id. at 543-48. The district court's lengthy and careful opinions relied extensively on our recent case law, which is unfortunately complex and inconsistent.

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n1 Doubtless because the parties agreed as to artisans' general understanding of "solubilizer," the parties decided not to introduce expert testimony as to the meaning of this claim term at the Markman hearing at the district court.

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I. Applicable Law

We review the district court's claim construction de novo. E.g., Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). It is axiomatic that the claims mark the outer boundaries of the patent right to exclude. The critical challenge is to determine the meaning of the claims, i.e., their scope.

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A long line of cases indicates that evidence intrinsic to the patent -- particularly the patent's specification, including the inventors' statutorily-required written description of the invention -- is the primary source for determining claim meaning. We have embraced that proposition frequently. See, e.g., Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Indeed, that proposition has been accepted doctrine in patent law for many years. See, e.g., Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 397-98 (Ct. Cl. 1967) ("The use of the specification as a concordance for the claim is accepted by almost every court, and is a basic concept of patent law. Most courts have simply stated that the specification is to be used to explain the claims; others have stated the proposition in different terms, but with the same effect."); Musher Found., Inc. v. Alba Trading Co., 150 F.2d 885, 888 (2d Cir. 1945) (Hand, J.) ("As in the case of any other claim, a product claim may, and indeed must, be read upon the specifications: its terms are no more than a shorthand from the fuller explanation which the specifications should contain."). On this view, the patent is an integrated document, with the claims "pointing out and distinctly claiming," 35 U.S.C. § 112, the invention described in the rest of the specification n2 and the goal of claim construction is to determine what an ordinary artisan would deem the invention claimed by the patent, taking the claims together with the rest of the specification. See, e.g., United States v. Adams, 383 U.S. 39, 49, 15 L. Ed. 2d 572, 86 S. Ct. 708, 174 Ct. Cl. 1293 (1966) ("It is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."). Under this approach to claim construction, evidence extrinsic to the patent is useful insofar as it "can shed useful light on the relevant art -- and thus better allow a court to place itself in the shoes of a person of ordinary skill in the art" reading the claims alongside the rest of the specification. Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004).

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n2 I.e., the invention vel non taught by the specification, as distinct from particular, idiosyncratic embodiments disclosed in the specification. See, e.g., Alloc, Inc. v. ITC, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("This court recognizes that it must interpret the claims in light of the specification, yet avoid impermissibly importing limitations from the specification. That balance turns on how the specification characterizes the claimed invention. In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation to be a part of every embodiment." (citations omitted)).

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Language in some of our recent cases suggests that the intrinsic record, except for the claims, should be consulted only after the ordinary and customary meaning of claim terms to persons skilled in the pertinent art is determined. See, e.g., Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002) ("The presumption in favor of a dictionary definition [of a claim term] will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.") (citations omitted). The language in these cases emphasizes the use of technical and general-usage dictionaries in determining the ordinary meaning. Id. Under this approach, where the ordinary meaning of a claim is evident, the inventor's written description of the invention, for example, is relevant only insofar as it provides clear lexicography or disavowal of the ordinary meaning. See, e.g., id.

Against this backdrop, the question becomes whether the intrinsic evidence takes priority in our construction of the claim term "solubilizer," or if instead the ordinary meaning of the term, as determined from sources such as treatises and dictionaries, controls our construction in the absence of intrinsic evidence of clear lexicography or disavowal. Given that the parties agree that the extrinsic meaning of solubilizer is broad, Astrazeneca unsurprisingly urges the latter approach to claim construction.

We need not decide which approach is proper as a matter of law, n3 as even under Astrazeneca's preferred methodology, the district court's claim construction must be reversed. The intrinsic evidence, we hold, clearly binds Astrazeneca to a narrower definition of "solubilizer" than the extrinsic evidence would support.

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n3 Resolution of this question may be approaching. See Phillips v. AWH Corp., 376 F.3d 1382, 2004 WL 1627271 (Fed. Cir. 2004) (granting petition for en banc rehearing, to address broadly the law of claim construction).

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II. Specification of the '081 Patent

The specification of the '081 patent begins by stating that

the present invention is related to pharmaceutical extended release preparations of active compounds with very low solubility, especially substituted dihydropyridines, and to methods of preparing such preparations.

The object of this invention is to obtain a solid preparation with high extent of bioavailability and extended release of an active compound which normally has very low solubility.

'081 patent, col. 1, ll. 6-15. The specification continues with a "Background of the Invention" section, which states that

pharmaceuticals with very poor water solubility present formulation problems due to their slow rate of dissolution. Their efficacy can by [sic] severely limited and large interindividual variations of absorption can occur. Examples of drugs with very low solubility are some substituted dihydropyridine compounds such as nifedipine and felodipine. The mentioned dihydropyridines are commonly classified as calcium antagonists, which are widely used for the treatment of cardiovascular disorders such as ischaemic heart disease and arterial hypertension. One of the mentioned dihydropyridines, namely felodipine, has a solubility of only .5 mg/l in water. . . .

Several ways to increase drug absorption have been described in the prior literature. . . . Of particular relevance to the present invention is that surfactant solubilizing agents may be employed in order to increase the bioavailability of the drugs with very low solubility.

Id. at col. 1, ll. 18-30, 33-34, 46-49 (emphasis added). The specification proceeds with a "Description of the Invention," which states that

it is the object of the present invention to provide a preparation of a drug with very low solubility that shows prolonged and nearly constant rate of drug absorption for a long period of time and concurrently maintains a high extent of bioavailability. The object is reached by using a solubilizer which is mixed with the drug with very low solubility. The solubilizers suitable according to the invention are defined below. The active compound is preferably dissolved or dispersed in the solubilizer. The mixture of active compound (drug) and solubilizer can be diluted with water or intestinal juice without significant precipitation of the dissolved drug. In the solution the drug is included in a micelle-structure formed by the solubilizer. With other commonly used solubilizers or co-solvents dilution may cause precipitation of the drug. The mixture of the drug and the solubilizer is incorporated into a pharmaceutical formulation, which gives prolonged release.

Drugs suitable for the extended release preparation according to the inventions are compounds characterized by their very low solubility, that is less than 0.1 per cent by weight in water. . . .

The solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents, especially such containing polyethyleneglycols as esters or ethers. They are preferably chosen from polyethoxylated fatty acids, hydroxylated fatty acids and fatty alcohols. It is especially preferred to choose the solubilizer from the group polyethoxylated castor oil, polyethoxylated hydrogenated castor oil, polyethoxylated fatty acid from castor oil or polyethoxylated fatty acid from hydrogenated castor oil. Commercially available solubilizers, which can be used are known under the trade names Cremophor, Myrj, Polyoxyl 40 stearate, Emerest 2675, Lipal 395 and HCO 50. A specially preferred solubilizer is Cremophor (R) RH 40 (BASF).

The active compound mixed with the solubilizer is incorporated into different kinds of known controlled release systems, e.g. a hydrophilic gel system, beads coated with a rate controlling membrane, which can be a diffusion retarding coating or a disintegrating coating or tablets with an inert porous matrix. According to the invention the solubilized drug is preferably

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combined with a hydrophilic gel system, namely a hydrophilic swelling matrix e.g. HPMC. This form of controlled release mechanism is a suitable way to control the release of the micelles of drug and solubilizer.

Id. at col. 2, ll. 67-68, col. 3, ll. 1-20, 33-58 (emphases added). The specification then provides five detailed working examples of drug formulations embraced by the invention.

Mutual contends that the specification limits the scope of the claim term "solubilizer" to surfactants, and we agree. First, we hold that the inventors deliberately acted as their own lexicographers. The "Description of the Invention" states that "the solubilizers suitable according to the invention are defined below" (emphasis added), and two paragraphs later, states that "the solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents" (emphasis added). Astrazeneca maintains that these statements simply refer to preferred embodiments of "suitable" solubilizers. We might agree if the specification stated, for example, "a solubilizer suitable for the preparations according to the invention," but in fact, the specification definitively states "the solubilizers suitable for the preparations according to the invention" (emphasis added). Astrazeneca seems to suggest that lexicography requires a statement in the form "I define ____ to mean ____," but such rigid formalism is not required. See, e.g., Bell Atl. Network Servs., Inc., 262 F.3d at 1268 ("[A] claim term may be clearly redefined without an explicit statement of redefinition. . . . The specification may define claim terms 'by implication' such that the meaning may be 'found in or ascertained by a reading of the patent documents.'" (citation omitted)). Certainly the '081 specification's statement that "the solubilizers suitable according to the invention are defined below" provides a strong signal of lexicography.

Second, we hold the specification clearly disavows nonsurfactant solubilizers. The inventors' lexicography alone works an implicit disavowal of nonsurfactant solubilizers, but the rest of the specification goes further. The "Description of the Invention" twice describes micelle structures as a feature of the novel formulation structure conceived by the inventors. See '081 patent, col. 3, ll. 11-12 ("In the solution the drug is included in a micelle-structure formed by the solubilizer."); id. at col. 3, ll. 56-58 ("This form of controlled release mechanism is a suitable way to control the release of the micelles of drug and solubilizer."). It is undisputed that surfactants are the only solubilizers believed to form micelle structures in watery environments. Indeed, immediately after the reference to the "micelle-structure formed by the solubilizer" of the invention, the specification criticizes other types of solubilizers -- and specifically co-solvents -- as leading to undesirable precipitation. See id. at col. 3, ll. 12-14 ("With other commonly used solubilizers or co-solvents dilution may cause precipitation of the drug.").

Again, Astrazeneca contends that these statements in the specification simply address the features of preferred embodiments. Astrazeneca seems to suggest that clear disavowal requires an "expression of manifest exclusion or restriction" in the form of "my invention does not include ____." But again, such rigid formalism is not required: Where the general summary or description of the invention describes a feature of the invention (here, micelles formed by the solubilizer) and criticizes other products (here, other solubilizers, including co-solvents) that lack that same feature, this operates as a clear disavowal of these other products (and processes using these products). See, e.g., SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-45 (Fed. Cir. 2001) (construing claims to be limited to catheters with coaxial lumens where written description emphasized coaxial lumens as a feature of the invention and criticized catheters using other types of lumens). Indeed, Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313 (Fed. Cir. 2002), the first case to use the formulation "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope," cited as authority our decision in SciMed, n4 where we held the claims-in-suit were limited by written-description statements -- none of which was in the form "my invention does not include _____." See SciMed, 242 F.3d at 1342-44 (discussing the content of the written description at issue).

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n4 Teleflex stated: "The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, 299 F.3d at 1325 (citing SciMed, 242 F.3d at 1344).

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Third, while it is of course improper to limit the claims to the particular preferred embodiments described in the specification, the patentee's choice of preferred embodiments can shed light on the intended scope of the claims. After

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defining the term "solubilizer," the "Description of the Invention" section goes on to list a number of solubilizers that are preferred or even "especially preferred":

The solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents, especially such containing polyethyleneglycols as esters or ethers. They are preferably chosen from polyethoxylated fatty acids, hydroxylated fatty acids and fatty alcohols. It is especially preferred to choose the solubilizer from the group polyethoxylated castor oil, polyethoxylated hydrogenated castor oil, polyethoxylated fatty acid from castor oil or polyethoxylated fatty acid from hydrogenated castor oil. Commercially available solubilizers, which can be used are known under the trade names Cremophor, Myrj, Polyoxyl 40 stearate, Emerest 2675, Lipal 395 and HCO 50. A specially preferred solubilizer is Cremophor (R) RH 40 (BASF).

'081 patent, col. 3, ll. 33-47. At oral argument, Astrazeneca conceded that every one of these preferred solubilizers is a surfactant. Similarly, it is uncontested that in each of the five detailed working examples that follow the "Description of the Invention," the listed solubilizer is a nonionic surfactant identified by its commercial trade name (either "Cremophor" or "Myrj"). The fact that all of the solubilizers listed in the specification and used in the working examples were surfactants adds further support to the conclusion that the term "solubilizer" in the claims should be limited, according to the definition employed in the specification, to surfactants.

In sum, we hold that the specification of the '081 patent overcomes any "ordinary meaning" of "solubilizer" derived from extrinsic evidence, limiting the claim term to surfactants.

III. Prosecution History of the '081 Patent

Although the specification, by itself, compels the above claim construction, we briefly discuss additional confirmation for this construction: the patent applicants' remarks during the prosecution history of the '081 patent. On December 11, 1987, the examiner rejected the pending claims as anticipated by or obvious in light of several prior-art references. In response, the applicants submitted remarks that included the following:

The second reference cited by the Examiner is U.S. Patent No. 4,673,564 to Kawata et al. ("Kawata"). Kawata discloses preparations in which an amorphous medical material such as amorphous nifedipine is combined with a "basic substance" and a solvent, mixed and then dried to form an amorphous powder which is then mixed with polyethylene oxide. Only one component of these formulations could be a "nonionic solubilizer" in the context of the present invention, however, in view of the definition on Page 4, line 33 - Page 5, line 6 of the specification, i.e., Kawata's optional 2nd component of the basic substance.

(Underlined emphasis added, italicized emphases in original.) This passage is notable for two reasons. First, the reference to the "definition" in the specification includes a citation to the sentence in the specification stating that "the solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents." The applicants' characterization of this sentence in the specification as a "definition" confirms that the applicants acted as their own lexicographers to redefine "solubilizer" differently from its ordinary meaning. Second, the applicants highlighted the second component of the composition taught by the Kawata patent as the only component that "could be a 'nonionic solubilizer' in the context of the present invention." In its brief to our court, Astrazeneca concedes that "Kawata emphasizes surfactants for the second component." See also U.S. Patent No. 4,673,564, col. 2, ll. 56-61 ("As the surface active agent of 2nd substance, there are anionic surface active agents such as sodium alkylsulfate, nonionic surface active agents such as polyoxyethylene sorbitan fatty acid ester, polyoxyethylene castor oil derivative, etc.") (emphasis added).

Finally, we note that near the end of the above-excerpted remarks to the examiner, the applicants stated: "Thus, none of the references disclose materials in which solutions or dispersions of the active material in a nonionic surfactant are formed into a solid preparation with extended release." (Emphasis added.) This general description of the applicants' invention substitutes the term "surfactant" for the term "solubilizer," further evidence that, in the context of the application, "solubilizer" embraced only surfactants.

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1. Nonionic Solubilizer

Claim 1 of the '081 patent provides: "A solid preparation providing extended release of an active compound with very low solubility in water copmrising [sic] a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer, wherein the amount by weight of the solubilizer is at least equal to the amount by weight of the active compound, and a release controlling system to provide extended release." (Emphasis added). The additional claims in which the term "nonionic solubilizer" are recited are dependent claims 8, 12, 14 and 15 and independent claim 17.

Astra argues that the term nonionic solubilizer should be construed as: "a nonionic compound that increases the solubility of a substance in a particular solvent." (Pls.' Mem. at 24.) Mutual contends that the proper construction is: "nonionic surface active agents (i.e., surfactant) which, when mixed with the active (dihydropyridines such as felodipine and nifedipine) in a 1:1 to 1:10 active/surfactant ratio and diluted with water, preclude significant precipitation of the active (visible to the names eye or using photospectography) and, further, incorporate the active within a micelle structure." (Def.'s Mem. at 14.) Thus, the dispute really focuses on the term solubilizer as the parties do not dispute the meaning of nonionic.

Astra takes the position that its construction is consistent with the ordinary meaning of the term and that the intrinsic record does not indicate that the heavy presumption in favor of giving full effect to the ordinary meaning should be overcome. Solubilizer is defined in the dictionary as: "an agent that increases the solubility of a substance." Merriam Webster's Third New International Dictionary (1993). Solubility is defined as "the amount of a substance that will dissolve in a given amount of another substance." Meriam-Webster's Collegiate Dictionary available at http://www.m-w.com. 3 Dissolve is defined as "to cause to pass into solution." Id. The parties agree that solubilizers fall into three categories: (1) surface active agents, referred to as surfactants, (2) co-solvents, and (3) complexation agents. (Pls.' Mem. at 11, Def. Mem. at 11, Tr. at 59.) The key issue is whether the '081 patent claims all groups of solubilizers, as urged by Astra, or whether the patent covers only surfactants, as urged by Mutual.

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3 Solubilize is defined as "to make soluble or more soluble," Meriam-Webster's Collegiate Dictionary available at http://www.m-w.com, or "to make (a substance such as a fat or lipid) soluble or more soluble, especially in water, by the action of a detergent or other agent," The American Heritage Dictionary of the English Language (4th ed. 2000) available at www.bartleby.com. Soluble is defined as "susceptible of being dissolved in or as if in a liquid and especially water." Meriam-Webster's Collegiate Dictionary available at http://www.m-w.com.

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Mutual argues that the intrinsic record mandates that nonionic solubilizer be limited to surfactants. I begin with the specification. As explained above, the heavy presumption that terms be given their ordinary meaning can be overcome if a claim term completely lacks clarity or if the patentee chooses to be his own lexicographer. See Bell Atlantic, 262 F.3d 1258 at 1268 (quoting Johnson, 175 F.3d 985 at 989). It is unclear to this Court on precisely which ground Mutual seeks to have the presumption overcome. Beginning with the first ground, the term solubilizer is easily found in the dictionary, and the parties agree that those skilled in the art would understand the term solubilizer to encompass all three groups of solubilizers: surfactants, co-solvents, and complexation agents. I therefore conclude that the scope of the claim term can be determined by the claim language. See id.

As to the alternate ground, as detailed above, in order to demonstrate that the inventor chose to be his own lexicographer, the specification must clearly express an intent to redefine the ordinary term. See id.Mutual presents three grounds in support of its argument that Astra has offered a special definition of solubilizer in the specification. First, Mutual contends that the specification clearly expresses an intent that surfactants are the only type of solubilizer which can be used in the invention. The specification provides: "The solubilizers suitable according to the invention are defined below. . . . The solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents." (Col. 3, lns. 5-6, 33-35) (emphasis added). Mutual contends that this language explicitly offers a definition of solubilizers which includes only surfactants. Mutual notes that the language employed is definitive, i.e., the patentee did not write "may be," "could be," or "are optionally" surfactants. Thus, contends Mutual, those skilled in the art, who are well aware of the differences between types of solubilizers, would understand the invention to be limited to surfactants.

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Astra responds that this quote merely refers to the preferred embodiment, and it is well recognized that claims are generally not limited to the preferred embodiment. See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1343-44 (Fed. Cir. 2001); Interactive Gifts, 256 F.3d 1323 at 1331-32; Karlin Technology Inc. v. Surgical Dynamics Inc., 177 F.3d 968, 973 (Fed. Cir. 1999). Astra argues that Mutual is impermissibly attempting to limit the claims to specific examples provided in the specification. See Specialty Composites v. Cabot Corp., 845 F.2d 981 (Fed. Cir. 1988) ("What is patented is not restricted to the examples, but is defined by the words in the claims. . . . The emphasis is on the suitability of any plasticizer that will achieve the specified properties, not on the particular class of plasticizers."). Astra contends that those skilled in the art recognize that Astra claimed all types of solubilizers. In support, Astra offers U.S. Patent No. 6,048,548 which provides: "[the '081 patent] describes compositions and processes for preparing controlled release formulations that include low solubility active ingredients . . . dissolved in a liquid or semi-solid solubilizing agent." (Pls.' Ex. 44, Col. 2, lns. 11-15). Thus, contends Astra, the '548 patent inventor acknowledges that the '081 patent is not limited to surfactants. This Court agrees with Astra that the written description, by highlighting surfactants, does not expressly redefine the term solubilizer to include only surfactants. The specification appears to promote surfactants as the superior solubilizer but never explicitly provides that other solubilizers cannot work. In order to overcome the presumption, the specification must clearly redefine a term, and I therefore conclude that the specification does not limit the claim term to surfactants.

Related to this argument, Mutual contends that because Astra failed to specifically mention polyethylene glycol 400 ("PEG 400"), a co-solvent, despite the fact that it conducted research using PEG 400, an inference should be drawn that PEG 400 was intentionally left out of the '081 patent because it failed to work and therefore Astra surrendered claiming this co-solvent. 4 Thus, Mutual stresses that because the patentee listed only surfactants and not other types of solubilizers, Astra is limited to surfactants. As Astra points out, however, the patentee is not required to include in the description every instance of research and development into the patent specification. See Rexnord, 274 F.3d at 1344 ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.") (citation omitted). Just as patentees are generally not limited to claiming only the preferred embodiments, they are likewise not required to list all compounds used in the research process. Thus, Mutual's argument fails as a matter of law.

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4 Whether the '081 patent claims the use of PEG-400 as a solubilizer is important because Mutual's proposed invention uses this type of solubilizer.

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Third, Mutual argues that the specification clearly disclaims the use of any solubilizer which would cause any precipitation and that the claim term is further limited to an invention which incorporates the active within a micelle structure. The specification provides: "The mixture of active compound (drug) and solubilizer can be diluted with water or intestinal juice without significant precipitation of the dissolved drug. In the solution the drug is included in a micelle structure formed by the solubilizer. With other commonly used solubilizers or co-solvents dilution may cause precipitation." (Col. 3, lns. 8-14). Mutual takes the position that these words show that Astra has not claimed any solubilizer which would cause precipitation and because co-solvents are identified as a solubilizer that causes precipitation, Astra has disclaimed co-solvents.

Astra responds that this section of the specification identifies a test to see how well a chemical acts as a solubilizer for a particular active ingredient, and that this test is part of the well known description requirement to include the preferred embodiment; the test, however, cannot be imported into the claims. This Court agrees with Astra that acknowledging that a co-solvent may cause a negative outcome does not constitute an express disavowal of those solubilizers which may cause this less desirable result. See Amerikam Inc. v. Home Depot Inc., 99 F. Supp. 2d 810, 813 (W.D. Mich. 2000) (reasoning that statement in specification that certain plastic part is less durable is not the same as stating that invention cannot be made of that plastic part). The specification never clearly indicates that a micelle-forming solubilizer is required for the invention to work, nor does it clearly indicate that "without significant precipitation" means no precipitation. Accordingly, I conclude that the claim term is not limited to a solubilizer which precludes significant precipitation of the active drug or to a solubilizer which incorporates the active within a micelle structure.

In summary, this Court concludes that the specification fails to unambiguously indicate that the patentee intended to redefine the term solubilizer. Accordingly, the specification supports the view that the term nonionic solubilizer includes all

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categories of solubilizers without any limitations.

I now turn to the prosecution history. As recited above, "Unless altering claim language to escape an examiner['s] rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage." York Products, 99 F.3d 1568 at 1575. Thus, the patentee must make a statement that concedes or disclaims coverage of the claims at issue based on a piece of prior art. In essence, Mutual argues that Astra overcame the initial rejection of the '081 patent as being obvious over the Kawata patent, (United States Patent No. 4,673,564, Pls.' Ex. 4, Def.'s Ex. B, (hereinafter "the Kawata patent")), by distinguishing the '081 patent as using a surfactant and not a co-solvent. Mutual contends that the sole difference between Kawata and the '081 patent is the use of surfactants in the latter. In essence, Astra argues that the '081 patent was not distinguished by particular chemicals being used; rather, it was distinguished as an entirely different system from the Kawata patent. Specifically, argues Astra, Kawata, unlike the '081 patent, does not disclose the possibility of a controlled-release preparation based upon a solution or dispersion of a drug in a nonionic solubilizer. In fact, argues Astra, Kawata teaches against solubilizers.

The Amendment Astra submitted to the PTO to overcome the initial rejection provides:

Kawata discloses preparations in which an amorphous medical material such as an amorphous nifedipine is combined with a "basic substance" and a solvent, mixed and then dried to form an amorphous powder which is then mixed with polyethylene oxide. Only one component of these formulations could be a "nonionic solubilizer" in the context of the present invention, however, in view of the definition on Page 4, line 33 - Page 5, line 6, i.e., Kawata's optional 2nd component of the basic substance. Even if the drug in Kawata's formulations can be said to be dissolved or dispersed, however, it is not in the 2nd component alone, but principally in the required 1st component of the basic substance.

Furthermore, not a single example in Kawata discloses a preparation in which a nonionic solubilizer as defined herein is used in an amount by weight equal to or exceeding the amount of the drug.

(Amendment at 4-5, Pls.' Ex. 6 at AZ 82-83, Def.'s Ex. C at AZ 82-83 (hereinafter "Amendment")) (underline in original; italicize added). The reference to Page 4, line 33 - Page 5, line 6 refers to that portion of the '081 specification quoted above which outlines suitable surfactants.

Mutual contends that by inserting the words "defined" and "definition" and referring to that portion of the specification which discusses only surfactants, Astra provided a special meaning for solubilizers. Astra responds that the reference to the specification was made to demonstrate that while Kawata uses an optional component that could be a nonionic solubilizer, Kawata, unlike the '081 patent, does not use that component as a solubilizer; conversely, the citation is used to point out that the '081 patent, unlike the Kawata patent, uses solubilizers. Astra explains that Kawata teaches making sparingly soluble drugs amorphous in order to increase the dissolution rate; the amorphous form is attained through either micronization (also referred to as milling) of the active compound, (citing Col. 3, lns. 58-62 of the Kawata patent), or co-precipitating the active compound with what is called in the Kawata patent the first basic component, (citing Col. 2 ln. 64- Col. 3, ln. 9 of the Kawata patent). Astra notes that Kawata also teaches a second optional component, as noted in the above quoted portion of the Amendment, which can be used to aid in the co-precipitation process. Astra further explains that Kawata Example 2 (Col. 5, ln. 64 - Col. 6 ln. 9 of the Kawata patent) demonstrates this second optional component using PEG 400. Thus, Astra explains that in writing the Amendment to the PTO, the inventors were informing the PTO that while Kawata uses PEG 400 as a second optional component, Kawata does not use PEG 400 as a solubilizer, but rather to aid in the co-precipitation process.

Mutual responds to Astra's detailed explanation with a conclusory and insubstantial argument that Astra's assertion that Kawata was distinguished as teaching an amorphous drug fails from a factual and legal perspective. Mutual fails to articulate reasons or point to specific portions of the prosecution history in support of its conclusory argument. Rather, Mutual focuses its position on the fact that the Kawata Example 2 uses PEG 400 and that Astra surrendered the solubilizer that is used in Kawata. Mutual further argues that Example 2 discloses equal amounts of the co-solvent and the active drug, just as in the '081 patent. Mutual, however, never expressly denies that the two patents use completely different processes, and that Kawata does not use PEG 400 in Example 2 as a solubilizer. At the Markman hearing, this Court specifically asked defendant to show where in the Kawata patent PEG 400 was used as a solubilizer. (Tr. at 108). Defendant responded by directing the court to Example 2 and highlighting that PEG 400 is used; however, Mutual never explained how it is used as a solubilizer.

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Mutual's argument is most weakened by the uncontested fact that the Kawata patent explicitly provides that the second optional component can be PEG 400 as well as a surfactant: "This pharmaceutical composition may further contain at least one basic substance (2nd component) selected from the group consisting of a surface active agent, polyethylene glycol, propylene glycol, glycerin, a glycerin fatty acid ester and vegetable oil." (Col. 1, ln. 66 - Col. 2, ln. 2 of the Kawata patent) (emphasis added). Thus, as argued by Astra, it would not have been possible for Astra to distinguish the '081 patent on the ground that the '081 patent invention used a surfactant when the Kawata patent expressly teaches that a surfactant can be used. Mutual attempts to diminish the clear import of this uncontested fact by arguing that Kawata, in mentioning surfactants, only demonstrates that those skilled in the art know the difference between the types of solubilizers and would not confuse them. The problem with this rebuttal is that it ignores the true flaw in Mutual's argument: Astra could not distinguish its invention on the ground that Kawata does not teach a surfactant because, in fact, Kawata does claim the use of a surfactant as a possible optional second element.

Astra further highlights that while Kawata teaches the use of a surfactant (in addition to PEG 400, a co-solvent) to aid in co-precipitation, Kawata teaches against using either compound as a solubilizer: "the inventors of the present invention have found that a sustained release pharmaceutical composition of nicardipine can be obtained by using amorphous nicardipine without adding any substance improving the solubility in the intestines." (Col. 3, lns. 48-52 of the Kawata patent) (emphasis added). This Court found no response to this argument by Mutual.

In further support of its position, Astra highlights the following additional portion of the Amendment:

Kawata does not appreciate the possibility of a control release preparation based upon a solution or a dispersion of a drug in a nonionic solubilizer. Kawata requires the presence of the 1st component of the basic substance, and requires that the drug be in an amorphous form. The claimed invention relies on neither of these requirements. Kawata also expressly teaches that "no substance improving solubility in the intestines" is added (Col. 3, lines 48-52).

(Amendment at 5). This statement to the PTO is consistent with the arguments presented for claim construction. Astra has always taken the position that Kawata is distinguishable because it uses a different process from the process of the '081 patent which relies on solubilizers.

Mutual also points to this statement in the Amendment: "Thus, none of the references disclose materials in which solutions or dispersions of the active material in a nonionic surfactant are formed into a solid preparation with extended release." (Amendment at 8) (emphasis added). Mutual contends that this statement indicates that Astra defined its invention as one using only surfactants. Astra responds that this statement is merely a description of prior art (beyond Kawata) which use surfactants. The reference immediately preceding this statement cited by Mutual provides: "both [references] describe increased solubilization of griseofulvin in the presence of nonionic surfactants. There is no basis in the cited art which would lead a person skilled in the art to apply this teaching in a sustained release drug formulation." (Amendment at 7). Astra contends that the statement relied upon by Mutual was written to show that the surfactants previously used were not dissolving or dispersing the active material and were not formed into a solid preparation with extended release. Mutual contends that the passage on which it relies is not distinguishing only the secondary references which teach the use of surfactants, but all the references, including Kawata. While the language is not crystal clear, given the multiple references in which Astra describes its invention as using solubilizers and not specifically surfactants, I construe the passage on which Mutual relies as referring only to the secondary references which specifically taught the use of surfactants. In either event, however, this lone passage does not constitute an unambiguous disavowal of non-surfactant solubilizers.

In summary, this Court agrees with plaintiff that the prosecution history indicates that Astra did not distinguish its patent from Kawata (1) on the ground of a particular solubilizer because not only does Kawata use an entirely different process, but the specification teaches against solubilizers; and (2) the claims do not require surfactant type solubilizers because Kawata discloses both surfactants and co-solvents as possibilities for the optional second component. It is further noted that Astra points out that nowhere in the prosecution history did Astra define nonionic solubilizer as excluding PEG 400. I therefore conclude that the prosecution history does not limit the claim term nonionic solubilizer beyond its ordinary meaning.

Accordingly, the claim term nonionic solubilizer is construed as meaning: a nonionic compound that increases the solubility of a substance in a particular solvent.

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2. Mutual's Arguments for Reconsideration

In its reply memorandum in support of the motion for reconsideration, Mutual specifies that the basis for the instant motion is its contention that the claim construction of the term "nonionic solubilizer" was a clear error of law and fact. Mutual thus does not rely upon, nor has it pointed to, any new evidence or intervening change in the controlling law.

In support of its argument that the Court committed clear factual and legal error, Mutual presses its previous contention that Astra did not distinguish the '081 patent from Kawata on the basis of a different process, but that in fact Astra limited its definition of the term "solubilizer" to include only surfactants. Specifically, defendant argues the following: (1) that the '081 patent claims at issue do not contain a process limitation, and that Astra has not met its burden in proving that PEG 400 does not act as a solubilizer in Example 2 of Kawata; (2) that the '081 patent claims at issue do not contain language that distinguish between amorphous drugs, as taught by the Kawata patent, and non-amorphous drugs; (3) that the first of the two Kawata embodiments, relied upon by Mutual, does not teach against the use of solubilizers, and therefore Astra's reliance upon the second Kawata embodiment, which does teach against the use of solubilizers, is irrelevant; and (4) that Astra distinguished the '081 patent from the Kawata patent by including the limitation "wherein the amount by weight of the solubilizer is at least equal to the amount by weight of the active" in combination with limiting the term "solubilizer" to include only surfactants.

In its reply memorandum, Mutual further argues the following: (1) that PEG 400 must act as a solubilizer in the Kawata patent because its properties as a solubilizer is inherent in its chemical composition; (2) the '081 patent claims as widely construed by the Court would be invalid over the Kawata patent because the components are identical; (3) Astra could not have distinguished the '081 patent based upon the amorphous form of the active ingredient in Kawata; and (4) there was no factual or legal basis to support a distinction between the Kawata and '081 patents based upon a "purported co-precipitation property."

The Court has already considered and rejected Mutual's arguments that Astra distinguished the '081 patent from the Kawata patent based on the limitation of the term "solubilizer" to include only surfactants. Unless otherwise compelled, a court should give full effect to the ordinary meaning of claim terms, even if the terms are broad. See Johnson Worldwide Assoc., Inc. v. Zebco Corporation, 175 F.3d 985, 989 (Fed. Cir. 1999). "Although the prosecution history can and should be used to understand the language used in the claims, it [] cannot 'enlarge, diminish or vary' the limitations in the claims." Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995) (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880)). "Unless altering claim language to escape an examiner's rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage," that is, by making a statement that concedes or disclaims coverage of the claims at issue based on a piece of prior art. York Products, Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1575 (Fed. Cir. 1996). I had previously determined after a thorough review of the prosecution history that Astra had not clearly disavowed claim coverage of all solubilizers, including PEG 400. I find no reason to change that conclusion.

In the instant motion, Mutual presents arguments that dance around but do not directly challenge this Court's conclusion that Astra did not distinguish its patent from Kawata based on a particular solubilizer. Mutual persistently contends that there is no legal or factual basis to distinguish the patents on the grounds that they utilized different systems, but again fails to expressly state that Kawata does not use a co-precipitation formula or PEG 400 in Example 2 as a solubilizer. The fact that the PEG 400 used in Example 2 of the Kawata patent has the properties of a solubilizer, without any further illustration, does not indicate that it is functioning as a solubilizer. Mutual's belated argument of patent invalidity based on the identical components of the '081 and Kawata patents is of no avail. The Court found in its August 19th Opinion that the '081 patent was accepted by the USPTO based on its distinct preparation process, a solution or dispersion of a drug in a nonionic solubilizer, unlike the Kawata patent which taught against solubilizers and required the use of an amorphous drug. Mutual has not persuaded me otherwise, and the record supports my conclusions. Finally, Mutual fails to counter effectively the fatal finding that Astra could not have distinguished the '081 patent based on its use of a surfactant because the Kawata patent expressly teaches that a surfactant can be used as a possible optional second element.

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Mutual presents no new arguments nor any grounds to show clear error by the Court in its claim construction of the August 19th Order, nor any evidence that manifest injustice would result if the motion were denied. As numerous district courts in this circuit have commented, "dissatisfaction with the Court's ruling is not a proper basis for reconsideration." Evans v. United States, 173 F. Supp. 2d 334, 335 (E.D. Pa.2001); Burger King Corp. v. New Eng. Hood & Duct Cleaning Co., 2000 U.S. Dist. LEXIS 1022, *5, Civ. No. 98-3610 (E.D. Pa. Feb. 4, 2000); Central Reserve Life Ins. Co. v. Marello, Civ. No. 00-3344, 2001 U.S. Dist. LEXIS 281, *5 (E.D. Pa. Jan. 17, 2001). "A motion for reconsideration is not properly grounded on a request that a court reconsider repetitive arguments that have been fully examined by the court or a request to raise arguments that could have previously been asserted." Tobin v. General Elec. Co., Civ. No. 95-4003, 1998 U.S. Dist. LEXIS 693, *7 (E.D. Pa. Jan. 27, 1998). "It is improper on a motion for reconsideration to ask the Court to rethink what it had already thought through -- rightly or wrongly." Glendon Energy Co. v. Borough of Glendon, 836 F. Supp. 1109, 1122 (E.D. Pa. 1993) (citation, internal quotation marks and brackets omitted). I find that Mutual has not met its burden under these standards for a motion for reconsideration. Consequently, there is no need to revisit the merits of the arguments presented.

Conclusion

For the foregoing reasons, Mutual's motion for reconsideration of this Court's claim construction for the term "non-ionic solubilizer" will be denied.
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2. A solution or dispersion of an effective amount of the active compound; and dissolving or dispersing an effective amount of the active compound

As recited above, claim 1 of the '081 patent provides: "A solid preparation providing extended release of an active compound with very low solubility in water copmrising [sic] a solution or dispersion of an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer. . . ." (Emphasis added). The highlighted term is incorporated into dependent claims 8, 12, 14, and 15. In addition, claim 17 provides: ". . . .dissolving or dispersing an effective amount of the active compound in a semi-solid or liquid nonionic solubilizer. . . ."

Mutual argues that the claim limitations require clarification because the claims are directed toward "solid preparations," yet the claims require a solution or dispersion of the active compound in a liquid or semi-solid nonionic solubilizer. Mutual contends that the claims alone suggest that the proper construction is one which requires that the active compound be solubilized or dispersed within the nonionic solubilizer not simply during the manufacture of the solid preparation (e.g., tablet), but after the solid preparation is in its finished form. In support, Mutual points to the following portion of the specification: "in the solution the drug is included in the micell-structure (sic) formed by the solubilizer . . . . The mixture of the drug and solubilizer is incorporated into a pharmaceutical formulation, which gives prolonged release." (Col 3, lns. 11-16).

Astra begins with the premise that the ordinary meanings of the terms "solution" and "dispersion" are apparent to those of skill in the art. A "solution" or "dispersion" is the dispersed or dissolved substance(s) and the medium in which it is dispersed or dissolved. Dissolve is defined in the dictionary as "to cause to pass into a solution," while disperse is defined as "to distribute (as fine particles) more or less evenly throughout a medium." Meriam-Webster's Collegiate Dictionary available at http://www.m-w.com. Astra notes that these terms are commonly used and were not coined in the '081 patent.

As observed by Astra, Mutual's construction attempts to exchange the word "solubilized" for "dissolved." As explained above, solubilize is defined as "to make soluble or more soluble," Meriam-Webster's Collegiate Dictionary available at http://www.m-w.com, or "to make (a substance such as a fat or lipid) soluble or more soluble, especially in water, by the action of a detergent or other agent," The American Heritage Dictionary of the English Language (4th ed. 2000) available at www.bartleby.com. Thus, it is clearly evident that the terms solubilized and dissolved are not interchangeable.

This Court agrees with Astra that the claim terms do not contain an inherent conflict which requires a narrowed construction that the active compound be solubilized or dispersed within the nonionic solubilizer after the solid preparation is in its finished form. Nor did Mutual clearly articulate how the portion of the specification to which it cites, supports its proposed construction.

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This Court therefore concludes that the terms "A solution or dispersion of an effective amount of the active compound" and "dissolving or dispersing an effective amount of the active compound" will be given their ordinary meaning: a solution or dispersion is the dispersed or dissolved substance(s) and the medium in which it is dispersed or dissolved.
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That claim, claim 1 of the '035 patent, reads:

1. A method of preparing a benzothiazepine derivative of the formula:

[Insert structure for compound I]

[SEE ILLUSTRATION IN ORIGINAL].

wherein R is a hydrogen or acetyl, or a pharmaceutically acceptable acid addition salt thereof, which comprises condensing a compound of the formula:

[Insert structure for compound II]

[SEE ILLUSTRATION IN ORIGINAL].

wherein R is the same as defined above, with 2-(dimethylamino)ethyl halide either in the presence of potassium hydroxide in acetone or in the presence of potassium carbonate in a solvent selected from acetone, lower alkyl acetate, a mixture of acetone and water and a mixture of lower alkyl acetate and water, and if required, further converting the product into a pharmaceutically acceptable acid addition salt thereof.

(emphasis added).

The chemical reaction recited in claim 1 is known as an "N-alkylation" reaction. Compound II, the starting material for the N-alkylation reaction, is sometimes referred to as "TZP." At issue on appeal is the emphasized portion of the claim, which recites five combinations of "bases" and "solvents" used in performing the chemical reaction. The five base-solvent combinations disclosed in the '035 patent and recited in claim 1 are:

Combination	Base	Solvent
1	potassium hydroxide	acetone
2	potassium carbonate	acetone
3	potassium carbonate	acetone and water
4	potassium carbonate	lower alkyl acetate
5	potassium carbonate	lower alkyl acetate and water

The accused Fermion process involves performing the N-alkylation of TZP in the presence of the base potassium carbonate and, rather than acetone, the solvent butanone (also known as "methyl ethyl ketone" or "MEK") mixed with water. Because the parties agree that the use of this base-solvent combination is not within the literal language of claim 1, the issue before the Commission, and now before us, is whether claim 1 is infringed under the doctrine of equivalents. More specifically, the issue is whether the use of butanone in the Fermion process instead of the acetone in the patent claim constitutes a "substantial" or "insubstantial" difference between the accused process and the patent. If the difference is substantial, there would be no infringement under the doctrine as it has recently been enunciated by this court, see Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 35 U.S.P.Q.2D (BNA) 1641, (Fed. Cir. 1995) (in banc), rev'd on other grounds, 137 L.

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Ed. 2d 146, 117 S. Ct. 1040, 1997 WL 84999 (U.S. 1997); if the difference is insubstantial, there would be infringement, and therefore the importation and sale of the product produced by the process would be in violation of § 1337.

2.

Solvents are used to dissolve reactants, which permits the reactants to come into contact with each other and undergo chemical reactions. Butanone and acetone are similar in that they are both "ketones" (organic compounds having a "carbonyl group"). Moreover, they are "homologs," that is, they differ only in that butanone contains an additional "methylene group." Their structures are illustrated below:

[Insert structures]

[SEE ILLUSTRATION IN ORIGINAL].

Acetone Butanone

In interpreting claim 1, and in assessing infringement under the doctrine of equivalents, the Commission 3 considered the claim language, the patent specification, the prosecution history, and certain extrinsic evidence. The Commission noted that Tanabe filed a Statement of Art with the PTO dated January 6, 1983. The statement called the examiner's attention to the '257 patent (the earlier product patent) and one other reference. In distinguishing the claimed invention of the '035 patent from the '257 patent, Tanabe stated:

In contrast, Applicants' invention is the condensation of the acylated form of reference compound II (our II) without prior conversion to the alkali metal salt thereof but rather in the presence of potassium hydroxide in acetone or potassium carbonate in acetone, lower alkyl acetate, water-acetone, or water-lower alkyl acetate.

The Commission noted that in this statement, as well as in claim 1, Tanabe chose to describe its invention in the form of exact base-solvent combinations, rather than in terms of categories of bases and solvents, which Tanabe had done in its '257 patent, and in other patents.

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3 The opinion of the Commission itself is a relatively brief nine pages, and essentially approves the findings and conclusions of the ALJ as recited in his much more extensive opinion. References therefore to "the Commission's" findings and conclusions incorporate the findings of the ALJ as well as the conclusions of both the ALJ in his initial decision and the Commission in its final decision.

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The Commission also noted that Tanabe distinguished the invention claimed in the '035 patent over the prior art '257 patent on the basis that the precise base-solvent combinations claimed by Tanabe provide high yields under safe and economical conditions. Tanabe represented to the PTO: "It is clear that the reference process yields are in the range of 65 to 70% . . . . Applicants' invention, on the other hand, gives yields which are no less than 87%. It is therefore clear that applicants' invention is patentable over the prior art."

The Commission noted that the '035 patent does not mention the use of any organic solvent other than acetone and lower alkyl acetates. The Commission found it "particularly noteworthy that although the '035 patent discloses a subclass of 'lower alkyl acetates,' it did not disclose a class or subclass of lower alkyl ketones. Rather, the disclosure of ketones was limited to a single ketone, i.e., acetone."

The Commission contrasted the language of claim 1 and the disclosure of only two solvents with Tanabe's disclosure of a range of solvents in the '257 patent. In that patent, Tanabe disclosed that the N-alkylation reaction is carried out in "a solvent (e.g. dioxane, toluene, xylene, dimethylsulfoxide)." The Commission concluded that one of ordinary skill in the art reading the '035 patent and file history "would conclude that the only solvents taught by the '035 patent as suitable for the claimed

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N-alkylation reaction were acetone and lower alkyl acetates, which in some cases may be mixed with water."

The Commission also considered statements made by Tanabe to foreign patent offices in prosecuting '035 counterpart applications in Finland and Israel, and before the European Patent Office ("EPO"). The '035 counterpart applications were initially rejected by all three of those patent offices, all citing United States Patent No. 3,075,967 to Krapcho (" '967 patent"). In response to those rejections, Tanabe argued that the invention was patentable over the '967 patent because Tanabe's five specific base-solvent combinations gave unexpectedly better results than other combinations of bases and solvents. Tanabe submitted a Comparative Test Report to show the examiners that the five specific base-solvent combinations were better than other base-solvent combinations. Tanabe argued to each of the three patent offices that its invention was not obvious, stating:

Judging from the facts (i) that [the '967 patent] teaches neither the use of potassium carbonate as the base nor the use of specific base-solvent combinations to be employed in the method of the present invention; (ii) that, when the condensation reaction was carried out by the use of sodium hydroxide or sodium carbonate as the base, the yield of the product was less than 10%; and (iii) that, even if potassium hydroxide or potassium carbonate was used as the base, the yield of the product was less than 30% in the case where dioxane, toluene or methanol was used, it is believed that the above mentioned advantages of the present invention have never been taught or suggested by [the '967 patent]. Thus [use of] the specific base-solvent combinations of the present invention is not obvious.

(emphasis added).

The Commission concluded that, based on claim language and the statements made to foreign patent offices as part of the prosecution history, Tanabe showed that it "intended to exclude all bases and solvents other than as particularly claimed, including those that might generally be thought of as equivalent, because the inventors believed that only through the unique base/solvent combinations stated could their requirements to produce diltiazem in high yield be realized."

In evaluating whether Fermion's process infringes under the doctrine of equivalents, the Commission noted that the burden was on Tanabe to show that the substitution of butanone for acetone was an insubstantial change. The Commission observed that acetone is chemically related to butanone and that a person skilled in the art might normally be expected to try to substitute butanone for acetone. However, it determined that a person skilled in the art would notice the specificity and exclusivity of claim 1 regarding the use of acetone in the N-alkylation reaction, and would conclude that other ketones, such as butanone, were not included because they did not work. It also noted that simply substituting butanone for acetone in the '035 patent examples would not generally work, unless conditions were carefully controlled, and that the '035 patent does not teach how to optimize critical process variables. The Commission concluded that:

In view of Tanabe's decision to use restrictive language in the claims of the '035 patent, specifying only acetone and no other keytone [sic, ketone] solvent, and given the admissions made to the PTO about the specificity of the claimed invention, and the further admissions Tanabe made to the EPO and other foreign patent offices, it has not been shown that Fermion's use of MEK is equivalent to the acetone covered by claim 1 of the '035 patent. Therefore, it has not been demonstrated that the accused Fermion process infringes claim 1 of the '035 patent.

DISCUSSION

On appeal, Tanabe asserts that the Commission erred in its construction of claim 1 and in its consequent determination that Fermion's process did not infringe under the doctrine of equivalents. Tanabe further asserts that the Commission erroneously invoked an estoppel against Tanabe regarding the proper range of equivalents based upon the purported subjective intent of the inventors, limitations not a part of claim 1, and irrelevant statements made to foreign patent offices.

The determination of whether an accused product or process infringes a claim in a patent is universally understood to involve two steps. First, we construe the claim asserted to be infringed to determine its meaning and scope. Second, we compare the properly construed claim to the accused product or process. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 U.S.P.Q.2D (BNA) 1321, 1326 (Fed. Cir. 1995) (in banc), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). In addressing these two steps, the burden is on the patent owner to establish infringement by a preponderance of the evidence. SmithKline Diagnostics Inc. v. Helena Lab. Corp., 859 F.2d 878, 889, 8 U.S.P.Q.2D (BNA) 1468, 1477 (Fed. Cir. 1988). The patent owner must show that every limitation of the patent claim asserted is found in the accused process or product,

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either literally or under the doctrine of equivalents. Id.

Whether a product or process infringes the properly construed claims of a patent, literally or under the doctrine of equivalents, is a question of fact. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1520, 35 U.S.P.Q.2D (BNA) 1641, 1647 (Fed. Cir. 1995) (in banc), rev'd on other grounds, 137 L. Ed. 2d 146, 117 S. Ct. 1040, 1997 WL 84999 (U.S. 1997). We review factual determinations of the Commission under the "substantial evidence" standard. 19 U.S.C. § 1337(c) (1994); 5 U.S.C. § 706 (1994). The proper construction of a claim, on the other hand, is solely a matter of law, over which on appeal we exercise complete and independent review. Markman, 52 F.3d at 979, 34 U.S.P.Q.2D (BNA) at 1329.

To determine the meaning and scope of a claim, we examine the claim language, the specification, and the prosecution history. Extrinsic evidence, that is, evidence outside the record before the PTO, such as expert testimony about how those skilled in the art would interpret certain language in the claim, may also be considered when appropriate as an inherent part of the process of claim construction and as an aid in arriving at the proper construction of the claim. Id.

To determine whether solvents other than those recited in claim 1 could be used in the claimed N-alkylation reaction without fear of infringement, a competitor would look to the claim language, the specification, and the patent's prosecution history. The Commission correctly noted that, in the specification and claims, Tanabe chose to define its invention in terms of specific base-solvent combinations, rather than in terms of categories of bases and solvents. A person skilled in the art would know that Tanabe could have used the term "lower alkyl ketone" to describe a class of ketone solvents including butanone and acetone. Tanabe used a similar term to describe a class of acetate solvents, claiming the use of a "lower alkyl acetate" solvent, either by itself or with water, rather than claiming only a specific acetate solvent.

For ketone solvents, Tanabe took a different approach to describing and claiming its invention, describing and claiming acetone as the only ketone solvent, to be used either by itself or with water. This specific claim language would suggest to a person skilled in the art that ketones other than acetone may not be useful for the N-alkylation reaction. In other words, the claim language itself, and the specification, suggest that substituting butanone for acetone is not an insubstantial change. Although we do not speculate on Tanabe's reasons for disclosing and claiming the use of only one ketone solvent, we note that: the doctrine of equivalents is not available for the attainment in court of a scope of protection which encompasses subject matter deliberately removed from examination by the PTO during prosecution through narrow claiming. . . . It is impermissible to erase under the doctrine of equivalents "meaningful limitations of the claim on which the public is entitled to rely in avoiding infringement."

Genentech, Inc. v. Wellcome Found., Ltd., 29 F.3d 1555, 1568 n.41, 31 U.S.P.Q.2D (BNA) 1161, 1171 n.41 (Fed. Cir. 1994) (citation omitted).

In considering the prosecution history of the '035 patent, the Commission correctly noted that in a Statement of the Art filed by Tanabe with the PTO, Tanabe defined its invention in terms of the exact base-solvent combinations recited in claim 1. Tanabe also stated that its process resulted in "yields which are no less than 87%." Consequently, a review of the prosecution history by a competitor would reinforce the suggestion in the claim language and specification that using other ketone solvents, such as butanone, is not an insubstantial change from using acetone. Moreover, the prosecution history suggests that other ketone solvents may result in lower yields than the claimed solvents.

The sharply restricted nature of the claims has much to do with the scope we accord to the doctrine of equivalents. Tanabe contends that the Commission erred in limiting the scope of equivalents based upon the inventors' purported intent and in relying on the inventors' pre-application experiments. In support, Tanabe cites the following statement in a footnote in the initial decision:

Tanabe's decision not to disclose the use of other ketones might have been based on experimental failures, such as Tanabe's failed TZP N-alkylation experiment with potassium hydroxide as the base and toluene as the solvent. Testimony at the hearing by the inventors might have elucidated this subject further.

Tanabe also refers the court to other statements in the initial decision, including: "Tanabe's [1981] experiments with MEK either resulted in no product or impure product," and a statement in a footnote that "this failure on Tanabe's part may explain why MEK was not claimed in the '035 patent." Tanabe then cites Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 224 U.S.P.Q. (BNA) 409 (Fed. Cir. 1984), and argues that the Commission erred in relying on the inventors' pre-

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application experiments to determine that butanone is not interchangeable with acetone. Tanabe asserts that the Commission improperly relied on Tanabe's confidential laboratory notebooks in concluding that experiments not part of the prosecution history create an "experimental estoppel" that limits the application of the doctrine of equivalents in this case.

We do not read the Commission's opinion to establish any estoppel based on pre-application experiments performed by Tanabe. On the contrary, the Commission properly considered Tanabe's pre-application experiments in assessing whether there is a substantial difference between the claimed and accused processes. Tanabe's unsuccessful experiments with butanone indicate that the inventors did not consider butanone to be interchangeable with acetone for use in the claimed N-alkylation process.

The Commission also considered the statements made by Tanabe in prosecuting foreign counterparts to the '035 patent. As earlier explained, in response to rejections for obviousness Tanabe argued that its process was patentable over the prior art because its five specific base-solvent combinations gave unexpectedly better results than other combinations of bases and solvents. Tanabe submitted a Comparative Test Report to demonstrate the effectiveness of its base-solvent combinations. Tanabe argued before the EPO, and the Finland and Israel patent offices, that use of "the specific base-solvent combinations of the present invention is not obvious."

Tanabe argues that the Commission erred in considering foreign prosecution history, improperly finding a "foreign prosecution estoppel" to limit the application of the doctrine of equivalents. We do not read the Commission's decision to establish any estoppel related to the prosecution of foreign counterparts to the '035 patents. In evaluating infringement under the doctrine of equivalents, "representations to foreign patent offices should be considered . . . when [they] comprise relevant evidence." Caterpillar Tractor Co. v. Berco, S.p.A., 714 F.2d 1110, 1116, 219 U.S.P.Q. (BNA) 185, 188 (Fed. Cir. 1983).

In the present case, the representations made to foreign patent offices are relevant to determine whether a person skilled in the art would consider butanone or other ketones to be interchangeable with acetone in Tanabe's claimed N-alkylation reaction. Because Tanabe represented that its "specific base-solvent combinations" distinguish its process from the prior art, Tanabe's statements to foreign patent offices suggest to a person skilled in the art that other solvents, including butanone, may not be interchangeable with the claimed solvents.

In determining that butanone is not interchangeable with acetone in the claimed N-alkylation reaction, the Commission reviewed experiments performed by Fermion and by Tanabe's expert, Professor Baldwin. The Commission found that Professor Baldwin's tests demonstrate that substituting butanone for the claimed solvents resulted in lower yields or productivity than that achieved in the examples in the patent. As for Fermion's tests, the Commission found that Fermion duplicated examples disclosed in the patent, substituting butanone for the disclosed solvents, and found that butanone generally produced substantially worse results.

There was an exception. The Commission found that when Fermion substituted butanone for acetone in Example 2, the reaction produced a slightly better yield with butanone. Tanabe argues that these results are "dispositive," and indicate that Fermion's process infringes under the doctrine of equivalents. Example 2 teaches conditions for performing the N-alkylation reaction using potassium carbonate as the base and acetone and water as the solvent system. Although when Fermion substituted butanone for acetone in this example, it achieved similar results to those reported in the patent for Example 2, the Commission also found that Fermion was unable to duplicate Example 2 using butanone in larger-scale pilot plant tests on two occasions.

To determine how to adjust reaction conditions to achieve consistent results in its N-alkylation process, Fermion conducted numerous experiments between 1983 and 1986. By performing these experiments, Fermion learned to adjust critical process conditions to achieve consistent high yields for the N-alkylation reaction. The extensive experimentation performed by Fermion, which involved a variety of solvents, bases, and reaction conditions, suggests that Fermion's activities are better described as "designing around" the '035 patent rather than "copying." Moreover, these experiments support the conclusion that butanone is not readily interchangeable with acetone in the claimed process.

Although the preceding review of the claim and its proper construction is more than sufficient to affirm the Commission's conclusion, the record shows that the parties also presented evidence on whether Fermion's process satisfies the function-way-result test for infringement under the doctrine of equivalents. See Hilton Davis, 62 F.3d at 1517-18, 35 U.S.P.Q.2D

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(BNA) at 1645. The Commission found that the claimed process operates by way of a "surface solvent phase," and that Tanabe offered no evidence that a surface solvent phase was present in the Fermion process.

The Commission's decision that Fermion's process does not infringe the '035 patent under the doctrine of equivalents reflects a proper construction of the patent claim, and to the extent it is dependent on factual determinations, is supported by substantial evidence. We have considered Tanabe's other arguments on appeal and find them to be unpersuasive.
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Suitable Solvent System or Solvent System

The final term for which the parties have sought construction is "suitable solvent system" or "solvent system." The parties offer similar interpretations for this phrase, suggesting that there is substantial agreement as to the construction of this term. Nonetheless, there is some dispute. While both sides agree that a "suitable solvent system" or a "solvent system" is a "solvent or mixture of solvents," Defendants wish to add to the definition the language "suitable for bringing aniline and nitrobenzene into reactive contact."

The Court agrees with Plaintiff that this additional language is superfluous. Indeed, to adopt Defendants' definition in toto would be redundant, as certain claims, such as claims 30 and 61 of the '063 patent, and claims 7,11, 23, and 29 of the '111 patent, already discuss bringing aniline or substituted aniline derivatives and nitrobenzene into reactive conduct in the same sentence in which the term "suitable solvent system" appears. Therefore, the Court findsthat the proper construction of "suitable solvent system" or "solvent system" is "a solvent or mixture of solvents."
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The final claim construction issue TKT raises is aimed at the district court's alleged failure to discern "source and process" limitations in claims of the '080, '349, and '422 patents. According to TKT, the trial court erred by concluding that the asserted claims are product claims, i.e., that they are directed to a structural entity that is not defined or limited by how it is made. TKT summarily states that this holding must be erroneous because, it asserts, the patentability of the claims depended on the process since "Amgen tried, but failed, to distinguish rEPO from prior art EPOs based on physical differences." We do not agree.

It is telling that neither in the briefing nor at oral argument did TKT direct us to any specific statement in the prosecution history to support the contention that the patentability of the product claims in suit depended upon the process by which those products are obtained. In fact, the original claims of at least one of the patents (the '080 patent) were drafted as product-by-process claims, which claims were cancelled and replaced with "pure" product claims. This is strong evidence that both the patentee and the examiner viewed the claims that ultimately issued as lacking a process component. See Vanguard Prods., Inc. v. Parker Hannifin Corp., 234 F.3d 1370, 1372, 57 USPQ2d 1087, 1089 (Fed. Cir. 2000) ("Parker Hannifin argues that the prosecution history shows that the Vanguard inventors viewed co-extrusion as 'fundamental' to manufacture of the claimed gasket, thereby imposing this process of manufacture upon the product claims . . . . However, review of the prosecution history shows that during examination the examiner as well as the applicant treated the product claims as directed to the product itself, and examined the application accordingly.").

In any event, we are not convinced that the source limitations in the asserted claims convert the claims into anything other than product claims. As to the '080 patent, the "non-naturally occurring" limitation in claims 3 and 4 merely prevents Amgen from claiming the human EPO produced in the natural course. By limiting its claims in this way Amgen simply avoids claiming specific subject matter that would be unpatentable under § 101. This court has endorsed this approach, recognizing that patentees can use negative limitations such as "non-human" and "non-natural" to avoid rejection under § 101. See Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 923, 18 USPQ2d 1677, 1680 (Fed. Cir. 1991). The district court arrived at a similar conclusion, Amgen, 126 F. Supp. 2d at 89, 57 USPQ2d at 1462-63, and TKT has not demonstrated any error in that

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conclusion. Similarly, the "not isolated from human urine" limitation in claims 2 and 4 of the '080 patent simply requires that the claimed EPO, however made, be obtained from a source other than human urine. Each of these limitations only excludes human EPO from specific sources and does not restrict the claimed EPO to that produced from any particular source or by any particular method. In sum, claims 2, 3, and 4 of the '080 patent remain broadly drawn to the described "erythropoietin glycoprotein" or "pharmaceutical composition" produced by any method, or obtained from any source, other than those specifically excluded.

As to the '422 patent, the limitation "purified from mammalian cells grown in culture" in claim 1 clearly limits the source of the EPO used in the claimed "pharmaceutical composition." The limitation only speaks to the source of the EPO and does not limit the process by which the EPO is expressed. Rather, the claim is broadly drawn to a "pharmaceutical composition" having certain elements, one of those being EPO "purified from mammalian cells in culture." This reading is in line with the district court's construction and, again, TKT directs us to no error. n5

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n5 We do not hold that these limitations lack meaning, only that they mean just what they say. Accordingly, they limit only the source from which the EPO is obtained, not the method by which it is produced.

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2. "Spans [a Non-Coding Region Sequence]"

The parties agree that the term "spans" can be construed as "amplifies." However, Applera argues that the term "spans a non-coding region sequence" must be further limited to encompass the further requirement that the sequence in question include introns as non-conserved DNA sequences. GTG argues that no limitation is necessary.

A conserved sequence is one which does not vary significantly between individuals. Thus, if a conserved sequence is included in the non-coding region of the DNA to be analyzed, that section will not show any significant differences between the strand in question and the other strands used in comparison. Thus, non-conserved sections must also be included in the DNA region analyzed in order to find the necessary variations between the strand under analysis and the comparator strands to perform the method described in the patent.

Applera argues that because the specification defines a "non-coding" region as synonymous with the term "intron," and because the specification defines the term "intron-spanning primer" as spanning non-conserved regions, the term "spans" must require that non-conserved sequences be included in a non-coding region sequence. However, nothing in the claims or prosecution history implies that the description in the specification for "intron-spanning primer" should be imported into the claim interpretation for the term "spans," and thus to do so would be improper. See Texas Digital, 308 F.3d at 1204-05; Teleflex, 299 F.3d at 1326. The term "spans" is thus construed as: amplifies, with no further limitation that the region spanned must include a non-conserved intron section.
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"Specific to PCV-2 and Not Specific to PCV-1"

The parties below could not agree on what terms of claim 32 were disputed, and the district court decided to construe the claim in its entirety. The district court construed claim 32 to mean "an isolated DNA molecule that includes, but is not necessarily limited to, a DNA sequence which codes for an immunodominant region of a protein, wherein the sequence is from the genome of a PCV-2 circovirus, and not from the genome of a PCV-1 circovirus." The district court explained that due to the "comprising" transition term, the claim may read on molecules that contain sequences that encode epitopes common to PCV-1 and PCV-2, as long as the molecule contains at least one sequence that encodes an epitope unique to

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PCV-2. We see no error in this construction, and it appears that at the time of the Markman hearing, Merial did not see any either.

Merial challenges this construction on appeal because in the district court's subsequent infringement analysis, the court explained that the part of the claim construction specifying that the sequence be "from" the genome of a PCV-2 circovirus, etc., excluded sequences that were physically derived from a non-PCV-2 source. Merial argues that sucha manufacturing requirement has no place in a proper analysis of this claim, and is inconsistent with the district court's otherwise correct claim construction. We agree. For purposes of our review of the district court's opinion, we focus our analysis on the term "specific to" in claim 32, since it appears that this term is the hook for the requirement that the sequence be unique to and derived from PCV-2.

As Intervet explains, the term "specific to" is a specialized term of art in immunology that typically refers to one structure's proclivity for binding to another structure. For example, antibodies will attack a viral antigen if paratopes of those antibodies are "specific to" an epitope in the viral antigen. The specialized definition of this term does not make sense in the context of claim 32, however, because the claimed epitope is not described as binding to porcine circoviruses; it is described as located within a porcine circovirus. The epitope is thus bound by antibodies that are "specific to" PCV-2. In light of the patent description and a general understanding of the relevant art, the claim would be understood by one of skill in the art to be using the term "specific to"in a colloquial or non-technical sense. Cf. Intervet, Inc. v. Merial Ltd., No. 1:06-cv-00658, 2007 U.S. Dist. LEXIS 98471 (D.D.C. Nov. 28, 2007) (claim construction order at 21). As construed, a nucleotide sequence encoding an epitope that is specific to PCV-2 and not specific to PCV-1, as that term is used in claim 32, is a nucleotide sequence that encodes part of a polypeptide sequence of PCV-2, but not part of a polypeptide sequence of PCV-1. More specifically, it encodes at least one epitope found on the PCV-2 virus, but not found on the PCV-1 virus.

The district court found that Intervet's vaccine could not have contained a sequence encoding an epitope specific to PCV-2 because the sequence was derived from a non-PCV-2 source. This analysis may be mooted by our reversal of the district court's claim construction of "PCV-2", since it is no longer clear that the source of the sequence in Intervet's product is not PCV-2. Nevertheless, to the extent that the district court's application of its claim construction requires that the encoded epitope be unique to PCV-2 among all possible antigens, it is erroneous. If the term "specific to PCV-2" meant that the epitope must be found only on PCV-2 and no other antigen,then the subsequent limitation "and not specific to PCV-1" would be redundant. Thus an infringing epitope may be common to PCV-2 and some other antigen, as long as it is not also common to PCV-1. Whether one isolates the sequence directly from a PCV-2 virus or engineers a sequence obtained from another source such that it encodes a PCV-2 epitope makes no difference to the proper application of the district court's otherwise correct claim construction.

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a. What is the proper construction of claim 1?

Plaintiffs' noninfringement argument largely derives from its proposed construction of claim 1. Plaintiffs argue that the phrase "wherein said antigen is stage specific and not lineage dependent, and said antigen is also specifically bound by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-8483" (the "'wherein' clause") refers to the antigen now identified as CD34. In addition, they argue that the phrase "specifically binds" refers to the chemical interaction between an antigen and an antibody. Thus, plaintiffs propose the following construction of claim 1 -- any monoclonal antibody that binds to the CD34 antigen through an antibody-antigen interaction. CellPro argues that plaintiffs' claim construction impermissibly seeks to rewrite claim 1 by avoiding specific limitations of the claims. CellPro apparently does not contest the court's previous construction of these claims.

1) What is the meaning of the "wherein" clause?

Plaintiffs' proposed claim construction of the "wherein" clause is highly unorthodox in that it seeks to define a large number of words in the claim with reference to a single alphanumeric reference, CD34. The basis for this unorthodox construction, however, appears to derive from the difficulty of describing the antigen to which the '204 patent refers. As Justice Burton observed in Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 92 L. Ed. 588, 68 S. Ct. 440 (1948):

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Machines lend themselves readily to descriptions in terms of mechanical principles and physical characteristics. On the other hand, it may be that a combination of strains of bacterial species, which strains are distinguished from one another and recognized in practice solely by their observed effects, can be definable reasonably only in terms of those effects.

Id. at 136-38 (Burton, J., dissenting). Similarly, those skilled in the art of making monoclonal antibodies distinguish and define antigens based on their observed characteristics. Accordingly, the phrase "wherein said antigen is stage specific and not lineage dependent, and said antigen is also specifically bound by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-8483" (the "'wherein' clause") is a verbal attempt to describe a specific physical entity, which those skilled in the art now call the CD34 antigen.

The parties appear to agree that the "wherein" clause refers to the antigen now identified as CD34. CellPro contends that it does not agree and that the phrase refers only to the antigen identified by Civin as My-10. Those skilled in the art of making monoclonal antibodies, however, clearly understand that My-10 and CD34 are the same. The attorney prosecuting the application for the '204 patent argued that My-10 was becoming known in the art as CD34 as a result of the International Leukocyte Workshops. The examiner recognized this when she observed that claim 1 "limits the claimed monoclonal antibodies to species that react with a particular antigen (now identified as CD-34)." Furthermore, the testimony of Dr. James D. Griffin, one of plaintiffs' experts, and of Civin establish that My-10 and CD34 are the same. Griffin is a professor at Harvard Medical School and the Associate Director of the Division of Hematologic Malignancies at the Dana Farber Cancer Institute. Therefore, it appears that the "wherein" clause refers to CD34.

Assuming that My-10 is CD34, CellPro nevertheless objects to what it considers the removal of the phrase "stage specific" from claim 1 because it seeks an opportunity to prove that CD34 is not in fact stage specific. CellPro's argument is inapposite for two reasons. First, by construing the "wherein" clause, the court is not removing the language in that clause from the claims. Rather, it is determining the meaning of that language for the purpose of determining whether CellPro's devices infringe the patent. Thus, the phrase "stage specific" merely attempts to describe an aspect of the CD34 antigen at the time the patent issued, that it is was detectable on immature cells and not detectable on mature cells. To the extent the court previously construed the phrase "stage specific" to be inconsistent with the true characteristics of the CD34 antigen, that construction was incorrect.

The second reason CellPro's argument is inapposite is that the issue of whether CD34 is found on mature cells -- and thus is not "stage specific" in CellPro's view -- goes to whether the invention claimed in the '204 patent lacks utility or is inoperable, not to whether there is infringement. The utility of the '204 patent appears to derive from the fact that CD34 was detectable only on immature cells at the time the patent issued. Civin concluded from this fact that he could use antibodies to the CD34 antigen to label immature cells and separate them from mature cells. If CellPro can prove by clear and convincing evidence that CD34 antibodies cannot serve this function, then the '204 patent may be invalid for lack of utility or inoperability. This is not an issue of claim construction or infringement, however. If an antibody "specifically binds" to the CD34 antigen, it infringes claim 1 of the '204 patent whether or not that claim is invalid.

2) What is the meaning of "specifically binds"?

Griffin testified that "specifically binds" is synonymous with words such as "recognizes" and "adheres" in that it refers to the specific chemical interaction that occurs between an antigen and an antibody. He further testified that "specific binding" is in contrast to "nonspecific binding," which refers to the attachment of an antibody to an antigen due to some other factor, such as the stickiness of the antigen or cell. The specification and the prosecution history of the '204 patent support this construction because the phrase "recognize" is used interchangeably with "specifically binds." In fact, the examiner herself altered the words "recognizes" and "recognized" to "specifically binds" and "specifically bound" without any indication that the latter phrases implied a special meaning or limitation. Furthermore, the prosecution history of the re-examination of the '680 patent also differentiates specific binding from nonspecific binding in the way Griffin does. Thus, plaintiffs' proposed construction of "specifically binds" as referring to antigen-antibody recognition appears correct.

Plaintiffs' proposed construction is partially incomplete, however, in that it does not necessarily reflect an inherent limitation in the concept of antibody-antigen recognition. Griffin testified that a particular monoclonal antibody recognizes only one antigen. Therefore, the concept of "specific" binding in the '204 patent also refers to the fact that the claimed antibody only binds to CD34. The specification supports this limitation at column 2, lines 16-20:
In one embodiment, the present invention provides a monoclonal antibody that recognizes an antigen on human pluripotent

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lymphohematopoietic stem cells, but does not recognize an antigen on normal, human mature lymphoid and myeloid cells.

Thus, the court will modify plaintiffs' proposed construction of claim 1 to state the following -- any monoclonal antibody that binds only to the CD34 antigen through an antigen-antibody interaction.

CellPro argues that this construction of the phrase "specifically binds" removes two specific limitations from claim 1. The first such limitation is that the claimed antibody must "specifically bind" to an immature cell, which means that the antibody cannot bind to a mature human cell. Claim 1 does not speak in terms of the antibody binding to particular cells, however; it speaks in terms of the antibody binding to a particular antigen. This limitation is captured by the requirement that the claimed antibodies must bind only with CD34 and not another antigen.

When the '204 patent application initially was filed, claim 1 did refer to the antibody binding to immature cells and not to mature cells. The claims subsequently were rewritten to focus on the location of the antigen to which the antibody bound, rather than the type of cell to which the antibody bound. Therefore, CellPro's proposed claim limitation really reflects the utility and operability issues discussed above with respect to the location of the CD34 antigen. In other words, if an antibody binds only to the CD34 antigen through an antigen-antibody interaction, even if the CD34 antigen is found on a mature cell, that antibody infringes claim 1. Of course, if CellPro can prove by clear and convincing evidence that CD34 is found on mature cells, claim 1 of the '204 patent may be invalid as inoperable or lacking utility.

The second limitation CellPro proposes is that the claimed antibodies must "specifically bind" to an antigen on a human cell, which means that the antibodies cannot bind to an antigen on nonhuman cells. CellPro relies on the portion of claim 1 that describes the CD34 antigen as "on non-malignant, immature human marrow cells." It is clear, however, that this phrase does not attempt to describe every possible location of the CD34 antigen. For example, the specification itself teaches that CD34 is found on the KG-1a cell line, which contains malignant cells. Therefore, the claim language alone does not suggest that the claimed antibodies cannot bind to an antigen on nonhumans as long as that antigen is CD34.

CellPro also relies on a statement made by the prosecuting attorney during the reexamination of the '680 patent. In distinguishing an article by Castignola et al. entitled "Purification of Rat Pluripotent Hemopoietic Stem Cells" (the "Castignola article"), the attorney stated:

Castignola, et al., is concerned with rat cells obtained by a method including separating bone marrow cells from rats treated with hydrocortisone on a density gradient and then using a fluorescence cell sorter to select cells showing high fluorescence with a fluorescent anti-Thy-1 antibody (specific for T cells). . . . Furthermore, there is no indication that the properties of human pluripotent stem cells are similar to those of the rat cells studied by Castignola, et al.

CellPro argues that this statement, in combination with the claim language, established a limitation that the claimed antibodies cannot bind to an antigen on nonhuman cells.

This argument fails for two reasons. First, the examiner stated that Castignola et al. was not pertinent prior art, and thus she did not consider it in allowing the claims. Second, the prosecuting attorney was not discussing the meaning of the phrase "specifically binds" in the '204 patent or the binding properties of the claimed antibodies. Rather, he was arguing that the Castignola article does not teach that human stem cells may have an antigen that can be used to separate immature from mature cells to form a cell suspension as claimed in the '680 patent. The attorney never argued that the CD34 antigen is not on nonhuman cells, nor did he argue that the claimed antibodies only bind to an antigen on human cells. Consequently, the court will adopt the following construction of claim 1 of the '204 patent -- any monoclonal antibody that binds only to the CD34 antigen through an antigen-antibody interaction.

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1. Claim Construction and Infringement

CellPro asserts that the district court erred in construing the "wherein" clause of the '204 patent as referring to "the CD34 antigen." CellPro contends that reference to "the CD34 antigen" was unnecessary and incorrect: it was unnecessary because the "wherein" clause clearly refers to a single antigen, the My-10 antigen, that is disclosed in the specification; it was

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incorrect, CellPro continues, because "CD34" refers to a genus of antigens and thus erroneously sweeps into the claims all CD34 antibodies, regardless whether they bind to the My-10 antigen. CellPro states that what the scientific community refers to as "the CD34 antigen" is in fact "a collection of different molecules, all based on the same protein backbone, [with] a number a molecular forms." CellPro's Opening Brief at 32 (quoting its expert's declaration). Apparently CellPro considers these different molecules to be different antigens, because it explains that its 12.8 antibody binds to "a CD34 antigen" that is different from My-10. CellPro's Reply Brief at 13 (emphasis added).

Significantly, Hopkins agrees with CellPro that the claims cover a single antigen, not a genus of antigens, but contends that "the CD34 antigen" is an apt description of that claimed antigen. In support of its position, Hopkins points, inter alia, to the prosecution history. Specifically, Hopkins highlights the applicant's reference during prosecution to the conclusion of the Third International Workshop on Leukocyte Differentiation ("Workshop") and the applicant's statement to the examiner that "the antigen recognized by the monoclonal antibodies of this invention has been designated My-10 . . . by the inventor, and subsequently CD-34 (antibody cluster designation) by the [Workshop]." The Workshop's report, also submitted by the applicant to the examiner, describes the antigen to which anti-My-10 is bound as "the CD34 antigen." n23 In support of the district court's grant of summary judgment of infringement, Hopkins points to several other pieces of documentary evidence in which CellPro admits either that its 12.8 antibody binds to "the CD34 antigen" or otherwise binds to the same antigen as anti-My-10. Thus, Hopkins contends that CellPro infringes the claims regardless whether the antigen of the claims is referred to as "the CD34 antigen," "My-10," or (to paraphrase the "wherein" clause) "the antigen bound by the antibody produced by the hybridoma on deposit."

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n23 Hopkins also points out that the examiner subsequently placed her imprimatur on the idea that My-10 and "the CD34 antigen" were synonymous, noting that the claims were limited to those monoclonal antibodies reactive with "a particular antigen (now identified as CD34)." See Joint App. at EA7954.

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We agree with Hopkins that the district court's claim construction was not in error. The district court may have been correct that it was "unorthodox" to condense the meaning of the "wherein" clause into the simpler language of "the CD34 antigen." However, this treatment was not erroneous, as Hopkins' citations from the prosecution history show; the applicant directly equated My-10 and thereby the entirety of the "wherein" clause with what the scientific community had come to understand as "the CD34 antigen." Furthermore, the record makes clear that the term "the CD34 antigen" is synonymous with the antigen discovered by Civin.

CellPro cites no intrinsic evidence and no credible extrinsic evidence in support of its theory that "the CD34 antigen" encompasses a genus of antigens. Instead, what the evidence does show is that the CD34 antigen contains a number of epitopes n24 on its surface to which the various CD34 antibodies can bind. For example, the Workshop report explains that the various CD34 antibodies known as of that date all bind to the CD34 antigen, but to different epitopes, Joint App. at EA7275-82, and one study concluded that "at least three distinct CD34 epitopes" were expressed on the surface of the CD34 antigen, id. at EA7283. The same conclusion is confirmed by CellPro's own internal documents. For example, Dr. Berenson concluded that "[Antibody 12.8] recognizes the same antigen as does [anti-]My-10 . . . . Unlike [anti-My-10], antibody 12.8 recognizes a distinct epitope that is also present on a similar population of marrow cells in nonhuman primates." Id. at A1390. Other evidence supports the conclusion that 12.8 and anti-My-10 bind to the same antigen, see id. at A5846 (testimony of CellPro's expert, Dr. D.R. Sutherland) ("So collectively we think that this data suggests that the [anti-]My-10 and 12.8 binding sites are distinct and nonoverlapping binding sites on the CD34 molecule."); id. at EA5462 (Bloomberg '204 opinion letter) ("It is our understanding, based upon discussions with CellPro scientists, that the monoclonal antibody used by CellPro does not bind to the same epitope in the My-10 antigen as does the Civin anti-My-10 monoclonal antibody."), and that this antigen is the CD34 antigen, see id. at EA3781 (CellPro's FDA filing) ("The primary reagent is a monoclonal antibody (Mab) 12.8 which specifically binds to a unique antigen (CD34) on the target cells (stem cells).").

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n24 An "epitope" is defined as "any region of the [antigen] macromolecule with the ability or potential to elicit, and combine with, specific antibody." Singleton & Sainsbury, supra note 3, at 269, 323.

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CellPro cites no evidence to refute the clear conclusion to be drawn from these documents that its 12.8 antibody binds to the CD34 antigen, albeit to a different epitope than does the anti-My-10 antibody disclosed in the patent, and therefore literally infringes the claims of the '204 patent. Accordingly, the district court's construction of the "wherein" clause and its subsequent grant of summary judgment of infringement are affirmed.
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F. "specifically immunoreactive"

Claim 1 states that the antigen is "specifically immunoreactive with anti-fillagrin antibodies present in the serum of subject suffering from rheumatoid arthritis." '724 Patent col.15 l. 29-31.) Plaintiff argues that the phrase "specifically immunoreactive" requires that the antigen recognize and bind to form complexes "only with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis." 9Doc. No. 105 at 6.) Defendant's construction is less demanding, requiring only that the antigen "preferentially reacts with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis." (Id.) The Court agrees with Defendant.

A patent's specification is "always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quotation omitted). Here, the specification consistently uses the term "specifically" as a matter of degree, not an absolute. For example, it states that the claimed peptide is "suitable for diagnostic research with increased specificity." '724 Patent col.1 l.49-50. It explains that the use of a cyclic peptide enhances "specificity." col.6 l.14-17. It points out that a prior art test is "not very specific." col.1 l.65 - col.2 l.1. Finally, it states that the claimed invention is suitable for "high-specificity testing." col.2 l.54-55. In the context of binding specificity, the specification refers to an "organic compound comprising a part that is able to compete with a peptide of the invention for binding to an antibody which is specific for said peptide." '724 Patent col.3 l.4-7. Even though this antibody is "specific" for the peptide, the invention relates to another compound that also binds with the antibody. Thus, the specification describes specificity as something that can be increased and enhanced, something that varies from antigen to antigen. This treatment is inconsistent with Plaintiff's construction that specificity equals exclusivity. Under Federal Circuit law, "when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term by implication." Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc., 262 F.3d 1258, 1271 (Fed. Cir. 2001).
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D. "Spheroid"

The term "spheroid" is found in asserted claims 13 and 14 of the '120 patent. Wyeth proposes that the term be construed to mean

> one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round. The term spheroid may include granules, beads, and pellets.

Mylan, on the other hand, proposes the following alternative:

> One or more particles that are generally shaped like a sphere resulting from an extrusion and spheronization process.

Thus, Mylan argues that, as used in these patents, the term "spheroid" is limited to spheroids created by a certain method of manufacture, specifically an extrusion and spheronization process.

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Mylan argues that a person of ordinary skill in the art would understand that the specification limits the term to spheroids created through an extrusion and spheronization process. It points out that the specification repeatedly refers to this method of manufacture, and, indeed, mentions no other potential methods. While it admits that "spherical particles" can be manufactured through other methods, such as drug layering on a sugar crystal or seed, Mylan contends that a person of ordinary skill in the art would expect that, had the inventors intended to include spheroids made by other methods, they would have explained those methods. According to Mylan's pharmaceuticals expert, Glenn A. Van Buskirk, Ph.D. ("Van Buskirk"), other methods of manufacture could affect the sphere density and size of the spheroids, which, in turn, could affect the release of the drug in a patient's system. Mylan, Barry Dec., Ex. C, P 30. 3 Thus, Mylan contends, the methods are not easily interchangeable and a person of ordinary skill in the art seeking to duplicate the dissolution rates using spheriods that have been manufactured using a technique other than the extrusion and spheronization process would be required to do significant experimentation to achieve the same results. Id.

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3 Mylan attaches Van Buskirk's affidavit as Exhibit C to the "Declaration of George J. Barry III In Support of Defendant Mylan Pharmaceuticals Inc.'s Responsive Claim Construction Brief." Barry represents Mylan in this case.

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Mylan further points out that the specification provides a table of dissolution rates, entitled "Acceptable Coated Spheroid Dissolution Rates," and limits the invention to the specific dissolution rates listed there. '171, Col. 6:55-65. Because the inventors only explain how to achieve those dissolution rates using a process of extrusion and spheronization, Mylan argues that they have implicitly limited the term "spheroid" to that method.

Wyeth, on the other hand, urges the Court to adopt the ordinary meaning of "spheroid," which it contends is "any particle generally shaped like a sphere, including granules, beads, and pellets." It cites expert testimony and extrinsic evidence, including dictionary definitions and scientific literature, to support this definition. Although only one method of manufacture for the spheroids is disclosed in the specification, Wyeth contends this is merely a preferred method and there is no evidence that the inventors intended to narrow the scope of the term.

1.

The term "spheroid" appears in two of the asserted claims. Claim 13 of the '120 patent states "[t]he method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid." (Emphasis added). Similarly, Claim 14 of the same patent states "[t]he method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." (Emphasis added.) Thus, the plain meaning of the term, as used in the claims, does not imply a specific method of manufacture.

"Spheroid" also appears throughout the specification. Initially, in the "Background on the Invention," the inventors describe the convention in the drug industry for producing extended release capsules when the production of tablets is not feasible. '171, Col. 1:35-45. To that end, the inventors explain that

in this situation, extended release capsule dosage forms may be formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water . . . to form an extrudable plastic mass from which small diameter . . . cylinders of drug/matrix are extruded, broken into appropriate lengths and transformed into spheroids using standard spheronization equipment.

Id. (emphasis added). Although this section describes the extrusion and spheronization manufacturing process, the context makes clear that this is the convention of the drug industry for producing encapsulated extended release formulations, rather then a description of the claimed invention. In addition, despite Mylan's arguments to the contrary, the use of the term "may" in this context indicates that this is one possible method of formulating extended release dosage capsule forms.

Although the term appears several times throughout the "Brief Description of the Invention," no reference to a specific manufacturing process is made in this section. Rather, the term is used in the context of describing the percentages of specific ingredients found in the formulations, i.e. "spheroids comprised of [the specific ingredients]."

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The "Detailed Description of the Invention" makes several references to "spheroids" and their manufacturing process. First, the inventors describe the drug formulation as being "formed as beads or spheroids." '171, Col. 4:13. The inventors then give a brief history of the invention, explaining that, after attempting, but failing, to create extended release tablets, id. at Col. 4:60-65, they then tried to create an encapsulated extended release formulation. Explaining that process, they state:

Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose . . . in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of hydroxypropylmethylcellulose 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.

Id. at Col. 5:1-13. Thus, as asserted by Mylan, the inventors clearly focused their efforts on the extrusion and spheronization process to create an encapsulated extended release formulation of Effexor (R). This review of the steps the inventors took in reaching the invention does not, however, appear to be intended to limit the invention itself.

Finally, the inventors provide several examples "to illustrate the applicant's solution to the problem of preparation of the extended release drug containing formulations of this invention." Id. at Col. 5:29-31. In Example No. 1, entitled "Venlafaxine Hydrochloride Extended Release Capsules," the inventors describe a mixture that is "extruded, spheronized and dried to provide uncoated drug containing spheroids." Id. at Col. 5:40-45. In Example No. 6, they state:

Spheroids comprising 16.5% venlafaxine Hcl and 83.5% microcrystalline cellulose were mixed with approximately 50% water to granulate in a Littleford Blender . . . at a fixed speed through a 1.25 mm screen using a Nica extruder/spheronization machine . . . for a 12/20 mesh cut after drying. Two portions of the resulting spheroids were coated with a 5% and 7% coating level . . . .

Id. at Col. 5:65-67, 6:1-8. The remaining examples do not reference any process for creating spheroids.

While these illustrations refer to only one method of manufacturing spheroids, the method appears to be a preferred embodiment, not an attempt to limit the scope of the invention. The Federal Circuit has repeatedly counseled against limiting a term on the basis of a preferred embodiment or other specific example from the specification. Phillips, 415 F.3d at 1323 ("[T]hough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."). The Court, therefore, cannot conclude that the inventors limited the term "spheroid" by referencing the extrusion and spheronization process in the Examples.

2.

Having carefully analyzed the language used in the claims and specification, the Court concludes that "spheroid" should be given its ordinary and customary meaning. See Phillips, 415 F.3d at 1313 (courts should look to the specification to understand the ordinary meaning of a claim term). As discussed earlier, a "heavy presumption" exists "that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc., 288 F.3d at 1366. Although "[a]n accused infringer may overcome this 'heavy presumption' and narrow a claim term's ordinary meaning, . . . he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." Id. (citing Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989-90, 992 (Fed. Cir. 1999). Rather, the presumption may only be overcome in several specific instances, such as when a court concludes that the inventor acted as his own lexicographer and "clearly set forth a new definition of the disputed claim term," or that the intrinsic evidence establishes that the inventor distinguished the term from the prior art on the basis of a particular embodiment. Id. at 1366-67. Moreover, when a new definition is bestowed on a term, it must be done deliberately. In re Paulsen, 30 F.3d at 1480.

Here, although the specification references only one manufacturing process for spheroids, it does not "clearly set forth a new definition" for the term. Because the Federal Circuit has cautioned against narrowing a term's ordinary meaning on the basis that the specification reveals only one preferred embodiment, the Court declines to limit the term "spheroid" in the manner requested by Mylan.

Moreover, Mylan's argument that, because the inventors set forth a table of dissolution rates and described only one method

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of achieving those rates, they necessarily limited the invention to only that method is unpersuasive. While those specific dissolution rates must be met, nothing in the patents require that they be met only with spheroids made through a process of extrusion and spheronization. Indeed, Wyeth's expert, James McGinity, Ph.D. ("McGinity"), a Professor of Pharmaceutics in the College of Pharmacy at the University of Texas, Austin, states in his declaration that "[t]he method of manufacture of spheriods . . . would be considered by one of ordinary skill in the art as totally irrelevant to how they work in delivering the drug to the body." Wyeth Ex. 19, P 44. He explains that the coating that is applied after the spheriods have been manufactured actually controls the release of the drug in an extended release formulation; thus, the success of that formulation "is not dependant upon the process by which the spheroids are made." Id. Although Mylan's expert disagrees on this point, McGinity's explanation is compelling. Accordingly, the Court finds Mylan's argument without merit.

3.

Although the Court agrees with Wyeth that the inventors intended the term "spheroid" to be understood by its ordinary and customary meaning, it cannot adopt Wyeth's proposed construction in its entirety. McGinity states that his understanding of the term "spheroid" as used by those in the pharmaceutical industry is "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round." Wyeth, Ex. 19, P 38. As support, he points to the definitions for "spheroid" that appear in the American Heritage College Dictionary (3rd ed. 1993), and in Merriam-Webster's Collegiate Dictionary (10th ed. 2001), both of which are consistent with Wyeth's proposed construction. Id. at P 39.

Mylan does not dispute that definition. Indeed, its proposed construction similarly begins with "one or more particles that are generally shaped like a sphere." Thus, the Court finds that this constitutes the ordinary and customary meaning of this term to one of ordinary skill in the art.

Wyeth, however, seeks to add an additional sentence to this definition; specifically, that the term "spheroid" includes "granules, beads, and pellets." In McGinity's opinion, "the terms granules, beads and pellets can be used interchangeably with the term spheroid." Wyeth, Ex. 19, P 38. He provides no basis for this opinion, however, and neither of the definitions that support the first part of Wyeth's proposed construction make reference to granules, beads or pellets.

Mylan argues that Wyeth is improperly attempting to broaden the definition of spheroid. Its expert, Van Buskirk, explains that a person of ordinary skill in the art would not consider a granule to be a spheroid because "granules would be the base units composed of the active ingredient and excipient(s) that make up the extrudate," which is then "broken into smaller lengths and then spheronized." Mylan, Barry Dec., Ex. C, P 31. Thus, he contends that multiple granules may make up a spheroid, but one granule would not be considered a spheroid. Id.

Finally, the Detailed Description of the Invention refers to "beads or spheroids." If, as Wyeth contends, the term "spheroid" should be construed to include "granules, beads, and pellets," this language of the specification would be redundant. Thus, the Court rejects the assertion that the term "spheroid" includes "granules, beads, and pellets."

In sum, the Court finds that the inventors intended to apply the ordinary and customary meaning of the term "spheroid," which is "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round." Because Wyeth has failed to establish that the ordinary and customary meaning of the term encompasses "granules, beads, and pellets," the Court rejects that portion of Wyeth's proposed construction.
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2. "spheroid"

Wyeth contends that "spheroid" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round", including "granules, beads and pellets." (Chart). Teva asserts that "spheroid" means "one or more particles that are generally shaped like a sphere and result from an extrusion and spheronization process." (Id., emphasis added). Essentially, although the parties agree that "spheroid" means "one or more particles that are generally shaped like a sphere," they dispute whether the term should be limited to a particular manufacturing process. Because the intrinsic evidence does not narrow the meaning of "spheroids," which connotes shape, the Court will not limit its construction to a specific manufacturing process.

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The term "spheroid" is contained in asserted claims 13 and 14 of the '120 patent. Wyeth argues that these claims are drawn broadly to include any "spheroid," regardless of the method of manufacture. Claim 13 recites: "The method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid." '120 patent, claim 13 (emphasis added). Claim 14 is similarly broad: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." '120 patent, claim 14 (emphasis added). Thus, the plain language of the claims does not suggest that the term "spheroid" has anything other than its ordinary meaning. Morever, the specification uses the ordinary meaning of "spheroid," equating "beads" with "spheroids" without any apparent limitation on the method of manufacture. See '171 patent, col. 4, lines 12-13 ("Formed as beads or spheroids, the drug containing formulation is coated. . . ."). This ordinary, unrestricted meaning is consistent with how "spheroid" is defined in a dictionary - "a body that is shaped like a sphere but is not perfectly round, esp. an ellipsoid that is generated by revolving an ellipse around one of its axes." Am. Heritage College Dict. 1310 (3d ed. 1993).

Teva does not dispute that Wyeth's construction comports with the ordinary meaning of the word "spheroid." (See Teva's Opp'n Br. at 23). Rather, it contends that in this case the patents do not support the broader definition because they only identify one method of manufacture - the extrusion and spheronization process. For example, in the "Background of the Invention," the patentees described the process they used for making "spheroids:"

In this situation, the extended release capsule dosage forms maybe formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water or a solvent such as ethanol to form an extrudable plastic mass from which small diameter, typically 1 mm, cylinders of drug/matrix are extruded, broken into appropriate lengths and transformed into spheroids using standard spheronization equipment. The spheroids, after drying, may then be film-coated to retard dissolution.

'171 patent, col. 1, lines 38-47 (emphasis added); see also col. 5, lines 1-13 (stating that the addition of microcrystalline cellulose and HPMC made manufacture of spheroids with extenders possible); col. 6, lines 6-11 (stating that different extruders allowed spheroids to be made without HPMC).

Teva overreaches. Although the patents disclose only one method of manufacturing "spheroids" - the extrusion and spheronization process - it appears to be described as a preferred method of manufacture, not the only method of manufacture. See '171 patent, col. 1, lines 38-47 (stating that the extended release formulations "may be formulated by" extrusion and spheronization, not must be formulated by this method). Teva appears to be attempting to import the preferred process into the claims. But there is no clear disclaimer of the term's ordinary meaning, nor do the patentees define "spheroid" as being limited to that method of manufacture. Further, the Federal Circuit has held that merely disclosing only one method of manufacture in the specification does not, by itself, limit the term to that one method. See Vanguard Products Corp. v. Parker Hannifan Corp., 234 F.3d 1370, 1371-72 (Fed. Cir. 2000) (construing the word "integral" to define the relationship between layers in a gasket, and refusing to limit the formation of those layers by co-extrusion, the only manufacturing process disclosed in the specification and extolled in the prosecution history); AFG Indus., Inc. v. Cardinal IG Co., Inc., 375 F.3d 1367, 1373 (Fed. Cir. 2004).

Teva raises one additional argument to support its narrow construction. It alleges that because the patentees neither described nor enabled the making of "spheroids" by any method other than by extrusion and spheronization, the term "spheroid" should be limited to maintain the validity of claims 13 and 14. (Teva's Br. at 28). Teva notes that the named inventors were aware of other methods of making "spheroids," but did not disclose them to the public. Absent that disclosure, Teva contends that the claims are not enabled or described. This argument is flawed. A court should not construe a claim term to preserve a claim's validity unless, "after applying all the available tools of claim construction," the claim term remains ambiguous. Liebel-Flarsheim, 358 F.3d 898 at 911. Here, the term "spheroid" is not ambiguous and, therefore, the Court will not embark on a validity analysis at this time.

In conclusion, the Court finds that "spheroids" should not be limited to a particular method of manufacture. As such, the Court finds that "spheroids" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round."

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1. Spinel

The major claim construction dispute involves the term "spinel." Each of the representative claims is directed to a composition, or the use of a composition, which contains a bimetallic spinel within certain size and valence restrictions. (See, e.g., PTX-3, col. 20, lines 17-25). The specification describes what is meant by the term spinel:

The spinel structure is based on a cubic close-packed array of oxide ions. Typically, the crystallographic unit cell of the spinel structure contains 32 oxygen atoms; one-eighth of the tetrahedral holes (of which there are two per anion) are occupied by a divalent metal ion, and one-half of the octahedral holes (of which there are two per anion) are occupied by trivalent metal ions.

(PTX-3, col. 7, lines 44-50). The specification continues, "This typical spinel structure or a modification thereof is adaptable to many other mixed metal oxides" of various types. (PTX-3, col. 7, lines 51-53) (emphasis added). The specification includes magnesium aluminate spinel as one example, out of more than fifty examples, of a bimetallic spinel. (PTX-3, col. 8, lines 16, 20). The patent specification explains that alkaline earth metal spinels, "in particular magnesium aluminate spinel," are the "preferred metal-containing spinels for use in the present invention." (PTX-3, col. 8, lines 44-46).

The specification notes that the metal-containing spinels useful in the invention "may be derived from conventional and well known sources." (PTX-3, col. 8, lines 62-64). As a result, detailed descriptions of how to synthesize spinel were omitted from the specification. (PTX-3, col. 8, lines 62-64). The patentees did include, however, "a brief description of the preparation of the most preferred spinel, i.e. magnesium aluminate spinel." (PTX-3. cols. 8-9, lines 67-2) Specifically, the patentees refer the reader to U.S. Patents 2,992,191 and 3,791,992, which include descriptions of how to prepare spinel. (PTX-3, col. 9, lines 5-8, 35-37). The patentees also include 25 examples which disclose how to synthesize spinel. (PTX-3, cols. 15-19). The patentees did not, however, refer to any particular method for analyzing a material to determine whether that material contains spinel.

In contrast to the specification, the prosecution history is relatively unenlightening in regard to the definition of spinel. Defendants urge that the patentees relied upon the classic spinel definition included in U.S. Patent No. 4,233,186 to Duprez in order to overcome the prior art and that the scope of the claims should therefore be limited to that classic definition. It is true that the patentees explained to the PTO that certain materials produced in a prior art example were not spinel, relying in part on the definition of spinel in the Duprez patent. The patentees did not argue, however, that the magnesium aluminate disclosed in that prior art patent was not spinel. Rather, the patentees distinguished the magnesium aluminate disclosed in that prior art patent on the basis of surface size. (DTX 39 at 115; JSPH 5 at 35-36, 75). This Court finds that there were no representations made in the prosecution history that would limit the scope of claim terms so as to exclude Grace's proposed interpretation of the term spinel. See Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995).

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5 "JSPH" stands for "Joint Statement of Undisputed Facts Regarding the Prosecution Histories of the Patents in Suit and Their Related Applications."

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The parties agree that in order to determine the existence of spinel in a composition a person of skill in the art at the time the invention was made would perform X-ray diffraction ("XRD") analysis and compare the resulting pattern of peaks to a standard reference card. The parties have stipulated that XRD is the most reliable method for determining whether spinel is present in a sample. (UF-95). An organization called the International Center for Diffraction Data ("ICDD") archives, collects, and distributes a data file of single-phase 6 product X-ray diffraction patterns, also known as reference cards. (Tr. 184-85). The general manager and corporate secretary of the ICDD, Dr. Ronald Jenkins, testified on Grace's behalf at trial. (Tr. 183-85).

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6 A "single-phase" material is one that contains only one component, such as a magnesium aluminate spinel. The accused products contain several different phases, including magnesia, ceria, and a magnesium aluminate material. Each of these components has its own XRD pattern.

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Dr. Jenkins explained that the first step in performing XRD analysis is to determine the elemental content of a sample material in order to focus the search toward reference cards for compounds that contain those elements. (Tr. 332). Then, one would perform an XRD analysis of the sample material to compare with the reference cards kept by the ICDD. (Tr. 184-85). A person skilled in the art would identify the three strongest peaks in the XRD pattern of the tested material and would, most likely, consult the Hannawalt index. (Tr. 222-23). The Hannawalt index is organized so that every permutation of the three strongest peaks from each reference card appears in the index. (Tr. 222). For example, if the three strongest peaks on a reference card were at positions A, B, and C, the material would be listed in the Hannawalt index as ABC, BCA, BAC, CBA, CAB, and ACB. (Tr. 222). The Hannawalt index would refer its user to appropriate reference cards, so that the patterns of the reference card and the XRD analysis of the material could be compared.

Dr. Jenkins testified that the Hannawalt index includes every permutation of the three strongest peaks because "the intensities [of the peaks] are unreliable." (Tr. 1748). Dr. Jenkins explained that "very commonly one finds that the three strongest lines may be in reverse order or some other combination of orders." (Tr. 224). In fact, even with respect to well-ordered, well-crystallized materials deviations in relative intensities of up to 40% are not uncommon. For a magnesium aluminate spinel that has a high surface area, the relative intensities could deviate by 200-300% from the reference card. (Tr. 433-34, 1752). Rather than being based on the most common real world materials, reference cards are intentionally based on material that is remarkably well crystallized, so that the material gives "very good sharp peaks" which enables the ICDD to determine peak positions with greater accuracy. (Tr. 219).

The dispute between the parties is whether, when comparing a composition's XRD pattern with the magnesium aluminate spinel reference card, a person of ordinary skill in the art would require fairly strict conformity with the peak intensities on the reference card before identifying a material as spinel or whether that person would recognize a particular composition as containing spinel within the definition of the patent if there was substantial variation in the peak intensities, even though the peak positions generally matched the reference card. Grace contends that there can be substantial variation in peak intensity while Defendants assert that the peak intensities must largely match the reference card.

As previously mentioned, the '589, '267, '305, and '304 Patents contain a number of examples for synthesizing spinel. Example I of those patents ("Yoo Example I") provides one method for synthesizing magnesium aluminate spinel. The parties agree that the material produced by following the teaching of Yoo Example I is characterized by the patentees as magnesium aluminate spinel, yet that material does not match the applicable reference card in the relative intensities of the key peaks. 7 Defendants contend that the patentees have therefore provided a disclosure that is in internal conflict. Grace, on the other hand, argues that a claim interpretation of spinel which would exclude the material of Yoo Example I would run counter to Federal Circuit precedent holding that a claim interpretation that would exclude from the scope of the claim the preferred embodiment described in the specification "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics, 90 F.3d at 1583.

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7 Grace also argues that materials made in accordance with U.S. Patent Nos. 3,791,992 and 2,992,191 do not match the magnesium aluminate spinel reference card in relative intensities, yet are referred by the patentees as spinel. (D.I. 264 at 11-12). Defendants, on the other hand, contend that the materials made in accordance with these patents are spinels according to their more stringent definition. (D.I. 266 at 4-5 n. 4). Dr. Uhlmann noted that while the relative intensities of the peaks of those materials were not an exact match with the magnesium aluminate spinel reference card, the relative intensities were within 20% deviation. (Tr. 1284, 1287). The magnesium aluminate spinel created by following the teachings of those patents do, therefore, fall within defendants' more narrow definition of spinel.

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This Court agrees with Grace. The patentees explain that "the spinel structure is based on a cubic close-packed array of oxide ions." Then, the patentees describe the typical arrangement of the crystallographic unit cell of the spinel structure. The patentees do allow, however, for "a modification" of this typical arrangement. (PTX-3, col. 2, lines 51-53). The patentees use the term spinel in a fairly broad sense. In reading the specification as a whole, the patentees emphasize using the examples of the patent and the prior art to synthesize spinel. In particular, the patentees explain that the product created by Yoo Example I is a spinel. The claim construction urged by Defendants would exclude that preferred embodiment of the invention from the scope of the claims.

This Court finds as fact that the evidence points clearly toward Grace's interpretation of the term spinel. Each of the parties agrees that a person of ordinary skill in the art would utilize XRD analysis to determine the presence of spinel. This Court finds the testimony of Mr. Jenkins to be credible and extremely helpful in understanding XRD technology and the importance of the relative intensities of the peaks. Dr. Jenkins explained that the measurement of the intensities of the peaks in XRD analysis is "unreliable." (Tr. 1748). Indeed, the entire Hannawalt indexing system is designed with this unreliability in mind. This certainly weighs heavily against finding that a person of ordinary skill in the art would reject a phase identification of magnesium aluminate spinel when all of the major peaks are present but differ somewhat from the reference card in their relative intensities.

Defendants point to a text by Klug and Alexander which states that "there must be agreement within experimental error for all lines of the compound's pattern both as to d spacing and relative intensity." (DTX-727). Grace, however, points to testimony from Dr. Jenkins that the Klug and Alexander test is "way, way outdated" and reflects the state of the art in the early 1950's when there were only 100 powder diffractometers in the entire world. (Tr. 1746-49). 8 Indeed, the above-quoted sentence from Klug and Alexander is directly contradicted by an authoritative text, the Hannawalt search procedure guidelines, which was published only a few years before the invention at issue. (PTX-478). The Hannawalt procedure recognizes that:

> Because of various factors which frequently quite drastically affect intensity values, the experimental sample intensities may not agree with the File standard. But though the analyst does not know which of the three lines is strongest and which is second strongest, he can still rather quickly locate the entry by trying various combinations. . . . In the extreme case with enough tries, one could locate the pattern in a single entry search manual without any data on the intensities of any of the lines of the pattern.

(PTX-478 at iv) (emphasis in original).

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8 Today there are approximately 30,000 diffractometers. (Tr. 1749).

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Other extrinsic evidence points toward Grace's claim interpretation of spinel. In the Bratton article admitted at trial (PTX-481), Dr. Bratton identified material as spinel when the XRD patterns matched in peak position but not in peak intensity. In contrast to Grace's evidence of Yoo Example I and the Bratton article, Defendants have provided no evidence of a circumstance in which a person skilled in the art declined to call magnesium aluminate a spinel when the peak positions matched the reference card but the relative intensities did not. This leads the court to conclude that Defendants' definition of spinel is litigation-inspired and not in accordance with the practice in the art. Even Dr. Wuensch, a defense witness, candidly admitted that the term spinel is used more loosely in practice than is technically precise.

This Court finds that if a person of ordinary skill in the art, in comparing an XRD analysis of his or her material with the reference cards kept by the ICDD, would be led by the Hannawalt index to a reference card for spinel and would determine that such a material is spinel after comparing the XRD patterns, then that material is spinel within the meaning of the patents-in-suit. This Court finds as fact that a person of ordinary skill in the art would not demand strict compliance, or compliance within some arbitrary amount of acceptable deviation, 9 with the relative intensities of the major peaks. This Court does not find that relative intensities are unimportant, however. They are important to an identification of the major peaks, and a greater match with relative intensities would yield greater confidence in a particular phase identification.

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9 Defendants' expert, Dr. Uhlmann, testified that relative intensities must match to within about 20% in order to make an accurate phase identification. (Tr. 1319-1321).

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The term "sprayable" has a common accepted meaning. "Spray," according to Webster's Third New International Dictionary, means "to apply something by atomizing and allowing to strike the surface in a uniform manner." The patentee added the suffix "-able" to indicate that the claimed formulation must be capable of being sprayed. To vary from the common meaning of the term "sprayable," UVC would need to show either that the written description of the '451 patent specified a different meaning, see Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249, 48 U.S.P.Q.2D (BNA) 1117, 1121 (Fed. Cir. 1998), or that artisans of ordinary skill at the time of the invention would have understood the term to have a different meaning, see K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1365, 52 U.S.P.Q.2D (BNA) 1001, 1006 (Fed. Cir. 1999). The '451 patent's written description does not specify a meaning of "sprayable" beyond its common definition. Moreover, nothing in the written description requires "sprayable" to include the concept of homogeneity. The record also shows no common understanding by artisans of ordinary skill that "sprayable" had a definition that varied from its ordinary meaning.

Although UVC claims that "one part" modifies "sprayable" to include a homogenous requirement, the prosecution history of the '451 patent undercuts this argument. During prosecution of the '451 patent, Mr. Sokol, the '451 patent's inventor, distinguished a prior art reference by arguing that the reference taught a two-part rather than a one-part coating. The prior art reference employed a second activating agent added just prior to application. Mr. Sokol's representations to the patent office during prosecution indicate that the "one-part" limitation means that the composition could be mixed long before application, as opposed to a multi-part composition mixed only upon application. Moreover, Mr. Sokol did not argue that "one-part" required homogeneity. The patent specification is devoid of evidence that supports UVC's argument that "one-part" requires homogeneity.
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b. "Stable Nonagglomerating Suspension"

Next, EEI argues that the district court misconstrued the claim term "stable nonagglomerating suspension." After consideration of the court's Findings of Fact and Conclusions of Law and the parties' arguments, the primary contention centers on the the word "stable." 6 Though the court does not give a short concise construction of the term as it did for other terms in its Markman order, we may paraphrase the court's construction from its findings as follows: a suspension is stable under the '937 patent when the density of the polymer closely matches the density of the suspending material and thickening agent. The suspension may separate over time, but when the suspension is injected into the pipeline it is stable.

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6 The parties do not contest the meaning of "nonagglomerating," which requires that the ground polymer particles remain separate individual particles.

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EEI maintains that the court improperly construed the term to mean stable "at the time the DRA is introduced into the pipeline." Appellant's Br. at 42. Alternatively, EEI argues that the proper construction requires a suspension capable of being "shipped over large distances while retaining [its] properties." Id. at 43. EEI's argument stems from a section of the specification stating:

> The suspensions obtained by the described procedures are homogeneous dispersions, stable and nonagglomerating, and

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may be shipped over large distances while retaining these properties.

'937 patent, col.4, ll.46-49. We agree in part with EEI's argument, but we do not find error in the district court's reasoning. Rather, the court's apparent construction can be read congruently with EEI's proposed construction. In other words, a stable suspension at the time of pipeline injection will be stable enough to retain its properties over a long period of time, e.g., a period long enough to ship the product over large distances. As the court's construction implicitly recognizes, there is no limitation in the claim that requires the patented DRA to be transported over large distances or sit for long periods of time before it is introduced to a pipeline.

Claim construction involves the search for the ordinary and customary meaning of a claim term to a person of ordinary skill in the art. Phillips, 415 F.3d 1303 at 1312. This meaning may be informed by the surrounding claim language, the specification, the prosecution history, and extrinsic evidence. Id. at 1314-19. Though not preferred over intrinsic evidence, id. at 1317,

> extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology . . . , to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or prior art has a particular meaning in the pertinent field.

Id. at 1318. In this case, the claim language itself suggests that a person practicing the patent will create a stable suspension from a mixture of the polymer, suspending material, and thickening agent. '937 patent, col.8, ll.8-13. Further, the specification elaborates that "[o]ther things being equal the nearer the density of suspending medium is to the density of the polymer the easier it is to form the stable suspension of the invention." Col.5, ll.12-14. The specification describes an embodiment of the process to include adding thickening agent--thereby increasing density of the suspending medium--"until a stable suspension is obtained." Col. 4, ll. 34-35. These statements suggest that stability is inversely proportional to the density difference between the suspending liquid and the solid polymer particles. In other words, as the difference between the density of the polymer particles and the suspending liquid decreases (i.e., their densities reach the same or similar value), the stability of the suspension increases.

However, the experts agreed that any suspension will eventually separate given enough time. As Conoco's expert witness, Joel Barlow, noted in his direct testimony,

> And as we discussed . . . stable has a time frame associated with it, . . . you can look at a mountain and say it's stable, but it's not stable geologically. So, it's a time frame issue.
>
> And here I think everybody in the business says stable has to mean that the material stays suspended long enough to be useful in delivery and pumping into the pipelines.

Therefore, considering both the intrinsic and extrinsic evidence for the ordinary meaning of "stable nonagglomerating suspension," the district court's construction was not in error. The court's construction requiring that the suspension be stable at the time it is introduced was merely a recognition that the process could be completed at the time of pipeline introduction and did not have to be shipped over long distances. The court's construction of the term "stable" is correct.

Likewise, the court did not err in its application of the facts to that construction. EEI contends that it presented evidence that the accused product was not stable and that the polymer quickly settled out. However, Conoco presented contrary evidence comprising (1) EEI's representations to customers that its product was stable and nonagglomerating, (2) EEI's representations of stability to the PTO, and (3) EEI's concession that the product is stable when injected into the pipeline. Moreover, the district court determined that Conoco's witnesses were more credible than EEI's. See Energy Capital Corp. v. United States, 302 F.3d 1314, 1329 (Fed. Cir. 2002) ("As for the relative weight given to the testimony of both sides' expert witnesses, we accord the trial court broad discretion in determining credibility because the court saw the witnesses and heard their testimony."). Thus, there is sufficient evidence to support the district court's finding.

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1. "Stabilized" (all asserted claims) -- means resistant to decomposition, particularly the opening of the isothiazolone ring. The backdrop, or explanation, is that shelf-life of the stabilized composition is significantly longer than that for an unstabilized composition under the same storage conditions. See Joint Markman Hearing Statement, at 10.

The language of the 827 patent specification, its prior art, and the prosecution history support this construction. The 827 patent specification states:

Unfortunately, solutions of the 3-isothiazolones, especially aqueous solutions or solutions in polar organic solvents such as alcohols, are unstable, leading to reduced biological effectiveness.

* * * *

The instability results from an opening of the isothiazolone ring to form linear compounds which do not have the same biological properties as the ring compounds. To inhibit ring cleavage, nitrate salts . . . can be added to isothiazolone solutions. Thus it is commercially desirable today to formulate many of the 3-isothiazolone biocides in solutions containing water or organic solvent or mixtures thereof together with nitrate stabilizers to prevent decomposition of the 3-isothiazolone (see U.S. Pat. No. 3,870,795).

827 patent, at 1:53 to 2:2. The 827 patent specification also explicitly references prior art -- U.S. Patents Nos. 3,870,795 (795 patent), and 4,067,878 (878 patent) 3 -- which bolster the same construction. See 795 patent, at 1:23-29 ("While such formulation [of 3-isothiazolones in water or polar organic solvents] has no effect on [their] stability or function . . . if used relatively quickly, extended storage of the formulated solutions, especially at elevated temperatures, may result in chemical decomposition of the 3-isothiazolone active ingredient and, thus, lead to reduced biocidal effectiveness of the solution."); 878 patent, at 1:29-36 (same language). 4

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3 The title of the 795 patent is "Stabilization of solutions of 3-isothiazolones employing certain metal nitrates and nitrites." The title of the 878 patent is "Stabilization of solutions of 3-isothiazolones."

4 The 795 and 878 patents describe methods for stabilizing 3-isothiazolone solutions using metal nitrates and nitrites. Both patents include tables illustrating the percentage decomposition of 3-isothiazolone solutions under a variety of active ingredient concentrations and types of nitrate salt stabilizers. See 795 patent, Tables I to X; 878 patent, Tables I to X; see also 795 patent, at 3:33-38 ("The amount of metal nitrate or nitrite needed to stabilize the solution will be partly dependent on the solvent, the isothiazolone and its concentration, the nitrate or nitrite used, the length of time the solution is to be kept, and other related factors"); 878 patent, at 3:39-44 (same language).

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The prosecution of application no. 383,858, the original ancestor of the 827
patent, also confirms this construction of "stabilized." A letter from plaintiff dated September 19, 1983, supplementing the application, explicated:

Shortly after discovering the novel group of 3-isothiazolone compounds, it was discovered that such compounds were not stable upon storage in solutions such as aqueous solutions and alcohol solutions. This problem was obviated when it was discovered that such compounds could be stabilized in solution using metal nitrates and nitrites. (U.S. Pat. 3,870,795).

Applicants now have discovered that the second invention, i.e., the discovery of a means for stabilizing the 3-isothiazolones, while effective and necessary in order to ship and store solutions of 3-isothiazolones, causes a new problem. The new problem resulted from a finding that the nitrate stabilizer, added for the purpose of preventing decomposition of the isothiazolone, reacts with by-products formed in the isothiazolone reaction to produce nitrosamines.

Prosecution History, Serial No. 383,858, Paper No. 5, Sept. 19, 1983 letter of Marc S. Adler, at 1-2 (plaintiff's exh. 7; defendants' exh. 1).

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Defendants' position is that the 827 patent's reference to the 795 patent is vague because the 795 patent tolerates continuing decomposition even after addition of the nitrate salt. See Joint Markman Hearing Statement, at 13-14. Examination of the explicitly referenced 795 patent, however, reveals that plaintiff never intended "stabilized 3-isothiazolone solution" -- as used in the 827 patent -- to mean a solution forever resistant to decomposition. 5 Defendants do not propose an alternative meaning. To the extent that defendants' argument comes down to vagueness, it is inappropriate in a Markman proceeding. "Ambiguity, undue breadth, vagueness, and triviality are matters which go to claim validity for failure to comply with 35 U.S.C. § 112-P 2, not to interpretation or construction." Intervet Am. v. Kee-vet Laboratories, 887 F.2d 1050, 1053 (Fed. Cir. 1989) (emphasis in original).

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5 In his testimony, Dr. Smith described stabilization as a "qualitative term" that "depends, by and large, on the system that one is concerned with, and the conditions under which it is placed." Dr. Smith, tr. at 12, Aug. 7, 1997. A precise durational definition of "stabilized" was, in his opinion, unnecessary to an understanding of what the 827 patent teaches -- i.e., removal of potentially carcinogenic nitrosamines from 3-isothiazolones in solution. See id. at 14, 16.

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Penreco argues for the following construction of the term "stabilizer" in claim 1: "any substance that tends to keep another from changing its physical form or chemical nature." Hanna's seeks to limit this definition to "a chemical preservative, specifically not including any physical stabilizer or gelling agent." Hanna's argues that "stabilizer" should not include a "physical stabilizer or gelling agent" because to do so would conflict with the prosecution history of the '694 Patent.

THE OXFORD ENGLISH DICTIONARY (2d ed. 1989) defines "stabilizer" as "2. [A]n additive which inhibits chemical or physical change in a substance, esp. one used to prevent the breaking of an emulsion." Likewise, HAWLEY' S CONDENSED CHEMICAL DICTIONARY (13th ed. 1997) defines "stabilizer" as "Any substance that tends to keep a compound, mixture, or solution from changing its form or chemical nature!' Hanna's argues that these definitions of the term "stabilizer" are too broad in the context of claim 1 because they include subject matter expressly disclaimed in light of relevant prior art during the prosecution history of the '694 Patent. That prior art, specifically United States Patent No. 5,578,089 (the "Elsamoloty Patent"), teaches a candle made from a gel which contains mineral oils and blends of triblock and diblock copolymers. According to Hanna's, Penreco's attorneys argued during the prosecution of the '694 Patent that the claimed invention "expressly excluded gel candles that used more than one gelling agent" and that the attorneys "expressly disavowed any intent to cover the two gelling agent candle of the [Elsamoloty] Patent." See Document No. 62, at 3; Document No. 87, at 12.

Nothing in the prosecution history, however, makes mention of the terms "gelling agent" or "stabilizer." Instead, the "express disavowal" made by Penreco's attorneys in light of the Elsamoloty Patent during the prosecution history of the '694 Patent involved revision of the independent claim language to exclude the presence of diblock copolymer, so that the claim "directed to candles made from gels formed only from triblock copolymers." Amendment, Document No. 69 ex. 15, at PEN00112. An entry in the file wrapper for the '694 Patent states:

In the Official Action, the Examiner has held that Applicants' claims are broader than the Declaration and that Applicants' claims are open ended and are still potentially readable on the Elsamoloty reference. In response to this objection, Applicants have revised main independent claim 19 to indicate the gel is one "consisting essentially of" the hydrocarbon oil and triblock copolymer. It is believed that this language is sufficient to exclude the presence of a diblock copolymer and places the claim in a form which is not open-ended with respect to the gel from which the candle is made.

Amendment Under 37 C.F.R. § 1.116, id., at PEN 000128-000129. There is no support in the prosecution history for Hanna's contention that by excluding diblock copolymers from the ingredients that make up the gel, Penreco surrendered the inclusion of all substances that perform the function of a diblock copolymer, that is, substances that control the physical characteristics of the gel. The definition of stabilizer, therefore, should not be limited to those substances that inhibit only chemical, as opposed to chemical and physical, change. Based on the foregoing, the Court agrees with Penreco's

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construction of the claim term "stabilizer" to mean "any substance that tends to keep a compound, mixture, or solution from changing its physical form or chemical nature." Nothing in the prosecution history suggests a construction to the contrary.
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B. The Meaning Of The Disputed Term "Stabilizer" And The Disputed Phrase "Which Maintains The Size Distribution Of [Cyclosporin] Particles"

Novartis contends that the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles" should be construed to mean "a substance which inhibits an increase in the size of the solid particles of cyclosporin." (D.I. 298 at 2, 9).

Eon contends that the term "stabilizer" should be construed to mean: a) an excipient which forms a "protective colloid" about solid particles of cyclosporin, i.e., completely surrounds the solid particles of cyclosporin; b) an excipient in which cyclosporin is not soluble; and c) a gelatin. (D.I. 302 at 4). Under this construction, Eon further contends that the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles" should be construed to mean: a) the stabilizer keeps the size distribution of the solid particles constant, i.e., the stabilizer prevents the solid particles of cyclosporin from increasing or decreasing in size; and b) the stabilizer maintains the size distribution of the particles for at least several hours after the hydrosol is formed. (D.I. 302 at 4).

In construing the term "stabilizer" and the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles," the Court has considered the claim language, specification, and prosecution history of the '382 Patent. (See D.I. 303, '382 Patent, at A4, col. 4, lns. 35-40, 49-53, at A6, col. 7, lns. 29-39, at A5, col. 6, lns. 12-17; D.I. 303, at A66, pgs. 2, 4, at A345, PP113, 114). Based upon this review, the Court concludes that there is support for Eon's position. Specifically, the specification provides that:

One difference from the prior art process is that the . . . hydrosol particles are bound-when a water soluble colloid stabilizer is used-to exchangeable colloid molecules . . . .

(D.I. 303 at A5, '382 Patent, col. 6, lns. 12-17). Additionally, the prosecution history indicates:

To avoid coagulation and crystallization, a protective colloid must be present during the formation of the drug compound colloid particles.

(D.I. 303 at A66). In view of this language, the Court is persuaded that a protective colloid must be present in the disclosed stabilizer, and, in order to "avoid coagulation and crystallization," such a colloid must not be soluble in the target "drug compound", i.e., cyclosporin. (See D.I. 303 at A345, PP113, 114). As for whether the term "stabilizer" includes a gelatinous component, the Court concludes that the specification discloses such a vehicle only as a preferred embodiment, and therefore does not require such a form. (See D.I. 303 at A4, '382 Patent, col. 4, lns. 49-53, 65-68).

Turning to the disputed phrase "which maintains the size distribution of [cyclosporin] particles," the '382 Patent specification describes the function of the disclosed stabilizer as follows:

In order to inhibit an increase in the size of the particles of active agent in water, e.g. to prevent an increase in the size of the larger particles at the expense of the smaller particles, a stabilizer is preferably added, which maintains the size distribution of the active hydrosol particles in the dispersion constant.

(D.I. 303 at A4, '382 Patent, col. 4, lns. 35-40) (emphasis added). The Court is persuaded that this language contemplates a stabilizer which, in addition to inhibiting particle growth, also "maintains" and keeps "constant" the size distribution of the hydrosol particles. The Court concludes that a person of ordinary skill in the art would understand that pharmaceutical preparations, including the invention disclosed in the '382 Patent, must remain stable for at least six hours so as to ensure their pharmacological integrity. (See D.I. 303 at A605-606, P6).

For all of the above reasons, the Court construes the term "stabilizer" to mean: a) an excipient which forms a "protective

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colloid" about solid particles of cyclosporin, i.e., completely surrounds the solid particles of cyclosporin; and b) an excipient in which cyclosporin is not soluble. In addition, the Court construes the phrase "a stabilizer which maintains the size distribution of said [cyclosporin] particles" to mean: a) the stabilizer keeps the size distribution of the solid particles constant, i.e., the stabilizer prevents the solid particles of cyclosporin from increasing or decreasing in size; and b) the stabilizer maintains the size distribution of the particles for at least six hours after the hydrosol is formed.
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2. "Stabilizing Amount of a Saline or Buffer Solution"

The parties also dispute the phrase "stabilizing amount of a saline or buffer solution" contained in claim 2 of the '925 patent. Claim 2 states "the therapeutic composition according to Claim 1 wherein the platinum coordination complex is dissolved in a stabilizing effective amount of a saline or buffer solution." See Dudzik Cert. Ex. A ('925 patent col. 6, ln 39-41). Plaintiffs assert that the phrase "stabilizing amount of a saline or buffer solution" means "dissolution in an amount of saline or buffer solution that enhances the stability of the claimed therapeutic composition in solution." See Pls.' Br. at 6. The three defendants contend that it means "that the solution contains sufficient chloride or other ions so as to effect some stabilization of the platinum complex against hydrolysis in aqueous solutions." 7 See Three Defs.'s Br. at 4.

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7 Defendant Pharmachemie adopts the three defendants' interpretation of this disputed phrase.

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A review of the 1995 patent application reveals that the specification states that "test solutions were freshly prepared just prior to use by dissolving the text complex in physiological saline or in the buffered "C" medium . . . it has been found that the presence of salt in such solutions tends to stabilize the complex." See Dudzik Cert. Ex. G at 4. Similarly, the 1995 amendment claims that "the platinum (II) coordination complex is dissolved in a stabilizing effective amount of a salt solution" and "dissolved in a saline or a salt-containing buffer solution." See Dudzik Cert. Ex. L at 1-2 (Claims 87 & 88). In the remarks section of amended application, plaintiffs assert that "when made up into therapeutic compositions, the materials are stabilized by saline, for example, in concentrations suitable for dilution into unit dosage form for the therapeutic application." Id. at 4-5. After the Patent and Trademark Office rejected the 1995 patent application, plaintiffs' resubmitted a new claim which retained the language found in Claim 2 of the "925 patent. Specifically, the claim states that "the therapeutic composition according to Claim 92 wherein the platinum coordination complex is dissolved in a stabilizing effective amount of a saline or buffer solution." See Dudzik Cert. N at 1 (GEN003486). Furthermore, the specification of the '925 maintains that "the test compounds were dissolved in saline or buffer solution as indicated. . . ." See Dudzik Cert. Ex. A ('925 patent col. 3, ln 22-24). Reading the claim, specification, and prosecution history reveals that the platinum complexes are stabilized when dissolved into a saline or buffer solution. Whether this necessarily means that the platinum complex is stabilized against hydrolysis in aqueous solutions cannot be determined from the intrinsic evidence. Thus, the Court must look to the extrinsic evidence of record. In reviewing the extrinsic evidence, the Court will construe the claim as they would be understood by a cancer researcher.

Plaintiffs argue that adopting defendants' claim construction "would limit the claim to a single chemical reaction, i.e. hydrolysis in aqueous solution." See Pls.' Br. at 6. Plaintiffs point out that "these words are not contained in the claim and should not be read into it." Id. Defendants, however, explain that the '925 patent contains merely one reference to the stability of the solutions: "it has been found that the presence of salt in such solutions tends to stabilize the complex." See Three Defs.' Br. at 5. Defendants concede that "at first blush it may appear that their interpretation includes an extraneous limitation that there is some stabilization of the platinum complex against hydrolysis in aqueous solutions." Id. Nevertheless, defendants claim that their interpretation simply describes what a cancer researcher would comprehend from reading "the specification that salt (sodium chloride) in saline and Robert's buffered C medium provided stability by increasing the amount of chloride ions present given teachings in the prior art, such as Perumareddi, et al." Id.

Defendants further claim that stabilization to hydrolysis was a main concern of the inventors Drs. Krigras and Rosenberg. 8 In testifying about the significance of having the platinum complexes in water in contrast to solution, Dr. Krigras testified

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that the chloride ions in saline stabilize the platinum complex to aquation. See id.; see also Deposition testimony of Thomas Krigas at 85 (Three Defs.'s Br. Tab 7) ("Q: What is the significance, if any, sir, with regard to treating tumors of having dichlorodiammineplatinum(II) in water in contrast to solution? A: We believe that it's important to be a saline-type solution or something akin to that, ammonium chloride. Q: And why is that? A: Well, first of all, it's done to make it more physiologically suitable for an organism to inject it that way. And secondly, we feel that it helps maintain the chemical structure. Q: How does that occur? A: How does that occur? It occurs by helping to keep the platinum from substituting other -- other ligands for those [chloride ligands].").

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8 Defendants also proffer Dr. DeSombre's January 23, 1998, deposition testimony as support for their position on the stabilization of the aquation reaction. Plaintiffs, however, object to the use of Dr. DeSombre's deposition testimony because it is not part of the record. To cure this situation, plaintiffs' request that the Court admit the entire deposition of Dr. DeSombre. In reply, defendants withdraw Dr. DeSombre's deposition testimony. Consequently, the Court will deny as moot plaintiffs' request to admit Dr. DeSombre's deposition testimony.

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As to Dr. Rosenberg, defendants point to the March 30, 1970, grant application in which Dr. Rosenberg expressly mentioned the danger of hydrolysis in regard to the stability of platinum complexes. Specifically, Dr. Rosenberg wrote:

The hydrolysis product of Cis-Pt (II) (NH[3])CL[2] is by far the most dangerous contaminant. We have found, by conductrimetric tests, that this compound hydrolyzes in distilled water at 37 [degrees]C with a half life of approximately 7 hours. Presumably, the water replaces the labile chloride ligands to form the aquo complex. . . . The hydrolysis effect is not detectable (using spectrophotometric analysis in the near U.V.) in normal saline after 24 hours at 37 [degrees]C. Thus, the original compound is stable in solutions containing a high concentration of chloride ions.

Three Defs.'s Br. at 6 (Dudzik Cert. Ex. W at 9 (1007608)).

Although defendants' proposed construction does include an apparently extraneous limitation, that is, against hydrolysis in aqueous solution, "a court may rely on prior art offered by one of the parties . . . to demonstrate how a disputed term is used by those skilled in the art." Vitronics, 90 F.3d at 1584. Here, defendants proffer the testimony of Dr. Krigas and Dr. Rosenberg's grant application to demonstrate that a cancer researcher would interpret the statement in the specification "that salt (sodium chloride) in saline and Roberts buffered C medium provided stability by increasing the amount of chloride ions present given the teachings in the prior art." Three Defs.' Br. at 5. Further, Professor Cotton wrote in his expert report that as of 1968 or before "[platinum] complexes that the '925 patent referred to as 'chloroplatinum amines' would undergo a reaction, called 'aquation' or 'hydrolysis,' in which means that the complex when in an aqueous (water) solution would tend to undergo a reversible substitution of a water molecule for the ligand when the complex is exposed to light. . . ." See Dudzik Cert. J (Cotton Expert Report at 10). Hydrolysis of platinum complexes in aqueous solution was studied by J.R. Perumareddi and A.W. Adamson who found that Peyrone's 9 chloride would undergo an aquation reaction described as cis-Pt(NH[3])Cl[2] + H[2]O [reversible reaction] cis-[Pt(NH[3])[2]H[2]OCl]+ +Cl-. 10 See id.; see also Dudzik Cert. Ex. U (J. Phys. Chem. 72(2): 414-40 (February 1968) at 416). It is also clear that Dr. Krigas was aware of the hydrolysis aquation reaction. At the Markman hearing, Dr. Krigras was requested to diagram the chemical equation of claim 2. See Three Defs.' Br. at 5, Tab 5 (Krigras Testimony at 591). In response, Dr. Krigas wrote out the above equation which is the exact chemical equation that Perumareddi, et al described. See id. Thus, although the defendants' construction appears to insert extraneous language into Claim 2, the extrinsic evidence demonstrates that cancer researchers would interpret the phrase "stabilizing effective amount of a saline or buffer solution" as a sufficient amount of chloride ions to guard against hydrolysis in aqueous solutions. This is evidenced by the fact that cancer researchers were aware that combining platinum complexes in water without sufficient chloride ions would destabilize the platinum side of the equation through a hydrolysis reaction. See Cotton Expert Report at 10-11; Krigas deposition at 85. The extrinsic evidence also reveals that the inventors understood that a sufficient amount of saline or buffer solution was required to prevent a known problem, i.e. hydrolysis in aqueous solutions. 11 Consequently, this Court finds that the phrase "stabilizing effective amount of a saline or buffer solution" must be construed as meaning "that-the solution contains sufficient chloride or other ions so as to effect some stabilization of the platinum complex against hydrolysis in aqueous solutions."

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9 A platinum complex also known as cisplatin. See Dudzik Cert. Ex. J (Cotton Expert Report at 7).

10 "In this reaction one molecule of the Peryone's chloride reacts with one water molecule to form one cis-diammineaquochloroplatinum (II) ion and a chloride ion." See Cotton Expert Report at 10. This reaction is a reversible equilibrium meaning that "a change in the concentration of any one species involved in the equilibrium will perturb the concentrations of all species such that equilibrium, in which the relative quantities are changed, is reestablished." See id. At 10-11.

11 It should be noted that the parties have limited their discussion to water based solutions. It is not clear what other solutions but water could be used to inject the test substance into the bloodstream of a mammal given the fact that the bloodstream of a mammal is based upon a water compound. There is no evidence of what other solutions they would rely upon. Thus, the Court has limited the present discussion to water based solutions.

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"Stabilizing the level of serum glucose"

This term appears in Claims 1 and 7 of the '623 Patent. Neither party addresses this term in its briefs. In the Joint Claim Construction Chart, Nutrition 21 asks the Court to construe the term as "to cause a decrease in the relative fluctuations of a human's blood sugar." GNC does not ask the Court to construe this term.

Construction of the term will aid the jury. The specification explains that glucose is blood sugar that is metabolized, that insulin dependent diabetes is a condition characterized by an inability to metabolize glucose normally, and that CP relieves undesirably high levels of glucose. See '623 Patent, cols. 1:46-50, 4:48-53. Therefore, the Court construes "stabilizing the level of serum glucose" to mean "to cause a decrease in the relative fluctuations of a human's blood sugar."
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"Stably"

The district court construed the claim term "stably" in the phrase "stably overexpressed" to require that "the nucleotide sequence encoding human alpha-galactosidase A stays in place once integrated into the chromosome, i.e. the chromosomal change is not transient." During prosecution, the examiner rejected the claims for indefiniteness under § 112(2). In response, the applicant gave the examiner a definition of "stably," namely a "stable level and duration of expression of the human alpha-galactosidase A gene." This definition, as the applicant noted, "denotes persistent expression, as distinguished from the short-term transient expression systems of the prior art."

Indeed the specification discloses several working examples that show the stable expression of the human alpha-galactosidase A gene. The specification particularly points out that the applicant disclosed high levels of alpha-Gal A expression can be achieved with vectors that do not integrate into the host's chromosome. Instead, these vectors achieve stable extra-chromosomal expression via transcription of cDNA in the presence of a selectable marker. See '804 patent at col. 13, ll. 63-67. Thus, the invention as described in the specification achieves stable expression by chromosomal integration and extra-chromosomal gene expression. The applicant surrendered the extra-chromosomal embodiment of stable expression during prosecution.

Thus, the district court correctly discerned that the claims only embrace stable expression of gene sequences integrated into a host's chromosome. However, the specification and prosecution history do not discuss this stability in terms of duration of chromosomal change. Rather, the applicant explicitly described the term "stably" as referring to the level and duration of

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gene expression. Therefore, the district court erred in construing this term, but the error is harmless given the proper construction of the claim term "chromosomally integrated."
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1. "Stainless steel"

The term "stainless steel" is used in claims 1, 7, 13, and 15 of the '668 patent. The parties have offered the following constructions of this term:
THE '668 PATENT

	Claim Term	Rivard's Proposed Definition is required)	Ideal's Alternative Definition (if any definition
a.	Stainless steel (In claims 1, 7, 13, and 15)	A large group of corrosion resistant steels that contain 10% or more of chromium and may contain other elements.	Corrosion resistant steel

a. Arguments of the parties

Rivard contends that "stainless steel" is ambiguous, in part, because "stainless steel" is sometimes specified in the patent as comprising, inter alia, 4-25% by weight of chromium, but Rivard asserts that an alloy containing as little as 4% chromium is not "stainless steel" within the ordinary meaning of the term or within the meaning disclosed by the specification. Rivard points out that the specification states that "[t]he stainless steel alloy can comprise any corrosion-resistant magnetic material with an elemental composition within the range set forth in" certain specified patents. See the '668 patent, Co. 5, ll. 24-28. Rivard asserts that the patents referred to specify that chromium in excess of 8% is required to obtain the corrosion resistance desired, not as little as 4% as elsewhere stated in the claims and specification of the '668 patent, and those patents suggest other conflicts with the percentages of other components expressly stated in the '668 patent. Rivard acknowledges that the patent states that, in case of conflict between the specification and patents incorporated therein by reference, "the present description, including definitions, will control," see the '668 patent, Col. 3, ll. 44-48, but apparently contends that this statement does not dispel the ambiguity. Rivard also notes that one of the patents for "stainless steel" incorporated by reference in the Detailed Description, U .S. Patent No. 4,969,963 to Honkura, is described contrariwise in the prosecution history to the '668 patent as "completely unsuitable for the needle of the method claimed in the ['668 patent]." Joint Exhibit 1002, Joint Appendix at 492. Rivard also points out that the prosecution history reveals that the patentee confirmed that the properties of stainless steel are dependant upon the constituents of the steel. Finally, Rivard cites extrinsic evidence in the form of ordinary and technical dictionary definitions defining "stainless steel" as having at least 10 percent chromium. Consequently, Rivard argues that the ordinary meaning of "stainless steel" is "a large group of corrosion resistant steels that contain 10% or more of chromium and may contain other elements." In the alternative, Rivard argues that the patents sufficiently redefine "stainless steel" to mean alloys limited to the compositions disclosed in the patents. Indeed, in its rebuttal brief, Rivard argues that the use of "stainless steel" in the specifications and claims of the patents-in-suit results in defining five particular formulations of stainless steel. Rivard then contends that only one of those formulations is explicitly claimed in independent claims 1, 7, 13, and 15 of the '668 patent and claims 5 and 12 of the '196 patent, while any of the five formulations could apply to references to "stainless steel" without specification of a chemical composition in claims 1-4, 7-11, and 14 of the '196 patent.

Ideal, on the other hand, contends that the meaning of "stainless steel" is well known to one of ordinary skill in the art. Ideal also asserts that Rivard's attempt to narrow the definition is improper, because it lacks even an iota of support in the intrinsic evidence, and the extrinsic evidence that Rivard cites is irrelevant. More specifically, Ideal argues that both the patentee and the examiner recognized that "stainless steel needles" were well known in the prior art, but that nowhere in the prosecution history was there any reference to or unmistakable limitation of "stainless steel" to an alloy comprised of 10% or more of chromium. Ideal contends that the extrinsic evidence on which Rivard relies is irrelevant, because resort to such evidence cannot overcome the ordinary and customary meaning of the term in the context of the claim term and the embodiments described in the patents-in-suit. In the alternative, Ideal asserts that "corrosion-resistant steel" is an appropriate construction

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of "stainless steel" that is found in, and well-supported by, the intrinsic evidence, stays true to the claim language, and naturally aligns with the description of the invention.
b. Analysis

The appropriate place to begin construction of claim terms is with the words of the claims. Nystrom, 424 F.3d at 1142 (courts must "begin [their] claim construction analysis with the words of the claim"); see also Playtex Prods., Inc., 400 F.3d at 906 ("It is axiomatic that claims, not the specification embodiments, define the scope of protection."). The court notes that the term "stainless steel" is never used in the claims of the '668 patent without specification of its chemical composition. See the '668 patent, Claim 1 ("stainless steel which comprises" certain elements in ranges of percentages by weight); Claim 7 ("stainless steel comprises" certain elements in ranges of percentages by weight); Claim 13 ("stainless steel comprising" certain elements in ranges of percentages by weight); Claim 15 ("stainless steel tubular injection needle, wherein the injection needle . . . comprises" certain elements in ranges of percentages by weight). Consequently, the court concludes that it is unnecessary to construe the term "stainless steel" in isolation.

More specifically, "comprising" is an "open-ended" term, which raises a presumption that the list of elements is nonexclusive. Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1343 (Fed. Cir. 2007). Nevertheless, it "'is not a weasel word with which to abrogate claim limitations.'" Id. (quoting Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1380 (Fed. Cir. 1998)). As the Federal Circuit Court of Appeals has explained,

"Comprising" appears at the beginning of the claim--"comprising the steps of"--and indicates here that an infringing process could practice other steps in addition to the ones mentioned. Those six enumerated steps must, however, all be practiced as recited in the claim for a process to infringe. The presumption raised by the term "comprising" does not reach into each of the six steps to render every word and phrase therein open-ended--especially where, as here, the patentee has narrowly defined the claim term it now seeks to have broadened.

Dippin' Dots, Inc., 476 F.3d at 1343.

Similarly, here, "comprising" is "open-ended" only to the extent that it indicates that the alloy may be comprised of other elements not specified. Cf. id. Indeed, the Detailed Description demonstrates the correctness of such an interpretation, because it specifies, first, that the alloy comprises several elements in specified weight percentage ranges, then adds that preferred embodiments may include additional elements in specified weight percentage ranges. See the '668 patent, Col. 5, ll. 23-44. On the other hand, "comprising" cannot be used as a "weasel word" to abrogate the express claim limitations requiring that the "stainless steel" be comprised of specific elements. Cf. Dippin' Dots, Inc., 476 F.3d at 1343 ("[Comprising] 'is not a weasel word with which to abrogate claim limitations.'") (quoting Spectrum Int'l, Inc., 164 F.3d at 1380). Thus, from the plain language of the claim term, whatever the term "stainless steel" might mean, standing alone, in other contexts, in the context of the '668 patent claims, "stainless steel" necessarily "comprises" specified elements. That being so, the court declines to construe the term "stainless steel" in isolation. Instead, the court will pass on to the question of the proper construction of "stainless steel comprising" specified elements, which is the second term in the '668 patent for which the parties dispute the proper construction.
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C. Starch

Defendants ask the court to construe the term "starch" in step [i] of the claimed method to mean a carbohydrate that is granular in form, consisting of two polysaccharides (amylose and amylopectin), whether in native form or modified in order to improve the properties of starch, but the end products of starch hydrolysis are not "starch." In essence, defendants ask the court to exclude from the meaning of the term end-product starch hydrolysates, including the syrups and sugars resulting from the breaking down of starch granules and the polysaccharides that form those granules--in other words, any products of a hydrolysis process. To put the matter in context, defendants explain that they use a hydrogenated starch hydrolysate (or "HSH") product that is a liquid combination of two simple sugar alcohol products (maltitol and sorbitol). Plaintiffs state that they do not dispute that products such as pure maltitol and sorbitol do not fall within the literal claim language, but that the starch in most commercial syrups (HSHs) is only partially hydrolyzed and therefore those syrups still constitute starch or starch equivalents. Thus, plaintiffs contend that the claim term "starch" must be construed, as it is broadly defined in the

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specification, to include all types of starch.

The court squarely rejects every aspect of defendants' proposed claim construction. Defendants' suggestion that the starch must be granular in form is contradicted by the specification. By way of background, starch occurs naturally as discrete particles, or granules. Food Chemistry 191 (Owen R. Fennema ed., 3d ed. 1996). In attempting to give meaning to the term "starch," the specification states as follows:

[A] variety of starches could be used, such as those taken from the group consisting of corn, wheat, potato, and tapioca starches and mixtures thereof. The starches can be native or modified by gelatinization or chemical treatment (e.g., oxidized, acetylated, carboxymethyl, hydroxyethyl, hydroxy-propyl, high amylose, and alkyl-modified starches).

'152 Patent, col. 2, ll. 66-67 to col. 3, ll. 1-5 (emphasis added). This specification gives meaning to the claim term "starch," broadly including within its breadth not only native starch, but also starches modified by chemical treatment. Additionally, a starch need not consist of two polysaccharides (amylose and amylopectin), as plaintiff's counsel explained that there is at least one starch, a waxy maize corn, that exists in its native state that only has amylopectin, not amylose. Thus, excluding all starches which do not consist of two polysaccharides would exclude at least some native starches.

Defendants' suggestion that all end products of hydrolysis should be excluded from the definition of "starch" is also without merit. Hydrolysis of starch occurs when the granules are depolymerized. Food Chemistry at 199. This generally involves the starch being chemically treated with acid, such as hydrochloric acid or hydrogen chloride gas, or enzymes. Id. at 199-200. Thus, the process of hydrolysis, which involves modifying a starch by chemical treatment, falls within the meaning of the claim term "starch." Consequently, the court rejects defendants' proposed claim definition that the claim term "starch" should be defined to exclude all end products of starch hydrolysis, as this definition is plainly inconsistent with the intrinsic record.

Beyond this, the parties do not provide the court with any further suggestion about how it should construe the claim term "starch." A starch can be completely, or only partially, hydrolyzed. See generally id. Plaintiff concedes that the starch hydrolysates maltitol and sorbitol, in their pure form, do not fall within the literal claim language. See also '152 Patent, col. 3, ll. 16-19 (listing sorbitol and maltitol as among the preferred class of plasticizers). But it is unclear from the record where sorbitol and maltitol fall along the hydrolysis spectrum. They may be starches which have been completely hydrolyzed, and therefore have ceased to be starches. In the absence of more meaningful evidence concerning the impact of hydrolysis and its relation to the various starches listed in the specification, the court will not endeavor to assign a different meaning to this claim term other than the one suggested by defendants, which the court rejects. The parties have presented no evidence from which the court could determine how a person of ordinary skill in the art would understand this claim term to define it more precisely. Thus, the court declines to give further meaning and scope to the claim term "starch," other than as set forth in the specification. Accordingly, the court defines the claim term "starch" to mean starch, whether native or modified by gelatinization or chemical treatment.

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(3) A segment coding for a stable stem and loop structure with a negative [DELTA] G of formation operatively linked down stream of said promoter segment . . . The Court interprets the phrase "stem and loop structure" to mean a single strand of nucleic acid that folds back onto itself and then hybridizes by forming and collapsing. The Court construes the phrase "negative [DELTA] G of formation" to mean that the stem and loop structure requires a negative measurement of [DELTA] G to insure that the stem and loop structure is stable. (Simmons Tr. at 1708-10; D.I. 518 at 193-94). To be "operably linked," the nucleic acid segments must function together as they are attached to create the stem and loop construct. Finally, the Court concludes that this Claim requires that the stem and loop segment must be linked downstream of the transcriptional promoter segment identified in element (2).

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K. Sterilize

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The patent also includes the term "sterilized." Michael Foods interprets the term to mean "clean to reduce the level of microorganisms on a surface or in an environment equivalent to the sanitization and cleaning described in the Egg Pasteurization Manual." (Michael Foods' Initial Markman Br. at 38.) Sunny Fresh interprets the term to mean "subjected to conditions that will eliminate all microorganisms." (Kempf Aff., Ex. 26 at 10.) The term therefore requires construction.

While the claim language and specification do not help explain the term "sterilized," the prosecution history shows that "sterilize" means to make free of all viable microorganisms. In the reissue/reexamination proceedings, the examiner confirmed that definition of "sterilization," stating:

> It would have been obvious to one having ordinary skill in the art at the time of the invention to have pre-sterilized said equipment to make same free of all viable microorganisms and, therefore, avoid contamination via the equipment used to treat said liquid egg such is the basic definition of sterilization, and this is the reason used by Padley et al to pre-treat their equipment in such a way prior to the egg pasteurization process.

(Stewart Decl., Ex. 101 at 61-62 (emphasis added).) Here, the Examiner explicitly defined "sterilization" to mean "to make free of all viable microorganisms." (Id.)

Michael Foods argues that because the Board of Appeals equated sterilized and sanitized the two terms are synonymous. The Board of Appeals stated: "The Egg Pasteurization Manual teaches (pp. 35-39) to sanitize/clean/sterilize the pasteurization apparatus before passing the next run of liquid egg material to the pasteurization apparatus." (Kempf Aff., Ex. 20 at 32.) While the Board may have intended to equate sanitize and sterilize in that opinion, the court cannot rely upon the Board's statement because the relevant portion of the Egg Pasteurization Manual does not equate sterilization and sanitization. In fact, it does not even mention sterilization; it only teaches sanitization.

Michael Foods also relies on 7 C.F.R. § 59.5, which defines sanitization. However, that definition only describes treatments that may be used in cleaning pasteurizing equipment, not the severity of that treatment or the thoroughness of the treatment necessary to achieve "sterility." The regulation never mentions "sterilized," let alone defines the term.

Additionally, even though the court does not rely upon extrinsic evidence because the prosecution history is clear, Vitronics, 90 F.3d at 1582 (stating it is improper for the court to rely on extrinsic evidence when intrinsic evidence is clear); Interactive Gift Exp., Inc. v. Compuserve Inc., 256 F.3d 1323 (Fed. Cir. 2001); Bell & Howell Document Mgmt. Prod. Co. v. Altek Sys., 132 F.3d 701 (Fed. Cir. 1997), the court notes that the extrinsic evidence shows that distinction between "sanitize" and "sterilize" exists within the industry. Michael Foods' packaging supplier Elopak testified that there is "absolutely" a distinction recognized in the packaging industry between "sanitizing" and "sterilizing:"

> Q: (Mr. Schroer) Is there a distinction in the packaging industry between sterilization and sanitation?
>
> A: (Elopak) Absolutely.
>
> MR. VITEK: Objection, foundation.
>
> Q: (By Mr. Schroer) I'm sorry. Your answer was?
>
> A: Absolutely.
>
> Q: And would you explain the difference between sanitizing and sterilizing?
>
> A: From my vantage point, sanitation will minimize contamination on a surface, but not totally eliminate it.

Sterilization, simply stated, is to eliminate contamination. (See Stewart Decl., Ex. 93 at 24, ll. 13-25 (emphasis added.)

Accordingly, the court construes the term "sterilize" to mean to make same free of all viable microorganisms. 17

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17 Relying on the court's construction of "sterilized" and "liquid whole egg," the court construes the term "non-sterile pasteurized liquid whole egg" to mean liquid whole egg that has been pasteurized but not made free of all viable microorganisms.

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K. "Stimulate High Tissue Ingrowth"

Claim 8 of the '418 patent describes "[t]he sheet of claim 1 wherein the second surface is arranged to stimulate high tissue ingrowth." Plaintiffs contend that "stimulate high tissue ingrowth" means to "encourage an increased rate or level of tissue growing inward or into the second surface." Gore contends that "stimulate high tissue ingrowth" is fatally indefinite because it is not amenable to construction.

The specifications of the '418 patent detail that the ridges, channels and troughs exist on the textured surface of the implant in order to encourage the growth of scar tissue into the implant. See U.S. Patent No. 6,921,418, at 6:53-64, 8:53-64. The patent's specifications also disclose that the implant device should be made from materials that have a high degree of ultramicroporosity because such materials promote high levels of tissue growth into the implant. See id. at 8:21-23, 28-30. Therefore, the Court finds that "stimulate high tissue ingrowth" means to "encourage an increased rate or level of tissue growing inward or into the second surface."

Gore argues that the term "high tissue ingrowth" is fatally indefinite because no objective measure exists to provide notice whether the rate of tissue ingrowth is high or low. A claim is indefinite only when a person of ordinary skill in the art could not determine the scope of the claim. See Halliburton Energy Svcs., Inc., v. M-I LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008). To show indefiniteness, an alleged infringer must show by clear and convincing evidence that a skilled person in the field could not determine the scope of the claim based upon background knowledge, the claim language, the specifications and the prosecution history. See Exxon Research Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Gore has not introduced any evidence regarding whether a person of ordinary skill in the field could determine the boundaries of claim 8; rather, Gore's argument for indefiniteness relies upon speculation. Therefore, Gore has not shown by clear and convincing evidence that claim 8 is indefinite because it does not define when the rate of tissue ingrowth is high or low.
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THE CLAIMS

Claim one of the '323 patent claims a:

method of identifying a peptide, polypeptide or protein having a binding property to a ligand, comprising:

(a) providing a ligand for detecting said binding property;

(b) synthesizing a diverse population of stochastically generated polynucleotide sequences;

(c) inserting said diverse population of stochastically generated polynucleotide sequences into a population of expression vectors to form a diverse population of expression vectors containing stochastically generated polynucleotide sequences;

(d) expressing in host cells said diverse population . . . ; and

(e) screening said diverse population of peptides, polypeptides or proteins with said ligand under conditions which allow binding and detection of one or more peptides, polypeptides or proteins having said predetermined property.

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('323 patent, Col. 17, 1. 45-65; emphasis added). Claim 17 of the '483 patent claims:

A method of producing a peptide, polypeptide or protein having a predetermined property, comprising:

(a) producing a population of peptides, polypeptides or proteins encoded by stochastic polynucleotide sequences; 19

(b) screening said population of peptides, polypeptides or proteins for said predetermined property under conditions which allow detection of one or more peptides, polypeptides or proteins having said predetermined property;

(c) isolating the polynucleotide sequence encoding said one or more peptides, polypeptides or proteins having said predetermined property; and

(d) producing said peptide, polypeptide or protein.

('483 patent, Col. 19, 1. 54-67; emphasis added).

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19 Although step(a) does not expressly claim the synthesis of stochastic polynucleotide sequences, the specification elaborates on and defines, as does the prosecution history, the fact that "stochastic polynucleotide sequences" do not encompass the mutagenesis of a known target sequence with the insertion and replacement of a known nucleotide sequence at a particular juncture. Accordingly, neither Morphosys nor its licensees in the United States produce a population of polypeptides encoded by "stochastic polynucleotide sequences," as this phrase is constructed by this court infra.

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Applied also expressly cites to claim 41 of the '323 patent which claims, "An isolated, diverse population of vectors comprising stochastically generated polynucleotide sequences encoding a diverse population of ligand binding peptides, polypeptides, or proteins comprising greater than about 1 x [ten to the fifth] different stochastic amino acid sequences." ('323 patent, Col. 20, 1. 59-63; emphasis added).

All of the independent (and dependent) claims at issue employ the term "stochastically generated polynucleotide sequences" or "stochastic polynucleotide sequences." A number of dependent claims also use the term "at least partially stochastic polynucleotide sequences." 20 ('483 patent, Col. 19, 1. 18-21 & 31-35; '483 patent, Col. 20, 1. 6-10 & 18-22; '514 patent, Col. 20, 1. 10-12; '862 patent, Col. 19, 1. 43-45).

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20 As demonstrated infra, the specification accommodates a construction interpreting this dependent modification of the independent claims containing "stochastically generated polynucleotide sequences" and "stochastic polynucleotide sequences" as claiming a method for creating a fusion protein that is partially stochastic. The specification does not separately define stochastic from partially stochastic. The specification describes to one skilled in the art the linearization of a vector with a stochastically generated sequence to create a fusion protein. The stochastically generated DNA is grafted onto an end of the linearized vector to create the claimed "population of at least partially stochastic polynucleotide sequences." The resulting sequence thus includes a part that is stochastically generated as well as a part that is not stochastically generated. During prosecution, the applicants explained that the latter part can be known or unknown. (Binder I, Ex. 10).

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THE SPECIFICATION

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21 Additional detail is provided in footnote number 14.

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The specification describes two preferred, albeit non-limiting, methods of stochastic synthesis in columns five and six. Both methods bias the mixture of nucleotides to reduce stop codons. ('323 patent, Col. 5, 1. 8 & 31-33; Col. 6, 1. 39-43). While both embodiments also describe the use of enzymes, the specification does not limit the synthesis of stochastic sequences to such methods. Rather, consistent with the chemical synthesis claims, the specification recognizes the use of chemical synthesis although it fails to detail such synthesis. ('323 patent, Col. 8, 1. 35-40).

The first method describes "Stochastic Synthesis Using the Enzyme Terminal Transferase." ('323 patent, Col. 5, 1. 25-27). Under this method, the expression vector is cut and "stochastic copolymerization" proceeds to occur at the two ends when the vector is placed in a solution containing a mixture "of the four kinds of deoxyphosphonucleotides." ('323 patent, Col. 1, 1. 62-65; Col. 5, 1. 16-17 & 28-31). In other words, the nucleotides randomly 22 attach to both ends of the expression vector. In addition, choosing a low concentration of one of the deoxyphosphonucleotides reduces the frequency of stop codons. ('323 patent, Col. 5, 1. 31-33). The process is stopped "[w]hen the reaction attains or passes a mean value of 300 nucleotides." ('323 patent, Col. 5, 1. 40-44). After further polymerization, two stochastic, single stranded DNA sequences are produced with complimentary ends. ('323 patent, Col. 1, 1. 65-67; Col. 2, 1. 1-3; Col. 5, 1. 46-55). The strands of stochastic DNA are then synthesized into double strands. ('323 patent, Col. 2, 1. 2-3; Col. 5, 1. 52-67).

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22 As explained infra, stochastic is a synonym for randomly.

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The second preferred, albeit non-limiting, embodiment details the polymerization of short palindromic oligonucleotides (octamers or heptamers of either seven or eight nucleotides in length). ('323 patent, Col. 2, 1. 4-6; Col. 6, 1. 55; Col. 7, 1. 35-36). The stochastic polymerization of the octamers or heptamers is performed in the double stranded state without cohesive ends to form fragments of stochastic DNA. ('323 patent, Col. 2, 1. 4-8; Col. 6, 1. 55; Col. 7, 1. 35-36). The process is controlled to a limited degree by "judiciously" choosing the oligonucleotides to reduce stop codons while simultaneously assuring a balanced representation of triplets to specify all amino acids and avoid repetitive sequences. 23 ('323 patent, Col. 6, 1. 19-28 & Col. 7, 1. 30-32). The stochastic DNA is then inserted and ligated into a previously linearized expression vector. ('323 patent, Col. 2, 1. 4-8).

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23 See footnote number 14.

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The described modes of performing stochastic synthesis allow for a level of control through biasing the mixtures to reduce stop codons and choosing "the respective concentrations of the nucleotides or oligonucleotides present in the reaction mixture." ('323 patent, Col. 8, 1. 21-24). The mixture, however, is not directed towards a known, target DNA sequence or mutagenesizing a known protein. The oligonucleotides are not removed and replaced in a target DNA sequence. Indeed, in describing the methods of stochastically generating polynucleotide sequences, the specification does not contain an example or explanation of mutagenesizing a known, target DNA sequence. Rather, the resulting "stochastically generated polynucleotide sequences" is inserted into a population of expression vectors. Control over the length of the stochastic sequences is determined by the general conditions in the reaction mixture. ('323 patents, Col. 5, 1. 31-33; Col. 6, 1. 19-27 & 1. 39-43; Col. 8, 1. 21-24).

It is true that the specification notes that the process may produce genes "partially composed of stochastic synthetic polynucleotides." ('323 patent, Col. 1, 1. 46-49; Col. 4, 1. 47-50 & 58-61). These descriptions, however, apply to the invention or the process according to the invention as opposed to the construction or explanation of the term "stochastically

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generated polynucleotide sequences" or "stochastic polynucleotide sequences." They do not import into the claim language a method of replacing and inserting a partially stochastic DNA sequence into a target DNA sequence. 24 Moreover, the aforementioned language recites the "simultaneous [emphasis added] production in the same medium, of genes at least partially composed of stochastic synthetic polynucleotides" ('323 patent, Col. 4, 1. 47-50 & 58-61) as opposed to taking the stochastic sequence and separately inserting it into a target DNA sequence such as a master gene. The prosecution history, detailed infra, supports this construction.

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24 See also footnote number 20.

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The specification recognizes the over-riding aim of the method or process as identifying stochastically generated peptides, polypeptides or proteins with desired properties. Screening and treatment after polymerization of the stochastic nucleotides and oligonucleotides allows for identifying which of the novel proteins will have the desired, predetermined property. Such properties can be structural, enzymatic, pharmacologic or ligand binding. ('323 patent, Col. 1, 1. 1-4 & 27-39; Col. 8, 1. 50-52).

Throughout, the specification depicts the end result as the creation of completely "new" or "novel" proteins and genes. 25 ('323 patent, Col. 1, 1. 30; Col. 9, 1. 9-10 & 62; Col. 10, 1. 38; Col. 11, 1. 14; Col. 12, 1. 3, 23, 50-51 & 63-66; Col. 14, 1. 23; Col. 16, 1. 9). In addition, the specification contrasts the "common techniques" of "point mutations" and "mutagenesis by recombination" with the claimed methods of generating "novel genes." ('323 patent, Col. 8, 1. 11-15; col. 12, 1. 34-37). As described in the specification, the common technique of mutagenesis is done after the creation of the stochastic genes in order to improve the desired catalytic functions. ('323 patent, Col. 16, 1. 12-14).

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25 In contrast, the accused method exhaustively attempts to produce synthetic libraries mimicking human antibody fragments.

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PROSECUTION HISTORY

On November 20, 1986, the applicants filed Patent Application Serial No. 942,630 ("the '630 application"). The application, after being abandoned and after the abandonment of several continuing applications, 26 evolved into the five patents in suit with the first patent (the '323 patent) issuing on March 3, 1998. The 13 year history with the PTO evidences that the applicants repeatedly disclaimed that the claimed methods involving "stochastically generated polynucleotiode sequences" or "stochastic polynucleotide sequences" as well as "partially stochastic sequences" involved target sequences. In particular, the applicants disclaimed mutagenesis of a target DNA or nucleotide sequence such as where the inserted DNA replaces a pre-existing region of a target sequence. Indeed, applicants repeatedly informed the PTO that the stochastic sequences (corresponding to the oligonucleotide synthesis with the trinucleotide mixtures in the HuCAL process, according to Applied) did not encompass a method that uses a target DNA sequence (such as a known master gene) that encodes an intended protein (such as a synthetic antibody fragment mirroring a human antibody fragment).

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26 The related data on the '514 patent describes the '630 application "filed as PCT/CH85/00099 Jun. 17, 1985, abandoned" as opposed to "Nov. 20, 1986, abandoned." (Declaration of Christine Saunders Haskett, No Docket Entry No. Assigned ("Haskett Declaration"), Ex. A-E).

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In May 1996, in response to an office action rejecting then claims 1, 2 and 67 as anticipated under 35 U.S.C. § 102(e) ("section 102") by Sirotkin (U.S. Patent No. 4,959,312) (Haskett Declaration, Ex. W, p. 6), the applicants distinguished the

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claimed methods of producing stochastic polynucleotide sequences as well as partially stochastic polynucleotide sequences from Sirotkin because Sirotkin involved the "mutagenesis of a known target DNA." 27 (Haskett Declaration, Ex. BB, p. 7). In particular, the applicants differentiated the claimed methods from Sirotkin because their claims involved a process comprising the production of "stochastic or partially stochastic polynucleotide sequences." (Haskett Declaration, Ex. BB, p. 8). In so doing, the applicants did not simply discuss and explain the state of the prior art. To the contrary, in their discussion, as elsewhere in other discussions shown below, the applicants explicitly distinguished the prior art because their claims involving stochastic sequences did not use a target sequence or target DNA. Furthermore, the May 1996 argument refers not only to the term "stochastic" but also to the term "partially stochastic" in distinguishing the prior art with the argument that the claimed methods did not employ target sequences or target DNA. Thus, in May 1996, the applicants asserted that:

Sirotkin is directed to the mutagenesis of a known target DNA. The mutagenesis methods described by Sirotkin result in a single randomly-located region in the target DNA with random substitution mutations . . .. Applicants contend that Sirotkin does not teach or suggest the invention as claimed. Applicants claim a process comprising the production of a population of stochastic or partially stochastic polynucleotide sequences . . .. Applicants claimed method does not utilize a template molecule nor does it result in substitution mutations within a single randomly-located region within the target DNA. Therefore, the methods described by Sirotkin do not result in or even suggest the production of stochastic sequences as presently claimed and cannot anticipate the invention.

(Haskett Declaration, Ex. BB, pp. 7-8; emphasis added). The applicants thereby differentiated substitute mutations into a target DNA from their claimed process of generating not only stochastic polynucleotide sequences but also partially stochastic polynucleotide sequences. 28

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27 Sirotkin discloses the use of a template before randomly adding nucleotides to the ends of the primer and synthesizing the random DNA. (Binder III, Ex. 29). An analysis of the file history may include examining the prior art cited therein. Vitronics Corporation v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed.Cir. 1996).

28 In response to an office action, the applicants explained to the examiner, who contended that the term "partially stochastic polynucleotide sequences" was not clear, that "'at least partially stochastic polynucleotide sequences' is intended to include sequences that are random." They further noted that the phrase can also:

include a sequence, part of which is stochastically generated, and part of which is not stochastically generated. The part that is not stochastically generated can be a known or unknown sequence. The phrase can additionally include a sequence that contains a biased amount of any one or all of the four nucleotide triphosphates or other building blocks which comprise the polynucleotide sequence. Thus, the meaning of the term "at least partially stochastic synthetic polynucleotide sequences" would have been clear to one skilled in the art.

(Binder I, Ex. 10).

Applied analogizes the master gene as partially stochastic inasmuch as the randomly generated stochastic cassettes are inserted into the known master gene to create a partially stochastic gene. As argued to the examiner, however, "partially stochastic" did not result in substitution mutations of a target DNA. Inserting the cassettes into the master gene results in mutating, through substituting the cassettes for the dummy sequences, the CDR3 encoding region (albeit not a randomly located region) within the target DNA. Footnote 20 recites additional reasons refuting this argument.

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Similarly, in June 1996, in response to an office action rejecting then claims 75 to 119 as obvious under 35 U.S.C. § 103 ("section 103") in light of Sirotkin (U.S. Patent No. 4,959,312) (Haskett Declaration, Ex. AA, p. 6), the applicants distinguished the claimed methods of producing stochastic molecules from Sirotkin because Sirotkin was "directed to the mutagenesis of a target DNA." (Haskett Declaration, Ex. FF, p. 12). Moreover, the applicants made the distinction by emphasizing that the claimed methods involved stochastic molecules. Accordingly, the applicants were arguing for a construction of the term "stochastic" that disclaimed mutagenesis of a target DNA sequence. They stated the following:

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Applicant [sic] contends that Sirotkin does not teach or suggest the claimed invention. Applicants claim methods of producing and populations of stochastic molecules. Such populations are diverse in sequence and complexity and are produced by, for example, the random copolymerization or chemical coupling of nucleotide monomers. In contrast, Sirotkin is directed to the mutagenesis of a target DNA. The mutagenesis methods described by Sirtokin result in random substitution mutations of a known sequence. Such methods do not result in or suggest the production of stochastic sequences as presently claimed.

(Haskett Declaration, Ex. FF, p. 12; emphasis added). The applicants therefore argued that random substitutions of a known or targeted DNA sequence did not even suggest the claims because the claims involved stochastic sequences.

The applicants proffered a similar argument to the examiner in June 1996 in response to another rejection on the basis of being anticipated by Sirotkin. The argument reads as follows:

None of the cited art or general knowledge contains any specific suggestion to create stochastic sequences independent of "target sequences."

In contrast, Sirotkin is directed to the mutagenesis of a "target" DNA. The methods described by Sirotkin are for mutagenesizing known DNA sequences and result in random substitution mutations or insertions within a known sequence, described as a "target sequence." 29 The methods of Sirotkin generate mutants containing a single, randomly-generated region in the target sequence with random substitution or addition mutations. However, such methods do not result in or suggest the production of stochastic sequences claimed in this invention.

(Haskett Declaration, Ex. CC, pp. 15-16; emphasis added). Again, the applicants distinguish "stochastic sequences" from methods mutagenesizing known target sequences.

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29 The applicants therefore equate "known" with "target."

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In response to a February 1996 office action rejecting a claim as obvious over Joyce in light of Childs and Kalderon, the applicants distinguished Kalderon by the fact that it did not teach "stochastically-generated sequences." (Docket Entry # 179, Ex. C, p. 27). The applicants explained that, "Kalderon relates to inserting defined mutations into a target molecule, specifically, the nuclear localization signal of the large T antigen molecule, i.e., it teaches a 'mixed oligonucleotide mutagenesis' procedure for the introduction of single, precisely defined mutations." (Docket Entry # 179, Ex. C, pp. 27-28). One skilled in the art reading this explanation and the cited 1984 Kalderon article (Docket Entry # 179, Ex. F) would conclude that the synonymous term "stochastically generated polynucleotide sequences" did not involve synthesizing a mixture of oligonucleotides at a few selected positions, a process similar to inserting and mutagenesizing the master gene with the oligonucleotide cassettes.

In response to another rejection of certain claims as unpatentable by virtue of section 103 based on two other patents, the applicants argued that:

Any reference or combination of references which only teach the cloning of known sequences or the modification of known ("target") sequences cannot render the instant invention obvious . . .. None of the cited art or general knowledge contains any specific suggestions to create sequences independent of a [sic] "target sequences."

(Haskett Declaration, Ex. DD, p. 19; emphasis added). Even more to the point, in describing a prior publication authored by Joyce to the examiner challenging the enablement of the invention, the applicants asserted that their "claimed process does not utilize a template molecule or a known target molecule." 30 In so doing, the applicants were discussing their "claim" which they described as "comprising the production of stochastically generated nucleotide populations and libraries of such sequences." (Docket Entry # 179, Ex. C, p. 18; emphasis added). Thus, one skilled in the art reading this excerpt would conclude that the claimed methods did not use a target molecule.

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30 The Joyce article involved mutagenesis of RNA molecules. (Docket Entry # 179, Ex. E).

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In short, the applicants dispelled any doubt that the claims covered inserting DNA (whether random or known) into a known target DNA that replaced a pre-existing region of the target DNA. 31 Indeed, they repeatedly distinguished the claimed methods from the mutagenesis of a target DNA or polynucleotide sequence by the insertion of DNA into an existing region of the target DNA that replaces, substitutes or alters the pre-existing nucleotides in that region. Simply put, the applicants distinguished, repeatedly, their claimed methods from mutating target DNA or target polynucleotide sequences.

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31 Viewing "the totality of the prosecution history," as required, Elkay Manufacturing Company v. Ebco Manufacturing Company, 192 F.3d 973, 979 (Fed.Cir. 1999), the aforementioned disavowments are consistent with the applicants' initial description of prior publications to the PTO in March 1991. In stating their belief that the prior art did not anticipate the invention or make the invention obvious, the applicants described such art as discussing "site-directed mutagenesis of nucleotide sequences producing random mutations." (Haskett Declaration, Ex. R, p. 6). In contrast to the invention, the applicants explained that a 1983 article authored by Matteucci and Heyneker "disclos[ed] a targeted random mutagenesis method employing the ligation of an ambiguously synthesized oligonucleotide duplex into a previously engineered gap in an expression plasmid for bovine growth hormone specifically in the nine base pairs immediately 5' to the initiation codon. The disclosed method allows for saturation of a precise area with point mutations." (Haskett Declaration, Ex. R, p. 7). The applicants also contrasted a 1985 article by Wells as disclosing "a method for insertion of mutagenic oligonucleotide cassettes which allow saturation of a target amino acid codon with multiple mutations." (Haskett Declaration, Ex. R, p. 7).

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The TRIM process and the insertion of cassettes in the master genes in HuCAL thereby mutagenesizing the known master gene, similar to the described disclosures of Sirotkin and the other publications the applicants distinguished, involves replacing the dummy CDR regions in the master genes with the CDR3 trinucleotide cassettes generated from mixed trinucleotides carefully and exhaustively biased at each position towards the human antibody sequences in that region (as opposed to generally biased to avoid stop codons). Even incorrectly concluding that the CDR3 cassettes were randomly generated, as urged by Applied, the accused method involves inserting the cassette into a known, target sequence, i.e., the HuCAL master gene, which is mutagenesized. The insertion into and mutagenesis of the known master gene is not merely another step in the process. Rather, the TRIM process and the creation of the cassettes always has the target of mutagenesizing the master gene by replacing the dummy CDR3 sequences with the oligonucleotide cassettes. The cassettes serve no purpose by themselves and are only built in combination with the master genes to create HuCAL's combinational libraries. (Binder I, Ex. 5, p. 18). Stated otherwise, the cassettes are intermediates and useless by themselves. (Docket Entry # 168, P 24).

Finally, in 1994, an examiner recited the dictionary definition of "stochastic" as "relating to conjecture 32 or involving random variables, probability or chance." (Binder III, Ex. 30). In a February 1996 office action, another examiner gave the dictionary definition of "stochastic" as "involving or containing a random variable." (Docket Entry # 179, Ex. B, p. 10). In response to the office action reciting the latter definition in the context of a section 112 challenge, the applicants acknowledged the examiner's dictionary definition and noted that the specification taught several protocols for producing "randomly generated polynucleotide sequences." (Docket Entry # 179, Ex. C, p. 20). These statements would lead one skilled in the art to surmise that the applicants used "stochastic" to mean containing random variables as opposed to involving the laws of probability.

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32 Indeed, "stochos" is Greek for guess. Gould Medical Dictionary (4th ed. 1979) (defining stochastic process as, "random process, covering practically all the theory of probability from coin tossing to harmonic analysis").

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4. "storage stability"

a. The Parties' Proposed Constructions

The term "storage stability" appears only in claim 9 of the '285 patent. The parties agree that "storage stability" should be defined to require 90% potency for a period of time, but they dispute what that time period is, and whether the solution must remain "physiologically acceptable" during that time period. (D.I. 232 at 32-37; D.I. 234 at 21-22.) Pharmacia asserts that "storage stability" should be defined to mean "retaining physiological acceptability and at least 90% potency for at least 18 months." (D.I. 232 at 32.) In support of that construction, Pharmacia cites the first thirteen experiments described in the patent specification, as well as statements in the prosecution history and expert testimony on the ordinary meaning of that term. (Id. at 32-37.) Sicor, however, asserts that "storage stability" should be construed to mean that "at least 90% of the original amount of anthracycline glycoside dissolved in solution remains in the solution when stored at a temperature of about 4 [degrees] C or 8 [degrees] C for a period of at least 180 days." (D.I. 234 at 23.) Sicor relies on the specification of the patent, and particularly on the fourteenth example, in support of its construction. (Id. at 21-22.)

b. The Court's Construction

The parties first dispute revolves around whether "storage stability" requires 90% potency for 180 days or 18 months. The only direct statement regarding the length of time required for storage stability in the intrinsic evidence comes from the prosecution history. During prosecution of the patent, the applicant stated in a declaration filed by one of the inventors that "the stability at 22 [degrees] C of doxorubicin HCI dissolved at 2 mg per ml diluted hydrochloric acid pH 3.0 is higher than the stability at 22 [degrees] C of doxorubicin HCI dissolved at 2 mg per ml 0.06 M phosphate buffer pH 3.0 and 6.0, and can reach 18 months at a storage temperature between 2 and 8 [degrees] C[.]" (D.I. 232, Ex. 8 at PI 939.) This statement suggests that the applicants expected stability for a period of 18 months when prosecuting the patent.

The examples provided in the specification also support a construction of "storage stability" that requires stability for 18 months. Examples 2-13 show, through extrapolation of data, that when the claimed solution is stored at either 4 [degrees] C or 8 [degrees] C, it is stable for at least 18 months. ('285 patent at cols. 6-21, examples 2-13.) In each of these twelve examples, the percent potency was measured at four, eight or twelve weeks. (Id.) That data was then used to extrapolate at what point in time the potency of each sample would reach 90%, a time point which is referred to in the patent as t[90]. (Id.) In all but one of these examples, n6 t[90] at both 4 [degrees] C and 8 [degrees] C was greater than 18 months. (Id.) Furthermore, even without extrapolating from the actual data, in examples 2, 3, and 8, at twelve weeks (84 days) of storage at 4 [degrees] C, the solutions were 99%, 98.7%, and 98.1% potent, respectively. (Id.) All of this data indicates that "storage stability," as it is used in the patent, requires 90% potency for longer than the 180 days that Sicor suggests, and closer to the 18 months that Pharmacia argues.

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n6 In example 9, t[90] was 505 days, or approximately 16.8 months, at 8 [degrees] C. ('285 patent, col. 16, example 9.)

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Additionally, in Example 14 of the patent, stability of the solution was measured at one, three, and six months when it was stored at 4 [degrees] C and 8 [degrees] C. (Id. at col. 22, table 14.) At 4 [degrees] C, after six months, the solution still contained 98.7% of the initial doxorubicin concentration. (Id.) At 8 [degrees] C, 98.2% remained. (Id.) Because, in both of these instances, far more than 90% of the doxorubicin remained in the solution after six months, or 180 days, both of these figures suggest that the t[90] of the solution is longer than the 180 days that Sicor suggests. Because the available data suggest that t[90] is longer than 180 days, and because the only number that appears anywhere in the intrinsic evidence is 18 months in the prosecution history, I will construe "storage stability" to require 90% potency for at least 18 months.

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The parties also dispute whether the solution must remain "physiologically acceptable." Because claim 9 depends from claim 1, the preamble of claim 9, when rewritten as an independent claim, reads "[a] physiologically acceptable solution of anthracycline glycoside... ." ('285 patent at 23:5-6.) Thus, while the term "storage stability" does not specifically require that the solution remain "physiologically acceptable," the claim itself requires a "physiologically acceptable solution." Therefore, I will not include this particular limitation in the construction of this term, and I will construe the term "storage stability" to mean "retaining at least 90% potency for at least 18 months."
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D. "Strong Staining"

The term "strong staining" appears in several dependent claims. Claim 2 is representative:
The monoclonal antibody of claim 1, wherein the monoclonal antibody exhibits strong staining intensity as determined an immunoassay with three or less of the normal tissues and blood cells selected from the group consisting of pancreas, esophagus, lung, kidney, colon, stomach, brain, tonsil, liver, heart, ovary, skin, breast, platelets, red cells, lymphocytes, monocytes and granulocytes.
'561 Patent, Claim 2.

Genentech's initial claim construction brief proposed that "strong staining" means staining that is more than weak. (Genentech Claim Construction Brief at 33). In light of Magistrate Judge Hollows' findings and recommendations, Genentech now argues that the court should construe "strong staining" to refer to a "clear, definite, readily detectable signal." (Genentech Opp'n to F & R's at 18.) Chiron, on the other hand, construes "strong staining" to mean "a clear and definite, intense readily detectable signal resulting directly or indirectly from an interaction between an antibody and antigen, for example a color change as determined by light microscopy or a change in fluorescence determined by FACS. 'Strong staining' does not encompass staining that is less than strong, such as weak or moderate staining." (Chiron Opp'n to F & R's at 5.)

Staining is used by those skilled in the art to determine how many antibodies are interacting with antigens on a particular tissue or cell. n24 Staining involves tagging antibodies with a stain so that they "signal" their attachment to an antigen on a cell or tissue by staining that cell or tissue. This can be accomplished either directly (by attaching the tag to the antibody of interest) or indirectly (by attaching the tag to another antibody that will bind to the antibody of interest). Stronger staining occurs when many antibodies attach to the surface of a cell or tissue. Given the common understanding of how staining works, the construction proposed by Genentech is incomplete in that it does not convey that the signal results from an interaction between an antibody and an antigen.

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n24 The degree of staining is important in ascertaining the selectivity of a particular monoclonal antibody (i.e. the degree to which the antibody binds to the cancer antigen of interest but not to normal tissues). The more antibodies that attach to normal tissue, and the more normal tissues to which they attach, the less value the antibodies will have for diagnosis and treatment. Thus, the patent claims monoclonal antibodies that exhibit strong staining with only a small percentage of normal tissues and cells. See '561 Patent, Claim 2 (claiming antibodies that exhibit strong staining with no more than three of eighteen specified normal tissues or cells); id. Claim 4 (claiming antibodies that exhibit strong staining with no more than one of eighteen specified normal tissues or cells).

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Genentech's proposed construction also fails to clarify the important question of whether "strong staining" includes moderate staining, an issue which the parties debated at length during the Markman Hearing. The '561 patent specification contains a series of tables that grade staining intensity on a 0-1-2 scale, 0 being "negative," or no staining, 1 being "weak" staining, and 2 being "strong" staining. Genentech has taken the position that the grading system described in the patent indicates that "strong" means "not weak," while Chiron has argued that "strong" means "strong." Because "strong staining"

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is not defined in the specification, and because its meaning is ambiguous from the tables depicted in the '561 patent, it is appropriate to resort to extrinsic evidence. See Vitronics, 90 F.3d at 1583.

Experts for Chiron and Genentech agree that "strong staining" is a term of art that is commonly used and understood by pathologists. (Parslow Reply Decl. P 11; Cote Decl. P 6). However, they disagree as to whether "strong staining" can encompass moderate staining when the 0-1-2 scale described in the '561 patent is employed.

This disagreement arises from the fact that scientists have not used uniform scales for grading staining intensity. Some use the 0-1-2 criteria described in the '561 patent, while others use a four-point scale, with "0" indicating no staining, "1" barely perceptible staining, "2" weak to moderate staining, and "3" strong staining. (See F & R's at 44; Yu Decl. Ex. 6.) At the Markman Hearing, Genentech's expert, Dr. Cote, testified that a grade of strong staining on a three point scale encompassed both the strong staining grade and the moderate staining grade on the four point scale. Chiron's expert, Dr. Parslow, disagreed, testifying that strong staining was the same no matter what scale was used.

Magistrate Judge Hollows found Dr. Parslow's testimony to be more persuasive, and after a review of the record, this court agrees with that finding. The "virtually universal" use of the term "strong staining" among pathologists, (see Parslow Reply Decl. P 11), indicates that those skilled in the art share a common understanding of the term that does not change depending on what scale is used to grade the staining intensity. Dr. Cote's testimony on cross examination supports this observation. As Magistrate Judge Hollows notes:

On cross examination Dr. Cote could not point to one exhibit where "strong staining" was ever defined in other than the last category no matter what scale was used, or one exhibit where moderate staining was included within a "strong" score. His opinion was impeached significantly by Exhibit 125 - the staining done by his own company. In fact, the "moderate" staining found in Exhibit 125 was segregated from the strong staining description. The testimony indicated that for most immunoassay purposes, the categories between negative staining and strong staining ran a rather large area because the most significant categories for staining purposes, negative and strong, were much more precise, objective, and consistent in their definitions.
(F & R's at 45.)

Thus, the court adopts the following construction of the term "strong staining":
The term "strong staining" refers to a clear and definite readily detectable signal resulting directly or indirectly from an interaction between an antibody and antigen, for example a color change as determined by light microscopy or a change in fluorescence determined by FACS. "Strong staining" does not encompass staining that is less than strong, such as weak or moderate staining. n25

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n25 This construction is identical to the one recommended by Magistrate Judge Hollows, except that it adds the sentence "'Strong staining' does not encompass staining that is less than strong, such as weak or moderate staining." These changes simply make explicit that which was implicit in the definition recommended by Magistrate Judge Hollows. Chiron argues that the adjective "intense" should be added so that the first sentence refers to "a clear and definite, intense readily detectable signal." However, adding the adjective "intense" unnecessarily clutters the sentence without conveying much useful additional information.

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Genentech objects that the references to the light microscopy and FACS immunoassay procedures are superfluous. Although these examples are not necessary to define the term, they may assist the jury in understanding the meaning of "strong staining." Therefore, the court sees no reason to exclude them from the definition of "strong staining."
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C. The Claim Construction Of The '893 Patent

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Pfizer asserts Claims 1-4, 8 and 9 of the '893 patent against Ranbaxy's ANDA product. Claim 1 is the only independent claim of the '893 patent and recites a compound of structural formula I drawn as:

[SEE FORMULA IN ORIGINAL]

This compound has a backbone of two rings joined by a bridge, designated as "X." The five-membered ring on the left contains a nitrogen atom designated as "N" and is a "pyrrole" ring. The six-membered ring on the right contains an oxygen atom ("O") and is a "pyran" or "lactone" ring. The left-hand ring has four possible substituents designated R[1] through R[4]. Claim one of the patent designates the possible substituents for each of R[1], R[2], R[3], and R[4]. The patent also designates the particular groups for X.

The parties' only claim construction dispute with respect to the '893 patent is what structural formula I represents. Ranbaxy contends that structural formula I represents only a genus of racemates. Pfizer agrees that claim 1 represents racemates, but contends that it is not limited to racemates. Pfizer contends that claim 1 also represents R-trans enantiomers, S-trans enantiomers and unequal mixtures of R-trans and S-trans enantiomers. The parties agree that structural formula I depicts an enantiomer; however, the parties also agree that this is not the meaning of structural formula I and that the meaning of structural formula I must be determined by reference to the context of the '893 patent.

After considering the claim language, the specification and the prosecution history of the '893 patent, the Court concludes that the '893 patent is not limited to racemates and embraces the two individual trans-form isomers, the R-trans and S-trans, as well as their transform mixtures, including racemates. The Title, Abstract and Background sections of the '893 patent describe the invention as "trans" compounds. The Summary of the Invention then describes "certain trans" compounds and then defines the "broadest aspect of the present invention" as "compounds of structural formula I." DTX-13, col. 2, 1. 2. In the Detailed Description section, the specification goes on to describe the "compounds of the present invention" as a "class of trans . . ." compounds. Id. at col. 3, 1. 36-37. The patent expressly states:
The compounds of structural formula I above possess two asymmetric carbon centers, one at the 4-hydroxy position of the pyran-2-one ring, and the other at the 6-position of the pyran 2-one ring where the alkylpyrrole group is attached. This asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the transform of the compounds of formula I above.

Id. at col. 3, 1. 45-54 (emphasis added). The Court understands this language to contemplate all trans-form compounds, including the individual R-trans isomer. In reaching this conclusion, the Court observes that the terms "racemate" or "racemic mixture" do not appear anywhere in the '893 patent, and there are no words of limitation or chemical symbols used in claim 1 to restrict the meaning of "trans" or "trans-form" to the trans-racemate form. n2

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n2 The expert witnesses of both Pfizer and Ranbaxy agree that the term "trans" refers to two groups on opposite sides of the plane. The term does not denote any specific three dimensional configuration such as only R-trans, only S-trans, or only a 50/50 mixture or racemate. (Clive Tr. 1553:5-1554:9; Roush Tr. 884:7-23). Further, both experts also agree that each of the individual R-trans and S-trans isomers, along with all mixtures of those isomers are in the "trans-form." (Clive Tr. 1572:12-1574:15; Roush Tr. 233:23-234:5, 882:2-883:24).

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In contrast to claim 1, dependent claim 5 of the '893 patent uses the designation "Trans-(+/-)" to designate a racemic mixture. Ranbaxy contends that the use of this terminology should not be dispositive, because the patent identifies racemates in its examples without using the "+/-" designation. However, it is well-established that a claim is not limited by its examples or embodiments, unless the intrinsic evidence suggests an intent to so limit the claim. See e.g. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004); Home Diagnostics, Inc. v. Lifescan, Inc., 381 F.3d 1352, 1357 (Fed. Cir. 2004) ("The applicant's choice to describe only a single embodiment does not mean that the patent clearly and unambiguously disavowed other embodiments."). As discussed by the Court in more detail below, the express language of the patent indicates to intention to limit the claims to the compounds exemplified. Further, that the "+/-" designation was used in the express language of claim 5 and not in the language of the other claims suggests to the Court that the inventor knew how to limit a claim to a racemate, but chose not to so restrict the other claims of the patent. Liebel-Flarsheim, 358

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F.3d at 910 ("The presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.") (citations omitted); Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1119 (Fed. Cir. 2004) (recognizing that "when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms"). In the Court's view, a contrary conclusion would make the "+/-" term in claim 5 surplusage. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed. Cir. 1996)

Ranbaxy contends that "by common convention, a racemate can be represented by depicting one of its constituent enantiomers." (D.I. 292 at 4) (emphasis added). Ranbaxy is correct that a depiction of an enantiomer can sometimes include or specify a racemate, but Ranbaxy has not demonstrated that, to one skilled in the art, such a depiction always or even usually specifies a racemate. Further, the fact that external sources may use an enantiomer to indicate a racemate does not overcome the intrinsic evidence of the '893 patent that the claimed invention is not limited to racemates. Phillips, 415 F.3d at 1319 (recognizing, to the extent extrinsic evidence is used in claim construction, it must be considered in the context of the intrinsic evidence to be reliable).

Ranbaxy also seeks to limit the claimed invention to racemates because the reaction sequences and examples of the '893 patent are racemic. As the Court has concluded, however, the '893 patent is not limited to its examples and provides no indication that it should be so limited. For example, Table 1 of the patent reports results for test procedures used to determine the biological activity of examples of formula 1. However, the patent expressly identifies the Table 1 examples as "representative examples." Similarly, the '893 patent presents four working examples which also produce racemic mixtures; however, the patent states that these four examples "illustrate particular methods for preparing compounds in accordance with this invention. These examples are illustrative and are not to be read as limiting the scope of the invention . . ." DTX-13, col. 10, 11. 33-38 (emphasis added). Because the patent expressly evidences an intention that these examples be illustrative and the law disfavors limiting the patent based on its examples, the Court concludes that the reaction sequences and examples contained in the '893 patent do not limit the claimed invention to a racemic mixture or racemate.

Ranbaxy contends that if the Court accepts Pfizer's construction of the '893 patent, the patent is invalid for lack of written description, because the patent does not disclose any methods for making enantiomers. In Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), the Federal Circuit recognized that "in claims involving chemical materials, generic formula usually indicate with specificity what the generic claims encompass." However, the Federal Circuit also acknowledged in Lilly its holding in Utter v. Hiraga, 845 F.2d 993, 998-999 (Fed. Cir. 1988), that "[a] specification may, within the meaning of § 112 P1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." While the Federal Circuit declined to extend Utter in Lilly to claims involving genetic material, it did not abandon its holding for chemical materials noting that in the case of generic formula, "one skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." Lilly, 119 F.3d at 1568. In this case, the written description of the '893 patent is a generic formula which the patent specification expressly indicates includes all trans-enantiomers. Ranbaxy acknowledges that one skilled in the art would know how to resolve racemates into their constituent enantiomers, and therefore, the Court concludes that the generic formula description contained in the '893 patent is sufficient to satisfy the written description requirement, regardless of whether the specific isomeric compounds are individually described in the patent.

Ranbaxy also contends that Warner-Lambert's representations during the prosecution of foreign counterparts to the '893 patent demonstrate that the '893 patent is limited to racemates. During the prosecution of the foreign counterparts to the '893 patent in Denmark and Europe, Warner-Lambert represented that the term "trans-" referred to "trans(+/-)." However, the Federal Circuit has recognized that "'the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate' for consideration in a claim construction analysis of a United States counterpart." TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C., 375 F.3d 1126, 1136 (Fed. Cir. 2004) (citations omitted). In the circumstances presented here, the Court finds that Warner-Lambert amended the Danish claims to limit them to racemates in response to the legal and procedural requirements specified by Danish law. Specifically, the Danish examiner found that under Danish law the scope of the claims was "too comprehensive." DTX 241 at P0279442. With respect to the European counterpart, Warner-Lambert made no actual amendments to the claims or specifications, but offered the "trans(+/-)" designation in response to the examiner's concerns that the chemical nomenclature used in the patents was insufficiently articulated under European laws. The United States PTO raised no such concerns during the prosecution of the '893 patent, and Ranbaxy has not demonstrated to the Court any

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similarities between the foreign laws and the laws of the United States that would lead the Court to conclude that these changes and/or interpretations were not made in response to the unique aspects of the respective foreign laws under which patentability of the '893 counterparts was sought. Accordingly, the Court is not persuaded that Warner-Lambert's statements during the prosecution of foreign counterparts of the '893 patent are relevant to the Court's construction of the '893 patent issued in the United States.

In a similar vein, Ranbaxy contends that Pfizer is precluded from pursuing its proposed claim construction of the '893 patent based on statements made by Warner-Lambert during the prosecution of the '995 patent. However, the Federal Circuit has repeatedly held that arguments from a later, unrelated patent prosecution cannot be used to interpret and/or limit an earlier, unrelated and already issued patent. n3 Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 868 (Fed. Cir. 2003), cert. granted on other grounds, 543 U.S. 1041, 125 S. Ct. 823, 160 L. Ed. 2d 609 (2005). Ranbaxy proffers a similar argument under the doctrine of judicial estoppel, but the Court is not persuaded that the principles of judicial estoppel are applicable in this context. Ranbaxy has offered no case law applying the doctrine of judicial estoppel in the context of claim construction, and in the court's view, application of judicial estoppel in such a context would essentially undercut the Federal Circuit's clear pronouncements in the Integra line of cases.

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n3 See also Abbott Labs. v. Dey, L.P., 287 F.3d 1097, 1099-1100, 1104-1105 (Fed. Cir. 2002); Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 862 n. 16 (Fed. Cir. 1988)

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In the alternative, even if the Court were to consider the doctrine of judicial estoppel, the Court concludes that Ranbaxy has not demonstrated its applicability. Whether judicial estoppel applies is determined by regional circuit law. In the Third Circuit, the party asserting the doctrine of judicial estoppel must establish that: "(1) the party to be estopped is asserting a position that is irreconcilably inconsistent with one he or she asserted in a prior proceeding; (2) the party changed his or her position in bad faith, i.e. in a culpable manner threatening to the Court's authority or integrity; and (3) the use of judicial estoppel is tailored to address the affront to the Court's authority or integrity." Montrose Med. Group Participating Sav. Plan v. Bulger, 243 F.3d 773, 777-778 (3d Cir. 2001). Ranbaxy contends that Pfizer's position in this case is irreconcilably inconsistent with its position during the prosecution of the '995 patent. Although there may be a degree of tension between the positions taken by Pfizer in each instance, the Court cannot conclude that those positions are irreconcilably inconsistent. The arguments Pfizer made in the '995 prosecution were directed to the issue of whether the '995 patent claims were anticipated in light of the '893 patent, an analysis which is different from the infringement analysis. Further, the Court is not persuaded that Pfizer's positions demonstrate bad faith or that the use of judicial estoppel is necessary to address an affront to the Court's authority or integrity.

In sum, the Court concludes that its construction of the '893 patent is supported by the specification and the express language of the claims. In contrast, Ranbaxy's proffered construction is primarily based on extrinsic evidence, which is irrelevant to claim construction and inconsistent with the intrinsic evidence of the '893 patent. Accordingly, the Court reads structural formula I of the '893 patent to embrace all trans-form isomers, including enantiomeric atorvastatin calcium.
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1. Correct Claim Construction.

Claim construction is a question of law reviewed de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). We determine the ordinary and customary meaning of claim terms as understood by a person of ordinary skill in the art, using the methodology first set forth in Vitronics Corp v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996), and reaffirmed in Phillips v. AWH Corp., 415 F.3d 1303, 1312-19 (Fed. Cir. 2005) (en banc). The subsequent infringement analysis is reviewed "for clear error if performed by the court and for substantial evidence if performed by a jury." Young Dental Mfg. Co. v. Q3 Special Prods., 112 F.3d 1137, 1141 (Fed. Cir. 1997).

The parties agree that under the district court's claim construction, Ranbaxy's ANDA product infringes claim 1. On appeal,

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Ranbaxy argues that the district court erred in construing structural formula I "to embrace all trans-form isomers, including enantiomeric atorvastatin calcium" in lieu of accepting its proffered construction limiting claim 1 to racemates. Pfizer, 405 F. Supp. 2d at 507. Instead, Ranbaxy contends that structural formula I is limited to racemates, because (1) one skilled in the art would represent a racemate by depicting one of its constituent enantiomers; (2) the specification only discloses reaction sequences that produce racemates; (3) during prosecution of foreign counterparts to the '893 patent, the patentee represented that its references to "trans" should be read as "trans-(A+/-);" and (4) during prosecution of the '995 patent, the patentee argued that the '893 patent was limited to mixtures of enantiomers rather than the R-isomer. Thus, Ranbaxy argues, its ANDA product does not infringe claim 1 of the '893 patent because it is the R-enantiomer of atorvastatin calcium. We disagree.

It is undisputed that the drawing in claim 1 depicts an R-trans enantiomer. All four isomers of structural formula I are shown here.

[SEE DRAWING IN ORIGINAL]

These compounds are labeled "R" and "S" based on the stereochemistry of the chiral center at the top (i.e., 4-hydroxy position) of the pyran-2-one ring. The "cis" and "trans" designations refer to the spatial relationship between the hydroxyl group (-OH) and the alkylpyrrole group relative to the plane of the pyran-2-one ring.

The district court correctly observed that the '893 patent consistently describes the invention as a class of "trans" compounds. The specification of the '893 patent explains at col. 3, ll. 45-54:

The compounds of structural formula I above possess two asymmetric carbon centers . . . [which] gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above.

We read this language to mean that the invention would otherwise encompass all four isomers of the compounds of structural formula I, but for the patentee's express disclaimer of the R-cis- and S-cis-isomers. There is no further disavowal of claim scope that would limit the '893 patent to trans-racemates. Indeed, as noted by the district court, the terms "racemate" or "racemic mixture" do not appear in the '893 patent; nor is claim 1, unlike claim 5, limited by a "trans-(A+/-)" designation. In sum, the district court correctly found that no intrinsic evidence limits claim 1 of the '893 patent to trans-racemates, as opposed to an R-trans enantiomer, an S-trans enantiomer or any (equal or unequal) mixtures thereof.

We are not persuaded by Ranbaxy's arguments to the contrary. First, even accepting Ranbaxy's contention that a racemate is commonly represented by depicting one of its constituent enantiomers, it does not follow that the depiction of an R-enantiomer always represents only a racemate. Here, only an R-trans enantiomer is depicted in the '893 patent, yet the specification expressly indicates that there are four possible isomers of the compounds of structural formula I and limits the invention to the trans- form. If one skilled in the art would have understood the drawing of structural formula I to limit the scope of claim 1 to trans-racemates, then an express disclaimer of the cis- form would not have been necessary.

Second, while the examples do describe reaction sequences that produce racemates, restricting claim 1 on this basis would improperly import limitations from the specification into the claims, which should be avoided unless the patentee clearly "intends for the claims and the embodiments in the specification to be strictly coextensive." Phillips, 415 F.3d at 1323. But here, the specification, at col. 10, ll. 36-38, states that "[t]hese examples are illustrative and are not to be read as limiting the scope of the invention as it is defined by the appended claims."

Third, we agree with the district court's conclusion that the statements made during prosecution of foreign counterparts to the '893 patent are irrelevant to claim construction because they were made in response to patentability requirements unique to Danish and European law. See TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am. LLC, 375 F.3d 1126, 1136 (Fed. Cir. 2004). Likewise, statements made during prosecution of the later, unrelated '995 patent cannot be used to interpret claims of the '893 patent. See Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1167-68 (Fed. Cir. 2004) (finding statements in another patent or its prosecution history irrelevant to claim construction "[a]bsent a formal relationship or incorporation during prosecution" of the patent at issue); cf. Abbott Labs. v. Dey L.P., 287 F.3d 1097, 1104-05 (Fed. Cir. 2002) (finding arguments made during prosecution of a commonly-owned but unrelated patent did not create prosecution history estoppel). Finally, insofar as Ranbaxy restates the same argument under the guise of judicial estoppel, we are not persuaded.

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Because claim 1 was correctly construed to include the enantiomeric trans-forms of the compounds of structural formula I, we affirm the finding of infringement.
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1. Ordinary Meaning of the Term Subcoating

Part (b) of claim 1 of the '505 patent requires "an inert subcoating which is soluble or rapidly disintegrating in water disposed on said core region, said subcoating comprising one or more layers of materials selected from among tablet excipients and polymeric film-forming compounds." (P1, col. 16:48-52; see also P2A, col. 13:10-15.) Part (b) of claim 1 of the '230 patent does not contain any material differences. (See P2A, col. 13:10-15.) The meaning of the term "subcoating" is apparent simply from a reading of the claims and the ordinary meaning of the terms contained therein. The subcoating is a layer of material that "coats" and is "disposed on" the core region; therefore, it must be physically on or in contact with that core region. The plain meaning of the noun "coating" requires a "material that will form a continuous film over a surface." McGraw-Hill Dictionary of Scientific and Technical Terms, 5th ed. at 394 (1994). See Interactive Gift Express Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 n.1 (Fed. Cir. 2001) ("Dictionaries, which are a form of extrinsic evidence, hold a special place and may sometimes be considered along with the intrinsic evidence" when determining the ordinary meaning of claim terms.); Vitronics, 90 F.3d at 1584 n.6. A "coating," like a film, must conform to the contours of the thing it "coats." The subcoating is also "sub," under or beneath, the enteric coating layer. In the context of the claims of the '505 and '230 patents, the court finds that the "subcoating" claim limitation requires a coating or covering that is physically on, or in contact with, and conforms to the contours of the core region. 27 The patent specifications support the court's finding that the patentees employed the ordinary meaning of the term "subcoating." The '505 patent describes "subcoated pellets" where the subcoating "was sprayed on the uncoated pellets." (P1, col. 8:6-15.) An additional four examples of subcoated pellets use this same technique. (P1, col. 8:55-62, col. 9:25-32, col. 10:8-10, col. 11:17-27.) Another subcoated core using a drying coating technique is described as well. (P1, col. 11:68 - col. 12:22; see also P2A, col. 12:1-22.) In each of these coatings, the subcoating is physically on, in contact with, and conforms to the contours of the core region. In conclusion, a subcoating is a layer that is physically on and conforms to the contours of a core and is underneath another layer--the enteric coating.

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27 Even Defendant Genpharm agrees that the term "disposed on" requires "the subcoating to be physically on the core." (Genpharm's Mem. On Cl. Constr. of the '230 and '505 Patents at 17.)

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Defendants misconstrue the term subcoating by (1) attempting to broaden the claims by ignoring the prosecution history in which the applicant and the examiner acknowledged that the claimed subcoatings do not include a capsule separating layer, (2) ignoring basic grammar rules to require more than one material in the subcoating, (3) attempting to narrow the claims by reading process limitations and the preferred embodiment from the specification into the claims, and (4) requiring a super-coat with no imperfections--a standard that no formulation meets in the real world.

2. Gelatine Capsules Are Not Subcoatings

Defining the term "subcoating" to encompass gelatine capsules, Genpharm focuses on the word "subcoating" and finds it synonymous with the term "separating layer" while ignoring the requirement of the claims that the subcoating be "disposed on the core region." Genpharm adopts this construction largely to create a definition for the claim term so broad that it encompasses certain aspects in the prior art that Genpharm then argues invalidate the patents. Turning first to the intrinsic evidence relative to Genpharm's argument, the claims in question all use the language "subcoat;" they do not mention the term "separating layer," which appears only in the specification. Genpharm is correct, however, that both subcoatings and gelatine capsules are types of separating layers; the patent specification itself makes that clear. When read in context, the specifications disclose that a subcoating is a type of separating layer. For that reason, when describing subcoating techniques in column 4 of the '505 patent, the specification acknowledges "the subcoating layer, in the following defined as the separating layer." The specification then goes on to describe other separating layers such as gelatine capsules, (P1, col.

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4:57-58); however, the specification nowhere suggests that every separating layer is a subcoat. Thus, the specifications of the '505 and '230 patents describe two types of separating layers--subcoatings and capsules. (P1, col. 4:3-58; P2A, col. 8:66 - col. 9:52.) Genpharm's assertion that the '505 and '230 patents expressly teach that hard gelatine capsules are subcoatings is simply erroneous. The portions of the patents to which Genpharm refers do not use the word "subcoating." (See P1, col. 3:66-68, 4:57-58; P2A, col. 8:62-65, col. 9:51-52.) The first part in each patent states only that the powder mixture can be formulated into hard gelatine or soft gelatine capsules. The second reference in both patents says the gelatine capsule can serve as a "separating layer." Thus, according to the specification, both subcoatings and gelatine capsules are different species of the generic term "separating layer."

The fact that the specification expressly states that a gelatine capsule also can serve as a "separating layer," (P1, col. 4:57-58), does not mean a gelatine capsule is a subcoating. In fact, gelatine capsules are not subcoatings. This is understood from the plain meaning of the term "capsule," which is defined as "a soluble shell in which drugs are enclosed for oral administration," McGraw-Hill Dictionary of Scientific and Technical Terms, 5th ed. at 308 (1994), "a small gelatineous case containing medicine," New Webster's Dictionary and Thesaurus at 66 (1992), and "a shell usu. of gelatine for packaging something (as a drug or vitamins); also: usu. medicinal or nutritional preparation for oral use consisting of the shell and its contents," Merriam Webster's Collegiate Dictionary, 10th ed. at 170 (1993). As is apparent, the appropriate definitions for gelatine capsules are clearly incompatible with the requirements of a subcoating when that term is understood based upon its ordinary meaning as it appears in the claims of the '505 and '230 patents.

The prosecution history makes it unequivocally clear that gelatine capsules are not subcoatings. After the patent examiner had already granted the claims, Astra petitioned USPTO to consider a reference by authors Pilbrant and Cederberg. That reference mentions enteric-coated capsules containing omeprazole: "The dosage form - a tablet, a capsule, or granules - is coated with a polymer, which is insoluble in acid media but soluble in neutral to alkaline media [i.e., an enteric coating]." (P84, Pilbrant & Cederberg at 115, left column (emphasis added).) In distinguishing the '505 patent application over Pilbrant & Cederberg, Astra argued that the reference "does not, however, disclose preparations having a subcoating layer, such as in the claimed invention." (P7A at 2-3, '505 File History, Petition for Consideration of Prior Art After Payment of Issue Fee of 9/16/88 (App. 1, '505 Pros. History at 279-80); P8A at 5-6, '230 File History, Amendment of 12/19/88.) The USPTO granted Astra's petition and the '505 patent was issued over the Pilbrant and Cederberg reference. ('505 Pros. History at 282.) Astra's statement in the prosecution history that the enteric-coated gelatine capsule in the Pilbrant and Cederberg reference was not the subcoat of the claimed invention and the USPTO's subsequent allowance of the application excludes the possibility that gelatine capsules are "subcoatings" as required by the '505 patent claims. Goldtouch Techns. Inc. v. Microsoft Corp., 2000 U.S. Dist. LEXIS 3370, No. A99CA336ss, 2000 WL 85555, at *3 (W.D. Tex. Jan 14, 2000) (excluding possibility during claim construction that claims covered matters disclaimed during prosecution history). Simply put, a gelatine capsule is not a "subcoating" within the meaning of the claimed invention of either the '505 or the '230 patent.

In support of its argument that gelatine capsules are subcoatings as that term is understood in the claims of the '505 and '230 patents, Genpharm relies heavily on statements made by Astra when it filed patent applications corresponding to the '505 and '230 patents in various foreign jurisdictions. Genpharm improperly seeks to rely on these foreign proceedings, since Genpharm has not even tried to lay a foundation for its argument that foreign prosecutions should be considered on an issue of United States law--namely, claim construction. See Heidelberger Druckmaschinen AG v Hantscho Commercial Prods. Inc., 21 F.3d 1068, 1072 n.2 (Fed. Cir. 1994); Medtronic, Inc. v. Daig Corp., 789 F.2d 903, 907-08 (Fed. Cir. 1986). The cases cited by Genpharm for the proposition that certain statements made by a patentee in connection with counterpart foreign applications may be relevant to claim construction of a United States patent, Tanabe Seiyaku Co. v. United States ITC, 109 F.3d 726, 733 (Fed. Cir. 1997); Caterpillar Tractor Co. v. Berco, SpA, 714 F.2d 1110, 1116 (Fed. Cir. 1983), both relate to analysis under the doctrine of equivalents, a question of fact. See Insta-Foam Prods., Inc. v. Universal Foam Sys., Inc., 906 F.2d 698, 702 (Fed. Cir. 1990). Even assuming the alleged foreign "admissions" are admissible, however, they fail to support Genpharm's position.

During the prosecution of Astra's European omeprazole formulation patent application that corresponds to the '505 and '230 patents on July 27, 1990, the European Patent Office ("EPO") rejected Astra's application for lack of novelty, citing EP-A-124 495 (the "'495 patent"). (11/5/01 Hovden Decl., Ex. 7.) The '495 patent discloses a formulation that contains an alkaline omeprazole salt in a hard gelatine capsule that is enteric coated. (11/5/01 Hovden Decl., Ex. 8.) The examiner stated that the '495 patent referred to omeprazole salts in cores that were filled in hard or soft gelatin capsules allegedly functioning as a subcoat or separating layer. The following appeared at page 7 of the European application, lines 11-12: "In case of gelatin capsules the gelatin capsule itself serves as separating layer." (11/5/01 Hovden Decl., Ex. 9.) To overcome the examiner's

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lack of novelty rejection based on the gelatine capsule formulation disclosed in the '495 patent, Astra made the following amendments to its application on November 23, 1990:

D1 [the '495 salts patent] is the Applicant's own patent. According to D1 it is either enteric coated granules or a powder that are filled into the hard gelatine capsules or a solution that is filled into the soft capsules. The wording on page 7, lines 11 and 12 in our specification, which the Examiner has pointed out and also the lines 31-34 on page 5 of our specification has been amended on the attached copies of said pages in order to define the invention without difficulty and clearly restrict us from D1.

(11/5/01 Hovden Decl., Ex. 10, at 2.) In a follow-up communication from Astra to the European Patent Office three days later, Astra directly addressed the issue of whether a separating layer-capsule falls within the meaning of the term subcoating in the patent claims:

We refer to our letter of November 23, 1990 and would like to further define the difference between citation D1 [the '495 salts patent] and this application. Please be informed that the enteric coated granules in D1 have no subcoating. As this was obvoius [sic] to us we forgot to stress this important difference. As a consequence we are enclosing a further amended page 4, where this is clarified and we kindly ask the Examiner to perform this amendment in the file copies.

(Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 64, Margareta Linderoth's 11/26/90 Letter to EPO.) The amendment provided the following changes to the European Specification, handwritten in at the bottom of page 4 of Exhibit 64: "E-P-A-124 495 describes enteric coated granules without subcoating or powder that are filled into hard gelatine capsules or a solution that is filled into soft capsules. (Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 64, Margareta Linderoth's 11/26/90 Letter to EPO, at 3; Ex. 66, EP 247 983 B1, at 4:19-20.) About a year later on October 11, 1991, Astra again communicated with the EPO in correspondence that states, "further there is no subcoating according to D1 [the '495 patent]. Thus the claimed invention is novel over D1. The examiner also recognized inventiveness of the invention at the interview, but wanted to have a written explanation of the citations." (Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 65.) Again, Astra informed the EPO that the '495 patent did not disclose a subcoat, and this communication pointed out that the examiner agreed, as shown by the fact that the examiner recognized inventiveness at the interview. (Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 67.) These facts, which Genpharm admitted in its claim construction briefing, show that all separating layers are not subcoatings and that the hard and soft gelatine capsules in the reference at issue were not subcoatings. Thus, Astra's European prosecution is consistent with the ordinary meaning of the claim term "subcoating" and the plain language of the '505 and '230 patents.

Genpharm also refers to foreign patent proceedings in the Republic of South Africa during Astra's prosecution of an omeprazole formulation patent that corresponds to the '505 and '230 formulation patents. Genpharm relies upon the following language from an amendment discussing the '495 patent:

EP-A-0 173 664 (A B Hassle) and EP-A-0 124 495 (A B Hassle) are citable as prior art. The Applicant believes that these patent specifications do not destroy the novelty of claim 1 of the patent because gelatine capsules where the capsule serves as a subcoating, fall outside the scope of claim 1 when properly construed. In order to avoid a possible adverse finding based on these prior art documents, the Applicant seeks to delete reference to gelatine capsules at the passages cited, thereby ensuring that the patent specification is clear in this regard and is not vulnerable to an attack based on this prior art.

(11/5/01 Hovden Decl., Ex. 11, at 3.) Even the portion quoted by Genpharm acknowledges that gelatine capsules fall outside the scope of claims 1 of the '505 and '230 patents when properly construed. (See 11/5/01 Hovden Decl. Ex. 11, at 3.) Once again, a document from the South African file expressly refutes Genpharm's assertion that the claimed subcoating covered gelatine capsules. (Astra's Resp. to Defs.' Cl. Constr. Briefs Ex. 36, Application to Amend South Africa Specification, filed 9/17/97, at 7.)

Additional extrinsic evidence also supports Astra's construction. Dr. Langer testified that a subcoating was a substantially continuous film, distinguishing between subcoatings on one hand and separating layers or gelatine capsules on the other. (Langer Tr. 419:1-4, 421:8-16, 442:16-18, 5026:4-5027:9, 5029:3-16.) While a subcoating and gelatine capsules both separate, the subcoating conforms to and is in contact with the core. (Langer Tr. 5026:1-5027:3.) The inventors also distinguished between subcoatings and separating layers or gelatine capsules. (Pilbrant Tr. 1631:20-24, 1718:5-23, 1719:1-11; Lovgren Tr. 4520:14-24.) Prior to trial, others of at least ordinary skill, including Genpharm's expert Dr. Story and Cheminor's expert Dr. Porter, construed the term "subcoating" so that it did not include gelatine capsules and acknowledged

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that the subcoatings of claims 1 were missing from the prior art describing such gelatine capsule separating layers. (See Story Tr. 4798:9-4799:11, 4799:21-4801:8.) Dr. Porter stated categorically that the '974 patent, 28 which refers to enteric-coated gelatine capsules, is missing the subcoating. (Astra's Cl. Constr. Resp. of 11/12/01, Ex. 34, Porter Dep. Tr. 86:7-87:10.) In other words, Dr. Porter recognized that the gelatine capsules are not subcoatings as they are claimed in the '505 and '230 patents. Dr. Goldberg, Andrx's expert, expressly noted the difference between coatings and capsules in a sworn affidavit:

The process of making capsules is substantially different than the process of microencapsulation. The process of microencapsulation involves coating the individual particles of the material, while the manufacture of capsules involves placing multiple particles into a pre-existing shell capsule. Capsules can also contain drugs that have been microencapsulated.

(Astra's Resp. to Defs.' Cl. Constr. Briefs, Ex. 61, Decl. of Dr. Arthur H. Goldberg dated 2/26/98, at 6.)

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28 The '974 patent, G345, is the U.S. patent corresponding to the '495 patent, EP 124,495.

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To sum up, based upon the ordinary meaning of the terms "subcoating" and "capsule," the patent specifications and file histories, the foreign proceedings raised by Genpharm, and other extrinsic evidence, the court finds that the phrase "subcoating . . . disposed on said core region" that appears in claims 1 of the '505 and '230 patents does not include gelatine capsules.
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The district court correctly construed "subcoating" as "a layer that is physically on and conforms to the contours of a core and is underneath another layer -- the enteric coating . . . [wherein] . . . subcoatings and gelatin capsules are different species of the generic term 'separating layer.'" By choosing the term "coating," the applicant identified a covering that conforms to the shape of the underlying core. The specifications use the term "separating layer" in connection with the claim term "subcoating." This description of the function of subcoating, however, does not expand the term to embrace any layer that separates the core from the surrounding environment. "Separating layer" refers only to the function of the form-fitting cover, with little information about the structure that supplies the separation. The patents do not otherwise define "separating layer" and "subcoating" or even "coating." Finally, the district court gave due weight to the fact that during prosecution of the '505 patent before the United States Patent and Trademark Office (PTO), Astra distinguished a reference that disclosed a gelatin capsule between a core and an enteric coating. Astra, 222 F. Supp. 2d at 465-66.
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Thus, the sole issue raised on appeal is whether the district court properly construed the claim terms "subject" and "patient" as referring only to individuals with a negative nitrogen balance. For the reasons stated below, we agree with Appellants that the district court erred in its claim construction and improperly limited the claims of the '979 patent.

We begin our analysis with the claim language itself. First, the claim uses the terms "subject" and "patient" generically and apparently interchangeably. There are no qualifications of those terms, aside from being human subjects. Importantly, there is no mention of sick or elderly individuals in the claim language. Next, the language provides that a "substantial decrease[]" in a subject's urinary nitrogen level is key to the claimed method. The claim does not use the phrase "normalizing nitrogen balance" or otherwise refer to returning individuals in a negative nitrogen balance to a normal state. Instead, the plain meaning of the claim language indicates simply that a change in urinary nitrogen level--from some initial level to a "substantially decreased" level--is necessary. That relative change in nitrogen levels is all the claim language requires, contrary to the district court's construction that instead limits the claim to the treatment of individuals in a negative

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nitrogen balance. Finally, the claim's terminal phrase, "continuing the said administration of HMB until the amount of nitrogen in the patient's urine has substantially decreased," does not mean that the claim covers only a person with negative nitrogen balance. That is so because HMB will decrease the level of nitrogen in the urine of a healthy person as well as in the urine of a sick person, as the study noted below indicates.

We continue our analysis by examining the specification. First, the only experimental example in the specification is a controlled double-blind human study, subjects for which were described as having "been screened for normalcy [and] were well-nourished, healthy adults." '979 patent, col. 5, ll. 25-27. Those normal human subjects were studied for changes in urinary nitrogen levels after the administration of HMB and placebo. Strikingly, in describing the results of the experiment, the specification concludes: "HMB appears to be a potent agent for promoting nitrogen retention even in normal subjects." Id., col. 6, ll. 3-5 (emphasis added). Normal, healthy humans are clearly the subject of the sole experiment detailed in the specification.

Secondly, other passages in the specification describe the treatment of normal, healthy subjects. For example, the "Summary of the Invention" begins: "This invention is based on the discovery that nitrogen retention in humans can be dramatically improved by the administration of [HMB]." Id., col. 2, ll. 61-64. The same paragraph later provides that "[a] substance that can increase nitrogen retention in humans who are not experiencing a negative nitrogen balance has manifest therapeutic potential." Id., col. 3, ll. 9-12. Those passages do not describe a limited "target population" for the claimed method consisting solely of individuals with a negative nitrogen balance, nor do they distinguish one group of subjects from another. Indeed, on balance, the claims, when read in light of the specification, are fairly read as encompassing the treatment of healthy subjects with a normal nitrogen level.

Finally, we turn to the prosecution history. The district court focused on an Examiner's Action dated June 16, 1993, in which the examiner rejected the inventors' claims as being obvious in view of United States Patents 4,677,121 ("Walser") and 5,087,472 ("Nissen"). In the action letter, the examiner stated:
To the skilled artisan motivated by a reasonable expectation of success, it would have been obvious to employ HMB in patients in a state of excess muscle protein degradation because as highlighted by Nissen, HMB has been found to be more effective for improving growth metabolism of domestic mammals than KIC and the major effect of HMB is to increase markedly the development of lean tissue. ...The skilled artisan would have immediately appreciated that HMB improves nitrogen balance because muscle development in mammals, i.e., anabolism, necessarily requires a positive nitrogen balance.

(Emphases added.) From that excerpt, the district court determined that the examiner considered the claims to cover the treatment of patients afflicted with muscle protein degradation, not healthy subjects. It also found that the phrase "improves nitrogen balance" implies that the claims cover normalizing nitrogen levels in the body from a prior imbalanced state. Claim Construction Order, 291 F. Supp. 2d 883 at 891.

Appellants assert that the examiner's statements do not state or infer that the claims are limited to the treatment of individuals with a negative nitrogen balance because the rejection addressed only obviousness. They contend that the examiner's rejection and the inventors' response should be considered in context and should not be interpreted as limiting the claim scope. On the other hand, Wiley argues that the examiner plainly compared the scope of Walser and Nissen to the proposed claims and concluded that the same basic subject matter--treatment of protein degradation in the human body--was at issue. Because the inventors did not clarify the examiner's understanding of the claim terms, Wiley argues, that acquiescence shows that they also believed that their claims covered only individuals with a nitrogen imbalance, not healthy subjects.

We agree with Appellants that the examiner's statements and the inventors' subsequent response do not present a sufficiently clear definition of the claim terms "subject" and "patient" to merit limiting the claim scope. Read in context, the passage was intended to establish a prima facie case of obviousness and did so by explaining the examiner's interpretation of the relevant prior art, Walser and Nissen. The examiner focused on the relative effects of a-ketoisocaproate ("KIC") and HMB in the treatment of certain domestic mammals, as described in the prior art. As pointed out by Appellants, the examiner's use of the phrases "muscle protein degradation" and "improves nitrogen balance" originated from the Abstract of the Walser patent, not the application from which the '979 patent issued. The inventors' failure to rebut the examiner's alleged interpretation of the claim scope is of no moment, as the substance of the rejection is more about the state of the prior art and the general applicability of HMB, not whether the claims at issue were limited to treating sick patients. The rejection letter as a whole can hardly be described as having limited the intended subjects and patients in the claims to individuals "in

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a state of excess muscle protein degradation" in a manner warranting some form of rebuttal from the inventors.

Accordingly, based on our analysis of the claims, the specification, and the prosecution history, we conclude that the claim terms "subject" and "patient" are fairly read to include normal, healthy humans and are not limited to individuals with a nitrogen imbalance or negative nitrogen levels. We also construe the claim language "continuing the said administration of HMB until the amount of nitrogen in the patient's urine has substantially decreased" according to its plain meaning to mean that the administration of HMB must continue up to the time that a patient's urinary nitrogen levels have been reduced by a substantial amount. Whether Appellants can show that Wiley met that claim language is more appropriately an issue of infringement that the district court may address on remand. Insofar as the district court's JMOL of noninfringement was based on an erroneous interpretation of those terms, other factual issues remain on infringement. We thus remand for the district court to consider in the first instance whether Wiley infringes the '979 patent under our revised claim construction.
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8. "Subseries of Adjacent Selected Chromosomal Regions"

GTG proposes the construction "a successive subset of chosen chromosomal regions," and Applera proposes "a subseries of selected chromosomal regions within the same locus or, for intron DNA sequences not associated with a genetic locus, immediately preceding or following the locus."

The construction of this claim is a close call, but GTG's arguments are slightly more persuasive than Applera's. The claim language here is admittedly ambiguous as to whether the subseries covers chromosomal regions that are adjacent to one another within a selected series of regions (GTG's proposal), or chromosomal regions that are adjacent to one another on the DNA strand before they are selected (Applera's proposal). In this circumstance, the court may properly rely on the specification to clarify the language. See, e.g., CCS Fitness, 288 F.3d at 1367.

The specification describes a method by which individual haplotypic regions on the DNA strand, separated by anywhere from .01 to 2 million DNA base pairs, are selected and analyzed. See '762 patent col. 13:7-21 (after one region is analyzed, the next haplotypic region appearing on the DNA strand is analyzed to create a map of "contiguous overlapping haplotypic regions."). In contrast, there is no description in the specification supporting Applera's interpretation of the claim that a continuous section of DNA is first selected, and then a second continuous subsection is then selected from within the first selected section.

While Applera proposes a plausible reading of what appears to be a rather poorly-drafted claim, when looking at the claim language in the context of the specification, the court is persuaded that GTG's position better describes the intended steps of the method described. Teleflex, 299 F.3d at 1324-25 (citations omitted). However, the court finds that GTG's construction is not entirely clear either. The court thus construes the disputed term as follows: a group of chromosomal regions identified by the following process: Chromosomal regions on a DNA strand are selected. The regions need not be adjacent to each other on the DNA strand. The selected regions are then arranged in the order in which they appear on the DNA strand. Regions that are next to one another in this reconfiguration are then selected to comprise a group.

The court acknowledges that this construction, while simplistic, may be imprecise. Accordingly, the court offers the parties the opportunity to stipulate to an alternate construction that embodies the court's basic finding that the chromosomal regions in question need not be adjacent to one another on the actual DNA strand. Any stipulation shall be submitted no later than one week after the filing of this order. If the parties are unable to reach an agreement, the court's construction will be the final construction of this claim.
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2. Substance

The parties next dispute the meaning of "substance" found in claims 1-3, 6, 6, 8, and 9. Plaintiff contends that the term

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means "physical material from which something is made or which has discrete existence." This definition, states Plaintiff, is the plain and ordinary meaning of the term and is quoted directly from the 11th edition of Merriam-Webster's Collegiate Dictionary. Defendants propose that "a 'substance' taken or administered with metaxalone means a substance that affects the safety, bioavailability, plasma concentration, efficacy, or a combination comprising at least one of the foregoing of metaxalone or the substance. A 'substance' can be an active agent, an herbal supplement, a nutritional supplement, a vitamin, a xenobiotic, or an environmental contaminant." Defendants derive this proposed definition from language in the specification concerning "a 'substance' taken or administered with metaxalone." (Ex. A at 10:38-44; Doc. No. 1.)

As the term "substance" does not have any particular meaning in this field, Defendants' construction is limiting. While Defendants'definition does derive from language found in the specification, this language defines the term substance taken or administered with metaxalone rather than disputed term substance. As the intrinsic evidence available does not provide a definition of "substance," resort to an extrinsic source--here, a dictionary--is appropriate. See Phillips, 415 F.3d 1303, 1322-33 (Fed. Cir. 2005) ("Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words."). Furthermore, adopting the lay understanding found in a dictionary does not conflict with what intrinsic evidence is available. Thus, Defendant's construction does not give the word the full breadth of its ordinary meaning as it is found in the claim.

Accordingly this Court will adopt Plaintiffs' proposed definition and will construe the term "substance" to mean the following: "physical material from which something is made or which has discrete existence."
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2. "substantial"

In contrast to the claim phrases construed above, in some instances the Applicant did claim a parts washer configuration where the biodegradation is claimed to occur at or near the surface of the fluid. For example, dependent claim 2 of the '110 patent recites a system for cleaning hydrocarbons from a part "wherein the fluid defines a fluid surface in the tank, and wherein [a] substantial portion of the microorganisms live in the fluid proximate to said fluid surface." '110 patent, col. 8, ll. 42-44. Similarly, claim 3 recites "[t]he combination of claim 2, wherein a substantial portion of the microorganisms and hydrocarbons accumulate proximate to said fluid surface such that a substantial amount of biodegradation takes place proximate to said fluid surface." Id., col. 8, ll. 45-49. In these claims, the parties dispute the meaning of "substantial."

Plaintiff ChemFree argues that the term "substantial" as used in these claims should mean "a part of the whole that is considerable in extent relative to the whole" or "a quantity that is considerable in extent." J. Walter argues that "substantial" should mean a majority, or more than 50%. (E.g., Def.'s Opening Brief at 35 ("Although the term 'substantial portion' has more than one ordinary meaning, it should be construed to mean 'majority' because it is used throughout the entire intrinsic record in a manner consistent with this ordinary meaning.").)

The intrinsic record is unhelpful in discerning a precise meaning of the term. For instance, the specification notes that "a large percentage of the microorganisms and organic contaminants will tend to accumulate proximate to the surface of the cleaning fluid 72 such that a large portion of the biodegradation takes place proximate to the surface of the cleaning fluid 72." '110 patent, col. 6, l. 66 - col. 7, l. 3 (emphases added). Notably, this discussion of biodegradation is made with respect to a preferred embodiment of the invention, which militates against its use in limiting the term. Moreover, these relative terms do little to inform what "substantial" or "large" mean in context with the whole.

Nor does the prosecution history enlighten the meaning of "substantial." In a Preliminary Amendment, made prior to any action by the PTO in that particular application, Applicant added new claims and made the following remarks:

> As recited in claims 23 and 31-37, as now amended, the fluid defines a fluid surface in the tank and a substantial portion of the microorganisms and hydrocarbons washed from the part tend to accumulate proximate to the fluid surface so that a substantial amount of the biodegradation takes place proximate to the fluid surface. Such a feature is not taught by the cited references.

'110 Patent File History, Applicant's Preliminary Amendment at 7. The amendment also states that

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[b]y having the biodegradation occur primarily at the fluid surface within the tank, a vapor barrier is created within the tank to minimize evaporation of the cleaning fluid and thus minimize the amount of cleaning fluid that must be replenished.

Id. While these remarks certainly make clear that the Applicant intends the systems in these claims to have a "substantial" amount of biodegradation take place proximate to the fluid surface, they do little to inform the meaning of what a "substantial" amount of microorganisms or biodegradation is.

Despite the words "large" and "primarily" in the specification and prosecution history, nowhere does the intrinsic record of the '110 patent indicate that "substantial" as used therein should have anything other than its plain and ordinary meaning. Certainly, the record does not evidence an intent to redefine the term to mean an amount more than 50%. Cf. Phillips 415 F.3d at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."). If Applicant had intended for substantial to have such meaning, it could have said so, or it could have used an equivalent term -- for example, "most" or "almost all."

"Without an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996); see also Phillips 415 F.3d at 1312 ("[T]he words of a claim 'are generally given their ordinary and customary meaning.") (citation omitted). Dictionaries are often consulted to determine a term's plain and ordinary meaning. Phillips, 415 F.3d at 1314. The plain and ordinary meaning of "substantial" is a portion or amount that is considerable in quantity. See Merriam-Webster's Collegiate Dictionary 1170 (10th ed. 2001) ("considerable in quantity: significantly great").

The Court accords "substantial" its plain and ordinary meaning: "a portion or amount that is considerable in quantity." While this definition does not lend itself to numerical exactitude, it is faithful to the term's plain meaning. It will be a question for the factfinder to further delimit the scope of the phrase in determining whether the claim reads upon the accused device or whether a prior art reference invalidates the claim. This analysis may also require expert testimony.
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Claim 24

The process according to claim 1, wherein the process further comprises adding the recycled ladle metallurgy additive to the molten steel in granular form in at least two separate steps wherein a substantial portion of the granular recycled ladle metallurgy furnace slag is added before the raw materials.

The parties agree that Claim 24 has all the limitations of Claim 1. Defendant argues, and the Court agrees, that this claim calls for a "further" process which consists of at least two separate steps requiring "a substantial portion" of the slag to be added before the raw materials. The parties dispute whether a mixture is required as an additive. Defendant argues there is no way the claim can be performed in two steps without having a mixture in at least one of the steps (Tr. 61).

The key phrase here is "substantial portion" (Tr. 58). Plaintiff says this means up to 100% and Defendant says it must be less than 100%. Plaintiff's position is that neither Claim 1 nor Claim 24 mention a mixture of LMF slag and raw material and that Claim 24 calls for at least two steps in the process. Defendant's position is that Claim 1 is limited to a mixture and Claim 24 is limited to at least one step which is the addition of a mixture of recycled LMF slag and raw materials as described in Claim 1.

The Court agrees with the common sense reading that "a substantial portion" could be up to and including 100%, depending on the number of steps. As described by Plaintiff's counsel (Tr. 63):

If you want to do it in two steps, you keep them [recycled slag and raw materials] separate; you put them in separately. The substantial portion there is 100 percent. But the claim is drafted to accommodate 75 percent, and then all of the raw material, then 25 percent, . . . The claim is drafted to cover all of those possibilities. And it clearly does.

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The Court's reading of Claim 24 is consistent with its reading of Claim 1.
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A. Indefiniteness

On appeal, Enzo first argues that the district court incorrectly determined that the "not interfering substantially" language in the '824, '767, and '928 patents is indefinite. In Enzo's view, the specifications provide specific examples of linkage groups that do not substantially interfere with hybridization and detection, as well as general criteria for selecting suitable linkage groups. Moreover, Enzo asserts that the specification provides a testfor measuring the degree of interference, namely, comparing the thermal denaturation profile (i.e., melting temperature) of a modified polynucleotide with that of an unmodified polynucleotide.

Applera responds that the district court correctly determined that the "not interfering substantially" language is indefinite, arguing that nothing in the patents explains how to measure "interference" or how to determine whether it is "substantial." Because even a minor alteration of a single nucleotide may have profound effects on the ability of a DNA strand to hybridize, depending on the length and sequence of the strand, Applera argues that identical linkage groups may cause interference in some strands but not in others, thus rendering the claims hopelessly ambiguous.

We agree with Enzo that the claims are not indefinite. "Indefiniteness requires a determination whether those skilled in the art would understand what is claimed. To make that determination, we have explained that '[i]n the face of an allegation of indefiniteness, general principles of claim construction apply.'" Young, 492 F.3d at 1346 (quoting Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1348 (Fed. Cir. 2005)). "Inthat regard, claim construction involves consideration of primarily the intrinsic evidence, viz., the claim language, the specification, and the prosecution history." Id. When a "word of degree" is used, the court must determine whether the patent provides "some standard for measuring that degree." Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc., 731 F.2d 818, 826 (Fed. Cir. 1984). Similarly, when a claim limitation is defined in "purely functional terms," a determination of whether the limitation is sufficiently definite is "highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area)." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

Because the claim language of the '824 and '767 patents differs from that of the '928 patent with regard to "hybridization" and "detection," we address these two terms separately.

1. Hybridization

The claims of the '824 and '767 patents provide that the linkage group must not substantially interfere with both hybridization and detection: '824 patent col.31 ll.31-34 ("said linkage group not interfering substantially with the characteristicability of said compound to hybridize with said nucleic acid or of A to be detected" (emphases added)); '767 patent col.31 ll.1-7 ("a linkage group that does not substantially interfere with the characteristic ability of the oligo- or polynucleotide to hybridize with a nucleic acid and does not substantially interfere with formation of the signalling moiety or detection of the detectable signal" (emphases added)). By contrast, the claims of the '928 patent provide only that the linkage group must not substantially interfere with detection: "said linkage group not interfering substantially with detection of A." '928 patent col.30 ll.28-30 (emphasis added)). The district court, however, adopted an identical construction for all three patents that refers to both hybridization and detection: "the linkage group neither substantially interferes with the ability of the compound to hybridize with the nucleic acid nor substantially interferes with the ability of A to be detected." Claim Construction, 2006 U.S. Dist. LEXIS 74570, 2006 WL 2927500, at *6 (emphases added).

As a preliminary matter, we see no basis to read a "hybridization" requirement into the claims of the '928 patent. Nothing in the claims refers to hybridization,and neither the specification nor the prosecution history contains a clear disclaimer or a contrary definition regarding the "not interfering substantially" language that would require us to read such a requirement into the claims. The applicants knew how to claim a linkage group that does not substantially interfere with hybridization, as they did in the '824 and '767 patents, but specifically omitted that language from the claims of the related '928 patent. We therefore modify the construction of this limitation with regard to the '928 patent to read: "the linkage group does not substantially interfere with the ability of A to be detected."

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With regard to the '824 and '767 patents, the term "hybridization" has a definite meaning. The district court correctly understood the term to mean "the binding of two separate, complementary strands of nucleic acids to form nucleic acid hybrids." 2006 U.S. Dist. LEXIS 74570, [WL] at *1 n.1. The ambiguity, in the district court's view, was that a person of ordinary skill would not understand whether a linkage group interferes with hybridization "substantially."

We begin with the language of the claims. The word "substantially," when used in a claim, can denote either languageof approximation or language of magnitude. See Deering Precision Instruments, LLC v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1323 (Fed. Cir. 2003). As used in the phrase "not interfering substantially," the word "substantially" denotes language of magnitude because it purports to describe how much interference can occur during hybridization, i.e., an insubstantial amount of interference. See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1031 (Fed. Cir. 2002) ("[T]he phrase 'substantially below' signifies language of magnitude, i.e., not insubstantial."). The claims in this case provide at least some guidance as to how much interference will be tolerated. A dependent claim in both patents specifies that the linkage group has a particular structure (-CH=CH--CH[2]--NH--). See '824 patent col.32 ll.66-68; '767 patent col.31 II.38-40. A person of ordinary skill would presume that a structure recited in a dependent claim will perform a function required of that structure in an independent claim. See AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scopethan the independent claims from which they depend."). Thus, it may be presumed that the term "not interfering substantially" in the independent claims allows for at least as much interference as that exhibited when the linkage group has the structure specified in the dependent claims. 4

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4 Of course, if this particular embodiment is inoperable, because a linkage group having the structure -CH=CH--CH[2]--NH-- entirely precludes hybridization, then the basis for invalidity would be a lack of enablement, not indefiniteness. Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1382 (Fed. Cir. 2001) (stating that inoperable embodiments present "an issue of enablement, and not indefiniteness"); Miles Labs., Inc. v. Shandon Inc., 997 F.2d 870, 875 (Fed. Cir. 1993) ("The invention's operability may say nothing about a skilled artisan's understanding of the bounds of the claim.").

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The specification provides additional examples of suitable linkage groups, including some criteria for selecting them. After stating generally that the linkage group "may include any of the well known bonds including carbon-carbon single bonds, carbon-carbon double bonds, carbon-nitrogen single bonds, or carbon-oxygensingle bonds," the specification goes on to note that "[i]t is even more preferred that the chemical linkage group be derived from a primary amine, and have the structure --CH[2]--NH--, since such linkages are easily formed utilizing any of the well known amine modification reactions." '824 patent col.8 ll.54-58, col.9 ll.1-5. Moreover, one of the "essential criteria" of a modified polynucleotide noted in the specification is that "the linkage that attaches the probe moiety should withstand all experimental conditions to which normal nucleotides and polynucleotides are routinely subjected, e.g., extended hybridization times at elevated temperatures, phenol and organic solvent extraction, electrophoresis, etc." Id. col.6 l.29, col.7 ll.3-8.

The specification also teaches that the polynucleotides' "thermal denaturation profiles and hybridization properties" can be used to measure the degree to which a linkage group interferes with hybridization. Id. col.18 ll.61-62. Because hybridization occurs via hydrogen bonding between complementary bases, any interference in this bonding will result in weaker intermolecular forces and thus a lower melting temperature (Tm) of the hybrid. For example,the specification states that a DNA strand was modified by substituting every thymidine residue of the strand with a biotinyl-nucleotide. The resultant hybridization exhibited by the modified DNA strand was reported to be acceptable: "the Tm is only 5 [degree] C less than that of the unsubstituted control." Id. col.19 ll.5-8 (emphasis added). A similar test was performed on poly d(A-bioU), in which every base pair contained a bio-dUMP residue. This modified polynucleotide showed a significantly lower Tm than the unsubstituted control, yet its hybridization was still deemed acceptable: "Although the Tm . . . is 15 [degree] C lower than the poly d(A-T) control, the degree of cooperativity and the extent of hyperchromicity observed both during denaturation and renaturation were the same for the two polymers." Id. col.19 ll.9-14 (emphases added). Thus, as a general guideline, when a linkage group is incorporated into a DNA strand having a length and sequence similar to those used in the specification, a decrease in Tm of up to 5 [degree] C implies that the linkage group does not "substantially interfere" with hybridization, and a decrease of up to 15 [degree] C is acceptable if the degreeof cooperativity and the extent of

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hyperchromicity are the same for the modified and unmodified strands.

The prosecution history of these patents is also helpful. Before the U.S. Patent and Trademark Office ("PTO"), Enzo overcame an indefiniteness rejection over the "not interfering substantially" language by submitting a declaration under 37 C.F.R. § 1.132, which was signed by its vice president, Dr. Engelhardt ("Engelhardt Declaration"), listing eight specific linkage groups that Enzo declared did not substantially interfere with hybridization or detection. Among the named linkage groups was --CH=CH--CH[2]--NH-- (the same group recited in the patents' dependent claims) and --NH--(CH2)[6]--NH-- (a new group that is not found in the specification and which contains only single bonds). J.A. 4320. Based on this submission, the examiner withdrew the indefiniteness rejection.

Because the intrinsic evidence here provides "a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine [the scope of the claims]," In re Marosi, 710 F.2d 799, 803 (Fed. Cir. 1983), the claims are not indefinite even though the construction of the term "not interferingsubstantially" defines the term without reference to a precise numerical measurement, see Young, 492 F.3d at 1346 (holding that a word of degree was definite, even without a numerical claim construction); Exxon, 265 F.3d at 1381 (same); Marosi, 710 F.2d at 803 (same); In re Mattison, 509 F.2d 563, 565 (CCPA 1975) (same). When deciding whether a particular linkage group is or is not "substantially" interfering with hybridization within the meaning of the district court's construction, a person of ordinary skill would likely look to the thermal denaturation profiles and hybridization properties (including Tm) of the modified nucleotide, to see whether they fall within the range of exemplary values disclosed in the intrinsic evidence. See Young, 492 F.3d at 1346 (stating that a figure in the specification "provides a standard for measuring the meaning of the term 'near,'" even without a numerical claim construction); Exxon, 265 F.3d at 1380 (stating that a "period sufficient," recited in the claim, can be ascertained by performing activity checks).

Contrary to Applera's assertion, the fact that the binding strength of a DNA strand may vary, based on the length and sequence of the strand,does not mean that the choice of a linkage group will "depend solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention," as in Datamize. 417 F.3d at 1350. In Datamize, the invention was directed to a computer interface screen with an "aesthetically pleasing look and feel." Id. at 1344-45. The patentee sought a construction of the term "aesthetically pleasing" that depended solely on the subjective opinion of the person selecting features to be included on the interface screen. Nothing in the intrinsic evidence provided any guidance as to what design choices would result in an "aesthetically pleasing" look and feel. Id. at 1352. The claims were held indefinite because the very same interface screen may be "aesthetically pleasing" to one user but not to another.

Here, by contrast, the binding strength of a DNA strand will depend on the length and sequence of the strand, not on the subjective opinion of the particular chemist performing the hybridization. This is because, under a given set of experimental conditions, a DNA strand of a given length and sequence will have a fixed, measurable denaturation profile, which can be comparedwith the examples in the specification to determine whether interference with hybridization is substantial. The claims are not indefinite simply because the binding strength of a DNA strand will vary based on the strand's length and sequence. See Young, 492 F.3d at 1346 (holding claim definite even though "the size of the appendage and the amount of skin required to be incised will vary from animal to animal based on the animal's size").

Thus, we hold that the claim language regarding "hybridization" is not indefinite.

2. Detection

With regard to "detection," we agree with Enzo that the claims are not indefinite for most of the same reasons discussed in connection with "hybridization." The eight linkage groups listed in the Rule 132 declaration were said not to "interfere[ ] with the ability of biotin in an oligo- or polynucleotide probe of this invention to form a detectable complex with one of avidin, streptavidin or antibodies to biotin or iminobiotin." J.A. 4318. According to the specification, when biotin is used as the moiety A, the resultant complexes can be detected "by means of conventional detection techniques." '824 patent col.18 ll.4-6. So long as moiety A can be detectedwithin the level of detection achieved by the applicants using the exemplary linkage groups disclosed in the intrinsic evidence, a person of ordinary skill would understand that a different linkage group (one that is not disclosed in the intrinsic evidence) likewise does not "substantially interfere" with the detection of moiety A. The claims are not indefinite even if some experimentation is required to determine the exact level of detection achieved by the applicants using their exemplary linkage groups. See Exxon, 265 F.3d at 1379 ("Provided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation may be necessary to determine the scope of

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the claims does not render the claims indefinite.").

* * *

For the foregoing reasons, we conclude that the "not interfering substantially" language in the '824, '767, and '928 patents is not indefinite.
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4. What is the Proper Construction for the Phrase "substantially above the softening temperature" in the '311 Patent?

Claims 1 and 94 of the '311 patent contain the phrase: "substantially above the softening temperature of said binder material but to a temperature less than the softening temperature of said primary material." KXI contends the phrase "substantially above . . ." means the temperature is sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point-bonds. KXI contends no specific temperature is required. Culligan contends the phrase "substantially above . . ." means the temperature exceeds the binder's softening temperature by at least approximately 20 degrees Celsius.

KXI argues that this phrase is similar in meaning to the same phrase used in the '092 and '948 patents. KXI argues that the plain meaning of the words defines the meaning of the claims. According to KXI, no specific temperature is required under the claims, and setting out such a requirement would not even be feasible because the temperature needed to convert the binder varies based upon the size and shape of the object being produced and the binder selected. KXI cites in support column 14, lines 56-59 of the '311 patent. This reads in relevant part: "The [continuous web matrix] . . . process is . . . usually carried out within a preferred operational range. This range may vary with the size and shape of the object being produced."

Culligan derives its definition of the phrase at issue from the '311 patent's specification at column 12, lines 36-40, in the "Detailed Description of CWM/FPB Process" section. This states as a basic requirement that "in the absence of any significant pressure or shear, the mixture is first brought to a temperature sufficiently above (preferably at least about 20 degrees Celsius, most preferably about 40 degrees Celsius above) the softening point of the binder resin. . . ."

Culligan also argues that the patentee disclaimed processing temperatures used in the Degen '683 patent in distinguishing it. Culligan cites the '311 patent's specification at column 2, line 52 to column 3, line 2. This passage describes the prior art process disclosed in the Degen '683 patent and distinguishes it from the present invention. The passage reads in relevant part:

Degen et al. . . . describes a process using a temperature of approximately 275 degrees F (135 degrees C), which is generally below the temperatures required in the subject invention to achieve the desired novel structures. Formation of a novel continuous polymer phase or forced point-bonding, according to the present invention, even with the lowest melting point resin available, ethylene-vinyl acetate copolymer (EVA), usually occurs at 145 degrees Celsius . . . and is optimal in the range of 165-210 degrees Celsius. The temperatures required by the process of the subject invention are therefore substantially higher than required for diffusion bonding processes such as that described by Degen et al., even for the binder resin having the lowest melting point. Degen et al. teach the use of temperatures only sufficient to produce a softening of the binder because they are seeking a point bond and are not seeking a more dramatic conversion of the thermoplastic binder into a different physical form. (Emphasis added).

Culligan contends the manufacturer's specification sheet specifies that the EVA binder used in the Degen '683 process (532 EVA) has a softening temperature of approximately 75 degrees Celsius and a melting point of approximately 96 degrees Celsius. U.S. Patent No. 4,664,683, col. 6, lines 31-34; col. 14, line 66 to col. 15, line 1. The Degen '683 patent uses a processing temperature of 135 degrees Celsius, which is 60 degrees Celsius higher than the softening point of the 532 EVA binder. The '311 patent distinguishes the Degen '683 patent's prior art based upon the temperatures required for the respective processes. The '311 patent characterized the temperatures disclosed by the Degen '683 patent as "generally below" the temperatures needed to produce the "continuous web matrix" and "forced point-bonding" structures disclosed in the '311 patent.

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Culligan also cites examples 17 and 18 from the '311 patent's specification. These examples disclose that pellets produced by compression molding mixtures of stainless steel powder, 532 EVA binder and powdered ion exchange resin crumbled when heated to temperatures at and below 170 degrees Celsius, which is 95 degrees Celsius above the 532 EVA's softening temperature. Culligan also cites a passage from the '311 patent's specification characterizing temperatures necessary to process activated carbon and 532 EVA as 190 to 210 degrees Celsius, or 125 to 155 degrees Celsius above the 532 EVA binder's softening temperature. KXI argues in response that the Degen '683 patent talks about process temperature, and not the mixture temperature, and that example 17 of the '311 patent talks about the mold's temperature.

The court agrees with KXI that the temperature needed to convert the binder varies based upon the size and shape of the object being produced and the binder selected. Accordingly, the court construes the phrase "substantially above the softening temperature" to mean sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point-bonds.
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6. What is the Proper Construction for the Phrase "substantially above the softening temperature of said binder material" in the '092 and '948 Patents?

Claim 1 of the '092 patent includes the phrase "heating said substantially uniform mixture within said die to a temperature substantially above the softening temperature of said binder material . . . ." Claim 1 of the '948 patent includes the phrase "means in said die adjacent to the inlet end thereof for heating said particulate mixture within said die cavity to a temperature substantially above the softening temperature of said binder material . . . ." KX contends the phrase "substantially above" means the minimum heat required by the claims. This is a temperature which is sufficiently high both to form a composite and to keep the mixture from solidifying in the extruder. Culligan contends the phrase "substantially above" means that the temperature exceeds the softening temperature of the binder by approximately 25 degrees Celsius.

Culligan relies on statements in the specifications of the '092 and '948 patents that the heat applied to the mixture be "generally about 25 degrees Celsius above" the softening temperature of the binder. See U.S. Patent No. 5,189,092, column 2, lines 12-15; '092 patent, column 9, lines 9-10; U.S. Patent No. 5,249,948, column 2, lines 16-19. KXI argues that "generally about 25 degrees Celsius above" the softening temperature of the binder is a preferred example, but does not define the term "substantially above." According to KXI, the specification sections relied on by Culligan are "neither attempts to define the claim terms nor are they expressed as requirements in order to practice the claimed invention." Therefore, KXI argues, the court should not read them as defining the claim.

KXI argues that Culligan's interpretation violates the doctrine of claim differentiation with respect to the '092 patent. Claim 5 of the '092 patent, which is dependent upon claim 1, includes the limitation "at least about 25 degrees Celsius above the softening temperature of said binder material."

KXI also argues that a set temperature increase would fail to account for the variety of different binders that may be used, each of which may have different temperature requirements. According to KXI, the specifications set out an operating window within which the temperature must fall. This operating window necessarily varies based upon the specific binder material used. The parameters are set by column 5, lines 31-36 of the '092 patent, and column 5, lines 37-41 of the '948 patent. These passages read: "There is a minimum heat and a maximum heat--if a substance is heated insufficiently, it will not solidify and will be very prone to 'locking' within the extruder die. If overheated, it will have a strong tendency to lock up within the die." According to KXI, defining the phrase "substantially above" to mean 25 degree Celsius is contrary to the teaching of the invention that the parameter for the heating temperature be set according to the qualities of the binder used.

KXI recognizes that the "minimum heat and . . . maximum heat" requirement is "intended to teach that there is a limited range of temperatures that can be used in plaintiff's process." But, KXI argues, this requirement does not provide a definition of "substantially above" as used in both claims.

Claim 5 of the '092 patent is dependent upon claim 1. If the court were to construe "substantially above" to mean the temperature exceeds the softening temperature of the binder by approximately 25 degrees Celsius, claim 5 would be

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superfluous. See, e.g., Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987) ("To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant.") The court notes "there is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims." Id.

The specification has stated that "substantially above" is "generally at least about 25 degrees Celsius" and is "preferably at least about 25 degrees Celsius above the softening point of the binder. . . ." The court finds, however, the specification does not define the term "substantially above" to mean "about 25 degrees Celsius." The court finds a lower temperature difference might satisfy the "minimum heat and . . . maximum heat" requirement, depending upon the binder used. Accordingly, the court construes the phrase "substantially above" to mean a temperature which is sufficiently high both to form a composite and to keep the mixture from solidifying in the extruder.
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Step B -- "substantially all" non-ink contaminants

(1) Claim construction

The Federal Circuit has construed this claim "to require removing substantially all the non-ink contaminants including the stickies before the occurrence of steps (c) and (d), during which ink is dispersed." Kamyr II, 1998 WL 15223 *5. The meaning of the phrase "substantially all" may still be uncertain, but AMI does not advance any particular interpretation on this renewed motion for summary judgment. In any event, Clement's proposal to use a dictionary definition of "substantially" is sound and essentially unopposed. "Substantially all" is accordingly construed to mean "largely but not wholly that which is specified." Def. Opp'n. at 15 (quoting Webster's New Collegiate Dictionary (1980); see also, York Products, Inc. v. Central Tractor Farm and Family Center, 99 F.3d 1568, 1572 (Fed. Cir. 1996).
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VI. "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer" 24

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24 The term "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer" is contained in claim 1 of the '183 patent.

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Plaintiff's Proposed Construction	Defendants' Proposed Construction
At least 90%, and preferably greater than 95%, of the total therapeutic agent present in the tablet is included within one distinct layer. "a first layer" means one or more distinct areas of triptan. "a second, separate layer" means one or more distinct areas of naproxen. The rest of the phrase	At least 90% of the total amount of triptan in the tablet is in a first distinct layer of the tablet and at least 90% of the total amount naproxen in the tablet is in a second distinct layer of the tablet.

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is ordinary and customary meaning
in light of the agreed construction
for naproxen.

The'183 patent contains the term "substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer." The parties agree that the patentee chose to be its own lexicographer by providing a specific definition for "substantially all." 25 See OPENING at 27; RESPONSE at 27. The parties dispute, however, whether to include the "preferably greater than 95%" language. The Court concludes that by specially defining "substantially all" and using it in the claim, the patentee instructed those skilled in the art as to how the claim should be read. See '183 patent at 2:43-46.

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25 As acknowledged by both parties, the '183 patent specification, provides: "The term 'substantially all' indicates that at least 90% and preferably greater than 95% of the total therapeutic agent present in the tablet is included within one distinct layer." '183 patent at 2:43-46.

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The remaining claim construction dispute concerns the meaning of the phrases "a first layer" and "a second, separate layer." 26 The parties' dispute revolves around whether the terms "first" and "second" refer to (A) triptan and naproxen as first and second agents that must be keptseparate but could be present in multiple "first" and "second" layers of each agent, or (B) two physical but separate layers.

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26 The parties continue to dispute whether "layer" should be defined as "distinct areas" or by a particular geometry associated with planar "layers." Having already discussed these proposals in section V, supra, the Court will not again address these arguments in this section. Instead, the previous discussion is incorporated into the Court's construction for this claim term.

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Pozen contends that "first" and "second" refer to the drugs-- naproxen and triptan-- and not to the number of layers. OPENING at 27-28. Pozen particularly argues that different words or phrases used to describe the tablet in separate claims is presumed to indicate that dependent claim 9 is differentiated from claims 1-8. Pozen points out that the dependent claim is drawn to a "bilayer dosage" for the preferred embodiment and contends that the use of "bilayer" is distinguishable from "multilayer." Specifically, Pozen infers that one of skill in the art would understand that the broader claims contain more than two layer of drugs, and therefore, Defendants' bilayer dosage construction shouldbe rejected. OPENING at 28 (citing Karlin Tech, Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed. Cir. 1999)).

Defendants contend that the language of the claim, the specification and the prosecution history all support the conclusion that all of the naproxen is found in one single layer and all the triptan is found in a single second separate layer. RESPONSE at 26-28 (citing '183 patent at 2:4-6 and 3:34-35). Under Defendants' proposed construction for claim 1, the terms "first" and "second" are understood to refer to layers, not agents.

The Court finds that the terms "first" and "second," as used in claim 1 of the '183 patent, refer to first and second physical layers. First, by specially defining "substantially all" in the specification, the patentee instructed those skilled in the art that the agents would be present in "one distinct layer." See Cook Biotech Inc. v. Acell, Inc., 460 F.3d 1365, 1372 (Fed. Cir. 2006) (recognizing that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification).Where, as here,the inventor provided a definition for "substantially all," that special definition will govern. Phillips, 415 F.3d at 1313. While there is no explicit disclaimer of multiple layers of each agent in the intrinsic evidence, neither is there any specific teaching or reference to such a structure. If the patentee intended to describe and claim a tablet architecture where all the triptan and naproxen were present in multiple separate areas, the patentee could have more acutely

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defined such geometry in the specification. Instead, the specification states that "[s]ubstantially all of the triptan is found in one layer of the tablet and substantially all of the naproxen is found in a second, separate layer." '183 patent at 2:4-6. The disclosed examples further illustrate this architecture because the superior performance of the tablet is linked to circumstances where there are first and second physical layers of the drug when it was made and tested. See, e.g., '183 patent at 2:4-11 (discussing the superior properties of the tablet arrangement and describing "two layers" that allow for optimal dissolution); see also '183 patent at 18:41-49 and 18:54-63 (disclosing the arrangement of layersin the preferred embodiment).

Second, the Court also rejects Pozen's "multilayer" versus "bilayer" distinction in claims 1 and 9 because the different descriptions are reconcilible with the teachings of the '183 patent specification. The specification points out that the tablets can include layers of materials other than triptan or naproxen. See, e.g., '183 patent at 2:65-3:4 (describing "a barrier layer or coating which prevents the therapeutic agents from interacting with one another"). Thus, "multilayer" can refer to a tablet that has (1) a single layer of triptan, (2) a single layer of naproxen, and (3) additional layers of inert material that separates the naproxen and triptan. Claim 1, which uses the term "comprising" would read on a tablet that had one layer each of triptan and naproxen and a third layer of another therapeutic agent since it is limited to multilayer forms. Claim 9, however, is of different scope since it would exclude the third agent because it is limited to bilayer. In either case, however, the naproxen and the triptan could be present in "one distinct layer." Thus, claim 9 and claim 1 can be understood to be of different scope even if both would require thatall the naproxen be in one single layer and all the triptan be one second single layer.

Lastly, it is axiomatic that each word in a claim is presumed to have some meaning. Pozen contends that the terms "first" and "second" refer to the triptan and the naproxen and do not further define or restrict the number of layers. Thus, in Pozen's view, the multilayer tablet can have many layers of triptan and many separate layers of naproxen. If that were so, claim 1 could have simply read "substantially all said triptan is in a layer of said tablet and substantially all of said naproxen is in a separate layer." Such language would have expressed exactly what Pozen now contends is the case--a structure with any number of layers-- so long as the two compounds were found in different layers. Nonetheless, that is not how the claim was drafted. Instead the patentee chose to insert "first" and "second" into claim 1 before "layer" and "separate layer." To give "first" and "second" any meaning at all, they must refer to a first layer and a second layer and not to the two different compounds.

Accordingly, the Court finds that the definition for this term should be "at least 90%, and preferably greaterthan 95%, of the total triptan present in the tablet is included within one distinct layer and at least 90%, and preferably greater than 95%, of the naproxen present in the tablet is included within a second distinct layer."
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C. What is the meaning of "substantially 1:1" and "about 1:1" in the context of the patents in suit?

Each of the claims of the '052 and '120 patents calls for an antigen in which the ratio of proline to glutamic acid is "substantially 1:1," while each of the claims of the '080 patent describes that ratio as "about 1:1." There can be no dispute as to the importance of this limitation in the claims, for it was added to the broadest claims during prosecution to overcome their rejection as unpatentable over the Hewlett & Wolff article, and the amended claims were allowed only after the filing of Hewlett's declaration attesting that the adenylate cyclase disclosed in the article did not have a proline:glutamic acid ratio of "substantially 1:1."

Both parties apparently agree that the terms "substantially" and "about" have the same meaning in the context of the patents in suit but, as might be expected, they differ considerably as to what that meaning is. Plaintiffs argue that "these are not terms which would have a unique meaning in the art to which the patent relates" and that they merely "indicate that the ratio of proline to glutamic acid explicitly does not have to be exactly 1:1." (Pls.' Mem. in Opp. to Non-infringement/Markman Mot. at 17.) Plaintiffs accordingly argue that it should be left for the jury to decide whether the 0.86:1 ratio of defendants' products is "substantially" or "about" 1:1.

Defendants urge the Court to interpret the terms in light of both intrinsic and extrinsic evidence. First, defendants point out that the only guide in the specification to the meaning of the terms is found in "Example 6," which involves amino acid

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analysis of ACAP. This analysis found proline and glutamic acid (including glutamine) residues of 60 and 62 respectively -- a ratio of 0.97:1.

Defendants also rely upon the deposition of Dr. Erik Hewlett, whose declaration was submitted to the PTO to overcome a rejection of the claims as unpatentable over two articles co-authored by him. In that declaration, Dr. Hewlett stated that his tests of a 70kD portion of the adenylate cyclase toxin disclosed in the aforementioned Hewlett & Wolff article (curiously, not one of the two articles cited in the rejection) was subjected to amino acid analysis and found to have a proline:glutamic acid (+glutamine) ratio of 0.32:1. Thus plaintiffs have presented Dr. Hewlett as an expert in this branch of protein analysis. In his deposition, Dr. Hewlett expressed his understanding, as one skilled in the art, of the meaning of the term "substantially 1:1":

Q: . . . At the time you were executing this declaration, I want to find out if you had some understanding in your mind what you as a person skilled in the art thought that claim meant?

A: Yes.

Q: Okay. And in particular what "substantially 1 to 1" meant to you.

A: I can tell you what it meant to me.

Q: Okay.

A: Because I was --

Q: Why don't you --

A. -- making the interpretation. Substantially I interpreted as being the equivalent of statistically -- not statistically significantly different than 1, which is essentially plus or minus 5 percent.

(Hewlett Dep., Aug. 13, 1997, Exh. 54 at 208-09.)

In their briefs, plaintiffs attempted to stretch this range to twice its width by interpreting it as contemplating "5 percent plus or minus per amino acid" (emphasis added), so that it would encompass the entire span from 0.9:1 to 1.1:1. That is a creative approach, but is inappropriate in this context. It would be logically applicable if there were a potential error of plus or minus 5% in measuring the value of each of the two amino acids, so that one might be 5% too high and the other 5% too low, for a possible spread of 10%. However, the question put to Dr. Hewlett did not contemplate measurement tolerances, but merely asked what the expression "substantially 1:1" in the patent claims means to him as a person skilled in the art. His testimony is therefore subject to only one reasonable interpretation: that "substantially 1:1" means within plus or minus 5% of equality -- that is, between 0.95:1 and 1.05:1.

Moreover, even if the Court were to accept plaintiffs' imaginative approach and construe "substantially 1:1" as covering any ratio between 0.90:1 and 1.1:1, it still would not encompass the proline:glutamic acid ratio of 0.86:1 in defendants' antigen. Realizing this, plaintiffs' counsel strained his ingenuity still further and, at oral argument, contended that the plus or minus 10% range should be measured from the "starting point" of the 0.97:1 ratio calculated from "Example 6" of the specification. This would extend the range all the way down to 0.87:1, which plaintiffs argue is so close to defendants' 0.86:1 ratio that a jury could find the difference "insubstantial." (Tr. at 42-45.) In his desperate advocacy, plaintiffs' able counsel ignored the fact that the patent claims specify a ratio of "substantially 1:1," not "substantially 0.97:1." Thus the "starting point" from which to measure whether there is "substantial" equality is clearly 1:1, not 0.97:1.

The only intrinsic evidence as the meaning of the terms "substantially 1:1" and "about 1:1" is the one example given in the specification, in which the ratio of the residue values of the two amino acids is 60:62 (or 0.97:1), which is to say that they are within 3% of one another. And the only extrinsic evidence as to such meaning which has been presented to the Court is the testimony of plaintiffs' own expert that the terms mean to him, as a person skilled in the art, that the residue values of the two amino acids are within 5% of each other.

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Faced with such evidence, plaintiffs understandably urge the Court to make no Markman ruling as to the meaning of the terms in question and leave this determination for the jury. However, the Court believes that course of action would be an abdication of the responsibility which Markman places on the Court. The jury is not likely to have any better evidence as to the meaning of the terms than is now available to the Court. At the trial, each side would surely present its own partisan expert to testify as to what the claims mean to those skilled in the art, and surely the plaintiffs' expert would assign to the terms a range of ratios broad enough to include the 0.86:1 proline:glutamic acid ratio in defendants' antigen, while defendants' equally eminent expert would narrow the range to exclude defendants' antigen. With those contradictory opinions offsetting one another, the issue would have to be determined on the basis of the evidence now available: the intrinsic evidence of the example given in the specification (+/-3%) and the extrinsic evidence of the testimony against interest of defendants' expert (+/-5%).

In light of such evidence, the Court concludes that the terms "substantially 1:1" and "about 1:1" mean that the proline and glutamic acid values are within 5% of each other -- that is, the ratio between these values must fall within the range of 0.95:1 to 1.05:1. There is no evidence in the record, intrinsic or extrinsic, which would support any broader reading of the language.
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2. Claim Construction

The "substantially to completion" or "substantially completed" phrase used in the 268 patent is found in all of the independent claims; the step in which it appears requires a reaction between the sample and the reagent to proceed "substantially to completion" or to be "substantially completed" before the next step. See 268 Patent, col. 13, ll. 66-67; col. 14, l. 61; col. 18, l. 11; col. 18, ll. 45-46. The parties dispute two facets of this phrase: what "substantially completed" actually means and where the reaction must reach "substantial completion."

Roche argues that the common meaning for the term "substantially" as defined in binding precedent, see York Products, Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed. Cir. 1996), is the correct meaning in the context of the 268 patent. Specifically, "substantially" means either "largely but not wholly," or "considerable in extent." Id. (quoting from WEBSTER'S COLLEGIATE DICTIONARY and AMERICAN HERITAGE DICTIONARY 2ND COLLEGE EDITION, respectively). Moreover, Roche argues that the predetermined reaction that happens when the sample is placed on the cell "does not have to proceed to completion in the entire sample, but rather only in that portion of the sample in which the reagents have dissolved before the potential is applied." Roche Reply Br. on Claim Constr., at 6 ("Roche Reply"). In other words, the reaction need only go to substantial completion in the "reagent layer." Id.
at 10 (citing 268 Patent, col. 7, ll. 29-30). See also 268 Patent, col. 12, ll. 28-32.

In contrast, Bayer asserts that "the glucose/oxidant reaction has gone 'substantially to completion' when at least 99.9% of the glucose in the sample placed in the cell is oxidized [before the potential is applied]; the reaction is not substantially completed when substantially all of the analyte in only a thin layer of the sample placed in the cell has been oxidized." Bayer Br. at 22. Bayer contends that this construction is consistent with the specification and the prosecution history of the 268 patent. Id. at 23-28. In particular, the fact that this step must be "substantially completed" before measurement of the Cottrell current implies that the concentration of the sample is constant before the potential is applied. See id. at 23-24. In addition, Bayer contends that the PTO specifically allowed these claims in the 268 patent over prior art because the inventors argued that in their invention the entire sample in the well had to react in order for the Cottrell equation to accurately predict that amount of biological compound in the sample. See id. at 12-13 (citing Defs.' Joint App. at B78-79, B276-78, B280, B284); id. at 24 (citing Defs.' Joint App. at 73, 82, D183).

Similarly, Inverness argues that the "substantially completed" limitation means "the reaction involving the glucose in the entire sample must proceed as far as it can, at which point, the specification teaches, '99.9+ percent' of the glucose in the sample has been converted to gluconic acid." Inverness Br. at 21. Inverness avers that "substantial" is an open-ended word or a "word of degree" that would render the claims meaningless without quantification. Id. at 21-22. Moreover, Inverness relies upon the portion of the specification that states, "Gluconic acid yields of 99.9+ percent were attained in the presence of glucose oxidase," for the proposition that "substantially" must mean "99.9+ percent." Id. at 23 (citing 268 Patent, col. 8, ll. 23-25). In addition, like Bayer, Inverness argues that the prosecution history confirms that the inventors distinguished

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their invention on the basis that the "entire well volume" was reacted. Id. at 23-24. Therefore, substantial completion requires that the "entire well volume" react before a potential is applied.

In the context of the 268 patent, including the disputed claims, the undisputed claims, the specification and the prosecution history, the Court finds that "substantially to completion" or "substantially completed" means nearly to the end or nearly ended. With respect to where the reaction must be substantially completed, the Court finds that the reaction must be substantially completed in the entire sample.

a.) The Meaning of "Substantially Completed"

The Court starts with the plain meaning of the claim language. Claim 1 uses the term "substantially to completion" in the context of what happens to the reaction between the sample fluid and the oxidant. See 268 Patent, col. 13, ll. 63-67. Similarly, the other independent claims at issue, claims 12, 43, and 47, talk about a reaction or an oxidation that has "substantially completed." Id. col. 14, ll. 59-61; id. col. 18, ll. 10-11; id. col. 18, ll. 45-46. The non-asserted independent claims also teach reactions that have "substantially completed." Id. col. 16, l. 6; id. col. 16, l. 33; id. col. 16, l. 65; id. col. 17, l. 21. In the context of the claim language where the focus is on what happens to a chemical reaction or oxidation (a special type of chemical reaction), the term "substantially to completion" or "substantially completed" likely means that the reactants are nearly all used up and there is little transformation continuing. This understanding is more succinctly phrased by consulting a dictionary, keeping in mind the context of a reaction between two or more chemicals.

The term "substantially" in normal usage implies considerable in amount or extent. See WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2280 (Unabridged 1981) ("WEBSTER'S UNABRIDGED"); AMERICAN HERITAGE DICTIONARY (3d Ed. SoftKey Int'l Inc. 1994). Or, as suggested by Roche, largely but not wholly. See Roche Br. at 28 (citing York Prods., 99 F.3d at 1572 (quoting WEBSTER'S COLLEGIATE DICTIONARY)). Completed, or completion, in normal usage implies finished, done or ended. This common language definition comports with the dictionary definition for complete: "brought to an end or to a final or intended condition." WEBSTER'S UNABRIDGED, at 465. In the context of the claims, where the subject at issue is a reaction between chemicals, "substantially completed" likely means considerably or largely finished.

In contrast to the claim language where the extent of the reaction is qualified by the word "substantially," the 268 patent's specification rarely makes such qualification. Specifically, the patent teaches that a preferred embodiment "involves a two-step reaction sequence utilizing a chemical oxidation step using other oxidants than oxygen, and an electro-chemical reduction step suitable for quantifying the reaction production of the first step." 268 Patent, col. 3, ll. 16-19. There are no words of limitation here on the extent of the oxidation reaction. Moreover, the patent teaches the importance of a chemical reaction system that uses an oxidant other than oxygen "in a large excess of the analyte" to "ensure that the oxidant is not the limiting reagent" because the inventors wanted "a quantitative conversion of the analyte." Id. col. 3, ll. 19-25. Therefore, it appears that largeness in quantity of the oxidized chemical is important to the invention. Moreover, in the preferred embodiment where the analyte is glucose, the patent reads that the "chemical oxidation reaction has been found to precede to completion in the presence of an enzyme . . . ." Id. co. 3, ll. 29-30. Similarly, the patent teaches: "The first reaction is an oxidation reaction which proceeds to completion in the presence of the enzyme glucose oxidase." Id. col. 4, ll. 26-28. Again, there are no words qualifying the extent of the oxidation reaction in these descriptions of the preferred embodiment, implying that the reaction is fully complete. This conclusion follows from the earlier emphasis on the importance of the quantity of the oxidized reaction product.

In another description of the preferred embodiment, the patent teaches:

> The main difference between these two techniques consists of applying the appropriate controlled potential after the glucose-benzoquinone reaction is complete
>
> . . . .
>
> It should be noted that Cottrell chronoamperometry of metabolites needs the dual safeguards of enzymatic catalysis and controlled potential electrolysis. Gluconic acid yields of 99.9+ percent were attained in the presence of glucose oxidase.

Id. col. 8, ll. 13-25. Again, there are no words of limitation on the extent of completeness of the oxidation reaction. In fact,

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the patent teaches that when the catalyst glucose oxidase is used in the method described, experiments showed that 99.9+ percent of the glucose was converted to gluconic acid. All of these descriptions, however, specifically refer to a preferred embodiment of the invention where glucose is the analyte and glucose oxidase is used as the catalyst.

In addition, the patent also states that "it has now been discovered that the preferred oxidants described [in the patent for glucose, ferricyanide, ferricinium, cobalt III orthophenanthroline and cobalt (III) dipyridyl,] have sufficiently positive potentials to convert substantially all of the B-D-glucose to gluconic acid." Id. col. 4, ll. 38-41. Here, even with reference to the preferred embodiment of oxidation of glucose to gluconic acid, the patent qualifies the extent of the reaction using "substantially." However, it seems that the patent teaches the importance of allowing the reaction between the analyte and the oxidant to proceed as close to completion as reasonably possible. As described above, the description of the preferred embodiments for glucose make this apparent. Therefore, a definition for "substantially to completion" or "substantially completed" that incorporates the concept that the reaction has nearly ended best captures the intent of the claims.

Both Bayer and Inverness argue that "substantially" is a word of degree, which in the context of the 268 patent is specifically defined as "99.9+ percent." Bayer Br. at 23; Inverness Br. at 23, 37-38; Inverness Surreply Br. on Claim Constr. at 20-22 ("Inverness Surreply"); Inverness Reply to "Roche's Resp. to Inverness' Surreply Br. on Claim Constr.", at 7 ("Inverness Reply to Roche Resp."). But, the defendants ignore the plain language of the claims themselves and the context in which the value "99.9+ percent" appears. The language of the claims disclose no special meaning for the term "substantially." In addition, independent claims 1, 12, 30, 37, and 43, are generic as to analyte or type of compound to be measured. See 268 Patent, col. 13, ll. 58-59 ("A method of measuring the amount of a selected compound in body fluids . . . ."); id. col. 14, ll. 53-54 ("A method of measuring the amount of an analyte in a blood sample . . . ."); id. col. 15, ll. 61-62 ("A method of measuring the amount of an analyte in a blood sample . . . ."); id. col. 16, ll. 51-52 ("A method of measuring the amount of an analyte in a blood sample . . . ."); id. col. 17, ll. 47-48 ("A method for measuring the amount of a selected compound in a blood sample . . . ."). Yet, all the claims contain the "substantially completed" limitation.

In addition, the limit of "99.9+ percent" in the specification refers to the description of the preferred embodiment for detection of glucose concentration. The specification reads:

> In order to prove the application of the technology according to the present invention, a large number of examples were run in aqueous solution at 25[degrees] C. . . . In these tests it was found that any potential between approximately +0.8 and 1.2 volt (vs NHE) is suitable for the quantification of hydroquinone when benzoquinone is used as the oxidant.
>
> * * *
>
> It should be noted that Cottrell current chronoamperometry of metabolites needs the dual safeguards of enzymatic catalysis and controlled potential electrolysis. Gluconic acid yields of 99.9+ percent were attained in the presence of glucose oxidase. Concomitantly, equivalent amounts of benzoquinone were reduced to hydroquinone, which was conveniently quantitated in quiescent solutions, at stationary palladium thin film anodes or sample cells.
>
> The results of these many tests demonstrates the micro-chronoamperometric methodology of the present invention and its practicality for glucose self-monitoring by diabetics.

Id. col. 7, ll. 61-67 to col. 8, ll. 1-31. The reference to gluconic acid yields in this passage is to the results of a specific set of experiments run by the inventors to prove the application of the method for determination of glucose concentration, one of the preferred embodiments of the invention. There is nothing in the specification that incorporates this yield value for different analytes. This is made clear by reading the portion of the specification that describes an alternative preferred embodiment for determination of cholesterol concentration. No language in that portion of the specification requires that the reactions described yield 99.9+ percent of the oxidized form of cholesterol. The Court is not persuaded that the specification only supports a definition for "substantially completed" of 99.9+ percent.

Based on the language of the claims and the specification, the Court finds that "substantially to completion" or "substantially completed" means nearly to the end or nearly ended.

b.) Where the Reaction Must Proceed "Substantially to Completion"

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This finding does not complete interpretation of the "substantially completed" limitation. Both Bayer and Inverness argue that in the context of the asserted and unasserted claims, the reaction must be substantially completed in the entire sample or throughout the entire well volume. Bayer Br. at 12-13, 25-28; Inverness Br. at 23-24, 32-37; Inverness Reply to Roche's Resp. at 5-6. Further, the defendants argue that during prosecution of the '015 patent application, the inventors differentiated their invention on the basis of where the reaction must go substantially to completion. Bayer Br. at 11-13, 25-28; Inverness Br. at 23-24; Inverness Surreply, at 12-13. Bayer and Inverness aver that the arguments made to secure issuance of the '015 patent were expressly incorporated into prosecution of the '564 application, upon which the 268 patent is based; therefore, the prosecution history of the '015 patent is relevant to interpretation of the claim language in the 268 patent. Bayer Br. at 14; Inverness Br. at 23-24, 24 n.13.

In contrast, Roche argues that the claim language, the specification and the prosecution history support a construction of the "substantially completed" limitation requiring the reaction to proceed substantially to completion "only in that portion of the sample in which the reagents have dissolved before the potential is applied." Roche Reply, at 6. In other words, the reaction must proceed substantially to completion "in the relevant region." Roche Resp. at 9. Roche avers that this construction is supported by the language of claim 1, which requires the oxidant and buffer to reconstitute in the sample fluid. Id. at 6-7. In addition, Roche argues that the specification provides that the reaction takes place in a "'reagent layer' which contains the reconstituted or dissolved reagents." Id. at 8 (citing 268 Patent, col. 7, ll. 12-25; id. col. 7, ll. 29-31; id. col. 12, ll. 28-32). Further, Roche states that the reaction must only go substantially to completion in a fixed amount of the sample, not the entire sample, because the method must operate independently of sample volume. Id. at 10-11. Roche also argues that the prosecution history of the '015 patent is irrelevant to construction of the "substantially completed" limitation in the 268 patent because the claim limitations are completely different. Id. at 3-6; Roche Reply, at 11-14. Finally, Roche argues that the extrinsic evidence supports its claim construction that the reaction may proceed only where there are reactants.

The Court finds that in the context of the 268 patent claims, specification and prosecution history, the reaction must proceed "substantially to completion" in the entire sample. Starting with the language of the independent claims, the Court finds no language that indicates the reaction goes substantially to completion in only a portion of the sample or in only a reagent layer. Claim 1 states that the method provides for a "measuring cell" into which "a sample of fluid" is placed, then an oxidant and buffer is "reconstituted . . . with said sample fluid to generate a predetermined reaction." 268 Patent, col. 13, ll. 59-65. Once the reaction has proceeded substantially to completion, "a potential is applied across said electrodes and sample." Id. col. 14, l. 1. These references in claim 1 support a finding that the reaction takes place throughout the sample because there is no limitation on where the potential is applied or where the predetermined reaction takes place.

Similarly, claim 12 teaches "adding [a] blood sample to an electrochemical cell that includes an electron transfer agent that will react in a reaction involving the analyte, thereby forming a detectable species[,]" then "incubating the reaction involving the analyte and electron transfer agent." Id. col. 14, ll. 54-60. There is no suggestion in this claim that the incubated reaction occurs only in a small portion of the sample that was added to the cell. The language in independent claims 30, 33, 37, 38 use similar language to claim 12. See id. col. 15, ll. 63-67 to col. 16, ll. 1-6; id. col. 16, ll. 23-33; id. col. 16, ll. 53-65; id. col. 17, ll. 9-21. The language in independent claims 43 and 47 is slightly different. Those claims read in pertinent part:

43. A method for measuring the amount of a selected compound in a blood sample, comprising:

providing a measuring cell having at least first and second electrodes for contact with the blood sample introduced into the cell,

* * *

placing the blood sample into the cell,

* * *

selectively oxidizing the compound in the blood sample with an oxidized electron acceptor to produce an oxidized form of the selected compound and a reduced electron acceptor, and

re-applying a potential across the cell electrodes after the selective oxidation of the compound in the blood sample has

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substantially completed . . . .

* * *

47. A method for measuring the amount of glucose in blood, comprising: providing a measuring cell with at least first ant second electrodes for contact with blood introduced into the cell,

* * *

placing a volume of blood into the cell,

* * *

oxidizing the glucose in the blood with an oxidized electron acceptor in the presence of glucose oxidase to produce gluconic acid and a reduced electron acceptor,

re-applying a potential across the measuring cell electrodes after the oxidation of glucose has substantially completed, . . .

Id. col. 17, ll. 47-53 to col. 18, ll. 1-46. The first step in these methods suggests that there is some area of the blood sample that contacts the electrodes, but some that does not, which could lead to an inference that the relevant area is that closest to the electrodes. However, the remainder of the claim language is not limiting. Particularly in claim 43, the language describing where the oxidation reaction is occurring is broad because it refers to "selectively oxidizing the compound in the blood sample" and "re-applying a potential across the cell electrodes after the selective oxidation of the compound in the blood sample has substantially completed . . . ." Id. col. 18, ll. 4-11. This claim language talks about the reaction occurring in the entire sample, not just the portion of the sample nearest the electrodes.

The remaining language in claim 47 is no less broad. That claim teaches "placing a volume of blood into the cell" and "oxidizing the glucose in the blood," then "re-applying a potential across the measuring cell electrodes after the oxidation of glucose has substantially completed . . . ." Id. col. 18, ll. 36-46. This claim does not refer to oxidizing the blood closest to the electrodes; it teaches "oxidizing the glucose in the blood." Id. col. 18, ll. 40. In the context of the claim, "the blood" can only refer to the "volume of blood" that was earlier placed in the measuring cell. Id. col. 18, l. 36.

The Court also finds support for its conclusion that the language of the independent claims suggests a broader construction for where the reaction must be "substantially completed" than "near the electrode" or "in the reagent layer" in the language of some dependent claims. The only reference in the claim language to a reagent layer occurs in dependent claims 18, 20, 22, and 25. Claim 18, the most generic of the dependant claims, states: "The method of claim 12, wherein the electron transfer agent is included in a reagent layer that is coated directly onto the electrochemical cell or is incorporated into a supporting matrix that is placed into the electrochemical cell." Id. col. 15, ll. 16-20. Later dependent claims describe further limitations on claim 18; only some reference the reagent layer specifically. See, e.g., id. col. 15, ll. 21-23 ("The method of claim 18, wherein the supporting matrix is filter paper, membrane filter, woven fabric, or nonwoven fabric."); id. col. 15, ll. 24-25 ("The method of claim 18, wherein the reagent layer further includes a binder."); id. col. 15, ll. 26-28 ("The method of claim 20, wherein the binder is gelatin, carrageenan, methylcellulose, polyvinyl alcohol, or polyvinylpyrrolidone."); id. col. 15, ll. 29-30 ("The method of claim 21, wherein a dispersing; spreading, or wicking layer overlays the reagent layer."); id. col. 15, ll. 31-34 ("The method of claim 18, wherein adding the blood sample to the electrochemical cell causes a sudden charging current, which automatically initiates incubation step b) performed under open circuit."); id. col. 15, ll. 37-40 ("The method of claim 24, wherein the reagent layer further includes an enzyme catalyst in sufficient amount to catalyze the reaction involving the analyte and the electron transfer agent."). Arguably, in the method of claim 18, the reaction could only take place in the reagent layer or the supporting matrix; therefore it would only require the reaction to proceed "substantially to completion" in the part of the sample that was adsorbed by or was close to that layer. However, nothing in the 268 patent claim language incorporates this concept into the independent claims. The Court will not import an inferred limitation from a dependent claim into the independent claims.

The Court notes that the independent claim limitations are incorporated into the dependent claims by definition. See Robotic Vision Sys., Inc. v. View Eng'g, 189 F.3d 1370, 1376 (7th Cir. 1999) (citing 35 U.S.C. § 112). Therefore, the construction of "substantially to completion" cannot exclude the possibility of a limitation in a dependent claim. Moreover, "a claim

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interpretation that would exclude the inventor's device [or preferred embodiment] is rarely the correct interpretation; such an interpretation requires highly persuasive evidentiary support . . . ." Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996), cert. denied, 518 U.S. 1005, overruled on other grounds, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 574 (Fed. Cir. 2000). A construction for the substantially completed limitation in the 268 patent that requires a reaction in the entire sample might violate the first maxim and would violate the second. The Court, then, must determine whether the specification or the prosecution history provide "highly persuasive evidentiary support" for the defendants' proposed construction that the reaction must proceed substantially to completion in the entire sample.

The references in the specification to where the reaction in the 268 patent must be "substantially completed" support a construction that refers to a test area that is defined by the measuring cell. One simple reference to the "sample" suggests that the oxidation reaction occurs in the entire sample contained within the sample cell. The patent reads: "In the oxidation reaction, a sample containing glucose, for example, is converted to gluconic acid and a reduction of the oxidant. This chemical oxidation reaction has been found to precede [sic] to completion . . . ." Id. col. 3, ll. 27-30.

Other references indicate that the sample cell itself provides the means for determining the test site, but do not disclose the shape or region of that area. The specification states that one of the purposes of the invention is to provide "reproducible output from sensor to sensor . . . ." Id. col. 2, ll. 63-64. The specification then states that the invention addresses this requirement "by providing miniaturized disposable electroanalytic sample cells for precise micro-aliquote [sic] sampling . . . ." Id. col. 2, ll. 66-67 to col. 3, l. 1. This phrase implies that the disposable cells control the sample size, even if it is a fraction or aliquot of the amount of sample available. Further, the patent teaches that the disposable cell is preferably laminated layers of plastic with an opening "designed to provide the sample containing area or cell for the precise measurement of the sample." This language would not require the area in which the reaction would proceed "substantially to completion" to be the entire sample available, merely the amount of sample contained in the "sample containing area" or "sample containing . . . cell." Both of these references suggest that the physical parameters of the "measuring cell" defines where the reaction in the method takes place.

Later references also suggest that the "measuring cell" itself provides the means for controlling sample size. The patent reads: "The sample cell according to the [] present invention, provides the testing of controlled volumes of blood without premeasuring. Insertion of the sample cell into the apparatus thus permits automatic functioning and timing of the reaction allowing for patient self-testing with a very high degree of precision and accuracy." Id. col. 4, ll. 3-9 (omission and emphasis in original). Further, in briefly describing the preferred embodiment with respect to glucose, the specification provides that "the sample cell of the invention is used to control the sampling volume and reaction media and acts as the electrochemical sensor." Id. col. 4, ll. 15-18. And, "sample cell 20 is a metallized plastic substrate having a specifically-sized opening 21 which defines a volumetric well 21, when the cell is assembled, for containing a reagent pad and the blood to be analyzed." Id. col. 5, ll. 45-49. See also id. col. 6, ll. 38-43 (describing an alternative embodiment of a sample cell in which "opening 121 is dimensioned to contain the sample for testing"). The patent specification specifically allows for adding reagents to the sample rather than adding a sample to the reagents. The patent reads:

In this embodiment, after a sample has been positioned within well 21, cell 20 is pushed into window 19 of the front panel to initiate testing. In this embodiment, a reagent may be applied to well 21, or, preferably, a pad of dry reagent is positioned therein and a sample (drop) of blood is placed into the well 21 containing the reagent.

Id. col. 6, ll. 31-37. Again, this suggests that the "measuring cell" itself is used to ensure the proper sample size or volume for the reaction.

The 268 patent specification discloses a reagent layer in the context of the preferred embodiments of the invention. With respect to the preferred embodiment for glucose monitoring, the specification teaches:

[]To fully take advantage of the above apparatus, the needed chemistry for the sell [sic] testing systems is incorporated into a dry reagent layer that is positioned onto the disposable cell creating a complete sensor for the intended analyte. . . . The reagent layer is either directly coated onto the cell or preferably incorporated (coated) into a supporting matrix such as filter paper, membrane filter, woven fabric or non-woven fabric, which is then placed into the cell. When a supporting matrix is used, its pore size and void volume can be adjusted to provide the desired precision and mechanical support. . . . The coating formulation generally includes a binder . . . that acts to delay the dissolution of the reagents until the reagent

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layer has absorbed most of the fluid from the sample. . . .

The reagent layer imbibes a fixed amount of the sample fluid when it is applied to the surface of the layer thus eliminating the need for premeasurement of sample volume. . . . While the fluid sample could be applied directly to the surface of the reagent layer, to facilitate spread of blood across the entire surface of the reagent layer the sensor preferably includes a dispersing spreading or wicking layer. This layer, generally a non-woven fabric or adsorbant [sic] paper, is positioned over the reagent layer and acts to rapidly distribute the blood over the reagent layer.

Id. col. 7, ll. 6-42 (omission and emphasis in original). The description of the preferred embodiment for measurement of cholesterol uses a similar description. It states: "The concentrations provided are [] those of the solutions which are coated onto porous supports, filter paper or membranes; [] those concentrations are reestablished when the membrane imbibes the serum or whole blood specimen." Id. col. 12, ll. 28-32. The common definition of "imbibes" is absorb. WEBSTER'S UNABRIDGED, at 1128. The description for the glucose preferred embodiment specifies that only a fixed portion of the sample fluid is absorbed by the reagent layer because such a method ensures that one of the objects of the invention, to eliminate user error due to sample size inaccuracy or inconsistency, is achieved. The "imbibes the . . . specimen" language in the description of the cholesterol preferred embodiment suggests the same concept of absorption of the sample fluid in some amount; however, it is not as specific about whether the amount is a portion of or the whole of the sample fluid. These descriptions indicate that the "substantially completed" limitation could occur in something less than the entire sample. However, the area is still defined by the test area of the measuring cell, albeit here, the test area of the measuring cell is the reagent layer.

Analysis of the specification points to a construction of the substantially completed limitation that allows for the reaction to occur in less than the entire sample. Perhaps most persuasive of this point is the description of the preferred embodiment for glucose testing that discloses the use of a reagent layer that "imbibes a fixed amount of the sample fluid." See 268 Patent, col. 7, ll. 29-30. In context, a fixed amount is less than the entire sample. Moreover, a construction of "substantially completed" that would exclude the preferred embodiment is rarely correct. See Modine Mfg., 75 F.3d at 1550. Here, adopting the defendants' construction, that the reaction must proceed substantially to completion in the entire sample, would exclude the preferred embodiment described in the specification for glucose. The defendants primarily rely upon prosecution history for their position that the reaction must occur in the entire sample. Therefore, the Court now turns to the merits of those arguments.

Both Bayer and Inverness argue that the inventors specifically claimed that the reaction must go "substantially to completion" in the entire well volume during prosecution of the 268 patent's parent, the '015 patent. See, e.g., Bayer Br. at 11-13 (citing Joint App. at A18, A34-42, C43, C63, B276-78, B280, B284). The '015 patent and the 268 patent have identical specifications. Compare Defs.' Joint App. at 33-46 ('015 patent specification) to id. at 1-15 (268 patent specification). In addition, claim 1 of the 268 patent originally appeared as claim 1 of the application that matured into the '015 patent, but apparently was withdrawn (along with other method claims) pursuant to the PTO's request under 35 U.S.C. § 121. See Defs.' Joint App. at B71; id. at 108. The defendants focus on what the inventors argued once the method claims were severed from the apparatus claims. Specifically, with reference to what was prosecuted as claims 5 and 12 of the '015 patent application (claims 1 and 2, respectively, in the '015 patent as issued), the inventors distinguished their invention from prior art stating:

By way of summary, Claim 5, as amended, is an independent claim directed towards a sample cell for determining the concentration of a selected compound in a sample aqueous fluid. . . . The opening [therein] forms a well to receive the sample aqueous fluid and to place the fluid in the known electrode area in contact with the first and second electrode, whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction.

* * *

Claim 12, as amended, is an independent claim directed towards the overall apparatus for measuring compounds in a sample aqueous fluid. This apparatus includes the sample cell of Claim 5. . . .

* * *

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In addition, Applicants' device entirely eliminates the need for a diffusion limiting layer. Diffusion limiting layers are typically used for kinetic measurements and they are analogous to membranes used in an enzyme electrode. Applicants device eliminates this need entirely because it is not a kinetic measurement device. Instead the Cottrell current, as claimed in Claim 12, is what is being measured. As claimed in Claim 5, substantially the entire contents of the well of sample fluid can be reacted simultaneously. This is not true with a sensor which has a diffusion limiting layers [sic].

* * *

[In U.S. Patent No. 4,579,643 and U.S. Patent No. 4,655,901, both to Mase et al. (prior art patents),] the diffusion limiting layer determines the rate at which the gas reaches the electrode. In contrast, Applicants['] cell as claimed in Claim 5 is not rate limited and Applicants['] device eliminates the need for a diffusion limiting layer or membrane. The entire well volume, i.e. [sic] the entire sample, is reacted in Applicants['] device as claimed in Claim 5 and measured using a Cottrell current rather than a steady state signal.

* * *

Applicants have developed a unique apparatus for measuring the Cottrell current in which the entire well volume, i.e. the entire sample, is reacted and measured.

Def.'s Joint App. at B275-78. Amended claim 5, as referred to above, reads:

5. (Twice Amended) A sample cell for determining the concentration of a selected compound in a sample aqueous fluid, comprising

a metallized first electrode which acts as a working electrode,

a metallized second electrode which acts as a reference electrode, said second electrode being operatively associated with said first electrode, and

at least one non-conducting layer member having an opening therethrough [sic], said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrodes to form a known electrode area within said opening such that said opening forms a well to receive said sample aqueous fluid and to place said fluid in said know electrode area in contact with said first electrode and second electrode, whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction.

Def.'s Joint App. at B269-70 (emphasis in original to indicate amendments). Clearly, the inventors specifically limited the invention in the '015 patent to a cell in which the "entire contents of said well" is reacted. Id. at B270. Such a limitation would have been convincing evidence that the inventors intended to exclude the preferred embodiment described in the specification of the '015 patent. See Modine Mfg., 75 F.3d at 1550 ("Indeed, a claim interpretation that would exclude the inventor's device is rarely the correct interpretation; such an interpretation requires highly persuasive evidentiary support . . . .").

Bayer and Inverness argue that the 268 patent must also be construed to have this limitation because the 268 patent issued from a division of the '015 patent's original application, the two patents contain nearly identical specifications, the inventors expressly incorporated the prosecution history of the '015 patent into that of the '564 patent (parent of the 268 patent), the patent examiner issued the '015 patent and the '564 patent for essentially identical reasons, and the 268 patent contains the substantially completed limitation in all but claim 1 in response to the examiner's rejection of those claims without the limitation. But, Roche argues, the language of the '015 patent's claim 1 (prosecuted as claim 5) is not identical to that of the 268 patent. Further, the '015 patent does not contain the substantially completed limitation. Therefore, Roche concludes, the prosecution history of the '015 patent cannot limit the term in the 268 patent.

The Court agrees in large part with the defendants that the evidence establishes the relevance of the '015 patent's prosecution history to the claims of the 268 patent. The Federal Circuit states that "the prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit." 3 Advanced Cardiovascular Sys. v.

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Medtronic, Inc., 265 F.3d 1294 (Fed. Cir. 2001). See also Watts v. XL Sys., Inc., 232 F.3d 877, 884 (Fed. Cir. 2000) (citing Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995)). The focus is on whether the same claim limitation appears in the parent and the subsequent patents. See Elkay Mfg., 192 F.3d at 980. Apparently, however, the language of the claim limitation need not be identical. See Builders Concrete v. Bremerton Concrete Prods., 757 F.2d 255, 259-60 (Fed. Cir. 1985); see also Modine Mfg., 75 F.3d at 1551 ("It is incorrect to construe a claim as encompassing the scope that was relinquished in order to obtain allowance of another claim, despite a difference in the words used.").

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3 The Court notes that the Federal Circuit's use of the phrase "for example" implies that there may be other reasons why the prosecution history of a related patent is relevant to claim construction. Moreover, "the rules of construction must be understood in terms of the factual situations that produce them and applied in fidelity to their origins." Modine Mfg., 75 F.3d at 1551.

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At the outset, the Court finds a time line of the pertinent events in the history of the 268 patent important. Application serial number 07/322,598 ("'598 application"), which matured into the '015 patent, was filed on March 13, 1989. Defs.' Joint App. at B2. A preliminary amendment filed June 13, 1990, amended claims 1 and 5 of the '598 application as follows:

1. (Amended) A method for measuring the amount of a selected body compound in body fluids comprising,

a) [placing a sample of fluid to be tested in a sample] providing a measuring cell having at least a first and second electrode and said cell containing an oxidant and a buffer;

b) placing a sample of fluid to be tested in said cell,

[b. mixing said sample with an oxidant and a buffer;]

c) reconstituting said oxidant and buffer with said sample fluid to generate a predetermined reaction,

d) allowing said reaction to proceed substantially to completion,

[c.] e) applying a potential across said electrodes and sample; and

[d.] f) measuring the resultant Cottrell current to determine the concentration of said select compound present in said sample.

* * *

5. (Amended) A sample cell for determining the concentration of a selected compound in a sample fluid, comprising

[a. first and second nonconductive substrates, said first substrate having an opening therethrough [sic];]

[b.] a metallized first electrode which acts as a working electrode, [positioned on one of said second substrate; and]

[c.] a metallized second electrode which acts as a reference electrode, said second electrode being operatively associated with said first electrode, and [a second electrode positioned on said first electrode, whereby said first electrode is positioned over a portion of said second electrode to form a laminate with said first and second electrodes positioned therebetween [sic] and said opening exposing said electrodes to define a sample well.]

at least one non-conducting layer member having an opening therethrough [sic], said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrode to form a known electrode area within said opening such that said opening forms a well to receive said sample

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fluid and to place said fluid in said known electrode area in contact with said first electrode and second electrode.

Id. at B71-72. Although the file history appears incomplete on this issue, 4 on or about March 1, 1991, the PTO ordered the restriction of the '598 application pursuant to 35 U.S.C. § 121, to either the method claims, of which claim 1 was a part, or the apparatus claims, of which claim 5 was a part. See id. at B108. The patent examiner stated that the method and apparatus claims were distinct because the method could "be performed by a materially different apparatus such as a crystal oscillator for measuring substances within a body fluid." Id. The inventors elected to pursue the apparatus claims under the '598 application. Id.

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4 The file is obviously incomplete at this point because the document referenced here is numbered page 2, but no page 1 appears in the file. Several documents in the file history are missing pages and/or are not dated or signed. In addition, some documents have their multiple pages separated by other complete documents.

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Shortly thereafter, on April 12, 1991, the PTO wrote an office action that was apparently mailed on May 7, 1991. See id. at B109-14. In it, the examiner rejected claims 5 and 12 of the '598 application, under 35 U.S.C. § 103, the statute for obviousness, in light of Mase et al. The examiner stated: "Mase et al [sic] teaches a sample cell with first and second metallized electrodes mutually associated with said layer members sealed against at least one electrode and forms a well to receive sample." Id. at B111.

The divisional application containing the method claims from the '598 application was filed on August 15, 1991, application serial number 07/745,544 (the "divisional application"); this application matured into the '564 patent. Defs.' Joint App. at C2. Claim 1 of the divisional application was identical to the original, unamended claim 1 of the '598 application. See id. at C43. Contemporaneously with the divisional application, the inventors filed a preliminary amendment that added the substantially to completion limitation to claim 1 in the same way that the preliminary amendment to the '598 application had added it. Compare id. at B71, to id. at C63.

On September 6, 1991, the inventors filed the amendment to the '598 application in which they modified claim 5 by limitation to a cell "whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction." Defs.' Joint App. at B270.

Apparently, a telephone conversation between the inventors' attorney and the examiner for both the '598 application and the divisional application occurred on October 23, 1991, although there is no formal record of the conversation by the examiner. See id. at C68 & C101. 5 The conversation is referenced in an amendment to the divisional application filed November 11, 1991. See id. at C68 & C101.

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5 There are two copies of the amendment filed on November 11, 1991. It appears from the file that the one copy was an attachment to a fax, to which the inventors' attorney expected a response from the PTO examiner. See Defs.' Joint App. at C67. Only one copy is signed. See id. at C73.

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It is this amendment that the defendants claim expressly incorporates the prosecution history of the '015 patent into the '564 patent history. The amendment states in pertinent part:

This Amendment is in response to a request from the Examiner to amend the subject case, thereby placing it in condition for allowance. In a telephone conference on October 23, 1991, between the Examiner in the above case, Mr. Bell, and attorney for Applicants, Michael J. Kline, the Examiner sated that the parent case, S.N. 07/322,598 was allowable as is, and that a Notice of Allowance would issue shortly in that case. The Examiner further requested that the subject divisional case be amended to conform with amendments made in the parent case. In view of these conforming amendments, made herein,

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Applicants respect fully [sic] request early allowance of the subject case.

Please amend the above application as follows:

In the Specification:

* * *

All of the above amendments to the specification conform to amendments made in the parent case. The bases and reasons for the above amendments are adequately set forth in the remarks to the Preliminary Amendment, dated June 13, 1990, and the Amendment, dated September 6, 1991, both in the parent case, which remarks are incorporated by references as if set forth fully herein.

In the drawings:

* * *

In the Claims:

Kindly amend the claims as follows:

In Claim 18, line 13, change "Cattrell" to -- Cottrell -- .

Please add the following new claim:

22. The method of claim 1 wherein step b) said placing of the blood sample to be tested in the cell generates a current and initiates a timing sequence, and wherein the reaction of step d) is allowed to proceed with an open circuit between said first and second electrode.

Remarks

The amendments presented herein conform the subject case S.N. 07/745,544, to the parent case, S.N. 07/322,598. New claim 22 simply further limits allowable claim 1, requiring that the first and second electrode have an open circuit during step (d). Support for this new claim limitation is on page 10, lines 12-20, page 16, lines 5-11 and page 19, lines 18-21 and Figure 8 of the specification as filed. In view of these amendments, and the October 23, 1991 telephone conference with the Examiner, the Applicants respectfully request early allowance of the present case.

Id. at C68-73 (excluding page C72, filed out of order).

The examiner allowed the '598 application as the '015 patent on October 28, 1991. Id. at B297-98. The examiner allowed the divisional application as the '564 patent on November 20, 1991. The examiner's reasons for allowance of the two patent applications are remarkably similar. The text is set forth below in a side-by-side comparison.

'015 Patent Allowance	'564 Patent Allowance
The following is an Examiner's Statement of Reasons for Allowance: The references cited by the examiner fail to teach the key feature of the applicant [sic] invention which is a method for measuring the amount of a selected compound in body fluids whereby providing a measuring cell have [sic] at least two electrodes and the call [sic] contains an oxidant and a buffer. The method used places a sample of fluid in the cell whereby the oxidant and buffer are reconstituted with the	The following is an Examiner's Statement of Reasons for Allowance: The prior art cited by the examiner fails to teach the key feature of the applicants [sic] invention which is providing a measuring cell having at least two electrodes wherein the cell contains an oxidant and a buffer and a sample fluid is

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sample fluid to generate a reaction whereby the reaction proceeds to completion. A potential is applied across the electrodes and the resulting Cottrell current is measured to determine the concentration of the selected compound present in the sample solution. provide [sic] substantially to

introduced into the cell thereby reconstituting the oxidant and buffer with a sample fluid to generate a predetermined reaction and allowing the reaction to

completion; and applying a potential across the electrode and sample, then measuring the resulting Cottrell current to determine the concentration of selected [sic] compound present in the sample.
Defs.' Joint App. at C80.

Defs.' Joint App. at B298.

The examiner cited no prior art in the prosecution history on file for the '564 patent.

The same examiner reviewed Roche's reissue application, application serial number 08/679,312 ("'312 application"), filed July 12, 1996, that matured into the 268 patent. Defs.' Joint App. at D2. The '312 application sought to reissue claims 1-6 of the '564 patent, and added claims 12-48. Id. at D27-35. Claims 12-48 did not include the substantially completed limitation. In an office action mailed April 27, 1995, the examiner stated:

Claims 12-48 are rejected under the recapture rule of cancelled subject matter.

The applicants amended their claims to add the limitation that a buffer and oxidant were included in the cell and that the buffer and oxidant were reconstituted with the sample fluid. The limitation with respect to the reaction proceeding to completion or substantially to completion was also added. Applicant now has deleted these aspects from the claims rejected above and therefore, the recapture rule applies.

The amendment filed 12/30/93 is objected to under 35 U.S.C. § 132 because it introduced new matter into the specification. . . . The claims also contain new matter because the allowed claims were restricted to allowing the reaction to proceed to completion or substantially to completion before applying the potential across the electrodes and measuring the resulting Cottrell current and the claims presently do not restrict the reaction to having to come to completion.

Applicant is required to cancel the new matter in the response to this Office action. Id. at D110-11.

Roche tried to convince the examiner that the amendments he referenced for the substantially completed limitation were made voluntarily; therefore, the recapture rule did not apply. However, the examiner rejected its argument. He stated:

Applicants argue in their response that there is support for allowing the incubation reaction to proceed for a specified time period. However, this is not the issue. The issue is whether the applicant is trying to recapture material that was cancelled from the claims in the original application to obtain a patent. By not stating that the reaction has to come substantially to completion in the instant claims, applicant is in fact trying to recapture the cancelled material from the original application. Therefore, the examiner does maintain the rejection.

Id. at D143 & D183. See also id. at D215-16, Jan. 22, 1997 (rejecting the applicants' incomplete response to the prior office action and citing the substantially completed limitation again). Roche amended the claims to include the substantially completed limitation and the examiner allowed them as amended.

This history of the substantially completed limitation evidences that the patent examiner allowed the claims of the 268 patent over prior art because of the limitation. However, the only time the examiner cited prior art in reference to this limitation was in the parent application, the '598 application, which matured into the '015 patent. The Court is convinced that the examiner read the substantially completed element in the '564 patent (and the 268 patent by necessity) the same as

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the "substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction" element of the '015 patent.

A side-by-side comparison of the claims supports this conclusion.

'015 Patent Claim 1 Language	'268 Patent Claim 1 Language
A sample cell for determining the concentration of a selected compound in a sample aqueous fluid, comprising	a) providing a measuring cell . . . containing an oxidant and a buffer
a metallized first electrode which acts as a working electrode	having at least a first
a metalized second electrode which acts as a reference electrode, said second electrode being operatively associated with said first electrode, and	and a second electrode
at least one non-conducting layer member having an opening therethrough, said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrodes to form a known electrode area within said opening such that said opening forms a well to receive said sample aqueous fluid and to place said fluid in said known electrode area in contact with said first electrode and second electrode,	b) placing a sample of fluid to be tested into said cell
whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction,	c) reconstituting said oxidant and buffer with said sample fluid to generate a predetermined reaction,
	d) allowing said reaction to proceed substantially to completion

Claim 1 of the '015 patent discloses a sample cell in which a predetermined reaction substantially, simultaneously happens to substantially the entire contents of the well defined by the sample cell. Claim 1 of the 268 patent discloses a measuring cell in which a predetermined reaction proceeds substantially to completion. The Court finds these limitations to refer to the same concept as it is presented in the specification of both patents. In other words, in the context of the patents at issue, the claim limitations are the same. See Biovail Corp. v. Andrx Pharmaceuticals, Inc., 239 F.3d 1297, 1301-02 (applying a limitation from a parent patent's prosecution history to progeny, in part, because the term was used in the same context in both patents).

Other factors also persuade the Court that the prosecution history of the '015 patent is relevant to construction of the substantially completed limitation of the 268 patent. The timing of certain key events in the prosecution of the '015 and '564 patents evidences the close relationship between the two inventions. The divisional application, which matured into the '564 patent, was filed on August 15, 1991, complete with preliminary amendments that included the substantially completed limitation. The inventors' amendments to the '015 patent application that led to issuance of the '015 patent were filed on September 6, 1991. The telephone conference between the inventors' attorney and the examiner occurred on October 23, 1991, at which time the examiner indicated he would allow the '015 patent soon. The '015 patent issued on October 28, 1991.

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On November 13, 1991, the inventors filed amendments to the '564 patent application referencing the telephone conference with the examiner and conforming the application to that of the parent. The '564 patent issued a mere seven days later on November 20, 1991. The patent examiner issued the '564 patent approximately three months after it was filed. Further, he discussed the content of the '564 patent application with the inventors' attorney asking that it conform to the parent patent, so that he could issue it that quickly. The examiner clearly relied upon his understanding of the invention as disclosed to him during prosecution of the parent application, which issued as the '015 patent, when he issued the '564 patent so quickly. To find otherwise would ignore the presumptive integrity of the patenting process.

In addition, the patent examiner's statement of reasons for allowance of the '015 patent and the '564 patent are virtually identical. The statement for the '015 patent reads: "The method used places a sample fluid in the cell whereby the oxidant and buffer are reconstituted with the sample fluid to generate a reaction whereby the reaction proceeds to completion." Defs.' Joint App. at B298. The statement for the '564 patent reads: "[The] invention . . . is providing a measuring cell . . . wherein the cell contains an oxidant and a buffer and a sample fluid is introduced into the cell thereby reconstituting the oxidant and buffer with a sample fluid to generate a predetermined reaction and allowing the reaction to provide [sic] substantially to completion . . . ." Id. at C80. These statements evidence that the examiner found the substantive invention of the '015 apparatus patent and the '564 method patent identical. The statements also refer to the examiner's cited references or prior art. Compare id. at B298 (using "the references cited by examiner fail to teach the key feature . . ." language), with id. at C80 (using "the prior art cited by the examiner fails to teach the key feature . . ." language). But, the examiner never cited prior art in prosecution of the divisional application that matured into the '564 patent. The prior art he cited was discussed during prosecution of the '015 patent approximately two months earlier. The Court finds this strong evidence that the prosecution history of the '015 patent is relevant to construction of the '564 patent or its progeny, the 268 patent.

Further, although the Court is not persuaded that the language of the amendment to the divisional application expressly incorporates into the '564 patent history all of the prosecution history for the '015 patent, the amendment is strong evidence that the patent examiner allowed the '564 patent because it conformed to his understanding of the '015 patented invention. When the amendment to the divisional application was filed, the claims had already been amended in a preliminary amendment, thereby conforming them, in pertinent part, with those the patent examiner had seen in the earlier '015 patent application. The references in the amendment to the divisional application to a conversation with the patent examiner in which he expressed his interest in seeing the divisional application conform to that of the parent, is strong evidence that the examiner viewed the invention in the divisional application as the method version of the '015 patented invention.

Finally, the prosecution history of the 268 patent confirms this understanding of the parent patents. In the application for the 268 patent, only claim 1 (and its dependent claims by incorporation) as originally filed contained the substantially completed element; this claim is identical to claim 1 of the '564 patent. The examiner rejected the other claims, stating:

> [They] introduced new matter into the specification. . . . The claims also contain new matter because the allowed claims were restricted to allowing the reaction to proceed to completion or substantially to completion before applying the potential across the electrodes and measuring the resulting Cottrell current and the claims presently do not restrict the reaction to having to come to completion.

Id. at D110-11. Despite Roche's attempts to circumvent the patent examiner's reasoning, the examiner maintained the objection throughout prosecution of those claims. See id. at D143 & D183; id. at D215-16 (rejecting the applicants' incomplete response to the prior office action and citing the substantially completed limitation again). This series of rejections evidence that the patent examiner found the substantially completed element important for patentability of the original claims in the '564 patent. However, the only time the examiner and the inventors discussed that element was during prosecution of the original application that matured into the '015 patent.

The Court finds that the prosecution history of the '015 patent is relevant to construction of the substantially completed element of the 268 patent because that element appears in the '015 patent, albeit using different phrases, the patent examiner relied upon statements made during prosecution of the '015 patent in issuing the original claims of the 268 patent as the '564 patent, and the patent examiner maintained the objection to claims without that element during prosecution of the 268 patent. Although the Court is mindful that claim construction that excludes the preferred embodiment is rarely correct, the Court is convinced that the inventors limited the substantially completed element to overcome the PTO examiner's prior art objections. Therefore, the Court finds that the reaction must proceed substantially to completion in the entire sample.
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E. Claim Construction

The court conducted a Markman hearing on September 15, 1998. On November 5, 1998, the court issued its Markman opinion. The parties had disputed the meaning of four claim terms: 1) "pultrusion;" 2) "thermoformable;" 3) "substantially completely wetted;" and 4) "a composition containing at least 30% by weight of fibre reinforced pellets." Because RTP has challenged the court's construction of the term "substantially completely wetted" in its post-trial motions, the court will briefly review its findings regarding this limitation as presented in its Markman opinion.

During claim construction, the parties contested the meaning of the claim term "substantially completely wetted." LNP sought a claim construction that reflected the literal wording of the claims, and that did not refer to the flexural modulus test. LNP's proposed construction, which was largely adopted by the court, stated that "substantially completely wetted" meant that the filaments be "largely, but not necessarily wholly, surrounded by resin." As a measure to quantify the degree of wetting, LNP's proposed construction, as is recited in the claim language, recites use of the dispersal/length test.

RTP, on the other hand, sought to construe the term "substantially completely wetted" in reference to the flexural modulus test. RTP noted that the specification and the prosecution history of the patents in suit used the flexural modulus test to characterize the claimed plastics, and to distinguish them from products in the prior art. As such, RTP advocated incorporating language from the specification into the construction of the claims, and asserted that "substantially completely wetted" means the product must attain at least 90% of the theoretically attainable flexural modulus."

The court rejected RTP's proposed construction. The court reasoned that the flexural modulus test was only an indirect test that did not directly measure the characteristics of the claimed wetted strand and pellets. Moreover, the court found that the prosecution history of the patents did not compel a finding that the term "substantially completely wetted" is tied to the flexural modulus test. Thus, the court concluded that the term "substantially completely wetted" should be defined in terms of the dispersal/length test, as follows:

> Largely, but not necessarily wholly, surrounded by resin. In the context of LFRT pellets, it is surrounding the individual filaments by resin to the extent that in articles injection molded from such pellets, the individual filaments are randomly dispersed and at least 50% by weight of the filaments retain a length of 2 millimeters or greater.

LNP Engineering Plastics, Inc. v. Miller Waste Mills, Inc., No. 96-462 (D. Del. Nov. 5, 1998) (claim construction opinion).

* * *

A. Reconsideration of Claim Construction

RTP has moved for the court to reconsider its construction of the claim term "substantially completely wetted." RTP seeks reconsideration in two contexts. First, it asserts that the court should define the claim term in relation to the flexural modulus test for determining wettedness. RTP notes that the court's present construction, which defines wettedness in relation to the dispersal/length test, creates "an ever-changing definition of infringement." RTP argues that improvements in injection molding technology will permit LFRT pellets of poorer quality to yield molded products with sufficiently long and dispersed filaments. It is improper, RTP argues, to establish infringement criteria in relation to technology outside the scope of the patent claims.

RTP's second argument is that the court should reconstrue the claims of the '450 patent, as reexamined, and the '889 patent, as reexamined, and find that the claim term "substantially completely wetted" is a distinct claim limitation.

As a procedural matter, the court may reconsider a prior ruling in three circumstances: 1) where the court has patently misunderstood a party; 2) where the court has made a decision outside the adversarial issues presented to the court by the parties; or 3) where the court has made an error not of reasoning but of apprehension. Stairmaster Sports/Medical Products, Inc. v. Groupe Procycle, Inc., 25 F. Supp. 2d 270, 292 (D. Del. 1998). The issues presented to the court for reconsideration were directly addressed by the court in its Markman opinion. Because the court therein apprehended the arguments, and

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resolved them, there are no procedural grounds for reconsidering these issues in the present posture. For the benefit of the record, the court will consider the motion on its merits.

The challenged claims relate to LFRTs wherein the reinforcement filaments are "substantially completely wetted." To measure the degree of wettedness, the claims, as construed by the court, call for a determination of whether the filaments in the molded sample are randomly dispersed and sufficiently long. While this method may present complications by tying the threshold of infringement to the state of the art in injection molding technology, the same difficulties would be present if "substantially completely wetted" were measured in terms of the flexural modulus test. It was undisputed at trial that the flexural modulus test cannot be performed on a pellet. RTP's proposed construction thus requires that the strand or pellets be injection molded prior to analysis by the flexural modulus test. This measure of infringement would suffer from the same alleged deficiencies as the dispersal/length test.

Second, RTP asserts that the term "substantially completely wetted," as it appears in claim 1 of the '450 patent, as reexamined, and claim 1 of the '889 patent, as reexamined, should be a distinct claim limitation. RTP notes that both these patents, prior to being reexamined, recited the dispersal/length test as a means to determine the strength of the plastic, but that neither of the patents contained the claim term "substantially completely wetted." This term, RTP recognizes, was introduced into the claims during reexamination, with neither the '450 patent 3 nor the '889 patent 4 originally reciting this language. RTP reasons that the introduction of the term "substantially completely wetted" constitutes a further limitation upon the claims, and that this limitation serves to restrict the range of plastics covered by the claims. See Laitram Corporation v. NEC Corporation, 163 F.3d 1342, 1347 (Fed. Cir. 1998).

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3 Claim 1 of the '450 patent, as originally issued, reads:

1. Pellets of reinforced thermoplastics material containing at least 30% by volume of parallel, aligned reinforcing filaments between 2 and 100 mm in length, the filaments extending through the length of the pellets, the pellets having been cut from a continuous reinforced product prepared by melt protrusion and which pellets can be injection moulded into an article in which the fibres are present in the form of randomly dispersed individual filaments at least 50% by weight of the filaments of the pellets retaining a length of greater than 2 mm in the moulded article.

4 Claim 1 of the '889 patent, as originally issued, reads:

A molded article formed from a fibre reinforced thermoplastic composition in a process which includes the step of melting and homogenizing a composition containing at least 30% by weight of fiber reinforced pellets between 2 mm and 100 mm long which pelts have filaments extending the length of the pellet, characterized in that the molded article contains reinforcing filaments in the form of individual filaments and at least 50% by weight of the filaments in the pellets being present in the molded article at a length of greater than 2 mm, the pellets having been cut from a structure of continuous, parallel, aligned, reinforcing filaments which have been wetted by a molten

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The history of the reexamination of the patents indicates that the court's construction of the claims in question need not be amended. The file history of the '450 patent shows that the term "substantially completely wetted" was introduced into claim 1 not to distinguish the claim from the prior art, but to provide an antecedent basis for terms recited in claim 6 of the patent.

For the '889 patent, the file history indicates that the term "substantially completely wetted" was introduced to distinguish the claims from the prior art. The examiner found that the British GB-849 reference, and the JP-653 reference, anticipated claim 1, as originally issued. The applicant indicated that these references disclosed that the plastic products claimed therein suffered from a lack of adequate wetting of the reinforcement filaments. The applicant thus introduced the language "substantially completely" to modify the term "wetting" as originally recited. The added language serves to limit the scope of the claims to those plastics where the filaments are substantially completely wetted, and where the filaments are not bundled and loose, as characterized the referenced prior art products. The court's claim construction, which states that the filaments must be "largely, but not necessarily wholly, surrounded by resin," adequately reflects this structural limitation, and does not require reconstruction.

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For these reasons, RTP's motion for reconsideration of the court's claim construction is denied.
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4. "substantially crystalline form"

This phrase is found in claim 4. Plaintiff proposes the following construction of the terms in this phrase: "crystalline form" means "a compound having a repeating pattern of atoms or molecules of the constituent chemical species," and "substantially crystalline form" means "sufficient crystallinity present to permit further optical purification of the enantiomer if required." DRL asserts that the phrase "substantially crystalline form" means "almost entirely consisting of a solid in which the constituent molecules are arranged in an orderly, repeating pattern in all three special dimensions." Plaintiff's proposed definition of "crystalline form" is consistent with that of DRL. As DRL points out, "crystalline form" is a term that is widely understood by persons of ordinary skill in the art, and the definitions of this term proposed by both parties are consistent with this understanding. See, e.g., DRL Ex. 6, McGraw-Hill Dictionary of Scientific and Technical Terms at 390 (1984); Ex. 8, Hawley's Condensed Chemical Dictionary at 240 (1977).

The difference in the parties' construction centers on the term "substantially." DRL asserts that the term has no special meaning to one skilled in the art and, therefore, its ordinary, non-technical meaning should be applied. DRL's proposed construction, however, merely separates the terms in the phrase "substantially crystalline form" and defines each, with the resulting construction being the combination of those definitions. The proper question when making a claim construction determination is how the phrase would be understood by a person of ordinary skill in the art reading the patent. Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1119-20 (Fed. Cir. 2002) (the term "substantially" may serve to describe the subject matter so that its scope would be understood by persons in the field of the invention and to distinguish the claimed subject matter from the prior art).

Astra asserts that the specification of the '504 patent identifies to persons skilled in the art when a material is in substantially crystalline form. The specification shows that crystallization may be used to purify optically impure or partially pure salts of omeprazole enantiomers to achieve optically pure compounds. '504 patent, col. 3, lines 43-47. The examples further show the optical purification. See, e.g., examples 1 and 2, col. 6, line 36 to col. 7, line 10 (material purified from 94% ee to 99.8% ee); example 6, col. 8, lines 16-53 (material that is 49% crystalline purified from 80% ee to 98.4% ee); example 7, col. 8, line 54 to col. 9, line 30 (80% ee to approximately 99% ee). Consequently, a person skilled in the art would understand from the specification that the meaning of "substantially crystalline form" is consistent with Astra's proposed construction. The Court, therefore, shall construe the phrase to mean "sufficient crystallinity present to permit further optical purification of the enantiomer if required."
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1. "Substantially different charge"

Caliper proposes that the term "substantially different charge" be construed as: "a difference in electrical charge between the first reagent and the fluorescently labeled product of an amount sufficient to permit a non-specific and charge-dependent differential binding of the polyionic polymer with either the first reagent or the fluorescently labeled product."

MDC proposes: "the net charge on the product differs from that of the first reagent by an amount sufficient to permit the differential association (i.e., binding) of the substrate (i.e., first reagent) and product with a polyionic compound. It is the charge difference between the first reagent and product, not any structural differences, that is the basis for their differential association with a polyionic compound."

The term "substantially different charge" is used in the patents to describe the key difference between the original substrate (the first reagent) and the reaction product. The specification expressly defines the term: "As used herein, the phrase 'substantially different charge' means that the net charge on the product differs from that of the first reagent by an amount

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sufficient to permit the differential association of the substrate and product with a polyionic compound." ('774 Patent at 5:29-34.) The patent expressly defines the disputed term, and where the patentee "acted as his own lexicographer," and clearly set forth a definition of the disputed term in either the specification or the prosecution history, the Court will defer to that definition. See CCS Fitness, Inc., 288 F.3d at 1366. Accordingly, the Court adopts the express definition and construes the term "substantially different charge" as: the net charge on the product differs from that of the first reagent by an amount sufficient to permit the differential association of the substrate and product with a polyionic compound.

Caliper urges the Court to interpret the term "differential association" to mean "non-specific and charge-dependent binding"; MDC interprets the term to indicate merely "binding." MDC also urges the Court to adopt the further explanatory language for the term binding indicating that it is the charge difference, not any structural differences, that is the basis for the differential association. Thus, the crux of the argument concerns the disputed language "non-specific and charge-dependent binding" versus language indicating that it is the charge difference and not structural differences that is the basis for the binding.
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2. "substantially equal amounts"

Carlisle argues that the claim term "substantially equal amounts [of rubbery polymer and tackifier]" should be construed to mean "almost equal with a variation of only a few percent (i.e., 1-5%)." Carlisle argues that without a numerical limit on the relative proportions of rubbery polymer and tackifier, the claim would be indefinite, and therefore invalid.

Adco argues that the plain meaning of this term should control, or that it should be construed to mean "largely, but not wholly equal amounts." Adco argues that Carlisle has no support for its proposed numerical limitation, and that it would be improper to read such a limitation into the claims.

When a claim term is expressed in general descriptive words, it is generally improper to limit the term to a numerical range. See Renishaw, 158 F.3d at 1249; see also Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999) ("[A] court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms."). In this case, Carlisle proposes limiting the term "substantially equal" to a numerical range of "almost equal with a variation of only a few percent (i.e., 1-5%)." The court identifies no support in the specification for imposition of this numerical limit on the claim language. The claim term "substantially equal amounts" is sufficiently clear that no additional construction is necessary.
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(2) Claim 4 Construction

Claim 4 repeats the description of the pharmaceutical composition from claim 1 and adds that "upon oral ingestion, maximum peak concentrations of the erythromycin derivative are lower than those produced by an immediate release pharmaceutical composition, and AUC and the minimum plasma concentration are substantially equivalent to that of the immediate release pharmaceutical composition." '718 patent, at col. 11:ll. 48-58.

This means that the concentration-time curve representing the concentration of drug in blood plasma will be flatter and lower for the extended release formulation than for the immediate release formulation, but will have an AUC that is substantially equivalent to that of its immediate release corollary. At the same time, the minimum plasma concentration for the extended release formulation will be substantially the same as that of the immediate release formulation, meaning that the drug will be present in the blood at the same minimum level at all times for both the immediate release and extended release formulations.

The parties disagree as to the proper construction of the term "substantially equivalent to that of the immediate release composition" with regard to Cmin values in this claim. Sandoz argues that it should be construed to encompass the FDA

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definition of bioequivalence (measured by the use of 90% confidence levels) as applied to the term "bioavailability" in claim 1. Abbott argues that here "substantially equivalent" with respect to Cmin values simply means not statistically significantly different. Abbott responds that FDA guidance does not call for bioequivalence in terms of Cmin values, only in overall AUC values and usually in respect to Cmax values. What is persuasive here is that Abbott provides evidence showing that Sandoz's definition of "substantially equivalent" in this claim would exclude Abbott's own preferred embodiments from the scope of claim 4 if the 90% confidence levels advised by the FDA. A claim construction that excludes preferred embodiments from the scope of the claim "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp.. 90 F.3d at 1583. Sandoz lacks such support. Indeed, in discussing the comparison of Cmin values of the claimed formulation versus the immediate release formulation, only statistical significance is discussed, not the use of the FDA guidelined bioequivalent 90% confidence levels.
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(1) "C-min substantially equivalent to"

The parties disagree as to the proper construction of the term "substantially equivalent to that of the immediate release composition" with regard to C-min values in claim 4. Sandoz argues that it should be construed to encompass the FDA definition of bioequivalence (measured by the use of 90% confidence levels) as applied to the term "bioavailability" in claim 1. In support of its contention, Sandoz asserts that the same words in one portion of a patent's claims should be accorded the same meaning. Fin Control Systems Pty, Ltd. v. OAM Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001). Abbott argues that here "substantially equivalent" with respect to C-min values simply means not "statistically significantly different". It points out that FDA guidance does not call for bioequivalence in terms of C-min values, only in overall AUC values and usually in respect to C-max values.

Like many of the other principles and presumptions utilized in claim construction, the principle of same words/same meaning is rebuttable when it is clear from the specification and the prosecution history that the words have different meanings at different appearances in the claims. Id. In the preliminary injunction hearing, this Court concluded Abbott's construction was more appropriate because the Court was persuaded that Sandoz's definition of "substantially equivalent" in this claim would exclude Abbott's own preferred embodiments from the scope of claim 4 if the 90% confidence levels advised by the FDA were applied. A claim construction that excludes preferred embodiments from the scope of the claim "is rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics Corp., 90 F.3d at 1583. The Sandoz construction lacked such support. Indeed, in discussing the comparison of C-min values of the claimed formulation versus the immediate release formulation, only statistical significance is discussed in general, not the use of the FDA guidelined bioequivalent 90% confidence levels. Therefore, the Court concludes that here, "substantially equivalent to" means not different than; it does not mean "bioequivalent as measured by the use of 90% confidence levels" nor does it mean "not statistically significantly different." The plain and ordinary meaning of the term "statistically significantly" means mathematically consistent to varying degrees of probability, not merely aberrational or subject to chance. Abbott uses the term "statistically significantly" elsewhere but not here, implying that when the drafters meant "statistically significantly" they incorporated the term.
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1) What is the meaning of the phrase "substantially free"?

In their post-trial briefs, plaintiffs argue that the court should have given the jury some explanation of the phrase "substantially free," but they fail to offer any alternative construction. Based on plaintiffs' arguments before and at trial, the court assumes that plaintiffs seek to establish that "substantially free of mature lymphoid and myeloid cells" means at least 85-90% purity. The court is reluctant to impose mathematical certainty on an ambiguous term when a patent applicant has strenuously avoided doing so. See Johns Hopkins University, 894 F. Supp. at 827. The parties appear to agree, however, that the cell suspension required by the claims of the '680, '994, and '144 patents must contain no more than 10% mature lymphoid and myeloid cells. Moreover, this construction is consistent with the specification and the expert testimony offered at trial.

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Although the specification does not provide a specific percentage required for a cell suspension to be "substantially free," it does give a reference by which one skilled in the art could ascertain such a percentage. The specification states at column 3, lines 62-67:

Various assay techniques have been employed to test for the presence of the My-10 antigen, and those techniques have not detected any appreciable number (i.e. not significantly above background) of normal, mature human myeloid and lymphoid cells in My-10-positive populations.

In a deposition offered in connection with plaintiffs' motion for summary judgment before trial, Civin testified that a person of ordinary skill in the art would interpret the phrase "substantially free" in light of the practical limitations of the separation technique taught, which is the FACS method. He further testified that the FACS method would produce a cell population of 85-90% purity. This is consistent with the disclosure of a stem cell suspension of 90% purity in Table 9 of the specification.

At trial, experts for both plaintiffs and CellPro confirmed Civin's testimony. In response to cross-examination by CellPro on the meaning of the term "substantially free," plaintiffs' expert Griffin stated that "Let's say that everything over 10 [percent] would be outside that range. On direct examination on the issue of the meaning of the phrase "substantially free," CellPro's expert Dr. Kenneth D. Shortman testified:
Well, in my laboratory, it -- it would mean 97-percent-plus pure, I have to say. We seem to have --I have a bit of a lack standard here and everyone seems to have agreed around 10 percent... Obviously, there's going to be a range of interpretations here, but I think 10 percent is the -- the bottom end.

Shortman is a Senior Principal Research Fellow with the National Health and Medical Council in Australia and the head of a research unit called the Lymphocyte Differentiation Unit. Therefore, the court will construe the phrase "substantially free" to require a cell suspension of at least 90% purity. In other words, the cell suspension must contain no more than 10% mature lymphoid and myeloid cells.
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1. Claim Construction and Infringement

CellPro asserts that the district court's construction of the "substantially free" limitation to require no more than 10% mature cells was in error. Instead CellPro believes that this limitation should be construed to mean an immeasurable amount of mature cells. Accordingly, CellPro contends that JMOL of infringement was erroneously granted, because cell suspensions produced by its technique and equipment contained measurable amounts of mature cells numbering in the "millions."

To support its claim construction, CellPro points to the prosecution history of the '680 patent, which progressed in relevant part as follows: The examiner rejected the claims as anticipated by two prior art publications by Bodger et al. The applicant responded by noting that Bodger's antibodies could not be used to produce a cell suspension that was "substantially free" of mature cells as required by the claim language. The examiner was not persuaded and noted that "the metes and bounds of 'substantially free' have not been established" by the applicant, to which the applicant responded:

"Substantially free" is defined by its plain meaning and further by the stated characteristics of the anti-My-10 antibody . . . . At page 5, lines 27-31, of the specification [see '680 patent, col. 6, ll. 62-67] it is explicitly stated, "Various assay techniques have been employed to test for the presence of the My-10 antigen, and those techniques have not detected any appreciable number (i.e., not significantly above background) of normal, mature human myeloid and lymphoid cells in My-10-positive populations." For example, when My-10+ cells are incubated with a series of monoclonal antibodies which react with T-lymphocytes [i.e., a type of mature cell], no cells are found to be reactive. Thus, by the means presently available to the art, no T-lymphocytes are found in My-10+ cell populations.

(emphasis in original). n17 The applicant also noted that "Bodger's cell population has some T-cells present, but [that] the present invention has none," and therefore that Bodger's cell suspension would be ineffective in preventing GVHD.

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n17 CellPro also notes that the applicant referred to this purported definition of the words "substantially free" during the reexamination of the '680 patent, at which time the applicant was attempting to distinguish its claims over the Beverley reference. Because the relevant excerpts from the reexamination prosecution history are largely redundant with the prosecution history summarized above, we do not reiterate them here.

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Hopkins responds that the district court's claim construction was correct and was consistent with the intrinsic evidence. Hopkins notes that the specification, reflecting the imperfect state of the art and specifically the imperfect nature of cell separation techniques such as the FACS method, teaches that the disclosure concerning preparation of antibodies would enable the creation of only "relatively pure" stem cell suspensions. See '680 patent, col. 4, ll. 55. Hopkins asserts that the highest disclosed purity for a stem cell suspension created by the disclosed technique, viz. 90%, see '680 patent, col. 18, tbl. 9, should define the outer bounds of the words "substantially free." Hopkins argues that CellPro's proposed claim construction and citation from the prosecution history are inconsistent with Table 9, which describes small but measurable amounts of mature cells.

We agree with Hopkins that the district court's construction of the words "substantially free" was not in error. Table 9, the only disclosed embodiment of the claimed cell suspension, n18 is highly indicative of the scope of the claims. A patent claim should be construed to encompass at least one disclosed embodiment in the written description portion of the patent specification. This maxim flows from the statutory requirement that "the specification shall contain a written description of the invention," 35 U.S.C. § 112, P 1 (1994), which requires a patent applicant to disclose in the specification sufficient subject matter to support the breadth of his claim. See Specialty Composites v. Cabot Corp., 845 F.2d 981, 987, 6 U.S.P.Q.2D (BNA) 1601, 1604 (Fed. Cir. 1988) (noting that what is patented "is defined by the words in the claims if those claims are supported by the specification in the manner required by 35 U.S.C. § 112."); Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1219, 36 U.S.P.Q.2D (BNA) 1225, 1230-31 (Fed. Cir. 1995). A claim construction that does not encompass a disclosed embodiment is thus "rarely, if ever, correct and would require highly persuasive evidentiary support." Vitronics, 90 F.3d at 1583, 39 U.S.P.Q.2D (BNA) at 1578. Accordingly, CellPro's claim construction, that the cell suspension of the claims can contain only an immeasurable amount of mature cells, is undermined by Table 9 of the specification, which describes the only embodiment of the invention disclosed in the specification and discloses a cell suspension that contains 3% mature neutrophils, 6% mature monocytes, and 1% mature lymphocytes, all of which constitute measurable quantities of mature lymphoid cells. See '680 patent, col. 18, tbl. 9 n. * .

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n18 Hopkins intimates in its brief that the specification discloses other cell suspensions of lesser purities, but it has not specifically identified them and we do not find them in the specification.

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CellPro also notes that in response to the examiner's request to clarify the "metes and bounds" of the words "substantially free," the applicant, quoting the specification, noted that "various assay techniques have been employed to test for the presence of the My-10 antigen, and those techniques have not detected any appreciable number (i.e., not significantly above background) of normal, mature human myeloid and lymphoid cells in My-10-positive populations." However, this passage does not describe the purity of a cell suspension produced by the disclosed technique, but rather describes the various species of cells that are present in "My-10-positive populations," i.e., in populations which express the My-10 antigen. Thus, the quoted passage merely clarifies that a population of cells expressing the My-10 antigen contains no "appreciable number" of mature cells; it does not support the inference that such a population, when included with other mature cells and sorted according to the technique disclosed in the '680 patent, can be sorted to recover only My-10-positive cells. Not only is this inference directly contrary to the reality of the cell suspension disclosed in Table 9, but it is also contrary to the expert testimony at trial which established that sorting techniques such as FACS suffer from "practical limitations" and are capable of producing cell suspensions of only 85-90% purity, the upper value of which is consistent with the district court's construction. See Hopkins I, 931 F. Supp. at 318. Moreover, the record is silent concerning the expected background levels for mature cells in a sorted cell suspension. Thus, reference to "background level" sheds little light on the construction of the words "substantially free."

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CellPro next calls attention to the prosecution history in which the applicant notes that "when My-10+ cells are incubated with a series of monoclonal antibodies which react with T-lymphocytes, no cells are found to be reactive." Like the portion of the prosecution history cited above, this statement does not address the purity of a suspension produced by separation.

Finally, the applicant's statement that "Bodger's cell population has some T-cells present, but the present invention has none" does not support CellPro's proffered construction. That the inventive cell suspension might contain no (or an immeasurable amount of) T-cells does not mean that the cell suspension does not contain measurable amounts of other mature myeloid and lymphoid cells. Table 9 illustrates this point. Mature lymphocytes, of which T-cells are a subset, constituted a mere 1% of the stem cell suspension. However, other mature cells, including neutrophils (3%) and monocytes (6%), were also present in the suspension. See note 10, supra. In the end, it is unremarkable that the claims issued over Bodger, a reference which disclosed the use of an antibody that, unlike My-10, was specifically reactive with T-cells and consequently produced a cell suspension that was not substantially free of mature lymphoid cells. n19

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n19 Equally unremarkable is the confirmation of the patentability of the claims during reexamination over the Beverley reference, which the applicant and the examiner agreed were "significantly contaminated with small lymphocytes," including T-cells.

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Thus, none of the statements in the prosecution history that CellPro cites constitutes "highly persuasive" evidence to suggest that we should deviate from a claim construction that is required in order to encompass the only disclosed embodiment of a cell suspension in the '680 patent. We therefore affirm the district court's construction of the language "substantially free of mature lymphoid and myeloid cells" as requiring no more than 10% mature lymphoid and myeloid cells and its grant of JMOL in favor of Hopkins on the issue of literal infringement.
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Substantially free

Baker Hughes offers the construction "nearly all." ReedHycalog proposes "substantially devoid of catalyzing material, except that many, if not all, the surfaces of the adjacent diamond crystals may still have a coating of catalyzing material." At the hearing, ReedHycalog argued that its construction would "clarify for the jury they are not looking necessarily for something that is essentially clean; but that, in fact, many, if not all--as the phrase says--of the diamond crystals could, in fact, still have a coating on them." Hearing Transcript, 95:23-96:1. The parties then agreed that "substantially free" means "many, if not all." However, replacing "substantially free" in the claim language with "many, if not all" does make sense. Therefore, since the parties agreed during the hearing that the area that is substantially free of the catalyzing material may still contain some catalyzing material, the Court construes "substantially free" to mean "free of most, but not all, of the catalyzing material."
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Over the course of this prosecution history, Clement's claims were narrowed significantly.

Step A. Clement's initial claim called for early-stage pulping at "low temperature." Exhibit 2-29. In the Examiner's initial rejection, that term (along with others) was rejected as "too relative to be capable of any fixed meaning." Exhibit 2-57. Clement then amended it to "room temperature." Exhibit 2-61. He also changed the cleaning and screening step from "ambient temperature" to "room temperature." 4 The "room temperature" limitation was later added to the screening and cleaning step (Step B). Exhibit 2-224. Kamyr now argues that "room temperature" is a scientific term with a standard meaning and points out that, in the Kamyr process, the temperature at which the initial pulping, screening and cleaning

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processes are done is higher than the 20-25 degree Centigrade range normally considered to be room temperature. Clement responds that "room temperature" is not a defined term; that "so long as the temperature is not sufficiently high to melt the stickies, and is lower than the pulp temperature in the MDR disperser, the temperature is not critical;" and that any temperature in the Kamyr process within that range is at least subject to scrutiny by a jury under the doctrine of equivalents. 5

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4 The suggestion was made at oral argument that change from "ambient" to "room" temperature was made because "ambient" is a French word that was not fully understood by the Examiner.

5 Clement did not propose a jury instruction to implement his legal theory that "one must determine whether the temperatures are equivalent from the point of view of a stickie, not a human."

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Step B. The "primary reason" for the allowance of the '179 patent was Clement's limitation of his claims to distinguish his process from Burns:

"Burns clearly cleans non ink contaminants from his stock after the dispersal unit and flotation as well as before the dispersal unit whereas applicant cleans only before the disperser, which is claimed in step (b) via cleaning substantially all the non ink contaminants . . . ." Exhibit 2-276-7 (emphasis added).

It is not disputed that the Kamyr process removes most non-ink contaminants -- on the order of 97-98 percent -- at the initial stage, but Kamyr insists that removing "most" is not the equivalent of removing "substantially all." Kamyr urges that Clement's limitation to "substantially all" meant "all" and points out that the Kamyr process, unlike Clement's, screens and cleans downstream of Step B.

The prosecution history is instructive. Clement's amendment filed July 9, 1985, distinguishes his process from Ortner, pointing out that Ortner separates ink particles by chemical action, a "feeble and short mechanical action," and flotation, while in Clement's process "all the non-fibrous contaminants are separated at room temperature and before the thermo-chemi-mechanical treatment takes place . . . ." Exhibit 2-64-5. An examiner interview summary dated April 17, 1987, records the argument of Clement's representative that Burns "does not eliminate all non ink contaminants before the ink dispersing step" and his proposal of a claim "limited to removing all non ink contaminants before the disperser step" so that the second aqueous fibrous suspension would be "substantially free of non-ink contaminants. . . ." Exhibits 2-210-11. This change is reflected in handwritten notes on an amendment filed June 29, 1987, Exhibit 2-224, and argued at length in the "remarks" section of the same submission. Exhibits 2-227-9. The "fundamentally different" approach Clement claims is the removal of non-ink contaminants from the pulp before the deinking step, without dispersing them as finely divided particles throughout the first fibrous suspension:

"This is accomplished at relatively low temperatures through the application of mechanical energy. Once the non-ink contaminant are [sic] released from the surface of the fibers, they are removed from the first fibrous suspension substantially free of non-ink contaminants. When the second aqueous fibrous suspension reaches the kneader where the ink contaminants are removed from the pulp, the high temperatures required for this step of the process will not cause any 'stickies' to re-adhere to the surface of the fibers together with the ink contaminants, because no non-ink contaminants are present."

Again, in Clement's appeal brief filed September 30, 1987:

"The fundamental distinction between the Burns process and the present invention is that in the Burns process both the non-ink contaminants such as binders, hot melts, plastics and other 'stickies' and the ink-based contaminants are removed from the surface of the pulp fibers in the dispersal unit at the same time. In contradistinction, Applicant removes substantially all of the non-ink contaminants prior to the removal of the ink-based contaminants in the dispersal unit."

Steps C and D. In remarks accompanying his July 9, 1985 amendment, Clement was at pains to distinguish the "thermo-chemi-mechanical treatment" stage of his process from Eriksson, which, he argues,

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"does not teach the combined use of high temperature, intense mechanical energy and chemical action for a short period of time in order to prepare the . . . contaminants to be removed. As a matter of fact, the material is simply treated within a kneading apparatus (Frotapulper) and discharged at a final temperature of about 70-90 C, without the use of any chemical dispersing agent. Furthermore, [Eriksson] provides for the application of just one type of energy (mechanical), while the increase of the temperature is only due to the internal mechanical friction . . . ." Exhibit 2-67.

The "thermo-chemi-mechanical treatment" upon which Clement relies to avoid Eriksson (dispersal in a Frotapulper without added heat) is not part of the Kamyr's processes employ the Frotapulper after pulping, screening and cleaning, without the application of any heat source except the heat generated by mechanical energy, and without the simultaneous application of chemicals.

Step E. In his July 9, 1985, amendment, Clement limited his "thermo-chemi-mechanical treatment" to "less than 10 minutes" and recited that "the total duration of the ink releasing and dispersing treatment [was] kept between 2 and 10 minutes." Exhibits 2-61-62. Kamyr asserts, and Clement does not deny, that the limitation of 10 minutes at the upper end of the range was necessary to avoid the Ortner patent. See Exhibits 2-56, 2-61, 2-136. The focus of the parties is at the lower end of the range. At the Kieffer and AMR installations using Kamyr's process, the durations of the step that Clement claims as infringing were measured at 1 minute 23 seconds and 49 seconds, respectively.

Analysis

Whatever the fortunes of the Hilton Davis decision in the Supreme Court, it will remain the latest and most authoritative starting point for analysis of a prosecution history estoppel claim, 62 F.3d at 1525:

Whenever prosecution history estoppel is invoked as a limitation to infringement under the doctrine of equivalents, a close examination must be made as to, not only what was surrendered, but also the reason for such a surrender." (internal citations and quotes omitted).

In that case, a limitation of "from approximately 6.0 to 9.0" in pH was found to be open to a doctrine of equivalents claim and not estopped by prosecution history because, although the 9.0 pH upper limit had been selected to distinguish the claims in that case from prior art, there was no indication that the 6.0 pH had been argued as a distinguishing feature, or that a pH lower than 6.0 was in the prior art.

The application of Hilton Davis to the facts of this case is most clearly seen in the dispute over the 2-10 minute time range specified in Clement's Step E. Kamyr asserts that Clement specifically argued the lower limit of 2 minutes in order to distinguish his claims from prior art. That assertion does not find support in the file wrapper citations Kamyr provides for that proposition. Exhibits 2-65, 2-134, 2-136, 2-243. Kamyr goes on to argue, however, that its invitation of file wrapper estoppel on this point has a "coup de grace" -- that Clement had to specify 2 minutes as the shortest time for his "thermo-chemi-mechanical treatment" because otherwise his claims would have read on the prior art of Eriksson. That argument cannot be sustained either. The Eriksson patent 3,957,572 claims only a "dwelling time . . . shorter than the time necessary for complete impregnation of the paper with water and just sufficient for pumpability. . . ." A residence time of less than 2 minutes does not appear to have been a subject of argument or discussion between Clement and the Examiner. 6 "[A] change that did not in fact determine patentability does not create an estoppel." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1219 (Fed. Cir. 1995); Laitram Corp. v. NEC Corp., 952 F.2d 1357, 1361 (Fed. Cir. 1991).

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6 It is true that the '179 patent specifies a precise time range, unlike the pH range in Hilton Davis, which had an "approximate" lower limit. Kamyr's argument on this point, however, falls under the rubric of the doctrine of equivalents and not prosecution history estoppel. If Clement were permitted to proceed to trial under the doctrine of equivalents, there might well be a genuine issue of fact with respect to the equivalence of residence times, because Clement argues that Kamyr uses two residence times that should be accumulated for purposes of comparison, or because the actual parameters in use at the Kamyr process plants are disputed, or for both reasons.

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Kamyr fares no better with its estoppel argument addressed to Clement's claim that the temperature of Kamyr's initial step is equivalent to that of the '179 patent process. The prosecution history establishes that the Examiner required Clement to use terms more specific than "low temperature," but it does not reflect a requirement by the Examiner or an intent by Clement to specify any particular temperature in order to overcome prior art. "When claim changes or arguments are made in order to more particularly point out the applicant's invention, the purpose is to impart precision, not to overcome prior art. Such prosecution is not presumed to raise an estoppel . . . ." Pall Corp., 66 F.3d at 1220; Mannesmann Demag Corp. v. Engineered Metal Products Co., 793 F.2d 1279, 1285 (Fed. Cir. 1986).

A prosecution history estoppel does arise, however, with respect to Clement's claim that the Kamyr process infringes the '179 patent by removing most of the non-ink contaminants from the first aqueous fibrous suspension. The allowance of Clement's patent turned on Clement's willingness to limit his claims to specify cleaning of "substantially all" the non-ink contaminants at this stage -- and none downstream of the disperser. This limitation of Clement's earlier, broader claims, and its importance, was made explicit by the Examiner. Exhibits 2-276-77.."[A] concession made or position taken to establish patentability in view of prior art on which the examiner has relied, is a substantive position on the technology for which a patent is sought, and will generally generate an estoppel." Pall Corp., 66 F.3d at 1220.

The parties have briefed this issue as a contest about the meaning of a few words and phrases: "substantially all," "most," and "all." The correct question is a different one: whether, in order to avoid the prior art of Burns, Clement surrendered his claim to a process that involved screening and cleaning downstream of the disperser. The prosecution history establishes that he did.

The creation of an estoppel is not necessarily fatal to a claim of infringement under the doctrine of equivalents. In Hughes Aircraft Co. v. United States, 717 F.2d 1351, 1363 (Fed. Cir. 1983), the Federal Circuit observed that,

"Depending on the nature and purpose of an amendment, it may have a limiting effect within a spectrum ranging from great to small to zero. The effect may or may not be fatal to application of a range of equivalents broad enough to encompass a particular accused product. It is not fatal to application of the doctrine itself."

In this case Clement's infringement counterclaim attempts "'to reclaim the very thing [he] surrendered by way of amendment,'" Mannesmann, 793 F.2d at 1285, and is fatal to his claim that the limitations of Steps A and B of his claim are found in the Kamyr process. Clement cannot prevail on his claim of infringement unless he establishes that every limitation of his claim is found in the Kamyr process, either literally or under the doctrine of equivalents, SmithKline Diagnostics v. Helena Laboratories Corp., 859 F.2d 878, 889 (Fed. Cir. 1988); Lemelson v. United States, 752 F.2d 1538, 1551 (Fed. Cir. 1985). It follows that Clement's claim of infringement must be dismissed.

Findings and Conclusions

During the prosecution of the '179 patent, Clement limited his step (b) claim. The claim of removing non-ink contaminants including stickies by screening and cleaning to form a second aqueous fibrous suspension "substantially free" of non-ink contaminants including stickies is construed, in the light of the patent and its prosecution history, to mean that so nearly all of the non-ink contaminants are screened and cleaned from the first aqueous fibrous suspension that no screening and cleaning is done downstream of the disperser. The Kamyr process removes most but not all non-ink contaminants at step (b), and it does screen and clean downstream of the disperser. Clement's surrender of the broader claim during prosecution was critical to the allowance of his patent and estops his argument that the Kamyr process infringes the '179 patent by the doctrine of equivalents.

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4. "Topcoat is substantially free of an elutable material."

Consistent with the claim language and its ordinary meaning 9 and the specification, 10 the court construes this phrase to mean "the topcoat is largely or approximately free of an elutable material."

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9 See, e.g., Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1360. (Fed. Cir. 2003).

10 '536 patent, col. 6, 11. 28-32 (explicitly defining "elution")

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2. "Substantially free of nitrosamines or precursors"

(all asserted claims) -- means that the combined content of nitrosamine and nitrosamine precursors is sufficiently low that no appreciable danger to humans or animals will result from contact with the compositions at issue. See Joint Markman Hearing Statement, at 14.

Defendants contest this construction. They contend the meaning is that the claimed compositions contain "either (1) a detectable amount, but less than 100 ppm, of nitrosamines or (2) a detectable amount, but less than 100 ppm, of precursors of nitrosamines." Joint Markman Hearing Statement, at 24. This view conflicts with the 827 patent specification and the prosecution history.

The 827 patent specification describes the invention as "directed to 3-isothiazolone compositions containing little or no nitrosamine impurities." 827 patent, at 1:13-14. It also states:

The stabilized 3-isothiazolone compositions which can be prepared according to the processes of the present invention are "substantially free" of nitrosamine precursors and nitrosamines, that is, they contain less than about 100 ppm of such materials, preferably less than 50 ppm. Even more preferred for sensitive applications or uses which require only minimal dilution, are compositions containing less than 20 ppm of precursors and nitrosamines. As will be demonstrated hereinafter it is even possible to produce compositions with no detectable nitrosamine or precursor compounds.

827 patent, at 5:47-57. The specification expressly contemplates solutions with no "detectable nitrosamine impurities." Here, the patentee was its own lexicographer in that it provided a special definition of "substantially free" in the specification. Also, in claim 10 of the 827 patent -- a claim dependent upon claim 1, in which "substantially free" first appeared -- a second claim is made for a composition containing "no detectable nitrosamine or nitrosamine precursors." Id. at 18:6-8.

The "no detectable" wording of the specification is also consistent with adding together the combined amounts of nitrosamine and nitrosamine precursors, as against considering each amount separately. Defendants insist that "or" should be read in the disjunctive. See Joint Markman Hearing Statement, at 26. The specification defines "nitrosamine precursor" as "a secondary amine (and if present, a tertiary amine) by-product compound which can be converted into a nitrosamine." 827 patent, at 3:16-20. A nitrosamine precursor is a potential nitrosamine. Since the evident purpose of the patent is to maintain nitrosamine amounts below a certain level, it makes sense to aggregate potential nitrosamines with existing ones. 6

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6 The prosecution history of the 827 patent is in accord. A decision of the Board of Patent Appeals and Interferences regarding the 827 patent application stated: "While the precursors themselves do not appear to be particularly toxic, they are converted into highly toxic nitrosamines as a direct result of adding the metal nitrate salt [as described in the 795 patent], whereupon nitrosation takes place to form the toxic nitrosamine." Prosecution History, Serial No. 383,858, Paper No. 29, May 30, 1989 decision of Board of Patent Appeals and Interferences, at 6 (plaintiff's exh. 7; defendants' exh. 1).

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C. "Said Compound or Salt Being Substantially Free of Other Isomers"

1. The Parties' Arguments

While the term "a compound" does not appear to be particularly contested by the parties, the phrase "said compound or salt being substantially free of other isomers" is hotly contested. Aventis maintains that the phrase means "that other isomers may be present so long as the presence of other isomers does not materially affect the basic properties of the recited compound." Pl.'s Pre-Trial Claim Construction Brief at 1. Aventis argues that, given the qualifier "substantially," "[a] person of ordinary skill in the pharmaceutical arts would not construe the condition -- 'free of' -- to mean a purity of 100.00%." Id. at 6-7. In addition, in Aventis' view, the prosecution history "establishes that 'substantially free of other isomers' carries the same meaning as the phrase "consisting essentially of," a term of art in patent law that allows for the presence of other components beyond the claimed compound as long as they do not materially affect the basic characteristics of the claim compound." Id. at 8.

Lupin, in contrast, maintains that, properly construed, claim 1 "does not have any detectable isomers." Def.'s Pre-Trial Claim Construction Brief at 9.
In other words, a compound is the pure 5(S)-isomer or "being substantially free of other isomers" if one cannot "see" it, i.e., it contains no detectable amount of other isomers by NMR or TLC testing. Conversely, a compound with the 5(S)-isomer that contains detectable amounts of other isomers that a test method can "see," is not pure or "substantially free of" other isomers. This is the only construction that is consistent with the intrinsic evidence and the inventors' own understanding and use of these phrases before the PTO.

Id. Lupin relies heavily on the prosecution history of the patent to make this argument, and its arguments are discussed more fully in the analysis below.

2. Claim Construction of "Said Compound or Salt Being Substantially Free of Other Isomers"

I. The Language of Claim 1

The Court shall begin with the language of claim 1. Again, in its entirety, the claim reads as follows:

A compound of the formula

[SEE FORMULA IN ORIGINAL]

or a physiologically acceptable salt thereof, wherein R<2> is hydrogen, methyl, ethyl, or benzyl, and wherein hydrogen atoms on the ring carbon atoms in the 1- and 5-positions are in the cis-configuration relative to one another, the carboxyl group on the ring carbon atom in the 3-position is in the endo position relative to the bicyclic ring system, and the chirality centers in the chain and on the ring carbon atom in the 3-position all have the S-configuration, said compound or salt being substantially free of other isomers.

'722 patent.

Beginning with "substantially free," the words particularly contested by the parties, the Court observes at the outset that the United States Court of Appeals for the Federal Circuit has defined the "term 'substantial' [as] a meaningful modifier implying 'approximate,' rather than 'perfect.'" Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 907 (Fed. Cir. 2005) (quoting Liquid Dynamics Corp. v. Vaughan Co., Inc., 355 F.3d 1361 (Fed. Cir. 2004)). The Federal Circuit has also stated that, "ordinarily . . . 'substantially' means . . . 'largely but not wholly that which is specified.'" Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358 (Fed. Cir. 2001) (quoting WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 1176 (9th ed.1983)). In Ecolab, the appellate court went on to note that, "like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" Id. (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)). "Substantially," unless contradicted or

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defined differently by the intrinsic evidence, "avoids the strict 100% nonuniformity boundary." Id. The Playtex court similarly emphasized that it has "refused to impose a precise numeric constraint" on phrases such as "substantially uniform thickness" unless "something in the prosecution history imposed the 'clear and unmistakable disclaimer' needed for narrowing beyond this plain-language interpretation." Playtex, Inc., 400 F.3d at 907. See also Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333, 1337-38 (Fed. Cir. 2001) (construing "essentially free" and concluding that the prosecution history defined "essentially free from crystalline material" as a maximum crystalline cefuroxime axetil content of less than 10%).

In this case, "substantially" modifies "free," a term that the parties agree means "pure" in this context. Given the definitions above, the fact that "substantially" modifies "free" indicates that "free" is something "approximate, rather than perfect." Id. "Substantially free" therefore means something less than "100% free" or "100% pure." See Ecolab, Inc., 264 F.3d at 1358. To conclude otherwise, the Court would be reading "substantially" out of the claim. Reading express limitations out of claims is impermissible. Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1105 (Fed. Cir. 1996) (holding that a court cannot construe claims to read an express limitation out of the claim). "Courts can neither broaden nor narrow claims to give the patentee something different than what he has set forth." Texas Instruments v. United States ITC, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (internal citation omitted).

Of course, given the technical nature of claim 1, "substantially free" must be understood as one of ordinary skill in the art at the time of the invention would use the phrase. Apotex, 403 F.3d at 1338-39. The inventor's words used to describe the invention in the prosecution history are good indications of how persons skilled in the field of invention would use the term. Phillips, 415 F.3d at 1313. Accordingly, a review of the of the '722 patent prosecution history and a consideration of how persons of ordinary skill in the art would use the phrase are merited. n4

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n4 The parties agree that the specification does not inform the terms "substantially free" in claim 1.

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ii. The Prosecution History

"[T]he prosecution history provides evidence of how the [Patent and Trade Office ("PTO")] and the inventor understood the patent." Phillips, 415 F.3d at 1317. This is so because "it was created by the patentee in attempting to explain and obtain the patent," and it is possible that the "inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. As the Phillips court explained, however, reviewing the prosecution history is not an easy task.

[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of the negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.

Id. Statements made in the prosecution history therefore must be "clear and unmistakable" in order to limit the scope of a claim beyond its plain-language interpretation. Playtex, Inc., 400 F.3d at 907; Resqnet.com, Inc., 346 F.3d at 1378.

a) Aventis' Construction

Aventis contends that "substantially free of other isomers" has the same meaning as "consisting essentially of," a term of art in patent law that allows for the presence of other components beyond the claimed compound as long as they do not materially affect the basic characteristics of the claim compound." Pl.'s Pre-Trial Claim Construction Brief at 8. To make this argument, Aventis asks the Court to take several steps in logic that are not supported by the prosecution history or the caselaw.

Aventis first points out that claim 24, which was subsequently canceled, was added during the prosecution of the patent to clarify that the claimed compounds were "substantially free of other isomers." Id. Claim 24 differed from claim 19 only in that it used the language "consisting essentially of" instead of "substantially free of other isomers." Id. The Examiner

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ultimately asked Aventis to cancel claim 24 because "[it] appear[ed] to be claiming the same compounds free of other isomers as claim 19." Id. at Ex. I (Examiner Record dated April 19, 1991). Aventis did so. Based on this cancellation, Aventis now asserts that the applicants essentially defined the phrase "substantially free of other isomers" to mean the same thing as "consisting essentially of." The cancellation of claim 24, in other words, is dispositive on the meaning of "substantially free of other isomers." Notably, Aventis provides no legal support for its last assertion that the cancellation of one claim is dispositive as to the meaning of another.

Assuming, then, that "substantially free" means the same thing as "consisting essentially of," Aventis notes that "consisting essentially of" is a term of art in patent law that has a clearly defined meaning, namely, that "[a] patent claim using this phrase allows for the presence of ingredients that do not materially affect the basic properties of the invention." Id. at 9 (citing PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998)). Aventis further supports its argument by pointing out that the United States Court of Appeals for the Federal Circuit has held that "'consisting essentially of as used in the pharmaceutical arts does not exclude the presence of impurities." Id. (citing Abbott Labs. v. Baxter Pharmaceuticals Prod., Inc., 334 F.3d 1274 (Fed. Cir. 2003); Talbert Fuel Sys. Patents Co. v. Unocal Corp., 275 F.3d 1371, 1375 (Fed. Cir. 2002)). Aventis thus urges this Court to graft the meaning of "consisting essentially of" as a term of art onto the phrase "substantially free."

The Court has several problems with Aventis' construction and concludes that it impermissibly broadens the scope of the claim by reading "free of other isomers" as "free of impurities" generally. n5 See Texas Instruments, 988 F.2d at 1171 ("[c]ourts can neither broaden nor narrow claims to give the patentee something different than what he has set forth."). While Aventis argues that the cancellation suggests that "substantially free of other isomers" and "consisting essentially of" were redundant phrases, the Court perceives a difference between the two. "Substantially free of" focuses on what is not included in a substance or compound. "Consisting essentially of" focuses on what is included in a compound. The Court observes that, while claim 24 was indeed cancelled, the Examiner represents it was done so because it "appear[ed] to be claiming the same compounds free of other isomers as claim 19." Pl.'s Pre-Trial Claim Construction Brief at Ex. I (Examiner Record dated April 19, 1991) (emphasis added). In this way, the Examiner focused on what the same compounds were free of and specifically pointed out "other isomers." The phrase "consisting essentially of ramipril" simply does not indicate what should not be there -- either isomers or elephants could be lurking around as possible unwanted materials. "Substantially free of other isomers," on the other hand, indicates that other isomers should not be in the compound in significant quantities. The phrase is much narrower.

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n5 The Court is not deciding that isomers are not impurities in the context of ramipril; rather, the Court is deciding that the claim is limited to being free of "other isomers," regardless of whether they are impurities or not.

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The Court also rejects Aventis' effort, after equating the two phrases, to read into "substantially free of" the meanings associated with the term of art "consisting essentially of." A term of art is "a word or phrase having a specific, precise meaning in a given specialty, apart from its general meaning in ordinary contexts." BLACK'S LAW DICTIONARY 1483 (7th ed. 1999). Even assuming "consisting essentially of" is a term of art, the Court can only wonder why it wasn't used, given it has a "specific, precise meaning." The fact that a term of art was not used suggests an intent not to use it. Moreover, PPG Industries defines "consisting essentially of" as "a transition phrase commonly used to signal a partial open claim in a patent." PPG Indus., 156 F.3d at 1354. That Aventis would even suggest that claim 1 is a partially open claim is quite surprising, as it would indicate that ramipril is a compound "open to unlisted ingredients." Id. To be sure, Aventis urges that these unlisted ingredients would be those "that do not materially affect the basic and novel properties of the invention." Id. Such ingredients, Aventis argues, would be nothing more than "impurities." Yet even this construction is broader than what is provided for in claim 1 by the phrase "substantially free of other isomers." As far as the Court reads claim 1, ramipril is a well-defined chemical compound that is not open to "unlisted ingredients" or various "impurities" but may possibly contain "other isomers." There is nothing in the prosecution history to suggest otherwise.

b) Lupin's Construction

While Aventis provides a construction that is impermissibly broad, Lupin provides one that is impermissibly narrow. Lupin

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gives great weight to the fact that the phrase at issue was included after Aventis lost an interference proceeding with a company called Schering over who was the first person to invent ramipril. That proceeding involved U.S. Patent No. 4,587,258 (the '258 patent) and the parent '284 application. According to Lupin, Aventis represented to the PTO that its invention in the '722 patent was distinct from the '258 patent because its claims were narrower based on the fact that its invention was "substantially free of other isomers." Id. at 12. Moreover, Aventis, in Lupin's view, analogized this term as "substantially pure isomers." Id. (emphasis added). The Examiner apparently rejected this effort "under 35 U.S.C. § 112 for lack of support." Id. at 14. Lupin urges this rejection was addressed by a declaration of one of the inventors, Dr. Hansjorg Urbach, who "noted that the synthetic procedures employed in Example 1 would eventually lead only to the 5(S) isomer, not the other undesired isomers." Id. According to Lupin, Dr. Urbach referenced thin layer chromatography ("TLC") and "column chromatography" to show that "[i]n each of the both separated products no other isomer could be detected." Id. at 15. By explaining that the product was one where "no other isomer could be detected," Lupin argues that Aventis essentially limited the term "being substantially free of other isomers" to a "pure" compound being "free from other detectable isomers." Id.

Aventis, for its part, maintains that Lupin misreads the prosecution history. Aventis emphasizes that the PTO rejection occurred not because the claim was "indefinite" under 35 U.S.C. § 112, paragraph 2, but because, under 35 U.S.C. § 112, paragraph 1, there was "no embodiment in the specification that falls within the scope of those claims." n6 Pl.'s Pre-Trial Claim Construction Brief at 14. The distinction, according to Aventis, is significant because it suggests the Examiner understood the meaning of the claims, but objected because no embodiment was disclosed. Id.

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n6 Under 37 C.F.R. § 1.71(b), the specification "must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth."

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Given these arguments, the Court begins by observing that the fact that Aventis represented to the Examiner that it added claim 19 (which subsequently became claim 1 in the '722 patent) "to make it clear that these isomeric compounds and salts are substantially free of other isomers, i.e. are substantially pure isomers" does not alter this Court's view that the term "substantially" is being utilized as qualifier -- the fact that it appears, in this sentence, to be qualifying both the compound and the isomers themselves does not necessitate the conclusion, as Lupin argues, that somehow the isomers themselves have been defined as 100% pure. See Def.'s Pre-Trial Claim Construction Brief at 12 (citing the Preliminary Amendment dated April 7, 1989 at 9). Nor is this Court's view changed by the fact that Aventis also represented that "it is evident from the form of the claims submitted ab initio in this application . . . that substantially pure isometric compounds having five chiral centers, all in the S-configuration, were defined or intended to be defined by Applicants." Id. (citing the Preliminary Amendment dated April 7, 1989 at 19). Once again, "substantially" is modifying the purity of "isometric compounds." Undoubtedly, all of the five chiral centers are supposed to be in the S-configuration, as the language of claim 1 itself represents. Yet this emphasis on the configuration of isomers does not expressly change the phrase "substantially free of other isomers" or "substantially pure isomers" to mean 100% pure isomers, as Lupin contends. Id. If anything, it indicates to the Court that the chiral centers in the S-configuration should be "substantially pure isomers" in addition to the fact that the compound itself should be "substantially free of other isomers." The problem for Lupin is that the term "substantially" qualifies both possibilities, indicating that 100.00% pure isomers of any kind are not described.

Lupin goes on, however, to urge that Aventis narrowed the scope of "substantially free of other isomers" to mean a "pure" compound when Reinhard Becker, one of the inventors of the '722 patent, allegedly argued that the term was analogous to pure isomers when he compared

the ACE-inhibiting effect of two pure isomers (i.e., isomers have all five chiral centers in the S-configuration) according to original claim 19 and new claim 19 with a mixture of isomers of the same formula having five chiral centers, but in which not all of these centers were in the S-configuration as they are in the compounds and salts claimed in both claim 19 of the parent application and now -- more explicitly -- in new claim 19 of the present application.

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Id. (citing the Preliminary Amendment dated April 7, 1989 at 20)(emphasis in original). Lupin then makes much of the statement by the Examiner that, "[h]ence, new claim 19 in the present application makes explicit the isometric purity of the compounds recited therein." Id. (citing the Preliminary Amendment dated April 7, 1989 at 21). Lupin, however, does not quote the rest of the paragraph following this statement, which reads:
Namely, claims 19-23 as presented herein explicitly define compounds and salts thereof having five chiral centers, all of which are in the S-configuration and which are substantially free of other isomers. While it is urged the original claims 19-23 of the parent application read on or are intended to read on such substantially pure isomers, and were so understood to read by both Applicants and the Patent Office, new claim 19 of the present application makes this limitation explicit.

Id. As this Court reads the prosecution history, what the application makes explicit is that the isometric purity of the invention is "substantially free of other isomers" and contains "substantially pure isomers." It does not make explicit Lupin's contention that there are "no other detectable isomers."

Lupin also argues that the Examiner's rejection of the application and Aventis' response to this rejection reveals that the term "substantially free of other isomers" means "pure isomers." The Examiner rejected the application for two reasons. Claim 22, not at issue here, was rejected under 35 U.S.C. § 112, paragraph 2, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Id. (Examiner's Action dated Oct. 4, 1989 at 2). Claims 19-23, which subsequently became claims 1-5 of the '722 patent, were rejected as being unpatentable in Interference proceeding 101,833, under 35 U.S.C. 102(g). n7 The Examiner concluded that the judgment rendered in the interference proceeding applied, stating: "[t]he term 'being substantially free of other isomers' is not considered to be a limitation which distinguishes the instant claims from the claims involved in the interference." Id.

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n7 35 U.S.C. § 102(g) provides:
during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

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In response to this rejection, Aventis filed another amendment. Id. (Amendment dated April 4, 1990). Aventis contended that "claims 19-23 to the specific isomer, substantially free of other isomers, represent a separate patentable invention over the broad count of the interference is not inconsistent with the judgment rendered in the interference because the judgment was not referring to these specific claims." Id. (Amendment dated April 4, 1990 at 8) (emphasis added). In the Amendment, Aventis went on to note that the "specific '5S' isomer is claimed as being substantially free of other isomers" and that the "Examiner will search in vain for similar disclosure of these specific 5S compounds substantially free of other isomers in any of the prior, predecessor applications . . . ." Id. (Amendment dated April 4, 1990 at 9-10)(emphasis added). Aventis then pointed to several examples in the parent application that do not indicate the 5-S configuration. "Accordingly," Aventis urged, "there is no teaching of any isomers in which all chiral centers are in the S-position and which are substantially free of other isomers as is the case of the compounds in claims 19-23." Id. (Amendment dated April 4, 1990 at 12) (emphasis added). After reviewing this portion of the prosecution history, nowhere does the Court find that the phrase "substantially free of other isomers" clearly and unmistakably means "100% pure" or "no other detectable isomers."

Even so, Lupin attempts to support its arguments by pointing to the methods Aventis used to show when a product is substantially free of other isomers. On June 21, 1990, the Examiner once again rejected claims 19-23. Id. (Office Action dated June 21, 1990). This time she rejected the claims under 35 U.S.C. § 112, paragraph 1, which states:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying

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out his invention.

The Examiner rejected the claims under this provision because
the specification, as originally filed, does not provide support for the invention as now claimed. There is no express support in the specification for the limitation "being substantially free of other isomers." Additionally, the working examples do not indicate the exact purity obtained.

Id. (Office Action dated June 21, 1990 at 2). In response to this rejection, Aventis submitted the declaration of Dr. Hansjorg Urbach, one of the inventors, who, at the outset, stated that Example 1 of the specification was the only example involving the "5-S" compound. Id. (Urbach Decl. at 2). n8 He then provided a series of drawings explaining the "reaction scheme described in Example 1." Id. At the conclusion of these schematic depictions, which were explained subsequently in the declaration, he stated:
Thus, the methods of Example I(1)-I(5) lead only to a single compound in which each of the five chirality centers in the compound has the S-configuration, being substantially free of other isomers.

The methods of Example I(1)-I(5), establishing that the necessary and only reasonable construction to be given the disclosure of Application Serial No. 07/296,513 is that the methods provide only the "5S" compound being substantially free of other isomers, are now examined in greater detail.

Id. (Urbach Decl. at 8-9) (emphasis added).

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n8 Example 2 is described as a "mixture of cis, endo "SSS" and "RRR" Intermediate compounds. Id.

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In spite of Dr. Urbach's use of the phrase "substantially free of other isomers," Lupin emphasizes that the two methods Dr. Urbach utilized to distinguish and/or separate isomeric mixtures -- TLC and column chromatography -- led him to conclude that "no other diastereomer could be detected" -- in other words, no other isomers could be "seen." Id. (Urbach Decl. at 16). Unfortunately for Lupin, although the tests did not detect any other isomers, the Court is unconvinced that this fact clearly and unmistakably changes the meaning of the phrase "substantially free of other isomers." If no isomers were detected, the tests simply revealed that Example 1 produces a version of ramipril "substantially free of other isomers," just as the application stated. The tests do not compel the conclusion that no isomers may ever be detected or that 100% purity is guaranteed.

Moreover, the Urbach Examples were provided in response to the Examiner's paragraph 1 rejection, which relates to the support (or lack thereof) provided in the specification. It was not a rejection under § 112, paragraph 2 for indefiniteness. Thus neither the Examiner's question nor Dr. Urbach's response was related to the meaning of "substantially free of other isomers." Indeed, if the phrase had not been understandable to the Examiner, she would have rejected claim 19 (later claim 1 of the '722 patent) under paragraph 2. In any event, in order to accept Lupin's argument that Dr. Urbach's declaration reveals that he chose to be his own "lexicographer" and change the ordinary meaning of "substantially free," the Court would have to find the plain and ordinary meaning of this phrase "clearly disclaimed" during the prosecution of the patent. E-Pass Tech. Inc. v. 3Com Corp., 343 F.3d 1364, 1370 (Fed. Cir. 2003) (emphasis added); Playtex, Inc., 400 F.3d at 907. It has not been. Contrary to Lupin's assertions, the Court sees nothing that would clearly and unmistakably indicate that Aventis (or Dr. Urbach) intended to limit the phrase "substantially free of other isomers" to "no detectable isomers."

iii. Persons of Ordinary Skill in the Art

Aventis maintains that a person of ordinary skill in the art would understand the phrase "substantially free of" "to mean something less than 100.00% purity." n9 Pl.'s Pre-Trial Claim Construction Brief at 5. Aventis asserts that persons of ordinary skill in the art understand "there is no such thing as a 100.00% pure compound." Id. at 6. In Ortho-McNeil Pharmaceuticals, Inc., 348 F.Supp. 2d at 729, an expert testified "there is always that molecule hiding somewhere in the corner. There is no such thing as an absolutely 100 percent .0000 pure substance." Id. The district court in that case agreed that the "realities of science would [lead] a skilled artisan to conclude that the purity was not 100 percent." Id. at 730.

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n9 The Court addresses how a person of ordinary skill in the art would understand "substantially free of other isomers" after the prosecution history because the discussion includes, in part, evidence not found in the prosecution history, i.e., extrinsic evidence.

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Indeed, Lupin's own chemist seems to agree. On April 18, 2006, in a deposition related to this matter, Girij Pal Singh responded in the following way when asked about when he prepared a "pure sample of Isomer-1."
Q. I think you used the word pure to describe it a minute ago, didn't you?

A. Purity.

Q. You said -- I just want to make sure, you said pure Isomer-1?

A. Pure Isomer-1. Pure means, you know, the quality may be more than 95 percent, 98 percent.

Q. So it wasn't 100 percent of Isomer-1?

A. No, it was not 100 percent. I recall, perhaps, you know, I need to see the document, it was 95 or 98 percent purity.

Q. And you considered that pure?

A. That's pure, more than 95%.

Id. at Ex. F, Singh Tr. at 59: 20, 24; 60: 2-12. Given this testimony, like the district court in Ortho-McNeil Pharmaceuticals, this Court concludes that the "realities of science would [lead] a skilled artisan to conclude that the purity was not 100 percent." 348 F. Supp. 2d at 730. In other words, a person having ordinary skill in the art would conclude that "substantially free" means "largely free" but something less than 100% free. A person of ordinary skill in the art would not read the phrase as meaning "no detectable isomers."

For all of the above reasons, based on the plain language of the claim, the prosecution history, and how a person having ordinary skill in the art would understand the claim, the Court FINDS that "said compound or salt being substantially free of other isomers" means that ramipril, the "said compound," is largely but not necessarily free of other isomers. In other words, "substantially free of other isomers" qualifies the compound by indicating that it may not be 100% pure or 100% free of other isomers.
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B. (S)-enantiomer "substantially free" of (R)-enantiomer

1. Claim language

The Court begins its construction of the phrase at issue with the express language of Claim 1, which provides: "(S)-[enantiomer] substantially free of R-[enantiomer]." ('639 patent, col. 10, 11. 18-20.) n5 The term "substantially" is commonly used in patents. "[W]ords of approximation, such as 'generally' and 'substantially,' are descriptive terms commonly used in patent claims to avoid a strict numerical boundary to the specified parameter." Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310-11 (Fed. Cir. 2003) (quotation and citation omitted). To the extent the term "substantially" has been interpreted to have more than one meaning, the "cases recognize the dual ordinary meaning of this term as connoting a term of approximation or a term of magnitude." Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc., 347 F.3d 1314, 1323 (Fed. Cir. 2003); see also Ecolab. Inc. v. Envirochem, Inc., 264 F.3d 1358, 1366 (Fed. Cir. 2001) ("[O]rdinarily 'substantially' means considerable in extent, or largely but not wholly that which is

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specified."). Here, the claim language urges interpreting the term "substantially" within the phrase "substantially free" as a term of approximation. n6 See Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1031 (Fed. Cir. 2002) ("The phrase 'substantially constant' denotes language of approximation, while the phrase 'substantially below' signifies language of magnitude, i.e., not insubstantial."); see also Deering, 347 F.3d at 1323 (noting the term "substantially" has numerous definitions, including, inter alia, "largely" or "essentially"). That is, "substantially" is used to modify and qualify the word "free" with which the term "substantially" is associated. This interpretation is consistent with the manner in which the word is customarily defined. See Blacks Law Dictionary, 1428 (6th ed. 1990) (defining substantially as "essentially, without material qualification, in the main"); Webster's Encyclopedic Unabridged Dictionary 1897 (1st ed. 2001) (defining "substantial" as "of or pertaining to the essence of a thing; essential, material, or important").

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N5 The phrase "substantially free" is used in a similar way in Claim 2 of the '639 patent. ('639 patent, col. 10, 11. 21-23.)

n6 Defendants acknowledge "substantially" in this context is a "word of approximation. . . ." (Hearing Tr. at 72.)

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The ordinary and customary meaning of "free" is without, or devoid of. This comports with the relevant definition of "free," which is "uncombined chemically" or "not containing a specified substance." Webster's Encyclopedic Unabridged Dictionary 763 (1st ed. 2001). Because the claim language explicitly ties the adverb "substantially," used as a term of approximation, to the adjective "free," the ordinary meaning of the phrase "substantially free" necessarily envisions some amount of deviation from a completely free state. See Anchor Wall Sys., Inc., 340 F.3d at 1311 (holding the phrase "'generally parallel' envisions some amount of deviation from exactly parallel").

2. Specification

The Court next examines the specification. "[C]laims must be construed so as to be consistent with the specification, of which they are a part." Merck & Co., Inc., 347 F.3d at 1370. In this case, the phrase "substantially free" is used one time in the specification, which provides: "Accordingly, the present invention relates to the . . . S absolute configuration, the said compound being substantially free from . . . the R absolute configuration." ('639 patent, col. 1, 11. 54-59.)

The usage of the phrase "substantially free" in the specification is virtually identical to its usage in the claim language. Accordingly, the specification does not contradict or modify the plain meaning of these claim terms. n7

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N7 No party urged the Court to focus on the specification.

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Defendants do not discuss the interpretation of the claim terms themselves or their usage in the specification. Instead, Defendants argue that the prosecution history of the '223 and '639 patents requires the Court to interpret the claim differently than what the plain meaning provides. n8 n9

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n8 Defendants argue if Claim 1 of the '639 patent is constructed as UCB proposes to allow inclusion of any (R)-enantiomer, then it is invalid for indefiniteness. The Court does not agree. Use of an indefinite term such as "substantially" is common in patents and has been approved by the Federal Circuit on numerous occasions. See, e.g., Ecolab, 264 F.3d at 1367 (finding "the use of the term 'substantially' to modify the term 'uniform' does not render this phrase so unclear such that there is no means by which to ascertain the claim scope"). The Court finds its use here to be appropriate, not invalid or indefinite, and sufficient to notify the public of the patentee's right to exclude. The Court notes Defendants did not focus on their invalidity argument at the Hearing.

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n9 Defendants acknowledge they rely on the prosecution history in arguing their construction of the claim in dispute. (See Hearing Tr. at 73-74.)

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3. Prosecution history

Defendants claim the prosecution history of the '223 and '639 patents demonstrates UCB unmistakably defined "substantially free" during prosecution to exclude any (R)-enantiomer, and they urge the Court to construct the phrase "substantially free" to mean "excludes" (R)-enantiomer or "pure" (S)-enantiomer. "[T]he prosecution history may demonstrate that the patentee intended to deviate from a term's ordinary and accustomed meaning . . . [and] limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." Teleflex, 299 F.3d at 1326. The Court examines the prosecution history to determine whether UCB unambiguously defined the phrase "substantially free" during prosecution sufficiently to rebut the "'heavy presumption' that claim terms carry their full ordinary and customary meaning. . . ." See Omega, 334 F.3d at 1323 (citations omitted).

a. The '223 patent

Defendants' analysis of the prosecution history begins with the application which matured into the '223 patent (the "'223 application"). n10 UCB's original claim simply claimed the (S)-enantiomer and did not contain the "substantially free" of (R)-enantiomer language. (See '223 Prosecution History, attached as Ex. D to Mylan's Opening Br., at UCB CC 0131.) On June 16, 1987, the PTO rejected the claims as being obvious and unpatentable over a prior art British patent for the racemic mixture. n11 The Examiner noted an isomer "is unpatentable over the racemate absent unobvious properties." (Id. at UCB CC 0143.) In response to this rejection, on November 16, 1987, UCB filed with the PTO its Amendment to the application, submitting the declaration of Jean Gobert to overcome the obviousness rejection by demonstrating the (S)-enantiomer produces unexpectedly superior results when compared to the mixture of (R) and (S)-enantiomers. In the remarks section of its Amendment, UCB, incorporating the language of the Gobert declaration, states:

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n10 At the Hearing, Defendants began their analysis with the original application for these claims -- Application No. 733,790 (the "'790 application"). The '223 application was a divisional application of the '790 application. Defendants agreed the record of the '790 application is replicated in material aspects in the '223 application. (Hearing Tr. at 54.) Because Defendants in their briefing begin their analysis with the '223 patent prosecution history, (see Mylan's Opening Br. at 9), the Court will do so here.

n11 The racemic mixture refers to a fifty-percent (S)-enantiomer and fifty-percent (R)-enantiomer mixture.

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Since the S-enantiomer shows a substantially higher anti-hypoxia and anti-ischemia activity than the racemate, and the R-enantiomer is completely inactive, removal of the latter and isolation of the S-enantiomer free of the R-enantiomer is important in providing a more potent drug.

. . .

(Id. at UCB CC 0150 (emphasis added); Hearing Tr. at 53-54.)

On February 26, 1988, the PTO again rejected UCB's claims. The Examiner stated:
Certainly the pure (S) isomer is obvious from the (R, S) mixture, since in the particular utilities urged only the (S) isomer is active. Thus while the activity therein of the (R, S) mixture is expectedly diluted by the presence of the (R) isomer nothing unexpected is evident by the use of the pure (S) isomer versus the (R, S) isomeric mixture of the prior art. . . . In fact the (R, S) isomeric mixture and all pharmaceutical uses is fully embraced by composition claim 6. The (R) isomer would merely be an "inert diluent".

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(Id. at UCB CC 0162; Hearing Tr. at 56.) After this rejection, on May 31, 1988, UCB met with the Examiner to discuss the rejection. At the conclusion of the interview, the Examiner recorded in his summary record:
Arty's urged that pure (S) isomer only obtained by steriospecific [sic] synthesis, and pharm. compositions thereof clearly are distinguished from Brit. Pat. (R, S) mixture which is non-enabling for pure isomer. This will be urged in response and also will amend comp. claim to exclude the other isomer (R) and intended pharmaceutical uses.

(Id. at UCB CC 0164.)

On July 19, 1988, UCB amended its claims to cancel all remaining claims and to add new Claim 8. The new Claim 8 stated "(S)-[enantiomer] substantially free of(R)-[enantiomer]." (Id. at UCB CC 0168.) This is the first time the "substantially free" language was included in the claims. In the remarks, UCB stated:
Additionally, the claim as now presented specifies that the composition is substantially free of the dextrorotatory enantiomer. This is specified in order to clearly avoid the Examiner's argument set forth in the Official Action to the effect that the (R) isomer could be present merely as an inert diluent. . . . The Examiner indicated that upon the filing of the instant response, he would give full consideration to the arguments presented and would make his decision based upon such arguments.

(Id. at UCB CC 0170.) On November 15, 1988, the PTO rejected Claim 8 containing the "substantially free" phrase, stating: "Applicant[']s arguments have been carefully considered but [are] unpersuasive that the rejection of the pure 'S' compound is improper." (Id. at UCB CC 0189.) n12

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n12 The Examiner allowed Claim 9, which contained a process limitation in addition to the "substantially free" language, and further indicated the PTO would allow UCB to rewrite its claim to make it a product-by-process claim. (Hearing Tr. at 67-68.) In its Amendment after final rejection, UCB added the product-by-process claim and obtained a patent on that claim. (Id. at 74.)

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b. The '639 patent

On February 16, 1989, UCB filed the application which matured into the '639 patent (the "'639 application"). n13 Claim 8 of the '639 application, which issued as Claim 1 of the '639 patent, claimed the (S)-enatiomer "substantially free" of (R)-enantiomer. (See '639 Prosecution History, attached as Ex. E to Mylan's Opening Br., at UCB CC 0059.) This claim was rejected again for obviousness based on the British patent, which discloses the racemic mixture. In response to this rejection, UCB filed an amendment on December 4, 1989, noting the Examiner's position is that "the pure (S) isomer would be prima facie obvious from the (R, S) mixture." (Id. at UCB CC 0069.) UCB again submitted the Gobert declaration, stating that "removal of the [(R)-enantiomer] and isolation of the S-enantiomer free of the R-enantiomer is important in providing a more potent drug. . . ." (Id. at UCB CC 0071.) Claim 8 of the '639 application ultimately issued as Claim 1 of the '639 patent without further discussion of the "substantially free" language. (Mylan's Opening Br. at 14.)

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n13 The '639 application was filed as a division of the '223 application.

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c. Analysis

Defendants argue the prosecution history of both the '223 and '639 patents compels the conclusion that "substantially free" excludes the (R)-enantiomer. Defendants argue the '223 patent prosecution history demonstrates UCB understood the claim would be allowed only if the (R)-enantiomer was excluded because: (i) UCB stated "removal of" the (R)-enantiomer and "isolation" of the (S)-enantiomer "free of" the (R)-enantiomer was important, (ii) UCB represented to the Examiner that the

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claim would be amended "to exclude the other isomer (R)" and used the phrase "pure (S) isomer," and (iii) UCB told the Examiner its new claim "clearly avoid[ed] the Examiner's argument that the (R)-isomer could be present merely as an inert diluent. . . ." (Mylan's Opening Br. at 15; Sandoz's Opening Br. at 8.)

Defendants further argue the prosecution history of the '639 patent confirms UCB defined "substantially free" as "excluding" the (R)-enantiomer. Defendants refer to the following evidence of UCB's actions: (i) the Examiner noted, and UCB confirmed, the claim was directed towards the "pure" (S)-enantiomer, and (ii) UCB again argued the importance of "removal" of the (R)-enantiomer, "isolation" of the (S)-enantiomer and that the (S)-enantiomer was "free" of the (R)-enantiomer. (Mylan's Opening Br. at 17.) Defendants claim this history "compel[s] the conclusion that the term 'substantially free' as it appears in claim 1 of the '639 patent excludes the (R)-isomer." (Mylan's Opening Br. at 18; Sandoz's Opening Br. at 9-10.)

The Court has reviewed the prosecution history presented by Defendants and UCB, including the arguments set forth in the parties' briefs and at the Hearing. During prosecution of the patents, the PTO initially rejected UCB's claims for the (S)-enantiomer based on the prior art, which included a racemic mixture of the (R) and (S)-enantiomers. To overcome the PTO's obviousness objection to the patentability of the (S)-enantiomer, UCB was required to demonstrate the unexpected benefits and results of the (S)-enantiomer as compared to the racemate. The language used by UCB to distinguish the (S)-enantiomer from the racemate, for purposes of demonstrating unexpectedly better results, was "removal of the [(R)-enantiomer] and isolation of the S-enantiomer free of the R-enantiomer. . . ." This language clearly distinguished the new claim from the prior art, which included a fifty-fifty mixture of the (R) and (S)-enantiomers.

However, the prosecution history does not focus on the distinction between "substantially free" and "free." Instead, the exchanges between UCB and the PTO concerned whether UCB could patent the (S)-enantiomer in light of the previously issued patent for the racemate. That UCB was participating in a back and forth negotiation with the PTO is clear. The Court cannot conclude from the prosecution history cited by Defendants that UCB intended to alter the language of the patent claim or that the PTO interpreted the "substantially free" terms to mean pure (S)-enantiomer. The Court finds this discussion between the PTO and UCB does not disclose a clear and unambiguous disclaimer, disavowal, alteration or modification of the ordinary and customary meaning of "substantially free." See generally Phillips, 415 F.3d at 1317 ("[B]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes."); Salazar v. Procter & Gamble Co., 414 F.3d 1342, 1347 (Fed. Cir. 2005) ("[A]n applicant's silence regarding statements made by the examiner during prosecution, without more, cannot amount to a 'clear and unmistakable disavowal' of claim scope."). Indeed, the exchanges illustrate UCB's resolve to resist characterizing the (S)-enantiomer as pure.

The Examiner's notes recorded after the meeting with UCB's attorneys do not compel a different conclusion. At the conclusion of the interview, the Examiner, in his own words, recorded his belief that UCB would amend its claims to distinguish them from the prior art and to "exclude the other isomer (R)." After the interview, however, UCB did not unequivocally, completely "exclude" (R)-enantiomer, but instead elected to use the phrase "substantially free" of (R)-enantiomer. The Examiner did not require UCB to remove the term "substantially," and UCB did not represent that "substantially" should be construed in any way other than its ordinary meaning. Thereafter, the patent issued with this language. The prosecution history cited by Defendants simply does not persuade the Court that UCB intended, or that the PTO envisioned or processed the application with, the claim interpretation advocated by Defendants. Defendants have not overcome the heavy presumption that claim terms carry their customary and ordinary meaning, and the Court constructs the disputed phrase in the '639 patent according to its customary and ordinary meaning.

III. CONCLUSION

For the reasons stated above,

IT IS HEREBY ORDERED that the term "substantially free" in Claim One shall be constructed in the litigation as "essentially free."

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B. "substantially immiscible"

1. The Parties' Proposed Constructions

Safas proposes that I construe "substantially immiscible" to mean that the granules remain suspended as discrete entities in the neat gel coat, i.e., that they do not largely mix or dissolve into the gel coat, remaining visually differentiable. (D.I. 78 at 9.) In support, Safas refers to dictionary definitions of the claim terms and to several instances in the specification discussing problems with the prior art granules "dissolving within a thermoplastic matrix" and how, in contrast, the granules of the '895 patent remain suspended in the gel coat matrix. See '895 patent, Col. 2, Ins 8-12; Col. 3, Ins. 36-38. Etura proposes that I construe "substantially immiscible" to mean substantially incapable of being mixed or of becoming homogeneous, citing the specification as support. (D.I. 80 at 16.)

2. The Court's Construction

I construe "substantially immiscible" to mean that the granules are largely, but not wholly, incapable of being dissolved into the gel coat. The word "substantially" carries an ordinary and non-technical meaning in the asserted claims, permitting construction by reference to a dictionary definition. I construe "substantially" to mean "being largely but not wholly that which is specified." Merriam-Webster's Collegiate Dictionary at 1170 (10th ed. 2002). The dictionary definition of "immiscible" is "incapable of mixing or attaining homogeneity." Id. at 579. The dictionary definition of "homogeneity" is "the quality or state of being of uniform structure or composition throughout." Id. at 554.

The '895 patent teaches that, in order to simulate the distribution of particles in natural granite, the granules must remain visible and be uniformly distributed and suspended in the gel coat. See, e.g., '895 patent, Col. 3, Ins. 36-38. Further, the invention of the '895 patent overcomes the problems identified in the prior art, namely, that the "thermoplastic particulates dissolved within a thermoplastic matrix …." Id. at Col. 2, Ins. 8-12. The prosecution history of the '895 patent also supports Safas' proposed construction. (D.I. 59, Exh. 2 at 3 ("there were inherent problems pertaining to the dissolution of thermoplastic particulates in a thermoplastic matrix").)

Etura's proposed construction of "substantially immiscible" would mean that the granules are literally incapable of being mixed into and distributed throughout the gel coat. This runs counter to the teachings of the '895 patent. It is apparent from the claim language and the intrinsic evidence that the granules do not dissolve and are distributed evenly throughout the gel coat, purportedly providing a solution to shortcomings encountered in the prior art. 4

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4 Both Safas and Etura cite deposition testimony to support their proposed claim constructions of "substantially immiscible;" however, the meaning of this claim term is clear from the intrinsic evidence, and therefore I need not consider the extrinsic evidence. See Interactive Gift Express, 256 F.3d at 1332.

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9. What is the Proper Construction for the Phrase "substantially incapable of fibrillation under normal conditions" in the '722 Patent?

Claim 1 of the '722 patent contains the phrase "said binder particles being substantially incapable of fibrillation under normal conditions into microfibers of less than 10 micrometers diameter at room temperature. . . ." KXI contends this phrase means that prior to any type of processing, the binder particles are substantially incapable of forming fibers of less than 10 micrometers diameter by shear and pulling alone without heating or substantial compression. Culligan contends this phrase means that the binder particles are substantially incapable of forming fibers of less than 10 micrometers when mechanically worked at room temperature. According to KXI, "the only real area of dispute between the parties is the requirement that the test for fibrillation occur prior to any processing of the binder, i.e., prior to any heating or substantial compression."

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KXI argues that the '722 patent's specification only mentions fibrillation of binder particles when it discusses prior art processes utilizing a polytetrafluoroethylene ("PTFE") binder. This is at column 3, lines 53-55, which reads: "PTFE is unique in that it fibrillates without heating or applying substantial compression but by shear and mixing." KXI contends this sentence from the specification defines the phrase "normal condition" to mean applying shear and pulling alone without heating or substantial compression prior to processing.

In support of its "mechanically worked" definition, Culligan cites column 3, lines 58-61 of the '722 patent specification. This section reads: "the foregoing process using PTFE is complex and time consuming and involves the evolution of fine fibers by mechanically working and shearing a mixture of PTFE and particles."

According to Culligan, the '722 patent's specification is silent as to the meaning of the phrase "substantially incapable of fibrillation." Culligan asserts that the prosecution history of the Australian counterpart to the '722 patent states that this language "was employed to exclude PTFE." The patentee apparently argued in prosecuting the Australian patent, "this is because the PTFE fibrillates by shear and pulling alone at room temperature, i.e., without the necessity for heating or applying substantial compression."

Culligan argues KXI's definition is incorrect because KXI appears to contend that no compression at all may be applied during the test to determine fibrillation, as opposed to no "substantial compression." Also, Culligan objects to the phrase "prior to processing" if it means something other than "prior to processing the binder in accordance with the method disclosed in the '722 patents. . . ."

KXI argues the court need not decide which party is correct because, as a matter of law, this claim limitation must include the crystalline thermoplastic polymers, including polyolefin, listed in claim 33 of the '722 patent. Claim 33 depends from claim 1. It reads: "the composition of claim 1 wherein the binder material forming the matrix is a crystalline thermoplastic polymer selected from the group consisting of . . . polyolefins. . . ." KXI argues that, as a matter of law, the independent claim must be interpreted broadly enough to include the dependent claim, citing Wright Medical Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1445 (Fed. Cir. 1997) ("We must not interpret an independent claim in a way that is inconsistent with a claim which depends from it"). KXI contends that, as a matter of claim interpretation, polyolefin is "substantially incapable of fibrillation under normal conditions into microfibers of less than 10 micrometers diameter at room temperature" as that phrase is used in claim 1 of the '722 patent.

Culligan argues that KXI has inverted the law of claim interpretation concerning dependent claims. Instead of reading the dependent claim (claim 33) as a further limitation on the independent claim (claim 1), KXI reads the independent claim as a limitation on the dependent claim. Instead, KXI argues dependent claim 33 must meet the conditions of independent claim 1.

Without further evidence, the court declines to construe claim 33 to mean that polyolefin is "substantially incapable of fibrillation under normal conditions into microfibers of less than 10 micrometers diameter at room temperature" as that phrase is used in claim 1 of the '722 patent. The court declines to add a "prior to processing" requirement to claim 1, as the court finds this is not supported by the evidence. Otherwise, the court agrees with KXI that the phrase "said binder particles being substantially incapable of fibrillation under normal conditions into microfibers of less than 10 micrometers diameter at room temperature. . . ." means that the binder particles are substantially incapable of forming fibers of less than 10 micrometers diameter by shear and pulling alone without heating or substantial compression.
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C. "substantially isopycnic"

1. The Parties' Proposed Constructions

The parties agree as to the meaning of the term "substantially isopycnie" but they disagree as to the degree or breadth to be afforded to the term. (D.I. 78 at 11.) Safas proposes that I construe "substantially isopycnic" to mean that the granules are sufficiently close in density with the gel coat so that they do not settle in the gel coat during preparation and use of the

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composition. (D.I. 78 at 11.) Etura proposes that I construe this claim term to require the specific gravity of the granules and the gel coat resin to be nearly identical with one another and to differ by no more than 0.1. 5 (D.I. 80 at 17.) In support of its position, Etura states that "references in the patent specification and the cited prior art require that the term 'substantially isopycnic' receives a narrow construction." (D.I. 59 at 6; D.I. 80 at 17.) Specifically, Etura argues that the teaching of the prior art Nogi, et al. patent, 6 which is referenced in the '895 patent, should be adopted in construing this claim term. (D.I. 80 at 17); see '895 patent, Col. 1, Ins. 64-67. Because Nogi, et al. taught "that the specific gravities of the granules and the resin matrix should differ by no more than +/- 0.1," Etura argues that the patent-in-suit should be construed to include the same teaching as a limitation. (Id.)

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5 Specific gravity is a unitless measure of density compared to the specific gravity of water, which is 1.0. (D.I. 80 at 17.) 6 The Nogi, et al. patent, United States Patent No. 5,043,377 is entitled "Granite-like artificial stone" and issued on August 27, 1991.

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2. The Court's Construction

I construe "substantially isopycnic" to mean that the granules are largely, but not wholly, of equal density with the gel coat. I again construe "substantially" to mean "being largely but not wholly that which is specified." Merriam-Webster's Collegiate Dictionary at 1170 (10th ed. 2002). The dictionary definition of "isopycnic" is "of, relating to, or marked by equal or constant density." Id. at 621. Apart from the plain meaning of the claim terms, the specification of the '895 patent describes the densities of the gel coat and the granules as being "close to each other," a "match," and "almost the same." '895 patent, Col. 2, Ins 2, 5; Col. 6, Ins. 44-45.

Substantially is a term generally used "to avoid a strict numerical boundary to the specific parameter." Anchor Wall Sys. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1310-11 (Fed. Cir. 2003). Etura has offered no authority to support its argument that the teachings of the Nogi, et al. prior art reference should be imported to the claim construction of the patent-in-suit. Therefore, I decline to adopt Etura's proposed claim construction to limit "substantially isopycnic" to a +/- 0.1 range in difference of specific gravity between the granules and the gel coat.
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3. "the tetracycline compound has substantially no anti-microbial activity"

Plaintiffs construe the term "the tetracycline compound has substantially no anti-microbial activity" to mean "the tetracycline compound has been modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect." (D.I. 53 at 16) Mylan, on the other hand, construes the term "the tetracycline compound [that] has substantially no anti-microbial activity" to mean "a non-antibiotic tetracycline compound." (D.I. 55 at 11) I recommend that the Court adopt Plaintiffs' proposed construction.

During the Markman hearing, Mylan agreed to the portion of Plaintiffs' construction relating to a "tetracycline compound that has been modified chemically to reduce or eliminate its antibacterial activity" because, in its view, that phrase is synonymous with Mylan's proposed construction, i.e., a "non-antibiotic tetracycline compound." (Tr. at 53-55) Mylan does not agree, however, that the claim term also encompasses tetracycline compounds with antibacterial activity that are employed in an amount which has substantially no antibacterial effect. (Tr. at 59) Instead, according to Mylan, the language of the claims mandates a construction that excludes tetracycline compounds having antimicrobial activity because "it is the compound (and not the amount of the compound as [P]laintiffs argue) that 'has substantially no antimicrobial activity.'" (D.I. 55 at 11)

The disputed claim term is found in (among other places) claim 2 of the Amin '395 patent, which reads: "The method according to claim 1, wherein the tetracycline compound has substantially no anti-microbial activity in the mammal system"

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(emphasis added). Read in full, and in the context of the entire patent including the specification, I find that it refers to a functional limitation of the tetracycline compound as it is administered to a mammal, rather than a physical characteristic of the compound itself. This conclusion is supported by the multiple references in the patent specification indicating that a preferred embodiment of the Amin patents' invention is the administration of an antibiotic compound in an amount that does not have antibiotic effect. For example, the Amin '395 patent states:

Preferably, the tetracycline compound is provided in an amount which has little or no antimicrobial activity…. Accordingly, the method can beneficially employ a tetracycline compound which has been modified chemically to reduce or eliminate its antimicrobial properties. …

The invention can also use tetracycline compounds which possess antibacterial activity. However, such compounds are preferably employed in an amount which has substantially no anti-bacterial effect but which is effective for inhibiting iNOS activity in the involved tissue.

(Amin '395 patent, col. 8 lines 24-43)

Mylan's construction would improperly read out of the claims at issue a preferred embodiment. While "[i]t is often the case that different claims are directed to and cover different disclosed embodiments," Federal Circuit case law "generally counsels against interpreting a claim term in a way that excludes the preferred embodiment from the scope of the invention." Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1383 (Fed. Cir. 2008). This is especially true when the term "has multiple ordinary meanings consistent with the intrinsic record," as is the case here. Id.

Accordingly, I recommend that the Court construe the term "the tetracycline compound has substantially no anti-microbial activity" to mean "the tetracycline compound has been modified chemically to reduce or eliminate its antibacterial activity, or the tetracycline compound possesses antibacterial activity but is employed in an amount which has substantially no antibacterial effect."

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II. Construction Of The Disputed Phrases

The parties dispute the construction of four phrases: "substantially powdered form," "mixing the drug and the carbohydrate material," "solid integral mass," and "drug-containing matrix." The four disputed phrases appear in independent Claims 1, 6, 18, and 37 of the '737 patent. Claims 1 and 18 are method claims and Claims 6 and 37 are article of manufacture claims. The language of Claims 1 and 6 are representative of the disputed phrases. In full, Claim 1 provides (emphasis added):

1. A method for producing a drug-containing lollipop for use in transmucosal delivery of the drug to a patient, the method comprising the steps of:

(a) obtaining a pharmacologically effective dose of the drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus;

(b) obtaining a soluble carbohydrate material capable of forming a compressible confectionary matrix and capable of dissolving in the mouth of the patient;

(c) mixing the drug and the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material to form a drug-containing matrix such that the drug is dispersed substantially throughout the matrix, the drug-containing matrix being capable of releasing the drug for absorption through the mucosal tissues upon dissolution of the matrix in the mouth of the patient;

(d) compressing the drug-containing matrix in a mold to form an integral mass such that, when the integral mass dissolves in the mouth of the patient, the drug is released for absorption through the mucosal tissues; and

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(e) incorporating a holder as part of the integral mass in order to form the drug-containing lollipop.

('737 patent, col. 26, 11. 35-60).

In full, Claim 6 provides (emphasis added):

6. A drug-containing lollipop for use in transmucosal delivery of the drug to a patient comprising:

a soluble, compressible carbohydrate material;

a pharmacologically effective dose of a drug in a substantially powdered form, the drug being capable of absorption through mucosal tissues of the mouth, pharynx, and esophagus and being dispersed substantially uniformly throughout the carbohydrate material at a temperature below the melting points of the drug and the carbohydrate material and compressed with the carbohydrate material into a solid integral mass which is capable of dissolving in the mouth of the patient so that the drug is released for absorption through mucosal tissues of the mouth, pharynx, and esophagus upon dissolution of the integral mass in the mouth of the patient;

holder means secured to the integral mass so as to form a drug-containing lollipop, the holder means being configured so as to permit convenient insertion and removal of the drug-containing integral mass into and out of the mouth of a patient.

('737 patent, col. 27, 11. 12-33).

The essence of the dispute with regard to all four disputed phrases is whether they should be construed to require the absence of "free liquid." "Free liquid" is defined by Barr as "any liquid that is not incorporated chemically into the fine particles, beyond that which may be sorbed naturally." (D.I. 41 at 15 n.8.) Cephalon takes no position with regard to whether Barr's definition of "free liquid" is correct. (D.I. 50 at 7 n.17.) The Court construes "free liquid" in accordance with Barr's definition.

Cephalon contends that the disputed claim phrases should not be limited by requiring the absence of free liquid, first, because the plain and ordinary meaning of the phrases does not require it, and second, because neither the specification nor the prosecution history shows any clear disclaimer of the use or presence of free liquid. In response, Barr contends that statements in the specification that describe the "present invention" limit the scope of the claims to preclude free liquid. Barr further contends that the prosecution history shows an effective disclaimer of the use of free liquid in the methods and articles of manufacture claimed by the '737 patent.

The Federal Circuit's recent decision in Phillips v. AWH Corp. clarified the approach that a court should take in construing disputed terms of a patent claim. 415 F.3d 1303 (Fed. Cir. 2005) . Rather than beginning with a broad, dictionary definition and then limiting it in accordance with the specification and the prosecution history, the preferred approach is to focus "at the outset on how the patentee used the claim term in the claims, specification, and prosecution history . . . ." Id. at 1321. Here, both the specification and the prosecution history demonstrate that the inventions actually described and claimed by the '737 patent are a method of producing drug-containing lollipops using the compression of dry, powdered ingredients, and the products resulting from the use of that method. Nowhere in the claims, the specification, or the prosecution history do the inventors ever discuss the possibility of using a liquid as part of their invention. In addition, and more significant, many of their statements indicate that the inventors viewed their invention as enveloping only the dry mixing and compression of powders to form the drug-containing lollipops.

The following are illustrative examples. In the Summary of the Invention section, the '737 patent states that "the present invention teaches the combination of dry powdered ingredients by geometric dilution," ('737 patent, col. 5, 11. 43-45); and "flavorings, drugs, and other components (which may be insoluble in liquid form) are easily mixed when they exist as a dry powder," (Id. at col. 6, 11. 6-8). In the General Discussion of the Preferred Embodiments section, the '737 patent states that "the present invention teaches the mixing of solid powders at room temperature, as opposed to liquid components at elevated temperatures," (Id. at col. 7, 11. 62-65); and "because solid powders are combined together, constituents which may be chemically incompatible when in a heated solution or suspension can be mixed," (Id. at col. 8, 11. 3-6). In the Methods of Manufacture of the Preferred Embodiments section, the '737 patent states that "each of the components is mixed

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with the other components in dry form to produce the compositions of the present invention." (Id. at col. 11, 11. 47-49).

Cephalon argues that these examples do not amount to a clear disclaimer of the use of liquid in the claimed manufacturing method (D.I. 50 at 12-13), but that argument is misplaced. Whether or not there was an explicit disclaimer, the consistent use of a claim term by the inventor in the specification may serve to limit the scope of a claim. Nystrom v. Trex Co., 424 F.3d 1136, 2005 U.S. App. LEXIS 19748, 2005 WL 2218632, 6-7 (Fed. Cir. 2005).

"What Phillips now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to . . . those of ordinary skill in the art . . . that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."

Id. 2005 U.S. App. LEXIS 19748, at 7 (citing Phillips, 415 F.3d at 1321). Here, the inventors consistently referred to the "present invention" as teaching the formation of drug-containing lollipops through the compression of "dry" or "solid" powders. There is nothing in the written description or the prosecution history to suggest that they intended the disputed phrases to cover methods or articles using free liquid. Therefore, it would be improper for this Court to broaden the inventors' use of the disputed phrases and construe them to encompass the use of free liquid.

This result is not, as Cephalon argues (D.I. 50 at 12-13), the improper importation of limitations from the specification into a claim. This is a case where "the specification read as a whole suggests that the very character of the invention requires the limitations to be a part of every embodiment." Alloc, Inc. v. ITC, 342 F.3d 1361, 1369 (Fed. Cir. 2003).

For the reasons discussed above, the Court construes the disputed claim phrases as follows:

A. "Substantially powdered form" means "largely in the form of fine particles absent the presence of free liquid."
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"Substantially pure"

This term appears in Claims 7 and 25 of the '156 Patent. The parties agreed during oral argument that the term does not require construction. The Court agrees and does not construe the term.
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1. "Substantially pure DNA sequence . . . coding on expression for only a single polypeptide chain"

The Claim 8 35 dispute revolves around the meaning of "substantially pure." Schering contends that a mathematical degree of purity is not required, but only that the desired DNA segment must be identified and available for purposes of conducting a hybridization probe for identifying related DNA sequences and for using in a plasmid to express the alpha interferon in the host cell. Additionally, Schering maintains a DNA sequence remains substantially pure even if it is synthetically derived and subsequently, inserted into a particular cloning vehicle (plasmid) and used to express a protein. Amgen counters this contention by arguing that a DNA sequence is "substantially pure" when naturally-occurring DNA is isolated from other DNA sequences. Accordingly, Amgen disagrees with Schering that a DNA sequence may be synthetically derived and that it may be simultaneously "substantially pure" and part of a plasmid within a host cell.

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35 Claim 8 reads:

8. A substantially pure DNA sequence selected from the group consisting of: (a) the DNA inserts of Z-pBR322(Pst)/HcIF-

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4c (DSM1699), Z-pBR322(Pst)/HcIF-2h (DSM 1700), Z-pBR322(Pst)/HcIF-SN35 (DSM 1701), Z-pBR322(Pst)/HcIF-SN42 (DSM 1702) and Z-pKT287(Pst)/HcIF-2h-AH6 (DSM 1703), (b) DNA sequences which hybridize to any of the foregoing DNA inserts and which code on expression for a polypeptide of the IFN- [alpha] type, and (c) DNA sequences which code on expression for a polypeptide of the IFN- [alpha] type coded for on expression by any of the foregoing DNA sequences and inserts, said DNA sequences coding on expression for only a single polypeptide chain.

Col. 37, lines 3-17.

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Consulting the language of the claim first as required under applicable claim construction principles, see Phonometric, 133 F.3d at 1464, "substantially pure DNA sequences" are selected from a group consisting of: the previously discussed DNA inserts (Group A), DNA sequences which hybridize to the DNA inserts and which code on expression for a polypeptide of the IFN- [alpha] type (Group B), and DNA sequences which code on expression for polypeptide of the IFN- [alpha] type coded for on expression by any of the foregoing DNA sequences and inserts and coding on expression for only a single polypeptide chain (Group C). See Col. 37, lines 3-17. As for the Group A DNA sequences, although these DNA inserts have been deposited in the DSM as part of engineered plasmids in bacterial host cells that produce the desired interferon protein, the language of the claim specifically recites that it is the "DNA inserts," not the surrounding plasmid or host cell, that make up the "substantially pure DNA sequences." See Col. 37, lines 3-9. Similarly, only the "DNA sequences" of Group B and C are covered by the claim language. See Col. 37, lines 10-17. It follows the claim language itself makes clear that "substantially pure DNA sequences" refer to DNA sequences separate from the plasmid or bacterial host cell into which they are incorporated.

This interpretation of "substantially pure DNA sequences" is consistent with other claim terms already construed. See Southwall, 54 F.3d at 1579 (claims in the same patent are to be interpreted with reference to one another). Just as the construction given to "a polypeptide of the IFN- [alpha] type" only includes the immature, fused, and/or incomplete forms of leukocyte IFN- [alpha] -1, the DNA sequences are only "substantially pure" because they also may include additional adjacent nucleotides or have less than the full mature IFN- [alpha] -1 nucleotide sequence. In other words, the phrase "substantially pure" has nothing to do with a specific degree of purity, but only reflects that fact that the DNA sequences which code of expression for IFN- [alpha] -1 may be surrounded by additional adjacent nucleotides or be incomplete. Additionally, Claim 8 requires that the "substantially pure DNA sequence . . . code on expression for only a single polypeptide chain." See Col. 37, lines 3, 16-17. If, however, this DNA sequence were to be bound up with plasmid DNA of the bacteria host, more than a single polypeptide chain would be produced in violation of the explicit claim limitation. Further, this interpretation is in conformity with the structure of the '901 Patent as a whole. See Southwall, 54 F.3d at 1579 (individual patent claims should be construed in reference to one another). It is only in the other claims of the '901 Patent that the substantially pure DNA sequences are ligated to the foreign plasmid DNA, through the use of the Pst I restriction enzyme, to form the desired recombinant DNA molecule, see Col. 36, lines 4-24 (Claim 1), and subsequently transform a unicellular host. See Col. 36, lines 40-59 (Claim 5).

Nor does the specification support Schering's construction of this claim language. Although Schering admits that "substantially pure" is not used in the specification, it nevertheless points to an unrelated phrase, "sufficiently purified sample of IFmRNA or DNA . . . to act as a screening probe for the identification of the desired clones," See Col. 9, lines 66-69, as evidence that the substantially pure DNA sequences may be part of a plasmid in a host cell. This language, however, refers to the use of purified IFmRNA or cDNA as a hybridization probe, not to DNA sequences which express interferon in its active form. See Col. 10, lines 7-14. Additionally, this specification language makes no reference to plasmid DNA and/or host cell DNA. In any event, to use the cDNA and IFmRNA as screening probes, one of the explicit functions set out for these DNA sequences by Schering itself, they necessarily have to be separated from other plasmid and host cell DNA. All the other uses of the word "purified" in the specification are similarly unrelated to the disputed claim language in Claim 8. See Col. 24, line 66 through Col. 25, lines 14.

The prosecution history is more ambiguous in this regard. Schering cites the prosecution history for the proposition that substantially pure DNA sequences may be part of a plasmid in a host cell. In substituting the phrase "substantially pure DNA sequence" for "gene" in response to the examiner's rejection that "gene" refers to a product of nature in violation of 35 U.S.C. § 101, Schering asserts that it made clear that the DNA sequences were substantially pure in this invention because

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Before this invention such sequences may have been located somewhere among about the five billion nucleotides of the human chromosome. There, they were plainly not available for use in the production of interferon as described in this application. There, they were plainly not 'substantially pure.' Accordingly, the claimed sequences do not occur 'substantially unaltered' in nature. They are therefore patentable under 35 U.S.C. § 101.

See D.I. 172, Tab 11 at 8. Schering therefore used the phrase "substantially pure" to convey the idea that the interferon gene in question had been isolated, prepared and used for the first time in this invention. Schering urges these DNA sequences are pure in the sense they are separated from the nearly five billion nucleotides of the human chromosome. Schering goes on to argue that the DNA sequences are "substantially pure" in that where before they were part of five billion nucleotides, now they are only part of a bacterial plasmid made up of about five thousand nucleotides. So in comparison, the argument goes, these DNA sequences are "substantially pure."

An equally good argument could also be made that the reason these DNA sequences are considered "substantially pure," rather than just "pure," is because the nucleotide sequence that codes on expression for IFN- [alpha] -1 may have attached to it extraneous, additional nucleotides which code on expression for a leader sequence, fusion proteins, or other extraneous amino acids from adjacent genes on the human chromosome or tails used for ligation purposes. This line of reasoning could also lead to the conclusion that the DNA sequences were at one time or another ligated to plasmid DNA and thus, could be "substantially pure" and still part of the bacterial plasmid within a host cell.

In the end, the correct interpretation of the prosecution history cited above is irrelevant to the Court's analysis. Even assuming for the sake of argument that the prosecution history did allow for the DNA sequences which code for IFN- [alpha] -1 to be attached to DNA sequences from adjacent plasmid DNA, such an interpretation would be inconsistent with the claim language which only covers the DNA inserts and DNA sequences and does not cover the plasmid DNA to which it is ligated or the bacterial host which it transforms. Under such circumstances, the claim language which is the best guide to the meaning and scope of a patent must prevail over the prosecution history. See Phonometric s, 133 F.3d at 1464 (claim language is foremost in importance); see also Markman, 52 F.3d at 980 (prosecution may not enlarge, diminish or vary the limitations in the claim). The Court therefore find that "substantially pure" DNA sequences refer to the DNA sequences alone and apart from plasmid DNA in a bacterial host cell.

At the same time, the Court is persuaded that "substantially pure DNA sequences" can be both naturally occurring and non-naturally occurring DNA sequences. As demonstrated above, substantial purity has nothing to do with a mathematical degree of purity or with natural versus synthetic DNA sequences. The purity in question only refers to the alpha interferon DNA being separated, isolated and identified apart from the human genome and any Other relevant bacterial genome. 36 Further, the specification discloses that nucleotide tails must be added to both the DNA sequences and the spliced plasmid DNA in order to ligate the two components together. If these tails are part of the subsequent substantially pure DNA sequences, there is a segment of the DNA sequences that appears nowhere in nature. See Col. 13, lines 6-21. Additionally, the following specification language contemplates DNA sequences which do not occur in nature:

It is, of course, evident that this method of clone screening may be employed equally well on other clones containing DNA sequences arising from recombinant DNA technology, synthesis, natural sources or a combination thereof . . . .

See Col. 27, line 67 through Col. 28, line 3.

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36 Schering observes that the DNA inserts deposited at the DSM are actually cDNA, which is DNA synthetically derived in a test tube using enzymes. However, the Court does not believe that this is the distinction Amgen wishes to make. Amgen is not concerned whether copies of naturally-occurring DNA can be used, but whether DNA that occurs nowhere in nature may be used. Schering's argument is therefore unresponsive to Amgen's contention.

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The prosecution history also supports this construction. The examiner did in fact reject the following claim language:

DNA sequences from whatever source obtained, including natural, synthetic or semi-synthetic sources related by

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mutation, including single or multiple, base substitutions, deletions, insertions and inversions to [any of the foregoing DNA sequences].

See D.I. 172, Tab 1 at 68. This language was replaced by "DNA sequences which code for a polypeptide coded for by any of the foregoing DNA sequences." See D.I. 172, Tab 18 at 6. However, as explained above, the correction was made not to address the examiner's concerns about synthetic or semi-synthetic DNA sequences, but to address the problem of base substitutions, inversions and mutations which could potentially cover the whole human genome. See D.I. 172, Tab 17 at 3-4. Thus, the prosecution history does not now estop Schering from asserting that "substantially pure DNA sequences" include both naturally-occurring and non-naturally occurring sequences.

The Court holds the claim language "substantially pure DNA . . . coding on expression for only a single polypeptide chain" refers to a naturally occurring or non-naturally occurring DNA sequence, independent of any plasmid DNA in a host cell, which codes on expression for an immature, fused, and/or incomplete form of a naturally occurring human leukocyte interferon protein, subsequently labeled IFN- [alpha] -1.
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2. "Substantially pure" and "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract"

To ascertain what the claim terms "substantially pure" and "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract" mean, the Court must determine how lutein purity is measured.

Plaintiffs assert that the phrases "substantially pure" and "substantially free from other carotenoids and chemical impurities" must be read together and that, together, these phrases mean that "(1) lutein makes up at least 90% of the total carotenoids that are contained in the lutein composition, and (2) the proportion of non-caroteniod chemical impurities compared to total carotenoids in the lutein composition is sufficiently small to permit crystallization of the composition." (Doc. # 244 at 3).

Defendants, on the other hand, argue that the 90% lutein purity is measured in relations to the crystals as a whole, not just the carotenoid composition of those crystals. (Doc. # 103 at 21-22). Thus, Defendants request that the Court consider noncarotenoids, such as fats and waxes, when evaluating lutein purity.

In the PIVEG litigation, the alleged infringer advanced an argument that is very similar to Defendants' argument in the present case, which the district court in PIVEG rejected. The district court in the PIVEG case held that the phrase "substantially pure lutein" must refer to "an amount of lutein in the 'carotenoid composition.'" Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A., 301 F.Supp.2d 970, 985 (S.D. Iowa 2004). The court explained:

Claim construction insists that "the same word appearing in the same claim should be interpreted consistently." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998). The language of claim 1 states: "The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts." This clearly indicates that "substantially pure lutein" must refer to an amount of lutein in the "carotenoid composition." This contradicts PIVEG's interpretation which would include measurement of lutein against all other materials present and would not be limited to other carotenoids present. Contrary to PIVEG's assertions, the three phrases are not actually separate but together indicate the protected level of lutein purity in the carotenoid composition. Thus, lutein purity is to be measured as related to the carotenoid composition and the claim requires the lutein to be substantially free from other carotenoids and chemical impurities.

301 F.Supp.2d at 985 (emphasis in original).

This Court agrees that, when evaluating lutein purity, the Court should consider the percentage of lutein against the percentage of other carotenoids. Residual plant matter, fatty acids, and waxes that are not carotenoids are not to be considered in the "carotenoid composition."

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In a similar argument, Defendants contend that non-carotenoids (the same residual plant matter, fatty acids, and waxes) can undermine the lutein purity of a lutein crystal. Plaintiffs respond that the inventor, Dr. Khachik, recognized that lutein crystallization typically removes some, but not all, of these harmless "background" plant constituents. In fact, a lutein crystal can have up to 30% of these noncarotenoid constituents. (Dr. Khachik Dep., Doc. # 181-5, Ex. D at 65-71). 5

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5 However, at 49% noncarotenoid constituents, there would be no crystal. (Dr. Khachik Dep. Doc. # 181, Ex. D at 65-71).

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The Court agrees with Plaintiffs that if Defendants' claim construction on the issue of lutein purity were adopted, "nobody would be practicing under the '714 patent, including Kemin." (Doc. # 181 at 13). It cannot be disputed that Plaintiffs' as well as Defendants' lutein products contain the aforementioned noncarotenoid plant materials in meaningful quantities. As stated by Zoraida DeFreitas, Ph.D., "if lutein purity were measured against the total mass of the purified product, as OmniActive advocates, Kemin's own free lutein products would have only 74.4 to 80% lutein purity." (Dr. DeFreitas Decl. at P 5, Doc. # 181-6 at Ex. E). Thus, under Defendants' proposed construction, Kemin's own products would not fall within the ambit of Plaintiffs' patent.

The Federal Circuit explains that "[A] claim interpretation that would exclude the inventor's device is rarely the correct interpretation." Modline Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996), abrogated on unrelated grounds by Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000). Stated another way, patent claims should not be construed in a manner that excludes the very invention that the patent was intended to protect. Osram GmbH v. Int'l Trade Com'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007)(rejecting proposed claim construction because it "would exclude the OSRAM products that the patents were designed to cover").

After due consideration, the Court adopts Plaintiffs' position as follows:

The phrases "substantially pure" and "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract" must be read together. Together, these phrases mean that (1) lutein makes up at least 90% of the total carotenoids that are contained in the lutein composition, and (2) the proportion of non-carotenoid chemical impurities compared to the total carotenoids in the lutein composition is sufficiently small to permit crystallization of the composition.

(Doc. # 244 at 3).
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The primary issue for the Court to resolve, and the issue of the most disagreement between the parties, is the meaning of "substantially pure lutein." The Court will first define "substantially" and then construe the meaning of the phrase "substantially pure lutein." As part of this process, the Court will look at whether a numerical range is incorporated by the claim, and what method of measurement is to be used to determine purity.

i. "Substantially Pure Lutein"

Federal Circuit decisions discussing the definition of the term "substantially" are instructive. In a recent decision, Deering Precision Instruments, L.L.C. v. Vector Distributing Systems, Inc., the court was required to construe the meaning of the term "substantially" in a patent claim. Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc., 347 F.3d 1314, 1322 (Fed. Cir. 2003); see also Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1030-31 (Fed. Cir. 2002) (construing the term "substantially"); Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc., 206 F.3d 1408, 1414-15, 1418 (Fed. Cir. 2000) (same); York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572-73 (Fed. Cir. 1996) (same). The court recognized that reference to the dictionary and prior cases show the term "substantially" is capable of multiple interpretations. Deering Precision Instruments, L.L.C., 347 F.3d at 1322-23.

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As the Deering court noted, "substantially" has "a dual ordinary meaning … as connoting a term of approximation or a term of magnitude." Id. at 1323; see also Epcon Gas Sys., Inc., 279 F.3d at 1031. The court found it was proper to look to the specification to determine whether the term "substantially" is a term of magnitude or a term of approximation. Deering Precision Instruments, L.L.C., 347 F.3d at 1323. In Deering, the court went to the specification and found the term "substantially" from the phrase "substantially in the plane" was a term of magnitude. Id. The court then construed "substantially" to require a "not insubstantial" portion. Id. at 1324. The term "substantially" in the phrase "substantially pure lutein" as set forth in the '714 patent is a term of magnitude. This Court likewise construes "substantially" to require a not insubstantial portion of the carotenoid composition be lutein for it to be considered "substantially pure."

PIVEG focuses on the phrases "substantially pure lutein crystals," "substantially free from other carotenoids," and "substantially free from chemical impurities found in the natural form of lutein in the plant extract" as the terms in issue. 10 PIVEG argues that the three phrases, "lutein crystals," "other carotenoids," and "chemical impurities found in the natural form of lutein in the plant extract," were chosen by the inventor, who then used modifiers to describe the boundaries of the invention. The modifiers used are "substantially pure" and "substantially free from." PIVEG asserts that the word "substantially" has the ordinary and common meaning of "being largely but not wholly that which is specified" as evidenced by the definition found in the Merriam-Webster dictionary.

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10 In interpreting claim 1 of the '714 patent, PIVEG contends that:

one of ordinary skill in the art would understand that 'substantially pure lutein crystals" means the carotenoid composition as a whole usually contains more than 90% lutein as measured by UV/visible spectophotometry, and most often contains greater than 97% lutein as measured by UV/visible spectophotometry; "substantially free from other carotenoids" means that, as a percentage of all the carotenoids in the composition, lutein must constitute at least 97.82% of all the carotenoids (i.e., the measure of other carotenoids cannot be more than 2.18%), since the carotenoid profile within the composition is described in the patent specification as 97.82% lutein by HPLC; "substantially free from chemical impurities found in the natural form of lutein in the plant extract" means that chemical impurities such as anthocyanins, plant sterols, and other materials found naturally in the plant extract have been removed at least to the extent that they are not detectable by NMR measurements. "Substantially free from chemical impurities found in the natural form of lutein in the plant extract" does not address chemical residues from any other sources, including those that may remain from the reagents used in the process to extract, saponify, or recrystallize the lutein, and does not limit the presence or absence of chemical residues from other sources in any way.

PIVEG maintains this is the interpretation required by the plain meaning of the claim language and further supported by the patent specification.

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Meanwhile, Kemin argues the phrase "substantially pure lutein" relates to the carotenoid composition, and the additional phrases are not to be considered separately, but rather all relate to the level of lutein purity in the carotenoid composition. Moreover, the same methods of analysis are used to make the determination as to whether "substantially pure lutein crystals" are "substantially free from other carotenoids" and "substantially free from chemical impurities found in the natural form of lutein in the plant extract."

The Court finds PIVEG' proposed construction is inconsistent with the language of the claim itself. Claim construction insists that "the same word appearing in the same claim should be interpreted consistently." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998). The language of claim 1 states: "The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts." This clearly indicates that "substantially pure lutein" must refer to an amount of lutein in the "carotenoid composition." This contradicts PIVEG's interpretation which would include measurement of lutein against all other materials present and would not be limited to other carotenoids present. Contrary to PIVEG's assertions, the three phrases are not actually separate but together indicate the protected level of lutein purity in the carotenoid composition. Thus, lutein purity is to be measured as related to the carotenoid composition and the claim requires the lutein to be substantially free from other carotenoids and chemical impurities.

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ii. Numerical percentage

The next issue concerns whether a certain numerical percentage is required to be considered "substantially pure lutein," and if so, quantifying the required percentage. Kemin asserts that the construction of the term "substantially pure" should not be limited to a strict numerical boundary. Kemin argues the Federal Circuit has recognized that "like the term 'about,' the term 'substantially is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" Ecolab Inc., 264 F.3d at 1367 (quoting Pall Corp., 66 F.3d at 1217). Accordingly, Kemin urges the Court to not construe the term "substantially pure" in claim 1 as limited to a strict numerical boundary.

"It is usually incorrect to read numerical precision into a claim from which it is absent …." Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996) (discussing meaning of "relatively small"). "Thus, when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." Renishaw, 158 F.3d at 1249; see also Modine Mfg. Co., 75 F.3d at 1551 ("Ordinarily a claim element that is claimed in general descriptive words, when a numerical range appears in the specification and in other claims, is not limited to the numbers in the specification or other claims.") (citing Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988) ("particular embodiments appearing in the specification will not generally be read into the claims")). In addition, the preferred embodiment in the specification cannot serve to limit the ordinary meaning of a claim term. CCS Fitness, Inc., 288 F.3d at 1366 (finding a patentee need not describe every possible future embodiment).

The Court notes, however, that prior art compositions such as those used in the poultry industry and acknowledged in the patent achieved 70% purity by UV/visible spectophotometry. ('714 patent, col. 2, Ins. 51-54; col. 4, Ins. 43-49). In the written description of the patent, the inventor provides examples of his composition to distinguish his composition from the prior art compositions with 70% purity used in the poultry industry. This is indicative as to what is meant by "substantially" in the '714 patent, and more precisely, the levels of purity required. Because 70% purity was considered "substantially pure" at the time of the '714 patent, and the "714 patent is premised on a composition of far greater purity, the Court finds a numerical boundary is necessary and proper when the claim and the specification are considered together. In other words, there needs to be some quantification of the phrase "substantially pure" as it relates to the level of lutein purity in the carotenoid composition.

Kemin argues that if a numerical boundary is to be set, the Court should construe the claim to require 90% purity. Kemin argues this is the interpretation supported by the specification as the claim does not indicate a specific numerical percentage to define "substantially pure." Specifically, Kemin points to the portion of the specification that indicates the purified lutein "exists in substantially purer form in comparison with lutein found in the matrix of any naturally occurring plant." ('714 patent at col. 5, Ins. 30-33). In addition, the specification states the purity of the resulting lutein within the carotenoid composition is "usually greater than 90%." ('714 patent at col. 5, Ins. 17-18). Kemin explains this statement to mean that "about 90% of the carotenoids present in the plant extract would be lutein crystals based on quantitative HPLC analysis of the carotenoid composition." Kemin also asserts that a person of ordinary skill in the art "would understand that in addition to the carotenoid composition, the plant extract would also contain certain residual plant material, such as waxes, and certain fatty acids, which could be quantified by UV/visible spectophotometry."

PIVEG contends that a separate numerical percentage is warranted for each of the three individual phrases it posits the claim contains. Briefly, PIVEG maintains that:

> one of ordinary skill in the art would understand that this patent discloses a carotenoid composition … consisting essentially of "substantially pure lutein crystals," i.e., crystals consisting of usually greater than 90% lutein by UV/spectophotometry; is "substantially free from other carotenoids,' meaning that lutein consists at least 97.82% of the carotenoids present leaving 2.18% for other carotenoids; and is "substantially free from chemical impurities found in the natural form of lutein in the plant extract," meaning that these chemical impurities are not detectable by NMR imaging.

The Court has already determined the three phrases urged as separate and distinct by PIVEG are not to be interpreted separately. Rather, the phrase "substantially pure" refers to the lutein purity in the carotenoid composition. Thus, separate numerical percentages for the phrases "substantially pure lutein crystals," "substantially free from other carotenoids," and "substantially free from chemical impurities found in the natural form of lutein in the plant extract" are not warranted.

Therefore, PIVEG asserts in the alternative that the claim terms "substantially pure lutein crystals" means "the carotenoid

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composition as a whole usually contains more than 90% lutein as measured by UV/spectophotometry, … most often 97%." To support its construction, PIVEG points out in the specification that the patent states "further purification of this [70% pure lutein] composition may be employed to produce lutein with purity greater than 97% …." (('714 patent, col. 4, Ins. 50-52). After describing the method used to further purify the lutein, the specification describes the resulting lutein purity as "usually grater than 90%, most often greater than 97% as determined by UV/visible spectophotometry." ('714 patent, col. 5, Ins. 17-19). The specification further describes the carotenoid composition in terms of HPLC analysis that "consists of 94.79% lutein, 3.03% of its geometric isonomers, and a total of 2.18% of other measurable carotenoids." ('714 patent, col. 5, Ins. 21, 22).

'"Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.'" Comark Communications, Inc., 156 F.3d at 1187 (quoting Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988)); see also Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986). In fact, "when a claim term is expressed in general descriptive words, [the court] will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." Renishaw, 158 F.3d at 1249; see also Modine Mfg. Co., 75 F.3d at 1551. Kemin argues PIVEG's reference to the specification to determine specific percentages required by the '714 patent is inconsistent with case law in that it serves to read a limitation into the claim that does not appear in the actual language of the claim.

Based on the claim language and the definition of "substantially" discussed above, along with the written description of the patent and the examples found in the specification, the Court construes the phrase "substantially pure" to require at least 90% purity. Clearly the patent only covers lutein with a purity level greater than at least 70%, as this is covered by prior art. Further, the specification makes clear that the lutein achieved by the patent inventor was usually in excess of 90%, and the Court finds that a person of ordinary skill in the art would read the claim and the specification as covering lutein with a purity level of at least 90% as compared to the carotenoid composition.

In addition, the Court finds the scope of the patent extends to lutein that is suitable for human consumption. The Court previously discussed this potential construction of the scope of claim 1 of the '714 patent in its order on the plaintiff's motion for preliminary injunction. In that order, the Court found the term "substantially pure lutein" covers lutein that is suitable for human consumption. One of the basic and novel properties of the '714 invention is that the purified lutein crystals are suitable for human consumption. The specification supports this construction. The further record made subsequent to the preliminary injunction application has not convinced the Court to the contrary.

The specification indicates that, prior to the '714 patent, "pure lutein suitable for human use has not been commercially available," and "pure lutein, free from chemical contaminants and suitable for human consumption is needed" for use in human intervention studies and as a color additive. ('714 patent, col. 2, Ins. 5-10; col. 2, Ins. 51-60). One of the objectives of the '714 patent was to fulfill this need by providing pure lutein suitable for human consumption for use in cancer prevention trials and treatment and as a food additive. ('714 patent, col. 3, Ins. 17-24). The examples from the specification further delineate the objective that the pure lutein be suitable for human consumption by providing for use of materials that are "food grade" by meeting the "qualifications for food ingredients," ('714 patent, col. 5, Ins. 50-53 (marigold flowers tested "to ensure they meet qualifications for food ingredients"); col. 5, Ins, 54-56 (use of "food grade aqueous potassium hydroxide"); col. 5, In 61 (use of "food grade" ethanol)), and discussing the preparation of lutein for oral supplementation ('714 patent, col.. 8, Ins. 3-61).

Claim 1 uses the transition phrase "consisting essentially of," which serves to exclude elements that are not specifically listed in the claim that would materially alter the novel and basic properties of the lutein. See, e.g., PPG Indus., Inc. v. Guardian Indus., Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). Thus, the language of the claim specifically excludes anything that would make the resulting purified lutein crystals unsuitable for human consumption.

With regard to whether lutein is "substantially pure" so as to be suitable for human consumption, the Court notes that the Federal Circuit has found "it is quite sensible to look to the FDA to determine what amounts are considered pharmaceutically effective." Key Pharms, 161 F.3d at 718. Likewise, this Court finds a person skilled in the art would know to look to the FDA standards governing whether a product such as lutein is suitable for human consumption.

iii. Method of measurement

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UV/visible spectophotometry does not distinguish between different carotenoids present and therefore cannot make absolute measurements as to the amount of lutein present. However, this measurement in conjunction with HPLC analysis can render a specific, quantitative measurement of lutein purity for purposes of the '714 patent. The Court therefore finds, and the parties agree, that both UV/visible spectophotometry and HPLC are required to accurately measure lutein purity. The Court finds the evidence is undisputed a person of ordinary skill in the art at all material times would recognize UV/visible spectophotometry in conjunction with HPLC is the correct method of measurement to determine lutein purity, and therefore must necessarily be considered the proper method of measurement for purposes of the '714 patent.

iv. Construction of Claim 1

Based on the foregoing, the Court's construction of claim 1 of the '714 patent, is as follows: One of ordinary skill in the art would understand the plain meaning of claim 1 of the '714 patent to provide for a carotenoid composition consisting essentially of substantially pure lutein crystals, where "substantially pure" refers to the lutein purity as compared to the carotenoid composition and requiring purity that is 90% or greater, as measured by UV/visible spectophotometry in conjunction with HPLC, and/or otherwise suitable for human consumption.
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In reviewing the district court's construction of the claims, we begin with the language of the asserted claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claims 1, 2, and 4 of the '714 patent, the only claims at issue in this appeal, read as follows:

1. The carotenoid composition consisting essentially of substantially pure lutein crystals derived from plant extracts that contain lutein, said lutein crystals being of the formula:

[SEE EXHIBIT IN ORIGINAL]

wherein the lutein is substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extract.

2. The lutein carotenoid composition of claim 1 wherein the plant extract is derived from naturally occurring plants selected from the group consisting of fruits, vegetables, and marigolds.

4. The lutein carotenoid composition of claim 1 wherein the lutein is derived from marigold flower extract.

'714 patent, col. 8,I.65 - col. 9,I.22.

The district court did not formally construe the claims. Implicit in the court's Supplemental Order, however, is the implication that the claims cover all "lutein crystals from plant extracts with a purity level of 90% or greater and/or suitable for human consumption," because that is what it enjoined PIVEG from making, using, importing, or selling. Supplemental Order, 240 F. Supp. 2d at 983. Also, in its Preliminary Order, the court explained:

The specification . . . delineates the importance of the '714 lutein crystals being suitable for human consumption. The '714 patent uses the transition phrase "consisting essentially of", which is used to exclude elements that are not specifically listed in the claim which would materially alter the novel and basic properties of the lutein. Thus, Kemin has specifically excluded anything that would make the resulting purified lutein crystals unsuitable for human consumption, since human consumption suitability is one of the basic and novel properties of the invention.

240 F. Supp. 2d at 970-71 (citation omitted).

For the reasons stated below, we essentially agree with the district court's interpretation that "substantially pure" means that the lutein crystals of the claimed compositions must be at least about 90% pure, but disagree with its inclusion of the "human consumption" limitation.

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The '714 patent's claims do not define the level of purity required for a composition to be deemed "substantially pure" or "substantially free from other carotenoids and chemical impurities," and thus we turn to the specification for guidance. See Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., 347 F.3d 1314, 1323 (Fed. Cir. 2003) ("Since the term 'substantially' is capable of multiple interpretations, we turn to the intrinsic evidence to determine which interpretation should be adopted."), cert. denied, 158 L. Ed. 2d 88, 124 S. Ct. 1426, 2004 U.S. LEXIS 1126, 72 U.S.L.W. 3452 (U.S. Feb. 23, 2004) (No. 03-958). Like its claims, however, the '714 patent's specification does not explicitly define the term "substantially." Nonetheless, the specification does provide some guidance, stating, for example, that "the purity of the resulting lutein is usually greater than 90%, most often greater than 97%." Id. at col. 5,II. 17-18. Thus, we conclude that "substantially pure" is properly construed to mean "greater than about 90% pure."

The claims of the '714 patent also require that lutein be "substantially free from other carotenoids and chemical impurities found in the natural form of lutein in the plant extracts." '714 patent, claim 1. The identity of the "other carotenoids and chemical impurities" from which the compositions must be "substantially free" is not stated in the claims, but representative examples are provided in the patent's specification:

Lutein is one of the major constituents of green vegetables and fruits such as broccoli, green beans, green peas, lima beans, Brussels sprouts, cabbage, kale, spinach, lettuce, kiwi, and honeydew. The lutein in these green vegetables and fruits exists naturally in the free non-esterified form and co-exists with other carotenoids.

. . . Many expensive and time-consuming purification steps are required to remove and purify lutein from the large quantities of chlorophylls, -carotene, and carotenoids epoxides [sic] that are also present in green vegetables.

. . . Lutein in . . . yellow/orange fruits and vegetables exists in the esterified form with fatty acids such as myristic, lauric, and palmitic acids. . . . These yellow/orange fruits and vegetables also contain high concentrations of a number of other carotenoids which make the isolation and purification of lutein costly and time-consuming.

Marigold flower petals are an excellent source of lutein because they contain high levels of lutein and no significant levels of other carotenoids. Extracts of marigold flowers are commercially available but consist of lutein that is esterified with fatty acids such as lauric, myristic, and palmitic acids.

Id. at col. 2,II. 11-43. Accordingly, we read the claim language to be limited to compositions containing lutein crystals that are substantially free from, for example, chlorophylls, -carotene, carotenoid epoxides, and fatty acid esters of lutein. There is no indication that any of those impurities would render the compositions unsuitable for human consumption--after all, they apparently do not render vegetables and fruits unsuitable for human consumption. Nonetheless, the presence of such impurities would take a composition outside the scope of the properly construed claims.

Although "substantially free" is also not defined, the '714 patent's specification states that, "generally, the concentration of other carotenoids in the starting material should be 10% or less," id. at col. 3,II. 57-59 (emphasis added). If the starting material (i.e., marigold petal extract prior to purification) generally contains 10% or less of other carotenoids, it follows that lutein that "is substantially free from other carotenoids . . . found in the natural form of lutein in the plant extract" must contain much less than 10% of the other carotenoids. Indeed, Example 2, the only example in the '714 patent to specify the concentration of "other carotenoids" present in an illustrative example of a product of the invention, recites 0.23% 2',3'-anhydrolutein, 1.51% zeaxanthin, 0.34% a-cryptoxanthin, and 0.10% -cryptoxanthin, for a total of 2.18% "other carotenoids." Id. at col. 7,II. 37-41. Finally, the specification states that "the purified lutein is required not to contain even traces of any toxic chemicals." Id. at col. 4,II. 16-17. Accordingly, consistent with the district court's opinion, we conclude that the claimed compositions must contain lutein crystals that are greater than about 90% pure, significantly less than 10% of other carotenoids, and no traces of toxic chemicals.

Nonetheless, it was error for the court to have read the limitation "suitable for human consumption" into the claims, either as an alternative to the 90% minimum or in conjunction with it. It may well be that all compositions that fall within the scope of claim 1 of the '714 patent would in fact be suitable for human consumption. However, that is not what the claim requires. Although provision of lutein suitable for human consumption is certainly one of the stated objectives in the '714 patent, see id. at col. 3,II. 17-19, the specification also indicates that other end uses for the claimed formulations may exist, id. at col. 3,II. 36-39. 1

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1 Although the above discussion focuses on claim 1 of the '714 patent, our construction of the terms of that claim apply as well to claims 2 and 4, both of which depend from claim 1.

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Having construed the claims, the next step is, as explained above, to compare the properly construed claims to the allegedly infringing compositions. The district court did not make any findings as to the identity or quantity of the impurities in those compositions. Kemin asserts that PIVEG's product contains 92.63% pure lutein, in which case it would meet the "substantially pure" limitation. On the other hand, PIVEG alleges that its accused products contain only 87% +/- 2% pure lutein, which will not fall within the scope of the properly construed claims. Accordingly, we conclude that a substantial question exists concerning infringement and that Kemin has not shown that it will likely prove infringement at trial. It therefore has not demonstrated a sufficient likelihood of success on the merits of its case to support a preliminary injunction.
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A. Tentative claim construction of "substantially pure regioisomer" in the process patent

At the preliminary injunction stage, the district court has the discretion to base its resolution on a tentative claim construction. Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1361 (Fed. Cir. 2002). "District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." Id.

The Court decides claim construction as a matter of law: "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman v. Westview Instruments, 517 U.S. 370, 372, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). "To ascertain the meaning of claims, we consider three sources: the claims, the specification, and the prosecution history." Markman v. Westview Instruments, 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996) (citations omitted).

1. Ascertaining the meaning based on the claims

The Court first looks to the language of the claims themselves to ascertain the meaning and scope of the phrase "substantially pure regioisomer." Claim 1 recites "a process of preparing a piperidine derivative compound" of a formula which includes both fexofenadine and fexofenadone, "said process comprising: providing a substantially pure regioisomer" p-CPK and "converting the substantially pure regioisomer to the piperidine derivative compound" using the compound azacyclonol ("AZA"). '703 Patent col.23 1.45 - col.24 1.34. Claim 6 adds onto this process a step in which the piperidine derivative compound is transformed into an end product in the fexofenadine family, Id. col.25 1.63 - col-26 1.16. Claim 7 recites the process of claim 6, with the end product being fexofenadine. Id. col.26 11.17-32. Thus, in claim 7, the patented process begins with the "substantially pure regioisomer" p-CPK, often referred to as an intermediate, and finishes with the end product fexofenadine. The parties agree that there is nothing express or implicit in the words of claims 1, 6, or 7 that delimits the purity of the p-CPK intermediate that the process begins with. They agree as well that "substantially pure" has no ordinary or customary meaning to one of ordinary skill in the art. (Def.'s Opp. Br. 44.)

Claim 2 provides information relevant to construction of the phrase at issue. Nonasserted dependent claims may be helpful in construing a term in an independent claim, because the claims must be interpreted consistently. See Wright Med. Tech., Inc. v. Osteonics Corp., 122 F.3d 1440, 1445 (Fed. Cir. 1997) ("We must not interpret an independent claim in a way that is inconsistent with a claim which depends from it"); accord Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1317 (Fed. Cir. 2005).

Claim 2 depends from claim 1 and recites steps comprising the "providing a substantially pure regioisomer" of the previous claim, Id. col-24 1.35 - col.25 1.22. These steps comprise, in brief, producing a first mixture of regioisomers, which is

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hydrolyzed to form a second mixture of regioisomers, and then "recovering from the second mixture of regioisomers the substantially pure regioisomer" p-CPK. Id. col.25 11.12-13. The parties do not dispute that "mixture" in claim 2 refers to a mixture of meta regioisomers and para regioisomers. The claim language thus establishes that a "substantially pure regioisomer" is something that is recovered from, and therefore, not the same as, a "mixture of regioisomers." This must mean that a "substantially pure regioisomer" is not a "mixture" of regioisomers. This supports an initial construction of "substantially pure regioisomer" as meaning "the regioisomer substantially different from a mixture." Moreover, if the mixture consists only of para and meta regioisomers, and a non-mixture is recovered, then this non-mixture must logically substantially consist of only the para regioisomer or the meta regioisomer. n1 Because the parties agree that, as a general rule, the meta regioisomers of fexofenadine are unwanted impurities that should be eliminated, and they do not dispute that one of ordinary skill in the art would have understood this at the time of application, it is reasonable to infer that "substantially pure regioisomer" in claim 2 means "the para regioisomer substantially not mixed with meta regioisomer." Because claims must be interpreted consistently, this analysis provides the initial construction of "substantially pure regioisomer," as used in claim 1.

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n1 Other unspecified impurities may be present. As will be discussed further infra, the parties dispute whether purity should be understood as regioisomeric purity (purity of the para regioisomer relative to the meta regioisomer) or as chemical purity (purity of the para regioisomer relative to all other substances). Resolution of that dispute is not necessary at this point in the analysis.

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Drawings in a patent may be a source of information in claim construction. Ferguson Beauregard/Logic Controls v. Mega Sys., LLC, 350 F.3d 1327, 1338 (Fed. Cir. 2003); Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002). In the chemical drawings used in the claims, benzene rings are drawn as hexagons with a circle inside. Each circle is labeled with a letter that corresponds to the substituent of the ring. Defendants observed, and Plaintiffs did not dispute, that the diagrams themselves indicate whether a chemical is or is not a mixture: the drawings of chemicals identified as mixtures in the claims all show a bond line connecting the hexagon to the circle, whereas the drawings of chemicals identified as substantially pure have no such connecting bond line.

This aspect to the drawings appears meaningful in examining claim 2. Thus, in claim 2, a diagram with a connecting line depicts "a first mixture of regioisomers" and "a second mixture of regioisomers." '703 Patent, col.24 1.58 - col.25 1.9. After stating the step of "recovering from the second mixture of regioisomers the substantially pure regioisomer," claim 2 shows a diagram without a connecting line. Id. col.25 11.11-22. This provides additional support for the inference that the "substantially pure regioisomer" of claim 2 is not a "mixture."

In addition, the diagram for the piperidine derivative of claim 7, depicting the end product fexofenadine, has no connecting line. Id. col.26 11.17-32. This supports the inference that the end product is also not a mixture. While this does not establish that the substantially pure intermediate and the end product have the same purity level, here is a place that the inventor could have expressly differentiated the purity of the substantially pure intermediate from the purity of the end product, but chose not to do so.

Because the inventor may be his own lexicographer, however, one cannot know from the claims alone exactly where to draw the line that distinguishes, in terms of purity level, between the "substantially pure regioisomer" and the "mixture."

2. Ascertaining the meaning based on the specification

The Court next looks to the patent specification as a source of information for claim construction. Federal Circuit law is clear that courts must exercise great care when using the patent specification to limit the scope of claims:
This court recognizes that it must interpret the claims in light of the specification, yet avoid impermissibly importing limitations from the specification. That balance turns on how the specification characterizes the claimed invention. In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. For example, it is impermissible to read the one and only disclosed embodiment

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into a claim without other indicia that the patentee so intended to limit the invention. On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.

Alloc, Inc. v. Int'l Trade Comm., 342 F.3d 1361, 1370 (Fed. Cir. 2003) (citations omitted). The test for limiting claim scope from the specification is a stringent one: "the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

Of particular interest to the parties are the last two paragraphs in the "Background of the Invention" section:

The above second mixture of regioisomers can be converted to a third mixture of regioisomers of formula: [diagram of fexofenadine] Although the second mixture of regioisomers and the third mixture of regioisomers can be analyzed by HPLC experiments, a practical separation to obtain gram quantities of substantially pure regioisomers has not been achieved.

Each mixture (including the first), would be expected to contain 33% of the para isomer and 67% of the meta isomer. Since these components are inseparable, it has not been possible to obtain either of the regioisomers in each mixture in substantially pure form.

'703 Patent col.3 1.66 - col.4 1.24.

Plaintiffs argue that the only clear disavowal of claim scope in the specification appears in the second paragraph above: because it states that a mixture is not in substantially pure form, and also that a mixture may contain one of the regioisomers at a level of 67%, a "substantially pure regioisomer" must contain one of the regioisomers at a level greater than 67%. This, Plaintiffs argue, draws the line between "substantially pure" and "mixture" that one cannot discern from the claims themselves. Defendants argue that the analysis of the specification need not stop here, and this argument has merit.

The parties do not dispute that this quoted section refers to the prior art Carr process, that the first mixture refers to the intermediate straight-chain PK, the "second mixture of regioisomers" refers to fexofenadone, and the "third mixture of regioisomers" refers to fexofenadine. The second paragraph states that, because the para isomer and meta isomer of fexofenadone or fexofenadine cannot be separated, it has not been possible to obtain these regioisomers in substantially pure form. This establishes that 1) "substantially pure regioisomers" is a term that the inventor applied not only to p-CPK, as in claim 1, but also to fexofenadone and fexofenadine; n2 and 2) that "regioisomers in substantially pure form" are not mixtures, but are either the para or the meta isomer only, formed by separating mixtures. This second inference confirms the initial construction derived from the claims discussed supra.

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n2 The parties agree that fexofenadine exists in the form of a regioisomer, using conventional chemistry terminology. The cited portion of the specification establishes that the inventor, acting as his own lexicographer, did not exclude fexofenadine from the category of substantially pure regioisomers. Rather, p-CPK, fexofenadone, and fexofenadine may all exist as substantially pure regioisomers.

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The parties dispute how the cited paragraphs in the specification should be construed to limit the claims. Defendants argue that they establish that the para and meta regioisomers of fexofenadone and fexofenadine are inseparable. Because mixtures of these products are inseparable, Defendants argue, any separation needed to purify the end product must occur at an early stage, prior to the reaction producing fexofenadone. This issue will be discussed in detail infra.

Other parts of the specification provide information relevant to the construction of "substantially pure regioisomer."

i. Both the end product and the p-CPK intermediate are described in the specification as "substantially pure."

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Although "substantially pure" describes only intermediates in the claims, it describes the end product at a number of points in the specification: in the abstract ("The present invention relates to a process for preparation of substantially pure piperidine derivative compounds" followed by generic formulae for fexofenadone and fexofenadine), '703 Patent at [57], in the summary of the invention ("The present invention relates to substantially pure piperidine derivative compounds" followed by the same formulae), Id. col.4 11.27-28, in the detailed description of the invention (repeating the statement just quoted in the summary), Id. col 6 11. 19-20, and in two examples of processes for converting the substantially pure regioisomer to the substantially pure piperidine derivative, Id. col.16 11.31 - col.19 1.35. In the background of the invention, in one sentence, the patent groups together intermediates and end products as "substantially pure." Id. col.4 11. 18-19.

Thus, the inventor describes the invention as involving substantially pure piperidine derivative compounds at three key, prominent points in the specification. While there are two additional points where this phrasing is used in the context of preferred embodiments, the first sentences of the abstract, summary, and detailed description do not refer to particular embodiments but to the invention as a whole. This clearly establishes a limitation of the invention to processes producing substantially pure piperidine derivative compounds. As will be seen infra, this conclusion is well-supported by the prosecution history. Moreover, the inventor does not in any way differentiate the meaning of "substantially pure" as it describes the end product from the meaning of "substantially pure" as it describes the intermediate.

ii. Both the end product and the p-CPK intermediate are described in the specification as "regioisomers."

Although only intermediates are described as "regioisomers" in the claims, the specification refers to fexofenadone and fexofenadine regioisomers. In the background of the invention, regarding prior art mixtures of fexofenadine and fexofenadone, the patent states: "a practical separation to obtain gram quantities of substantially pure regioisomers has not been achieved." Id. col.4 11.18-19. The patent then teaches that each mixture contains both meta isomer and para isomer, and that "since these components are inseparable, it has not been possible to obtain either of the regioisomers in each mixture in substantially pure form." Id. col.4 11.22-24. This expands the scope of "regioisomers" to include not only the intermediate p-CPK, as mentioned in the claims, but also fexofenadone and fexofenadine.

The import of this reading of the specification is that, because both the end product and the p-CPK intermediate are described in the specification as "substantially pure," and both the end product and the p-CPK intermediate are described in the specification as "regioisomers," the specification does not support two definitions of "substantially pure," one for the intermediate and one for the end product, nor can "regioisomer" be read to connote or distinguish purity.

iii. The piperidine derivative compounds have pharmaceutical uses.

"Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 864 (Fed. Cir. 2004).

The specification describes pharmaceutical uses of the substantially pure piperidine derivative compounds. The summary of the invention states: "These compounds are useful in pharmaceutical compositions, particularly as antihistamines, antiallergy agents, and bronchodilators." '703 Patent col.5 11.6-8. The detailed description of the invention describes pharmaceutical uses of the end products at some length, beginning by stating: "The piperidine derivative compounds of the present invention can be utilized as the biologically active components in pharmaceutical compositions." Id. col.1 1 11.34-36. The parties do not dispute that only the para regioisomer piperidine derivative compounds are biologically active; the meta regioisomer end product is not. Because only para regioisomer piperidine derivative compounds are biologically active, only these compounds can be utilized for the described use. This could suggest a limitation of the invention to a process producing para regioisomer piperidine derivative compounds. Yet this does not rise to the level of establishing a clear intention to limit claim scope through "words of manifest exclusion or restriction." n3

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n3 At oral argument, counsel for Plaintiffs stated that the para regioisomer is the end product, and that the meta regioisomer of fexofenadine "is not the end product" of the process patent. (Hr'g Tr. 10, Oct. 27, 2005.) Again, while strongly suggestive, this is not an expression of manifest exclusion either. Plaintiffs also stated that the para regioisomer of CPK leads to the biologically active form of fexofenadine, while the meta regioisomer of CPK does not. (Id. at 34.)

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The detailed description teaches how to use the "compounds of the present invention" to "treat" humans. Id. col.12 1.27. It discloses treatment methods using the compounds and makes no mention of further purification before such methods as intravenous administration. Id. col.11 1.44.

While these statements appear to describe the invention as a whole, rather than preferred embodiments, again, one cannot characterize them as establishing a clear intention to limit claim scope through words of manifest exclusion or restriction. One is not led to the "inescapable conclusion," based only on these specification statements, that the end product of every embodiment must be ready for pharmaceutical use or must be at a particular level of purity. See Microsoft Corp. v. Multi-Tech Sys., 357 F.3d 1340, 1348 (Fed. Cir. 2004) (employing the "inescapable conclusion" standard in determining whether to find claim limitations in the specification).

Moreover, Plaintiffs argue that, while it would be incorrect to limit the patent to processes producing end products pure enough for pharmaceutical use, such a limitation would not defeat their argument that Ranbaxy has infringed. If this Court construed "substantially pure regioisomer" as to the intermediate to mean "purity sufficient to obtain a pharmaceutical grade piperidine derivative compound," Plaintiffs argue, Ranbaxy would literally infringe, since it necessarily uses p-CPK intermediate at a purity level sufficient to obtain a pharmaceutical grade piperidine derivative compound. Thus, even if this Court found a manifest restriction in the specification to processes producing end product pure enough for pharmaceutical use, this would not shield Ranbaxy from a finding of infringement.

iv. The specification does not support two standards of substantial purity.

The language of the specification does not support two definitions of "substantially pure," one for the intermediate and one for the end product. The inventor applies the phrases "substantially pure" and "substantially pure regioisomers" indiscriminately to intermediate and to end product; there is no evidence that he intended anything other than one common definition. The specification does not, however, establish a clear scope for "substantially pure." Viewed as a whole, the language within the patent strongly suggests that "substantially pure" is a very high level of purity. While it is clear from the patent that a line separates what is "substantially pure" from what is a mixture, neither the claims nor the specification place that line with more clarity or certainty than the 67% line Plaintiffs point to. Because the inventor may act as his own lexicographer, he may define "mixture" and "substantially pure" in idiosyncratic ways. As such, the language of the patent, without more, does not justify limiting "substantially pure" beyond the 67% level Plaintiffs advocate; the language suggesting higher purity does not meet the standard of explicit restriction that the Federal Circuit requires in order to limit claim scope.

Plaintiffs argue that one of ordinary skill in the art would understand that purity standards for intermediates are "often different" from purity standards for end products. (Pls.' Reply Br. 101.) This statement, however, works against them. If one of ordinary skill in the art would understand that such purity standards are often different, one would sometimes understand that they are the same. This supports the conclusion from the specification that this is one of those times, and that "substantially pure" has one uniform meaning in the patent as a whole.

Plaintiffs state that there is nothing in the patent that expressly states that the purity standards are the same. (Id. at 101 n.38.) But, for this to get them to their conclusion, Plaintiffs require a default rule that makes no sense: the reader of the patent should assume that one phrase has different meanings in different contexts unless told otherwise. In reality, the default rule is opposite: the reader assumes that one phrase has a uniform meaning unless told otherwise. As such, in the absence of any express differentiation of the two standards in the patent or prosecution history, Plaintiffs have in effect admitted that one of ordinary skill in the art might understand that the "substantially pure" purity standard for the regioisomer intermediate is the same as that for the "substantially pure" regioisomer end product.

Further support for this interpretation comes from the deposition of the inventor, D'Ambra. Questioned specifically about this issue - whether "substantially pure" means one thing as applied to the end product and another thing as applied to the intermediate - D'Ambra admitted that this distinction does not appear in the patent: "Q: And where do I find that understanding in your patent? A: I don't believe it's clarified in there." (James Decl. Ex. 12 137:10-13.) Of course, Plaintiffs have failed similarly to provide any support for such an understanding either.

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3. Ascertaining the meaning based on the '703 prosecution history

The Federal Circuit restated the basic principles guiding the use of the prosecution history in claim construction in Seachange Int'l, Inc. v. C-Cor Inc., 413 F.3d 1361, 1372-73 (Fed. Cir. 2005):

In construing the claim, we consider the prosecution history to determine whether the patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms. In doing so, we examine the entire prosecution history, which includes amendments to claims and all arguments to overcome and distinguish references. Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language. A disclaimer must be clear and unambiguous.

Id. (citations omitted).

On March 3, 1994, in response to the first office action on the parent application, serial no. 08/083,102, the applicant submitted an amendment to the application in which he asked the examiner to amend claim 1, and argued that the rejection of claims 1 - 6 and 13 - 19 under 35 U.S.C. § 103 should be withdrawn. (James Decl. Ex. 67 at 10.) To support this argument, he distinguished the prior art Carr patents on two bases. One concerned the presence of substituent Z in the piperidine derivative, and the other was based on the purity of the end product. In describing the process in the Carr patents, D'Ambra stated that they:
suggest a recrystallization treatment ... In attempting to reproduce the synthetic procedures of the Carr patents, applicant has discovered that, even with such recrystallization, the yield of the desired para isomer is about 2%. In addition, the meta isomer is present in an amount of up to 5% in admixture with the desired para product. Accordingly ... although the recrystallization steps in the Carr terfenadine metabolite n4 patents are effective in removing some of the theoretically-present meta isomer, there remains a quantity of that impurity in the desired para-containing product stream which is inseparable.

The present invention is directed to a process capable of producing substantially pure piperidine derivative compounds of the formula set forth above in claim 1.

(Id. at 9.) As explained by Defendants, and not disputed by Plaintiffs, this states that the Carr process produced a yield of 2%, of that 2%, 5% was an impurity, the meta regioisomer, that could not be removed. It is only this remaining 5% that is inseparable.

The applicant proceeded to distinguish the Carr process:
The Carr terfenadine metabolite patents use a substantially different process than that claimed by the applicant. More particularly, the Carr terfenadine metabolite patents' product is prepared by the above-described prior art process which requires removal of a significant quantity of an impurity by recrystallization and, even after such treatment, it still contains that impurity at a level of up to 5%.

(Id. at 11.) The applicant then described the process of the present invention, asserting that it "achieves substantial benefits over the prior art process." (Id.) He explained that, by using the substantially pure regioisomer as starting material, the AZA coupling reaction:
yields the piperidine derivative compound of applicant's claimed invention with the desired para configuration. Unlike the prior art process, no separation step is required after that reaction and, even more interestingly, the product of the present process can be prepared in a substantially pure form suitable for pharmaceutical use.

(Id. at 11.) The use of the words "substantially pure" in the last sentence clearly expresses the inventor's understanding that the purity level he is defining is to be associated with these words.

The applicant concluded:
Even if a prima facie case of obviousness could be established from the combination of Carr, Sheehan, and Morrison (which it cannot), that combination is clearly rebutted by the advantageous results achieved with the process of the present invention. Here, as noted above, the prior art process for making the piperidine derivatives of the present invention produces an impure mixture which can only be partially purified to an impurity level of up to 5%. By contrast, as noted supra, the

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process of the present invention does not yield a product with such an impurity level and, as a result, is able to produce the desired piperidine derivative compounds at a purity level suitable for pharmaceutical use.

(Id. at 13.) D'Ambra here expressly used the purity of the end product to distinguish the prior art and overcome an obviousness rejection. This is a clear statement that the process of the invention does not yield a product with a 5% impurity level; this sets a minimum purity level for the end product of 95%. Moreover, it explicitly associates that purity level with the words "substantially pure." This operates as an unambiguous surrender of claim scope for claim 1: it does not cover processes which result in piperidine derivative compounds with an impurity level greater than or equal to 5%. It also establishes an unambiguous definition for "substantially pure" as "greater than 95% pure." Here the inventor, acting as his own lexicographer, unambiguously defines that phrase.

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n4 Fexofenadine is sometimes referred to as terfenadine metabolite or terfenadine acid metabolite.

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These statements clearly disavow processes which result in an impurity level greater than or equal to 5%. Because the language of the patent itself limits it to processes producing a "substantially pure piperidine derivative compound" end product, the prosecution history requires that "substantially pure" in this context be narrowed to the definition "having an impurity level less than 5%." Because, as discussed above, the patent does not support different definitions for "substantially pure," as applied to the intermediate, and "substantially pure," as applied to the end product, the prosecution history narrows the scope of "substantially pure" in claim 1 to "having an impurity level less than 5%."

The case of Hockerson-Halberstadt, Inc. v. Avia Group Int'l, 222 F.3d 951 (Fed. Cir. 2000) is instructive on this point. In that case, the prosecution history contained a statement in which the inventor distinguished the prior art by claiming that the invention had a narrower groove. The Court found this statement to be limiting, concluding: "flowing from this statement is the inventor's clear disavowal of footwear having a groove width greater than that disclosed in the prior art." Id. at 956. The Court explained that it could not disregard this statement, since to do so would:
erase from the prosecution history the inventor's disavowal of a particular aspect of a claim term's meaning. Such an argument is inimical to the public notice function provided by the prosecution history. The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention. In the present case, the inventor's statements about groove width are part of the prosecution history and form the totality of the public record upon which competitors rely. Were we to accept HHI's position, we would undercut the public's reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies.

Id. at 957 (citations omitted).

The instant case presents similar facts. In the prosecution history, the inventor distinguished the prior art as a process producing an end product with an impurity level as high as 5%. Flowing from this is a clear disavowal of processes producing an end product impurity level as high as 5%, as well as a manifest restriction of "substantially pure" end product to piperidine derivative compounds that are greater than 95% pure. These are statements in a public record on which Defendants were entitled to rely in forming their business strategies.

Plaintiffs argue that the "up to 5%" statement is ambiguous; it lacks sufficient clarity to operate as a disavowal. Plaintiffs contend that the statement "the process of the present invention does not yield a product with such an impurity level" is open to differing interpretations, as the antecedent to "such an impurity level" is "an impurity level of up to 5%." Plaintiffs propose, for example, that "an impurity level of up to 5%" literally includes all impurity levels between 0% and 5%, and thus could be read as characterizing the prior art as having a purity level of greater than 95%. This is an illogical reading, because it means 1) that the inventor argued to the patent office that his invention produced results inferior to the prior art; and 2) that the inventor distinguished the prior art by arguing that his process achieved the same result. Because the inventor asserted that the invention "achieves substantial benefits over the prior art process," the only reasonable interpretation is that the invention produces end product purer than the 95% pure end product of the prior art. (James Decl. Ex. 67 at 11.)

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The amendment from the '703 prosecution history also supports the conclusion that the end product is limited to substantially pure piperidine derivative compounds. As noted above, D'Ambra stated, "The present invention is directed to a process capable of producing substantially pure piperidine derivative compounds of the formula set forth above in claim 1." Id. at 9. This could not be more clear as a statement that the inventor intended "substantially pure" to characterize the end product of the invention as a whole.

4. Ascertaining the meaning based on the '610 prosecution history

Both the '703 patent and patent number 5,578,610 (the "'610 patent") derive from the same parent application, serial no. 08/083,102. The '610 patent issued on November 26, 1996. In September of 1997, an interference was declared; the examiner submitted two rejections, one based on 35 U.S.C. § 102 and one based on 35 U.S.C. § 103, requiring the applicant, D'Ambra, to demonstrate that claim 1 of the '610 patent was not unpatentable over the prior art. The parties do not dispute that the interference is within the prosecution history of the '610 patent. (Pl. Reply. Br. 93.)

The examiner's first rejection focused on the definition of "purity" in relation to the piperidine derivative compound in claim 1 of the '610 patent, cited prior art references that produced such compounds at higher levels of purity than that produced by the previously considered Carr U.S. Patent No. 4,254,129, and stated: "The term 'substantially pure' broadly reads on the prior art compound...." (James Decl. Ex. 49 at ALB006157.)

"The prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application." Microsoft, 357 F.3d at 1349. See also Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation"). In Microsoft, a statement in the prosecution history of an earlier issued patent was applied to the interpretation of a related, subsequently issued patent. Microsoft, 357 F.3d at 1350.

In the present case, the '703 patent issued on May 12, 1998, and so Defendants seek to apply a statement from the prosecution history of the earlier issued patent to the interpretation of a related, subsequently issued patent. n5

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n5 Defendants argue that the similarity between the '703 and '610 patents is supported by the fact that they have the same written description. (Hr'g Tr. 75, Oct. 27, 2005.) Plaintiffs termed the specifications "virtually identical." (Pls.' Reply Br. 94.) Defendants also observe that claim 12 of the '610 patent is a product-by-process claim that is highly similar to claim 1 of the '703 patent. Yet, even if the latter point is correct, claim 12 was not at issue in the '610 interference, and so its possible similarity to claim 1 is not useful here.

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Defendants point to several statements made in D'Ambra's October 17, 1997 response (the "D'Ambra response") to the interference submitted to the Board of Patent Appeals and Interferences. (James Decl. Ex. 41.) This response distinguishes at length the '610 patent from the prior art in terms of the purity of the fexofenadine end product. In particular, it states that the patent's "entire thrust as well as that of the subject invention is to produce the desired para product at a higher level of purity than the Carr patents could achieve. As demonstrated by the Wille letter, the purity of the para product prepared according to the Carr patents was no greater than 96.3%." (Id. at ALB005582.) The response also states:
When read in light of the specification, one skilled in the art would have understood the phrase 'substantially pure' ... to mean that the subject compound has pharmaceutical grade purity and is in a form purer than that attained by the prior art [Carr patents] ... As demonstrated, infra, those skilled in the art recognized that the pharmaceutical grade purity requires an impurity level no greater than 2%, and the Carr Patents were unable to achieve such purity.

(Id. at ALB005574.)

Defendants argue that the Board of Patent Appeals and Interferences accepted this definition, as reflected in its final opinion, which states as a finding: "27. A person having ordinary skill in the art would interpret the phrase 'substantially

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pure' in the context of the D'Ambra ['610] patent to mean no more than 2.0% impurities." (James Decl. Ex. 40 at ALB006988.) Thus, Defendants argue, this Court should construe "substantially pure" in the context of the '703 patent accordingly.

Plaintiffs, however, counter that, in the context of the interference, this construction applied to the purity of the fexofenadine end product, not to the purity of the p-CPK intermediate. This appears to be correct. Dr. D'Ambra's response distinguishes the prior art in terms of the purity of the final product, not the intermediate. The January 16, 1998 Opinion of the Board of Patent Appeals and Interferences examines claim 1 of the '610 patent, which refers only to the "substantially pure piperidine derivative compound" that is the end product of the '703 patent; there is no express reference to CPK intermediates either in '610 claim 1, the D'Ambra response, or the Opinion. In the last paragraph in the Board's discussion of claim construction, the opinion of the Board applies "substantially pure" only to "pharmaceutical products." (James Decl. Ex. 40 at ALB006991.) There is no basis to infer that the Board intended this construction to apply to intermediates.

Defendants argue that D'Ambra's response implicitly applies the 98% definition to the intermediates, as the response applies the discussion to claims 1-17, and claims 12-17 use "substantially pure" in reference to only the intermediate, not the end product. While this supports Defendants' argument, it does not satisfy the "clear and unambiguous" standard. The prosecution history of the '610 patent shows a clear and unambiguous disclaimer of fexofenadine and fexofenadone end products that are less than 98% pure para isomer. These statements were made to overcome the prior art and thus limit the scope of "substantially pure," as applied to the end product of the '610 patent, and thus, the end product of the '703 patent. They do not, however, show a clear and unambiguous disclaimer of p-CPK intermediates that are less than 98% pure. n6

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n6 The D'Ambra response does support construing "substantially pure regioisomers" to include end products as well as intermediates. In discussing prior art purification of the end product, D'Ambra stated, "separation to isolate any quantity of the substantially pure regioisomers has never been reported in the prior art ...." (James Decl. Ex. 41 at ALB005597 n.2.) This is another example of D'Ambra not distinguishing between "substantially pure regioisomers" as applied to end products and as applied to intermediates.

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This Court agrees with Plaintiffs that the cited '610 prosecution history was directed to interpretation of only the "substantially pure piperidine derivative compound" end products of the '610 patent. But this does not render the '610 prosecution history irrelevant to claim construction of "substantially pure regioisomer" in claim 1 of the '703 patent. To the contrary, it supports Defendants' proposed construction: because the '703 patent does not distinguish between "substantially pure" as applied to the intermediate and as applied to the end product, a definition of either applies to both. n7

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n7 Defendants' expert, Dr. Schuster, observes that, in the claims of the '610 patent, the inventor uses "substantially pure" to describe p-CPK, fexofenadone, and fexofenadine, with no indication that the phrase has different meanings in different contexts. (Schuster Decl. PP 28, 36.) This supports the conclusion that "substantially pure" has one uniform meaning in the context of the '703 patent.

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Absent a contrary indication, a descriptive phrase has one uniform meaning in a patent. As established above, the '703 patent does not distinguish between "substantially pure" as applied to end products and as applied to p-CPK. There is nothing within the patent that creates more than one uniform meaning for "substantially pure." n8 The prosecution history of the '610 patent defines "substantially pure" as "at least 98% pure" in regard to the piperidine derivative end product, and this further supports this Court's construction of "substantially pure regioisomers" in claim 1 of the '703 patent as "of greater than 95% purity." To decide this application for a preliminary injunction, this Court need not reach the question of whether the scope of "substantially pure regioisomer" should be further limited to mean "of purity greater than or equal to 98%." Thus, this Court finds that the cited '610 prosecution history provides additional support for its claim construction and, further, that the question of whether it requires a narrower construction need not be reached. n9

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n8 D'Ambra admitted this at his deposition. (James Decl. Ex. 12 137:3-13.) At oral argument, Plaintiffs characterized Defendants' quote of this admission as "one of their good points." (Hr'g Tr. 63, Oct. 27, 2005.)

n9 As an additional point, Plaintiffs argue that the Federal Circuit has endorsed a construction of "substantially" as "largely but not wholly" in other cases such as Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1369 (Fed. Cir. 2001). See also Hr'g Tr. 53, Oct. 27, 2005. This is misleading both as a characterization of Ecolab and as a statement of patent law. The construction of claim language in one patent is unlikely to be helpful in the construction of claim language in an unrelated patent in a different case. See, e.g., Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1318 (Fed. Cir. 2005) ("A particular term used in one patent need not have the same meaning when used in an entirely separate patent, particularly one involving different technology. In fact, there are many situations in which the interpretations will necessarily diverge"). As to Ecolab, the opinion states: "we presume that 'substantially uniform' . . . means what it says, 'largely, but not wholly the same in form.'" Ecolab, 264 F.3d at 1369. The court did not hold that this determined the completed construction of "substantially uniform," but, instead, remanded the matter to the district court for further determination based on the Federal Circuit's instructions. Id. at 1372.

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5. Claim construction based on "what the inventor invented"

Defendants argue that Plaintiffs' proposed claim construction attempts to expand the scope of the claim beyond what the inventor actually invented. Defendants rely on the following quote from Phillips: "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). Defendants argue that the specification, supported by extrinsic evidence, shows that the inventor did not invent a process for producing fexofenadine that used late stage purification, i.e., a process with a purification step occurring after the AZA reaction. This, Defendants contend, operates to limit the construction of "substantially pure regioisomers" to purity levels which will produce an end product of pharmaceutical purity without late stage purification.

This argument asks this Court to depart from Federal Circuit guidance on the role of the specification and extrinsic evidence in claim construction. It does not appear that, in Phillips, the Federal Circuit intended to create a new, additional branch of claim construction analysis based on construing "what the inventors actually invented." Rather, the quote is offered as support for the general principle that claims are construed in the context of the specification. Id. In the two sentences following Defendants' quote from Phillips, the Federal Circuit identifies two ways in which the specification may be used in claim construction: it may "reveal a special definition given to a claim term by the patentee," and it may "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." Id. Defendants here appear to contend that the specification reveals an intentional disclaimer of claim scope. Yet, as discussed supra, for such an argument to succeed, the Federal Circuit requires that the disclaimer be explicit in the specification. See Gillette, 405 F.3d at 1374 ("words or expressions of manifest exclusion or explicit disclaimers in the specification are necessary to disavow claim scope") (citations omitted).

Defendants here attempt again to use the '703 patent's "Background of the Invention" statements about the prior art described supra, (e.g., "these components are inseparable"), to limit claim scope; but these statements are not explicit disclaimers, and their meaning is not clear. It is difficult to understand how to reconcile "a practical separation . . . has not been achieved" (suggesting separation is possible but impractical) with "these components are inseparable" one sentence later (suggesting separation is impossible). '703 Patent col.4 11.18-22. Nor does the extrinsic evidence presented clarify what these statements mean. For example, the D'Ambra response describes separation in the prior art to a level of 96.3%, and points to the recrystallization step in example 5 of the Carr patent. (James Decl. Ex. 41 at ALB005581-2.) n10 The '703 amendment submission also points to the use of late-stage crystallization for purification of the end product. (James Decl. Ex. 67 at 11.) These pieces of extrinsic evidence contradict the statement that separation is impossible. It may be that D'Ambra meant "inseparable" to mean "not 100% separable," but the meaning is ambiguous. Moreover, Defendants agreed that these statements in the specification were directed to describing the prior art, not the present invention. (Hr'g Tr. 157,

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Oct. 28, 2005.) Thus, in any case, they are not statements about what the inventor actually invented. In sum, Defendants' argument based on "what the inventor invented" does not convincingly point to any clear disclaimer of claim scope.

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n10 At oral argument, the parties frequently referred to crystallization as a late-stage purification process. See, e.g., Hr'g Tr. 440-41, Nov. 3, 2005.

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6. Conclusion as to tentative claim construction

For the purposes of determining likelihood of success in showing infringement, it is sufficient for this Court to construe tentatively "substantially pure regioisomer," as used in claim 1 of the '703 patent, to mean "of greater than 95% purity." This construction is derived from the '703 patent's claims, specification, and prosecution history, with confirming support from the '610 prosecution history.
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Substantially Purified Purified to a substantial degree
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G. Purified beta (1,3) glucan

The term "purified beta (1,3) glucan" appears in claim 1 of the '015 Patent, quoted above. A similar term, "substantially purified beta (1,3) glucans," appears in claim 1 of the '719 Patent, also quoted above. Plaintiffs construe the terms as "beta (1,3) glucans having predominantly beta (1,3) linkages." Immudyne construes the terms as "pure beta (1,3) glucan that is protein and endotoxin- free."

Plaintiffs support their proposed construction with the following passage from the specifications:

The present invention is directed to substantially purified, beta (1,3) yeast extract glucans, in particular glucans having a fine particle size, which are useful in both dermatological and nutritional applications. As used herein, the term "substantially purified beta (1,3) yeast extract glucan" refers to a yeast cell wall extract comprising predominantly beta (1,3) glycosidic linkages, as illustrated in Fig. 1.

'015 Patent, col. 2, ll. 17-23; '719 Patent, col. 2, ll. 17-23.

Immudyne relies primarily on the prosecution history of the '015 Patent to support its proposed construction. Initially, "substantially purified beta (1,3) glucan" appeared in claim 1 of the '015 Patent. The examiner rejected the claim as being vague and indefinite based on the use of "substantially": "There is no particular level of purity which is apparent, and it is suggested that this term be deleted." The applicant responded by asserting that the level of purity was commensurate with that of U.S. Patent No. 5,223,491 ('491 Patent):

Applicant points to the specification . . . . Therein improved methods for isolating a purified water insoluble beta (1,3) glucan extract are discussed in the inventor's earlier patent, [the '491 Patent]. This earlier '491 Patent was incorporated by reference in its entirety . . . .

The level of purity claimed in the instant application is commensurate with the level of priority [sic] claimed in the '491 patent incorporated by reference. Claim 1 of the '491, and all claims that depend therefrom, recite "a substantially purified water insoluble glucan extracted from yeast cell walls . . . ." The '491 Patent, from column 2, line 65 through column 3, line

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10, under "Characteristics of Glucan," discusses the preparation of and properties of "purified glucan." E.g. Purified glucan is defined as essentially protein and endotoxin free, and is comprised of polyglucose having predominantly beta 1-3 glucosidic linkages. . . .

Applicant submits that the term "substantially purified" is appropriate in the instant application, as it was appropriate in the inventor's prior issued patent incorporated by reference. Thus, the claims are not rendered "vague and indefinite" by inclusion of the term "substantially." Retaining "substantially" is consistent with the improved beta (1,3) glucan disclosed and claimed.

The applicant's response did not overcome the examiner's rejection:

Applicant argues that the level of purity is described in parent application '491 which is incorporated by reference in this application. However, nothing in the section recited by applicants correlates "substantially" with these levels of purity. Since applicant has already incorporated the parent application by reference, it is suggested that these characteristics should be added to the instant specification with a sentence which clear[ly] sets out that "substantially" refers to those levels. Since there is nothing in the instant or parent application which . . . would lead those of ordinary skill to equate "substantially" with these or any other levels of purity, the rejection . . . is maintained.

The examiner concluded by stating that "[d]eletion of the term 'substantially' or an amendment clearly indicating that this term should set out a specific amount of purity would place the instant claims in condition for allowance." The applicant responded by deleting "substantially."

By deleting "substantially" instead of defining the term to incorporate the '491 Patent, the applicant declined to do what Immudyne advocates here. 3 Accordingly, the Court concludes that construction of the disputed terms based on the paraphrasing of the '491 Patent's specification in the '015 Patent's prosecution history is not appropriate. Cf. Pall, 66 F.3d at 1219-20 ("[W]hen claim changes or arguments are made in order to more particularly point out the applicant's invention, the purpose is to impart precision, not to overcome prior art. Such prosecution is not presumed to raise an estoppel, but is reviewed on its facts, with the guidance of precedent."). Instead, the Court construes the terms based on the specifications. Thus, "substantially purified beta (1,3) glucans" in claim 1 of the '719 Patent means glucans comprising predominantly beta (1,3) glycosidic linkages, and "purified beta (1,3) glucan" in claim 1 of the '015 Patent means glucans comprising beta (1,3) glycosidic linkages.

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3 Immudyne's proposed construction eliminates "essentially" from the alleged definition of "purified glucan."

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Claim 6 of BASF's '545 patent is the only claim at issue in this case. Claim 6 claims a process for the catalytic rearrangement of EpB to DHF

which consists essentially of the rearrangement being catalyzed by a system which contains components A and C from 60 [degrees] to 200 [degrees] C where A is an onium halide, which is substantially soluble in the reaction medium, and C is a Lewis acid or elemental iodine with the proviso that at least one of the components A or C is an iodide.

BASF and Eastman dispute the meaning of two phrases of claim 6. They dispute the meaning of "consists essentially of," and "substantially soluble in the reaction medium."

* * *

2. What Does "Substantially Soluble in the Reaction Medium" Mean?

BASF argues that the phrase "substantially soluble in the reaction medium" can be construed in three different ways.

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First, BASF argues that the term "reaction medium" is not limited only to the EpB reactant and the DHF product, and that the "reaction medium" includes the chemical components of the reaction or by-products of EpB, such as oligomer. Eastman argues that "reaction medium" means only the EpB reactant and DHF product.

Second, BASF argues that "substantially soluble in the reaction medium" means that small amounts of solubilizer or solvent can be added. Eastman argues that the phrase "substantially soluble in the reaction medium" means that no solubilizers need to be added.

Third, BASF argues that the phrase "substantially soluble in the reaction medium" only includes a liquid-phase homogenous process, which means a liquid EpB feed, liquid catalysts, and liquid end products. Eastman argues that the phrase does not preclude a process in which EpB is fed in gas form, the catalyst system is liquid, and the end product is in gas form, because having catalysis in a liquid phase is the only phase-related limitation implicit in claim 6.

a. Does the term "reaction medium" include only EpB and DHF?

At column 2, lines 56 to 61 of the '545 patent, the specification states that "component B of the catalyst system must, because it acts as solubilizer for component A, be chosen such that the particular salts A dissolve in the reaction medium, i.e. in particular in the alkenyloxirane II and in mixtures thereof with the dihydrofuran I which are produced during the reaction." This is the only place in the patent where "reaction medium" is described. Because the language of the patent itself is not clear as to the definition of "reaction medium," the court will turn to the prosecution history for a definition of the term "reaction medium."

During the prosecution of the '545 patent, BASF attorneys defined reaction medium as EpB and DHF alone, when they wrote about limiting component A to an onium halide "'which is substantially soluble in the liquid reaction medium,' i.e. in the epoxy-butene [EpB] itself or its dihydrofuran [DHF] product." BASF attorneys also wrote that "Fischer Claim 6 is applicable only to those onium halides which are substantially soluble in the liquid epoxybutene or its products. Otherwise it would be necessary to add the organic solubilizing component B as in Fischer Claim 1." Furthermore, the "advantage of the process of Fischer Claim 6 is that no other solvent is required except the liquid epoxyalkene reactant itself (or its products) as the solvent capable of acting as the organic solubilizer for the onium halide catalyst to produce a single homogenous liquid phase."

Accordingly, the prosecution history demonstrates that the reaction medium consists of the EpB and the DHF only.

b. Does the phrase "substantially soluble in the reaction medium" include the addition of solubilizer?

BASF argues that because component A, the onium halide, need only be "substantially soluble," some solubilizer can be added. However, there is no evidence that the patent requires that all of component A dissolve. Rather, the patent focuses on the reaction that occurs during the catalytic rearrangement of EpB to DHF. Thus, the onium halide need only be soluble enough for catalysis to occur. Thus, "substantially soluble" does not mean that some solubilizer must be added to dissolve any remaining portion of component A.

Additionally, as noted above, the language used in the prosecution history also demonstrates that the phrase "substantially soluble in the reaction medium" means that no solubilizer is necessary. During the prosecution of the '545 patent, BASF attorneys contended that the language "substantially soluble in the liquid phase reaction medium" constitutes "an essential limitation which omits any need for a third component which is an organic solubilizer B as set forth in Fischer Claim 1." Furthermore, BASF wrote that "claim 6 was added to the Fischer U.S. application to provide separate and explicit protection for this two-component catalyst system in the liquid phase reaction." This language makes it clear that claim 6 does not include the addition of any solubilizer.

Accordingly, the court concludes that the phrase "substantially soluble in the reaction medium" excludes the addition of any solubilizer.

c. Does the phrase "substantially soluble in the reaction medium" exclude gas feed processes?

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As noted above, claim 6 precludes the addition of solubilizer because component A, the onium halide, is soluble enough for catalysis to occur without the addition of component B. Because component A is soluble it is capable of being dissolved, and if it is dissolved, it is in a liquid state. Therefore, if a required element of claim 6 is that component A is soluble in the reaction medium, it necessarily follows that the catalyst system must be in liquid phase.

Aside from the requirement that the catalyst system be in liquid phase, claim 6 does not impose any additional limitations on the form in which the catalytic rearrangement occurs. Rather, because claim 6 describes the catalyst system, and the reaction medium, it addresses the point at which catalytic rearrangement occurs, not any time before or after. Accordingly, there is no limitation on whether the EpB is added in gas form, or the DHF is removed as a gas, so long as the conversion from EpB to DHF occurs in a liquid phase. This comports with the court's construction of the term "reaction medium" to mean only EpB and DHF, as component A must be in liquid form as the EpB converts to DHF.

The court concludes that the only phase-related requirement of claim 6 is that the reactant and the catalyst are dissolved in the same liquid phase. Therefore, the phrase "substantially soluble in the reaction medium" does not exclude gas feed processes. Rather, it only means that the catalysis must occur in a liquid phase.
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Claims 1-14, 16-19

Determinations regarding literal patent infringement involve a two-stage process. Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 889 (Fed. Cir. 1988). First, the claims are interpreted or construed. Id. Claim construction is a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d at 970-971. Second, the trier must determine whether the claims "read on" the accused product, i.e., whether the accused product is indistinguishable from what is declared in the patent claims. Smithkline, 859 F.2d at 889. To establish literal infringement, each of the elements set forth in a patent claim must be present in the accused product or process. Id. Whether an accused product infringes upon patent claims is a question of fact. Id.

The defendant contends that each claim of the '789 patent recites that the "nutrient indicators" are the only nutrients in the medium which support the growth of the targeted bacteria or microbes. Therefore, Millipore contends, a product containing additional nutrients which support substantial reproductive growth of coliform bacteria and E. coli would not infringe the '789 claims. Because Colisure contains additional nutrients which support substantial reproductive growth of coliform bacteria and E. coli, Millipore concludes, Colisure does not literally infringe the '789 patent.

Plaintiff contends that defendant's construction of the claims of the '789 is in error. Plaintiff contends that each of the claims (with the exception of Claim 15, discussed below) requires only that the nutrient-indicators are the preferred source of reproductive growth of the target microbe, and that the inclusion of other nutrients in the medium does not take the accused product, by virtue of its use of other nutrients, out of the claims. For this construction, plaintiff relies on the claims, the specification, and the prosecution history, as well as an apparently undisputed principle of microbiology that bacteria will consume simple molecule energy sources (like the nutrient indicators in both products) before consuming more complex ingredients.

Construction requires consideration of the language of the claims, the specification, and the prosecution history. Markman, supra, 52 F.3d at 979-980.

The '789 patent contains both independent and dependent claims, i.e., claims that add limitations to independent claims. Each of the disputed independent claims is phrased in one of two ways:

". . . a nutrient-indicator . . . which is substantially the only nutrient in said medium which can be metabolized by [the target microbe] to the extent needed to support continued reproductive growth thereof . . . ." (Claims 1, 10, 11, 19)

". . . there being no other nutrients in the medium which are able to support substantial reproductive growth of [the target microbe] in the sample." (Claims 4, 8, 16, 18)

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Defendant's construction seems plausible because the language of the claims suggests that in the absence of the nutrient-indicators, there are no nutrients which can support reproductive growth. But plaintiff contends that such a reading would be in error. The real emphasis of the claims is that in the actual medium with the nutrient-indicators present, only the nutrient-indicators will be metabolized sufficiently to support reproductive growth. In other words, what makes the invention distinct is that if the target microbes are present, they and they alone will metabolize the nutrient-indicators and hence produce a tell-tale visible change in the sample. Thus, false negative results, brought about by target microbes feeding on nutrients other than the indicator, are avoided because the bacteria's metabolic mechanism enabling it to consume other energy sources is repressed, and such secondary energy sources will only be consumed after the nutrient-indicator is substantially depleted, by which time the test results are in.

Plaintiff's construction is clearly supported by the specification. Throughout the specification, the reference is to the nutrient-indicator as the primary (or even preferred) nutrient in the medium rather than as the only nutrient. See, e.g., Col. 3, lines 20-25, 37-39. Moreover, the specification makes clear that what is unique about the invention is not that nutrient-indicator is the only nutrient in the medium, but that the target microbe (unlike other microbes) will, in fact, exclusively metabolize the nutrient-indicator producing the reaction enabling prompt detection of the target microbe in the sample.

The "file wrapper" or prosecution history of the '789 patent also supports plaintiff's construction. In response to the patent examiner's rejection of the proposed claims, Patentee Edberg narrowed the claims so that they would be limited to a medium in which only the nutrient-indicator was capable of sustaining reproductive growth. However, the patentee explicitly stated that narrowing of the claims was achieved by clarifying that the "key to the claimed invention is the use of the nutrient-indicator as the primary growth factor in the medium for target microbes." Pl.'s Ex. 7, Tab F at 8. (Emphasis added.). Again, patentee Edberg's amending of the claims during the prosection history was aimed at clarifying that the claims required that the nutrient-indicators be not the only nutrients in the medium, but the nutrients which the target microbes would, in fact, metabolize. Other nutrients might be included but would not compete with the nutrient-indicators as the source of the target microbe's reproductive growth.

Defendant's expert, Dr. McFeters, presented data which purported to show that the defendant's medium contains nutrients, other than the nutrient-indicators, which support the growth of the target microbes in the absence of the nutrient-indicators. See Def.'s Brief, at 19-23. However, Dr. McFeters' data are not inconsistent with the court's construction of the claims of the '789 patent as requiring that the nutrient-indicators be not the only nutrients in the medium, but the preferred nutrients which the target microbes would, in fact, metabolize. Consequently, Dr. McFeters' data do not demonstrate that the accused product does not infringe on Claims 1-14, 16-19 of the '789 patent.

Based on the construction given to Claims 1-14 and 16-19, defendant has failed to demonstrate the absence of genuine issues as to material facts regarding literal infringement.
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A. Claim Construction

In arriving at the ultimate claim construction of the phrase "substantially uniform," the district court noted that the "claim language makes clear the '818 patent protects a detergent cast containing . . . [the particularly recited ingredients] in a manner such that the active elements are present throughout the cast without significant variation in the amounts of each ingredient." Ecolab II, slip op. at 12. The court then looked to the written description and noted that "the 'substantially uniform' nature of Ecolab's cast was advanced as a solution to the problems associated with the casts of the prior art . . . [and that a] substantially uniform product meant less segregation in the ingredients and similar solubility throughout the entire cast, which in turn resulted in chlorine stability in the wash solution throughout the life of the cast." Id. at 13. Next, the court examined the prosecution history noting that Ecolab pointed out the homogeneity problems of highly alkaline detergent products unless flaked or granularized immediately from a melt. Moreover, the court noted that Ecolab presented the Tinker affidavit to show the problems in casting homogeneous prior art composition versus the claimed composition. Thus, the court concluded that Ecolab's efforts in obtaining allowance of its claims were directed at defining "its patent claim in a manner reflecting that its casts consisted of a homogeneous composition of elements from top-to-bottom, and therefore, Ecolab's process and casts had solved the problems associated with the prior art." Id. at 14. It was the foregoing analysis that prompted the district court to ultimately construe the phrase "substantially uniform" to mean "a level of continuity of the

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elements from top-to-bottom throughout the cast such that a homogeneous cleaning solution is formed over the life of the cast." Id. at 16.

Envirochem urges that the court's definition does not provide a meaningful standard against which infringement can be judged because at one extreme it requires absolute uniformity in composition of the cast and at the other extreme no uniformity, i.e., even a perfectly nonuniform cast would provide a "homogeneous" solution if the entire cast were dissolved in water. Envirochem contends on appeal that the proper construction of "substantially uniform" in view of the Tinker affidavit is that the top-to-bottom variation of ingredients in the cast does not exceed 5.57% on a relative basis. Arguing against Envirochem's asserted definition, Ecolab contends that a numerical limitation on the range of the ingredients in the cast from top-to-bottom is inappropriate because the claim language does not present any basis for inferring an unwritten numerical range, and because the claims, specification, and prosecution history do not evince an intent to impart such a novel meaning to the phrase "substantially uniform."

In support of the district court's construction, Ecolab relies on Laitram Corp. v. Cambridge Wire Cloth, 863 F.2d 855, 858, 9 U.S.P.Q.2D (BNA) 1289, 1293 (Fed. Cir. 1988), and asserts that descriptive claim terms that are not limited numerically are commonly defined according to the purpose or function of the invention. In this case, Ecolab asserts that the function of the invention is to provide sufficient alkalinity and sufficient phosphate to effectively clean the dishes and soften the water throughout the life of the product.

We agree with the reasoning expressed and the conclusion reached by the district court that no basis exists for inferring a numerical limitation as to what is a "substantially uniform" cast. However, we hold that the district court erred as to the proper construction of the phrase "substantially uniform." That error was in: (1) defining nonnumerically limited claim terms according to the purpose of the invention; (2) not giving the phrase "substantially uniform" its ordinary and accustomed meaning; and (3) not recognizing the proper relevance and effect of the Tinker affidavit on the scope of the '818 patent claims.

1. Nonnumerically Limited Descriptive Claim Terms

We disagree with Ecolab that nonnumercially limited descriptive claim terms are "commonly defined according to the purpose of the invention." Contrary to Ecolab's contention, nonnumerically limited descriptive claim terms are construed using the same rules of construction as any other claim term. In Laitram, we affirmed the district court's construction of the term "slightly greater" as related to the term "spacing" in terms of the purpose of the spacing. 863 F.2d at 858, 9 U.S.P.Q.2D (BNA) at 1293. However, we deemed this appropriate at least in part because the claim language itself contained functional limitations related to the spacing limitation. The prosecution revealed that the functional limitations in the claim required spacing that would minimize bending and maximize shear. Id., 9 U.S.P.Q.2D (BNA) at 1292-93 (the limitation at issue was: "said link ends being dimensioned and spaced apart by a distance slightly greater than said width so that said module is end-to-end reversible, so that a plurality of said modules may be engaged with each other at said ends."). We are not faced with the same facts in this case. While the claimed "three-dimensional, solid, cast, hydrated, substantially uniform alkaline detergent" is "for ware and hard surface washing," there is no claimed functional requirement as to forming a homogeneous wash solution throughout the cast life. The only functional requirement of the claimed "three dimensional, solid, cast, hydrated, substantially uniform alkaline detergent" is for that detergent to contain components capable of "ware and hard surface washing." Thus, while we agree with the district court and Ecolab that there is no basis in the intrinsic record on which to infer adding a numerical limitation to the phrase "substantially uniform," there is also no basis on which to require adding a functional limitation.

2. The Claim Language and the Written Description

In construing the claims of a patent, we review the intrinsic evidence, which consists of the claim language, the written description, and the prosecution history. Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 2001 WL 792669, at *5 (Fed. Cir. 2001). We first look to the claims themselves and turn next to the written description and the prosecution history, which should always be consulted to construe the language of the claims. Gart v. Logitech, 254 F.3d 1334, 1339-40, 59 U.S.P.Q.2D (BNA) 1290, 1293-94 (Fed. Cir. 2001). This intrinsic evidence is consulted to determine if the patentee has chosen to be his or her own lexicographer, or when the language itself lacks sufficient clarity such that there is no means by which the scope of the claim may be ascertained from the claim language itself. Id. (internal citations omitted). When the foregoing circumstances are not present, we presume that the terms in the claim mean what they say. Id. In other words, we

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follow the general rule that terms in the claim are to be given their ordinary and accustomed meaning. Id.

We begin with the phrase "substantially uniform" itself. Ordinarily, "uniform" means "always the same as in form or degree; unvarying." The American Heritage Collection Dictionary 1475 (3d ed. 1997). Additionally, "ordinarily . . . 'substantially' means 'considerable in . . . extent,' American Heritage Dictionary Second College Edition 1213 (2d ed. 1982), or 'largely but not wholly that which is specified,' Webster's Ninth New Collegiate Dictionary 1176 (9th ed. 1983)." York Prods., Inc. v. Cent. Tractor Farm & Family Cent., 99 F.3d 1568, 1573, 40 U.S.P.Q.2D (BNA) 1619, 1622 (Fed. Cir. 1996). Furthermore, the language "substantially uniform" expressly modifies the term "alkaline detergent." Thus, the claim language itself explicitly ties "substantially uniform" to the detergent itself, not to any overall function of the detergent-containing article of commerce.

The '818 written description does not reveal any special definition for the terms "substantially" or "uniform" or the phrase "substantially uniform." See, e.g., '818 patent, col. 18, ll. 30-31 ("the mixture was sufficiently viscous so that a uniform dispersion was maintained"); id. at col. 22, ll. 62-64 ("the solid cast detergent of this invention provides very uniform chlorine recovery when compared to a prior art formulation"); id. at col. 5, ll.13-15 ("an article of commerce capable of dispensing dissolved solids from substantially only one surface"); id. at col. 5, ll. 41-43 ("the cast detergent can be demolded and inserted in an inexpensive container or receptacle which has substantially the same configuration as the mold"). Furthermore, the use of the term "substantially" to modify the term "uniform" does not render this phrase so unclear such that there is no means by which to ascertain the claim scope.

We note that like the term "about," the term "substantially" is a descriptive term commonly used in patent claims to "avoid a strict numerical boundary to the specified parameter." Pall Corp. v. Micron Seps., 66 F.3d 1211, 1217, 36 U.S.P.Q.2D (BNA) 1225, 1229 (Fed. Cir. 1995); See, e.g., Andrew Corp. v. Gabriel Elecs. Inc., 847 F.2d 819, 821-22, 6 U.S.P.Q.2D (BNA) 2010, 2013 (Fed. Cir. 1988) (noting that terms such as "approach each other," "close to," "substantially equal," and "closely approximate" are ubiquitously used in patent claims and that such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts). In this case, "substantially" avoids the strict 100% nonuniformity boundary.

Certainly the written description teaches that Ecolab's inventive cast was advanced as a solution to the problems associated with prior art solid detergents. We also acknowledge that accompanying its amendment adding the term "substantially uniform" to the claim, the patentee noted it is "of vital importance to maintain the homogeneity of the cast so that sufficient hardness sequestering agent and alkali metal hydroxide are available at all times." However, this statement about the vital importance of having a homogeneous cast says nothing about having a homogeneous solution. Furthermore, the fact that the claimed composition was designed to solve certain problems of the prior art and the fact that the patentee noted the functional import of having a homogeneous cast does not mean that we must attribute a function to the nonfunctional phrase "substantially uniform." Where the function is not recited in the claim itself by the patentee, we do not import such a limitation. See Jeneric/Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377, 1382, 54 U.S.P.Q.2D (BNA) 1086, 1090 (Fed. Cir. 2000) ("This court rejects any attempt to carve out a portion of cerium oxide according to functions not recited in the claim.").

3. The Prosecution History

We turn next to the Tinker affidavit, which was submitted to overcome a 35 U.S.C. § 103 rejection of the claims over a combination of prior art references. The tabular results presented in the Tinker affidavit are reproduced below.
Table II

[SEE TABLE(S) IN ORIGINAL]

We note that Tinker asserted that the data demonstrated a significant difference in alkalinity and tripolyphosphate concentration between the top and bottom quarter of the casts of the prior art compositions, i.e., Formulae I-IV, but not in the claimed composition, i.e., Formula V. The data were not obtained by measuring the homogeneity of the cleaning solution formed after spraying the exposed surface of the cast with water. Rather, it was gathered by measuring the concentrations of these ingredients in the top and bottom quarters of the casts. Consequently, there is nothing in the Tinker affidavit requiring that the nonfunctional phrase "substantially uniform" be limited functionally.

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We recognize that the patentee states in the written description that a cast detergent prepared according to the invention had a "very uniform chlorine recovery" as compared to a conventional powdered detergent. '818 patent, Figure 5 and col. 22, ll. 61-65. Moreover, we agree with Ecolab that the term "very uniform" is more restrictive than "substantially uniform." However, the uniformity of the delivery of chlorine to the effluent does not aid our interpretation of the uniformity of the distribution of ingredients throughout the cast when there are no functional constraints on the terms "substantially" or "uniform." Consequently, any percentage difference in chlorine recovery of the claimed invention versus the prior art determined from Figure 5 of the '818 patent has no bearing on the percentage difference that "substantially uniform" would encompass as it relates to the distribution of ingredients throughout the cast.

We disagree with Envirochem that the Tinker affidavit limits the meaning of "substantially uniform" numerically, at least to the extent of what is "substantially uniform." Nowhere in the affidavit is it asserted that Formula V, made according to the claimed invention, is "the invention." Thus, while the percentage difference of the components from top-to-bottom of Formula V is within the scope of "substantially uniform," that percentage difference does not mark the outer bounds of the descriptive phrase.

However, we note that "all express representations made by or on behalf of the applicant to the examiner to induce a patent grant" limit the interpretation of the claims "so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452, 227 U.S.P.Q. (BNA) 293, 296 (Fed. Cir. 1985); Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 2001 WL 881465, *7 (Fed. Cir. 2001) (noting that if the patentee has defined a claim term as excluding a broader interpretation with reasonable clarity and deliberateness then the patentee has disclaimed certain subject matter and the claims must be so limited); Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 955, 55 U.S.P.Q.2D (BNA) 1487, 1490 (Fed. Cir. 2000) ("Review of the prosecution history . . . reveals that the inventor disclaimed a particular interpretation of groove, thereby modifying the term's ordinary meaning."); Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331, 56 U.S.P.Q.2D (BNA) 1208, 1210 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed."); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 U.S.P.Q.2D (BNA) 1673, 1676 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."); cf. Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054, 12 U.S.P.Q.2D (BNA) 1474, 1477 (Fed. Cir. 1989) (noting that an erroneous remark by an attorney in the course of prosecution cannot control the interpretation of a claim as finally worded and issued by the United States Patent and Trademark Office). In view of the foregoing, we determine that the Tinker affidavit is relevant to determining whether the express terms of the claim must be limited to exclude disclaimed subject matter. Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304, 41 U.S.P.Q.2D (BNA) 1364, 1368 (Fed. Cir. 1997).

As stated above, Tinker noted that there was a significant segregation of ingredients of caustic and hardness sequestering agent at the top and the bottom of Formulae I through IV, which were casts made according to the prior art. In other words, the patentee through the Tinker affidavit clearly asserted that these casts were not substantially uniform. It is clear, therefore, that the patentees disclaimed from "substantially uniform" the nonuniformity of caustic and tripolyphosphate exhibited by Formulae I through IV.

In view of the foregoing, i.e., the claim language, written description, and prosecution history, we presume that "substantially uniform" as related to the "alkaline detergent cast" means what it says, "largely, but not wholly the same in form." In the terms that the district court applied, that is "very near consistency of elements from top-to-bottom throughout the cast." None of the claim language, the syntax of the claim, the written description, the prosecution history, or our case law supports the addition of a functional limitation to this phrase.

The parties did not focus on the disclaimed subject matter in the Tinker affidavit in their briefs to the trial court and thus the trial court did not address it. Moreover, the parties did not focus on this issue in their briefs on appeal. In view of the foregoing, we think it better for the trial court to make an informed interpretation of the data in the first instance. See AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1251, 57 U.S.P.Q.2D (BNA) 1776, 1785 (Fed. Cir. 2001) (leaving the trial court to determine on remand what constitutes a "top coat," as distinguished from a "layer"). In so doing, however, the trial court must bear in mind that any cast composition having a percentage segregation of caustic and tripolyphosphate like that of Formulae I through IV of the Tinker affidavit cannot be "substantially uniform."
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1. Claim Construction

"[I]n interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics, 90 F.3d at 1582. Although the court may consider "the descriptions in the . . . patent specification, the prosecution history, and relevant extrinsic evidence" if necessary, "throughout the interpretation process, the focus remains on the meaning of claim language." Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed. Cir. 1997); Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998).

Envirochem urges this Court to construe the claim term "substantially uniform," as used in Ecolab's '818 patent, to mean not having more than a 5.57% variation among ingredients from top-to-bottom of the cast. The intrinsic evidence of record, however, makes clear that the term substantially uniform cannot be construed in such a narrow fashion.

The Court must first examine the claim language to determine the meaning of the disputed term. Claim 1 of the '818 patent provides protection for "a three-dimensional, solid cast, hydrated, substantially uniform alkaline detergent." See Weiss Cert. Exhibit A at 27. According to the claim, the protected cast includes the following: "(1) at least 30% by weight of an alkaline hydratable chemical consisting essentially of alkali metal hydroxide; (2) an effective amount of a hardness-sequestering agent; (3) [more than 15 parts by weight, per 100 parts by weight of said alkaline hydratable chemical, of] water of hydration, at least a portion of said water of hydration being associated with said alkali metal hydroxide, wherein the akali metal hydroxide and the hardness sequestering agent are present in an amount sufficient to render the cast detergent a solid at room temperature by virtue of the water of hydration." Id. The claim language makes clear that the '818 patent protects a detergent cast containing the above listed ingredients in a manner such that the active elements are present throughout the cast without significant variation in the amounts of each ingredient. The claim language, however, does not indicate that Ecolab sought to limit the variation of the elements throughout its cast to a specific numerical range.

"The written description supplies additional context for understanding whether the claim language limits the patent scope" to a numerical range below 5.57%, as argued by Envirochem. 4 Abtox, 122 F.3d at 1024. The summary of the invention found in the '818 patent makes clear that Ecolab sought to protect a product that minimized the "chlorine stability, differential solubility, segregation, and safety problems" associated with the prior art. See Weiss Cert. Exhibit A at 5. Thus, the "substantially uniform" nature of Ecolab's cast was advanced as a solution to the problems associated with the casts available in the prior art. A substantially uniform product meant less segregation in the ingredients and similar solubility throughout the entire cast, which in turn resulted in chlorine stability in the wash solution throughout the life of the cast. The patent included a chart comparing the chlorine stability associated with the prior art, specifically powdered detergent, with that resulting from a "substantially uniform" cast. See Weiss Cert. Exhibit A at Sheet 1 of 2, Figure 5.

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4 The written description of the '818 patent does not provide a basis for Envirochem to allege that the uniformity of the Ecolab cast should be limited to a specified numerical range.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

"The record of administrative proceedings at the Patent and Trademark Office (PTO) provides additional context for understanding the claim terms." Abtox, 122 F.3d at 1024. As set forth above, the Examiner initially rejected Ecolab's patent application based on the prior art. In response, Ecolab endeavored to distinguish its cast from the prior art, in particular the Brooker patent. In support of that endeavor, Ecolab submitted the Tinker Affidavit. The Tinker Affidavit included an experiment that compared four detergent casts made in accordance with processes taught by the prior art, particularly the Brooker patent, against one detergent cast made pursuant to the invention for which Ecolab sought protection. Tinker compared the casts, analyzing from top-to-bottom of each cast, the segregation of caustic, the segregation of tripolyphosphate, and the reversion of tripolyphosphate throughout the cast. The results of the experiment revealed that the variation of ingredients throughout the Ecolab cast was small in comparison to the variation of ingredients throughout those casts made in accordance with the prior art.

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The record reflects that Ecolab considered the central distinguishing factor of its cast to be the uniformity of the cast elements. See Weiss Cert. Exhibit G at 7. In support of its appeal from the Examiner's rejection, Ecolab argued that "the teachings in Brooker taken as a whole indicate a highly alkaline cleaning composition can be made only if it is immediately flaked or granularized from a melt to prevent the formation of nonuniform or nonhomogeneous composition." See Weiss Cert. Exhibit F at 14. In contrast, Ecolab argued that "the Tinker affidavit clearly points out problems inherent in casting highly akaline detergent materials that are reflected in the art and which has been solved by Appellants. Further, the Affidavit clearly shows that the prior art is not enabling with respect to forming the cast materials of the invention." See Weiss Cert. Exhibit F at 16. Noting the problems associated with the prior art, the Board reversed the Examiner's rejection and granted Ecolab's patent. See Weiss Cert. Exhibit H at 3-4.

The prosecution history of the '818 patent is devoid of any reference to a numerical limitation for the amount of variation between the elements comprising Ecolab's cast. Instead, the prosecution history reflects Ecolab's continued effort to define its patent claim in a manner reflecting that its casts consisted of a homogenous composition of elements from top-to-bottom, and therefore, Ecolab's process and casts had solved the problems associated with the prior art.

Envirochem relies on the Tinker Affidavit for its proffered numerical limitation of the definition of substantially uniform. Envirochem extracts figures from the Tinker Affidavit and applies those figures to a formula for the calculation of the relative percentage difference to arrive at the 5.57% definition of substantially uniform. The Court rejects this narrow definition of the term substantially uniform for several reasons.

First, the claim language and the specification language do not include a numerical limitation for the term "substantially uniform." Second, the prosecution history, specifically the Tinker Affidavit, does not evidence a numerical limitation for the term "substantially uniform." Instead, Ecolab sought to set apart its invention from the prior art based on the analysis of a variety of factors. Envirochem cannot extract figures from one analysis in the Tinker Affidavit in an attempt to narrowly define the patent claim. "What is patented is not restricted to the examples, but is defined by the words in the claims if those claims are supported by the specification . . . . Nowhere does the specification of the ['818] patent teach that" the uniformity of the Ecolab cast is subject to a numerical limitation. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988); see also Ekchian v. Home Depot. Inc., 104 F.3d 1299, 1302 (Fed. Cir. 1997) (holding that "[w]hile examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, the scope of a claim is not necessarily limited by such examples").

Furthermore, Envirochem has applied the numbers in the Tinker Affidavit to a formula not reflected anywhere in the claim, specification, or the prosecution history. Envirochem does not provide adequate support for its use of the relative percentage formula. Moreover, Envirochem's reliance on extrinsic evidence to define the patent claim is erroneous. "In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." Vitronics, 90 F.3d at 1583. This court does not consider the extrinisic formula relied on by Envirochem because the intrinsic evidence of the patent clearly sets forth the meaning of the claim term "substantially uniform." Id.; Allergan Sales Inc. v. Pharmacia & Upjohn Inc., 42 U.S.P.Q.2d 1560 (S.D.Cal. 1997).

Having rejected Envirochem's asserted definition of substantially uniform, this Court considers the proper definition for the claim term. "The United States Court of Appeals for the Federal Circuit has recognized that the term 'substantially' in patent claims gives rise to some definitional leeway." C.E. Equipment Co. v. United States, 17 Cl. Ct. 293, 299 (1989) (citing Seattle Box Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 829 (Fed. Cir. 1984)). "When a word of degree is used the district court must determine whether the patent's specification provides some standard for measuring that degree. The trial court must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification." Seattle Box, 731 F.2d at 826.

In this instance, a person of ordinary skill in the art could discern the meaning of substantially uniform from the intrinsic evidence of record. It is clear from the face of the patent that substantially uniform means a level of continuity of the elements from top-to-bottom throughout the cast such that a homogenous cleaning solution is formed over the life of the cast. See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 450 (Fed. Cir. 1986), cert. denied, 484 U.S. 823, 108 S. Ct. 85, 98 L. Ed. 2d 47 (1987) (holding "that 'smooth' means smooth enough to serve the inventor's purpose, i.e., not to inflame or irritate the eyelid of the wearer or be perceived by him at all when in place"); CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc., 893 F. Supp. 508, 521 (D.Md. 1995), aff'd, 92 F.3d 1203 (Fed. Cir. 1996) (defining the "soft

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and springy feel" limitation for eye glass frames, in light of the patent's purpose of comfort and durability, as implying "that the frame is easily wrapped around one's index finger"). "The use of the [term "substantially uniform,"] avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995), cert. denied, 520 U.S. 1115, 117 S. Ct. 1243, 137 L. Ed. 2d 326 (1997) (holding that meaning of claim term "about 5:1 to about 7:1" was not necessarily subject to an exact limitation).

Envirochem strenuously urges the Court to limit the claim term "substantially uniform" to having less than a 5.57% variation of ingredients from top-to-bottom. The Court declines to place such a limitation on the term because the term's meaning is clear from the face of the patent. The Court next considers whether Envirochem is entitled to summary judgment on the issue of infringement.
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1. What is the Proper Construction of the Phrase "substantially uniform mixture" in the '092 patent and "substantially uniform particulate mixture" in the '948 patent?

Claim 1 of the '092 patent contains the phrase "particles in a substantially uniform mixture" to describe the feed mixture composed of primary particles and binder particles. Claim 1 of the '948 patent contains the phrase "substantially uniform particulate mixture" to describe the feed mixture composed of primary particles and binder particles. KXI contends the words should be given their ordinary meaning, and that these phrases refer to a largely--but not necessarily wholly--even distribution of particles. KXI contends there are no other mixing requirements and no special methods of mixing required. The test for proper mixing, according to KXI, is stated in the '092 patent's specification at column 8, lines 7-14 and the '948 patent's specification at column 8, lines 13-19:

An experienced operator can also readily notice a reduction in the flow characteristics of the powder mixture that indicates the formation of the desired bonds between particles. Samples smeared on a black surface show no residual binder aggregates which would be indicated by the presence of small white streaks.

Culligan argues that the specifications of the '092 and '948 patents define the terms "substantially uniform mixture" and "substantially uniform particulate mixture" in a special way. According to Culligan, "substantially uniform" is a limitation requiring the formation of stable attachments between the primary particles and binder particles. Culligan argues that the claim requires vigorous mixing until stable "prebonds" or "microaggregates" are formed between the primary particles and binder particles throughout the mixture. Culligan points to provisions of the specifications reading:

Correct methods of mixing produce a material composed of microaggregates of primary particles and binder particles . . . . Poorly mixed materials, or use of binder or primary particles lacking the ability to form stable "prebonds" results in mixtures where binder and primary particles separate, or where primary particles of widely varying density or morphology separate because stable aggregates have not been formed. It is these stable aggregates, formed during mixing that allow this process to bond particles that cannot normally be maintained in a stable mixture. It appears that, as a rule, the process is generally not workable with poorly mixed materials or with materials in which the binder particles have not become attached to the primary particles during the mixing step.

Culligan argues that here the '092 and '948 patents' specifications tell a person knowledgeable in the art that they must mix the primary and binder particles in a certain way to practice the invention; so as to create stable "prebonds" or "microaggregates."

The Federal Circuit has held that "the specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Culligan argues that the specifications of the '948 and '092 patents expressly defines the phrase "substantially uniform." KXI argues in response that it is only appropriate to give a term a special meaning where "the special definition of the term is clearly stated in the patent specification or file history." Id. at 1582.

The court agrees with KXI that the patentee did not give special meaning to the phrase "substantially uniform mixture" or

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"substantially uniform particulate mixture" in the '092 and '948 patent's specifications The court construes the words "substantially uniform particulate mixture" and "substantially uniform mixture" according to their ordinary meaning. Accordingly, the court construes the phrases "substantially uniform mixture" and "substantially uniform particulate mixture" as meaning a largely--but not wholly--even distribution of particles.
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"Substantially Water Free"

The district court instructed the jury that "substantially water free" means that "the resulting mixture has a total water content of less than 5%, as measured by dividing the weight of the water in the resulting mixture by the weight of the starch, water, and additives." The defendants argue that the prosecution history requires not simply less than 5% water content, but substantially less than 5%, pointing to various statements in the prosecution history discussing a water content of 1% or 3%. The defendants state that a 3% limit would exclude all or most of the Novamont production.

The term "substantially water free" is not given a numerical limit in the specification of the '777 patent. The term was explained during prosecution as distinguishing the water content of the '777 product from that produced in the cited reference to Lay. Lay describes producing destructurized starch in the presence of additives such as glycerine and sorbitol (also used in the '777 patent), wherein the starch used as starting material has "a water content of 5 to 30% [by weight] based on the starch/water component."

The examiner of the '777 patent had initially objected to the usage in the claims of "substantially water free," stating that "nothing appears on the record which is clearly indicative as to what may be embraced by the term 'water free.'" In response Dr. Tomka filed two declarations, one by Jean Pierre Mercier, a professor of polymer science at Louvain University, and the other by Ulrich W. Suter, a professor of macromolecular chemistry at ETH-Zurich Instutut fhr Polymere. Both declarants were described as experts in the field of starch chemistry. Both stated that "those skilled in the art would not consider starch containing 5% water as being 'substantially water free,'" and that "it is necessary for the water content to be less than 5% before starch can be considered 'substantially water-free.'"

The defendants argue that the declarants worked with water contents of 1% or 3%, not 5%, and that they stated that water content above 3% resulted in brittleness on aging. Biotec responds that the 1% referred to in the declarations related to water content for processing of the TPS by any conventional processing methods, and the 3% related to processing by certain injection molding units. Biotec states that these figures do not affect the support in the declarations and elsewhere in the prosecution history for the construction that "substantially water free" means, simply, less than the 5% water in the Lay reference. Biotec states that the patent examiner accepted that "substantially water free" means less than 5% water, in accepting that this term distinguished the '777 invention from the Lay reference. Biotec also points to claim 24 (not in suit) which is specific to a "moisture content less than 1.0%," and invokes the doctrine of claim differentiation to support the broader scope of "substantially water free."

The meaning of "substantially water free" was the subject of testimony during trial, where Dr. Tomka and Biotec's expert Dr. Meijer explained the declarations and other parts of the prosecution history. The district court's ruling and jury instruction that "substantially water free" means a water content below 5% is in accordance with the prosecution history and was supported by the evidence. That claim construction is confirmed.
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Claim Interpretation

2. The formula set out in claim one of each of the patents describes the same hydroxy-terminated urethane compound, with two components identified as "R" and "R<1>." The patents are distinguished primarily by the different applications for which the urethane compound is claimed. In addition, the '260 patent claims a method for using the patented compound in a topical composition.

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3. Claim interpretation is a matter of law, solely within the province of the Court. Markman v. Westview Instruments, 52 F.3d 967, 978 (Fed. Cir.), aff'd, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). The Court interprets the meaning of the claim terms as would one skilled in the art. Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 867 (Fed. Cir. 1985). Because the inventor may be his or her own lexicographer, Autogiro Co. of American v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 397 (Ct. Cl. 1967), the Court may also determine whether a word or term used in the claims was intended to have a meaning which differs from the meaning used in the art.

4. Where there is question about the meaning that those skilled in an art give a term used in the claim, the specification and prosecution history (which contains the patent application as filed and the official record of the proceedings before the Patent and Trademark Office ("PTO")) can provide relevant information about the scope and meaning of the claim. Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988). To ascertain the meaning of the claims, the Court considers these three sources: the claims, the specification, and the prosecution history. Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991). The patent specification, in particular, is the principal source for determining the meaning of ambiguous terms used in a patent claim. Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452-53 (Fed. Cir. 1985); see also Specialty Composites, 845 F.2d at 987.

5. It is inappropriate to read limitations into the claims from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim. E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir.), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988).

6. Because the terms "linear" and "branched" do not appear in, nor are they required by, the language of the claims-in-suit, the claims do not contain any limitation based on the "linear" or "branched" nature of the claimed composition, or of its ingredients.

7. The claims also do not require the claimed urethane molecule to have been created by synthesizing an isocyanate with a diol, as opposed to a triol.

8. Thus, a person of ordinary skill in the art at the time the invention was made would understand that "R," as used in the claims, can be an alkylene or alkenylene radical containing from one to about 20 carbon atoms, or a cycloalkylene or cycloalkenylene radical containing from about 5 to about 10 carbon atoms, or a mononuclear or fused ring arylene radical containing from about 6 to about 10 carbon atoms, all of which may be unsubstituted or substituted with one or more lower alkyl, lower alkoxy, lower alkoxy-substituted lower alkyl, nitro or amino groups or halogen atoms.

9. Such person would also understand that "R<1>," as used in the claims, can be any alkylene or alkenylene radical, which may be the same or different alkylene or alkenylene radical as "R," and which may also be unsubstituted or substituted in various ways, including but not limited to substitutions with one or more lower alkyl, lower alkoxy, lower alkoxy-substituted lower alkyl, nitro or amino groups or halogen atoms. The patent does not limit the number of carbon atoms in "R<1>."

10. Neither the claims nor the specification of the patents-in-suit define the term "substituted," and that term is not discussed in the file history. Based on the expert testimony and other extrinsic evidence presented at trial, however, the Court concludes that a "substituted" alkylene is limited to alkylenes in which a pendant hydrogen atom has been replaced with one or more similarly pendant non-hydrogen atoms or groups of atoms. "Substituted" therefore does not include replacements made within the carbon backbone of the alkylene or alkenylene radical.

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1 . Construction Of "Substrate"

Affymetrix's proposed construction of "substrate" is "a material having a rigid or semi-rigid surface." (D.I. 243 at 15.) Illumina's proposed construction is "a material having a rigid or semi-rigid surface on which polymers are synthesized." (D.I. 240 at 8.) Thus, the dispute here is whether the Court should construe "substrate" so as to limit the term to mean a surface on which polymers are synthesized. The Court agrees with Affymetrix that no such limitation is required.

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A patentee "is free to act as his own lexicographer, and may set forth any special definitions of the claim terms in the patent specification or file history, either expressly or impliedly." Schoenhaus v. Genesco, Inc., 440 F.3d 1354, 1358 (Fed. Cir. 2006) (citing Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1300 (Fed. Cir. 2004)). When a specification reveals a special definition given to a claim term by the patentee, "the inventor's lexicography governs." Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005). The specification of the '243 patent includes a glossary section in which "substrate" is expressly defined as "[a] material having a rigid or semi-rigid surface." ('243 patent, col. 7, ll. 35-36.) Moreover, that definition is consistent with the use of the term "substrate" throughout the specification.

The glossary definition is followed by two sentences that read:
In many embodiments, at least one surface of the substrate will be substantially flat, although in some embodiments it may be desirable to physically separate synthesis regions for different polymers with, for example, wells, raised regions, etched trenches, or the like. According to other embodiments, small beads may be provided on the surface which may be released upon completion of synthesis.

(Id., col. 7, ll. 36-43.) Illumina contends that these sentences are part of the express definition and should serve to limit that definition to rigid and semi-rigid surfaces upon which polymers are synthesized. (D.I. 240 at 8-9.) However, these explanatory sentences are descriptive only of particular embodiments and the Court will not import limitations from particular embodiments into the claims. See JVW Enterprises, Inc. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005).

Illumina also contends that the Court should adopt Illumina's more narrow construction because, during prosecution of a parent application to the '243 patent, n2 Affymetrix distinguished a prior art reference "by arguing that this reference did not disclose how to synthesize sequences at known locations on a substrate, but instead taught how to attach pre-synthesized sequences." (D.I. 240 at 12.) "Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language." Seachange Intern., Inc. v. C-COR, Inc., 413 F.3d 1361, 1373-74 (Fed. Cir. 2005) (citations omitted). Such a disclaimer must, however, be "clear and unmistakable." Omega Engineering, Inc. v. Raytek Corp., 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). What Affymetrix actually disclaimed was that the invention claimed in the parent application could be practiced other than through in situ synthesis of sequences. The invention claimed in claim 14 of the '243 patent is very different from that invention, and, unlike the language of the parent application, the language of claim 14 does not expressly limit the invention to in situ synthesis. Therefore, the Court cannot conclude that the statements made in the prosecution history of the parent application amount to a clear and unmistakable disclaimer with regard to the scope of claim 14 of the '243 patent. For the reasons discussed above, the court construes "substrate" to mean "a material having a rigid or semi-rigid surface."

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n2 Application number 07/492,462 which issued as U.S. Patent No. 5,143,854 (the "'854 patent").

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C. Suffering From

Plaintiffs' contend that the plain and ordinary meaning of the phrase "sufferingfrom" is "having," and that the claim should be construed as such. Defendants counter that "suffering from" should be construed as "with symptoms of." While, as Defendants note, the specification discusses symptoms associated with hyperparathyroidism, there is no indication that the method described in claim 7 is intended to be limited to treating patients displaying those symptoms. See '116 patent, col. 2, ll. 57-63 ("hyperparathyroidism leads to markedly increased bone turnover and its sequela of renal osteodystrophy, which may include a variety of other diseases, such as osteitis fibrosa cystica, osteomalacia, osteoporosis, extraskeletal calcifcation, and related disorders, e.g. bone pain, periarticular inflammation, and Mockersberg sclerosis").

The Federal Circuit has held that, although dictionaries are extrinsic evidence, they "are often useful to assist in

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understanding the commonly understood meaning of words" and that consequently "judges are free to * * * 'rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'" Phillips, 415 F.3d at 1322-23(quoting Vitronics, 90 F.3d at 1584 n.6). Here, the dictionary definition and accompanying commentary regarding the term "to suffer" is helpful in construing the disputed claim term. The American Heritage Dictionary notes that "[i]n medical usage, suffer with is sometimes employed with reference to the pain or discomfort caused by a condition, while suffer from is used more broadly in reference to a condition, such as anemia, that is detrimental but not necessarily painful." The American Heritage Dictionary, 4th Ed., 2000, p. 1730, usage note. This definition supports the Plaintiffs' proposed construction, suggesting that "suffering from" refers to the existence of a medical condition, not the symptoms associated with that condition. Accordingly, the Court construes "suffering from" as "having."

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A. "[S]uffering or running a risk of depletion of muscle phosphoryl creatine storage"

OCPC maintains that the appropriate construction of the term "suffering or running a risk of depletion of muscle phosphoryl creatine storage" is much narrower than recommended by Judge Orenstein and should be limited to a depletion of creatine that occurs after intense physical exercise. In view of the fact that the patent specifications identify numerous uses for creatine, uses which are not limited to addressing the results of "intense physical activity," the Court rejects OCPC's attempt to narrow the language of the claim.

The specifications of the "159 Patent provides in relevant part:

Thus, nothing is disclosed or suggested in the above-mentioned prior documents which would lead a man skilled in the art to the findings that the supply of a daily dose of at least 15 g of creatine or 0.2-0.4 g/kg body weight or preferably about 0.3 g/kg body weight administered orally, enterally or parenterally to a mammal having no disorder in the creatine metabolism can be used for preventing the effects of depletion of the muscle phosphoryl creatine store during intensive activity and thereby improve the capacity of the muscles, to prevent muscular fatigue and shorten the recovery phase, or for pre-treatment in connection with heart surgery, to the treatment of anginose patients, respiratory insufficiency, decreased lung function, emphysema, to a patient in need of oxygen treatment, to patients treated with artificial respiration, postoperative and for general malnutrition, for fibromyalgia and to patients with different types of myopathies in order to increase the acutely available energy depots in muscle tissue with limited capacity of glycolytic or mitochondrial energy production. According to Sandstedt et al, Clinical Nutrition, Vol. 10, 1991, pages 97-104, see especially page 101, phosphocreatine levels generally are reduced in muscle tissues after they are subjected to injuries or surgical operations.

Thus, there has been a demand for a safe and simple preparation which without side effects can be given to mammals suffering from the above identified insufficiencies or whose muscular tissue of any reason needs a supply for correct and effective function.

. . .

The object of the present invention is to provide a cheap, simple and safe preparation, without side effects which can be given to mammals having no disorders in their creatine metabolism. Said preparation can be used in connection with the disorders identified above and also to prevent the effects of depletion of the muscle phosphoryl-creatine store during intensive activity and thereby improve the capacity of the muscles and also shorten the recovery phase.

'159 Patent col. 3 ll.1-28, ll 43-50 (emphasis added). As Judge Orenstein aptly noted "the invention's use for treatment to 'prevent[] the effects of depletion of the muscle phosphoryl creatine store during intensive activity' appears as one of several separately enumerated applications, only a minority of which are related to intense physical activity and most of which clearly concern the invention's medical applications." (R&R at 10.)

The recent decision in ICU Med., Inc. v. Alaris Med. Sys., 558 F.3d 1368 (Fed. Cir. 2009) is instructive. In ICU, the Federal Circuit upheld the district court's construction of the term "spike" as used in the patent at issue therein which construction relied upon the specifications. In reaching this result, the Court stated:

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We have consistently explained that claim terms should generally be given their ordinary and customary meaning and that such meaning is one "that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." . . . Moreover, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears but in the context of the entire patent, including the specifications.'" This last tenet derives from the fact that claims do not stand alone but rather "are part of a 'fully integrated written instrument,' consisting principally of a specification that concludes with the claims.'"

Id. at 1374 (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005). Although a court "should not import limitations from the specifications into to the claims," the ICU Court recognized that "the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court focus remains on understanding how a person of ordinary skill in the art would understand the claim terms . . . after reading the entire patent." Id. at 1375 (quoting Phillips, 415 F.3d at 1323 (emphasis added).

Here, to paraphrase the ICU Court, the "specification repeatedly and uniformly describes" the invention's medical applications and not just its application related to intense physical activity. See id. at 1374. Given that the specification is usually "dispositive" and "is the single best guide to the meaning of a disputed term," Vitronics, 90 F.3d at 1582, OCPC's proposed definition must be rejected.

Having considered all the arguments raised by the parties, OCPC's objections are denied and the Court adopts Judge Orenstein's recommendation, both in reasoning and result, that "suffering from or running a risk of depletion of muscle phosphoryl creatine storage" means "having reduced, or potentially reduced, phosphoryl creatine storage in muscle."
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III

The trial court held claim 1 of the '705 patent to be indefinite based on the absence of a specified period of time in the claim for treating the Fischer-Tropsch catalyst with hydrogen or a hydrogen-containing gas. The claim recites that the treatment should be "for a period sufficient to increase substantially the initial catalyst activity." The trial court broke that clause down into two parts for purposes of its indefiniteness analysis, and it ruled that both the phrase "for a period sufficient" and the phrase "to increase substantially" were indefinite.

A

The term "to increase substantially" in claim 1 of the '705 patent refers to the claimed increase achieved by the invention in the relative productivity of the catalyst used in the Fischer-Tropsch process. The specification defines "substantially increased" catalyst activity or productivity as an increase of at least about 30%, more preferably an increase of about 50%, and still more preferably an increase of about 75%. '705 patent, col. 1, ll. 59-63. Based on that language from the specification, the trial court found, and the parties agree, that the term "to increase substantially" requires an increase of at least about 30% in the relative productivity of the catalyst. Notwithstanding that numerical boundary, the trial court found the phrase "to increase substantially" to be indefinite because the court concluded that there were two possible ways to calculate the increase in productivity, the subtraction method and the division method, and the patent did not make clear which of those ways was used in the claim.

An example from the specification will illustrate the difference between the two methods of calculating the increase in catalyst productivity. The specification gives two examples showing the relative productivity "before" and "after" super-activation according to the method of the invention. In the experiment reported in Example 1, the "before" productivity was 60 and the "after" productivity was 100. In the experiment reported in Example 2, the "before" productivity was 25 and the "after" productivity was 100. The court found that the increase in relative productivity could be calculated either by the subtraction method or the division method. That is, in Example 2 there would be either a 75% increase (100 minus 25) or a 300% increase ([100 minus 25] divided by 25). The difference in the numerical outcome produced by the two results is relevant because in certain circumstances calculating relative productivity by the first method could produce an increase of less than 30% in relative productivity, but using the second method could produce an increase of more than 30%. In such a

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case, the trial court explained, a person of skill in the art would not be able to determine whether the claims of the '705 patent were infringed. That ambiguity, according to the court, rendered the claims indefinite.

We disagree with the court's conclusion as to the indefiniteness of the phrase "to increase substantially." The specification makes it reasonably clear that the patentee intended to use the subtraction method in calculating relative productivity. As noted above, the specification recites that catalyst productivity can "more preferably" be increased by as much as 75%. Corresponding to that preferable level of increased productivity, the best result reported in the patent is found in Example 2, which shows an increase in relative productivity from 25% to 100%, which is an increase of 75% by the subtraction method. The same result is shown graphically in Figure 1 of the patent, which depicts a 75% difference between the "before" and "after" relative productivity levels, as calculated by the subtraction method. In contrast, there is no suggestion in the specification that the claimed invention was able to achieve increases on the order of 300%, which would be the way the Figure 1 increase would be characterized if the division method were used. In light of the intrinsic evidence, one of skill in the art would likely understand that the patentee employed the subtraction method of measuring the increase in relative productivity. Thus, the term "to increase substantially" does not introduce any insoluble ambiguity into the claims of the '705 patent and does not render the claims invalid for indefiniteness.

B

The trial court also found that the "for a period sufficient" limitation in claim 1 of the '705 patent was indefinite and that it rendered claim 1 and the dependent claims of the '705 patent invalid. The court based that conclusion on the fact that neither the claims nor the specification identified any upper or lower boundary for the prescribed period. Without such boundaries, the court concluded, a person of ordinary skill in the art could not determine the scope of the claims.

Although the specification teaches away from treating the cobalt catalyst for a period longer than necessary to obtain maximum activity enhancement, see '705 patent, col. 3, ll. 21-23, the claims are not indefinite on the ground that they fail to recite an upper boundary for the "for a period sufficient" limitation. The claims provide that the catalyst must be treated "for a period sufficient" to attain a 30% increase in catalyst productivity. That limitation sets the minimum period of treatment, but any longer period would also fall within the reach of the claim language. Thus, the "period sufficient" limitation by its terms delineates only a lower boundary. While treatment of the catalyst for a much longer period might not be as effective as treatment for a period barely sufficient to achieve the prescribed increase in catalyst productivity, the fact that the invention may be inoperable with very long treatment periods does not make the claim language indefinite. See N. Am. Vaccine, 7 F.3d at 1579, 28 U.S.P.Q.2D (BNA) at 1339 (the fact that claims "include species which might not meet the objects of the invention does not by itself prove that one skilled in the art cannot ascertain the scope of the asserted claims"). The indefiniteness issue thus turns on whether the lower boundary of the "for a period sufficient" limitation is impermissibly vague.

The trial court rejected Exxon's contention that the lower boundary could be ascertained by conducting activity checks during the super-activation procedure. The court noted that the patent taught the use of such checks only to determine the initial activity of the fresh catalyst, and that conducting activity checks to determine whether the catalyst has been sufficiently exposed would risk corrupting the catalyst and would significantly disrupt the super-activation procedure. In addition, the court rejected Exxon's alternative argument that the claim term "a period sufficient" is as definite as possible given the varying conditions, including temperature and treat ratio.

Although the patent does not quantify the "period sufficient" limitation by reference to any specific period or range of periods, it does not leave those skilled in the art entirely without guidance as to the scope of that requirement. The specification states:

> The period necessary for activation is that period that results in substantial increases in initial, e.g., start of run, catalyst productivity, preferably at least about a thirty percent (30%) increase in relative catalyst productivity and may vary with temperature and treat ratio, etc., but is usually accomplished in about 0.25-24 hours, preferably about 0.5-2 hours.

'705 patent, col. 2, ll. 58-64. As the trial court noted, the specification does not give a specific example of a period of time sufficient to achieve a particular increase in catalyst productivity for a certain supported catalyst. However, a preferred treatment period is provided that presumptively correlates to the preferred catalyst, hydrogen treat rate range, and temperature range disclosed in the specification. By looking to the specification, one of skill in the art could determine that

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"a period sufficient" is about 0.25 hours, and preferably 0.5 hours. Because the patent makes clear that the period in question will vary with changes in the catalyst and the conditions in which the process is run, we conclude that the claim limitation is expressed in terms that are reasonably precise in light of the subject matter. See Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 U.S.P.Q.2D (BNA) 1081, 1088 (Fed. Cir. 1986) (construing "so dimensioned" as definite and stating that the term "is as accurate as the subject matter permits, automobiles being of various sizes").

In addition, it appears that one of skill in the art could measure the period "sufficient to increase substantially the initial catalyst activity" for a particular catalyst more precisely by conducting activity checks. As the trial court noted, conducting such checks could contaminate the catalyst or disrupt the super-activation procedure. However, that does not mean that the data collected would be any less relevant in determining the scope of the claim. Once the "period sufficient" for a particular catalyst is determined, there would be no need to duplicate the activity checks during normal slurry bubble column reactor operations, and there would be no continuing risk of contamination or disruption. Even the government's expert agreed that the "period sufficient" could be determined from conducting such checks, and that he "wouldn't say they are difficult to do." Provided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation may be necessary to determine the scope of the claims does not render the claims indefinite. See W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 U.S.P.Q. (BNA) 303, 316 (Fed. Cir. 1983).

Our predecessor court's decision in In re Jolly, 36 C.C.P.A. 825, 172 F.2d 566, 80 U.S.P.Q. (BNA) 504 (CCPA 1949), although offering support to the government's position, does not compel a contrary result. In re Jolly concerned an indefiniteness rejection based on similar claim language, "a time sufficient to produce a substantially homogeneous product but insufficient to cause the formation of a substantial proportion of oil-insoluble reaction products." The court there found that since the time of reaction was taught to be critical, the claims must recite a time range for the sulfurization step at issue. While an upper time limit was recited, at least in some claims and in the written description, there was no lower limit recited. For that reason, the court affirmed the examiner's rejection, stating that "so far as the time of reaction is concerned, it seems to us that all that appellant's specification teaches those skilled in the art is to experiment and find out for themselves how much time will be required where different amounts, or proportions, of nitriles and sulfur are used." In re Jolly, 172 F.2d at 569, 80 U.S.P.Q. (BNA) at 506.

In re Jolly is admittedly quite similar in some respects to this case. In Jolly, however, it appears that there was no lower boundary recited in the applicant's specification, while in this case the patentee has stated that the catalyst should be treated for about 0.25 hours, and preferably 0.5 hours. Moreover, the specification in Jolly taught that reaction time was critical to the patentability of the invention, and the court emphasized that point in holding the claim language indefinite. There is no equivalent representation as to the criticality of the treatment period in this case, and in a post-Jolly decision, the Court of Customs and Patent Appeals explained that it is not fatal for an applicant to express noncritical limitations with regard to factors such as time or quantity in functional rather than numerical terms. In re Caldwell, 50 C.C.P.A. 1464, 319 F.2d 254, 258, 138 U.S.P.Q. (BNA) 243, 246-47 (CCPA 1963) (upholding claim language that referred to the amount of aspirin to be used in a method for stimulating growth in certain animals as "an effective amount . . . for growth stimulation"). Finally, Jolly was a case in which the court was reviewing the rejection of a patent application, not an infringement action based on an issued patent. Patent applicants have the opportunity to amend their claims during prosecution in order to overcome an indefiniteness rejection. See In re Zletz, 893 F.2d 319, 322, 13 U.S.P.Q.2D (BNA) 1320, 1322 (Fed. Cir. 1989) ("During patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. . . . An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in that way can uncertainties of claim construction be removed, as much as possible, during the administrative process."). That factor explains, for example, the practice of construing claims according to their broadest reasonable interpretation consistent with the specification where the patent has not yet issued and the applicant has an opportunity to amend the claim to avoid invalidity. See, e.g., In re Wiggins, 488 F.2d 538, 541-42, 179 U.S.P.Q. (BNA) 421, 423-24 (CCPA 1973).

Unlike the applicant in Jolly, Exxon has the benefit of a statutory presumption of validity, 35 U.S.C. § 282. In light of that presumption and the difference in posture between an applicant whose application has been rejected and a patentee with an issued patent, close questions of indefiniteness in litigation involving issued patents are properly resolved in favor of the patentee. Thus, in cases subsequent to In re Jolly that have involved issued patents, this court has held claims definite even when some degree of experimentation was necessary, as long as the claims otherwise met the enablement requirement. See, e.g., Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., 145 F.3d 1303, 1312, 46 U.S.P.Q.2D (BNA) 1752, 1759 (Fed. Cir. 1998) (holding that the recitation of a quantitative drop rod test rendered definite a claim limitation); W.L. Gore &

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Assocs., 721 F.2d at 1557, 220 U.S.P.Q. (BNA) at 316. The government's expert admitted that the "period sufficient" can be ascertained by conducting activity checks. Therefore, a person of ordinary skill in the art would understand the scope of that claim limitation, which is all that paragraph 2 of section 112 requires.

Because we hold that the terms "for a period sufficient" and "to increase substantially" are not indefinite, we reverse the Court of Federal Claims' summary judgment of invalidity as to the '705 patent.
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A. Claim Construction

Independent claims 1, 6, 9 and 10 of the '176 patent speak of adding an amount of water to sevoflurane in an amount "effective" or "sufficient" to prevent degradation of the sevoflurane by a Lewis acid, such as that found in water. Only dependent claims 3 and 8 state that a numerical range of Lewis acid inhibitor is "at least about" or "about" 400 parts per million (ppm) to "about" 1400 ppm. However, generally, "limitations stated in dependent claims are not to be read into the independent claim from which they depend." Karlin Tech, Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 972 (Fed. Cir. 1999).

Therefore, the parties dispute the meaning of the term "effective" or "sufficient" amount. Specifically, because Baxter's product will contain no more than 130 ppm of water, Baxter argues that "effective" or "sufficient" amount should not be construed to reach as far down as 130 ppm. Baxter cites two main sources of information to support this argument: the specifications of the patent, which suggest that an effective amount is "believed to be from about 0.0150% w/w to about 0.14% w/w," and the prosecution history of the patent, which reveals that Abbot made a sale of sevoflurane with a water content of 131 ppm more than one year prior to filing for the '176 patent.

In interpreting a claim, "the court should first look to the intrinsic evidence of record," the claims, the specification and the prosecution history. Vitronics, 90 F.3d at 1582. Intrinsic evidence is the most important source of the meaning of disputed claims.Id. "Extrinsic evidence may not be relied upon during claim construction when the intrinsic evidence is sufficient to construe the claim." Sextant Avionique, S.A. v. Analog Devices, Inc., 172 F.3d 817, 826 (Fed. Cir. 1999) (citing Bell & Howell Document Mgmt Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997)). However, it is proper for the court to look to extrinsic evidence to interpret the patent if the public record is ambiguous in describing the scope of the patented invention. Markman, 52 F.3d at 978-79.

The court must first look to the claims "to define the scope of the patent invention." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). "A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention." Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). "A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention." Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996). However, words of a claim are given their ordinary and customary meaning unless the patentee has chosen to be his own lexicographer. Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995). If the patentee has chosen to be his own lexicographer, "the special definition of the term" must be "clearly stated in the patent specification or file history." Id.

Baxter argues that the specifications of the patent, stating that an effective amount is "believed to be from about 0.0150% w/w to about 0.14% w/w," limits the terms "effective" or "sufficient" amounts in the claims, essentially that Abbot acted as its own lexicographer. The specification in the "Summary of the Invention" states that the lower numerical range of effective stabilizing amount of Lewis acid inhibitor, that "can be used is" or "is believed to be" "about 0.150% w/w" (150 ppm). '176 Patent at Col 4, Lines 31-34, 45-47 and 56-58. However, it is difficult to construe the exact meaning of "about 0.0150% w/w." The examples in the specification show that the effective amount of Lewis acid inhibitor, namely water, will be dependent on the temperature and that the higher the temperature, the more water is needed to prevent the degradation of the sevoflurane. One example states that the degradation of the sevoflurane stopped when water was added at 1300 ppm at a temperature of 195 [degrees] C for three hours. The lowest range at which the examples showed the degradation was inhibited was that of water levels higher than 206 ppm, at 40 [degrees] C for 200 hours. However, no examples are given at room temperature (around 20 [degrees] C) or cooler. Thus, there is nothing in the specifications to suggest that at lower

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temperatures, 150 ppm of water or less would not be effective to prevent degradation.

In addition, the specification states that "the composition of the present invention contains a total of from about 98% w/w to about 100% w/w" sevoflurane. '176 Patent, Col. 4, Lines 1-2, 12-14. Since the composition at issue is sevoflurane and the Lewis acid inhibitor water, this could be read as stating that the amount of water required is from about 0% to 2%, which would be a range of about 0 ppm to 20,000 ppm. 130 ppm, the amount of water in Baxter's proposed product, is certainly much closer to 0 than to 20,000, as is 1300, the amount used in one of the examples. There is nothing to suggest that the "about 100% w/w" of sevoflurane referred to in the patent could not refer to sevoflurane with 130 ppm of water (99.987% sevoflurane). Therefore, nothing in the specifications inherently requires the amount of water to be 150 ppm or more.

The court would be prepared to decline to limit its interpretation of the terms "effective" or "sufficient" amount to 150 ppm or greater but for Baxter's second argument, that the prosecution history of the '176 patent shows a prior sale which must limit the claims of the patent, lest it be invalid under 35 U.S.C. § 102(b).

On July 29, 1998, during the prosecution of the '176 patent, Abbott filed an Information Disclosure Statement with the U.S. Patent Office. (Def.'s LR 56.1(a)(3) P 10.) As part of this statement, Abbott submitted a document entitled "Sevoflurane Water Content." (Id. at P 11.) It listed the water content of each lot of sevoflurane distributed by Abbott prior to the filing date of the application for the '176 patent. (Id.) The first lot of Abbott sevoflurane listed on the chart, Lot No. 3298DK, had a water content of 131 parts per million. (Id. at P 13.) This lot was manufactured on March 4, 1995. (Id. at P 14.) More than one year prior to January 27, 1997, the filing date of the '176 patent, Abbott sold bottles of sevoflurane from Lot No. 3298DK to hospitals in the United States. (Id. at P 15.) For example, forty-eight bottles from Lot No. 3298DK were sold on August 4, 1995 to Arlington Memorial Hospital in Arlington, Texas. (Id. at P 16.) At least forty-eight bottles from Lot No. 3298DK were sold on or about August 17, 1995 to St. Francis Hospital in Tulsa, Oklahoma. (Id. at P 17.) Forty-eight bottles from this lot were also sold on August 19, 1995 to St. John's Medical Center in Tulsa, Oklahoma. (Id. at P 18.) Abbott denies selling these lots in anything other than glass containers. (Pl.'s LR 56.1(b)(3)(A) P 15-18.)

Baxter's January 26, 2001 amendment to its ANDA states that Baxter's sevoflurane stored in aluminum containers will have not more than 130 PPM of water. (Def.'s LR 56.1(a)(3) P 19.) The revised ANDA states "the limit for Water Content for sevoflurane to be packaged in the alternate aluminum container/closure system is NMT 0.013% (NMT 130 ppm)." These facts are all admitted by both sides and do not require resolution at trial.

Baxter's argument is commonly used by defendants in patent infringement cases. While not asking this Court to declare the '176 patent invalid because of anticipation pursuant to 35 U.S.C. § 102(b), Baxter argues that if the patent were construed to encompass its product with a water content of 130 ppm, then such an interpretation would render the patent open to an anticipation claim, because a product containing sevoflurane with a water content of 131 ppm was on sale more than one year prior to the filing of the '176 patent. If the '176 patent is construed to encompass such an invention, then it is manifestly invalid under 102(b). Hence, the argument goes, the patent should be construed so as to preserve its validity, and, thus, should not encompass sevoflurane with a water content of 131 ppm or less. We agree.

The court "may consider the prosecution history of the patent, if in evidence." Vitronics, 90 F.3d at 1582, to interpret patent claims. The prosecution history is a complete record of the entire "proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Id. "The prosecution history limits the interpretation of the claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id. at 1583. An analysis of the prosecution history may include "an examination of the prior art cited therein."Id. The prior art cited in the prosecution history provides "clues as to what the claims do not cover." Id.

If possible, claims "are generally construed so as to sustain their validity". Whittaker Corp. v. UNR Industries, Inc., 911 F.2d 709, 712 (Fed. Cir. 1990)."However, when the claim's language embraces the prior art, the court is not unlimited in the extent to which it can interpret the claims." Karsten Manufacturing Corp. v. Cleveland Gold Co., 242 F.3d 1376, 1384 (Fed Cir. 2001) (pointing out the difficulty of balancing a patentee's argument that a claim should be read broadly and the alleged infringer's argument that if the claims are read so broadly that they 'reach the accused device, the claims also read on the prior art and are invalid.")

"A person shall be entitled to a patent unless-- (b) the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. 102(b). "A single sale . . . is enough to bar

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patentability." Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 830 (Fed. Cir. 1991). Here, the parties admit that sevoflurane with 131 ppm of water was sold in the United States more than one year prior to January 27, 1997, the date of filing of the '176 patent.

Abbott admits it made the prior sales of sevoflurance and water, with the water content of 131 ppm and less. However, Abbott argues that since the patent examiner knew of the prior sales and required no amendments because of those sales, and Abbott made no amendments because of the prior sales, it did not relinquish or disavow compositions with 131 ppm of water or less. Abbott cites to York Products, Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568 (Fed. Cir. 1996) for the proposition that disavowal and relinquishment of coverage of patent claims "arises as a result of amendment to overcome patentability rejections or as a result of argument to secure allowance of a claim." Nevertheless, that the examiner did not consider the prior sales invalidating does not mean that they are not such. The Court must still adhere to the rule expressed in Whitaker and many other cases that patent claims should, when possible, be read to preserve their validity.

Abbot also attempts to distinguish its prior sale from Baxter's proposed product by pointing out that the prior sales all involved sevoflurane in glass containers, while Baxter's product will be in an aluminum container. Because different containers may produce different amounts of Lewis acids, Abbot argues, different containers might require different amounts of water and, therefore, Abbot's prior sale would not be covered by the '176 patent, while Baxter's proposed product would be. Besides the fact that the Court can find no mention in the '176 patent that the type of container would make a difference, even assuming that Abbot's assertion were correct, there is still nothing in the '176 patent to suggest (as Abbot so aggressively asserts in response to Baxter's first argument) that 130 ppm would not be covered by the patent, regardless of the container. There is nothing to suggest that 130 ppm of water could never be effective with a glass container. Indeed, the patent clearly teaches that lower temperatures require lower amounts of water to stabilize the compound.

Therefore, because of the prior sales of the sevoflurane and water, if the Court holds that the amount of a Lewis Acid inhibitor required to prevent degradation is as low as 131 ppm, the patent would most likely be invalid. While the Court has grave concerns about the validity of the '176 patent in light of these prior sales, and is perplexed as to the patent examiner's allowance of the claims given that information, the Court is also unwilling to declare a patent invalid without being asked to do so. Moreover, the "clear and convincing" evidence required to invalidate a patent has not yet been shown here, although the patent's invalidity has been shown to be quite probable.

The only way to maintain the validity of the '176 patent, then, would be to interpret the terms "sufficient" or "effective" amount as requiring at least 131 ppm of water. Therefore, we hold that Abbott disavowed water limits of 131 ppm or less by disclosing the prior sales of sevoflurane and water that were made more than one year before the patent was filed. The "effective amount" of Lewis acid inhibitor that is covered by "about 0.0150% w/w" does not reach 131 ppm or lower. However, we decline to delineate any more specific boundaries for "about 0.150%," as this term could be narrowed further only through additional evidence not currently in the record.
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Effective Amount

The primary issue on appeal is the district court's construction of the claim term "effective amount." At the outset, this court notes that the term "effective amount" has a customary usage. Under this usage, the term would mean "the amount of Lewis acid inhibitor that will prevent the degradation of sevoflurane by a Lewis acid." See Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1299, 1304 (Fed. Cir. 2002) (affirming the district court's construction of the claim term "effective amount" to mean "a sufficient amount of the specified component to form an encapsulant having the specified properties under the specified conditions, if any").

Moreover, the '176 specification teaches that an effective amount of any given Lewis acid inhibitor will vary depending upon the conditions to which sevoflurane is subjected. The term "effective amount" is broadly described in the "Summary of the Invention" as an "effective stabilizing amount of Lewis Acid inhibitor" that "prevents the degradation of the fluoroether compound by a Lewis acid." '176 patent, col. 2, ll. 60-65. The specification teaches that degradation of fluoroether anesthetics, such as sevoflurane, vary depending upon the environment of the anesthetic. For example, the amount of Lewis

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acid inhibitor needed to prevent degradation of sevoflurane increases with increasing temperature. '176 patent, col. 8, ll. 18-20. Similarly, Type III glass, normally inert to sevoflurane, activates in some anhydrous, acidic environments. Activated glass exposes sevoflurane to Lewis acid reactive sites. '176 patent, col. 5, ll. 48-54. Examples 5-7 in the '176 patent inhibit degradation of sevoflurane by activated Type III glass by adding 400 ppm water.

Type I glass, chemically distinct from Type III glass, activates in the presence of 50 mg aluminum oxide, a known Lewis acid. Again, the specification addresses this degradation hazard by adding 260 ppm water. '176 patent, col. 5, ll. 55-col. 6, l. 16; Figure 1. The '176 patent thus explains that many different factors interact to dictate an "effective amount" of Lewis acid inhibitor to stabilize sevoflurane in a specific environment. Because the patentee did not deviate from the accustomed meaning of the disputed claim term, the term "effective amount" is construed in view of its ordinary and customary meaning. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (stating that claim terms are afforded a "heavy presumption" that their ordinary and customary meanings apply). At a minimum, the '176 patent provides support for defining an "effective amount" of inhibitor to be the amount of Lewis acid inhibitor needed to stabilize sevoflurane housed in a particular glass vessel under a given set of environmental conditions. Thus, the specification supports the concept that the amount of Lewis acid inhibitor depends on many environmental considerations.

These principles also explain the relevance of the prior sale disclosed in the IDS. Particularly because the prior sale involved sevoflurane in a specific glass container with a water content of no more than 131 ppm, Abbott's disclosure to the USPTO did not disavow or relinquish all water concentrations below 131 ppm in other conditions. In the context of this invention, Abbott's disclosure did not expressly disavow claim scope. See York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1575-76 (Fed. Cir. 1996) ("Unless altering claim language to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage."). In York, for example, this court found no surrender of claim scope because the file history of the asserted patent did not contain "a single statement that the inventors conceded any coverage based on the [the prior art]," and the "mere invocation" of prior art does not necessitate limiting claim scope. Id. Indeed, this court recently reiterated the rule that only a clear disavowal of subject matter divests claims of broader scope. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313 (Fed. Cir. 2002). In Teleflex, this court stated: "We conclude that claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Id. at 1324.

In this case, the district court incorrectly limited the term an "effective amount" of water to 131 ppm, despite the absence of a clear disavowal of water at lower amounts. Simply disclosing a previous sale of sevoflurane to the USPTO, without saying or doing anything more, does not disavow or relinquish all water concentrations below 131 ppm. As the patent itself discloses, the effective amount of Lewis acid inhibitor depends on the specific storage conditions of the sevoflurane. Moreover, mere submission of an IDS to the USPTO does not constitute the patent applicant's admission that any reference in the IDS is material prior art. According to Patent Office rules, "the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to the patentability defined in § 1.56(b)." 37 C.F.R. § 1.97(h) (2000). While valid prior art may be created by the admissions of a party, these admissions are generally characterized by statements made during prosecution describing certain work as "prior art." See In re Nomiya, 509 F.2d 566, 571 n.5 (CCPA 1975); In re Fout, 675 F.2d 297, 300-01 (CCPA 1982). Under certain circumstances, even an express representation that a reference cited in an IDS is prior art to pending claims is not sufficient to create prior art by admission. Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346 (Fed. Cir. 2003). Thus, with the mere listing of references in an IDS, the applicant has admitted no more than that references in the disclosure may be material to prosecution of the pending claims. 37 C.F.R. § 1.56(a) (2000); see A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392 (Fed. Cir. 1986).

Although Abbott sold sevoflurane having water content levels of no more than 131 ppm several years before filing the '176 patent application, Abbott made no express representations about the relevance of these prior sales to the claims. Moreover, the examiner did not reject the claims over the disclosed prior sales of sevoflurane. The mere disclosure of potentially material art to the USPTO does not automatically limit the claimed invention. As noted, the examiner did not consider the sale relevant and the applicant did not distinguish the claims over the disclosed sale. Thus, this court concludes that the district court incorrectly relied on the IDS disclosure to limit the term "effective amount."

In reaching this conclusion, this court notes three instances in the specification where the applicant states an "effective

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amount" of water ranges from about 0.0150% w/w (150 ppm) to 0.14% w/w (saturation level). '176 patent, col. 4, ll. 32-36; 43-47; 55-58. Contrary to the district court's characterization, these references are not part of the "Summary of the Invention." Instead, these column 4 references fall within the "Detailed Description of the Invention." Thus, these references refer to the preferred embodiments of the invention. Because these references refer only to narrow preferred embodiments and not the invention as a whole, the specification passages do not support the limitation imported into the claims by the district court. The specification simply does not indicate that Abbott restricted its claims to the preferred embodiments. Instead, the specification refers to the water content in these preferred embodiments as amounts that "can be used" or "is believed to be" an appropriate Lewis acid inhibitor. These descriptions in the specification are far from an express disavowal of other effective amounts.

This court interprets patent claims in light of the specification, but this axiom "does not mean that everything expressed in the specification must be read into all the claims." Teleflex, 299 F.3d at 1326. "Claims are not necessarily and not usually limited in scope simply to the preferred embodiment." R.F. Del. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1263 (Fed. Cir. 2003). Thus, the specification does not require the claims to be limited to the preferred embodiments. This court declines to so limit the claims in this regard.

Neither does the prosecution history of the '176 patent limit the disputed claim terms. Early in the prosecution, the examiner cited U.S. Patent No. 4,080,389 (issued to Moilliet) as anticipating the subject claims under 35 U.S.C. § 102. Moilliet discloses a fluoroether anesthetic composition containing water vapor. In response to this rejection, Abbott noted that Moilliet "merely indicates that water vapor may be present in the disclosed anesthetic composition . . . without specifying the amount of water present in the composition." At no time during this proceeding did Abbott reference the examples in its specification as the only specified water amounts that are "effective" to inhibit Lewis acids. In fact, Abbott never expressly represented that a particular concentration range of Lewis acid inhibitor was critical to distinguishing its claimed invention over Moilliet. Rather, Abbott overcame Moilliet by simply differentiating the trace amounts of water vapor taught in that reference from the claimed amount of water effective as a Lewis acid inhibitor in sevoflurane. At best, Abbott disavowed trace amounts of water as being effective in stabilizing sevoflurane. Thus, this prosecution history does not support limits on the terms "effective amount" or "amount sufficient."

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2. The Meaning of "Sufficient [Nitroglycerin] to Deliver to the Skin a Pharmaceutically Effective Amount of [Nitroglycerin] Over a 24-Hour Time Interval"

Hercon contends that the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" means an amount of nitroglycerin sufficient to provide a patient with 2.5 to 15 mg of nitroglycerin per day. Hercon's interpretation is based on the testimony of its expert witness, Dr. Richard H. Guy. Dr. Guy is a Ph.D. in pharmaceutical chemistry. He was an assistant professor of pharmacy and pharmaceutical chemistry at the University of California, San Francisco from 1980 until 1987, when he was granted tenure and promoted to associate professor there. In July of this year, he took a new post as the scientific director of an interuniversity research center outside of Geneva, in France. The focus of the work going on in this institute is the design and development of drug delivery systems. Dr. Guy is specifically responsible for a group within the institute that will be working on the delivery of drugs through the skin. Tr. at 1004-10.

At trial, Dr. Guy testified as to his understanding of the meaning of the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" to one of ordinary skill in the art of transdermal delivery systems at the time of the claimed invention. He explained that, as a general matter, there is a correlation between the concentration of a drug in a patient's blood and the effect that the drug produces. Therefore, it is desirable to sustain a certain concentration of drug in the blood over a specific period of time. That concentration of drug ideally falls in what is referred to as "the therapeutic window." The therapeutic window is a concentration of drug above that which is minimally effective and below that which is minimally toxic. The goal of administering a drug is therefore to achieve and sustain over a desired period of time a concentration that falls within the therapeutic window. Tr. at 1093-96.

Dr. Guy concluded that the term "pharmaceutically effective amount" means an amount which allows sustained drug delivery and which provides a concentration of drug that falls within the therapeutic window, and that the phrase "sufficient

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[nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" means the amount of nitroglycerin required to sustain the desired concentration over a 24-hour period. Dr. Guy further testified that there is nothing in the '938 patent or its file history that would lead him to a different conclusion because, in his opinion, the patent does not expressly disclose any numerical values that give meaning to the phrase. Tr. at 1096-97.

Dr. Guy testified that, in determining a numerical value for the term "pharmaceutically effective amount," one of ordinary skill in the art at the time of the claimed invention would have looked to the transdermal delivery systems conditionally approved by the FDA for guidance. He explained that such systems delivered between 2.5 and 15 mg of nitroglycerin per day. Tr. at 1098-99. Hercon thus concludes that one of ordinary skill in the art at the time of the claimed invention would have interpreted "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" to include, at least, an amount sufficient to provide a patient with 2.5 to 15 mg of nitroglycerin per day; that is, 2.5 to 15 mg of nitroglycerin, plus an excess amount to ensure that the desired amount is delivered.

Key, on the other hand, contends that the '938 patent discloses express numerical values for what is meant by "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval." First, Key contends that the phrase means nitroglycerin delivered at a flux rate of 0.3 to about 0.7 mg per square centimeter per day. Key's contention is based on a statement in the specification of the '938 patent that an "object of the invention is to provide a dosage system wherein nitroglycerin is delivered to the skin in an amount of from 0.3 to about 0.7 mg per square centimeter of the first component layer per 24-hour time interval." See col. 4, lines 67-68; col. 5, lines 1-3.

In construing a disputed term in a claim, a court looks first to the patent's claims, both asserted and nonasserted. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The invention of the '938 patent is an adhesive transdermal delivery system containing two component layers. Independent claim 1 is directed to a bilayer system containing both an adhesive layer and a backing layer. Independent claim 12 is directed to only an adhesive transdermal layer. With respect to the adhesive layer, the language of claim 1 is virtually identical to the language of claim 12, except that the term "nitroglycerin" is substituted for "pharmaceutically active drug." Claim 3, which depends from claim 1, requires that the nitroglycerin be "delivered to the skin in an amount of from about 0.3 to 0.7 mg per square centimeter . . . per 24-hour time interval." Under the doctrine of claim differentiation, "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" as that term appears in claim 1 must be presumed to have a different meaning from the flux rate stated in claim 3. See e.g., Tandon Corp. v. United States Internat'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims."). Indeed, if claim I were read to require nitroglycerin delivered in an amount of 0.3 to about 0.7 mg per square centimeter per day, then claim 3 would be superfluous. See id. ("To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant."). Because the claims of a patent must be interpreted in a consistent manner, Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995), it must be presumed that the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" in claim 12 likewise does not mean nitroglycerin delivered in an amount of 0.3 to about 0.7 mg per square centimeter per day.

Key argues that the presumption created by the doctrine of claim differentiation is overcome by a statement in the specification that one of the objects of the invention is to deliver nitroglycerin in an amount of 0.3 to about 0.7 mg per square centimeter per day. However, the mere fact that the specification states that this flux rate is an object of the invention does not require that claim 14 be read to include that flux rate. See Intel Corp. v. United States Internat'l Trade Comm'n, 946 F.2d 821, 836 (Fed. Cir. 1991) (refusing to read numerical value described as a goal of the invention into claims where limitation not contained in claims). Although Key relies heavily on United States v. Adams, 383 U.S. 39, 15 L. Ed. 2d 572, 86 S. Ct. 708 (1966), where the Supreme Court considered a stated object of the invention at issue in construing a claim, the Court did not simply read the stated object into the claims at issue, as Key proposes the court do here, but rather considered the stated object together with certain inferences that could be drawn from the language of the patent's claims. See 383 U.S. at 48-49. Here, Key has not identified any other support for reading the flux rate stated as an object of the invention into claim 14. Accordingly, the court concludes that Key has failed to overcome the presumption and that claim 14 does not require that nitroglycerin be delivered in an amount of 0.3 to about 0.7 mg per square centimeter per day.

Key also contends that the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" means nitroglycerin incorporated into the cross-linked adhesive in an amount

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of about 20 to 50 or 60% by weight based on the weight of the first component layer. Key bases its contention upon the statement in the specification that "the most preferred embodiment is nitroglycerin incorporated in the cross-linked adhesive and especially incorporated in an amount of about 20 to 50 or 60% by weight based on the weight of the first component layer." See col. 7, lines 11-15.

Key overlooks the well-established principle that claims are not necessarily limited to the preferred embodiment or specific examples disclosed in the specification. See Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997). Key has not identified anything else in the specification or prosecution history that suggests that "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" means nitroglycerin incorporated into the cross-linked adhesive in an amount of about 20 to 50 or 60% by weight based on the weight of the first component layer. Accordingly, the court concludes that claim 14 does not require that nitroglycerin be incorporated into the cross-linked adhesive in an amount of about 20 to 50 or 60% by weight based on the weight of the first component layer.

Finally, Key contends that claim 14 requires that the adhesive layer described therein be capable of delivering a pharmaceutically effective amount of nitroglycerin in a system having a 5 cm<2> surface area. Key's contention is based on a statement in the specification of the '938 patent that "the present invention allows for the delivery of enough pharmaceutically active drug such as nitroglycerin to provide efficacy with a dosage system having a 5 cm<2> surface area . . . ." See col. 9, lines 51-54. Key's interpretation, however, would require importing an extraneous limitation from the specification into claim 14, which is wholly improper. See E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988). An extraneous limitation is one "read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim." Id. Nothing in claim 14 or the specification suggests that the surface area of the adhesive layer should be considered in interpreting the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval."

Having rejected Key's proposed claim construction, the court must determine whether to adopt Hercon's proposed claim construction. At trial, Key offered the opinions of their expert, Dr. John K. Beasley, to counter Hercon's proposed construction. Dr. Beasley received a Ph.D. in physical chemistry from Massachusetts Institute of Technology in 1951. He worked for 35 years for E.I. DuPont de Nemours as a research chemist. His work there focused on research and development of various polymers. Since 1986, Dr. Beasley has worked as a technical consultant and expert witness on several patent matters.

Dr. Beasley opined that one of ordinary skill in the art at the time of the claimed invention would have interpreted the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" to require the numerical values that the court has concluded should not be read into claim 14. See Tr. at 1454-1507. Because Dr. Beasley did not otherwise undermine the testimony of Dr. Guy, the court concludes that the phrase "sufficient [nitroglycerin] to deliver to the skin a pharmaceutically effective amount of [nitroglycerin] over a 24-hour time interval" means an amount sufficient to provide a patient with 2.5 to 15 mg of nitroglycerin per day --that is, 2.5 to 15 mg of nitroglycerin, plus an excess amount to ensure that the desired amount is delivered.
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sufficient quantity

The parties and the Court agree that the term should be construed as "a required dosage."
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III. "sufficient temperature to soften," "softened wear layer," and "a softened state"

The phrase "sufficient temperature to soften" is used in claim 1 of the '903 patent to describe the temperature at which the

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wear layer is reheated to prior to being mechanically embossed. '903 12:4-6. Claim 1 of the '903 patent employs the phrase "softened wear layer" and claims 1 and 9 of the '008 patent employ the phrase "a softened state" to describe the state in which the wear layer is in when it is mechanically embossed. This claim language is in dispute and discussed here because it is related.

Mannington argues that the claim language "a sufficient temperature to soften" "means an exposure to a heating source capable of causing the cured wear layer to achieve a sufficient degree of softening to allow it to be mechanically embossed." D.I. 326 at 24-25. Again, Armstrong makes no argument with respect to this phrase since it is found only in the '903 patent. Domco, on the other hand, argues that the phrase "mean[s] that the material of the wear layer is moldable [as a result of heating], i.e.. the material would be displaced to take on the pattern and shape of the texture to be imprinted, during a mechanical embossing step." D.I. 142 at 18.

Mannington argues that both "softened wear layer" and "a softened state" should be construed to "mean that the wear layer is in a cured and softened condition … before the wear layer is mechanically embossed." D.I. 326 at 25 (emphasis in original). In support, Mannington makes a contextual argument to assert that "those skilled in the art would understand the claims to require the cured wear layer to be in a 'softened state' prior to, rather than during, mechanical embossing." Id. at 26 (emphasis in original). Armstrong argues that the process limitation "a softened state" should not be construed and, in the alternative, asserts that "softened state" means the wear layer is at a temperature range from 240 [degrees] F to 470 [degrees] F. D.I. 324 at 25. Domco argues that "softened wear layer" and "softened state" mean that "the material of the wear layer is moldable, i.e., the material would be displaced to take on the pattern and shape of the texture to be imprinted, during a mechanical embossing step." 1 D.I. 142 at 18.

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1 In its Markman brief, Domco groups the phrase "a sufficient temperature to soften" in claim 1 of the '903 patent and the phrase "a softened state" in claims 1 and 9 of the '008 patent into the same passage and makes the same argument as to each expression.

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Clearly, the parties' arguments as to the proper construction of the phrase "a sufficient temperature to soften" are similar. This court, therefore, construes the phrase consistent with these arguments to mean that the vinyl surface covering is softened by heating such that it is receptive of embossment by mechanical means. The more poignant question, however, is temporal and relates to the proper construction of the phrases "softened wear layer" and "a softened state." In other words, do these phrases as found in the contested claims mean that the surface covering reaches a softened state as a result of heating prior to reaching the mechanical embossing tool, or are these phrases put forth in the claims such that heating to a softened state can occur nearly simultaneously with mechanical embossing? To answer this question, one must look to the context in which the phrases are used in the claims and then to the remainder of the intrinsic evidence to determine whether the inventors limited the construction of these phrases in any manner.
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1. "copper ions in an amount sufficient to degrade"

Genentech contends that the phrase "copper ions in an amount sufficient to degrade" requires a specific numerical amount of copper ions. Genentech argues that Glaxo added this language to overcome the examiner's rejections for obviousness in light of Genentech's own patent, the '060 patent. Genentech cites the Interview Summary Record of November 9, 1995 in which the examiner wrote, "we agreed that an amendment regarding the level of copper and stabilizer in the solution would probably overcome the § 103 objections." During oral argument, counsel for Genentech argued that the claims require a specific level of copper ions based on the prosecution history.

Glaxo counters that the phrase "copper ions in an amount sufficient to degrade" should be construed according to its plain meaning. According to Glaxo, the specification and the prosecution history contain numerous references to the "trace" or "minute" amounts of copper ions that have a destabilizing effect on immunoglobulins. Therefore, Glaxo argues that the

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court should construe "copper ions in an amount sufficient to degrade" to mean enough copper to degrade whether or not the copper is detectable.

The specification of the '403 and '838 patents does not define "copper ions in an amount sufficient to degrade" as a numerical amount or a level of copper ions. Rather, the specification states that "it may be that the presence of copper ions in amounts below the detection limits of techniques such as atomic absorption spectroscopy still has a destabilizing effect on the immunoglobulin which can be eliminated by the addition of a suitable chelating agent." Glaxo correctly notes that the specification and the prosecution history contain a number of references to "trace" or "minute" amounts of copper ions.

The phrase at issue was apparently added to the claims after the applicants and the examiner agreed during an interview that an "amendment regarding the level of copper" would probably overcome the obviousness rejection. In the amendment that followed, the applicants stated that the phrase, copper ions in an amount sufficient to degrade, "makes explicit that which was implicit in the claim before, namely, that the composition of IgG1 immunoglobulin also contains copper ions." The applicants also stated that the claimed compositions comprise sufficient amounts of copper ion chelator to bind to the "trace amounts of copper" and thus prevent degradation.

After reviewing the specification and the prosecution history, the court finds that the phrase, "copper ions in an amount sufficient to degrade," should be construed according to its plain meaning. See Vitronics, 90 F.3d at 1582 (holding that words in the claims are generally given their ordinary and customary meaning unless a patentee clearly sets forth a different definition in the specification or file history). The inventors did not set forth an alternative definition of the phrase in the specification or in the prosecution history. Moreover, both the specification and the prosecution history provide support for Glaxo's argument that even small amounts of copper ions are sufficient to degrade. Therefore, the court finds that the phrase "copper ions in an amount sufficient to degrade" requires enough copper ions to degrade.
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b. "copper ions in an amount sufficient to degrade"

In Glaxo, this court construed the phrase "copper ions in an amount sufficient to degrade" to require enough copper ions to degrade. See 107 F. Supp. 2d at 487. In construing the phrase according to its plain meaning, the court rejected Genentech's argument that the phrase requires a specific numerical amount of copper ions to be present in the starting composition. See id.

Genentech now argues that the court's interpretation requiring enough copper ions to degrade imposes an affirmative limitation on Claims 1 of the '403-S and '838 patents. Genentech specifically argues that the cooper ions must actually degrade the accused composition when the copper ions present in the composition are not bound by the chelator. That is, the copper ions must have a demonstrable effect. Glaxo counters that the phrase requires enough copper ions to degrade by cleaving the IgG 1 immunoglobulin into fragments.

After reviewing the specification and file histories of the patents, the court sees no reason to modify the plain meaning construction of the phrase it set forth in Glaxo. As a result and for the reasons stated in Glaxo, the phrase "copper ions in an amount sufficient to degrade" requires enough copper ions to degrade IgG 1 immunoglobulin.
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IV. "sufficient to permit detection of hybridized labeled nucleic acid containing unique segments"

The phrase "sufficient to permit detection of hybridized labeled nucleic acid containing unique segments" appears in claim 1 of the '841 patent:

(b) employing said labeled nucleic acid, blocking nucleic acid, and chromosomal DNA in in situ hybridization so that labeled repetitive segments are substantially blocked from binding to the chromosomal DNA, while hybridization of unique

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segments within the labeled nucleic acid to the chromosomal DNA is allowed, wherein blocking of the labeled repetitive segments is sufficient to permit detection of hybridized labeled nucleic acid containing unique segments, and wherein the chromosomal DNA is present in a morphologically identifiable chromosome or cell nucleus during the in situ hybridization.

'841 patent at 17:13-25 (emphasis added).

Abbott argues that the phrase should be construed to mean "makes it possible to ascertain in a single chromosome or in a single cell nucleus the presence of labeled nucleic acid that includes unique segments hybridized to target unique sequences in the chromosomal DNA." Dako argues that the phrase should be construed to mean "sufficient to permit detection of the labeled nucleic acid containing unique segments hybridized to target chromosomal DNA in a morphologically identifiable chromosome or cell nucleus." The parties' constructions differ in only one respect: whether the hybridization and detection must take place in a morphologically identifiable chromosome or cell nucleus.

Abbott argues that Dako's inclusion of the "morphologically identifiable chromosome or cell nucleus" limitation is redundant in light of the following phrase, which requires that the hybridization take place in a morphologically identifiable chromosome or cell nucleus. Id. at 17:22-25. The court agrees that Dako's proposed language is redundant; the claim already expressly requires that the hybridization take place in a morphologically identifiable chromosome or cell nucleus, and further that the hybridization take place to an extent "sufficient to permit detection of hybridized labeled nucleic acid containing unique segments," in the same morphologically identifiable cell nucleus.

Abbott's construction is also redundant in that it repeats that hybridization and detection must take place "in a single chromosome or in a single cell nucleus." The parties have agreed that the phrase "a morphologically identifiable . . . cell nucleus" is singular.

The court therefore construes "sufficient to permit detection of hybridized labeled nucleic acid containing unique segments" to mean "sufficient to permit detection of the labeled nucleic acid containing unique segments hybridized to target chromosomal DNA."
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4. "pressure . . . sufficient to substantially immediately convert at least a portion of the binder material"

KXI and PUR disagree over how much pressure is "sufficient to substantially immediately convert at least a portion of the binder material." Based on the court's claim construction in Culligan, KXI contends that the claims require pressure greater than 40 psi. PUR counters that the pressure must be greater than 400 psi.

In the specification of the '311 patent, Koslow distinguishes his invention from Degen. Koslow explains that his invention applies pressures in excess of 400 psi while Degen applies "exceedingly low" pressures, "most preferred maximum 40 psi." The pertinent section of the specification of the '311 patent reads as follows:

> The levels of compression disclosed by Degen et al. are exceedingly low, 0.3-10 psi . . . most preferred maximum 40 psi . . . . Accordingly, it describes process conditions well outside the range of compression utilized in the present invention, which would be 400-1000 psi . . . for granular materials . . . and approximately 8,000 psi . . . or more for powders . . . . Without such higher pressures, the binder resins are not activated and the novel structures produced by the current invention are not obtained.

On its face, the language of the specification supports both KXI's position that Koslow disclaimed pressures below 40 psi and PUR's position that Koslow disclaimed pressures below 400 psi.

The specification of Degen states that "pressures in the range of up to the crush strength of the carbon, which is about 400 psi, are suitable although, from a practical perspective, pressures up to about 40 psi are preferred . . . ." Thus, while Degen teaches that pressures below 40 psi are preferred, Degen discloses that the claimed invention may work with pressures up to 400 psi.

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In Culligan, this court stated that "Koslow disclaimed using pressures below 40 psi in the claimed invention." The opinion published in the Federal Supplement, 2d series, however, states that "Koslow disclaimed pressures below 400 psi." Culligan, 46 F. Supp. 2d 308, 338 (D. Del. 1999). KXI argues that the "400 psi" in the published opinion is a typographical error which West Publishing corrected in a subsequent revised opinion. See Culligan, 90 F. Supp. 2d 461, 491 (D. Del. 1999). PUR counters that the "400 psi" appearing in the original published opinion is correct.

After reviewing Degen and the specification of the '311 patent, the court finds that its earlier opinion in Culligan about the scope of Koslow's disclaimer was wrong. Degen covers pressures up to 400 psi. Koslow distinguished his invention from Degen on the basis that his invention applies pressures greater than 400 psi. Therefore, the court agrees with PUR that Koslow disclaimed using pressures below 400 psi in the claimed invention. See Southwall, 54 F.3d at 1576.
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5. "shear . . . sufficient to substantially immediately convert at least a portion of the binder material"

KXI contends that the phrase "shear . . . sufficient to substantially immediately convert at least a portion of the binder material" requires some movement of particles relative to each other after the mixture has been heated to a temperature substantially greater then the softening temperature of the binder. PUR counters that the phrase refers to shear that exceeds the level of shear that is inevitable in any compression molding process, such as the process disclosed in Degen.

After reviewing the specification, the court finds that the phrase, "shear . . . sufficient to substantially immediately convert at least a portion of the binder material" should be construed according to its plain meaning. See Vitronics, 90 F.3d at 1582 (holding that words in the claims are generally given their ordinary and customary meaning unless a patentee clearly sets forth a different definition in the specification or file history). Koslow did not clearly set forth an alternative definition in the specification or file history. Therefore, the court will adopt the existing language of the claim.
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5. "Sufficient water" (claims 1, 2, 3, and 8) -- means enough water to form a solution of the active ingredient and the nitrate salt. See Joint Markman Hearing Statement, at 30.

The 827 patent specification and the prior art are clear. See 827 patent, at 1:38-43 ("When the 3-isothiazolone is one in which Y [in the formula described at 1:25-30] is lower alkyl, and at least one of R and R' is halogen . . . , the compounds are useful industrial biocides having almost unlimited solubility in water") (citing U.S. Patent No. 4,105,431 (entitled "3-isothialzolones as biocides") (431 patent)); 431 patent, at 20:51- 54 ("Compounds of this invention can be dissolved in a water- miscible liquid, such as ethanol, isopropanol, acetone, and the like. Such solutions are easily extended with water.").

Defendants' sole objection is that the claim term is "ambiguous" given "the other ambiguities in the claim limitations." Joint Markman Hearing Statement, at 31. 8 As an invalidity argument, it is premature. See 35 U.S.C. § 112-P 2 (1994); Intervet Am., 887 F.2d at 1053.

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8 Defendants advanced no alternative construction of this claim term either in the Joint Markman Hearing Statement or at the Markman hearing.

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The first clause requires that "said matrix material has a sufficiently high viscosity and low solubility in saliva that the

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matrix material provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours, thereby providing bleaching of the tooth surfaces." The patent's specification provides guidance in interpreting this clause. The description of the prior art observes that a disadvantage of prior art dental bleaching products and techniques is "that the bleaching agent must be frequently replaced during the day" and that "saliva dilution and swallowing of the bleaching agent cause[s] the volume of agent the tray to diminish rapidly over time, thereby decreasing the amount of active ingredient available for tooth bleaching." The discussion of the prior art further notes that clinical test results for at least one unidentified prior art composition "show that after one hour, less than one-half the original volume of bleaching agent was present" and therefore that prior art "bleaching agents should be replenished about every hour to be effective."

Additionally, among the stated objects of the invention are "to provide sustained release dental compositions for treating tooth surfaces which do not need to be continuously replaced" and "to provide sustained release dental compositions for treating tooth surfaces which provide a more constant level of dental agent in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth."

The prosecution history provides little clarification of the meaning of the clause, but it does reveal that the applicant added the two hour time specification in order to better define the claim and overcome a rejection under 35 U.S.C. § 112 para. 2. This further indicates that the claim is drawn to a long-lasting composition that provides constant levels of bleaching.

The specification also states that compositions within the scope of the patent have such high viscosity that positive pressure is needed to dispense them from their containers, such as a syringe or a squeeze tube. In contrast, the specification observes that existing low viscosity bleaching agents can be dispensed drop-wise from a bottle.

While somewhat illustrative of the initial viscosity of formulations which may fall within the scope of the patent, this specification cannot be read into the claims. The viscosity of the composition as it is dispensed into a dental tray is of only limited importance to the objects of the invention. The claimed inventions are improved methods and compositions that remain viscous for long periods of time and dilute more slowly in saliva. Thus, a very viscous composition that is dispensed with a syringe but which quickly loses its viscosity and dilutes rapidly in saliva might not be within the scope of the invention, while an initially less viscous material that is resistant to dilution or perhaps even reacts with saliva to become more viscous over time might be within the scope of claim 1. In fact, Proxigel(R), a commercial embodiment of U.S. Patent No. 3,657,413 to Rosenthal ("the Rosenthal patent" or "Rosenthal"), a prior art composition containing carboxypolymethylene, is dispensed from a squeeze tube, not drop-wise from a bottle. The viscosity of the claimed composition in and of itself is irrelevant; it is only important to the extent it facilitates long-lasting sustained release bleaching of a patient's teeth. This is evident from claim 1's requirement that the matrix material have a "sufficiently high viscosity . . . that [it] provides for the dental bleaching agent to be in contact with the tooth surfaces over a period of time greater than about 2 hours." (emphasis added). Thus, this court declines to limit claim 1 based on how a composition may be dispensed into the dental tray. Instead, the language of claim 1 must be interpreted in light of the specification language that states that "the present invention . . . provides sustained release dental compositions for treating tooth surfaces which permit a more constant level of the dental agent to be in contact with the teeth surfaces rather than periodic high and low levels of the dental agent in contact with the patient's teeth."

In light of the claim language, the specification, and the prosecution history, this court interprets the first clause of paragraph (b) of claim 1 to mean that at the end of 2 hours there must be a significant amount of dental bleaching agent remaining in the dental tray and that as a result of the remaining bleaching agent's proximity to a patient's teeth, clinically significant bleaching is taking place. This means that a significant amount of the matrix material must remain in the tray at the end of two hours and that the bleaching agent dispersed in the matrix material must remain active so as to provide more than an insubstantial level of bleaching.

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(2) Discussion

Claim 24 of the '234 patent depends from claim 21, which recites in relevant part: "conducting a subsequent thermal annealing of the semiconductor material substrate at sufficiently low temperature to substantially limit diffusion of gas from

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the semiconductor material substrate." No mention of a specific time, temperature, or gas is made in the claim.

The court's task in determining whether the foregoing functional limitation is sufficiently definite "is a difficult one that is highly dependent on context." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008). The context here is, as Examiner Fourson noted, a highly unpredictable chemical art. (JA-1845) The Aspar patents themselves claim as their inventive features small process modifications (such as an intermediate heating) that result in tremendous differences. The court concludes that the applicants did not use "reasonably precise" terms to describe the invention of claim 24 in light of the subject matter. See Exxon Research and Engineering Co. v. U.S., 265 F.3d 1371, 1379 (Fed. Cir. 2001) (citing Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed. Cir. 1986)).

The parties provide little extrinsic evidence to assist in the court's construction. See id. at 1376. Soitec relies on test results obtained from its litigation expert who completed a post-anneal analysis of the amount of hydrogen present in MEMC's wafers. (D.I. 247 at 15-16) Even assuming that these post-anneal tests (1) are accurate and (2) did not destroy the substrate (as MEMC suggests), this technique does not appear in the Aspar patents, and cannot be used to satisfy § 112. Soitec has not pointed to, and the court has not discerned, any portion of the Aspar patents' specification describing measuring the amount of hydrogen diffusing prior to, or during, the thermal annealing.

Soitec does not explain what a "sufficiently low temperature" is for purposes of the claims. Focusing on the "substantially limit the diffusion of gas" term, Soitec states that "substantially" is defined by the maximum temperature noted for all of the "various phases of the method," or 900 C. (See '009 patent, col. 5:46) Soitec also states that one skilled in the art would understand, based on the specification, that diffusion must be limited such that the amount of implant material retained in the wafer would be sufficient to permit "embrittlement" to take place during the thermal treatment. (D.I. 247 at 17) Soitec does not point to any extrinsic evidence in this regard. MEMC points to deposition testimony by Bruel, stating that he did not know the difference between the temperature at which helium and hydrogen would diffuse within the silicon lattice. (MA-0875-76 at 208-09) ("I even don't know if all the mechanism[s] are well known. Because diffusion is also something which is not as simple we should like it is [sic].")

As an initial matter, the "900 C" maximum temperature of the process of the invention says nothing about the "sufficiently low temperature" limitation at issue — no lower boundary is provided. The specification provides only that the wafer embrittles, but separation does not occur, at the appropriate temperature and diffusion rate. ('234 patent, col. 3:35-38) Notwithstanding that the claim is not specific as to what "gas" diffuses from the wafer, there is no disclosure how diffusion of free gas from the wafer is to be measured, before or after the annealing. As Bruel's testimony indicates, diffusion is not a phenonemon that occurs uniformly with respect to all gases. There is no indication of how much diffusion is too much. The specification provides that diffusion should be limited so that bridge fracture does not occur, but essentially "teaches those skilled in the art [ ] to experiment and find out for themselves" the proper balance of temperature and diffusion for the exuded gas. See Exxon Research and Enginnering Co., 265 F.3d at 1379 (quoting In re Jolly, 172 F.2d 566, 569, 36 C.C.P.A. 825, 1949 Dec. Comm'r Pat. 111 (C.C.P.A. 1949)). The court has no compelling extrinsic evidence before it indicating otherwise. For these reasons, the court finds that claim 24 of the '234 patent is not amenable to construction and is, therefore, indefinite as a matter of law. 20 MEMC's motion is granted in this regard. (D.I. 187)

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20 Compare Exxon Research and Engineering Co., 265 F.3d at 1377 (term "to increase substantially" not invalid where the specification defined "substantially increased" catalyst activity as an increase of at least 30%, more preferably about 50%, and still more preferably an increase of about 75%); see also id. at 1378 (term "for a period sufficient" not indefinite where the specification stated that the period must be sufficient to increase catalyst productivity preferably at least about 30% and that this is "usually accomplished in about 0.25-24 hours, preferably about 0.5 to 2 hours").

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The second clause of paragraph (b) requires that "said matrix material is sufficiently tacky to retain and hold the dental tray positioned over the patient's teeth for a period greater than about 2 hours without any significant mechanical pressure from

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the dental tray." The specification indicates that a sticky composition is desirable because it keeps the active bleaching agent in close contact with the tooth surfaces, it helps to keeps the tray from slipping off the teeth and diluting the composition, and it permits the use of tray designs that exert less pressure on the teeth and are therefore more comfortable to wear, specifically tray designs with reservoirs. The prosecution history sheds little light on the meaning of the language of this clause.

Ultradent urges the court to interpret this language as requiring that the dental tray be constructed of soft material, trimmed shy of the gumline, or have reservoirs. These limitations are described as preferred embodiments in the specification. However, the plain language of claim 1 simply discusses the use of a dental tray, without requiring any particular features other than it must fit the teeth and hold dental bleaching composition. By way of contrast, claim 5 specifically requires the dental tray be constructed with reservoirs. It is conceivable that dental trays may be made such that they do not exert significant mechanical pressure on the teeth, even though they are not made of soft material, trimmed shy of the gumline, or made with reservoirs. While the tray design features Ultradent urges the court to read as limitations on claim 1 may reduce mechanical pressure on a patient's teeth, those features are not the only means for doing so and are not essential to practicing claim 1, and thus will not be read into the claim.

Therefore, this court interprets the language of the second clause of paragraph (b) of claim 1 to mean that the matrix material must be sufficiently tacky or sticky as to contribute to the retention of a dental tray over a patient's teeth at the end of two hours, and that whatever dental tray is used not exert "orthodontic" forces on a patient's teeth such that it would cause discomfort. The dental tray may exert some small amount of mechanical pressure on the teeth; in fact, Ultradent's own dental trays typically do not fall off patients' teeth even in the absence of any bleaching material. The tray may not, however, be of such a snug fit that the addition of the bleaching composition does little to improve the adhesion to the teeth.
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7. Sugars

While not construed in Cargill, of necessity the parties both seek construction of the term sugars, a critical term predominating in the '622 patent. Like the word "carbohydrates", "sugars" is a commonly understood term among organic chemists. In this instance, however, the inventor has once again chosen, by employing specific language within the patent's specification, to define sugars more narrowly for purposes of the patent, to "include mono- to decasaccharides which have molecular weights from 180 to 1638." See '622 Patent, col. 9, lns. 63-67. As defendants acknowledge, a patentee is entitled to act as his or own lexicographer and give special definition to a particular claim term, in which instance that definition controls even if it "differs from the meaning [the claim term] would otherwise possess." Phillips, 415 F.3d at 1316.

I have reviewed carefully the '622 patent, and in particular the specification, in an effort to discern the intent of the inventors and the interpretation of the term "sugars" to a person of ordinary skill in the art. Generally speaking, sugars are defined to mean monosaccharides and oligosaccharides. The '622 patent, however, limits the qualifying monosaccharides to hexoses, or sugars each containing six carbon atoms with a resulting molecular weight of 180. The upper limits placed by the '622 patent corresponds to a polymerization of ten, which equates to a decasaccharide. Based upon the '622 patent, and consistent with the approach taken with respect to the related '793 patent, I construe the term "sugars" to mean "hexoses and higher saccharides based on hexoses up to decasaccharides, which are obtained from a refined and consistent source."
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6. "A Suitable Amount of"

The next term to construe is found in subsection (a) of claim 16, "a suitable amount of." Pejic Decl. 3d Ex. 1, col. 6:57-58. Schwarz Pharma construes this term similarly to its construction of this term in claim 1, and pursuant to the alleged context of the claim: "an amount sufficient, alone or in combination with any other excipient in the formulation, to render the product FDA approvable with respect to cyclization." Paddock's construction is "an amount of an alkali or alkaline earth metal carbonate sufficient (i.e. effective) to inhibit cyclization in a dosage form." Paddock argues that this construction is

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consistent with the related litigation, n11 and the examples in the specification which show that an amount of carbonate "significantly greater" than the amount of ACE inhibitor is needed.

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n11 In the related litigation, the parties stipulated that "a suitable amount" means "an amount sufficient to inhibit cyclization." Warner-Lambert I, No. 99-922, at 4. Teva did not appeal the district court's grant of summary judgment of infringement with respect to claim 16. Warner-Lambert III, 418 F.3d at 1339 n.12.

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As stated above, the same term repeated throughout the same claim and different claims in the same patent should be construed to have the same meaning. Consequently, the term "a suitable amount" means "an amount sufficient (i.e. effective) of an alkali or alkaline earth metal carbonate to inhibit cyclization to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval."
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The first contested term is found in subsection (a) of claim 1, "a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration." Pejic Decl. 3d Ex. 1, col. 5:58-60. Schwarz Pharma argues that the Court is not required to construe this term because Paddock has already admitted in its Claim Chart that the drug component element of claim 1 is present in its proposed moexipril hydrochloride product. See Malone Decl. [Docket No. 58] Ex. 3.

Paddock argues that this term is in dispute and was previously construed in related litigation in New Jersey. See Stipulation and Order, Warner-Lambert Co. v. Teva Pharm. USA, Inc. ("Warner-Lambert I"), No. 99-922, at 1-2 (D.N.J. May 8, 2002). Paddock further avers that the Federal Circuit has approved the construction given by United States District Judge Dickinson R. Debevoise in the New Jersey case. Warner-Lambert Co. v. Teva Pharms. USA., Inc., 418 F.3d 1326, 1340 n.13 (Fed. Cir. 2005). Consequently, Paddock argues the term should be construed to mean "an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor in a drug product is sufficient (i.e., effective) to treat hypertension or congestive heart failure." The only alteration Paddock has made to the claim construction in the prior related litigation is to add "(i.e., effective)" after the word "sufficient," to clarify what is meant by a suitable amount of an ACE inhibitor.

Despite Paddock having admitted that the drug component element of claim 1 is present in its proposed moexipril hydrochloride product, the Court must still construe this term because its meaning is in dispute, as is evident by the parties inability to agree on its meaning in their joint claim construction statement. See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) ("Only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."). Paddock admitted to the presence of claim 1(a) in its product based on its own interpretation of the meaning of claim 1(a), which is not necessarily the same meaning that Schwarz Pharma would attribute to claim 1(a).

Throughout its claim construction brief, Paddock argues that Schwarz Pharma is bound by Warner-Lambert's stipulation to the meaning of terms in the '450 patent in prior related litigation, as well as the construction of claim terms in the '450 patent by the New Jersey District Court in prior related litigation that was allegedly cited with approval by the Federal Circuit. However, Paddock overstates the binding nature of these prior constructions. Schwarz Pharma was not a party to the prior stipulation entered into by Warner-Lambert and Teva Pharmaceuticals USA, Inc. ("Teva") regarding the meaning of certain claim terms in the '450 patent. See Warner-Lambert III, 418 F.3d at 1334. In addition, the stipulation specifically states that the construction of the claim terms is "to be applied in this litigation." See Warner-Lambert I, No. 99-922, at 1 (emphasis added). As a non-party to a stipulation whose effect was limited to the confines of different litigation, Schwarz Pharma is not bound by the stipulation. See Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1376 (Fed. Cir. 2005).

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Next, Schwarz Pharma is also not bound by the claim construction of the New Jersey District Court in the previous related litigation. See Order, Warner-Lambert Co. v. Teva Pharm. USA, Inc. ("Warner-Lambert II"), No. 99-922 (D.N.J. June 13, 2002). Schwarz Pharma tried to intervene in the Markman hearing, but its intervention was denied by the district court. See Schwarz Pharma, Inc. v. Teva Pharms., USA, Inc., 2003 U.S. Dist. LEXIS 24653, No. 01-4995, at 8 (D.N.J. Mar. 24, 2003). As a non-party to the Markman hearing in New Jersey, Schwarz Pharma can not be bound by that court's construction.

Finally, while this Court is bound by the Federal Circuit's prior construction of terms in the '450 patent, the Federal Circuit has not yet construed all the claim terms that are at issue in this litigation. In Warner-Lambert III, the Federal Circuit stated in its thirteenth footnote that "we think the district court correctly construed the claims." 418 F.3d at 1340 n.13. The Federal Circuit's blanket statement regarding the district court's claim construction does not necessarily mean that the Federal Circuit closely examined and agreed with every aspect of the district court's constructions. While the Federal Circuit's generic endorsement of the district court's constructions is an important consideration for this Court, the passing reference in a footnote does not set in stone for all time the construction of claim terms of the '450 patent whose meaning were not challenged or addressed on appeal. n6

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n6 This Court, and the parties, are of course bound by the Federal Court's definitive construction in prior litigation of certain claim terms in the '450 patent: "discoloration" means oxidative discoloration, Warner-Lambert III, 418 F.3d at 1340; "alkali or alkaline earth metal carbonate" includes both carbonate and bicarbonate ions, Schwarz Pharma, Inc. v. Warner-Lambert Co. ("Schwarz Pharma II"), 95 Fed. Appx. 994, 997-99 (Fed. Cir. 2004); and "saccharides" includes polysaccharides, Pfizer, 429 F.3d at 1376. See Phonometrics, Inc. v. Choice Hotels Int'l, Inc., 21 Fed. Appx. 910, 912 (Fed. Cir. 2001) ("We have already addressed and answered the precise question presented in this appeal. . . . Under principles of stare decisis, moreover, future panels like the present panel will follow the claim construction set forth by our court in [our previous decisions construing the terms of this particular patent] and, therefore, we would not welcome further appeals seeking to re-litigate the meaning of that phrase.").

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In the aforementioned stipulation, Warner-Lambert and Teva agreed that "a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration" means "an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor is sufficient to treat hypertension or congestive heart failure." Warner-Lambert I, No. 99-922, at 1-2. Paddock proposes that the Court adopt this construction in its entirety save for the addition of "(i.e. effective)" after the word "sufficient." The construction of this term is drawn from the Background section of the specification, which states:

Certain ACE . . . inhibitors, which are useful as antihypertensives, are susceptible to certain types of degradation. Specifically, quinapril and structurally-related drugs can degrade via (1) cyclization via internal nucleophilic attack to form substituted diketopiperazines, (2) hydrolysis of the side-chain ester group, and (3) oxidation to form products having often unwanted coloration.

Pejic Decl. 3d Ex. 1, col. 1:5-12. The construction proposed by Paddock gives the claim term its intended meaning, as is confirmed by the specification of the patent, without improperly narrowing or limiting the meaning of the claim term. Therefore, Paddock's proposed construction is adopted in its entirety. n7

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n7 Whether the addition of "(i.e. effective)" to the construction of this claim term is appropriate will be discussed later.

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3. "A Suitable Amount . . . to Inhibit Cyclization and Discoloration"

The next term to construe is from subsection (b) of claim 1, "a suitable amount . . . to inhibit cyclization and discoloration." Pejic Decl. 3d Ex. 1, col. 5:61-63. Schwarz Pharma argues that this term means "an amount sufficient, alone or in combination with any other excipient in the formulation, to render the product FDA approvable with respect to cyclization and discoloration." Schwarz Pharma states that an excipient is "any ingredient in a pharmaceutical formulation other than the active pharmaceutical ingredient." Schwarz Pharma argues that its proposed claim construction follows the plain language of the claim and is supported by the specification. Nothing in the plain language requires the identified excipient to be solely responsible for inhibiting the identified degradation (hence, the addition of the words "or in combination with any other excipient").

Paddock construes "suitable amount" to mean "a sufficient (i.e., effective) amount to inhibit cyclization and oxidative discoloration for a given drug product; not a trace amount," and "to inhibit cyclization and discoloration" to mean "reducing cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Paddock argues that the term "a suitable amount," which appears several times throughout claims 1 and 16, should be given consistent meaning every time it appears, and the specification supports defining "suitable" to mean "effective" and "not a trace amount." Paddock supports its argument by referencing the examples in the specification, which generally show that an effective amount of alkali/alkaline earth metal carbonate is "significantly greater by weight" than the amount of ACE inhibitor. Paddock further argues that its proposed construction of "to inhibit cyclization and discoloration" is consistent with the construction determined in the related litigation. n8

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n8 In the related litigation, the parties stipulated that "a suitable amount" means "an amount sufficient to inhibit cyclization and discoloration," Warner-Lambert I, No. 99-922, at 2, and the New Jersey District Court found that "to inhibit cyclization and discoloration" means "reducing cyclization and discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Warner-Lambert II, No. 99-922, at 1. The Federal Circuit indicated its asset to this claim construction by stating "we think the district court correctly construed the claims." Warner-Lambert III, 418 F.3d at 1340 n.13.

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Schwarz Pharma's addition of the phrase "alone or in combination with any other excipient in the formulation" strays from the plain meaning of the claim terms and the teaching of the specification. While the meaning of the phrase in claim 1(b) "of an alkali or alkaline earth metal carbonate" is not in dispute in this litigation, it is significant that when claim 1(b) is read in its entirety, the language is "a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration." Pejic Decl. 3d. Ex. 1, col 5:61-63 (emphasis added). The plain language of the claim term specifies that the alkali or alkaline earth metal is to perform the stated function of inhibiting cyclization and discoloration. Also, the use of the open transition term "contains" in the preamble of the claim "does not free the claim from its own limitations." Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001).

Additionally, the specification describes the use of "excipients" as disintegrating agents, lubricants, and binders, but does not suggest that other excipients can be used to perform the function of inhibiting cyclization and discoloration. The section of the specification entitled Stabilizer(s) states:
The cyclization and hydrolytic instability which are exhibited by certain of the drugs discussed above can be overcome via the use of a suitable quantity, i.e., an effective amount of an alkaline stabilizer, together with saccharides.
The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred.
The anionic portion of the salt employee may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.
The quantity of the stabilizer component to be used will lie between about 1% and 90%, preferably about 10% to about 80%. In general, any amount which will effectively retard or prevent degradation of the ACE inhibitor component(s) can be

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used.

Pejic Decl. 3d Ex. 1, col. 3:25-45. The specification teaches that it is an effective amount of an alkaline stabilizer, together with saccharides, that performs the desired function of inhibiting cyclization and hydrolysis. While the exact alkaline stabilizer used in the drug product can vary with different formulations, it is the alkaline stabilizer that performs the stated function, not the alkaline stabilizer plus some other excipient.

Paddock correctly construes "suitable amount" to mean "effective" amount. The specification directly states that the suitable amount of alkaline stabilizer needed to inhibit degradation is an effective amount. Pejic. Decl. 3d Ex. 1, col. 3:27-28. Additionally, the plain language of the claim term indicates that a suitable amount of a stabilizer is an effective amount. Indeed, the entire patent is directed toward the invention of a stabilized composition of a drug product, and therefore the invention fails if the amount of stabilizer added to the drug product is not "effective" to perform its required function.

However, Paddock stretches too far from the plain language of the terms by attempting to import the phrase "not a trace amount" into the meaning of the claim terms. Paddock correctly identifies that in the two "effective" examples set forth in the specification, the amount of magnesium carbonate in the drug product greatly outweighs the amount of quinapril hydrochloride. Pejic Decl. 3d Ex. 1, col. 4:58-70; 5:1-13. From these examples, Paddock deduces that an amount of stabilizer can not be an "effective" amount if it is a "trace amount." However, the Federal Circuit has cautioned courts not to import limitations from the specification into the claim terms. Phillips, 415 F.3d at 1323-24. Because the stated examples show a greater amount of stabilizer by weight in comparison to ACE inhibitor does not necessarily mean that all drug products falling within the ambit of the '450 patent must contain such a ratio. Cf. Rexnord Corp., 274 F.3d at 1344 ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). In addition, the specification states that "the quantity of the stabilizer component to be used will lie between about 1% and 90%, preferably about 10% to about 80%. In general, any amount which will effectively retard or prevent degradation of the ACE inhibitor component(s) can be used." Pejic Decl. 3d Ex. 1, col. 3:40-45. Based on the teaching of the specification, the Court can not say with certainty that an "effective amount" of stabilizer is also "not a trace amount."

Therefore, based on the plain language of the claim terms and the teaching of the specification, "a suitable amount . . . to inhibit cyclization and discoloration" means "a sufficient (i.e. effective) amount of an alkali or alkaline earth metal carbonate to reduce cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval."

Paddock asserts that the term "a suitable amount," which appears multiple times throughout claims 1 and 16 of the '450 patent, must be construed identically each time it appears. The Court holds that "a suitable amount" means "a sufficient (i.e. effective) amount" each time it appears in the claims of the '450 patent. See Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1377 (Fed. Cir. 2004) ("The same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims."). This meaning is discerned from the plain language of the claim terms as well as the teaching of the specification. The invention of the patent is directed to stabilized compositions of certain drug products. The key ingredients in the drug products, namely the ACE inhibitors and stabilizers, are necessary because they perform the stated desirable functions. If the key ingredients were not effective at performing the stated desirable functions, then they would not be needed in the resulting drug product.

Further, it is immaterial that the word "effective" does not appear in the section of the specification entitled Drug Component(s). The phrase "a suitable amount" was not added to claim 1(a) of the '450 patent until after the patent was initially rejected by the patent examiner for obviousness. Pejic Decl. 3d Exs. 5-8. The patent was granted only after a responsive amendment by the patentee, and the phrase "a suitable amount" was added as an examiner's amendment to modify the phrase "of an ACE inhibitor." Id. Exs. 7-8. It follows logically that the patent examiner intended by his amendment to assert that "a suitable amount of an ACE inhibitor" is an "effective amount." See Phillips, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.").
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4. "A Suitable Amount . . . to Inhibit Hydrolysis"

The next term to construe is found in subsection (c) of claim 1 and reads "a suitable amount . . . to inhibit hydrolysis." Pejic Decl. 3d Ex. 1, col. 6:1-2. Schwarz Pharma construes this term as "an amount sufficient, alone or in combination with any other excipient in the formulation, to render the product FDA approvable with respect to hydrolysis." Schwarz Pharma asserts that this term has a similar meaning to the claim term previously discussed, and for the same reasons. By contrast, Paddock construes this term to mean "a sufficient (i.e., effective) amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Paddock asserts that it construes this term, as it did with the previous similar term, to follow the construction from related litigation. n9

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n9 Again, in the related litigation, the parties stipulated that "a suitable amount" means "an amount sufficient to inhibit hydrolysis," Warner-Lambert I, No. 99-922, at 2-3, and the New Jersey District Court found that "to inhibit hydrolysis" means "reducing hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Warner-Lambert II, No. 99-922, at 1-2. The Federal Circuit indicated its assent to this claim construction by stating "we think the district court correctly construed the claims." Warner-Lambert III, 418 F.3d at 1340 n.13.

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This claim term is identical to the previously construed claim term except that a different type of degradation is inhibited by a different type of substance, namely, a saccharide. Consequently, the Court construes this term consistently with the construction of the previous nearly identical term and for the same reasons. Paddock's construction of the term is adopted. "A suitable amount . . . to inhibit hydrolysis" means "a sufficient (i.e., effective) amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval."
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The first step in any invalidity . . . analysis is claim construction." See Rockwell Int'l Corp. v. United States, 147 F.3d 1358, 1362, 47 U.S.P.Q.2D (BNA) 1027, 1029 (Fed. Cir. 1998). Claim construction is a question of law, which this court reviews without deference. See Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1330, 52 U.S.P.Q.2D (BNA) 1590, 1597 (Fed. Cir. 1999). "In claim construction the words of the claims are construed independent of the accused product, in light of the specification, the prosecution history, and the prior art. . . . The construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims." Scripps Clinic v. Genentech, Inc., 927 F.2d 1565, 1580, 18 U.S.P.Q.2D (BNA) 1001, 1013 (Fed. Cir. 1991) (internal quotation marks omitted).

The claims of the '393 patent recite either "an unleaded gasoline suitable for combustion in an automotive engine" or "an unleaded gasoline fuel suitable for combustion in a spark ignition automotive engine." Thus, the '393 patent claims compositions of matter. The scope of these composition claims cannot, as the appellant refiners argue, embrace only certain uses of that composition. See In re Spada, 911 F.2d 705, 708, 15 U.S.P.Q.2D (BNA) 1655, 1657 (Fed. Cir. 1990). Otherwise these composition claims would mutate into method claims. The district court correctly applied this principle, refusing to narrow the scope of the claimed compositions to specific uses.

The district court read each claim in light of the specification, and concluded that the claims cover "fuels that will regularly be used in autos, not that conceivably could be." Union Oil Co. of Cal. v. Atlantic Richfield Co., No. CV-95-2379-KMW, slip op. at 7 (C. D. Cal. May 19, 1997) (Unocal III). The district court thus construed the claims to cover only a narrow class

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of fuel compositions, namely only standard automotive gasoline. The district court correctly excluded from claim scope a broader class of petroleum formulations such as aviation fuels or racing fuels. The claim language confirms the district court's reading of the claims to cover mass market automotive gasoline. The claim language specifies fuels for an "automotive engine," not an aviation engine. See, e.g., '393 patent, col. 18, l. 65. Moreover the explicit reference to "unleaded gasoline" again invokes standard automotive fuels, rather than specialized fuels. See, e.g., id. at col. 18, l. 64.

The district court's interpretation also finds extensive support in the specification. The patentees described the problem that their invention addressed:

One of the major environmental problems confronting the United States and other countries is atmospheric pollution (i.e., "smog") caused by the emission of gaseous pollutants in the exhaust gases from automobiles. This problem is especially acute in major metropolitan areas, such as Los Angeles, Calif., where the atmospheric conditions and the great number of automobiles account for aggravated air pollution.

Id. at col. 1, ll. 9-16. Similarly, the patentees describe their testing procedures and results in the specification. Specifically, the patentees used ordinary passenger automobiles in their tests. The '393 patent records the results of testing certain fuels in a 1989 Oldsmobile Calais, a 1988 Oldsmobile 98, a 1985 Ford Tempo, a 1990 Lincoln, a 1984 Chevrolet Caprice, a 1988 Honda Accord, a 1989 Ford Taurus, a 1990 Plymouth Shadow, a 1985 Chevrolet Suburban, and a 1990 Toyota Camry. See id. at fig. 9. None of these are aviation or racing vehicles.

Similarly, another passage provides context for the trial court's claim construction. The patentees describe their choice of test vehicles as follows:

A total of 22 different unleaded gasoline fuels was tested in a 1988 Oldsmobile Regency 98 automobile equipped with a 3800 cc V-6 engine. This automobile was selected because it represented a high sales volume product with close to the current state-of-the-art emission technology.

Id. at col. 7, ll. 61-6. The patentees tailored their research and their patent to ordinary fuels for use in standard passenger cars. Thus, the claim language, further informed by the specification, shows that the district court correctly read the claims to cover ordinary automotive fuel.

Because the '393 patent covers only standard automotive fuel, the district court correctly determined that specialty fuels within other limitations of the claims do not anticipate under 35 U.S.C. § 102. In other words, the aviation and racing fuels that allegedly invalidate the '393 claims do not anticipate because they do not contain each and every limitation of the claims. See Verdegaal, 814 F.2d at 631. Specifically, this alleged prior art does not include the limitation of being a standard automotive fuel composition.

Moreover, the record does not show that the aviation and racing fuels otherwise have the claimed characteristics of the particular standard automotive fuels recited in the '393 patent. While the record shows that some properties of the aviation and racing fuels coincide with the properties of the '393 patent's claims, the record does not show the presence of each and every limitation. An expert for the refiner appellants stated that the allegedly anticipatory Phillips B-35 racing fuel "is very different from typical [automotive fuel]." Tr. at 4782. When asked, "Is Unocal unleaded racing gasoline very different from typical motor gasoline?", the expert again answered "Yes." Id. at 5047. This expert similarly answered "yes" when questioned about whether the asserted aviation fuels were "very different" from typical motor gasoline. See id. at 5060.

The district court did not err in construing the claims of the '393 patent. Furthermore the record does not show each and every element of the asserted claims of the '393 patent present in any single prior art reference. Therefore, this court affirms the district court's denial of JMOL on anticipation.

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"Suitable for Oral Administration"

Claim 1, with the language now at issue underlined, reads in full:

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An aqueous pharmaceutical solution suitable for oral administration comprising as an active ingredient a steroid selected from the group consisting of prednisolone sodium phosphate, prednisone and methyl prenisolone, the steroid being present at a concentration of at least 0.3 mg/ml, the pH of the formulation being between 5 and 8 and the formulation containing a pharmaceutically acceptable preservative, a pharmaceutically acceptable chelating agent, and being substantially free of ethanol.

Because both parties agree that Patent 774 does not contain a special definition of "suitable for oral administration," the ordinary and customary meaning of that phrase controls.

Morton Grove argues that the ordinary meaning of the phrase is simply that "animals and/or humans can ingest the solution orally" (M. Mem. 5). According to Morton Grove, a solution would not be "suitable" for oral administration only "if it would lead to certain death or debilitating harm or, perhaps, contained ingredients humans are incapable of digesting and eliminating" (id.). n5 Fisons, on the other hand, contends that "suitable for oral administration" contemplates much more, including "patient acceptance, stability, toxicity and efficacy" (F. Mem. 12).

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n5 Although at first glance that characterization may seem somewhat stark, it really captures the essence of the term "suitable"--a view that is fortified when, as the ensuing discussion demonstrates, Morton Grove's suggested locution is contrasted with the insupportable contentions advanced by Fisons.

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That broad brush reading by Fisons clearly attempts to put more weight onto the phrase "suitable for oral administration" than it can possibly carry. What Fisons urges is a type of hindsight revaluation of what its patent counsel should perhaps have said if the intention were indeed to convey the multiple considerations it now seeks to advance. It cannot be gainsaid that "suitable for oral administration" is too cryptic and too inartful a phrase to prescribe to the relevant reading public--persons skilled in the art--or, indeed, to any objective reader the congeries of meanings now sought to be attributed to that phrase.

As Morton Grove points out, drugs are routinely administered orally despite their being unstable, horrid-tasting, highly toxic and without therapeutic activity (M. Mem. 2). For example, solutions made extemporaneously by pharmacists and used in a very short period of time need not be stable, yet they may be "suitable for oral administration" (M. Ex. F). Similarly, Morton Grove has pointed to various drugs that are administered orally yet are horrid tasting, such as dicloxacillin and potassium chloride (M. Ex. C 69; M. Ex. G 243-46). As admitted by Fisons' lead inventor on the 774 Patent, Dr. Emmet Clemente, n6 such a drug is "suitable for oral administration"--it just might not be a successful product (M. Ex. G 244-46).

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n6 This opinion gives credit where credit is due by initially attaching the appellation "Doctor" to the holder of a Ph.D. degree in any field. But this Court then follows its customary practice of limiting any later usage of the title "Dr. X" to anyone who is a medical doctor, using simply "X" to refer to the possessor of any different doctorate. After all, apart from Germanic ("Herr Doktor--") and similar usage, lawyers don't refer to any of our fellow possessors of J.D. degrees as "Doctor-."

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Fisons relies on the report of its claimed expert Dr. Joel Zatz ("Zatz") in arguing that toxicity is relevant to determining whether a solution is "suitable for oral administration" (F. Ex. F 5):
To be suitable for oral administration, pharmaceutical solutions must satisfy the requirements of oral preparations generally, as well as those related specifically to solutions. Ingredients must be non-toxic when ingested. This requirement excludes certain ingredients that may be commonly used for other delivery routes. For example, ophthalmic and other topical products may contain as a preservative benzalkonium chloride, a substance not generally used orally.

But as M. Mem. 12 points out, "virtually all drugs are 'toxic' to some degree, but nevertheless are 'suitable for oral

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administration.'"

While the concerns expressed in Zatz's report are obviously relevant to developing solutions for oral use, the phrase "suitable for oral administration" really does not raise those issues, let alone convey what toxins or toxicity levels are acceptable so that others are put on notice of what is and what is not within Patent 774's limited monopoly. Indeed, the very fact that Fisons found it necessary to resort to assertedly expert testimony--rather than relying solely on the phrase's admittedly unambiguous language n7--to explain what toxicity considerations it believes fall within the phrase demonstrates with devastating force that the phrase itself does not capture those considerations (see Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997), noting that purported "expert" testimony cannot be used to change claim terms' unambiguous meaning). This Court is constrained to add that Zatz's standing as a claimed expert was drastically undercut by his testimony in which, whenever he was pressed during cross examination to support his stated standards, he retreated to a "no opinion" position (see, e.g., Zatz Dep. 42-43, 86-88). It surely does not require a full-fledged Daubert analysis to find Zatz's asserted "expert" underpinning totally wanting.

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n7 Fisons points to language in Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298 (Fed. Cir. 1999) to suggest that it is relying on Zatz's testimony not to give the phrase a meaning other than its ordinary and customary meaning, but rather to demonstrate the ordinary and customary meaning in the pharmaceutical field. In that regard Pitney Bowes, id. at 1309 states:

Thus, under Vitronics, it is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field.

But this Court finds that Zatz's opinion does not reflect "clearly expressed, plainly apposite, and widely held understandings" in the pharmaceutical field. As the discussion above demonstrates, Zatz's construction of the disputed phrase rather operates to create ambiguity where it would not otherwise exist.

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Fisons' claim that "suitable for oral administration" contemplates a certain level of efficacy fails for the same reason. Once more Fisons is forced to rely on Zatz's expert report (F. Ex. F 5):
Another requirement for a pharmaceutical solution suitable for oral administration is that it be therapeutically active and efficacious. For example, a drug may be efficacious when injected intravenously but, because of breakdown in the gut by enzymes, lose its activity when administered orally. In addition, certain drugs are absorbed poorly or not at all from the gut.

Again M. Mem. 14 identifies the flaw in such reliance: It points out accurately that "drugs are routinely administered orally despite a lack of any efficacy." More importantly, "suitable" does not at all convey what level of efficacy is necessary.

Alternatively Fisons argues that Patent 774's written description demonstrates that "suitable for oral administration" implies palatability, stability, toxicity and efficacy. That is simply not the case. While the patentees clearly contemplated that their solution would have greater stability than previously developed oral formulations and, in its preferred embodiment, would be sweetened so as to be more palatable, those limitations cannot be read into the broader language in claim 1 (see Kemco Sales, 208 F.3d at 1362). As for toxicity and efficacy, the written description is virtually silent on those issues in any event.

Next Fisons argues that Patent 774's prosecution history demonstrates that "suitable for oral administration" implies those requirements. Fisons contends that it was able to distinguish the Pittman, Chow and Ayer Patents by adding the phrase "suitable for oral administration" to Patent 774's claim 1. Because the formulations set forth in those patents would not cause certain death or debilitating harm if taken orally, Fisons suggests that the Examiner recognized that "suitable for oral administration" means more than that and allowed Patent 774 to issue on that ground. n8

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n8 No court is of course bound by what an Examiner may have found persuasive, else no patent could ever be held invalid.

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It is true that the amended application pointed out that the Pittman Patent teaches formulations for intravenous use and the Chow Patent teaches formulations "directed very largely" to topical use (M. Ex. B 50). But Fisons also pointed to a variety of other purported differences between its proposed patent and the prior art. Regarding the Pittman Patent, Fisons noted not only that it is for a different use but also that it suggests an alcoholic solution of a different steroid (id. at 51). Regarding the Ayer Patent, Fisons noted that its compounds "mainly intended for topical application rather than oral administration" concern steroids structurally different from prednisone and that its compounds intended for oral administration are suspensions containing ethanol and no sequestering agent (id. at 50). As for the Chow Patent, Fisons noted that its formulations use different steroid compounds (id.).

Fisons did not argue that the Pittman, Ayer and Chow formulations are unsuitable for oral administration or argue that its patent is distinguishable from the prior art on that basis alone. Thus Patent 774's prosecution history does not reveal that the phrase "suitable for oral administration" in this context means something other than its ordinary meaning--that is, that the formulation can be ingested. n9

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n9 Moreover, the language of claim 1 does not invite reference to either the written description or the prosecution history. Thus it would be inappropriate to narrow the meaning of the claim terms in light of those sources in any event (Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989-90 (Fed. Cir. 1999)).

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Accordingly, this Court finds that Morton Grove's construction of "suitable for oral administration" accurately reflects the phrase's ordinary and customary usage. It does not carry the extra baggage sought to be loaded onto the phrase by Fisons.
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2. "Suitable for Therapeutic Administration by Injection in Solution Therefor"

Bristol argues that this limitation provides a patentable distinction over the method claims because it requires purity and maintenance of therapeutic properties after storage. We need not evaluate this argument because, even assuming its correctness, such a limitation would have been an obvious modification over the prior method claims, as we will discuss infra. We therefore proceed to address the double patenting arguments.

B. Double Patenting

Bristol argues that the grant of "therapeutic composition" claims in the '925 patent did not extend the term of its method claims and thus does not violate the "basic policy" served by the obviousness-type double patenting doctrine as a matter of law. Bristol cites cases such as General Foods and Symbol Technologies as supporting the proposition that there is no double patenting where one can practice the invention claimed in the earlier-issued patents without infringing the inventions claimed in the later-issued patent or vice-versa. Gen. Foods Corp. v. Studiengesellschaft Kohle mb H, 972 F.2d 1272, 1282-83, 23 U.S.P.Q.2D (BNA) 1839, 1847 (Fed. Cir. 1992); Symbol Techs., 935 F.2d at 1581, 19 U.S.P.Q.2D (BNA) at 1249. Bristol contends that because the claims in the prior method patents may be practiced without infringing the composition claims, we need not inquire further into obviousness-type double patenting. Alternatively, Bristol asserts that the defendants' double patenting defense should fail because the prior art does not suggest the need to protect a cisplatin-based therapeutic composition from light and stabilize it with saline to prevent the formation of TCAP. Bristol further argues that "protected from light" is not the only patentable distinction between the claims in the '925 patent and the claims in the prior method patents because saline in claim 2 of the '925 patent is used in a novel and different way to impart stability when the composition is protected from light. Bristol contends that saline in the claims in the prior method patents was used only for administration at levels isotonic with body fluids.

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The defendants respond that Bristol's proposed cross-infringement test applies only to "same invention-type" double patenting, and that it has been rejected for determining "obviousness-type" double patenting in Lonardo, 119 F.3d at 967, 43 U.S.P.Q.2D (BNA) at 1267. They assert that under the appropriate "obvious modification" inquiry, the only new limitation of the composition claim, "protected from light," is an obvious modification of the claims in the method patents in light of prior art references such as Perumareddi that teach the light sensitivity of platinum complexes. The defendants argue that the recitation of saline in claim 2 of the '925 patent does not distinguish it over the recitation of saline in the claims in the method patents because, if present for administration purposes, the saline would necessarily also stabilize cisplatin for the asserted storage purposes of the '925 patent.

We agree with the defendants that the district court did not err in concluding that double patenting existed here. General Foods and Symbol Technologies do not entitle Bristol to a threshold cross-infringement test or patent term extension test. In General Foods, we first stated that the two patents at issue did not claim the same invention and then found that "under an obviousness-type double patenting analysis, neither claimed process is a mere obvious variation of the other. No other kind of 'double patenting' is recognized, so there is no double patenting." 972 F.2d at 1278, 23 U.S.P.Q.2D (BNA) at 1843. Thus, we made the "obvious modification" inquiry that is required by precedent to resolve obviousness-type double patenting issues. See, e.g., Lonardo, 119 F.3d at 967, 43 U.S.P.Q.2D (BNA) at 1267; Vogel, 422 F.2d at 441, 164 U.S.P.Q. (BNA) at 622.

In Symbol Technologies, we first dismissed the double patenting challenge on the ground that 35 U.S.C. § 121 precluded the defense. n5 Symbol Techs. at 1580, 19 U.S.P.Q.2D (BNA) at 1249. We then decided, in the event that the safeguard of § 121 did not apply, that the differences between the claims at issue would not have been obvious. Id. at 1581, 19 U.S.P.Q.2D (BNA) at 1250. Finally, we stated as a matter of policy that the decision did not allow the unlawful extension of the patent grant. Id. However, the policy rationale upon which Bristol relies does not supplant the case law requirement that a court determine whether or not the claims at issue would have been obvious variations over the prior claims, an inquiry that we conducted in both General Foods and Symbol Technologies.

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n5 35 U.S.C.A. § 121 (West Supp. 2000) provides that a patent issuing on an application in which a restriction requirement to one of two or more independent and distinct inventions was made will not be used as a reference against a divisional application directed to the other invention if the divisional application is filed before the issuance of the patent on the other application.

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Our decision in Lonardo illustrates application of the proper obviousness-type double patenting test. Lonardo, 119 F.3d at 967, 43 U.S.P.Q.2D (BNA) at 1267. In that case, the United States Patent and Trademark Office had held the claims invalid because one could not practice the invention of the prior claims without infringing the later claims. Id. We affirmed the rejection, but on the ground that each additional limitation led only to an obvious modification of the device in the prior claims. Id. Likewise, in this case, the proper obviousness-type double patenting test inquiry is whether each additional limitation leads to an obvious modification of the invention of the prior claims. Accordingly, the district court did not err in rejecting Bristol's proffered double patenting threshold tests.

Furthermore, we discern no error in the court's conclusion that claims 1, 2, and 5 of the '925 patent are invalid for obviousness-type double patenting. The composition of the '925 claims, when there are two chloride and two ammonia ligands in a platinum (II) complex, is the same as the composition used in the claims in the method patents. Bristol is correct that the composition claims in the '925 patent do not define the same invention as the claims in the method patents because they are drawn to different statutory classes of subject matter. See Studiengesellschaft Kohle mb H v. Northern Petrochem. Co., 784 F.2d 351, 354, 228 U.S.P.Q. (BNA) 837, 840 (Fed. Cir. 1986) (holding that "because the two patents claim different statutory classes of subject matter, composition and process, they are not the same invention"). Nevertheless, even though the claims do not define the same invention, there is no per se nonobvious distinction between a method of using a device and the device itself. Lonardo, 119 F.3d at 968, 43 U.S.P.Q.2D (BNA) at 1268 (holding that method claims were invalid for obviousness-type double patenting over claims to the structure, which suggested the obvious method of using the device). In this case, as in Lonardo, the same invention is not claimed twice, but there is no nonobvious variation between the claimed composition and the composition to be used in the claimed methods.

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We have already determined that "protected from light" is a non-limiting direction for care and therefore cannot be a basis for distinguishing the composition claims over the prior method claims. We also conclude that "suitable for therapeutic administration by injection in solution therefor" is not a patentable distinction over those claims. Bristol asserts that the "invention" of the '925 patent is a pure and stable composition that degrades minimally to TCAP. We do not agree that a complex "suitable for therapeutic administration" requires a degree of purity greater than that already required by the claims of the method patents. Those claims are directed to treating malignant animal tumor cells by parenteral administration in an amount sufficient to cause regression of the tumor. '263 patent, col. 1, ll. 35-40; '437 patent, col. 6, ll. 35-44. Those method claims are also necessarily directed to the administration of therapeutic compositions because they are intended to cause regression of tumor cells. One of ordinary skill in the art would have employed the same purity standards for both the earlier claimed method and the instantly claimed composition.

Similarly, we are not persuaded by Bristol's argument that the limitation in claim 2 of the '925 patent, "dissolved in a stabilizing effective amount of a saline or buffer solution," patentably distinguishes that claim over the claims in the method patents reciting that the platinum compound is "administered in a saline salt-containing buffer solution." '263 patent, claim 4, col. 6, ll. 45-47; '437 patent, claim 4, col. 6, ll. 49-51. Although we may not use the disclosure of the prior patent as prior art in a double patenting analysis, it may be used to interpret the meaning of the claim. Vogel, 422 F.2d at 441, 164 U.S.P.Q. (BNA) at 622. Here, where Bristol asserts that the saline in the composition claims has a unique significance -- maintenance of therapeutic properties after storage -- that is lacking in the method claims, and the significance of saline is not evident from the claims themselves, we may look to the specification to construe how saline is used in each claim. The patents share the same written description, which indicates that saline was used to stabilize the solutions for the brief period of time between preparation and administration in the inventions of the various patents. '263 patent, col. 2, ll. 16-22; '437 patent, col. 2, ll. 21-27; '925 patent, col. 2, ll. 21-26. No other reason is given for the use of saline solution. We are thus not persuaded by Bristol's argument that the use of saline in the method claims merely facilitated administration of the solution at levels isotonic with body fluids and that the use of saline in claim 2 of the '925 patent means something patentably different. We therefore conclude that there is no nonobvious distinction between the use of saline in the claims of the method patents and the use of the saline in "a stabilizing effective amount" in claim 2 of the '925 patent.
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1. "Suitable for Therapeutic Administration by Injection in Solution Therefor"

As stated in this Court's Memorandum Opinion, both U.S. Patent No. 4,177,263 (hereinafter "the '263 patent") and U.S. Patent No. 4,339,437 (hereinafter "the '437 patent") respectively, did not claim that the platinum complex was "suitable for therapeutic administration by injection in solution therefor." As described more fully in the Court's Memorandum Opinion, plaintiffs' sought to overcome the Patent and Trademark Office's rejection of their 1995 application by canceling and resubmitting a new claim. In April 1996, plaintiffs submitted the new claim which stated in part: "A therapeutic composition comprising a therapeutically effective amount of an inorganic planar dsp<2> platinum (II) coordination complex, which complex is protected from light, and a pharmaceutical carrier therefor . . . ." See Certification of Christine Dudzik Ex. N (hereinafter "Dudzik Cert.") (1996 Patent and Trademark Amendment at 1 (GEN003486)). In July 1996, the Patent and Trademark Office accepted plaintiffs' application, but changed the term "a pharmaceutical carrier" to "which is suitable for therapeutic administration by injection in solution." See Dudzik Cert. Ex. O (Notice of Allowability at 2 (GEN003517)). The specification to the '925 patent further states that the "present invention is a method of treating malignant tumors in animals which comprises parenterally administering to an animal affected with a malignant tumor a solution . . . ." See Dudzik Cert. Ex. A ('925 patent col. 1, ln 24-29). A reading of the claim, the specification, and the prosecution history fails to produce a clear definition of the meaning of the phrase "suitable for therapeutic administration by injection in solution therefor." Consequently, because the intrinsic evidence does not resolve the ambiguity of the disputed phrase, this Court must examine the extrinsic evidence of record.

In reviewing the extrinsic evidence, the Court must construe the claim through the eyes of a "person of ordinary skill in the field of the invention." See Multiform, 133 F.3d at 1477. In the Court's August 10, 1998 Memorandum Opinion, the Court determined that the problem confronting the inventors at the time of the invention was to find a method of treating malignant tumors in animals. See Memorandum Opinion dated August 10, 1998 at 11 (hereinafter "Mem. Op."). Plaintiffs Research Corporation Technologies and Bristol-Myers Squibb assert that to properly construe the remaining disputed terms,

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"it is critical to recognize that the invention in the '925 patent involves the preparation of a stable composition, rather than a method of treating tumors." See Plaintiffs' Post-Hearing Claim Construction Memorandum at 1 (hereinafter "Pls.' Br."). Plaintiffs aver that in addition to finding a method of treating tumors, the inventors of the '925 patent were also addressing the problem of utilizing the first invention reflected in the two prior patents, "the '263 patent" and "the '437 patent" on a practical basis and that the claims of the '925 patent specifically references the stability of the compound. 2 See id. at 1-2. This position, however, is contrary to this Court's earlier finding. Moreover, the specification of the '925 patent does not specifically address the problem as stability, but rather as an effective anti-tumor agent. The '925 patent specification states in relevant part:

This invention relates to a method for treating tumors in animals.

We have discovered that complex compounds of platinum cause regression of malignant tumors in animals. More specifically, the present invention is a method for treating malignant tumors in animals which comprises parenterally administering to an animal affected with a malignant tumor a solution containing a complex compound of platinum in an amount sufficient to cause regression of the tumor.

See Dudzik Cert. Ex. A at 2 ('925 patent col. 1, ln 21-29). The Court finds the plaintiffs' reiteration of its earlier position that the relevant art is pharmacy rather than cancer research, is unsupported by the intrinsic evidence or the extrinsic evidence as discussed by the Court in its August 10, 1998 Memorandum Opinion. See Mem. Op. at 9-11. Accordingly, the Court rejects plaintiffs' reargument of its earlier position that the relevant art is that of a person skilled in the art of oncologic pharmaceuticals.

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2 Plaintiffs argue that "the '925 patent shares a common disclosure with the '263 patent, but the claims of the '925 patent, which concern the stability of the therapeutic composition, demonstrate that the inventors solved a multiplicity of problems [including] . . . therapeutic compositions that could be prepared by a pharmaceutical manufacturer, then shipped and stored at a health care facility for extended periods of time until needed for administration to a patient." See Pls.' Br. at 1. Whether the inventors of the '925 patent solved other problems besides a method of treating tumors, the claim and the extrinsic evidence demonstrate that the primary problem facing the inventors was a method of reducing tumors in animals. See Mem. Op. at 9-11. Thus, the Court is unpersuaded by plaintiffs' arguments.

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As stated in the prior opinion, the Court will construe the '925 patent claims as a cancer researcher would understand them. See Multiform, 133 F.3d at 1477. Plaintiffs contend that the phrase "suitable for therapeutic administration by injection in solution therefor" means that "the claimed therapeutic composition is in solution, or dissolves in a volume to become a complete solution, that is sterile and substantially free from harmful impurities, and that retains substantially the same therapeutic properties and characteristics that it possessed at the time of its manufacture." See Pls.' Br. at 2. Defendants Ben Venue Laboratories, Inc., Fujisawa USA, Inc., and Gensia Laboratories, Ltd. (hereinafter "the three defendants") assert that the phrase means "that the platinum complex is capable of being put into solution in water or other media for parenteral 3 administration, which is administration via routes other than the intestines." See Three Defendants' Additional Brief on Disputed Claim Terms at 2 (hereinafter "Three Defs.' Br."). Defendant Pharmachemie asserts that the phrase means "that the complex is capable of being put into a water or other solvent-based solution." See Defendant Pharmachemie B.V.'s Supplemental Brief on Disputed Claim Terms at 1 (hereinafter "Def. Pharmachemie's Br."). Thus, plaintiffs claim that while the complex must be capable of dissolving in liquid, it must be suitable for therapeutic administration. "Therapeutic means pertaining to the treatment of disease," and thus is not harmful to a human patient nor capable of detrimentally altering the platinum complexes. See Pls.' Br. at 3. To achieve this result, plaintiffs contend that "the claimed composition must be sterile, substantially free from harmful impurities and must retain its therapeutic properties over time." See id. at 4. Plaintiffs further maintain that defendants' claim construction ignore the words "suitable for therapeutic administration" and concentrates only on the phrase "injection in solution." 4 See Pls.' Br. at 5.

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3 The parties have agreed on the definition of parenteral. Plaintiffs' define parenteral as "'taken into the body or

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administered in a manner other than through the digestive tract, as by intravenous injection.'" See Pls.' Br. at 3, n.4 (quoting The American Heritage College Dictionary at 922 (3rd ed. 1993)). Plaintiffs' further explain that "administration by injection is an example of parenteral administration, but 'parenteral' is a broader term that includes any method not through the digestive tract. For example, transdermal and inhalation are two additional methods of parenteral administration." See id. The three defendants also refer to the dictionary definition and seem to take the same view as the plaintiffs. While defendant Pharmachemie is silent on the issue, it does adopt the three defendants' brief as to the meaning of one the terms. Thus, the Court will accept the proffered definition and apply it accordingly.

4 Plaintiffs also insist that defendants for the first time have defined the phrase "suitable for therapeutic administration" as an amount that "is sufficient to cause regression of the tumor" and that "therapeutically effective amount" is a different limitation in claim 1. See Pls.' Reply Br. at 1. Defendants assert that they are not altering their previous definition of "suitable for therapeutic administration by injection in solution therefor" as meaning "that platinum complex is capable of being put into solution in water or other media for parenteral administration." See Three Defs.' Reply Br. at 2. Defendants note that the parties have agreed on both the claim terms "therapeutic composition" and "therapeutic effective amount" and, as a practical matter, this settled the dispute as to meaning of "therapeutic." See id. The Court agrees with defendants position. "Therapeutically effective amount," is defined as "an amount sufficient to have an effect as an antitumor agent." When one considers this definition in construing "suitable for therapeutic administration," therapeutic means that the substance must provide some benefit in reducing tumors.

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On the other hand, the three defendants contend that there is no limitation that the composition be sterile but merely a solution of the complex sufficient to cause regression of the tumor. Specifically, the three defendants point out that the '925 patent simply describes "the administration by injection in mice of platinum complexes in physiological saline or Roberts C medium:

'Test solutions were freshly prepared just prior to use by dissolving the text [sic] complex in physiological saline or in the buffered "C" medium of Roberts et al, Carnegie Inst. Wash. Publ., 607,5 (1995); it has been found that the presence of salt in such solutions tends to stabilize the complex.'"

See Three Defs.' Br. at 3 (Dudzik Cert. Ex. A, col. 2, ln 21-26). Similarly, defendant Pharmachemie avers that the emphasis on sterility and pyrogen-free comes from the testimony of an oncological pharmacist and the Court has already found that pharmacy is not the relevant art. See Def. Pharmachemie's Br. at 2-3 citing Mem. Op. at 11, n.10. Pharmachemie further contends that plaintiffs' argument that "therapeutic" means sterile and pyrogen-free substance is foreclosed by their agreement in regard to the disputed definition of "therapeutic composition" and a "therapeutically effective amount" that therapeutic refers to its efficacy as an antitumor drug. See id. at 3-4 citing Mem. Op. at 2.

"Suitable for therapeutic administration" means suitable for administration as an effective anti-tumor agent. Whether "therapeutic" incorporates sterility and pyrogenicity freedom is another issue. The three defendants have a persuasive argument that this is not set forth in the specification of the '925 patent 5 and also that cancer researchers did not routinely conduct sterility and pyrogenicity tests because they were testing mice and not humans. See Three Defs.' Br. at 4, Tab 4 (Testimony of Eugene R. DeSombre at the Markman hearing held on February 2, 1998 at 122-123 ("Q: And before you inject a therapeutic agent into an animal you normally make sure that the solution is as pure as possible? A: Yes. Q: And when you test anti-tumor agents, you want to test the chemical in as pure a condition as possible? A: That's correct. Q: In the late 1960's the practice was to take normal precautions to make sure that material would not be harmful in terms of sterility? A: Are you talking about animal experiments? Q: Animal -- you took some precautions to make sure that -- A: Yes. You would use, for example, a sterile isotonic saline as the diluent for substance. You would not have gone to the extent you would use for human experiments, for example, actually doing bacterial cultures to see whether the injectant contained any bacteria; but you would be normally cautious to make sure that you were not harming the animal, which would, in fact, impinge on the results of your experiment. Q: And that your therapeutic-compositions were sterile? A: They were -- again, we didn't test them for sterility but we tried to see that they did not contain any bacteria. Q: And you would not consciously allow material to degrade therapeutic compositions before you injected it into animals? A: Yes, that's very true. I mean we wanted to test the compound we're interested in and not a degradation product.").

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5 The three defendants point out that all of the examples in the '925 patent simply describe the injection of mice with platinum complexes dissolved in saline. See Three Defs.' Br. at 3.

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The three defendants further contend that plaintiffs' interpretation includes a definition which "one would associate with an already approved drug product dispensed by a pharmacist or doctor to humans" and would avoid the application of co-inventor Dr. Rosenberg's prior art concerning solutions of platinum complexes previously defined in a biological chemistry journal which are the same platinum complexes described in the '925 patent. See Three Defs.' Br. at 4 citing J. Biol. Chem. 242(6): 1347-52 (1967) (Dudzik Cert. Ex. E).

However, the idea that the inventors would conduct animal experiments without first conducting sterility tests seems counterintuitive, since unknown impurities could prevent the reproducibility of the experiment from one test batch of mice to another. Yet, the intrinsic and extrinsic evidence does not support plaintiffs' arguments that the solution must be sterile 6 and substantially free of harmful impurities. Moreover, the Court finds that plaintiffs' emphasis on sterility and pyrogen-free substance is premised upon the testimony of their expert, Dr. Anderson, an oncological pharmacist, whose testimony the Court found was irrelevant to the discussion at hand because he applied the relevant art of pharmacy rather than cancer research. See Mem. Op. at 11 n.10. Lastly, the stipulated agreement that the phrase "therapeutically effective amount" means "an amount sufficient to have an effect as an antitumor agent" and that "a therapeutic composition" means "a composition that is an effective antitumor agent" does not necessarily imply that the word "therapeutic" contained in the phrase "suitable for therapeutic administration by injection in solution therefor" must encompass a sterile and pyrogen-free substance. See id. at 2. Sterility, by definition, is freedom from bacteria. Because the extrinsic evidence reveals that cancer researchers did not ensure bacteria free solutions prior to injecting the platinum complexes into mice, the solutions are not required to be sterile. This is not to say that the complexes are harmful to the subject, but rather the substance is as pure as possible short of ensuring its sterility. See DeSombre's February 2, 1998 testimony at 122-23. The Court is bound to interpret the claim term "therapeutic" consistently throughout the claim, see CVI/Beta Ventures, Inc., 112 F.3d at 1159, and thus the term "therapeutic" must refer to its efficacy as an antitumor agent without the limitation of sterility. Thus, upon reviewing all the intrinsic and extrinsic evidence of record, this Court finds that the phrase "suitable for therapeutic administration by injection in solution therefor" must be construed as meaning "a tumor reducing platinum complex that is capable of being placed into solution or other nonharmful media for parenteral administration." This definition recognizes that the solution, while not sterile, is sufficiently free of impurities so as to be capable of parenteral administration for the purpose of reducing tumor growth. To accept plaintiffs' argument would be to import a limitation in the phrase that is not contained in the claim or the specification. See Vitronics, 90 F.3d at 1583. Furthermore, the testimony of the three defendants' expert, Dr. DeSombre, reveals that cancer researchers did not perform sterility and pyrogenicity tests before injecting the platinum complexes into mice. See Dr. DeSombre's February 2, 1998 testimony at 122-23. Therefore, in conclusion, this Court finds that the phrase "suitable for therapeutic administration by injection in solution therefor" must be construed as meaning "a tumor reducing platinum complex that is capable of being placed into solution or other nonharmful media for parenteral administration."

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6 The dictionary defines "sterile" as "free from living microorganisms, as bacteria, or their viable spores." See Webster's New International Dictionary 2472 (2d ed. 1944).

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13. Preamble limitation. The parties do not contest the interpretation of any particular term in the claims of the '161 patent. Instead, they contest the limitation, if any, imposed by the phrase in the preambles to independent claims 1 and 15 "suitable for use in a biosensor." Biacore argues that the phrase defines the invention as a biosensor matrix. (D.I. 111 at 12-13) Consistent with this construction, Biacore maintains that the claims are limited to an activated hydrogel matrix that is employed under conditions in which the charged groups actually are bringing about a concentration of oppositely-charged

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biomolecules which are then covalently bound to the matrix coating by the reactive groups. (D.I. 111 at 12-13) Thermo, on the other hand, contends that the phrase imposes no such limitation, arguing that the claims of the '161 patent are directed to a structure having a recited capability not to a method of immobilizing ligands on a hydrogel. (D.I. 112 at 7-9)

14. "[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). Generally, a claim preamble, when read in the context of the entire claim, recites claim limitations only if "the claim cannot be read independently of the preamble and the preamble must be read to give meaning to the claim or is essential to point out the invention." Marston v. J.C. Penney Co., 353 F.2d 976, 986 (4th Cir. 1965) (citing Kropa v. Robie, 38 C.C.P.A. 858, 187 F.2d 150 (C.C.P.A. 1951)). Thus,"if a claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (quoting Kropa, 187 F.2d at 152).

Indeed, when discussing the "claim" in such a circumstance, there is no meaningful distinction to be drawn between the claim preamble and the rest of the claim, for only together do they comprise the "claim." If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.

Id.

15. In the case at bar, the preamble statement "suitable for use in a biosensor" does not merely state a purpose or intended use for the claimed structure. Rather, the phrase informs the construction of the remainder of the claims by defining the matrix coating. The body of the claims is directed to an article that cannot be divorced from the intended field of use. It is only under the conditions imposed by the phrase "suitable for use in a biosensor" that the elements of the claims perform the functions by which they are defined. Thus, the statement at issue is "necessary to give life, meaning, and vitality" to the claims. The phrase is "meshed with the ensuing language of the claim" because it defines the conditions under which the matrix coating is to be employed. Id. Those conditions must be such that the charged groups actually function to bring about a concentration of oppositely-charged ligands that are then covalently bound via the reactive groups. The statement further requires that the quantity of charged groups be that which would bring about a sufficient concentration of biomolecules to produce a useful signal for biosensor purposes. Consequently, the claims can be understood only in the context of this preamble statement, which constitutes a limitation on the claims.

16. With this construction in mind, the court now turns to the issue of infringement.
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C. "Super-Purifying Said Smoke to Reduce Taste Imparting Components Below Thresholds for Imparting Smoke Odor and Taste"

The language of Claim 67, discussed above, is quite similar to the language of Claim 1, which claims "super-purifying said smoke to reduce taste imparting components below thresholds for imparting smoke odor and taste." (Kowalski Patent, Col. 28, at 11-18.) TPI raises similar claim construction arguments here as it raised for Claim 67, once again requesting that numerical values listed in Table 3 be ascribed to the process of "super-purifying" the smoke "below thresholds for imparting smoke odor and taste." (TPI Brief 20). For the reasons discussed above, the Court finds that "super-purifying said smoke to reduce taste imparting components below thresholds for imparting smoke odor and taste" is supported by the disclosures made in the specifications. It will not be numerically limited by the Court.
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III. "Surface Active Material"

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Claim 1 of both the '301 and '839 patents initially describes the invention as a "surface active material" and then goes on to state the composition of the "surface active material." Plaintiffs argue that the phrase "surface active material," as used in the patents, means the lung surfactant extract material, which is in solid form 7, before it is combined, with a pharmaceutically acceptable carrier, such as physiological saline, to form a "pharmaceutical composition" that can be administered to premature babies. Thus, according to plaintiffs, the composition of the "surface active material" must be determined or measured for infringement purposes before it is made into a "pharmaceutical composition."

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7 Plaintiffs store the lung surfactant extract material in liquid chloroform.

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Defendants, on the other hand, argue that the phrase "surface active material" should be construed to cover any material, of whatever form, that exhibits surface tension reducing properties. Thus, according to defendants, the phrase "surface active material," as used in the patents, covers both the solid lung surfactant extract material before the physiological saline is added to form a "pharmaceutical composition" and the "pharmaceutical composition" itself, since the "pharmaceutical composition" also has surface tension reducing properties. In other words, defendants argue that the phrase "surface active material" covers both the solid precursor to Infasurf, known as CLSE, and Infasurf itself, which is in liquid form. Consequently, according to defendants' argument, plaintiffs can be found to infringe Claim 1 of the patents if either CLSE or Infasurf includes each and every element of that Claim. 8

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8 It is important to determine whether the composition of the "surface active material" is measured before or after the physiological saline is added because the addition of the saline solution, which is mostly water, changes the chemical composition of the lung surfactant extract material. For example, the addition of water causes a hydrolosis process that increases the amount of free fatty acids.

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The Court finds that plaintiffs' proposed construction of the phrase "surface active material" is the correct one. Both the claim language and the language in the specifications show that the term "surface active material," as used in Claim 1 of the patents, means the lung surfactant extract material in dry form before it is suspended in physiological saline to form a "pharmaceutical composition" and that the chemical composition of the "surface active material" must be determined for infringement purposes before it is made into a "pharmaceutical composition."

Claim 7 of the '301 patent and Claim 9 of the '839 patent conclusively demonstrate that "surface active material" and "pharmaceutical composition," as used in the patents, are different claim terms with different meanings. Claim 7 and Claim 9 provide as follows:

Claim 7

A pharmaceutical composition useable for the treatment of hyaline-membrane disease comprising an effective amount of surface-active material as set forth in claim 1 and a pharmaceutically acceptable non-toxic carrier thereof.

Claim 9

A pharmaceutical composition useable for the treatment of respiratory distress syndrome comprising an effective amount of a surface active material as set forth in claim 1 and a pharmaceutically acceptable carrier thereof.

As defined by the patentee, the "pharmaceutical composition" inventions covered by Claims 7 and 9 are made by combining the "surface active material" set forth in Claim 1 of the patents with a pharmaceutically acceptable carrier, such as physiological saline. Thus, according to the patent claims themselves, the "surface active material" is only a part or subset of

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the "pharmaceutical composition."

If, as defendants argue, the phrases "surface active material" and "pharmaceutical composition" were to be used interchangeably, then Claims 7 and 9 of the patents would teach that a "pharmaceutical composition" may be made by combining a "pharmaceutical composition," which is already comprised of the "surface active material" and physiological saline, with more physiological saline. Such a construction obviously does not make sense. The only way Claims 7 and 9 make sense as written is if "surface active material" means the lung surfactant extract material before it is suspended in physiological saline to form the "pharmaceutical composition." And, if that is what "surface active material" means for purposes of Claims 7 and 9, then it must mean the same thing for purposes of Claim 1.

Clearly, the patentees intended to give the terms "surface active material" and "pharmaceutical composition" distinct meanings. If the term "surface active material" was meant to include a "pharmaceutical composition," then there would have been no reason to include Claims 7 and 9 in the patents. As stated above, it is well established that a claim term must be interpreted so as not to make any other claim in the patent meaningless or superfluous.

Defendants' proposed construction would require the Court to ignore the distinction between the terms "surface active material" and "pharmaceutical composition" and to give these terms the same meaning. As stated above, however, the Court may not rewrite the patent. The patentees could have, had they wished, drafted Claim 1 to define "surface active material" and "pharmaceutical composition" synonymously. They chose not to do so.

Plaintiffs' proposed construction is not only supported by the claims themselves, but is confirmed by the specifications of the '301 and '839 patents. Throughout the '301 and '839 patents, when the patentees refer to the dried active ingredient before it is converted to a pharmaceutical composition, they use the term "surface active material." When they refer to a preparation including a pharmaceutical carrier, such as saline, they use the words "pharmaceutical composition." The terms "surface active material" and "pharmaceutical composition" are never used interchangeably, or synonymously. For example, in the '301 patent, in characterizing the "Field and Background of the Invention," the patentee specifically distinguished between "a surface active material having a new chemical composition" and a "pharmaceutical composition . . . containing the active material." Likewise, the '839 patent's "Field and Background of the Invention" section distinguishes between "a surface active material having a new chemical composition" and a "pharmaceutical composition . . . comprising the surface active material as active ingredient."

Further, under "Summary of the Invention," the '301 patent states: "According to one feature of the present invention there is provided a surface-active material." After describing the method of making that material, the Summary goes on to state: "According to a still further feature of the present invention there is provided a pharmaceutical composition . . . containing the surface active material as defined above."

The '839 patent has a similar recitation under "Summary of the Invention." First, the "surface active material" is described and the method of making it is discussed. Then the Summary states that "still another feature of the present invention" is a "pharmaceutical composition" comprising surface active material as previously described in the Summary.

More evidence supporting plaintiffs' proposed construction is found in the '839 patent's illustrative examples and Table VII. The '839 patent repeatedly teaches that the final step in the process of making a "surface active material" of the "invention" is to "lyophilize" or freeze dry the material. The '839 patent contains eleven examples that are directed to surface active materials and their preparation. In each example, the final product is described as a "surface active material" in a lyophilized or freeze-dried solid state and is measured in grams (a unit of measurement used to measure solids) rather than milliliters (a unit of measurement used to measure, liquids). The "surface active material" produced in each example was then analyzed for its chemical composition. The results of these analyses are set forth in Table VII of the '839 patent and provide the basis for the ranges of the amounts of the ingredients of the '839 surface active material as set forth in Claim 1 of the '839 patent. Thus, the eleven illustrative examples and Table VII confirm that the "surface active material" claimed in Claim 1 of the '839 patent is a dry product and that its chemical composition is to be determined before it is combined with physiological saline to form a "pharmaceutical composition."

Further support for plaintiffs' proposed construction is the fact that, separate and distinct from the eleven examples of how to produce a "surface active material," the '839 patent provides two examples of how to produce a "pharmaceutical composition," an ingredient of which is the "surface active material." For example, the '839 patent includes an example of a

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"pharmaceutical composition" that is made by introducing 60 mg of the "surface active material" and 6 ml of physiological saline into an ampule and storing the ampule under sterile conditions. Claim 13 of the '839 patent is directed to that example, calling for a "pharmaceutical composition" comprised of the "surface active material" set forth in Claim 1 and a water-based carrier of physiological saline. By including these separate examples of pharmaceutical compositions, the drafters of the patent once again distinguished the terms "surface active material" and "pharmaceutical composition."

Defendants argue that the plaintiffs' proposed construction of the phrase "surface active material" is too restrictive because the patent contains no requirement that the composition of the "surface active material" be measured at any particular point in time. Therefore, according to defendants, because the patents do not set forth a specific point in time at which the chemical composition of the "surface active material" described in Claim 1 of the patents is to be measured, the chemical composition may be measured for infringement purposes either before or after the lung surfactant extract material is made into a "pharmaceutical composition." The Court finds this argument unpersuasive.

Contrary to defendants' argument, the patents do require that the chemical composition of the "surface active material" be measured before the lung surfactant extract material is added to physiological saline to form a "pharmaceutical composition." This timing requirement is a function of the way the claims are written. As stated earlier, the "pharmaceutical composition" inventions covered by Claim 7 of the '301 patent and Claim 9 of the '839 patent are made by combining the "surface active material" set forth in Claim 1 of the patents with a pharmaceutically acceptable carrier, such a physiological saline. Thus, according to the patent claims themselves, the "surface active material" is a precursor ingredient of the "pharmaceutical composition." Because the "surface active material" is a precursor to the "pharmaceutical composition," it must logically be formed or exist before it is made into a "pharmaceutical composition." Therefore, the term "surface active material," as used in Claims 7 and 9, must mean the lung surfactant extract material before it is combined with physiological saline to form a "pharmaceutical composition." And, as stated before, if that is what "surface active material" means for purposes of Claims 7 and 9, then it must mean the same thing for purposes of Claim 1. Accordingly, the term "surface active material," as used in Claim 1, is limited to the lung surfactant extract material before it is combined with physiological saline.

Continuing the analysis, it follows that the chemical composition of the "surface active material" must be measured before it is added to the water-based saline solution. Once the "surface active material" is added to the physiological saline, the resulting product is, as stated in Claims 7 and 9 of the patents, a "pharmaceutical composition." At that point, the "surface active material" described in Claim 1 of the patents in effect no longer exists. Any subsequent measurement of the chemical composition of the resulting product would only provide a measurement of the composition of the "pharmaceutical composition," not the "surface active material" as defined by the patent. 9

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9 As stated previously, it is undisputed that the chemical composition of the lung surfactant extract material changes when it is added to water.

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Defendants further argue that plaintiffs' proposed construction must fail because there is nothing in Claim 1 or any place else in the patent "which limits the inventions to use in their dried weight state. Indeed, there is no effective way to administer surfactant in a dried form." See Defendants' Claim Construction Memorandum at 21, n.12 (emphasis in original). Not only is this argument unpersuasive, it actually supports the construction proposed by plaintiffs. Based on the above-referenced statement in defendants' Claim Construction Memorandum and the discussions at oral argument, it appears undisputed that lung surfactant extract material in its dry, pre-suspension state is not useable to treat premature babies. It must be added to a pharmaceutically acceptable carrier before it can be administered. Claim 9 of the '839 patent claims a "pharmaceutical composition useable for the treatment of respiratory distress syndrome." 10 (emphasis added). This "useable" language included in Claim 9, which deals with a "pharmaceutical composition," is omitted from Claim 1, thereby implying that, when referring to "surface active material" in Claim 1, the drafters of the patent were referring to lung surfactant extract material in its dry, pre-suspension state, at which point it is not useable to treat premature babies. 11

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10 Claim 7 of the '301 patent contains similar language.

11 Because the meaning of "surface active material" can be discerned from the language in the patents themselves, the Court need not consider the prosecution history or any extrinsic evidence.

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In sum, for the reasons stated, the Court will adopt plaintiffs' construction of the phrase "surface active material" and will instruct the jury as follows:

The claims of both the '301 and '839 patents include the phrase "surface active material." "Surface active material" means lung surfactant extract material before it is combined with a pharmaceutical carrier such as physiological saline.
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The Effect of Judge Arcara's Decision

Defendants argue that Judge Arcara construed the same claim language that is disputed in this case and that his construction should carry the day here as well; they contend that the doctrine of issue preclusion bars plaintiffs from relitigating those claim construction issues. Plaintiffs argue that the Court should not apply issue preclusion in this case because to do so would be unfair to them.

The doctrine of issue preclusion compels a court to honor the first actual decision of a matter that has been litigated. See Chicago Truck Drivers v. Century Motor Freight, 125 F.3d 526, 530 (7th Cir. 1997) (citing 18 Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure § 4416, at 136 (1981 & Supp. 1997)). 3 Generally, issue preclusion is appropriate if: (1) the issue sought to be litigated is identical to one decided in a prior action; (2) that issue was actually litigated in the first action; (3) the determination of the issue was essential to the final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action. Century, 125 F.3d at 530 (citing La Preferida, Inc. v. Cerveceria Modelo, S.A. de C.V., 914 F.2d 900, 906 (7th Cir. 1990)); A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 702 (Fed. Cir. 1983), cert. denied, 464 U.S. 1042, 79 L. Ed. 2d 171, 104 S. Ct. 707 (1984). All of these conditions are met here. The claim construction issues disputed in this case are the same issues litigated in the Forest case; Abbott and Tokyo Tanabe briefed and argued the issues before Judge Arcara, and the judge's claim construction ruling was necessary to the final judgment in the case concerning infringement.

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3 The Court looks to Seventh Circuit law because that is where the Federal Circuit would turn in applying issue preclusion in this case. See Epic Metals Corp. v. H.H. Robertson Co., 870 F.2d 1574, 1576 (Fed. Cir.), cert. denied, 493 U.S. 855, 107 L. Ed. 2d 117, 110 S. Ct. 160 (1989); Hartley v. Mentor Corp., 869 F.2d 1469, 1471 n.1 (Fed. Cir. 1989) (the application of principles of claim preclusion and issue preclusion is not a matter committed to the exclusive jurisdiction of the Federal Circuit, so the court looks to the law of the circuit to which an appeal would lie in non-patent cases from the particular district court).

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But that does not end the inquiry. In some circumstances, even when these conditions are met, the court may decline to apply issue preclusion. The United States Supreme Court, the Seventh Circuit and the Federal Circuit have all said that courts should not apply non-mutual offensive collateral estoppel (or issue preclusion), which is what this is, if it would be unfair to the defendant. See Parklane Hosiery Co. v. Shore, 439 U.S. 322, 331, 58 L. Ed. 2d 552, 99 S. Ct. 645 (1979); Century, 125 F.3d at 531; A.B. Dick, 713 F.2d at 702. The court should refuse to apply issue preclusion if, for example, the defendant had little incentive to defend vigorously in the first suit because he was sued for small or nominal damages, or if the first judgment is inconsistent with one or more previous judgments in the defendant's favor, or if the second action affords the defendant procedural opportunities (e.g., discovery procedures) unavailable in the first action that could cause a different result. See Parklane, 439 U.S. at 330-31, cited in Century, 125 F.3d at 531. Nor should the doctrine be applied

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"when the issue is of general interest and has not been resolved by the highest appellate court that can resolve it." Century, 125 F.3d at 531 (citing Restatement § 29 Comment i; United States v. Alcan Aluminum Corp., 990 F.2d 711, 719 (2d Cir. 1993)). The Seventh Circuit has held that "determining 'whether or not application of [issue preclusion] is fair depends upon a case by case analysis,' and that courts should be sensitive to the 'practical realities which surround the parties.'" Century, 125 F.3d at 531 (quoting Butler v. Stover Brothers Trucking Co., 546 F.2d 544, 551 (7th Cir. 1977)). Thus, in Century, where the issue involved the validity of the PBGC's regulation delaying withdrawal liability payments when an employer has filed for arbitration, the court refused to apply the doctrine to prevent the employer from relitigating the regulation's validity because the issue decided was an unmixed question of law that was likely to arise again, all other courts to consider the issue had come out the other way, and the district court failed to distinguish any of those cases. Id. 125 F.3d at 532.

This case does not appear to fall within any of these exceptions. The record suggests that Abbott and Tokyo Tanabe defended the Forest case with vigor, there are no judgments concerning the Tanabe patents that are inconsistent with Judge Arcara's, and the discovery procedures available in this Court are likely the same as those available in the Forest case. Although it is true that the Federal Circuit has not yet ruled on whether Judge Arcara correctly construed the patent claims in the Forest case, this issue is not a matter of general interest; indeed, the universe of parties who have an interest in how these claims are construed is quite small. And although claim construction presents a purely legal question, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995) (en banc), aff'd 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), the issue of how these particular claims should be construed is unlikely to arise again.

There appear to be only two reported decisions in which the court was asked to consider the preclusive effect to be given the claim construction decision of a prior court involving the same patents and the same patent holders but not the same opposing party. Sadly, the courts deciding those two cases reached opposite results. In TM Patents, L.P. v. International Business Machines Corp., 72 F. Supp. 2d 370 (S.D.N.Y. 1999), the district court held that issue preclusion foreclosed the patent holder from relitigating the meaning of certain claim limitations that had already been raised and litigated in a prior infringement action. In deciding to apply the doctrine, the court analyzed precedent--not only Markman v. Westview Instruments, Inc., 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996), which emphasized the need to promote uniformity in the meaning to be given a particular patent's claims and to that end took the question of claim construction away from the jury and handed it to the judge--but the cases leading up to that decision as well:

Even prior to Markman, the Federal Circuit had held that determination of the scope of a patent claim in a prior infringement action could have [issue preclusive] effect against the patentee in a subsequent case. See Pfaff v. Wells Elec. Inc., 5 F.3d 514, 517-18 (1993). After Markman, with its requirement that the Court construe the patent for the jury as a matter of law, it is inconceivable that a fully-litigated determination after a first Markman hearing would not be preclusive in subsequent actions involving the same disputed claims under the same patent. The nature of the Markman proceeding is such that finality is its aim. Id. 517 U.S. at 377.

By contrast, in Graco Children's Products, Inc. v. Regalo International, LLC, 77 F. Supp. 2d 660 (E.D. Pa. 1999), the court concluded that issue preclusion did not apply to bar relitigation of claim construction issues. In so doing, the court recognized that "by instructing courts to decide issues of claim construction in patent cases, the Court in Markman recognized the importance of uniformity in the treatment of a given patent." Id. at 663. But, the court reasoned, even Markman did not require courts to apply issue preclusion in every case; "circumstances may exist where . . . despite a previous court having held a hearing on the claim construction of a patent pursuant to Markman, [issue preclusion] will not apply to such decisions." Id. at 663, 665. Given the particular circumstances of the Graco case (Graco lost on the claim construction issues but won on the ultimate infringement issue and so could not have appealed the claim construction decision), this Court does not necessarily disagree with the outcome reached in that case. But such circumstances are not present in this case. Unlike Graco, Abbott and Tokyo Tanabe lost on both the claim construction issues and the infringement issue, and they can and have appealed. Although that appeal has not yet been decided, the law in the Seventh Circuit is clear that exhaustion of appellate remedies is not a normal requirement of issue preclusion, and a final judgment by a district court has preclusive effect even though judgment is pending on appeal. See, e.g., Amcast Industrial Corp. v. Detrex Corp., 45 F.3d 155, 160 (7th Cir. 1995); Prymer v. Ogden, 29 F.3d 1208, 1213 n.2 (7th Cir.), cert. denied, 513 U.S. 1057, 130 L. Ed. 2d 599, 115 S. Ct. 665 (1994).

Additionally, in Graco the claim construction was not the reason for the loss; here it was. Because of the way he construed the claims, Judge Arcara found that no reasonable trier of fact could find that Forest's product infringed the Tanabe patents. For these reasons, the Court does not believe it would be unfair to apply the doctrine of issue preclusion in this case. The

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Court finds that Judge Arcara's construction of "surface active material" and "based on dry weight" are binding on this Court.

The Court notes that even if it were not bound to follow Judge Arcara's ruling, it would nonetheless apply the same claim construction--at least with respect to the meaning of the phrases "surface active material" and "based on the dry weight of the material." Judge Arcara's reasoning on these points is persuasive. The plaintiffs argue that Judge Arcara's construction of these claim terms was "plainly wrong" for several reasons, and that they should therefore be permitted to relitigate the claim construction issues anew in this Court. There is some authority for the proposition that a "plainly wrong" determination may not be entitled to preclusive effect, see Restatement (2d) of Judgments § 29(8) and cmt. j (1980), but the Court does not believe that exception would cover the situation presented here. Section 29(8) instructs that a court need not apply issue preclusion if "other circumstances justify affording [the losing party] an opportunity to relitigate the issue"; comment j instructs that the "other circumstances" that may be important include "disclosure that the prior determination was plainly wrong or that new evidence has become available that could likely lead to a difference result." The fact that these two circumstances are linked in the same comment suggests that the "disclosure that the prior determination was plainly wrong" would not come from a second court revisiting the merits of the first court's decision, but from new evidence or a change in facts or circumstances. The Restatement does not seem to contemplate a second court being able to revisit the merits of the prior determination, as the plaintiffs urge here. Indeed, such an exception would make no sense in light of the purpose behind the doctrine of issue preclusion, which is to place the first judgment beyond question by subsequent courts; if the second court is going to examine the first court's decision to decide if it was right or wrong, what is the point of having issue preclusion to begin with?

Moreover, the Court does not believe Judge Arcara's decision was "plainly wrong." In support of its argument in this regard, the plaintiffs first argue that Judge Arcara should not have read a temporal limit into the term "surface active material" because the claims do not limit that term to dry powder or impose a temporal element on that material. The Court disagrees. The claims clearly contemplate that the "surface active material" exists first, and then, after a "pharmaceutically acceptable carrier" is added to the surface active material, the surface active material ceases to exist and becomes a "pharmaceutical composition." See, e.g., U.S. Patent No. 4,397,839, at col. 18, lines 15-19. As Judge Arcara noted, it was undisputed that the chemical composition of the lung surfactant extract material changes when it is added to water (one of the claimed elements of the "pharmaceutically acceptable carriers," see id., col. 18, lines 26-28). If that is the case--and the parties in this case certainly seem to agree that it is--once the pharmaceutically acceptable carrier is added to the surface active material, the surface active material no longer exists, or at least it does not exist in the same form.

Second, the plaintiffs argue that Judge Arcara's construction of "surface active material" is wrong because a solid, which is what the surface active material must be under Judge Arcara's view, cannot be added "dropwise" as required by claim 1, and cannot be administered orally or intraperitoneally (through a syringe) as discussed in the specification. The plaintiffs have not explained why this is so, however. In fact, their argument seems to assume that the terms "solid" and "liquid" are black and white, and that only "liquids" can be dropped or put into a syringe. Not that the Court has any particularized knowledge about the specific state of matter of the "surface active material" described in the patent, but as a matter of common sense, some "solids" are more solid (in the sense of being unmalleable) than others. For example, cake frosting and toothpaste, which most people probably think of as solids, can be added dropwise onto a surface, which is what the claims of the patent contemplate. So just saying something is a "solid" does not necessarily mean that it cannot be made to perform in the ways required under the patent. More importantly, the intraperitoneal insertion language comes from the examples provided in the specification, not from the claims themselves, and it therefore may not be read into the claims. See, e.g., Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.").

The plaintiffs next argue that Judge Arcara's claim construction was wrong because he held that claim 1 is a subset of claim 9, which is impossible if claim 9 depends from claim 1, which it unquestionably does. The Court disagrees with this characterization of the ruling. Judge Arcara did not hold that claim 1 depended from claim 9; rather, he held (correctly in this Court's view) that the "surface active material" claimed in claim 1 is one component of the "pharmaceutical composition" claimed in claim 9. The plain language of the claims makes this much clear; claim 9 claims "[a] pharmaceutical composition . . . comprising an effective amount of a surface active material as set forth in claim 1 and a pharmaceutically acceptable carrier thereof." U.S. Patent No. 4,397,839, col. 18, lines 15-19.

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Tying this argument in with their point that a solid cannot be inserted intraperitoneally, the plaintiffs argue that Judge Arcara was wrong to infer that "surface active material" is a solid because even Dey's own surfactant expert, Joseph Zasadzinski, testified that the phrase did not "fit within a particular state of matter." See Plaintiffs' Brief on the Correct Construction of [Claim Terms], p. 8 (quoting Zasadzinski's deposition testimony). But the deposition excerpt makes clear that Zasadzinski was asked to define the phrase as a general proposition, whereas Judge Arcara was asked to define that phrase as it used in the context of the '301 and '839 patents. Those patents define "surface active material" as something that must be combined with water and physiological saline (i.e., made more liquid) to form the "pharmaceutical composition" to be used in treating RSD. See U.S. Patent No. 4,397,939, col. 18, lines 15-19, 26-31. Judge Arcara was right to conclude that "surface active material" and "pharmaceutical composition," as used in the patent, do not mean the same thing.

As further evidence that "surface active material" is not limited to a solid state, the plaintiffs offer a copy of the extension it received from the PTO under 35 U.S.C. § 156. The plaintiffs reason that because the patentee submitted "testing conducted on the post-suspension product Survanta,(R) but did not submit any testing on a 'dry' precursor product" in support of its application for the extension, and because the PTO granted the extension, the PTO necessarily found that Survanta(R) was a "surface active material" within the meaning of claim 1. See Plaintiffs' Brief on the Correct Construction of [Claim Terms], at 7-8. This evidence is extrinsic and, absent an ambiguity in the patent's claims, specification and prosecution history (which is lacking here), it should not be considered in determining what the claims of the patent actually mean; certainly, this evidence cannot be used to contradict the claim construction unambiguously apparent from the intrinsic evidence. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999). Moreover, the granting of the extension appears to have had nothing to do with determining what the claims of the patent mean, and even if it did, the PTO is not required to interpret a patent's claims in the same manner as courts are required to during infringement proceedings, see In re Morris, 127 F.3d 1048, 1053 (Fed. Cir. 1997), which means that the PTO's claim interpretation would in no way be binding on Judge Arcara or on this Court.

Finally, the plaintiffs argue that Judge Arcara's ruling prevents the patentee from determining whether a publicly-available product produced by a potential infringer actually infringes the '839 patent because they would have to test the precursor to the publicly-available product--what Dey has referred to in court as "the paste"--which may well be unavailable to test (indeed, plaintiffs have had some difficulty obtaining it from Dey in this case). This is the most compelling (indeed the only compelling) of all the plaintiffs' arguments. The Court is mindful that the claims as construed require the plaintiffs to test the precursor, which may mean that the patent holder and licensees have to file an infringement suit just to have access to that material to determine whether it infringes the '839 patent. But that is, in fact, what the claims as written require, and the Court is neither willing nor able to rewrite the claims to alleviate this potential hurdle to enforcement of the patent rights. See K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1364-65 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.") (citing Texas Instruments Inc., v. International Trade Commission, 988 F.2d 1165, 1171 (Fed. Cir. 1993)).
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1. "Surface Active Material"

Abbott argues that the court erred by construing the term "surface active material" as a pre-suspension powder because the claims are not limited to either solid or liquid form. Abbott asserts that the claims to pharmaceutical compositions depend from claim 1, so that claim 1 of each patent necessarily has a scope covering a pharmaceutical composition as well as the surface active material contained within it. Thus, Abbott argues that the court erred in concluding that the "'surface active material' is only a part or subset of the 'pharmaceutical composition.'" Forest I at 18.

ONY responds that the independent claims to "surface active material" are limited to the dry state of the material before it is combined with saline to form a pharmaceutical composition, after which its properties are changed. ONY asserts that the court did not confuse independent and dependent claim concepts, but rather properly focused on the "surface active material" of claim 1 and found no infringement of that claim or of the dependent claims.

We conclude that the district court properly decided that the term "surface active material" means the material containing the prescribed materials in the prescribed percentages, when measured in the dry state, i.e., before being combined with the

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pharmaceutical carrier. Claim 1 contains the definition of the "surface active material." It indicates the nature and percentage of its components, and that the measurements are made when the material is dried. However, the court erred in its further construction of the claim. When the surface active material is combined with a pharmaceutically acceptable carrier, it does not necessarily cease to be the claimed surface active material, as the district court erroneously found. See id. at 24 ("[Once the surface active material is added to the physiological saline], the 'surface active material' described in Claim 1 of the patents in effect no longer exists."). The material as defined in claim 1 may still be present when a pharmaceutical carrier is added to it to make the compositions of claims 7 and 9. Claim 1 does not limit its scope to the material when in dried form. It simply indicates, for purposes of definition, the percentages of the components, as measured when in dried form. The claim can be infringed, even when the material is in the form of a liquid pharmaceutical composition, as long as the material has the components and percentages as recited in claim 1, when it is in dried form. That is a matter of proof, as we shall discuss infra. Stated another way, the measurement of water in dried form of surface active material is necessary to satisfy the definition of the claimed material even when the material is in the form of a pharmaceutical composition containing a greater percentage of water. We therefore conclude that claim 1 of each patent covers all surface active material that meets the claim limitations, regardless of its form as pre- or post-suspension material, and that claim 7 of the '301 patent and claim 9 of the '839 patent cover that material when combined with a pharmaceutically acceptable carrier. 3

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3 We also note that the pharmaceutical composition claims depend from the surface active material claims according to the test for proper dependency in the Manual of Patent Examining Procedure ("MPEP"). "The test [of proper dependency] is not whether the claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim." MPEP § 608.01(n) (7th ed. rev. Feb. 2000). Any pharmaceutical composition that would infringe the dependent claims must necessarily contain a surface active material that would also infringe the independent claims.

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A. Term in both the '299 and '448 Patent

1. The term "surface pasteurizing" 6 in claim 1 of the '299 Patent and claims 12 and 22 of the '448 Patent is construed as: "using heat for destroying bacteria on thesurface." 7 Cooper argues that this term should be construed as "heating already cooked food products in a manner effective to destroy bacteria on all of the outer surface of the already cooked food products without producing any substantial change in the color or other characteristics of the already cooked food products." Dkt. # 61-2, at 30. Unitherm argues that this term does not require construction or, in the alternative, proposes "a process using heat for destroying bacteria which may be present on the surface of the cooked product." Dkt. # 60, at 15.

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6 Cooper argued that the term "method of surface pasteurizing" in the '299 Patent and "surface pasteurizing" in the '448 Patent required construction. Dkt. # 56, at 1-2. The '448 Patent discusses a "process of surface pasteurizing." The terms "method" and "process" do not require construction.

7 The Court finds that the terms in both Patents should be construed consistently. However, the Court would adopt the same construction if only one patent were at issue. Further, Cooper argues that its proposed construction of the term in the '299 Patent "follows directly from Cooper's construction . . . for 'surface pasteurizing' under the "448 Patentand for substantially the same reasons stated therein." Dkt. # 61, at 26.

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Cooper's proposed construction would introduce two limitations into the methods claimed in which "surface pasteurizing" is used in the preamble: first, a requirement that the methods be effective to destroy bacteria on all of a food product's outer

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surface; and second, a requirement that the methods not produce any substantial change in the color or other characteristics of a food product. Nowhere in either of the Patents is it claimed that the inventive processes are effective to eliminate 100% of bacteria on a food product's surface. 8 In fact, the specifications discuss preferred embodiments wherein a 3, 4, or 6 log reduction in bacterial activity was achieved. '299 Patent, col. 3, lns. 61-62; '448 Patent, col. 4, lns. 60-61; '448 Patent, col. 5, lns. 1-2. If "surface pasteurization" required the complete elimination of all bacteria, then such embodiments would not be examples of the claimed inventions. Cooper cites no intrinsic or extrinsic evidence supporting its proposed requirement that surface pasteurization eliminate 100% of bacteria on a food product's surface.

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8 Cooper argues that the mention of the government's"zero tolerance" requirements in the Patents' specifications means that the inventions must kill 100% of bacteria. The "zero tolerance" requirement is for compliance with United States Department of Agriculture and Food and Drug Administration regulations regarding listeria monocytogenes and salmonella in ready-to-eat food products.

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The summary of invention in the '448 Patent states that "in its most preferred embodiments, 9 the inventive system is effective for destroying bacteria without producing any substantial change in the color or other characteristics of the product." '448 Patent, col. 2, lns. 25-28 (emphasis added). The same section in the '299 Patent states that "all of the steps of the inventive process are most preferably conducted in a manner such that substantially no change in surface color . . . occur[s]." '299 Patent, col. 3, lns. 3-7. These sentences necessarily imply that there are alternative or less preferable embodiments that are not identical. Throughout the Patents, references to a lack of change in color or other surface characteristics is discussed in the context of preferred or potential embodiments. E.g., '448 Patent, col. 3, lns. 14-20 ("the temperatureand exposure period employed in the inventive process will most preferably be effective for achieving such results without producing any discernible change in the surface, color . . ."; '448 Patent, col. 4, lns. 8-18 ("other heating apparatuses . . . can also be used in the inventive process but are less desirable [because they] may change the surface color and other characteristics of the product'); '299 Patent, col. 5, lns 4-8 ("[t]o assist in preventing any change in surface color … the packages fo cooked food product are preferably transferred from the hot water system 4 to the chiller 6 within not more than two minutes"). It would be improper to use these preferred embodiments to limit broader claim language. See Innova, 381 F.3d at 1117.

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9 Cooper failed to include this first clause of the sentence when quoting the '448 Patent in its brief. Dkt. # 70, at 14. Selective and misleading quotation is not helpful to any court.

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Further, Cooper's proposed construction would render claim 16 in the '448 Patent, "[t]he process of claim 12 wherein said step of exposing is conducted in a manner such that substantially no color change occurs in said outer surface," '448 Patent, col. 6, lns. 16-19,entirely superfluous.

With respect to the '448 Patent, Cooper argues that "the primary basis for distinguishing the invention from the prior art was its surface pasteurizing using continuous heating to destroy bacteria on the entire surface without altering the color or other characteristics of food products." Dkt. # 70, at 12. The specification describes how "the current industry practices and procedures for dealing with [the problems of food-borne illness] are not sufficiently reliable and are inadequate to meet the zero tolerance requirements now imposed by regulatory agencies. . . . It is thus apparent that a need presently exists for a process which will consistently and effectively kill surface bacteria . . . . A need particularly exists for such a process which will not alter the surface characteristics or internal characteristics of the products in any significant way." '448 Patent, col. 1, lns. 62-67, col. 2, lns. 1-16. Contrary to Cooper's contention, the '448 Patent specification does not distinguish prior art on the basis of whether surface characteristics are changed; it distinguishes prior art on the basis of the reliability and effectiveness of bacteria elimination. Thesame is true regarding Unitherm's distinguishing of the Singh patent in the prosecution history. Although Unitherm described the Singh process as one "which significantly changes the color and other surface characteristics of the product," Dkt. # 70-2, at 67, Unitherm did not explicitly distinguish the Singh process on this

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basis; rather, Unitherm distinguished Singh because it did not "discuss or suggest any packaging, cooling, or other steps following the browning procedure," did not "suggest any adaptation or modification of the browning process whereby the browning process could be effectively used to produce browned packaged products which are adequately surface-pasteurized for sale," and did not disclose or suggest a continuous infrared oven. Id. at 17. In the prosecution history, Unitherm did not expressly limit the claims in the '448 Patent to processes that produced no substantial change in the color or surface characteristics of food products.

The parties' proposed constructions of "pasteurization" are substantially similar to the Court's construction.
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C. The Meaning Of The Disputed Term "Surfactant"

Novartis contends that the term "surfactant" should be construed to include at least a hydrophilic surfactant. (D.I. 237 at 5-6). Abbott contends that the term "surfactant" should be construed to encompass both hydrophilic surfactants and lipophilic surfactants.

In construing the term "surfactant," the Court has considered the claim language and specification of the '625 Patent. (See D.I. 129, Ex. A, '625 Patent, col. 33, lns. 15-35, col. 8, ln. 58-col. 9, ln. 63, col. 12, lns. 42-48; D.I. 132 at A91, A110-111, A266, A496-501). Based on this review, the Court concludes that there is substantial support for Abbott's position. In relevant part, the specification provides:

The surfactant component may comprise (3.1) hydrophilic or (3.2) lipophilic surfactants, or mixtures thereof. (D.I. 129, Ex. A, '625 Patent, col. 9, lns. 42-44).

Compositions as defined under (A) above include systems comprising either a single surfactant or mixture of surfactants, e.g. comprising a first surfactant and one or more co-surfactants. Surfactant and co-surfactant combinations may be selected, e.g. from any of the surfactant types listed under (3.1.1) to (3.2.7) above [which includes lipophilic surfactants listed under (3.2.1) to (3.2.7)]. (D.I. 129, Ex. A, '625 Patent, col. 12, lns. 16-22).

Examples of suitable lipophilic surfactants for use as surfactant component are, e.g ... (D.I. 129, Ex. A, '625 Patent, col. 11, lns. 7-8).

Moreover the term "surfactant" as used in Claim 1 of the '625 Patent is not qualified in any way, as opposed to Claim 7 and the asserted claims of the '840 and '017 Patents, which require a hydrophilic surfactant. (D.I. 129, Ex. A, '625 Patent, Claim 7; D.I. 130, Ex. 3, '840 Patent, Claims 17-19, 22-24, 81-83, 86-88, Ex. 4, '017 Patent, Claims 13-15). Accordingly, the Court will construe the term "surfactant" to encompass both hydrophilic surfactants and lipophilic surfactants.
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A. Surfactant.

Broadly speaking (and with some discrete exceptions), a surfactant is any substance that, when added to a liquid, operates to reduce the liquid's surface tension to any degree. The question presented in this case is whether the term, as used in the 859 patent, has a more limited and functional definition. Polyclad says it does not and urges the court to adopt something akin to the broad definition set forth above or a similarly all-inclusive definition that one might find in almost any non-technical dictionary.

MacDermid, on the other hand, says that to those skilled in the relevant art, the word "surfactant" has a generally accepted meaning, and reliance upon a non-technical dictionary to ascertain that meaning would be inappropriate. It argues that while many additives of varying types will reduce the surface tension of a liquid, when the word "surfactant" is used in this particular field (and in industrial chemistry generally), it has a more focused (and widely understood) meaning. 1

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Accordingly, MacDermid urges the court to adopt a technical definition that specifically identifies several essential characteristics it says are shared by all industrial surfactants, and which are generally understood by those skilled in the relevant art to be possessed by industrial surfactants. Under MacDermid's proposed definition, a surfactant must, among other things, have an amphipathic structure, form micelles at sufficiently high concentrations, and adsorb or concentrate at phase interfaces. At a minimum, says MacDermid, the court should construe the term surfactant in a manner that, unlike Polyclad's proposed construction, adequately distinguishes between: (1) substances that are widely known and employed in the relevant field to dramatically reduce the surface tension of aqueous solutions; and (2) the universe of substances which, when added to an aqueous solution (in sufficiently high concentrations), will operate to lower the solution's surface tension to some measurable degree (including, for example, routine impurities or contaminants).

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1 For example, at the Markman hearing, coffee was repeatedly discussed as a substance that will reduce the surface tension of an aqueous solution. Ethanol is another example. Critically, however, neither works to dramatically reduce the surface tension when introduced in very low concentrations. Consequently, while both exhibit "surfactant-like" behavior in that they reduce the surface tension of an aqueous solution by some modest (though measurable) amount when added in sufficient quantities, neither falls within the scope of the term "surfactant" as it is used in the 859 patent.

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While both parties have presented plausible, well-supported arguments, the court concludes that the proper construction of the term lies closer to the position advocated by MacDermid. As used in the 859 patent, "surfactant" plainly has a meaning that is more focused than that ascribed to it in non-technical dictionaries, and more precise than a hyper technical construction that would include virtually any additive that has any propensity to lower the surface tension of any solution. See generally Bell Atlantic Network Service, Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 2001 WL 931103 at *6 (Fed. Cir. 2001) ("We have previously cautioned against the use of non-scientific dictionaries 'lest the dictionary definitions . . . be converted into technical terms of art having legal, not linguistic significance.'") (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Having reviewed the intrinsic evidence of record and having considered the expert testimony presented by the parties to inform its understanding of the field of chemistry as it relates to the printed circuit board manufacturing industry, the court concludes that the term "surfactant," as used in the 859 patent and as properly construed, means and would be understood by a person skilled in the relevant art to mean:

a substance that, when introduced into a liquid solution at comparatively low concentrations, dramatically reduces the surface tension of that solution or the interfacial tension between the solution and another surface. Typically, though not necessarily, surfactants have an amphipathic structure - that is, a hydrophobic tail and a hydrophilic head - and, at equilibrium, the concentration of the surfactant at a phase interface is greater than its concentration in the bulk of the solution. By way of example, when introduced at concentrations of less than one percent, "surfactants," as that term is used in the 859 patent, will reduce the surface tension of pure water (at room temperature) to at least 45 dynes/cm or less.

The essential characteristic of a surfactant, then, is its effect, at low concentrations, of dramatically reducing surface tension (i.e., by an amount substantially greater than would be expected based solely on its concentration) - a characteristic that is most typically the product of an amphipathic structure.
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1. "surfactant-based"

Claim 1 of the '226 patent recites a method of washing parts which includes a step of using "a cleaning fluid." '226 patent, col. 10, ll. 23-26. Claim 3 of the '226 patent, which is dependent upon Claim 1, describes "[t]he method of claim 1, wherein the cleaning liquid is surfactant-based." Id., col. 10, ll. 42-43. The parties agree that a surfactant is a surface active agent, or a substance that is capable of reducing the surface tension of a liquid in which it is dissolved. They differ, however, on what it means to be "surfactant-based." Plaintiff ChemFree argues it means "the cleaning fluid contains one or more surface active agents." Defendant argues it means that "the cleaning liquid is more than eighty percent surfactant."

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As discussed in the specification, prior art parts washers generally used a cleaning fluid composed of mineral spirits solvents to clean parts. Id., col. 1, ll. 19-48. Although using mineral spirits is an effective way to clean parts, there are many drawbacks to its use. Id., col. 1, ll. 28-30. For example, the use of mineral spirits poses safety and health concerns to users of parts washers. Id., col. 1, ll. 31-43. In addition, the use of mineral spirits creates disposal problems due to extensive governmental regulation. Id. col. 1, ll. 43-48. Thus, one of the aims of the parts washing patents, specifically the '226 patent, is to use a cleaning fluid solution that is not based on mineral spirits. Id. col. 1, ll. 58-61 ("There is, therefore, a need in the industry for a system which provides for parts washing and reduces environmental problems associated with mineral spirits as a cleaning (washing) component.").

As opposed to prior art cleaning fluids comprised of mineral spirits, the parts washing patents contemplate using a cleaning fluid solution comprised of surfactants instead. Id., col. 2, ll. 8-9. ("The cleaning fluid includes a surfactant that functions to remove organic waste from the parts being washed."); id., col. 3, ll. 25-26 ("An advantage of the parts washing system is that it does not employ a volatile and flammable cleaning fluid . . . ."). The specification does not, however, indicate that the surfactant portion of the cleaning fluid must constitute a certain portion or percent. 10 Rather, it merely indicates that surfactants are a substantial or significant ingredient of the contemplated cleaning solution. Id., col. 6, ll. 37-40 ("A suitable cleaning fluid 72, for example, is a mixture of pH neutral emulsifiers and surfactants containing no volatile organic compounds, phosphates, formaldehyde, biocides, or other toxic materials."); see also id., col. 2, ll. 8-9 ("The cleaning fluid includes a surfactant that functions to remove organic waste from the parts being washed.").

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10 Nor has J. Walter attempted to explain where its 80% figure comes from, other than to argue it is the "common and ordinary meaning" of the term.

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Instead of some kind of numerical quantification, it appears from the claims and specification that when the Applicant uses the phrase "surfactant-based," it is used in the sense that the cleaning fluid's active ingredient for cleaning and degreasing is a surfactant solution instead of a mineral spirits solution, much in the same way that a paint's designation as "water-based" or "oil-based" indicates that the paint's solvent (also known as the paint's vehicle) uses either water or oil. In other words, the "-based" designation here, as in the paint context, merely makes clear that the product uses one thing instead of another. The specification confirms this understanding. For example, it recounts a series of tests in which mineral spirits solvents are compared to surfactant-based solutions in order to determine the ability of surfactant-based solutions to clean and degrease parts. See generally id., col. 8, l. 37 - col. 9, l. 22. This demonstrates the Applicant's intent to use "surfactant-based" to distinguish between solutions which use mineral spirits as a cleaning agent and those which use surfactants as a cleaning agent.

The Court construes "surfactant-based" as "a cleaning fluid whose active cleaning agent is one or more surfactants."
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E. "surrounded by"

Claim 1 recites "[a] desiccant container comprising a desiccant material surrounded by a laminated, water vapor permeable desiccant packaging material." Multisorb contends that as written, the claim teaches that a container formed from the laminated packaging material surrounds the desiccant material. It urges, essentially, that the packaging material must be wrapped around the desiccant material, rather than encapsulating the desiccant material between the layers of the packaging material. The court does not agree.

The term "surrounded by" is not specially defined in Claim 1. Claim 1 teaches a desiccant container. The desiccant container comprises the desiccant material surrounded by the packaging material taught in the claim. The packaging material is multilayered. Multisorb urges that because it is multilayered, it cannot "surround" the desiccant material unless all layers wrap around it. There is, however, no concept of "wrapping around" suggested in the patent Further, the ordinary meaning of "surrounded by" does not exclude disposition between the layers of the packaging material. Surround is ordinarily defined as "encircle on all sides simultaneously; To confine on all sides so as to prevent escape..." Webster's II

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New Riverside University Dictionary. The desiccant material is surrounded by the packaging material as it is "secured within" or "encapsulated by" the packaging material, as described in the Background of the Invention and the Summary of the Invention. The specification is consistent with the ordinary meaning of "surround" as the desiccant material is confined on all sides or encircled on all sides by the packaging material when it is encapsulated between the layers of the packaging material.

The definition offered by Multisorb that all layers of the packaging material must be wrapped around the desiccant material is nonsensical. It reads into the claim a limitation as to the method by which the packaging material must be utilized to surround the desiccant. Nothing in the patent suggests this meaning of "surrounded by." Further, the result renders the patent inoperative as there would be no permeability. Therefore, we reject Multisorb's construction. Talbert Fuel Systems Patents Co. v. Unocal Corporation, 275 F.3d 1371 (Fed. Cir. 2002)(patent claim construction rendering invention inoperable viewed with extreme skepticism). The ordinary meaning of the term "surrounded by" controls. "Surrounded by" means "encircle on all sides" or "confined on all sides," for purposes of the '942 patent.
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B. Intrinsic Evidence
1. Language of the Claims

The plant and seed claims of the 236 patent consist of Claims 8-9 and 12-15. Claim 8, which is representative of claims 12-15, reads: 27

A plant which consists of the cells of claim 1 and which is susceptible to infection and transformation by Agrobacterium and capable of generation thereafter.

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27 Claim 9 claims "a seed of the plant of Claim 8."

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The wording of this claim is straightforward and precise. Simply put, Claim 8 purports to cover a plant which consists of the cells of Claim 1, subject to three further limitations. Specifically, the covered plants must be (1) susceptible to infection by Agrobacterium; and (2) susceptible to transformation by Agrobacterium and, after both of these events have occurred, (3) capable of regeneration. Given the agreement that the cells of Claim 1 include all plant cells - - including both monocots and dicots - - the plain language of Claim 8 means that the patentee is entitled to coverage of any plant that can be infected and transformed by Agrobacterium and is still capable of regeneration after these events have occurred. This construction, however, sheds little light on the true scope of these claims. It simply posits the following question: As of March 11, 1987, 28 which types of plants were susceptible to the specified biological manipulations by Agrobacterium and subsequently were still capable of regeneration? In an attempt to resolve this issue, the Court turns next to the written description.

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28 The plaintiffs filed the PCT application designating the United States on this date. At trial, PGS conceded in open court that it is the effective filing date for the 236 patent.

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2. Written Description

Unfortunately, the written description does little to resolve the meaning of the contested claims. The specification provides four examples: tobacco, tomato, potato and sugarbeet - - all of which are dicots. While the defendant vigorously argued both at trial and in its briefs that the lack of monocot examples in the specification compels the conclusion that "the plant and seed claims must be construed to [cover only] dicot plants and seeds," such suggestion is misplaced. While the inclusion of

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a working monocot example may have had considerable impact in allowing the Court to conclude that the plant and seed claims covered monocots, the lack of such example does not necessarily mean that the contested claims are limited only to dicots. It is well settled that a specification need not recite "every conceivable and possible future embodiment of [the] invention." SRI Int'l v. Matsushita Elec. Corp of America, 775 F.2d 1107, 1121 (Fed. Cir. 1985). Reading limitations into the claims from the specification is improper. See, e.g., Transmatic Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277-78 (Fed. Cir. 1995). While the Court does note that a significant portion of the plant kingdom, namely monocots, are not represented in the enumerated examples contained in the specification of the 236 patent, such omission is not necessarily determinative. The Court next turns to the prosecution history.

3. Prosecution History

The prosecution history reveals that numerous exchanges occurred between the patentees and the examiner on the subject of whether the plant and seed claims covered both monocots and dicots.

On April 27, 1989, the examiner rejected an initial set of consolidated claims directed at plant cells, plants and seeds because such claims were not enabled pursuant to 35 U.S.C. § 112. The examiner indicated that

> The disclosure is enabling only for claims limited to specific source cells or tissue of dicotyledonous plants in which transformation and regeneration has been shown . . . . In point of fact, there is a large body of evidence that regeneration can only be accomplished from cells or tissue derived from specific sources, such as immature embryos of leaf protoplasts, and with certain species and genotypes. Further, evidence exists that only certain dicotyledonous plants can be regenerated after plant cell/tissue transformation in which the end product is a fertile transformed plant capable of sexually transmitting the desired trait. Although gene transfer has been demonstrated with monocotyledonous plant protoplasts, there was at the time of filing, no report of plant regeneration from transformed monocot cells. Actually, to date there is no evidence that fertile transgenic plants can be regenerated in most agronomic monocots, as in the case of maize or rice . . . .
>
> See Plaintiffs' Exhibit 4, Tab 3, at 4-5 (internal cites omitted).

On August 17, 1990, after a series of exchanges with the examiner, the applicants separated the plant cell claims from the plant and seed claims. The revised plant and seed claims were now limited to those plants and seeds which are "susceptible of infection by Agrobacterium." See Plaintiffs' Trial Exhibit 4, Tab 12, at 2-4.

On November 19, 1990, the examiner rejected this new language for the plant and seed claims, indicating that it did not limit the claims to dicots. He repeated his assertion that the relevant scientific art did not demonstrate that the infection of monocots by Agrobacterium led to transformation. The examiner suggested that the rejection under § 112 would be obviated if the applicants limited "the claimed invention to plant cells and plant[s] which are capable of transformation by Agrobacterium and capable of regeneration." Plaintiffs' Trial Exhibit 4, Tab 13, at 3:15-19. On April 18, 1991, the applicants adopted the proposed language and the examiner subsequently withdrew his enablement rejection.

There can be little question from the exchanges between the examiner and the applicants that the issue of whether the plant and seed claims would cover both dicots and monocots arose on several occasions. The examiner's view was that, at the time the claims were being prosecuted, monocots were not susceptible to infection, transformation and regeneration. "Evidence exists that only certain dicotyledonous plants can be regenerated after plant cell/tissue transformation in which the end product is a fertile, transformed plant capable of sexually transmitting the desired trait." He was concerned that the plant and seed claims, as originally proposed, were not enabled for monocots such as corn. After several exchanges, the examiner did not require the applicants to limit their plant and seed claims to dicots. Instead, the modification limits the claim to only those plants "susceptible to infection and transformation by Agrobacterium and capable of regeneration thereafter." The intent of these modifications, however, is to limit the coverage of the issued claims to dicots.

While the intrinsic evidence indicates that this limitation was specifically added to exclude monocots, "it is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction . . . is not inconsistent with clearly expressed, plainly apposite and widely held understandings in the pertinent technical field." Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1308 (Fed. Cir. 1999). In this case, the Court had the benefit of hearing extensive testimony at trial concerning the technical capabilities and limitations in the art of plant transformation at the relevant time.

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C. Extrinsic Evidence

As discussed supra, a substantial portion of the testimony offered at trial was dedicated to establishing whether monocots could be transformed by Agrobacterium. As this Court has previously concluded, there is no evidence that a general methodology existed in 1987 by which a person skilled in the art could produce a transgenic monocot.

Further, the defendant offered evidence at trial that two of the plaintiffs' principal scientists. Dr. Leemans and Dr. Botterman, published articles indicating that monocots were not susceptible to Agrobacterium infection and transformation to insert a heterologous gene, such as the bar gene. For example, in 1987 Leemans co-authored a paper that stated "Agrobacterium-mediated transformation of [the] Graminae, including the important cereal crops, has not yet been achieved." Deblaere et al., Vectors for Cloning in Plant Cells, 153 Methods in Enzymology 277 (1987). Additionally, in 1990 - - three years after the 236 patent was filed - - Leemans and a co-author wrote

Most [genetically] engineered plants have been generated by infection with Agrobacterium tumefaciens, a plant pathogen[] causing tumorous crown galls. Agrobacterium tumefaciens is widely used because it is a very efficient and versatile vector to stably introduce genes into plants. However, Agrobacterium tumefaciens seems unsuccessful in the transformation of most monocotyledonous plants, especially of cereals.

M. Peferoen and J. Leemans, Engineering of Insect Resistant Plants with Bacillus turigiensis Crystal Protein Genes, Proceedings of the 6th International Symposium of Genetics of Industrial Microorganisms, at 844, Strasbourg, 1990. 29

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29 In its brief, the defendant cites numerous other articles co-authored by Leemans and/or Botterman that reach a similar conclusion. See Defendant's Initial Post-trial Brief at 10-11.

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The defendant also presented evidence that Leemans' conclusions concerning the inability of Agrobacterium tumefaciens to transform monocots were shared by the scientific community. In 1987, Dr. Goodman published an article in Science saying that

"although data have been cited that Agrobacterium can transfer T-DNA to monocotyledonous hosts, clear evidence of T-DNA integration exists only for asparagus and, even in that case, no transformed plants have been described. Because Agrobacterium tumefaciens does not induce crown galls on monocotyledonous plants, such as rice, corn and wheat, other methods of gene transfer are being developed for these important crops." Goodman et al., Gene Transfer in Crop Improvement, 236 Science 52 (1987).

Thus, the extrinsic evidence confirms what the intrinsic evidence suggests, as of the filing date of the 236 patent no methodology existed by which monocots could be infected and transformed by Agrobacterium to produce plants capable of regeneration. A person skilled in the art would have been aware of this limitation, as apparently Leemans and Botterman both were, and would understand the wording of the plant and seed claims to mean that they did not cover monocots such as corn.

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The '161 patent
The '161 patent "Abstract" states that "the present invention relates to metoprolol succinate, a new therapeutically active compound, and pharmaceutical preparations comprising this new compound."
Under the patent heading "Technical Field" the patent states that "the object of the present invention is to obtain a therapeutically active compound intended to be released close to or within the colon, and particularly to such active compounds which are soluble in the pH range 1 to 8" (emphasis added).
Under the heading "Description of the Present Invention" the patent states that

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"this compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, andl5 to 90% by weight of a water insoluble polymer selected from the group of quaternary ammonium substituted acrylic polymers.
...
When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered.
When administering, in order to achieve a steady blood plasma level of the therapeutically active compound, a split dose unit of the therapeutically active compound provided with a coating according to the present invention can be administered together with some particles/granules which are not coated. (emphasis added)

The sole claim of the '161 patent is "[a] 7 sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier."

7 The term "sustained release" was recently repositioned in the "claim" section of the '161 patent by the USPTO. The USPTO amended the patent to have the term follow the initial "a" in this claim sentence from following the second "a" as originally filed. The amendment was made at Astra's request.

For the purposes of their motion for summary judgment based on invalidity, Defendants agreed to the revised wording of the sole claim of the '161 patent. 8 Astra broadly construes the definitions of the terms used in this claim. Defendants disagree with Astra's definition of the term "sustained release." Astra contends that sustained release means dosage forms which, "upon ingestion, released active to achieve desired blood plasma levels and maintained relatively steady blood plasma levels for an extended period of time." (Pls.' Memo. in Opp. at 23.) Defendants assert that the term sustained release, as used in the mid 1980s by a person of ordinary skill in the art when this patent application was filed, was deemed interchangeable with the terms "extended release" and "controlled release."

8 The USPTO had not yet approved Astra's request to change the location in the claim of the term sustained release when the briefing of this motion was filed.

The term "sustained release" does not appear in the specification of the '161 patent. The invention described by the specification is a core of "active," metoprolol succinate, coated by an anionic polymer with the goal of releasing metoprolol succinate close to or within the colon. The specification also states that uncoated particles/granules of metoprolol succinate may be combined with metoprolol succinate "provided with a coating according to the present invention" (emphasis added) to achieve a steady blood plasma level of metoprolol succinate. This last specification clearly regards the invention as the coated metoprolol succinate. It does not state that the invention is the coated metoprolol succinate combined with uncoated metoprolol succinate to achieve a steady blood plasma level. Astra contends that the invention claimed in the '161 patent is this latter construction which Astra labels "sustained release."
In support of its construction of the term "sustained release," Astra offers the affidavit of its expert Gerald S. Brenner. In paragraph 35 of his affidavit, Brenner states that one skilled in the art in the mid 1980s would "generally have considered a sustained release dosage form one that initially (upon ingestion) releases active to achieve desired blood plasma levels and maintains relatively steady blood plasma levels of the active for an extended period of time." (Pls.' Opp'n Summ. J. Ex. A) In support of this statement Brenner's affidavit refers to three documents without identifying them or vouching for their use by experts in his field as reference tools. The three documents are excerpts from what appear to be pharmaceutical texts. I presume that these are treatises used in the field of pharmacology.
The first excerpt is from Robert E. Notari, Biopharmaceuticals and Clinical Pharmacokinetics, An Introduction (Marcel Dekker, Inc., 3rd ed. 1980). Notari discusses the term sustained release and states that

"general terms such as timed release, time release, extended action, or long-acting may or may not be meant to indicate that the formulation is a sustained release preparation. Unfortunately, there are no standard definitions or classifications. The following distinction will be used as a starting point, and later more precise terminology and definitions will be given to sustained release dosage forms."

Id. at 152. Notari then goes on to define the meaning of the terms "repeat- action tablets," "sustained release dosage forms,"

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and "prolonged-action preparations." He defines sustained action dosage forms as providing an "initial therapeutic dose that is available upon administration of the product followed by a gradual release of medication over a prolonged period of time." Id. He states that prolonged-action preparations provide the slow release of a drug and may differ from sustained release dosage only in that no initial dose in included in the prolonged-action formulation. Id.

Although Notari's definition of sustained release at first blush appears to support Astra's definition, Notari specifically notes that there were no standard definitions or classifications of dosage terms including sustained release. Rather, Notari's article was his attempt to create definitions that would presumably be adopted at some time in the future by a person skilled in the art. As a result, Notari's text does not support Astra's contention that sustained release had a specific meaning to one skilled in the art as of the effective date of the patent application. Instead, Notari's article establishes the opposite position; that in the mid 1980s there was no consistent interpretation of the term sustained release.

The second document relied on by Brenner is equivocal in supporting his definition of sustained release. That excerpt is from Howard C. Ansel, Introduction to Pharmaceutical Dosage Forms, (Lea & Febiger 1969). Ansel states that

some solid dosage forms are designed to release their medication to the body for absorption rapidly and completely; other products may be designed to release the drug slowly for more prolonged drug release and sustained drug action. The latter type of dosage form is commonly referred to by a designation such as a sustained-action, prolonged-action, sustained-release, prolonged-release, timed-release, extended-action, or extended-release tablet or capsule.

Id. at 274. Ansel then states that "most" sustained-action dosages are designed so that a single dosage provides the "immediate release of an amount of the drug that promptly produces the desired therapeutic effect and gradual and continual release of other amounts of drug to maintain this level of effect over an extended period...." Id. Ansel uses the term "most" which indicates that his definition is not universal to all sustained-action dosages. As quoted above, Ansel notes the term sustained release was also referred to as extended release, timed release, extended action among other terms. These terms interchangeably referred to dosages, which Notari highlighted in his treatise published ten years after Ansel's, that may not be an indication of sustained release as defined by Ansel because there were still no standard definitions of any of these terms in 1980.

Finally, the third treatise Brenner relies on for his definition of sustained release is Remington's Pharmaceutical Sciences (Mack Pub. Co., Arthur Osol ed. 1980). That treatise states that long-acting oral products have been described by a variety of terms. Id. at 1596. The treatise then proposes classifying long-acting products into the following three types: sustained release, prolonged release, and repeat action. Id. This treatise does not state that sustained release is defined similarly by those skilled in the art. To the contrary, it offers a definition that may be adopted at some time in the future by those skilled in the art.

The three treatises relied on by Astra and its expert Brenner are consistent only in that none of the treatises state that sustained release had a uniform definition used by those skilled in the art in the mid 1980s. At best these treatises offer definitions which may or may not have been uniformly adopted. What is clear is that sustained, extended, or timed release dosages were deemed to be dosages that released more slowly over time than immediate release dosages.

The prosecution history of the '161 patent also demonstrates that Astra's own definition of sustained release was not consistently maintained during the prosecution of the patent. As previously noted, the term sustained release does not appear in the specification of the patent. When originally filed, the claims of the patent were directed to metoprolol succinate and a "pharmaceutical composition, characterized in that the active compound is metoprolol succinate." (Defs.' Ex. Q at 145) The USPTO examiner rejected these claims as obvious over prior art. Id. at 167-169. Hassle (Astra) responded to the rejection with a declaration of Dr. John Anders Sandberg. Hassle represented that Sandberg's declaration showed that metoprolol succinate was "useful as a sustained release form of metoprolol." Id. at 174. Sandberg's declaration interchangeably used the terms extended release, sustained release, and controlled release in supporting the selection of metoprolol succinate. Id. at 181, 184, and 189. The examiner agreed to issue the '161 patent if the term sustained release was inserted into the claim. In his deposition for this case, Sandberg stated that he thought that controlled release, sustained release, and extended release dosages were essentially the same. (Defs.' Ex. V at 413) One of the named inventors of the '161 and '154 patents, Curt Appelgren, stated in his deposition that in 1983 the terms controlled release, extended release, and sustained release were use interchangeably. The other named inventor of the "161 and '154 patents, Eva Christina Eskilsson, stated in her deposition that sustained release could be the same as extended release, which could be a dosage form completely releasing an active drug from "one to many hours." (Defs.' Ex. T at 345)

Defendants have placed more treatises and articles into the record that state that sustained release, prolonged action, controlled release, extended action, and time release were all used interchangeably to describe preparations that release a drug over an extended period of time. (Defs.' Exs. AB, AC, and AD)

Astra itself uses the term "extended release" in their Complaints and various pleadings when they describe their drug

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Toprol-XL(R) which is the subject of this infringement action.
Based on the lack of a definition of sustained release in the '161 patent, the specification's statement that the "object of the present invention is to obtain a therapeutically active compound intended to be released close to or within the colon" and the extrinsic evidence offered by the parties, I conclude that sustained release simply refers to a dosage that is distinguished from immediate release in that it releases metoprolol succinate over a controlled or extended period of time close to or within the colon. Astra's definition requiring an immediate release is not supported by the specification. Astra's extrinsic evidence in the form of Brenner's affidavit "is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history" and is discounted. Phillips, 415 F.3d 1318. In addition, Brenner's definition is not even supported by the treatises he relies on in support of his position.
The specification itself states that if a steady blood plasma level of the therapeutically active compound is desired, an optional formulation of uncoated metoprolol succinate can be combined with metoprolol succinate with a coating according to the present invention. That statement, read in context of the entire patent, indicates that the invention of the '161 patent is a coated forms of metoprolol succinate that provides for a controlled or extended release of the drug; it is not a pharmaceutical composition that includes an immediate release of metoprolol succinate as Astra would define the term sustained release.
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The only differences between claim 1 of the '342 patent and claim 1 of the '303 patent is the inclusion of the phrase "sustained release" before each reference to "dental bleaching composition"; the substitution of the phrase "sustained release dental bleaching agent" for the phrase "dental bleaching composition" in paragraph (c); and the addition of the phrase "said sustained release dental bleaching agent remaining active during a substantial time while the dental tray is positioned over the patient's teeth surfaces" to paragraph (d).

The addition of the term "sustained release" does not alter the meaning of claim 1 such that the interpretation is any different than it is for claim 1 of the '303 patent, nor does the substitution in paragraph (c). The addition of the term "sustained release" simply emphasizes a feature inherent in the composition. Likewise, the additional language in paragraph (d) describes an inherent characteristic of a dental bleaching composition made with carboxypolymethylene. Therefore, as in the '303 patent, this court interprets "said matrix material including carboxypolymethylene in the range from about 3.5% to about 12% by weight of the sustained release dental bleaching composition" to mean that the composition used in dental bleaching in accordance with the claimed method contains from about 3.5% to about 12% by weight of carboxypolymethylene defined as a slightly acidic vinyl polymer with active carboxyl groups.
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ii. Swine infertility and respiratory syndrome virus, ATCC-VR2332

The parties also dispute the significance of the term "swine infertility and respiratory syndrome virus, ATCC-VR2332" located in the preamble of claim 1. In July 1991, made a deposit with the American Type Culture Collection in Rockville, Maryland. That deposit contained a strain of the PRRS virus. ATCC-VR2332 refers to the accession number assigned to the deposit. At the hearing, the court learned that the actual deposit was a strain of PRRS after its eighth passage. This particular isolate was the first PRRS virus to be deposited and Boehringer has described it as "'prototype' PRRS virus." Boehringer Finding No. 61.

Initially, Boehringer argues that as a matter of law, preamble language has no limiting effect. But, for reasons which I have already stated, Boehringer is wrong. See Bell Communications, supra. In what has become the seminal case on the import of preamble language, Bell Communications, the court interpreted a claim of a patent which recited in the preamble "a method for transmitting a packet over a system comprising a plurality of networks said packet including a source address and a destination address." Id. at 621. The claim then recited the steps of "assigning, by said source device, one of said trees to broadcast said packet and associating with said packet an identifier indicative one of said trees." Id. The court found that because the two steps of the claimed method referred to "said packet" and thereby "expressly incorporated by reference the preamble phrase 'said packet including a source address and a destination address," the claim should be limited to a method

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for transmitting packets that have both source and destination addresses. Id. While use of the word "said" does not have a "talismanic effect," Bell Communications typifies a situation where the court found that a preamble clearly defined an element of the claim. See ADC Telecommunications, Inc. v. Siecor, 954 F. Supp. 820, 829 (D. Del. 1997).

In the instant case, the claim speaks of a "a method of growing and isolating swine infertility and respiratory syndrome virus, ATCC-VR2332, which comprises inoculating the virus . . . ." Schering posits that the term, "the virus," refers to the "swine infertility and respiratory syndrome virus, ATCC-VR2332" because the only "antecedent" in the claim for the words "the virus" is that which is mentioned in the preamble. According to Schering, the claim drafter used both the preamble and the body of the claim to define its subject matter and therefore, Bell Communications compels this court to treat the preamble as a limitation.

There is no question that the preamble language "swine infertility and respiratory syndrome virus, ATCC-VR2332" "breathes life" into the body of the claim. A contrary conclusion would be incredible because without the preamble language, the claim would refer to any virus. Claim 1 clearly denotes "swine infertility and respiratory syndrome virus, ATCC-VR2332" as the virus upon which it focuses its attention. However, a larger question remains as to whether the language limits the patent to "virulent" viruses.

Boehringer argues that this language is "understood by those skilled in the art to be a name associated with the first PRRS virus isolated in North America, and therefore, representative of all PRRS viruses." Boehringer's Finding No. 130. Schering counters with two limitations. First, it posits, the language means the "virulent, disease-causing virus and etiological (causative) agent of [PRRS]." Schering Conclusion No. 7. Second, the phrase identifies the same strain of the PRRS virus deposited as ATCC-VR2332, thereby limiting the claim to a particular strain.

To this second limitation, Boehringer has not made a significant challenge. In its Reply Brief filed before the hearing, the plaintiff explained that it had used the ATCC accession number in the preamble to merely refer to the "strain" of virus represented by the deposit. See Plaintiff's Reply Br. at 5. Since its Reply Brief, Boehringer has made the following argument:
. At the time Boehringer made its deposit, the virus was the first of its kind.

. The deposit "is merely representative of the invention and permits the public to make and use the invention without having to 're-discover' the organism."

. Because the "inventors were the first ever to identify the viral agent associated with PRRS, it would be draconian to limit the scope of their claims to the exact form deposited at the ATCC, when that deposit was only made due to the necessity of . . ." the requirements of the patent act.

See Boehringer Finding No. 61.

I disagree. Regardless of when it was deposited, the ordinary meaning of the term refers to a specific strain of PRRS. Moreover, throughout the prosecution of its patent, the strain of virus was "essential" to the claimed invention. See Plaintiff's Ex. 30(B).

There is a more substantial debate over whether the patent is limited to cover "virulent" forms of the virus. The patent, itself, never uses the term virulence. For purposes of this analysis, to be virulent means to cause the symptoms of disease. But, being able to define the term "virulent" does not make claim interpretation any easier because the term, itself, is inexact. Virulence is not something that is turned off like a light switch, but instead, it is diminished over a continuum, as if it were controlled by a dimmer switch. After each passage in the attenuation process, the virus becomes more avirulent. Although the first passage is more virulent than the second, the second may still cause disease symptoms. Moreover, successful vaccine production does necessitate the creation of the most avirulent form of the virus because some level of virulence is needed to trigger the immune response. That immune response might not occur if the virus is too avirulent. Thus, vaccine producers must discover a point over the continuum where the most effective vaccine resides.

Notwithstanding that virulence operates on a continuum, Schering wants to argue that claim 1 of the '778 Patent only covers virulent forms of the virus. Boehringer argues that it covers both virulent and avirulent forms. Schering's vigorous defense of its position has less to do with sound claim interpretation, than with finding an interpretation that suits its strategy.

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Generally, in the game of patent construction, the patentee argues that the claim covers the world while the alleged infringer will argue that the claim extends to everything, but its continent. From Schering's virulence argument, it follows that Claim 1 would be limited to earlier passage levels that are "virulent." Because Schering's allegedly infringing vaccine production process starts at what it considers the later "avirulent" passage levels, its process would not infringe. This strategy was followed in its construction of "isolating." Under Schering's construction of isolating, claim 1 would be limited to the first passage level, thereby exempting any method used at subsequent passage levels. The "virulence" argument does not draw the line at the first level, but Schering believes that it only covers early passage levels. Metaphorically speaking, If Schering's process were California, its "isolating" argument would draw the line at New Jersey and its "virulence" argument would draw it at the Mississippi river. Both would have the same effect for Schering's purposes. Perhaps to Schering's chagrin, claim construction is not such a result oriented process.

Following Markman, the court should first turn to the claim language itself. That language says nothing about virulence, but merely describes a "method of growing and isolating swing infertility and respiratory syndrome virus, ATCC-VR2332 . . . ." In this analysis, it is of paramount importance to recognize something that Schering is not arguing. Interestingly, Schering does not limit the claim to a "method of growing and isolating" a virus that has characteristics identical to that which was actually deposited in Rockville. That deposit represents a Boehringer's strain of the PRRS at the eight passage. Even under Schering's construction of the claim, the patent would extend to passage levels beyond eight.

Neither party suggests that the ATCC-VR2332 should be read literally. If the language were read literally, the claim would be limited to the eighth passage. At the time Boehringer filed its application, using the accession number was the best way for the company to identify what it had found.

Both parties rely upon the fact that there is no modifying language before ATCC-VR2332. If the patent limited the claim to virulent viruses, Boehringer argues, the claim would have said as much. Conversely, Schering argues, that if the patent had not limited the claim, it would have included indicative language. Based upon the patent language itself, neither is convincing. The court must now turn to the specification.

Schering draws upon the following language from the patent specification to support its virulence argument. Under the heading "The Invention," the patent states:
A viral agent has been recovered from the tissue homogenate. The viral agent will [cause] a disease that mimics SIRS in piglets and pregnant sows. A deposit of the viral agent has been made on Jul. 18, 1991, with the American Type Culture Collection . . . under the accession number ATCC-VR2332.
'778 Patent, col. 2, lines 34-40.

Under the heading, "Viral Characteristics," the patent states:
ATCC-VR2332 consistently caused clinical signs and pulmonary lesions in gnotobiotic pigs . . . .
Id. at col. 4, lines 19-20.

Finally, under the section discussing "Modified Live Vaccine Preparation," the patent notes that:
The pigs vaccinated with the attenuated virus did not develop any symptoms of SIRS after challenge [injection] with ATCC VR2332 . . . whereas the control pigs did develop symptoms of SIRS.
Id. at col. 7, lines 9-12.

There is no question that the patent specification informs the reader that the virus deposited in Rockville is that which causes PRRS. If the deposit did not cause PRRS, it would have little utility. The existence of disease causing characteristics were crucial to obtaining a patent. Nevertheless, that the patent describes the deposit does little to advance Schering's argument. It would be different if Schering were claiming that the claims are limited to a virus identical to that which was deposited -- the PRRS virus in the eight passage. However the defendant does not propose that argument because the specification anticipates that the method will be performed at a number of passages and does not identify a stopping point.

In the patent, there is no discussion of either "virulence" or "final" passage levels. This further advances the court's belief that Schering's line drawing contributes little to the problem of reading the patent because the term is far too nebulous. The term is useless because virulence operates on a continuum. There can be obvious stopping point. Schering's interpretation only makes the claim language more confusing and difficult to follow. Under their interpretation, a reader would never know at which passage level it would be infringing.

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Finally, there is the prosecution history. Here Schering makes much of the fact that the Examiner rejected Boehringer's initial patent application because Boehringer had "provided insufficient evidence that the infectious agent [or the virus] is the etiological agent of mystery swine disease." Plaintiffs Ex. 30(E)(5) at 3 (copy of Office Action dated September 8, 1994). In a subsequent interview between the Patent Office and Boehringer, Boehringer agreed that it would "provide arguments and exhibits as set forth demonstrating ATCC-VR2332 is the agent which causes Mystery Swine Disease [PRRS]." Plaintiffs Ex. 30(E)(7). Boehringer submitted two published articles to the Examiner who eventually acknowledged that "applicants have provided [him] with copies of certain articles establishing that the infectious agent is the etiological agent of mystery swine disease." Plaintiffs Ex. 30(E)(8) at 2. Shortly thereafter, the patent issued. Based upon these facts, Schering has argued that Boehringer should be estopped from extending Claim 1 to avirulent viruses.

Initially, I note that Schering has misused patent law terms. While prosecution history is important to claim interpretation, the doctrine of "prosecution history estoppel" is a subsidiary of the doctrine of equivalents. Prosecution history estoppel operates within the universe of the doctrine of equivalents. It serves as a "check" on the application of the doctrine of equivalents so that patentees cannot regain, through an infringement action, subject matter which it relinquished during prosecution of the patent application in order to obtain allowance of the claims. Wang Laboratories v. Mitsubishi Electronics America, 103 F.3d 1571, 1577 (Fed. Cir. 1997); see also, Lockwood v. American Airlines, 107 F.3d 1565, 1997 WL 89016, *9 (Fed. Cir. 1997). At the claim interpretation stage, there is no concern with "regaining," because nothing has been defined yet. Nevertheless, prosecution history plays an important role in claim interpretation for many of the same reasons that it does in an equivalency analysis. The court may choose to limit claim language based upon the prosecution history.

However, in the instant case, Schering's argument is unavailing. As Schering has suggested, the Examiner found the utility of the patent to be dependent on the fact that the PRRS strain causes the disease, but there is nothing to indicate that the claims should be restricted to virulent strains. Boehringer did not surrender something to obtain the patent. Rather, it clarified that it is dealing with a strain of virus that causes PRRS. Thus the virus is a particular strain, but it is not necessarily virulent.

Thus, the preamble language, "swine infertility and respiratory syndrome virus, ATCC-VR2332" limits the claim to the PRRS strain deposited, but not to any level of virulence.
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B. "ATCC-VR2332"

The next claim term in dispute is "swine infertility and respiratory syndrome virus, ATCC- VR2332," which describes the virus employed in the method of claim 2. The term "ATCC- VR2332" derives simply from the deposit of the virus with the American Type Culture Collection (ATCC), which assigned the accession number 2332 to the virus upon receiving Boehringer's deposit. '778 patent, col. 2, ll. 37-40. The district court construed this term to mean the "specific strain of PRRS" deposited with the ATCC. Boehringer, 984 F. Supp. at 249. Schering argues that the term should be limited to disease-causing viruses only, which would exclude Schering's attenuated strain. Boehringer, in contrast, argues that the term should be expanded to cover "any PRRS virus," disease-causing or not, although Boehringer does not explain exactly what "any PRRS virus" would mean. We conclude that the district court again correctly chose the middle ground between the parties' contentions.

Schering's argument simply seeks to add another limitation ("disease-causing") to the claim, and such arguments rarely succeed. The district court's claim construction already specifies a disease-causing virus, since the viral strain deposited with the ATCC will indeed cause PRRS. Presumably, Schering seeks to add an explicit "disease-causing" limitation so that it may argue that a finding of equivalence would vitiate this limitation entirely. We are not persuaded. The specification, as Schering points out, does state that ATCC-VR2332 will cause disease when administered to pigs. See '778 patent, col. 4, ll. 19-21. However, the specification also refers to "modified or attenuated live ATCC-VR2332," id. at col. 5, l. 25, indicating that the term "ATCC-VR2332" does not by itself demand pathogenicity. At bottom, Schering's argument is based on a simple fallacy: given the premise that all PRRS is caused by "ATCC-VR332," all "ATCC-VR2332" must therefore cause PRRS. Because such an argument is logically unsound, the district court correctly rejected Schering's attempt to add an additional limitation to the claim.

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Boehringer, on the other hand, urges that the district court erred by construing "ATCC- VR2332" too narrowly. n1 The district court construed the term to mean the particular strain of PRRS virus that Boehringer deposited with the ATCC, Boehringer, 984 F. Supp. at 252, although the district court did not explain exactly what properties must be shown to establish that an accused virus meets this definition. Boehringer argues that this construction was erroneous, and that the term "ATCC-VR2332" should be understood as a "prototype" or "generic" term for all PRRS viruses, rather than as a reference to the deposited strain.

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n1 Boehringer based its cross-appeal on the district court's claim construction ruling and associated summary judgment order--an order which did not address the "ATCC-VR2332" limitation. Upon Schering's motion to dismiss the cross-appeal, Boehringer articulated a new rationale for its cross- appeal, arguing that the scope of the district court's injunction (and thus of Boehringer's rights) was limited by its erroneously narrow claim construction. While Boehringer's case for cross-appealability appears marginal, we decline to address the propriety of the cross-appeal. Boehringer was, of course, free to advance its rejected claim construction arguments as alternative grounds for affirmance. United States v. Am. Ry. Exp. Co., 265 U.S. 425, 435, 68 L. Ed. 1087, 44 S. Ct. 560 (1924). "Cross-appeals for the sole purpose of making an argument in support of the judgment are worse than unnecessary. They disrupt the briefing schedule, increasing from three to four the number of briefs, and they make the case less readily understandable to the judges. The arguments will be distributed over more papers, which also tend to be longer. Unless a party requests the alteration of the judgment in its favor, it should not file a notice of appeal." Jordan v. Duff & Phelps, Inc., 815 F.2d 429, 439 (7th Cir. 1987). These comments are doubly appropriate when parties overlay their dispute with a further quarrel regarding the propriety of a cross-appeal.

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We find Boehringer's arguments no more persuasive than Schering's on this point. Boehringer chose to claim its virus using the term "ATCC-VR2332," a term on its face referring to a particular ATCC deposit. Boehringer did not use the broader term "PRRS virus," nor did Boehringer attempt to claim the virus in terms of the more general functional and structural properties disclosed by the specification. Boehringer did not choose to define the term "ATCC-VR2332" in the specification, nor did Boehringer state that ATCC-VR2332 was a "generic" or "prototype" virus, nor did Boehringer assert that viruses related to but not identical to the isolated strain were within the scope of the invention. These choices must be held against it. We therefore conclude that the district court properly construed "ATCC-VR2332" to refer to the strain of virus deposited with the ATCC.
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3.

The third disputed phrase within the claim is "said composition exhibiting synergistic anti-proliferative activity against at least one form of cancer." "[S]aid composition" refers to the preceding "pharmaceutical composition comprising a synergistic combination of at least two compounds consisting of a limonoid, a flavonoid and a tocotrienol . . ." SourceOne proposes reading the disputed phrase as "the combination of two or more substances preventing or inhibiting the development of at least one form of cancer to a greater degree than would the same amount of any one of the individual substances" (SourceOne's Br. at 18). KGK proposes construing the phrase as "said combination of two or more substances prevents or inhibits transformation of preneoplastic cells to tumor cells, or tumor cell proliferation, invasion or metastasis; and an amount of the combination causes a greater effect than is caused by the same amount of any individual substance" (KGK's Br. at 23).

First, we address the disputed word "cancer," which appears in the claim for the second time. "[T]he same word appearing in the same claimshould be interpreted consistently." Acromed Corp. v. Sofamor Danek Group, Inc., 253 F.3d 1371, 1382 (Fed. Cir. 2001) (quoting Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1345 (Fed. Cir. 1998)); see also Phillips, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims."). Consistent with our construction of the previous phrase, we conclude that the word "cancer" requires no construction.

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Next, we look at each party's respective proposal to construe "exhibiting synergistic anti-proliferative activity." Both parties agree that the claim is limited to a combination of two or more substances that prevent or inhibit cancer. Their proposals differ, however, in that SourceOne maintains that the combination must "inhibit[] or prevent[]" cancer "to a greater degree" than an individual substance, while KGK proposes that the combination must simply "cause[] a greater effect" on cancer than an individual substance. KGK's construction is much broader because it could refer to any effect on cancer rather than the effect of preventing and inhibitingcancer. KGK's construction would impermissibly broaden the meaning of the claim beyond its stated limitation to prevent or inhibit cancer. Thus, we adopt the more accurate language in SourceOne's proposal, and we construe the phrase to mean "said combination of two or more substances preventing or inhibiting at least one form of cancer to a greater degree than would a same amount of any one of the individual substances."
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Thus, to escape the problem of substantially overlapping subject matter, GSK emphasized that the possible point of patentable distinction is the '352 and '552 claims' "synergistically effective amount" limitation. The corresponding limitation in Crowley is 20 mg to 500 mg of potassium clavulanate. The district court found the term "synergistically effective amount of clavulanic acid" ambiguous. Relying on a definition in the specification to resolve the ambiguity, the district court construed the term to mean 50 mg to 500 mg. The district court buttressed this conclusion with its finding that Geneva's two experts, Drs. Sanders and Benet, were more credible than GSK's expert, Dr. Schofield. Based on that construction, the district court held that the '352 and '552 patents are invalid for nonstatutory double patenting over the Crowley patent.

Our predecessor court has stated that "effective amount" is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation. In re Halleck, 57 C.C.P.A. 954, 422 F.2d 911, 914 (CCPA 1970). By its terms, a "synergistically effective amount" is a functional limitation. As explained in In re Swinehart, 58 C.C.P.A. 1027, 439 F.2d 210, 213 (CCPA 1971), a functional limitation covers all embodiments performing the recited function. Thus, this claim term should not be limited to the disclosed dosage range of 50 mg to 500 mg but instead should encompass any dosage amount that can achieve therapeutic synergy.

This construction yields no patentable distinction if the covered amounts nearly or completely encompass Crowley's disclosed range of 20 mg to 500 mg. To avoid invalidity, GSK seeks to read more into these claim terms to make the dosage range depend on the particular antibiotic and bacteria. According to GSK, a formulation falls outside the scope of the claims if a given antibiotic, bacteria, and disease combination provides no synergy.

This reading of the claim is indefinite. A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not. See 35 U.S.C. § 112 (2000). Here, "synergy" refers to activity against bacteria that the claims do not identify. By GSK's proposed construction, a formulation (including AUGMENTIN (R)) might infringe or not depending on its usage in changing circumstances. In other words, a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis. Thus, one of skill would not know from one bacterium to the next whether a particular composition standing alone is within the claim scope or not. That is the epitome of indefiniteness. This court therefore rejects this proposed construction.

The term "synergistically effective amount" must mean any amount that is synergistic against any bacteria. The fact that the same dosage amount does not yield synergy under other circumstances is irrelevant; once a particular amount yields synergy under any circumstance, that amount is "synergistically effective." This construction is almost certainly broader than that of the district court and encompasses Crowley's corresponding "20 mg to 500 mg" limitation. There is no reason to believe that a bacterium providing synergy could not be found for any and all amounts within, and even outside, the range of 50 mg to 500 mg disclosed in the '352 and '552 patents and adopted by the district court.

This broader construction strengthens the district court's conclusion that the '352 and '552 claims are invalid for nonstatutory double patenting over the Crowley patent. The '352 and '552 patents claim subject matter that encompasses a substantial part of the subject matter of the Crowley claim. The '352 and '552 claims are thus generic to a substantial part of the scope of the Crowley claim. This genus-species relationship makes the claims patentably indistinct, because the earlier species within the

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Crowley claim anticipates the later genus of the '352 and '552 claims.

The district court properly held that the '352 and '552 patents are invalid.
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A.

The language of a claim provides the starting point in a claim construction analysis. See Phonometrics, Inc. v. Northern Telecom Inc., 133 F.3d 1459, 1464 (Fed. Cir. 1998); Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998); see also Thermalloy, Inc. v. Aavid Eng'g, Inc., 121 F.3d 691, 693 (Fed. Cir. 1997) ("Throughout the interpretation process, the focus remains on the meaning of claim language."). In this case, the 365 Patent claims:

[a] process for ameliorating an undesirable anxiety state in a mammal comprising systemic administration to the mammal of an effective but non-toxic anxiolytic dose of [the 6-hydroxy-metabolite or BMY 28674] 5 or a pharmaceutically acceptable acid addition salt or hydrate thereof.

365 Patent, at col. 16.

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5 The claim uses the term "6-hydroxy-8-[4-[4-(2-pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione," which is the complete formulation of the chemical compound.

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The claim does not state that it covers the systemic administration of "buspirone" or of any "prodrug" of the 6-hydroxy-metabolite. The 6-hydroxy-metabolite is a distinct chemical compound from buspirone, and it would be incorrect to refer to a prodrug by the name of one of the metabolites it produces in the human body. 6 Indeed, the 365 Patent carefully distinguishes between the two throughout the entire specification, sometimes producing graphs of levels of one in the bloodstream as a function of dosages of the other, and sometimes recommending ways of using one so as to favor production of the other. See, e.g., 365 Patent, at cols. 1-2, 3-4, 5-7, 8-9, 13. Thus, on its face, the 365 Patent does not extend to the systemic administration of buspirone.

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6 Buspirone has the structure of 8-[4-[4-(2-pyrimidinyl)-1-piperazinyl]-butyl]-8-azaspiro[4.5]decane-7,9-dione, whereas the 6-hydroxy-metabolite has the structure of 6-hydroxy-8- [4-[4-(2-pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione.

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The claim also refers to systemic administration of a "dose" of the metabolite. Although the term "dose" can sometimes be used simply to mean "quantity," its primary meaning, as both parties agree, is "the measured quantity of a medicine or other therapeutic agent to be taken at one time or in a period of time." Webster's Third New International Dictionary 676 (1993) (emphasis added); Stedman's Medical Dictionary (26th ed. 1995) ("The quantity of a drug or other remedy to be taken or applied all at one time or in fractional amounts within a given period."). The 365 Patent consistently uses the word "dose" to refer to an externally-measured amount of a chemical, which is to be ingested or administered into the body at one time, and "blood level" to refer to the changing amounts of a substance in the bloodstream. See, e.g., 365 Patent, at cols. 2, 7, 8-9, 10 & figs. 3-5 (discussing, among other things, levels of the 6-hydroxy-metabolite in the bloodstream as a function of time, and after "multiple doses of oral buspirone"). This distinction in terminology makes sense, given the ordinary definition of "dose." The idea of a "dose" as a quantity that is "taken at one time" has a clear meaning in reference to an externally-measured amount of a substance that is to be ingested or administered into the body all at once, but would have no precise meaning if used to refer to in vivo levels in the bloodstream, which are constantly changing. See, e.g., 365 Patent figs. 3-5 (presenting graph of "blood levels" of buspirone and its metabolites over time as a function of "doses" of buspirone taken at

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daily intervals).

Thus, as used in the 365 Patent, the phrase "systemic administration to the mammal of an effective but non-toxic anxiolytic dose of the 6-hydroxy-metabolite" refers to the administration of an externally-measured quantity of the metabolite into the body, and not to the administration of a dose of buspirone into the body, which, in turn, produces variable and changing levels (not doses) of the metabolite in the bloodstream. See 365 Patent, at col. 16. The language of the claim does not support Bristol-Myers's construction.

B.

Bristol-Myers argues that this language must nevertheless be read in light of the patent specification, which states, at one point that:

> Systemic administration may also be realized by a second method of achieving effective anxiolytic blood levels of [the 6-hydroxy-metabolite] which is to orally administer a precursor form of [the 6-hydroxy-metabolite]. Such prodrug forms would be administered in dosage amounts that would produce effective anxiolytic effects without causing harmful or untoward side-effects. That is, systemic administration of [the 6-hydroxy-metabolite] may be accomplished by oral administration of a precursor or prodrug form of [the 6-hydroxy-metabolite], e.g., buspirone, to mammals.

365 Patent, at cols. 11-12. Bristol-Myers adds, correctly, that "[a] patentee may choose to be his own lexicographer, and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." See Vitronics, 90 F.3d at 1582 (citing Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996)). In Bristol-Myers's view, the specification language provides a definition of the term "systemic administration" as including any administration of buspirone that produces an effective but non-toxic anxiolytic amount of the 6-hydroxy-metabolite in the bloodstream.

The specification does not support Bristol-Myers's interpretation. As Bristol-Myers agrees, the term "systemic administration" has a common and well-understood meaning in the medical community. (See Bristol-Myers's Br. at 17.) It refers to administration of a medicine throughout the patient's system, as through introduction into the bloodstream, and as opposed to administration only to a local area of the body. See Declaration of James Barbee, M.D. dated Nov. 19, 2001, at P 8; see also Stedman's Medical Dictionary (26th ed. 1995) (defining "systemic" as "relating to a system; specifically somatic, relating to the entire organism as distinguished from any of its individual parts"). The term "systemic administration" should maintain this meaning in the 365 Patent because patent law instructs that technical words appearing in patents should be presumed to be used, and to be intended to be understood, as they would be by persons experienced in the field of the invention. See, e.g., Talbert Fuel Sys. Patents Co. v. Unocal Corp., 275 F.3d 1371, 1375 (Fed. Cir. 2002); Hoechst Celanese Corp., 78 F.3d at 1578.

The language that Bristol-Myers cites does not provide a special definition of the term or use it in any different way. Rather, it assumes the ordinary meaning, and relies on it to assert that the systemic administration of the 6-hydroxy-metabolite can be effected or achieved by oral administration of a prodrug such as buspirone. This is a statement about cause and effect, not a definition. Put simply, the specification says that one way of getting the 6-hydroxy-metabolite into the entire body through the bloodstream is to administer oral doses of buspirone to a patient -- a proposition that is undisputed among the parties. The specification does not say that the phrase "systemic administration" of a dose of the 6-hydroxy-metabolite means systemic administration of either a dose of the 6-hydroxy-metabolite or a dose of buspirone. Bristol-Myers attempts to claim that "systemic administration" is used in a specialized way in the 365 Patent, when the specification indicates no such specialized meaning.

The language of the specification must also be read in context. To the degree that it identifies a use of buspirone, the language appears as the introduction to a series of paragraphs in which Bristol-Myers tries to distinguish this use from those that appear in the FDA-approved labeling instructions for Buspar(R). The very next sentence says: "However, this method of systemic introduction of [the 6-hydroxy-metabolite] improves upon and differs from the known standard method of oral administration of buspirone." Id. at col. 12 (emphases added). The specification then outlines the purported differences between the methods and states that the new method is "in contradiction to currently accepted methods of administration that are directed to maximizing blood levels of unchanged buspirone"; and is "directly counter to the past method of orally administering buspirone." Id. (emphases added). To the degree that the specification refers to any novel use of buspirone,

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the specification is thus clear that the use in question is not the one that appears in the FDA-labeling instructions for Buspar(R).

Finally, as described above, the same specification was used for four separate patent applications, including two that explicitly claim a method of using buspirone. The two Improved Method Applications were rejected by the Patent Office. It would be remarkable if the same specification was attempting to convey that the term "systemic administration . . . of an effective . . . dose of [the 6-hydroxy-metabolite]" was Bristol-Myers's specialized way of describing the administration of buspirone when that definition would only be needed in two of the patents Bristol-Myers was seeking and when the other two explicitly used the word "buspirone" to claim an improved method of using buspirone.
C.

The third source of evidence for claim construction is the prosecution history of a patent. Facts from a prosecution history can be so critical to claim construction that they can trump otherwise clear language in a claim or specification. See, e.g., Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 1392 (Fed. Cir. 2001) ("Even where the ordinary meaning of the claim is clear, it is well-established that 'the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.'") (quoting Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995)); see also Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1325 (Fed. Cir. 2002).

In this case, the prosecution history leaves no doubt that the 365 Patent does not cover the use of buspirone. Bristol-Myers argues that the prosecution history, when viewed as a whole, reveals a persistent series of attempts to obtain a patent that extends to uses of buspirone. The relevance of a prosecution history to claim construction is not, however, to determine what coverage the patent applicant would have wanted to obtain but rather whether, in order to prosecute the patent that it actually did obtain, the applicant made definitive statements or amendments that disclaimed or disavowed any subject matter. See, e.g., Rheox, 276 F.3d at 1325-26; Digital Biometrics, 149 F.3d at 1347-48.

Use of this test serves an important public policy: the public and competitors have a right to rely on definitive statements made during prosecution history. See Digital Biometrics, 149 F.3d at 1347; Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995). There is also an equitable dimension to the test: it prevents applicants from construing claims more narrowly in order to obtain their allowance and then more broadly against accused infringers. See Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1379 (Fed. Cir. 1998). To that end, the prosecution history generally limits the interpretation of claim terms so as to exclude any interpretation that, based on the totality of the prosecution history, the patentee relinquished. See, e.g., Rheox, 276 F.3d at 1325.

i.

In this case, Bristol-Myers argues that the prosecution history of the 365 Patent supports its claim that the Patent covers both (i) certain uses of the 6-hydroxy-metabolite to treat anxiety and (ii) any uses of buspirone that favor production of non-toxic but anxiolytically effective levels of the 6-hydroxy-metabolite in the bloodstream. The very first Application that Bristol-Myers filed based on its new research into the anxiolytic potential of the 6-hydroxy-metabolite indisputedly covered both of these methods-of-use claims. This was the '842 Application, which was filed on August 5, 1999 and claimed, in relevant part,

> [a] process for ameliorating an undesirable anxiety state in a mammal comprising systemic administration to the mammal of an effective but non-toxic anxiolytic dose of [the 6-hydroxy-metabolite] or a . . . prodrug . . . thereof.

'842 Application, at 12. By claiming the systemic administration of specified doses of the 6-hydroxy-metabolite or a prodrug thereof, when buspirone is indisputedly a prodrug of the 6-hydroxy-metabolite, Bristol-Myers clearly applied for a patent covering the disputed uses of buspirone. However, any reasonable view of the subsequent history indicates that Bristol-Myers gave up a claim to the disputed uses of buspirone.

The '842 Application is the parent of the Application that finally resulted in the 365 Patent. When Bristol-Myers filed the '842 Application, Bristol-Myers applied to make it special and sought to expedite its processing. However, one condition on this kind of processing is that an application be limited to a single invention, see M.P.E.P. tit. VIII, § 708.02, and the Patent Officer found that the Application described two patentably distinct method-of-use inventions, one related to the "6-hydroxy-metabolite of Buspirone" and one related to "Buspirone itself." See Patent Office Action on '842 Application, at 2.

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Bristol-Myers was thus forced to elect between the two uses if it hoped to obtain expedited processing, and Bristol-Myers chose to pursue a patent limited to uses of buspirone in the '842 Application. See Election Letter 1.

On December 13, 1999, the Patent Officer rejected this narrowed Application pursuant to Sections 102(b) and 103(a) of 35 United States Code because such uses of buspirone were covered by the on sale bar in view of the prior years of Buspar(R) sales, and were obvious in light of the prior art of buspirone use. See Patent Office Action on '842 Application, at 2-4. This was the same Patent Officer who ultimately approved the final 365 Patent, and the Patent Officer never explicitly retracted these views. Thus, it is plain that the Patent Officer was unwilling to grant Bristol-Myers a patent extending to uses of buspirone.

ii.

Bristol-Myers's actions in response to the Patent Officer's rejection of the narrowed '842 Application on December 13, 1999 provide clear evidence for Mylan's and Watson's construction of the 365 Patent. In rejecting the narrowed '842 Application, the Patent Officer indicated that Bristol-Myers was still free to file "[a] divisional application . . . under 35 U.S.C. § 121 on the non-elected 6-hydroxy metabolite." Patent Office Action on '842 Application, at 1 (emphasis added.) On January 18, 2000, Bristol-Myers filed such a divisional application (the '161 Divisional Application), and Bristol-Myers generated its claim language by amending the original language from claim one of the '842 Application to delete the term "prodrug," which had clearly referred to buspirone. The resulting claim language, which is precisely the same language found in the 365 Patent, was first presented to the Patent Officer in the '161 Divisional Application. The 365 Patent application was also a continuation-in-part of the '161 Divisional Application, and the prosecution history of this Application thus has bearing on the present claim construction analysis. See, e.g., Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc., 248 F.3d 1303, 1315 (Fed. Cir. 2001) ("The prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit.") (collecting cases).

Bristol-Myers argues that its deletion of the word "prodrug" did not change the meaning of this claim language because the word "prodrug" is superfluous in light of Bristol-Myers's proposed definition of "systemic administration" from the specification. As discussed above, however, the specification does not contain a new definition of "systemic administration." Morever, Bristol-Myers's detailed and explicit actions in filing a divisional application and amending this language, just after the Patent Officer's rejection of the narrowed '842 Application, would make no sense if the amendment were superfluous.

Bristol-Myers's position is also inconsistent with the positions it took before the Patent Officer. In filing the '161 Divisional Application, Bristol-Myers told the Patent Officer that "amendment of the claim has been done in order to delete the claimed subject matter contained in the pending ['842 Application',] and that "this claim amendment elects the non-elected claimed subject matter of the parent ['842 Application.]" Preliminary Amendment at 1. Bristol-Myers's proposed construction would, however, reclaim that subject matter. The Patent Officer had also clearly indicated to Bristol-Myers that the original '842 Application contained two patentably distinct inventions.

Moreover, Bristol-Myers filed the '161 Divisional Application pursuant to 35 U.S.C. § 121. Section 121 is entitled "divisional applications" and states, in relevant part, that "if two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." 35 U.S.C. § 121. In construing this provision, the Court of Appeals for the Federal Circuit has held that:

Consonance requires that the line of demarcation between the "independent and distinct inventions" that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement.

Gerber v. Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990). The fact that Bristol-Myers obtained the 365 Patent in a continuation-in-part of the '161 Divisional Application, which contained the exact same claim language as the 365 Patent, strongly indicates that the 365 Patent claims a single invention directed to uses of doses of the 6-hydroxy-metabolite to treat anxiety.

Finally, any reasonable view of the prosecution history indicates that when Bristol-Myers filed its four patent applications on June 6, 2000, two of those applications -- the Improved Method Applications -- contained amended claim language

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explicitly using the word "buspirone" in order to claim certain limited uses of buspirone, while the other two -- the Non-Elected Subject Matter Applications -- omitted all explicit reference to the drug in order to distinguish the claim from the elected method of using buspirone that had been pursued in the '842 Application. It was one of the Non-Elected Subject Matter Applications -- the '221 CIP Application -- which used the same language as the '161 Divisional Application, and which did not refer at all to a use of the "prodrug," or "buspirone," that resulted in the 365 Patent.

In light of these facts, Bristol-Myers's declarations and amendments clearly narrowed the Application to uses of the 6-hydroxy-metabolite. See, e.g., Rheox, 276 F.3d at 1325; Spectrum Int'l, 164 F.3d at 1378.

iii.

Bristol-Myers argues that there is another part of the prosecution history that supports its reading of the 365 Patent as covering uses of buspirone. In particular, as Bristol-Myers correctly points out, it submitted a document, which it entitled the "Preliminary Communication," as part of its '161 Divisional Application, which stated in no uncertain terms that omission of the word "prodrug" was not meant to exclude uses of buspirone that result in systemic administration of the 6-hydroxy-metabolite. The Preliminary Communication also presented a number of arguments to the effect that Bristol-Myers's amendments in the '161 Divisional Application did not change the scope of the claim. 7

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7 The significance that Bristol-Myers places on the Preliminary Communication in this litigation is somewhat undercut by the fact that it was not even disclosed in the papers on the preliminary injunction in the case before the District Court for the District of Columbia, and was only brought to that court's attention at oral argument of that motion. See Mylan Pharm., Inc. v. Thompson, 139 F. Supp. 2d at 26.

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However, Bristol-Myers did not change the scope of the '161 Divisional Application by filing the Preliminary Communication. The Preliminary Communication was not and did not purport to be a formal amendment of the claim language. Bristol-Myers asked the Patent Officer not to act on the '161 Divisional Application until receiving the Preliminary Communication, but the document was not a required document. Rather, Bristol-Myers used the Preliminary Communication to present the Patent Officer with a series of legal arguments to the effect that its actions in filing the '161 Divisional Application and dropping the word "prodrug" from the original '842 Application did not change the meaning of the claim. Whether this is true is a matter of law, however, and, for the reasons discussed above, Bristol-Myers's amendments and conduct did limit the scope of the '161 Divisional Application.

The Preliminary Communication also presented statements concerning what Bristol-Myers meant to do when it dropped the word "prodrug" from the original '842 Application. The use of prosecution history in a claim construction analysis is not to uncover subjective intent on the part of an applicant, however, but rather to ensure that the public, including an applicant's competitors, may safely rely on the fact that an applicant will be bound by any definitive statements or amendments made to narrow a claim. See, e.g., See, e.g., Rheox, 276 F.3d at 1325; Spectrum Int'l, 164 F.3d at 1378.

Under this test, it is highly relevant that Bristol-Myers explicitly disclaimed uses of buspirone in filing the '161 Divisional Application, that Bristol-Myers did so in order to distinguish a method of using buspirone that the Patent Officer had deemed unpatentable, and that Bristol-Myers obtained the 365 Patent as the continuation-in-part of a divisional application that would have been reasonably understood by all relevant parties and the public to be limited to a single invention comprised of a method of using the 6-hydroxy-metabolite. It is also highly relevant that Bristol-Myers never formally amended the claim in order to broaden its scope, and that Bristol-Myers obtained expedited processing of the 365 Patent, which is a process limited to applications directed to a single invention. It is not relevant, in light of these facts, that Bristol-Myers may have desired to maintain coverage of some uses of buspirone or may have argued that the claim language had this scope.

iv.

Further evidence in favor of Mylan's and Watson's claim construction derives from the way the Patent Officer handled

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Bristol-Myers's two Improved Methods Applications. These Applications were explicitly directed to the purportedly new and improved methods of using buspirone that its new research into the 6-hydroxy-metabolite recommended, and which purportedly differed from the uses indicated in the FDA-labeling instructions for Buspar(R). The Patent Officer nevertheless rejected these Applications, explaining that (i) the Applications claimed inventions that were identical or overlapping in scope with the prior art of buspirone use identified in the Buspar(R) labeling; (ii) these patents were in violation of an on sale bar, given the prior years of Buspar(R) sales; and (iii) these uses were obvious from, or anticipated by, the prior art, because use of buspirone inherently produces in vivo the 6-hydroxy-metabolite. See Patent Office Action on '220 CIP Application, at 3-5; Patent Office Action on '223 CIP Application, at 3-5.

The Patent Officer rejected these Applications on September 8, 2000, well after receiving the Preliminary Communication, which was filed on July 18, 2000. Therefore, even after receiving the Preliminary Communication, the Patent Officer was unwilling to grant Bristol-Myers a patent directed at even those purportedly new methods of using buspirone that allegedly differed from the ones described in the FDA-labeling instructions for Buspar(R).

v.

In sum, every time Bristol-Myers explicitly claimed a use of "buspirone" or a "prodrug" of the 6-hydroxy-metabolite, the application was rejected. Bristol-Myers only obtained the 365 Patent after omitting all references in the claim to "buspirone" and any "prodrug," and after making express declarations that the amendments acted to exclude uses of buspirone. Viewed in its totality, this is a case where the prosecution history establishes beyond doubt that Bristol-Myers gave up a claim covering the use of buspirone in order to obtain a patent covering a method of using the 6-hydroxy-metabolite, and where, accordingly, Bristol-Myers cannot now reasonably assert a claim for the use of buspirone. See, e.g., Rheox, 276 F.3d at 1325; Spectrum Int'l, 164 F.3d at 1378-79; Ahlstrom Machinery, Inc. v. Clement, 13 F. Supp. 2d 45, 48 n.2 (D.D.C. 1998), aff'd sub nom. Kamyr, Inc. v. Clement, 217 F.3d 860 (Fed. Cir. 1999) (per curiam). Hence, the 365 Patent does not cover any uses of buspirone.
IV.

In any event, Mylan and Watson correctly argue that the 365 Patent would be invalid if construed to cover the use of buspirone, as Bristol-Myers contends. Mylan and Watson argue, more specifically, that the 365 Patent, so construed, would violate 35 U.S.C. § 102(b), which renders unpatentable any invention that "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ." Id. If Bristol-Myers's proposed construction would render the 365 Patent invalid, this fact would provide an additional reason to reject that construction. See, e.g., Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed. Cir. 1999) ("Claims are not properly construed to have a meaning or scope that would lead to their invalidity for failure to satisfy the requirements of patentability.").
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"Synthetic"

The parties and the Court agree that this term, which appears in Claim 1 of the '623 Patent and Claim 9 of the '156 Patent, means "outside a cell body."
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F. "tablet"

Claim 15 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

The composition according to claim 1, under the form of a tablet. ('670 patent, col. 10, ll. 46-47 (emphasis added).)

1. The Parties' Proposed Constructions

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Abbott proposes that I construe the term "tablet" to mean "an oral dosage form consisting of a small mass of medication." (D.I. 238 at 7, C.A. 02-1512-KAJ; D.I. 167 at 8, C.A. 03-120-KAJ.) Teva proposes that I construe "tablet" to mean something "made from the compression of granulates (as described below) together with an outer phase." (D.I. 238 at 7, C.A. 02-1512-KAJ.) Teva agrees that the meaning of the term encompasses an "oral dosage form." (D.I. 268 at 15, C.A. 02-1512-KAJ ("Solely insofar as this is concerned, Teva does not oppose this construction... .").) Impax proposes that I construe "tablet" to mean "an oral dosage form made from compressed structures wherein an inert hydrosoluble carrier is coated with micronized fenofibrate and a hydrophilic polymer or (the remnants of) some solvent for fenofibrate." (D.I. 167 at 8-9, C.A. 03-120-KAJ.)

Abbott argues that the term "tablet" should be construed according to its ordinary meaning to a person of skill in the art, and that the term is used in a manner consistent with its ordinary meaning. (D.I. 270 at 7, C.A. 02-1512-KAJ.) Teva and Impax make essentially the same arguments they made with regard to "composition" and "granulate," namely that the tablets are a type of "composition" which requires the coated-core structure. (See D.I. 268 at 15, C.A. 02-1512-KAJ; D.I. 205 at 15-16, C.A. 03-120-KAJ.) Additionally, Teva and Impax propose that the term should be construed to include the method by which it is made (i.e. compression) and the elements which comprise it (i.e., granulates with an outer phase, as proposed by Teva, or an inert hydrosoluble coated carrier, etc., as proposed by Impax). (See D.I. 238 at 7, C.A. 02-1512-KAJ; D.I. 167 at 8-9, C.A. 03-120-KAJ.)

2. The Court's Construction

I agree with Abbott that the term "tablet" should be accorded its ordinary and customary meaning in the art as "an oral dosage form consisting of a small mass of medication." (See Webster's Third New International Dictionary 2325 (3d ed. 1986) (defining "tablet" as "a small mass of medicated material").) The term "tablet" itself should not be construed to include a form of "compression" because subsequent claims in the '670 patent include this limitation. For example, claim 19 of the '670 patent is as follows:

The composition according to claim 15 under the form of a tablet resulting from the compression of elements (a) together with an outer phase.

('670 patent, col. 10, ll. 54-56.) Thus, claim 19 specifically claims a tablet resulting from a compression, and also discloses the specific elements which comprise it. "Elements (a)," refers to the elements listed in claim 1, which include: "an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 [um] m, a hydrophilic polymer and a surfactant." ('670 patent, col. 9, ll. 50-53.) Thus, it would be improper to read such limitations into claim 15, when claim 19 expressly contains those precise limitations.

Additionally, Teva cites a portion of the specification which states, "this tablet preferably results from the compression of elements (a) (under the form of granules) together with an outer phase." ('670 patent, col. 5, ll. 23-25 (emphasis added).) As indicated by emphasis, this disclosure is of a preferred method of making the tablet, not necessarily the only way. Thus, it would be inappropriate to limit the claim term "tablet" to a preferred embodiment. Therefore, in accordance with its customary meaning, I construe the term "tablet" to mean "an oral dosage form consisting of a small mass of medication."
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IV. "Tack Modifier"

Plaintiff argues that the term "tack modifier," as used in its patents, should be construed so as to include antioxidants when used in an amount greater than .03 percent of the total weight of the final product. 40 To support this construction, Plaintiff uses several steps, based on intrinsic evidence. First, Plaintiff asserts that the antioxidants used in its product have two functions: a primary function of preventing degradation, and secondary function of modifying tack. 41 Next, Plaintiff points to language in the '450 patent stating that "the use of excess antioxidants reduces or eliminates tack." 42 Plaintiff then notes that the '450 patent specification has fourteen examples of mixtures to make their product, three of which have "very minor amounts" of antioxidants. 43 These minor amounts are roughly .03 percent of the total weight of the final product. 44 Plaintiff argues that these minor amounts must serve at least to prevent degradation, and therefore, that the amounts in

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"excess" as previously referred to, must be amounts over .03 percent. 45

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40 Docket No. 355, at 31. 41 Id. at 30.42 Id. at 31.43 Id.44 Id.45 Id.

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Defendants argue that the term "tack modifier," as used in Plaintiff's patents, should include antioxidants only when used in an amount greater than three percent of the total weight of the product. 46 Defendants note that the '450 patent states, immediately preceding the language relating to excess antioxidants, that

the materials of the present invention include up to about three weight percent antioxidant. . . . When a combination of antioxidants is used, each may comprise up to about three weight percent. . . . In the presently most preferred embodiment of the present invention, the materials include 2.5 weight percent primary antioxidant and 2.5 weight percent secondary antioxidant. . . . Additional antioxidants may be added for severe processing conditions involving excessive heat or long duration at a high temperature. 47

Accordingly, Defendants argue that the patent teaches that up to about three weight percent of any one antioxidant is normal usage, and any more than this must be what the patent refers to as "excess."

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46 Docket No. 356, at 11.47 Id. at 11-12.

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Looking to the claim language itself, as well as the context in which that language is used, this Court finds that the proper construction of the term "tack modifier" should include an antioxidant only when that antioxidant is used in an amount greater than three percent of the total weight of the product. The '450 patent addresses a seeming upper threshold of antioxidant amounts when it states that "each [antioxidant] may comprise up to about three weight percent." 48 Because the subsequent paragraph begins "the Applicant has unexpectedly found that the use of excess antioxidants reduces or eliminates tack," 49 it follows that "excess" means amounts beyond those referred to in the upper threshold established in the preceding paragraph.

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48 '450 Patent, at col. 26, In. 43.49 Id. at Ins. 53-55.

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In comparison, Plaintiff's proposed construction is more attenuated, and illogical, as it essentially asks the Court to construe the terms in its patent to mean that any amount of antioxidants beyond "very minor amounts" must be "excess." Plaintiff seems to argue that because an amount of antioxidants equal to .03 percent of total product weight must serve the so-called primary antioxidant purpose of preventing degradation, this must somehow also be the bottom threshold at which the antioxidants begin to serve the alleged tack modifying function. However, the Court notes that there is no evidence within the patent terms that links prevention of degradation and tack modification in this manner. Therefore, acceptance of Plaintiff's proposed construction would require a substantial logical leap. Moreover, while Plaintiff argues that antioxidants are used in all of its products, nowhere does Plaintiff argue that its invention necessarily includes the excess antioxidant amounts necessary to serve a tack modifying function. To the contrary, the argument in Plaintiff's brief implies that at least some of its formulations exclude the amounts of antioxidants which would be necessary to modify tack. Accordingly, the Court will accept Defendants' proposed construction over Plaintiff's.
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4. "a compatible tackifier"

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Carlisle argues that the rubbery polymer components of the claimed invention (including the polymer diluent) must be distinct from the tackifier, and thus that the term "compatible tackifier" should be construed to mean "an ingredient for providing high initial adhesivity that is not a polymer diluent." Adco argues that the plain meaning of the term should apply, or that the term should be construed to mean "a material that gives the composition its softness and high initial adhesivity and is compatible with the other constituents in the adhesive composition."

The court finds no support in the patent to limit the claim term "a compatible tackifier" to compounds that are not also polymer diluents. The court finds that the it would be improper to read additional limitation into the term "compatible tackifier." Because the meaning of the term "tackifier" may be outside the understanding of some prospective jurors, the court finds that it is appropriate to include a definition of the term "tackifier" in the materials to be submitted to the jury. The court finds that the term should be defined, as suggested by Adco, as "a substance that gives the composition its softness and high initial adhesivity and is compatible with the other constituents in the adhesive composition."
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2.Construction Of "Target Nucleic Acids"

Affymetrix's proposed construction of "target nucleic acids" is "nucleic acids that have an affinity for the nucleic acid attached to the bead." (D.I. 243 at 18.) Illumina's proposed construction is "sample nucleic acids with sequence to be determined." (D.I. 240 at 12.)

The term "target nucleic acid" does not appear in the specification of the '243 patent. Affymetrix contends that the term is a synonym of the term "receptor," which is expressly defined in the '243 patent's glossary, and thus, the Court should adopt the glossary definition of "receptor" as its construction of "target nucleic acid." (D.I. 243 at 19-20.) However, it is not precisely correct to say that the two terms are synonymous. As Affymetrix recognizes, the set of "target nucleic acids" is a subset of "receptors," (Id. at 19.), so, while the terms are closely related, they are not synonymous. The construction of "target nucleic acids" must capture some meaning that differentiates that subset from the broader set of "receptors." Affymetrix's proposed construction does not do that and is thus, too broad.

On the other hand, Illumina's proposed construction is too narrow. Despite Illumina's references to particular examples and embodiments, (see D.I. 240 at 13-14; D.I. 249 at 12-13), there is nothing in the specification or in claim 14 that would limit the "target nucleic acids" to those "with sequence to be determined." While it is true that in some embodiments the purpose of exposing the "target nucleic acids" to the nucleic acids attached to the substrate is to determine the sequence of the target, (see, e.g., '243 patent, col. 10, ll. 3-24.), the Court will not import such a limitation into the claim. See JVW Enterprises, 424 F.3d at 1335.

It is clear to the Court, from the claim language itself, that the term "target nucleic acids" simply means nucleic acids that are deliberately exposed to the nucleic acids attached to the substrate. The Court construes the term accordingly.
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C. Target Protein.

The specification of the '277 patent defines a "target protein" as "a polypeptide, protein, or protein complex for which identification of a ligand or binding partner is desired, such as a polypeptide or protein that is known or believed to be involved in the etiology of a given disease, condition, or pathophysiological state, or in the regulation of physiological function." The specification also provides that the test ligand "is being tested for its ability to bind to a target protein, such as a protein or protein complex known to be associated or causative of a disease or condition in a living organism, such as a vertebrate, particularly a human and even more particularly a human."

The specification of the '582 patent provides a similar definition. In particular, it explains that "the term 'target protein' refers

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to a peptide, protein, or protein complex for which identification of a ligand or binding partner is desired. Target proteins include without limitation peptides or proteins known or believed to be involved in the etiology of a given disease, condition or pathophysiological state, or in the regulation of physiological function. Target proteins may be derived from any living organism, such as a vertebrate, particularly a mammal and even more particularly, a human."

In the face of these rather broad definitions, Scriptgen once again advances a fairly narrow interpretation. Specifically, Scriptgen contends that the term "target protein" is "specially defined as a protein known or believed to be involved in causing a given disease, condition, or pathophysiological state, or in the regulation of physiological function."

The court declines to adopt this interpretation. As the express language of the patent specifications make clear, while "target proteins include . . . peptides or proteins known or believed to be involved in the etiology of a given disease, condition or pathophysiological state, or in the regulation of physiological function," they are not limited to only these types of peptides or proteins. Instead, they include any "polypeptide, protein, or protein complex for which identification of a ligand or binding partner is desired."

Again, the court will not read a limitation into the claims which the specification does not expressly provide. See Intel, 946 F.2d at 836. Nor will the court draw inferences from either the specification or the preferred embodiment described within it in order limit the claim terms. See Johnson Worldwide, 175 F.3d at 992. For these reasons, the court affords the term "target protein" the meaning indicated by the patent claims and specifications--namely, as meaning "a peptide, polypeptide, protein, or protein complex for which identification of a ligand or binding partner is desired."
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2. Construction Of "Target Specific Sequence"

Affymetrix's proposed construction of "target specific sequence" is "a known polymer sequence that has affinity for another sequence." (D.I. 243 at 13.) Illumina's proposed construction is "a known sequence of a polymer that binds with specificity to the target at the sequence to be determined." (D.I. 240 at 18.) The dispute here is whether the known polymer sequence attached to a bead must have affinity merely for some other sequence or whether the sequence for which it has an affinity must be the sequence to be determined. The Court concludes that the attached polymer sequence must have an affinity for some other sequence, not necessarily the sequence to be determined.

The Court need look no further than the claim language to conclude that Illumina's proposed construction is inappropriate. The claim requires that each bead in the collection have attached to it a polymer with a unique, known, target specific sequence. Thus, for any given sequence to be determined, only one known polymer sequence will bind with specificity to that sequence to be determined. Under Illumina's proposed construction, therefore, only one bead in the collection would have a target specific sequence attached to it. This plainly contradicts the claim language, which requires each bead to have an attached target specific sequence. A construction that produces an unnecessary contradiction in the claim language cannot be correct. Therefore, the Court construes "target specific sequence" to mean "a known polymer sequence that has affinity for another sequence."
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4. Tartaric Acid

Finally, the parties dispute the meaning of the claim term "tartaric acid." The term "tartaric acid" is used in Claim 1, Step 2 and Claim 4(e) of the '311 Patent. Metametrix argues the term only includes tartaric acid (3-OH-malic). Great Plains and Dr. Shaw argue that the claim term not only includes tartaric acid (3-OH-malic) but also tartaric, tartarate, tartrate, 2-3-dihydroxybutanedioic acid, and meso-tartaric acid.

Again, the court is in agreement with plaintiffs. Tartaric acid has several synonyms including tartaric, meso-tartaric acid, and 2-3-dihydroxybutanedioic. See Chemical Abstracts Service, a division of the American Chemical Society, SciFinder

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database available at http://www.cas.org (subscription required) (last accessed July 12, 2006) (listing the other names of tartaric acid, registry number 87-69-4). The relevant conjugate bases include tartrate, which is also spelled tartarate. The patent appears to view this term broadly, and there is no evidence in the patent that tartaric acid should be construed narrowly. As repeated in the discussion of the various organic acids in question, since the inventor instructed collection of bodily fluids, it is logical to conclude that the aqueous solution includes both the organic acid and its conjugate base. A narrower interpretation is imprudent and counterintuitive. Accordingly, the court adopts plaintiffs' definition of tartaric acid.
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2. Template

For similar reasons, I conclude that the term "template" should be construed to mean a cloning vector, as plaintiff suggests. The only reference to a template in the specification identifies it as a cloning vector. '748 Patent at Col. 1, lines 61-65. Again, thisis not a case of limiting broad claims to a narrower preferred embodiment. Rather, the sole reference to the term "template" in the specification is found, predictably, in a discussion of DNA sequencing. The specification's near total fixation on DNA sequencing is not merely a discussion of a preferred application or embodiment. "The Federal Circuit has repeatedly emphasized that claim language is to be interpreted in light of the fundamental purpose and significance of the invention and in a manner consistent with and furthering the purpose of the invention." Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 98 F. Supp. 2d. 362, 375 (S.D.N.Y. 2000) (internal quotations omitted); Markman, 52 F.3d at 979 ("Claims must be read in view of the specification, of which they are a part."). This construction of the term "template" is harmonious both with the fundamental purpose and significance of the invention and with the construction of the term "primer" set forth above.
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(6) A transcription termination segment . . . The Court interprets the term "transcription termination segment" to mean a configuration of bases on the fragment of the DNA construct, which must signal the end point of the RNA molecule. (Green Tr. at 114; Falkinham Tr. at 1412). Accordingly, the genetic message must "stop" at the terminator sequence or segment. (Falkinham Tr. at 1414).
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B. Test Ligand.

The specification of the '277 patent explains that "the term 'test ligand' refers to an agent which can be a compound, molecule, or complex which is being tested for its ability to bind to a target protein . . . ." The specification goes on to state that a "test ligand . . . can be virtually any agent, including but not limited to metals polypeptides, proteins, lipids, polysaccharides, polynucleotides, and small organic molecules."

The specification of the '582 patent provides a similarly expansive definition. In particular, it defines the term "test ligand" as "an agent comprising a compound, molecule, or complex, which is being tested for its ability to bind to a target protein. Test ligands can be virtually any agent, including without limitation metals, peptides, proteins, lipids, polysaccharides, nucleic acids, small organic molecules, and combination[s] thereof."

Noting that inventors may act as their own lexicographers, see, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998), Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1343 (Fed. Cir. 1998), 3-DP asks the court to give the term "test ligand" the meaning expressly provided in the patent specifications--namely, "an agent [which is or which comprises] a compound, molecule, or complex which is being tested for its ability to bind to a target protein."

In response, Scriptgen argues that a narrower definition should control. In particular, Scriptgen claims that the term "test ligand" is "specially defined as an agent which is a compound, molecule, or complex screened to determine its potential

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therapeutic effectiveness." In support of this interpretation, Scriptgen cites to various portions of both patent specifications.

For example, the Summary of the Invention provided in the specification for the '277 patent states that:

The method of the present invention is useful for identifying a ligand of a target protein and is particularly useful for screening test ligands to identify a ligand which binds [to] a target protein, such as a protein which is associated with a condition or disease or which participates in physiological regulation. Thus, the present method is useful to identify a ligand which can be used therapeutically (i.e., for diagnosing, preventing, or treating a condition or disease) or a ligand which can be used to regulate physiological function or which can serve as a lead compound for identification of a therapeutically useful compound. Through the present method, a ligand which binds [to] a target protein is identified; such a ligand can then be further assessed, if needed, for its therapeutic effectiveness, as well as its safety, using known methods.

This specification continues by explaining that "the term 'test ligand' refers to an agent . . . which is being tested for its ability to bind to a target protein, such as a protein or protein complex known to be associated with or causative of a disease or condition in a living organism . . . ." Furthermore, as the specification from the '582 patent states, "if the target protein to which the test ligand binds is associated with or causative of a disease or condition, the ligand may be useful in diagnosing, preventing, or treating the disease or condition."

Thus, Scriptgen appears to argue that even though its patent specifications expressly define the term "test ligand" as "an agent . . . which is being tested for its ability to bind to a target protein," the court should adopt a more narrow definition since one of the main purposes of the invention (if not its primary purpose) is "to identify a ligand which can be used therapeutically (i.e., for diagnosing, preventing, or treating a condition or disease) or a ligand which can be used to regulate physiological function . . . ."

However, "where a specification does not require a limitation, that limitation should not be read from the specification into the claims." See Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 836 (Fed. Cir. 1991) (quoting Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)). In addition, "just as the preferred embodiment itself does not limit claim terms, mere inferences drawn from the description of an embodiment of the invention cannot serve to limit claim terms." See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 992 (Fed. Cir. 1992) (citing Renishaw, 158 F.3d at 1248; Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988)).

Here, neither the claims nor the specifications require a test ligand to be screened solely for the purposes of determining its potential therapeutic effectiveness. Instead, as these two forms of intrinsic evidence make clear, a test ligand is screened in order to determine whether or not it binds to the target protein. Admittedly, once this determination is made, the "ligand can then be further assessed, if needed, for its therapeutic effectiveness . . . ." (emphasis added). However, this step is neither contained within the asserted claims of the patents in suit nor required by the specifications. The court will, therefore, refrain from reading this limitation into these claims.

For these reasons, the court affords the term "test ligand" the meaning indicated by the intrinsic evidence--specifically, as meaning "an agent which is a compound, molecule, or complex that is being tested for its ability to bind to a target protein."
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1304

1. "tetracycline compound"

The parties agree that the term "tetracycline compound" includes both antibiotic and non-antibiotic tetracycline compounds. (D.I. 62 at 6; D.I. 53 at 13) The parties disagree, however, as to whether the term requires construction. Plaintiffs do not believe this term needs to be construed by the Court because one of skill in the art would understand its plain and ordinary meaning. (D.I. 53 at 11; D.I. 64 at 2) In the alternative, if the Court is to construe "tetracycline compound," Plaintiffs propose "a compound within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure." (D.I. 64 at 2; see also Tr. at 34.) Mylan proposes, instead, that "tetracycline compound" should be construed as "an antibiotic or non-antibiotic compound that has, or is a derivative of, the general [four-ring structure of tetracycline]. Non-antibiotic tetracycline compounds are structurally related to the antibiotic tetracyclines, but have had their antibiotic activity substantially or completely eliminated by chemical modification." (D.I. 55 at 7)

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I agree with Plaintiffs to the extent they contend that "tetracycline compound" should be construed according to its plain and ordinary meaning. I do not agree, however, that construing the instant term according to its "plain and ordinary meaning" to a person having ordinary skill in the art means that no construction is necessary. Instead, as Mylan argues, I conclude that construction is necessary to reduce confusion - which is particularly important here given the presence of many similar but not identical "tetracycline" claim terms - and to eliminate any ambiguity as to whether the term "antibiotic tetracycline compounds" includes "non-antibiotic compounds" (it does not).

Plaintiffs' proposed alternative construction is consistent with the patent specification. Accordingly, I recommend that the Court construe "tetracycline compound" as "a compound within the class of which tetracycline is the parent compound and is characterized by a unique four-ring structure." 3 Mylan's concern that "antibiotic tetracycline compounds" should not be construed to include "non-antibiotic compounds" will be dealt with in connection with construction of the remaining "tetracycline compound" terms.

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3 The four-ring structure of tetracycline is depicted in the Ashley patents at col. 1 lines 58-65 and the Amin patents at col. 3 lines 11-18.

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(C) "Tetrafluoroethylene"

A repeating molecular unit (monomer) comprised of two carbon atoms and four fluorine atoms, also known as C[2]F[4].

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1306

C. "amplification reaction "

Based on the presentations at the Markman hearing, the parties appear to agree that an "amplification reaction" is "any in vitro means for multiplying the copies of a target sequence of nucleic acid." The sole dispute is whether the reaction must comprise multiple thermal cycles, as suggested by the claim preamble.

A preamble limits the invention "if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)). The court may construe the preamble as part of the invention if it "helps to determine the scope of the patent claim." NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1305 (Fed. Cir. 2005), cert. denied, 546 U.S. 1157, 126 S. Ct. 1174, 163 L. Ed. 2d 1141 (2006). Similarly, the preamble should be construed as part of the invention when it provides antecedent basis for terms in the claim body. Id. at 1306.

Applera argues that the inventor intended the preamble to limit the scope of the claim to reactions "comprising multiple thermal cycles." Stratagene contends that the preamble merely recites a purpose of the invention. I agree with Applera. The claim refers to "the amplification reaction." As the Federal Circuit explained in NTP, Inc., when a term is preceded by "the" - a word of limitation - it is appropriate to look back to the preamble as the antecedent basis for that term. Id. at 1306. In this case, looking back to the preamble reveals that "the amplification reaction" referenced in the claim is "an amplification reaction comprising multiple thermal cycles."

Moreover, the preamble breathes meaning into the claim because it provides context for the term "automated thermal cycler." The combined use of "thermal cycler" and "comprising multiple thermal cycles" demonstrates that the inventor intended to limit the instrument to one involving nucleic acid amplification occurring over multiple thermal cycles.

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Although the specification does mention other types of amplification reactions that do not comprise multiple thermal cycles, the claim language, as construed in light of the preamble, speaks for itself. See Phillips, 415 F.3d at 1312-13.
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1. Claim Construction of "the Salt"

BASF argues that the district court incorrectly held that the term "the salt" in step (c) is limited to "the salt of the alkoxycarbonylcyclohexenolone produced in step (a)," which "is represented by formula (III)." BASF further argues that the claims specifically contemplate the difference between the neutral alkoxycarbonylcyclohexenolone, its salt, and its specific metal "salt (III)." As a result, BASF urges us to conclude that the district court's construction was incorrect because the product of step (a) may be the neutral alkoxycarbonylcyclohexenolone or its salt (III), and therefore one of ordinary skill in the art would understand that if one arrived at step (c) with such a salt, that same salt could be acylated, but if one arrived at step (c) with a neutral compound, it could be converted to a suitable salt of the alkoxycarbonylcyclohexenolone for the acylation in step (c) using standard techniques which were well known in the art. BASF argues that this is the only way to read the claim without reading out the recitation that the product of step (a) can be a neutral compound. BASF further asserts that under its reading "the salt" has an antecedent basis because it refers to the salt form of alkoxycarbonylcyclohexenolone as opposed to the neutral form, explaining that it is a salt form which must be acylated at step (c), whether it be a salt formed at step (a), a salt formed after step (a) from a neutral compound formed at step (a), or a second salt reformed by substituting one cation for another cation in a first salt formed at step (a).

We agree with the district court that the intrinsic evidence indicates that the term "the salt" refers to "salt (III)," the product of step (a). A plain reading of the claims shows that the term refers to the salt earlier described. The claim itself describes the "acylation, hydrolysis and decarboxylation of (III)." '856 patent, col. 8 l. 11. BASF's strongest argument to the contrary is that as a result of this construction, the neutral compound formed in step (a) is meaningless. However, no other construction of the term "the salt" is feasible given that the word "the" must have an antecedent basis. See Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1356-57, 52 U.S.P.Q.2D (BNA) 1029, 1033 (Fed. Cir. 1999) (noting the importance of an antecedent basis in claim construction). BASF's proffered construction that "the salt" refers to the salt form in general, does not address this concern because it would conflate "the salt" with the term "a salt," and would render meaningless the word "the." Furthermore, there is no mention in the patent of the process of converting the neutral form to the salt, or the process of reforming a salt with a different cation. There is certainly no enabling disclosure for these processes, suggesting that the patentee did not contemplate that the term "the salt" would include salts formed in a manner not taught in step (a). See In re Goodman, 11 F.3d 1046, 1050, 29 U.S.P.Q.2D (BNA) 2010, 2013 (Fed. Cir. 1993) ("The specification must teach those of skill in the art 'how to make and how to use the invention as broadly as it is claimed'") (citing In re Vaeck, 947 F.2d 488, 496, 20 U.S.P.Q.2D (BNA) 1438, 1445 (Fed. Cir. 1991)).

We therefore affirm the district court's construction of "the salt." It is undisputed that Eastman does not acylate the salt (III) produced in step (a), but rather converts the neutral compound of step (a) into a salt and acylates that salt.
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1308

A. "a therapeutic agent" ('753 patent)

46) The term "therapeutic agent" is not in the specification. The only support for this claim term is a single sentence explaining that the surgical devices of the invention "can also include tissue ingrowth promoters, antibiotics, or other additives as desired." D.I. 70, Ex. A ('753 patent) at 6:26-28. Consequently, the claim term "therapeutic agent" is limited to the only therapeutic agents taught in the specification - tissue ingrowth promoters and antibiotics. See The Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) (a disclosure of only rat insulin cDNA did not support claims to the genus of vertebrate or mammalian insulin cDNAs); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213-14 (Fed. Cir. 1991) (examples of preparing several EPO analog genes were insufficient to support claims to all EPO gene analogs); In re Vaeck, 947 F.2d 488, 495-96 (Fed. Cir. 1991) (example of transformation of a single strain of cyanobacteria was insufficient to support claim to gene expression in all cyanobacteria).

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47) Consistent with the claim language, the specification, and the prosecution history, the Court construes "therapeutic agent" from the '753 patent as meaning "a tissue ingrowth promoter or antibiotic."
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4. "therapeutic composition"

"therapeutic composition" is construed to mean "a composition that is useful for the treatment or prevention of diseases or disorders."
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D. Claims 11, 13, and 14

Claims 11, 13, and 14 of the '355 patent read as follows:

11. A method for treating incontinence in a patient, wherein the method comprises administering orally to the patient a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that is delivered from 0 to 20% of the dose in 0 to 4 hours, from 20 to 50% of the dose in 0 to 8 hours, from 50 to 85% of the dose in 0 to 14 hours, and greater than 75% of the dose in 0 to 24 hours for treating incontinence in the patient.

13. A method for treating incontinence in a patient, wherein the method comprises administering orally to the patient a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt which oxybutynin is administered in from 0 to 1 mg in 0 to 4 hours, from 1 mg to 2.5 mg in 0 to 8 hours, from 2.75 to 4.75 mg in 0 to 14 hours, and 3.75 mg to 5 mg in 0 to 24 hours for treating incontinence in the patient.

14. A method for treating incontinence in a patient, wherein the method comprises administering orally to the patient a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt, which oxybutynin is administered in up to 2 mg of the member in 0 to 4 hours, from 2 mg to 5 mg of the member in 0 to 8 hours, from 5 mg to 8.5 mg of the member in 0 to 14 hours, and greater than 7.5 mg in 0 to 24 hours for treating incontinence in the patient.

1. The Parties' Proposed Constructions

Claims 11, 13 and 14 each describe a method for treating incontinence in which the patient receives an oral administration of a "therapeutic dose" of an oxybutynin. The claims also enumerate the percentage or milligram amounts of oxybutynin that are either "delivered" (claim 11) or "administered" (claims 13 and 14) at the end of specific time intervals. The parties have stipulated that "therapeutic dose" means "a quantity of a drug that is useful in treating a particular disease or condition" and that "administer" and "deliver" mean "to release; to dispense; to mete out; to liberate." (JCCR at 2-3.)

Mylan contends that the term "therapeutic dose" is a means-plus-function limitation insofar as Alza argues that "therapeutic dose" is the device or means that performs the function of administering the specified percentages/amounts of oxybutynin at the specified time intervals. As such, Mylan argues that therapeutic dose covers only the osmotic pump system. Alza, however, does not assert that the "therapeutic dose" delivers or administers amounts of oxybutynin at certain times. In its opening claim construction brief, Alza observes that such a construction "would make no sense: The 'therapeutic dose of oxybutynin' is not the structure that delivers the drug according to the claimed rates; it is simply the therapeutically effective amount of [the] drug . . . ." (Alza CC Br. at 12.)

Alza also argues that method claims only invoke the "step-plus-function" arm of § 112, P 6, not the "means-plus-function" aspect of the statute. Alza contends that the claim unambiguously describes an act--"administering orally to a patient a therapeutic dose" of oxybutynin--which renders § 112, P 6 inapposite.

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2. The Court's Construction

As discussed above, the absence of the words "means" or "steps for" creates a rebuttable presumption that § 112, P 6 is inapplicable. See Masco Corp. v. United States, 303 F.3d 1316, 1326 (Fed. Cir. 2002). Claims 11, 13, and 14 do not contain such language. Therefore, Mylan has the burden to prove by a preponderance of evidence that, as understood by a person of ordinary skill in the art, the claims lack sufficient structure. Apex, 325 F.3d at 1372.

In O.I. Corp. v. Tekmar Co., Inc., 115 F.3d 1576 (Fed. Cir. 1997), the Federal Circuit explained that, in § 112, P 6, "structure and material go with means, acts go with steps." Id. at 1583. Thus, § 112, P 6 "is implicated only when means plus function without definite structure are present, and that is similarly true with respect to steps, that the paragraph is implicated only when steps plus function without acts are present." Id. Moreover, method claims need not recite structure because they consist of acts. See, e.g., Dennison Mfg. Co. v. Ben Clements & Sons. Inc., 467 F. Supp. 391, 405 (S.D.N.Y. 1979) (noting that, under 35 U.S.C. §§ 100(b) and 101, a method is patentable "in and of itself"). Accordingly, the Federal Circuit recently held that a method claim implicates § 112, P 6 "only when steps plus function without acts are present." Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1028 (Fed. Cir. 2002) (citing O.I. Corp., 115 F.3d at 1583) (emphasis added). In its response to Mylan's initial Markman brief, Alza persuasively cites Epcon Gas and O.I. Corp. In its reply, however, Mylan fails to address those plainly relevant cases, choosing instead to characterize Alza's argument as a "red herring" and an "obfuscation." (Mylan's CC Reply at 1-2.) Nonetheless, Mylan admits that "the method claims clearly recite a specified act -- i.e., 'administering orally to the patient a therapeutic dose of an oxybutynin.'" (Id.) (emphasis in original). Thus, Mylan's position is baseless. The Epcon Gas and O.I. Corp. decisions unquestionably dictate the construction of method claims in conjunction with § 112, P 6. Based on that direction, the Court finds that claims 11, 13, and 14 contain neither means-plus-function limitations nor step-plus-function limitations.
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Therapeutic level

The Court agrees with MRI and construes the term as "a level that is above the baseline level in the body and is sufficient to obtain the desired therapeutic result." BSN argues that the term should be construed as "at least 25 ng/mL of [AAKG] in the patient's circulatory system and in a sufficient level that is sufficient to treat the disease in the patient taking the formulation." BSN bases its argument on the specification, which states "a formulation of the invention releases active ingredient so as to obtain a blood serum level in a human patient in a range of about 25 to about 75 ng/mL of plasma." '707 Patent co1.6:22-25.

BSN's argument fails because it seeks to import a claim limitation from the specification. See Phillips, 415 F.3d at 1323-28. BSN construes a specification example that states "a formulation of the invention" to mean "every formulation" or "the only formulation." There is no basis for this narrow construction. n5 See id.

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n5 If the Court were to adopt BSN's approach of importing limitations from specification examples, then the term would also have at least two other limitations. See '707 Patent col.5:47 (giving an example of daily dosage); '707 Patent col.6:37-42 (giving a preferred number of days to maintain the therapeutic level).

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The specification states that "therapeutic level" is a general term which varies for each patient because the amount needed "to obtain an optimum therapeutic[] effect will vary with a number of factors known to those skilled in the art, e.g., the size, age, weight, sex and condition of the patient." '707 Patent col.5:48-50. The specification also states that a formulation releases AAKG "so as to obtain a blood serum level in a human patient in a range of about 25 to 75 ng/mL of plasma." '707 Patent col.6:22-25 (emphasis added). In light of the specification's clear statements that the therapeutic level is variable and that a formulation results in a serum level of about 25 ng/mL, there is no basis requiring a blood serum level of at least 25 ng/mL AAKG. See Phillips, 415 F.3d at 1323-28.

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Claim Construction

On remand, the district court construed "therapeutically effective amount" in claim 1 of the '422 patent to require that the claimed EPO increase hematocrit and also be useful in healing or curing the class of patients listed at column 33, lines 22-28 of the specification of the '422 patent:

A therapeutically effective amount is a quantity that produces a result that in and of itself helps to heal or cure. A therapeutically effective amount is one that elicits in vivo biological activity of natural EPO such as those listed in the specification, column 33, lines 24 through 28: stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis (see, Eschbach, et al., supra) and, as indicated in Example 10, increasing hematocrit levels in mammals.

Therapeutically effective is to be interpreted as being therapeutically effective with respect to the class of patients listed in the specification, column 33 lines 31 through 36: patients generally requiring blood transfusions and including trauma victims, surgical patients, renal disease patients including dialysis patients, and patients with a variety of blood composition affecting disorders, such as hemophilia, sickle cell disease, physiologic anemias, and the like.

Amgen III Validity & Literal Infringement Judgment, 339 F. Supp. 2d at 245-46. In arriving at this construction, the district court focused on the portion of the specification of the '422 patent found at column 33, lines 11-28. n6 Id. at 232-36. The court also pointed to statements in the prosecution history asserting that the claimed invention of recombinant human EPO could be used to treat anemia and other similar disorders. Id. at 238-42.

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n6 The district court's claim construction references passages of the '933 patent found at column 33, lines 24-28 and column 33, lines 31-36. Id. at 214, 236, 245. The '422 patent contains identical passages at column 33, lines 16-20 and column 33, lines 23-28 respectively. These passages are part of a larger portion of the specification that runs from column 33, lines 11-28.

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On appeal, HMR/TKT contends that the district court erred in construing the term "therapeutically effective" in claim 1 of the '422 patent by requiring that EPO increase hematocrit. HMR/TKT argues that the court incorrectly read the specification as limiting the scope of claim 1 to products that increase hematocrit. HMR/TKT urges that "therapeutically effective amount" means "an amount that elicits any of the biological effects listed in the specification." Under this construction, HMR/TKT asserts, claim 1 is anticipated by the Goldwasser reference.

Amgen responds that the district court correctly interpreted the specification to mean that "when a 'therapeutically effective amount' of EPO is used . . . it produces an increase in hematocrit-along with any or all of the biological affects[sic] previously attributed to natural EPO." Appellee's Br. 21 (quoting Amgen III Validity &Literal Infringement Judgment, 339 F. Supp. 2d at 234). Amgen points out that although the passage at column 33, lines 11-22 does not actually use the term "therapeutically effective," other passages do, in fact, use the term. For example, at column 33, lines 43-50, Amgen notes, the patent actually uses the words "therapeutically effective" before explaining the required dosages for patients. According to Amgen, this indicates that "therapeutically effective" amounts are those related to healing or curing disease. Amgen also directs our attention to the portion of the specification found at column 33, lines 22-28. This passage states, "Included within the class of humans treatable with products of the invention are patients generally requiring blood transfusions . . . and patients with a variety of blood composition affecting disorders, such as hemophilia, sickle cell disease, physiologic anemias, and the like." According to Amgen, only amounts of EPO producing effects-particularly increased hematocrit-that counteract these anemia-like diseases are "therapeutically effective." Amgen buttresses this argument with citations to the prosecution history where the patentee recounts the benefits of the claimed invention over prior art in treating disease.

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The district court's claim construction is a matter of law, which we review de novo. Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). In Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc), we stated that claim construction must begin with the words of the claims themselves. Id. at 1312. A claim term has "the meaning that the term would have to a person of ordinary skill in the art. . . ." Id. at 1313. This meaning is ascertained "in the context of the entire patent, including the specification." Id. In particular, we stated in Phillips that "we must look at the ordinary meaning in the context of the written description and the prosecution history." Id. (quoting Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005)). When dealing with technical terms, we noted, a court should look to "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

Using Phillips as a guide, we turn first to the language of the claims. Neither the language of claim 1, nor the language of claim 2, of the '422 patent offer any guidance as to the meaning of "therapeutically effective." n7 However, several passages of the specification shed light on the meaning of the term. In particular, the text found at column 33, lines 11-22 states:

[T]o the extent that polypeptide products of the invention share the in vivo activity of natural EPO isolates they are conspicuously suitable for use in erythropoietin therapy procedures practiced on mammals, including humans, to developany or all of the effects herefore attributed in vivo to EPO, e.g., stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis(see, Eschbach, et al., supra) and, as indicated in Example 10, increasing hematocrit levels in mammals.

'422 patent, col. 33, ll. 11-22 (emphases added). This language indicates that the claimed invention is used in "therapy" to produce "any or all" of the following "effects": stimulation of reticulocyte response, development of ferrokinetic effects, erythrocyte mass changes, stimulation of hemoglobin, and increasing hematocrit levels. Thus, increasing hematocrit is only one of the biological effects produced by the claimed invention. Accordingly, we agree with HMR/TKT that the district court misinterpreted this passage when it read it as limiting the claimed invention to products with "any or all" of the first four listed effects ascribed in vivo to EPO and also an increase in hematocrit.

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n7 Claim 2 is an independent claim, which provides: "A pharmaceutically-acceptable preparation containing a therapeutically effective amount of erythropoietin wherein human serum albumin is mixed with said erythropoietin." '422 patent, col. 38, ll. 42-44.

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Further, in the August 2, 1993 office action response, the patentee cited the above language of the specification and then stated, "It is believed that these sentences from the specification and others provide a clear and definite description of the uses for which the claimed erythropoietin compositions would be therapeutically effective." (emphasis added). Thus, the patentee interpreted the passage at column 33, lines 11-22 of the specification as listing the therapeutic effects of the invention disclosed in the '422 patent. We think the district court made an artificial distinction between the first four effects listed in column 33, lines 11-22, stimulation of reticulocyte response, development of ferrokinetic effects, erythrocyte mass changes, and stimulation of hemoglobin, and the fifth effect, an increase in hematocrit. The specification lists all five effects after stating that "any or all" of them may be an effect of therapy with the claimed invention. Thus, this section of the specification supports the construction that the '422 patent encompasses a pharmaceutical composition which produces "any or all" of the five listed effects.

As seen, the district court also determined that the specification indicates that the invention is limited to products that are "therapeutically effective" with respect to patients with anemia-like disorders, such as those listed at column 33, lines 22-28 of the '422 patent. Amgen III Validity & Literal Infringement Judgment, 339 F. Supp. 2d at 235-36, 245-46. For this determination, the court relied on a passage that recites several diseases that may be treated by the claimed invention. The passage begins, "Included within the class of humans treatable with products of the invention . . . ." '422 patent, col. 33, ll. 22-28. However, this passage does not state that the claims encompass only products that treat such patients. Rather, by using the non-limiting word "included," it suggests some persons, but not all persons, who may benefit from the invention.

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Moreover, an additional section of the specification states, "It is noteworthy that the absence of in vivo activity for any one or more of the 'EPO products' of the invention is not wholly preclusive of therapeutic utility (see Weiland, et al., supra). . . ." Id. col. 36, ll. 9-12. We think the message of this passage is that "therapeutic utility" is not limited to products with "in vivo" effects. Thus, "therapeutic utility" is not dependent on the product having an effect in a living being, such as curing disease. Although this passage relates to a different EPO product than the one disclosed in claim 1 of the '422 patent, we think it illustrates the broad meaning of "therapeutic utility" used throughout the '422 patent. It shows that the patentee did not use the word "therapy" in order to limit the scope of the '422 patent to only EPO that cured disease. Thus, products that are not necessarily effective in actually curing disease in humans are encompassed by claim 1 of the '422 patent. Based on a reading of the claims in light of the specification, it appears that the patentee used the words "therapeutically effective" in order to broadly claim a pharmaceutical composition with a wide range of effects. Those effects do not necessarily include curing disease in humans.

During the prosecution of the '422 patent, in an office action response filed October 23, 1997, the patentee noted that recombinant EPO, like that found in the claimed invention, "is the first therapeutic product which can be used to effectively treat hundreds of thousands of patients who suffer from anemia and other disorders involving low red blood cell counts." In our view, this statement merely lists some of the uses of the invention, without restricting the scope of the invention.

In sum, we disagree with the district court's claim construction to the extent that it limits the scope of claim 1 of the '422 patent to EPO products that have one of the in vivo effects listed at column 33, lines 16-20 and that also increase hematocrit. We also disagree with the district court's conclusion that claim 1 of the '422 patent is limited to EPO products that may be used to treat patients with the disorders listed at column 33, lines 22-28 of the '422 patent's specification. On remand, the district court should utilize the following revised construction of "therapeutically effective:"

A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22: stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals.

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DISSENT:

MICHEL, Chief Judge, dissenting-in-part.

I write separately to voice my strong disagreement with the majority's holdings that (1) contrary to the district court's construction, "therapeutically effective" in claim 1 of the '422 patent means simply eliciting in vivo biological effects even if not tending to cure certain diseases and (2) claim 1 of the '422 patent could therefore be invalid in light of the Goldwasser reference, which describes a prior art compound eliciting biological activity without curing. Because the majority concludes that the district court erred in construing "therapeutically effective" to mean having a disease-curing effect, it remands the case for a re-adjudication of whether the Goldwasser reference anticipates claim 1 of this particular patent, only one of several asserted.

At the outset, I compliment the district court for the meticulous attention it has given to this extraordinarily complicated, highly-technical, and very difficult case. The district court's two opinions on remand, the subject of our present review, were well-reasoned, well-grounded in the evidence, and well-written. The trial court clearly exerted tremendous effort to carefully consider all the issues raised by the parties as well as our remand instructions in Amgen II.

After discovery, the district court conducted a three-day Markman hearing and a bench trial spanning twenty-three days in 2000 and then, following our remand, a second Markman hearing and second bench trial spanning nine days in 2003. The district court also took the creative steps of employing Professor Chris Kaiser of the Massachusetts Institute of Technology as a technical advisor on the underlying technology and Michele D. Beardslee as a special master to aid in researching the law, analyzing the issues, and drafting the remand opinion. Assisted by them, the district court spent more than ten months

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rendering its revised claim constructions and making extensive findings of fact and conclusions of law; it subsequently issued two opinions, together totaling over 360 pages. * Plainly, these decisions were not reached in a haphazard or hurried manner by a court intimidated by either the science or the law. On the contrary, the district court's management and resolution of this case is, I think, a model for all trial courts confronted with such patent suits.

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* The district court's original opinion in this case contained 244 pages.

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I.

The district court construed "therapeutically effective amount" to mean "a quantity that produces a result that in and of itself helps to heal or cure." Amgen III Validity & Literal Infringement Judgment, 339 F. Supp. 2d 202, 245. It further elaborated that a therapeutically effective amount would elicit certain in vivo biological effects, such as those described in the specification, col. 33, ll. 17-22, (i.e., stimulation of reticulocyte response, development of ferrokinetic effects, erythrocyte mass changes, stimulation of hemoglobin C synthesis, and increasing hematocrit levels), which reflect a "healing" or "curing" effect in "patients generally requiring blood transfusions and including trauma victims, surgical patients, renal disease patients including dialysis patients, and patients with a variety of blood composition affecting disorders, such as hemophilia, sickle cell disease, physiological anemias, and the like." '422 patent, col. 33, ll. 23-28. I believe the court correctly recognized that merely eliciting a biological effect is not the same as being therapeutically effective.

Indeed, prior art compounds could trigger the very in vivo biological effects enumerated in the specification but were utterly incapable of "healing" or "curing" the class of patients described in the '422 patent. Notably, an article published in the Renal Extrarenal Sources of Erythropoietin Journal in 1971 revealed that a patient suffering from renal anemia was treated with an urinary EPO preparation but, despite experiencing an increase in reticulocytes, died five days later. The district court was particularly aware of this article and even mentioned it when addressing the issue of obviousness after the first bench trial. See Amgen I, 126 F. Supp. 2d 69, 116. Had this uEPO or any other prior art EPO product been shown to "heal" or "cure" anemia or similar blood disorders, there would have been little need for the claimed invention.

When a compound is truly "therapeutically effective," that is, when it "heals" or "cures" such a blood disorder, it necessarily increases hematocrit as well as causes one or more of the other listed in vivo biological effects. Reading lines 17-22 of column 33 in context, the patentee clearly recognized this.

As previously indicated, recombinant-produced and synthetic products of the invention share, to varying degrees, the in vitro biological activity of EPO isolates from natural sources and consequently are projected to have utility as substitutes for EPO isolates in culture media employed for growth of erythropoietin cells in culture. Similarly, to the extent that polypeptide products of the invention share the in vivo activity of natural EPO isolates they are conspicuously suitable for use in erythropoietin therapy procedures practiced on mammals, including humans, to develop any or all of the effects herefore attributed in vivo to EPO, e.g., . . . and,as indicated in Example 10, increasing hematocrit levels in mammals.

'422 patent, col. 33, ll. 6-22 (emphasis added). This disclosure clarifies three aspects of the claimed invention. First, the claimed EPO shares the in vitro biological activity of natural EPO. Second, the claimed EPO elicits the very same in vivo activity as natural EPO and, therefore, is suitable for use in EPO therapy procedures. Third, the claimed EPO increases hematocrit in mammals, as exemplified in Example 10 of the '422 patent. By reciting "therapeutically effective amount of human erythropoietin," the patentee thus demonstrated an intention to claim EPO that (1) causes the same in vivo biological effects as the natural EPO; and also (2) increases hematocrit.

The subsequent disclosure strengthens my view that the district court correctly construed the "therapeutically effective" limitation.

A preferred method for administration of polypeptide products of the invention is by parenteral (e.g., IV, IM, SC, or IP) routes and the compositions administered would ordinarily include therapeutically effective amounts of product in combination with acceptable diluents, carriers and/oradjuvants. . . . Effective dosages are expected to vary substantially

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depending upon the condition treated but therapeutic doses are presently expected to be in the range of 0.1 ([tilde]70) to 100 ([tilde]7000 U) Ag/kg body weight of the active material.

'422 patent, col. 33, ll. 41-52 (emphasis added). In the only part of the specification where the term "therapeutically effective" actually appears, the patentee uses the term in the ordinary sense of the phrase to mean promoting "healing" or "curing." That is, the patentee teaches the preferred amount of EPO product and a preferred method of administration for a patient suffering from a disorder characterized by a low red blood cell count. Inherently, the ultimate goal is to "heal" or "cure" the disorder. That healing is characterized by an increased red blood cell count, i.e., a higher hematocrit level.

Significantly, I note that the words "therapeutically effective" are conventionally employed in the pharmaceutical arts to indicate that the claimed pharmaceutical product has utility in the treatment of a human disease where such treatment tends to cause the "healing" or "curing" of the disease. The patentee, I think, intended to invoke that very convention. While the majority might be correct that the '422 patent is not necessarily limited to the exact class of patients described in the specification (as opposed to other blood disorders associated with low hematocrit levels), the district court correctly recognized that it would be "foolish to construe a term such as 'therapeutically effective,' without reference to a class of patients for which the product is intended to be 'therapeutically effective.'" Amgen III Validity & Literal Infringement Judgment, 339 F. Supp. 2d at 237.

The specification further discloses various analogs of EPO at columns 35-36:

In addition to naturally-occurring allelic forms of mature EPO, the present invention also embraces other "EPO products" such as polypeptide analogs of EPO and fragments of "mature" EPO. . . . Especially significant in this regard are those potential fragments of EPO which are elucidated upon consideration of the human genomic DNA sequence of FIG. 6, i.e., "fragment" of the total continuous EPO sequence which are delineated by intron sequences and which may constitute distinct "domains" of biological activity. It is noteworthy that the absence of in vivo activity for any one or more of the "EPO products" of the invention is not wholly preclusive of therapeutic utility (see, Weiland, et. al., supra) or of utility in other contexts, such as in EPO assays or EPO antagonism.

'422 patent, col. 35, ll. 34-37; col. 36, ll. 4-14. The majority mistakenly relies on this disclosure to support its view that the "therapeutically effective" means merely capable of triggering any in vivo biological activity, regardless of degree. Correctly read, the emphasized passage plainly concerns only analogs of EPO, not the EPO of claim 1. That is, the full disclosure teaches that analogs of EPO may offer therapeutic utility even though they may not have in vivo activity. The emphasized sentence says nothing about the claimed EPO and hence cannot be relied upon to construe the "therapeutically effective" limitation.

The prosecution history further confirms that "therapeutically effective" connotes more than simply eliciting any cited in vivo biological effect. The district court emphasized that during prosecution of the '422 patent, the patentee differentiated its invention from natural EPO, which also elicits the aforementioned biological activity, on the basis that the latter was not available in large enough quantities to treat patients, i.e., help cure their diseases. Amgen III Validity & Literal Infringement Judgment, 339 F. Supp. 2d at 239. Likewise, during the prosecution of the Application No. 07/113,178, a parent application of the '422 patent which itself issued as United States Patent No. 5,441,868, the patentee distinguished the claimed EPO from the prior art, emphasizing that the claimed EPO could be used as a therapeutic product to treat humans with blood disorders characterized by a low red blood cell count whereas the prior art EPO could not. In particular, the patentee stated:

[N]aturally occurring human erythropoietin is not a viable human therapeutic product; human recombinant erythropoietin, on the other hand, has been proved to be clinically effective, and is the first therapeutic product which can be used to effectively treat the hundreds of thousands of patients who suffer from anemia and other disorders involving low red blood cell counts.

In so differentiating the claimed EPO from the prior art, the patentee said that the claimed EPO is capable of doing more, i.e., the claimed EPO "heals" or "cures" anemia and other such disorders by raising a patient's red blood cell count.

Thereafter, during the prosecution of the Application No. 08/100,197, a continuation of Application No. 07/113,178 discussed above, the examiner objected that "Claim 62 is vague and indefinite because it is unclear what the claimed composition is required to be 'effective' for." In response, after quoting column 33, lines 11-28, which includes a description

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of the in vivo biological effects, the "increasing hematocrit" language, and various diseases treatable with the claimed invention, the patentee again explained that the claimed EPO could be used to treat, (i.e., "heal" or "cure"), various blood disorders:
It is believed that these sentences from the specification and others provide a clear and definite description of the uses for which the claimed erythropoietin compositions would be therapeutically effective. A person of skill in the art would understand that the amount of erythropoietin necessary to achieve these defined therapeutic results would vary for each use. However, clinicians can readily determine the "therapeutically effective" amounts for each condition, and indeed for each patient. Application submits that the claim language "therapeutically effective amount" is commonly used in this type of case where the product is usable to treat various conditions.

(emphasis added). Accordingly, I must conclude that the district court's construction of the "therapeutically effective" limitation comports with the patentee's own repeated descriptions of the claimed invention. It is exactly the way a skilled artisan would interpret the patent, as the district court held.
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A. "Therapeutically effective" or "therapeutically ineffective"

Stanford claims that these terms need not be construed because the plain meaning of these terms is sufficiently clear. As stated above, the court must "indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). Specifically, the Federal Circuit has held that if commonly understood words are used, then the "ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The terms "therapeutically effective" or "therapeutically ineffective" are commonplace--a juror can easily use these terms in her infringement fact-finding without further direction from the court.

These terms do not need to be construed because they are neither unfamiliar to the jury, confusing to the jury, nor affected by the specification or prosecution history. See United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir.1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."). First, the terms will not be unfamiliar to the jury since "therapeutic," "effective," and "ineffective" are all familiar words. The court will only rely on extrinsic evidence if the totality of the intrinsic evidence is insufficient to construe the claims. Here, it is clear that the patents in suit were designed to determine whether or not the anti-retroviral therapy was assisting in decreasing the amount of HIV in the sample ("the viral load"). The court, therefore, need not resort to dictionary definitions. Second, these terms are not confusing. Conducting this inquiry from the perspective of a person of ordinary skill in the art, the court is convinced that the meanings of these words would be clear to her. Third, there is no evidence that the specification or the prosecution history intended a different meaning be attached to these terms. In sum, the court is not persuaded that the terms are ambiguous.

Roche's proposed constructions for "therapeutically effective" and "therapeutically ineffective" are: "elicits the medical effect intended by the treating physician such that the course of treatment is not modified" and "fails to elicit the medical effect intended by the treating physician as a result of drug resistance such that the course of treatment is modified." These constructions do not address the ordinary and customary meaning of these terms and fail due to two specific flaws. First, Roche integrates a physician's mental or subjective state, namely an intended medical effect into the construction. Roche also limits the construction to a particular physician--the "treating" one--not just any physician. Second, Roche requires a particular course of action by the physician.

Roche's arguments combine three facts that are generally not in dispute. First, the only person who evaluates whether anti-HIV therapy for a patient is therapeutically effective or ineffective is the treating physician. Second, the patents in question relate to a decision about the effectiveness of the therapy. See Title of '730 patent. Third, the patent is silent as to what is therapeutically effective and ineffective. Thus, Roche contends, one of ordinary skill in the art would consider these terms to refer to the medical effect intended by the treating physician with respect to the prescribed treatment. Each premise is discussed below followed by a discussion of Roche's conclusion.

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First, Roche makes great attempts, both in its brief and its expert declarations, to demonstrate that the treating physician is the one who makes decisions regarding the patient's drug regimen. There is little doubt that it is the treating physician who usually makes determinations regarding a patient's treatment regimen and whether it is therapeutically effective. Neither Stanford nor the court disputes this. Indeed, the patent itself states that "[i]f a patient being treated with an antiretroviral therapeutic agent exhibits an increase in plasma HIV RNA copy number, a physician should consider altering the patient[']s treatment regimen." '730 patent at 2:45-49. The patent, however, does not limit itself to the treating physician. Therefore, the decision does not necessarily have to be made by the treating physician and could be made by other medical professionals.

Second, the patents are clear regarding their purpose--to determine if the given anti-retroviral regimen is aiding in the decrease of HIV viral load. The physician is told by the specification what should or should not be considered therapeutically effective. See, e.g., '730 patent Claim 1 ("the absence of detectable HIV-encoding nucleic acid correlates positively with the conclusion that the anti-retroviral agent is therapeutically effective."). It is clear that physicians take multiple factors into account when determining whether a particular antiretroviral therapy is effective or not and the result of the patented method would be but one of those factors.

Third, the patent is indeed silent as to what is to be considered therapeutically effective or ineffective. As discussed above, this ordinarily would be within the purview of the physician. The patents merely aid the physician in that determination by pointing her in the right direction--correlating certain results with effectiveness or ineffectiveness.

Roche wants the court to insert the physician's state of mind into the construction. State of mind has been discussed by the Federal Circuit. See Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343 (Fed. Cir. 2001). The Amazon court was "not prepared to assign a meaning to a patent claim that depends on the state of mind of the accused infringer." Id. at 1353. The court there refused to "inject[] subjective notions into the infringement analysis." Id. Here, however, the physician's ex-ante state of mind does not determine if the patent was infringed or not. Specifically, a physician's intent is nowhere mentioned in the patents or prosecution history. The patent is infringed if the particular method is practiced, not by the physician's eventual determination of the effectiveness or ineffectiveness of the therapy. The court is thus unwilling to incorporate that limitation into the claim terms. Furthermore, even if the physician's intended effect was taken into account, there can be but one ex-ante intended effect of antiretroviral therapy--to lower the patient's HIV viral load. This intended effect is already taken into account and incorporated into the patent specifications, which positively correlate a reduction with therapeutic effectiveness and vice versa.

Roche attempts to distinguish Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, rehearing denied, 469 F.3d 1039 (Fed. Cir. 2007), with its broad definition of "therapeutically effective amount" because the patents in question there specifically listed the intended medical effects. The Federal Circuit rejected the reasoning that listing the uses of the invention restricted the scope of the invention. Id. at 1303. Roche argues that "therapeutically effective" may be limited in this scenario because the intended medical effects are not listed. There are two flaws with this rationale. First, if listing the uses does not restrict the scope of the invention, it is unclear how not listing the uses would restrict the scope. And even if it did, it is unclear how the scope would in fact be restricted. Second, the patents do list markers of therapeutic effectiveness--determination of viral load count, CD4 count, and amenability to drug resistance. '730 patent at 2:14-52; 2:64-3:6; 7:50-8:14; 12:57-13:32. Finally, the fact that the patent prompts the physician to consider altering the treatment if an increase in HIV RNA copy number is detected does not inject the physician's intended effect into the definition of "therapeutically ineffective" because, as stated above, the result of the patented method is but one input into the physician's calculus when determining whether to alter the patient's drug regimen.

Furthermore, the patent may be practiced by others not physicians. For instance, the method described in the patent may be practiced on old samples to track a patient's viral load over time. They may even be practiced after patients are deceased in order to gather data regarding the effectiveness of a particular regimen on a large sample. Neither of these instances would require a physician's ex-ante intent or the physician's participation. The patents also describe identifying patients whose infection has become resistant to a particular anti-retroviral regimen. See, e.g., '730 patent at 1:21-25. The myriad ways in which the methods described in the patent can be practiced cautions against limiting the patent to the physician's intent.

Roche's construction would also require that the course of treatment be modified or not modified for the treatment to be considered therapeutically effective or not. Physicians, however, may choose to modify a course of treatment even if they consider the treatment to be effective. Similarly, a physician may choose not to modify a course of treatment even if it is not

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effective. For instance, the physician may want to wait and see if the treatment might become effective over a longer period of time. Roche itself states that physicians analyze multiple factors when determining a particular course of treatment. Bartlett Dec., P 28 (listing baseline resistance of patient's HIV strain, side effects, concurrent conditions, and patient preference as factors); see also Opp. Br. at 8. Thus, whether the treatment is modified or not does not necessarily demonstrate whether the treatment is therapeutically effective or not. This rationale applies equally as forcefully to the intended medical effect limitation because achieving or not achieving the intended medical effect does not necessarily determine whether a treatment is effective or not.

Reading the terms in context, it is clear that the terms are being used to describe the effectiveness of antiretroviral agents as defined by the viral load, not by subsequent actions, such as treatment modification. See '730 patent, Claim 9 ("A method of evaluating the effectiveness of anti-HIV therapy of a patient . . . in which an HIV RNA copy number greater than about 500 per 200 ul of plasma correlates positively with the conclusion that the antiretroviral agent is therapeutically ineffective."). Treatment modification may or may not occur depending upon the methods described in the patents, but neither treatment modification nor non-modification based upon the results of the presence or absence of HIV-encoding nucleic acid are taught by the patents. The methods described serve as one factor, albeit an important one, to consider when the physician is evaluating which anti-retroviral therapy to prescribe. The patents help determine the efficacy of anti-retroviral agents and do not dictate a course of action for the attending physician, if any. Id.

Finally, as discussed above, the patent's suggestion that the physician may alter treatment is but one embodiment of the innovation and the court refuses to limit the patent's scope to that one embodiment.

In sum, the court holds that no construction is necessary for "therapeutically effective" and "therapeutically ineffective."
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a. "therapeutically effective . . . effective in treating"

Genentech argues that the phrases "therapeutically effective" and "effective in treating" of Claims 1 of the Page patents 12 restrict the claims to a CHO-glycosylated antibody that has proven to be therapeutically effective when previously expressed in a different cell line. In support of its construction, Genentech contends that the Jepson format of both claims requires that the "improvement" claimed be limited by the preamble of the claim. Genentech also refers the court to papers submitted during an interference proceeding as evidence that the invention only includes antibodies previously shown to be effective. Finally, Genentech lists a number of reasons why a construction requiring that effectiveness depend on the antibody's capacity to have an effector function is unsupported and contrary to the plain meaning of the phrases.

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12 Claim 1 of the '403-P patent claims:

In a method for treating a human suffering from a disease or disorder comprising administering a therapeutically effective amount of a whole glycosylated recombinant human chimeric or CDR-grafted or bispecific antibody effective in treating said disease or disorder in said human, wherein the improvement comprises an antibody glycosylated by a Chinese hamster ovary cell.

Claim 1 of the '405 patent claims:

In a method for treating a human suffering from cancer by administering a therapeutically effective amount of a whole glycosylated recombinant human, chimeric, CDR grafted or bispecific antibody effective in treating said cancer, wherein the improvement comprises an antibody glycosylated by a Chinese hamster ovary cell.

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Glaxo counters that the phrase "therapeutically effective" describes an amount of CHO-glycosylated antibody that provides a therapeutic benefit when administered to a human patient, not treatment with antibodies derived from a different cell line.

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Glaxo argues that there is no basis in the patents or file histories for Genentech's proposed construction. Glaxo further argues that Genentech has misrepresented Glaxo's position in the interference proceeding papers. In light of these arguments, the essence of the dispute over these phrases is whether antibodies derived from Glaxo's invention must have demonstrated a therapeutic effect when previously produced by a non-CHO cell line.

During the prosecution of the '403-P patent, the PTO advised the applicants in the August 5, 1994 Office Action that the application was directed at patentably distinct species, such as vaculitis, lupus, cancer and infectious disease. The examiner instructed the applicants to elect a single species for prosecution on the merits in the event no generic claim was allowed. Rather than select a single species, the applicants submitted Claim 1 of the '403-P patent in Jepson format claiming an "improvement."

A claim drafted in the Jepson format "allows a patentee to use a preamble to recite 'elements or steps of the claimed invention which are conventional or known'" Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997) (quoting 37 C.F.R. 1.75e (1996)). When a patentee uses the Jepson format, the claim preamble defines the context of the claim. See id. Moreover, "if a claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (citations omitted).

After reviewing claims and the file history, the court concludes that Claims 1 of the Page patents are drafted in the Jepson format, and the plain language of the claims reveals that a portion of each preamble was previously known. The known portions, however, are limited to the phrases "in a method for treating human suffering or disease" and "in a method for treating cancer." The remainder of each preamble relates to CHO-glycosylated antibody treatment.

A broader construction rendering no portion of the preamble previously "known" would bring any method of treatment within the claim. This construction is inconsistent with the examiner's instructions in the August 5, 1994 Office Action rejecting the original broad multi-species claim. A narrower construction rendering the entire preamble "known" would negate the meaning of the term "wherein." The plain meaning of "wherein" shows that CHO-glycosylated antibodies contribute to the effect of the treatment described in the preambles. The court, therefore, concludes that the claims require a previously known method for treating human diseases, disorders or cancer, but the phrases "therapeutically effective" and "effective in treating" describe treatment with CHO-glycosylated antibodies, not previous therapy with antibodies derived from non-CHO cell lines.

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7. "therapeutically effective amount"

This term appears in claims 6 and 7. Astra contends that this term should be construed as "an amount sufficient to reduce the production of acid by the stomach." DRL contends that no construction of this term is necessary and the ordinary meaning as understood by those skilled in the art should apply. Alternatively, DRL proposes that the term be construed as "an amount that causes a therapeutic effect."

Once again, support for its proposed construction of this term is found nowhere in Astra's claim construction papers, and the Court finds its construction to be somewhat inconsistent with the ordinary meaning of the term. The Court, therefore, accepts DRL's argument that this term need not be construed. Because its ordinary and customary meaning would be clear to one skilled in the art, the Court declines to construe "therapeutically effective amount." The ordinary meaning of the term as understood by those of ordinary skill in the art shall apply.

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D. "therapeutically effective amount"

Claim 1 recites:

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A solid oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of impermeably coated famotidine granules for the treatment of gastric disorders . . . and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other . . .

(Emphasis added.) Plaintiffs construe "therapeutically effective amount" to mean "an amount appropriate for the treatment of gastrointestinal disorders." Defendants construe the term to mean at least 5mg of famotidine, at least 145.7mg of magnesium hydroxide and at least 130mg of aluminum hydroxide.

In view of the claim language this Court has already construed, it is unnecessary for the Court construe the term "therapeutically effective amount." The tablet envisioned by Perrigo's ANDA would contain 10mg of famotidine and 165mg of magnesium hydroxide. This tablet would infringe the '340 patent even if the Court were to adopt Defendants' proposed construction. Vivid Techs., Inc., 200 F.3d at 803 (stating that a court must construe "only those [claim] terms . . . that are in controversy, and only to the extent necessary to resolve the controversy"). Presumably, Defendants dispute the construction of this term to bolster the argument that claim 1 requires each of the therapeutically effective famotidine granules to be in contact with the antacid. The Court has rejected that argument, thereby mooting the construction of "therapeutically effective amount."
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1. "A Therapeutically Effective Amount"

The first disputed claim term, "a therapeutically effective amount," appears in Claim 1 of both the '569 and '565 Patents. Plaintiffs assert that "a therapeutically effective amount" should be construed to mean "an amount of calcitonin sufficient to produce a desired therapeutic effect" (Pl. Memo. at 9). They claim that this is the term's plain meaning and that this interpretation is supported by the specifications (Pl. Memo. at 9). Defendants contend that the term should be construed to mean "an amount of calcitonin when administered as a nasal spray or drop prepared as per the teachings of the '565 and '569 patent[s] [sufficient] to produce the desired therapeutic activity. The amount of calcitonin depends upon the source of calcitonin, the condition to be treated, desired frequency and the desired effect" (Def. Memo. at 12). Defendants claim that their definition should be adopted because it is taken directly from the '569 and '565 Patents' specifications (Def. Memo. at 12; see '569 Patent at col. 5, lines 44-49 ("The amount of calcitonin to be administered in accordance with the method of the invention and hence the amount of active ingredient in the composition of the invention will, of course, depend on the particular calcitonin chosen, the condition to be treated, the desired frequency of administration and the effect desired."); '565 Patent at col. 5, lines 43-48 (same)).

I first consider the plain and ordinary meaning of the claim as it would be read by one of ordinary skill in the art and conclude that "a therapeutically effective amount" of calcitonin is the amount of calcitonin that will produce the desired curative, or therapeutic, change, or effect. Thus, the plain meaning suggests that the term should be construed, as plaintiffs have proposed, as "an amount of calcitonin sufficient to produce a desired therapeutic effect." This construction is not contradicted by other claim language.

Although defendants contend "a therapeutically effective amount" should be qualified by the conditions set forth in the second sentence of their proposed construction, their construction is not supported by logic and appears to run afoul of the prohibition against importing limitations set forth in the specifications into the claims themselves.

First, defendants' suggested construction -- "an amount of calcitonin when administered as a nasal spray or drop prepared as per the teachings of the '565 and '569 patent[s] [sufficient] to produce the desired therapeutic activity. The amount of calcitonin depends upon the source of calcitonin, the condition to be treated, desired frequency and the desired effect" -- is internally inconsistent. Its first sentence defines "therapeutically effective amount" as the amount that produces the "desired therapeutic activity." Its second sentence, however, suggests that "desired effect," is only one of the factors that, in defendants' view, defines "therapeutically effective amount." Thus, defendants' definition is inconsistent with respect to whether the desired effect or activity is the factor that determines a therapeutically effective amount or merely one of the factors that determines a therapeutically effective amount.

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Although there can be no serious question that the specification must be consulted in construing a patents claims, the Court of Appeals for the Federal Circuit has repeatedly warned that limitations set forth in the specifications should not be imported into the claims. Varco, L.P. v. Pason Sys. USA Corp., 436 F.3d 1368, 1373 (Fed. Cir. 2006);CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005); Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1326 (Fed. Cir. 2002). Although "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be difficult to apply in practice," Phillips v. AWH Corp., supra, 415 F.3d at 1323, the Federal Circuit has offered the following counsel:

To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. See Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987). One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. See SciMed Life Sys. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1341. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent. See Snow v. Lake Shore & M.S. Ry. Co., 121 U.S. 617, 630, 7 S.Ct. 1343, 30 L.Ed. 1004, 1887 Dec. Comm'r Pat. 354 (1887) (it was clear from the specification that there was "nothing in the context to indicate that the patentee contemplated any alternative" embodiment to the one presented).

Phillips v. AWH Corp., supra, 415 F.3d at 1323; accord Lizardtech, Inc v. Earth Resource Mapping, Inc., 433 F.3d 1373, 1377 (Fed. Cir. 2006) (Lourie, J., concurring); Lasermax, Inc. v. Glatter, 2005 U.S. Dist. LEXIS 17136, 01 Civ. 6500 (LMM), 2005 WL 1981571 at *3 (S.D.N.Y. Aug. 17, 2005)

Reading the specification in light of the foregoing admonition, I conclude that the factors set forth in the specification relevant to the quantification of a "therapeutically effective amount" were included as part of the specification's teaching function and are not limits on the claimed invention. The second sentence of defendants' proposed construction appears in the specification of each patent between a discussion of the ethers that can be used in the compositions claimed by the patents ('569 Patent, col. 4 line 29 - col. 5, line 43; '565 Patent, col. 4 line 31 - col. 5, line 42) and the range of calcitonin dosages that can be administered by the compositions and methods claimed by the patents ('569 Patent, col. 5, line 61 - col. 6, line 19; '565 Patent, col. 5 line 60 - col. 6, line 18). The particular classes of ethers discussed in the specifications are expressly incorporated into the claims ('569 Patent, Claims 18-19; '565 Patent, Claims 11-14), just as the particular dosage ranges discussed in the specifications are also expressly incorporated into the claims ('569 Patent, Claims 11-14; '565 Patent, Claims 5-8). The presence of the specific ethers and dosage ranges in the specifications and claims of both patents strongly suggests that the omission from the claims of the factors relevant to quantifying a "therapeutically effective amount" was intentional and that these factors were included in the specifications to teach one skilled in the art to practice the invention, but not to define or limit the claimed invention. If the patentee intended the factors listed in the specifications to be read into the claims, it is inconceivable that it would be omitted from the claim language in light of the other limitations that were expressly imported to the claims from the specifications.

Thus, I conclude that the term "a therapeutically effective amount" should be construed as "an amount sufficient to produce a desired therapeutic effect."

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5. "therapeutically effective amount"

Amgen	Roche/Hoffmann	This Court (earlier case)
Amgen adopts the Federal Circuit's construction	A therapeutically effective amount is one that elicits any one or all of the effects often associated with in	The Federal Circuit has adopted Roche/Hoffmann's construction. Amgen, Inc., 457

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vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals	F.3d at 1303.

In view of the Federal Circuit's construction of this term in Amgen Inc., 457 F.3d at 1303, Amgen agrees that it has no choice but to submit to that construction here. Accordingly, this Court likewise adopts the Federal Circuit's construction:

"therapeutically effective amount": A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals

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1. Construction of Disputed Term

The parties contest the following portions of the proposed definition for the "a therapeutically effective amount of a beta adrenergic stimulator" element of claim 1:

Claim Element	Plaintiff's Proposed Construction	Defendant's Proposed Construction
a therapeutically effective amount of a beta adrenergic stimulator	an amount of a beta adrenergic stimulator, therapeutically effective for weight loss without the necessary addition of another active ingredient to render the beta adrenergic	an amount of a beta adrenergic stimulator, therapeutically effective for weight loss, alone, without the inclusion of any other ingredient to improve or change its function

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stimulator
effective

The starting point for interpreting a claim is the language of the claim itself. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir.), reh'g denied, in banc suggestion declined, (1999). As the Johnson court made clear, "a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." Id. (citations omitted). "Arguments and amendments made during the prosecution of a patent application and other aspects of the prosecution history, as well as the specification and other claims, must be examined to determine the meaning of terms in the claims." Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir.), reh'g denied, in banc suggestion declined (June 21, 1995), cert. denied, 516 U.S. 987 (Nov. 27, 1995) (citations omitted). "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Id. (citations omitted).

The first question is what is the effect of "comprising" on the term "a therapeutically effective amount." The transitional phrase "comprising"generally does result in an "open claim" that will read on processes that add additional elements. Stiftung v. Renishaw PLC, 945 F.2d 1173, 1178 (Fed. Cir.), reh'g denied (1991); DONALD S. CHISUM, CHISUM ON PATENTS, § 18.03[4][b] (2000) ("Generally, a claim using 'comprising' as a transition is construed as an 'open claim', i.e., it will read on devices or processes, which add additional elements."). Claim 1 reads: "[a] process for achieving a selective reduction in body weight, comprising the steps of . . . ." ('359 patent, col. 5, ln. 50-51). Clearly, "comprising" modifies "steps," so that the number of steps is opened-ended, not the contents within the steps. Therefore, the word "comprising" does not affect the interpretation of the disputed term.

Next, a proper construction must give full effect to the ordinary and accustomed meaning of the phrase "a therapeutically effective amount." Johnson, 175 F.3d at 989. "Therapeutic" means "of or relating to the treatment of disease or disorders by remedial agents or methods." WEBSTER'S NEW COLLEGIATE DICTIONARY 1201 (1973). "Effective" means "producing a . . . desired effect." Id. at 359. The desired effect in claim 1 is selective reduction in body weight. In light of these ordinary meanings, the term itself means delivering a sufficient amount of the remedial agent (the beta adrenergic stimulator) to produce a selective reduction in body weight. But this language sheds little light on the central question-whether claim 1 must be interpreted to cover the beta adrenergic stimulator alone, without the inclusion of any other active ingredient, or whether a proper construction rules out only the necessary addition of another active ingredient to render the beta adrenergic stimulator effective.

The prosecution history of the '359 patent resolves the question. During the course of prosecution, the Examiner cited U.S. patent No. 4,288,433 issued to Koulbanis ("Koulbanis"). Koulbanis teaches the use of theophylline, a beta adrenergic stimulator, in association with a sulphur-containing organic compound of the thioether type to achieve selective weight reduction. (Amendment after Final Action at 7-8, attached to Pls.' Reply at Ex. J; Koulbanis Patent, col. 2, ln. 11-13). In response to the Examiner's citation, Applicants distinguished their invention over the Koulbanis patent by stating: "Koulbanis cannot be taken to teach the proposition that theophylline can be used by itself to achieve . . . selective weight reduction. It is well established that omission of an ingredient previously thought to be critical can serve as the basis for patentability." (Amendment after Final Action at 8, attached to Pls.' Reply at Ex. J).

Plaintiffs argue that in distinguishing Koulbanis, the Applicants only distinguished the teaching that a beta adrenergic stimulator must be paired with an additional active ingredient for the compound to induce selective weight loss. According to Plaintiffs, beta adrenergic stimulators can themselves achieve selective weight loss. Thus, a construction that the '359 patent includes "any therapeutically effective amount for weight loss without the necessary addition of another active ingredient" would read on a compound such as the Khoulbanis reference. However, the Applicants argued during prosecution that the omission of an ingredient previously thought to be critical can be the basis of patentability. Accordingly, Plaintiffs' proposed construction conflicts with the Applicants' language to the Examiner. The court declines to adopt such a construction.

Therefore, the court construes "a therapeutically effective amount of a beta adrenergic stimulator" to mean: "an amount of a beta adrenergic stimulator, therapeutically effective for weight loss, alone, without the inclusion of any other ingredient to improve or change its function."
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Therapeutically effective period of time

The Court agrees with MRI that this term does not require construction. BSN argues that the term should be construed as "greater than four hours." BSN argues that the patentee explicitly excluded any time period less than four hours because the specification stated "[t]he [AAKG] blood plasma level obtained via the present invention is insufficient to obtain a desired therapeutic effect if that level is maintained for only a short period of time, e.g. 4 hours or less." '707 Patent col.6:56-59. Again, BSN improperly attempts to import a claim limitation from the specification. The language BSN cites is merely an example. The specification discusses effectiveness in general terms: "maintaining a minimal [AAKG] blood serum level over time" would treat a patient's symptoms or risk of developing disease.
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Plaintiff specifically alleges that Defendant infringes claims 1,3,4, 18-20, and 24 of the 724 patent. "A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). In other words, the claims point out limitations which must be interpreted by the Court. See id. at 1258. Claim 1 reads as follows:

1. A method of contraception by suppressing recruitment of the dominant follicle comprising:

(a) administering orally to a human female of childbearing age, daily from [about Day 2 to about] Day 3 or Day 4 through Day 7 of her menstrual cycle, wherein Day 1 is the first day of menses, a first composition containing as sole contraceptively active ingredient an estrogenic compound at a daily dosage equivalent in estrogenic activity in the range of about 0.01 to about 0.04 milligrams of 17-alpha-ethinyl estradiol: and thereafter

(b) administering orally to said female, daily through Day 28 of her menstrual cycle, at least one follow-up composition containing a contraceptively effective daily dosage of progestin.

Sipio Decl., Ex. A, at col. 7, lines 37-50 (emphasis in bold added). 4 As in the specification, claim 1 of the 724 patent uses sequential words.

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4 The text in brackets appears in the original 843 patent but forms no part of the reissued patent, whereas the text in italics indicate additions made to the 724 patent.

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The language used in the patent specification and in claim 1 suggest, at least at first glance, that the patented invention involves particular dosages being delivered to a female user in a particular order. Defendant argues that the bolded words such as "initial," "first," "follow-up," and "thereafter" indicate that a certain order of pill ingestion was contemplated by the inventor of the patented system.

Plaintiff, however, maintains that these terms should be read as meaning two different groups of pills, a first group and a second group, and that these words "do not connote a particular sequential order in a pack, but instead simply provide a way of distinguishing two pill types." Pl. Reply Br. at 13. Moreover, Plaintiff asserts that because there is a dispute as to these terms, expert testimony is needed to determine how the claims would be read through the eyes of a person of ordinary skill in the art.

The Court need not entertain expert testimony for an analysis of what these words mean if the patent history contains no

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indication that they mean something other than their ordinary meaning. See Key Pharm. v. Hercon Lab. Corp., 161 F.3d 709, 718 (Fed. Cir. 1998). It is, in fact, improper for a district court to rely on expert testimony if that testimony contradicts the file history of the patent. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1584 (Fed. Cir. 1996).

It is well-settled that the language in a patent is afforded ordinary meaning unless the patent or its history makes clear that a different meaning was intended. See Vitronics Corp., 90 F.3d at 1582; Carrol Touch, Inc., 15 F.3d at 1577 (citing Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387 (Fed. Cir. 1992) ("words of a claim are generally given their ordinary and accustomed meaning, unless it appears from the specification or the file history that they were used differently by the inventor.")

The Key Pharm. Court stressed that courts may rely on expert testimony in claim construction only if the patent record "does not answer the question." Key Pharms. 161 F.3d at 716. "Thus, if the meaning of a disputed claim term is clear from the intrinsic evidence -- the written record -- that meaning, and no other, must prevail; it cannot be altered or superseded by witness testimony or other external sources simply because one of the parties wishes it were otherwise." Id. 5

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5 Notably, The Key Pharm. Court entertained expert testimony for an interpretation of the term "pharmaceutically effective amount," which is perhaps a bit more challenging than words like "first" and "thereafter." See Key Pharm., 161 F.3d at 718.

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Where there is a dispute as to a term in the patent, courts should look to the patent specification for guidance, as the Federal Circuit has referred to the specification as "the single best guide to the meaning of a disputed term." Vitronics Corp., 90 F.3d at 1582. Here, the patent specification contains no indication that the inventor intended different meanings for the words "initial," "first," "following," "follow-up," and "second-stage." Indeed, the patent specification indicates that the particular sequence of pills is an important aspect of the invention, stating that the "drug delivery system embodying the present invention contains a pharmaceutical package having at least 24 active dosage units arranged sequentially therein. Preferably, the pharmaceutical package contains 28 dosage units, including placebo units." Sipio Decl., Ex. A, at col. 5, lines 33-37 (emphasis added).

Because no other definition was assigned these words in the patent specification, the Court will interpret them in accordance with their ordinary meaning. Accordingly, the Court will not consider the testimony of Dr. Gutmann proposed by Plaintiff for an analysis of these disputed terms. The Court is capable, without expert assistance, of figuring out what these words mean. But to be certain, the Court looked some of them up in the dictionary. The dictionary defines "initial" as "happening or being at the very beginning: first." Webster's New Riverside Univ. Dictionary. "Follow" means "to come or go after." Id.

Claim 1 indicates that certain pills, specifically an estrogenic compound, are to be taken in the first stage. After all of these pills are taken, the user shall take "follow-up" doses of progestin. In this Court's view, claim 1 therefore requires that an estrogenic 6 compound be administered first, i.e., from about Day 2 or 3 to Day 7 of the cycle, with the first one or two pills being placebos, and thereafter, the pills to be taken contain progestin 7, which the woman takes for the remaining twenty-one days of her cycle.

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6 "Estrogenic compounds, as the term is used herein, includes hormones as well as other compounds that exhibit estrogenic activity." Sipio Decl., Ex. A, col. 3, lines 28-30. Such compounds include "17-alpha-ethinyl estradiol 3-methylether mestranol, 17-beta-estradiol, 17-alpha-ethinyl estradiol, and the like." Id., at lines 34-37.

7 "Progestins utilizable in the present invention include progestrone and its derivatives such as, for example, 17-hydroxy progestrone esters, 17-alhpa-ethinyl testosterone, 17-alpha-ethinyl-19-nortestosterone and derivatives thereof." Id., at lines 38-42.

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The specification contains rationale for administering the estrogen early in the cycle. Because Defendant's product does not administer an estrogenic compound in the first-stage and progestin in the second-stage, it does not contain all elements and limitations of the claim and, therefore, does not literally infringe claim 1.
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Claim 1 of the '724 patent recites a method of contraception comprising two steps. The two steps are distinguished by the identity of the compositions administered in each step and the timing of the two steps. The first step consists of administering a composition containing an unopposed estrogenic compound from Day 3 or Day 4 through Day 7 of the woman's menstrual cycle, while the second step consists of thereafter administering a composition containing progestin through Day 28 of the woman's menstrual cycle. The patent specification makes clear that the days of the menstrual cycle are measured from the onset of menses: "Day 1 of the menstrual cycle is defined as the day on which onset of menses is noted." '724 patent, col. 3, ll. 8-9.

The district court correctly understood claim 1 to require administration of an estrogenic compound during certain designated days early in the woman's menstrual cycle, followed by administration of progestin for the last 21 days of the cycle. 2 Although in its discussion of the doctrine of equivalents the court stated that "the patent contemplates a particular order of pill ingestion within one package," to the extent that the court meant for that statement to restrict its earlier construction of claim 1, we reject the restriction. Nothing in the text of claim 1 or the written description limits the invention recited in claim 1 to a method practiced through the use of only a single package of pills. If, at any point in a contraceptive regimen, a woman takes the prescribed compounds on the prescribed days of her menstrual cycle, and in the prescribed order indicated in claim 1, the regimen infringes the claim.

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2 The district court seemingly construed claim 1 to require use of placebos. Although the specification discusses placebos, claim 1 does not require their use. That issue, however, does not affect the outcome of this case.

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This point is important because of a factual assertion made by BTG in support of its claim of infringement. BTG acknowledges that its pill packages start with progestin pills rather than estrogen pills, and that the product's package insert advises starting the 21 progestin pills on the first day of menses or shortly thereafter. However, BTG asserts that taking the pills causes the woman to experience a "menstrual shift" so that within a short period of time after a woman begins using the accused product, she will be taking the placebo and estrogen pills at the beginning of her menstrual cycle, followed by the progestin pills, just as recited in claim 1. For that reason, BTG asserts, a woman who experiences that menstrual shift will necessarily infringe claim 1 if she uses the accused product for a period of time following the shift. Because users of the Duramed product will infringe the '724 patent under those circumstances, BTG argues that Duramed is accordingly liable for contributory infringement and induced infringement.

BTG introduced several pieces of evidence into the summary judgment record regarding the existence of the "menstrual shift" in women using the accused product. BTG's expert, Dr. Jacqueline N. Gutmann, stated in her declaration that when a patient taking the Duramed product "completes the twenty-one tablet stage, she bleeds, and thus, the menstrual cycle 'resets' itself." She added that she had reviewed studies performed by BTG's licensee, Organon, Inc., which were submitted as part of the New Drug Application for the Mircette brand of oral contraceptives. Those studies, she stated, "show that a certain number of women taking Mircette had bleeding on the day immediately after having taken the last of twenty-one tablets containing [progestin]," and that for those women that day would become Day 1 of the menstrual cycle. Those patients and others like them, according to Dr. Gutmann,

> would therefore take two light-green placebo tablets on Day 1 and Day 2 of their menstrual cycles. From Days 3 through Day 7, those patients would then take [an estrogen compound]--namely the five light-blue tablets. . . . Accordingly, the use of the Duramed product by patients who begin bleeding on the day immediately following the twenty-first white tablet [containing progestin] would be understood by one skilled in the art as the practice of part (a) of the method of contraception described in Claim 1.

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Another piece of evidence relevant to the "menstrual shift" issue is an excerpt from the package insert for the Duramed product, which is identical to the corresponding portion of the package insert for the Mircette product. Referring to a woman who switches to the Mircette/Duramed product after using a 21-day contraceptive system, the excerpt explains that the woman should "wait 7 days to start the next pack. You will probably have your period during that week." The '724 patent explains that the 21-day products conclude with a series of pills containing progestin. The statement that the woman would "probably" experience the onset of menses after completing the progestin pills provides some further evidentiary support for BTG's contention that a menstrual shift is likely to occur in women taking the accused Duramed product after completing the 21-day regimen of progestin pills.

While the evidence that BTG offered on the issue of menstrual shift is neither extensive nor especially detailed, we think it is sufficient to satisfy BTG's burden at the summary judgment stage to offer evidence "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," Celotex Corp. v. Catrett, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986), particularly in light of the fact that Duramed did not offer any evidence to the contrary. If BTG is able to prove the occurrence of a menstrual shift of the sort described by Dr. Gutmann, BTG may be able to establish that women who use the accused product practice the method recited in claim 1. And if that is so, BTG may be able to establish that Duramed is liable under a theory of contributory infringement, 35 U.S.C. § 271(c) , or active inducement to infringe, id. § 271(b).

The district court has not yet addressed the issues relating to vicarious liability, and we do not suggest how those issues should ultimately be resolved. For present purposes it is enough for us to hold that the district court's construction of claim 1 was largely correct -- that the claim recites a method consisting of the administration of estrogen from Day 3 or Day 4 after the onset of menses to Day 7 and then progestin for the next 21 days -- but that the court's conclusion that BTG had failed to raise a disputed issue of material fact under that claim construction was wrong. The "menstrual shift" evidence offered by BTG, if credited, could support a ruling in BTG's favor on the issue of infringement. The evidence was therefore sufficient to overcome Duramed's motion for summary judgment as to claim 1. Accordingly, we reverse the grant of summary judgment of noninfringement with respect to that claim and its asserted dependent claims.
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(7) And therebetween, a DNA segment . . . The Court construes this element to require that the nonnative DNA construct must contain a DNA segment between the transcriptional promoter segment and the transcription termination segment.
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B. "automated thermal cycler"

Applera asks the court to construe this term as "an instrument for use in a nucleic acid amplification reaction comprising multiple thermal cycles for alternately heating and cooling samples." Stratagene advocates defining the term as "an instrument that can be programmed to heat and cool a surface or vessel." I adopt Applera's definition.

To define "automated thermal cycler," I must determine how a person trained in the art would have understood the term in 1991. In doing so, I "must define the term in a manner consistent with the scientific and technical context in which it is used in the patent." See AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1248 (Fed. Cir. 2001).

Although the specification does not define "automated thermal cycler," it uses the term in a way consistent with Applera's proposed construction. Every reference to "thermal cycler" or "thermocycler" appears to identify an instrument used for conducting nucleic acid amplification reactions comprising multiple thermal cycles.

At the Markman hearing, Applera presented the testimony of Dr. Carl Batt, who testified that persons trained in the art in 1991 would have understood "automated thermal cycler" as a specialized instrument for use in a nucleic acid amplification reaction comprising multiple thermal cycles for alternately heating or cooling samples. I credit his testimony. Based on the

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fact that he authored a paper describing PCR technology submitted for publication in 1991 (see Tr. 74-76), I find that he was trained in the art in 1991 and is qualified to testify on this issue. Stratagene has presented no evidence suggesting that persons trained in the art of nucleic acid amplification in 1991 would have understood this term in any other way.

I acknowledge the Federal Circuit's admonition that extrinsic evidence is less reliable than intrinsic evidence. Phillips, 415 F.3d at 1318. In Phillips, the Federal Circuit advised courts to discount expert evidence at odds with the intrinsic evidence. Id. Nonetheless, consulting extrinsic evidence is appropriate when the internal evidence is ambiguous. See Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 832 (Fed. Cir. 2003). Dr. Batt's testimony does not contradict the internal evidence; to the contrary, it is consistent with the specification's use of the term.

Stratagene's proposed construction is too broad and does not reflect the scientific and technical context of the patent. Stratagene's only support for its proposed construction is the specification's reference to "a spectrafluorometer capable of heating and cooling a surface, or vessel." (Col. 12, lns. 14-15.) The specification contrasts this to a spectrafluorometer housed independently of a thermocycler. As Stratagene itself notes in its post-hearing brief, the specification was first drafted for the method patent application. For this reason, the specification reads more broadly than the claim itself. For example, as discussed below, the specification refers to various methods of DNA amplification, including isothermal reactions. But the claimed instrument is limited to reactions comprising multiple thermal cycles. Likewise, the specification refers to various methods of detecting nucleic acid amplification, even if the claimed instrument performs only one such method. My conclusion that the amplification reaction must comprise multiple thermal cycles reinforces the proper construction of "thermal cycler." The evidence shows that a person trained in the art in 1991 would have understood "thermal cycler" or "thermocycler" in the context of amplification reactions comprising multiple thermal cycles in the way suggested by Dr. Batt.

After reviewing the claim language, the specification, and the extrinsic evidence (i.e., Dr. Batt's testimony), the only conclusion consistent with the context of this patent is that "thermal cycler" refers to "an instrument for use in a nucleic acid amplification reaction comprising multiple thermal cycles for alternately heating or cooling samples."
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2. "Thermogenically effective amount"

The parties apparently agree that the term "thermogenically effective amount" requires construction by the Court because it does not have a well understood, plain meaning. They disagree, however, about how it should be construed.

Iovate contends that the term means "an amount which results in a statistically significant increase in total energy expenditure or fat burning." It contends that the '765 Patent states that "thermogenesis" corresponds to "the energy expended by the body to maintain a constant temperature" and that the body burns fat when the energy it expends is greater than the energy supplied by food intake. It also argues that the "statistically significant" limitation is necessary to comport with the understanding of a person skilled in the art as described above for the term "increase" and as evidenced by the fact that the specification for the '765 Patent describes an amount that produced no statistically significant increase in thermogenesis by stating that it "does not increase thermogenesis."

By contrast, Allmax argues that the disputed term means "at least 125 mg ECGC and at least 50 mg caffeine." That proposed construction is based purely on the specification for the '986 and '765 Patents which provides only one example of the effect the invention's compounds have in humans, and 125 mg of catechols and 50 mg of caffeine were used in that example (and were determined to achieve thermogenesis).

Iovate rejects Allmax's construction as importing an improper limitation into the claim. It asserts that the quantities referenced in the specification were only one (and not the only) example of the invention. Indeed, the Federal Circuit Court of Appeals has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Phillips, 415 F.3d at 1323. Therefore, there appears to be no reason to construe the disputed term as narrowly as Allmax requests. Furthermore, Iovate's construction is reasonable with the exception of the "statistically significant" limitation (for the reasons explained above with respect to the '900 Patent). Thus, the Court will interpret "thermogenically effective amount" to mean "an amount which results in an increase in total

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energy expenditure or fat burning."
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a. "Thermoplastic" and "Effective Amount of the Processing Additive Composition"

These two terms are used in asserted Claim 20, and "thermoplastic" is used in asserted Claim 17. Dupont Dow and Dyneon agree on the proposed constructions for both terms. (Dyneon's Opp'n Br. at 16). The proposed construction for "thermoplastic" is "capable of softening or fusing when heated and of hardening again when cooled." The proposed construction for "effective amount of the processing additive composition" is "that which either (a) reduces the occurrence of melt defects occurring during extrusion of the host polymer below the level of melt defects occurring during the extrusion of a host polymer that does not employ the multimodal fluoropolymer-based processing additive composition of the invention, or (b) delays the onset of the occurrence of such defects to a higher extrusion rate (that is a higher shear rate)."

The proposed constructions for these claim terms are consistent with the ordinary meaning of the term to one of skill in the art ("thermoplastic"), or comport with the intrinsic evidence. See '919 Patent, c. 4, 11. 22-30 (defining "effective amount" as used in the specification and claims). Both terms are used in asserted claims, but may not be readily understood by a jury. The Court therefore adopts the proposed constructions for the claim terms "thermoplastic" and "effective amount of the processing additive composition" that are set out above.
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2. Claim 4, "thermoplastic elastomeric block copolymer"

The parties did not address the proper construction of "thermoplastic elastomeric block copolymer" at the hearing, as they hoped to arrive at an agreement on this term. (10-27-09 Letter at 1.) They have not done so, and now ask the Court to construe the term after considering their respective briefs. (Id.) According to DuPont, the Court should construe the term to mean: "A class of polymeric materials composed of two or more comonomeric units in extended segments having hard and soft blocks." (DuPont Responsive Br. at 19-20.) MacDermid offers the following construction: "Any one of a class of elastic polymers containing long stretches of two or more monomeric units linked together by chemical valences in one signal chain that become soft when heatedand returns to its original condition when cooled." (MacDermid Opening Br. at 32.)

DuPont asks the Court to adopt its proposed construction, as: (1) the patent's specification provides examples of acceptable "thermoplastic elastomeric block copolymers" ('758 Patent at col. 4, lines 13-26); (2) the specification also states that: "The elastomeric block copolymer is preferably an A-B-A- type block copolymer, where A is a nonelastomeric block, preferably a vinyl polymer and most preferably polystyrene and B is an elastomeric block, preferably polybutadiene or polyisoprene. The nonelastomer to elastomer ratio is preferably in the range of from 10:90 to 35:65" (id. at col. 4, lines 15-21); (3) "even though the patent does not expressly provide a definition of this phrase, it is readily understood by those of ordinary skill in the art in the context of '758 patent" (DuPont Responsive Br. at 20 (citing dictionary definitions)); and (4) the construction proposed by MacDermid is not consistent with the intrinsic evidence and is improperly cobbled together from separate dictionary definitions of "thermoplastic", "elastomer", and "block co-polymer". (DuPont Responsive Br. at 19-20.) MacDermidcontends that its proposed construction should be adopted because: (1) the "non-limited list of preferred substances" provided in the specification "is not a proper construction as the Federal Circuit has held numerous times that one cannot limit a construction to only those preferred embodiments found in the specification" (MacDermid Opening Br. at 33 (citation omitted)); and (2) its proposed construction of this term, which is "common in the field of flexography", is supported by Hawley's Condensed Chemical Dictionary's definitions of "thermoplastic," "elastomer," and "block co-polymer" (id. at 33 (citing definitions)).

The Court, upon considering the parties' respective arguments and the intrinsic and extrinsic evidence, agrees with DuPont. Accordingly, the term "thermoplastic elastomeric block copolymer" is construed to mean "a class of polymeric materials composed of two or more comonomeric units in extended segments having hard and soft blocks."
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5. Thickener

Claims four through six and eight of the '793 patent and claims five through eight of the '622 patent provide for inclusion of a thickener with the previously described solution and, unlike the case with regard to colorants, also provide weight by percentage limits for such thickeners. The parties also disagree upon the definition of this term, and specifically whether it must be a separately added ingredient, or instead can be inherent in the other materials included within the composition.

A "thickening agent" is described by one source as "[a]ny of a variety of hydrophilic substances used to increase the viscosity of liquid mixtures and solutions". Hawley's at 1234. The '793 patent describes the use of thickeners envisioned by the inventors as follows:

> Thickeners are used in certain applications as the third key component to increase the viscosity of the composition so that the liquid remains in contact with the road surface or with the solid particles in piles of rocksalt/sand, or rocksalt/aggregates, or salt alone, or sand or aggregate. Thickeners are mainly cellulose derivatives or high molecular weight carbohydrates.

'793 Patent, col. 2, ln. 63 - col. 3, ln. 2. To be sure, inclusion of the phrase "the third key component" in the '793 patent does provide reason for pause. Nonetheless, it is generally understood -- and indeed spelled out in the patent --that thickeners, whose sole function is to increase viscosity of a solution, are typically polymers, high molecular weight carbohydrates or cellulose derivatives, including carbohydrates.

In Cargill, the parties vigorously contested the question of whether the thickener described in claims four through six and eight of the claims of the '793 patent must be additives to the solution otherwise described, or instead could be inherent in the composition itself. After reviewing the patent and considering the opinions of experts, I concluded that a person of ordinary skill in the art would not understand that the thickener had to be a discrete, separately added constituent, as distinct from comprising a substance or material inherent in the composition. Accordingly, I construed the term to mean "a substance or material, whether inherent in or separately added to a composition, which causes an increase in the composition's viscosity." Cargill, 334 F. Supp. 2d at 222. The ADM defendants urge me to reverse fields and now hold that the thickener contemplated by the inventors must be separately added.

When originally presented to the PTO, the claims ultimately included within the '793 patent did not make reference to a molecular weight range for the specified thickener. This fact led the examiner to reject the claims as being impermissibly indefinite, noting that

> it is unclear as to the types of carbohydrates encompassed by the claim. Since the types are not recite[d] the claim is vague and indefinite since the carbohydrate and thickener can be one in the same

ADM Exhibits (Dkt. No. 172), Exh. H, at ADM 10210 (emphasis added). To overcome this objection the applicants added a provision defining the molecular weights for the thickeners, the specification language now providing that

> [t]hickeners are mainly cellulose derivatives or high molecular weight carbohydrates. Typical molecular weights for cellulose derivatives are for methyl and hydroxy propyl methyl celluloses from about 60,000 to 120,000 and for hydroxy ethyl celluloses from about 750,000 to 1,000,000. Carbohydrate molecular weights range from about 10,000 to 50,000.

'793 Patent, col. 3, lns. 1-7; '622 Patent, col. 3, Ins. 9-15. In their response to the examiner's rejection, the applicants noted that the thickener contemplated was separate from other components, observing that as a result of the amendment,

> [w]ith respect to the thickener, claim 5 and claim 14 now recite that the thickener is selected from the group consisting of cellulose derivatives and carbohydrates, and recites the specific molecular weight range for both of these components which clearly distinguish them by molecular weight from the carbohydrate component now specifically recited as to its type, and in the range of 180 to 1,000.

ADM Exhibits (Dkt. No. 172), Exh. H, at ADM 10254.

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It is true, as the ADM defendants now argue, that through prosecution estoppel a party may disavow coverage of a certain subject matter. See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1333 (Fed. Cir. 2003) ("[P]rosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications.") (citations omitted). It does not follow from this history, however, that because the thickener specified in the '793 and '622 patents must be of a distinctly different molecular weight than the carbohydrates and sugars involved it must by definition derive from a separately added ingredient. At no time during the prosecution process associated with the two patents in suit did the applicants state to the PTO that the thickener must be separately added. There are in fact many carbohydrate sources which contain both low and high molecular weight carbohydrates; indeed, example two, recited in both the '793 and '622 patents, reveals an inherent thickener increasing the specified composition's viscosity through the addition of high maltose corn syrup which is also a potential source of low molecular weight carbohydrates.

While I reject the ADM defendants' argument that the prosecution history bars Sears from now claiming inherency, as opposed to the requirement that the thickener be a separately added ingredient as they contend, I do agree that refinement of my original definition is necessary to reflect the specification of weight ranges for the thickeners. Accordingly, I will define the term "thickener" as "a substance or material, whether inherent in or separately added to a composition, separate from the low molecular weight carbohydrate and chloride salt, which consists of either 1) a cellulose derivative with molecular weights of about 60,000 to 1,000,000 or 2) a carbohydrate with molecular weights of about 10,000 to 50,000, which causes an increase in the composition's viscosity."

* * *

ORDERED as follows:

1) The disputed terms of the '793 and '622 patents are hereby construed by the court as follows:

Terms	Construction
* * *	
"thickener"	a substance or material, whether inherent in or separately added to a composition, separate from the low molecular weight carbohydrate and chloride salt, which consists of either 1) a cellulose derivative with molecular weights of about 60,000 to 1,000,000 or 2) a carbohydrate with molecular weights of about 10,000 to 50,000, which causes an increase in the composition's viscosity.

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vii) Thickener

Claims four through six and eight provide for inclusion of a thickener with the previously described solution and, unlike the case with regard to colorants, also provide weight by percentage limits for such thickeners. The parties also disagree upon the definition of this term, and specifically whether it must be a separately added ingredient, or instead can be inherent in the other materials included within the composition.

A "thickening agent" is described by one source as "any of a variety of hydrophilic substances used to increase the viscosity of liquid mixtures and solutions". Hawley's, at 1084, as cited in Marks Aff. Exh. 19. The '793 patent describes the use of thickeners envisioned by the inventors as follows:

Thickeners are used in certain applications as the third key component to increase the viscosity of the composition so that the liquid remains in contact with the road surface or with the solid particles in piles of rocksalt/sand, or

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rocksalt/aggregates, or salt alone, or sand or aggregate. Thickeners are mainly cellulose derivatives or high molecular weight carbohydrates.

'793 patent, col. 2, ln. 63-col. 3, ln. 2. To be sure, inclusion of the phrase "the third key component" in the '793 patent does provide reason for pause. Nonetheless, it is generally understood -- and indeed spelled out in the patent -- that thickeners, whose sole function is to increase viscosity of a solution, are typically polymers, high molecular weight carbohydrates or cellulose derivatives, including carbohydrates. Reviewing the patent as a whole and the other intrinsic evidence available, I am unable to conclude that a person of ordinary skill in the art would not understand, in the context of this patent, that the thickeners envisioned could be included within the other prescribed constituents. Accordingly, I will construe the term "thickener" to mean a substance or material, whether inherent in or separately added to a composition, which causes an increase in the composition's viscosity.
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2. '094 Patent, '731 Patent, and '324 Patent

As stated above, constructions of "whole [beta] - glucan" and "whole yeast [beta] - glucan" in the '094 Patent, '731 Patent, and '324 Patent refer to "three-dimensional in vivo morphology." The patents' specifications reveal that three-dimensional in vivo morphology refers to the shape of the cells from which the glucans are derived. For instance, the detailed descriptions of the inventions state that whole [beta] - glucan can be derived intact from yeast cell walls. The derivation process "yields intact particles of [beta] - glucan, which maintain the spherical, elliptical or rod shaped configuration of the [beta] - glucan as found in vivo." '094 Patent, col. 3, ll. 25-28; '731 Patent, col. 4, ll. 14-16; '324 Patent, col. 4, ll. 4-7. "Whole glucan is comparable in size and shape to whole yeast cells . . . ." '094 Patent, col. 3, ll. 29-31; '731 Patent, col. 4, ll. 17-18; '324 Patent, col. 4, ll. 8-9. The detailed descriptions distinguish structural properties from morphological properties: "Changes in the structure of the yeast cell wall induced by the mutation can then be evaluated for effect on the morphology and structure of the whole [beta] - glucan extracted from the mutant yeast. These changes may be reflected in the shape of the extracted whole cell walls . . . ." '094 Patent, col. 4, ll. 45-50; '731 Patent, col. 5, ll. 39-43; '324 Patent, col. 5, ll. 31-35. Accordingly, the "three-dimensional in vivo morphology" in constructions of "whole [beta] - glucan" and "whole yeast [beta] - glucan" in the '094 Patent, '731 Patent, and '324 Patent refers to the shape of the cells from which the glucans are derived.
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5. "through a computer-controlled printing device"

a. The Parties' Proposed Constructions

OGT provides no proposed construction for "through a computer-controlled printing device" and only repeats the words "through a computer-controlled printing device." (D.I. 174 at 17; D.I. 173 at 2.) Mergen proposes that I construe "through a computer-controlled printing device" to mean "the monomer by monomer synthesis of oligonucleotides to known locations on the impermeable surface of the support is done with a computer-controlled printing device." 12 (D.I. 175 at 18 (emphasis added).)

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12 In the parties Joint Claim Construction Chart, Mergen proposed that I construe "through a computer-controlled printing device" to mean "the monomer by monomer synthesis of oligonucleotides at known locations on the impermeable surface of the support is done with a computer-controlled printing device." (D.I. 173 at 2 (emphasis added).)

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b. The Court's Construction

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Reading the claim in light of the specification requires me to construe "through a computer-controlled printing device" to mean "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides." I reach this conclusion after careful consideration of the claim term and the specification. Although OGT argues that claim 1 covers both the in situ and deposition methods of oligonucleotide synthesis (D.I. 174 at 18), the specification does not support the conclusion that a computer-controlled printing device can perform the deposition method.

Specifically, OGT points to three places in the specification for support. First, column 6, lines 51-55 of the '270 patent state: "Laying down very large number of lines or dots could take a long time, if the printing mechanism were slow. However, a low cost inkjet printer can print at speeds of about 10,000 spots per second." OGT uses this as support for the decreased time spent manufacturing an array by using an inkjet printer. (D.I. 174 at 18.)

This example supports the proposition that inkjet printers reduce the time required to manufacture an array. This quotation, however, comes from a section entitled, "5.2 Laying Down the Matrix." '270 patent, col. 6, II. 29-56. The first five lines of this section clearly disclose the in situ method of building oligonucleotides on the array. "The method described here envisages that the matrix will be produced by synthesising oligonucleotides in the cells of an array by laying down the precursors for the four bases in a predetermined patten, an example of which is described above." (Id. at II. 31-35 (emphasis added).) There is no disclosure in this section that supports OGT's proposition that inkjet printers can also be used for depositing pre-formed oligonucleotides. Therefore, according to the claim language and the disclosure in the specification, the time advantage referred to above is in the context of the in situ method of synthesizing oligonucleotides.

The second place OGT cites to support its argument that the specification discloses the deposition method of oligonucleotide synthesis is Section 5.3 entitled: "Oligonucleotide Synthesis." "Although we know of no description of the direct use of oligonucleotides as hybridisation probes while still attached to the matrix on which they were synthesised, there are reports of the use of oligonucleotides as hybridisation probes on solid supports to which they were attached after synthesis." (D.I. 1, Ex.1, col. 6 line 63 through col. 7 line 1 (emphasis added).) This disclosure does refer to the deposition method, but does not provide support for OGT's argument that claim 1 includes this method. If anything, this disclosure seems to support Mergen's argument that: "This patent is a teaching of the new technology …. The only time they mention a deposit method, they talk about the known prior art, which they're just changing their patent from." (D.I. 269 at 72:18-73:3) Therefore, I do not believe that this disclosure gives added support to OGT's argument.

The third place in the specification that OGT cites for its construction is Example 5 which states: "A microcomputer was used to control the plotter and the syringe pump which delivered the chemicals." '270 patent, col. 11, ll. 52-53. This example, however, continues: "Filling the pen successively with G, T and A phosphoramidite solutions an array of twelve spots was laid down in three groups of four, with three different oligonucleotide sequences." '270 patent, col. 11, ll. 57-60 (emphasis added).) Reading Example 5 in full, makes it clear that it discloses the use of a microcomputer to control the in situ method of oligonucleotide synthesis because the nucleotides are filled "successively." This is different than depositing a preformed oligonucleotide as would be required in the deposition method. 13

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13 OGT makes another argument in its Answering Brief which seems to suggest that Example 5 does not even apply to claim 1. "Meanwhile, claim 7, contains a limitation to a computer-controlled printing device. Since it depends from claim 3, claim 7 is limited to in situ synthesis by its own terms. And because it is limited to in situ synthesis, claim 7 recites attaching 'nucleotide precursors.' Claim 1 does not apply 'nucleotide precursors.'" (D.I. 222 at 15-16 (emphasis added).)

This argument by OGT seems to contradict its reliance on Example 5 for disclosing support for the deposition method of oligonucleotide synthesis. Example 5 begins with the phrase, "To test an automated system for laying down the precursors …." (D.I. 1, Ex. 1, col. 11, ll. 42-43 (emphasis added).) If Example 5 does not pertain to claim 1, as OGT seems to suggest, then OGT has eliminated that example as support for its argument that claim 1 is not limited to in situ oligonucleotide synthesis.

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Based on the foregoing, I conclude that the language of the claim, when read in light of the disclosures in the specification, supports the conclusion that "through a computer-controlled printing device" means "through a computer-controlled printing

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device using monomer by monomer synthesis of oligonucleotides."

Even if this construction were not sufficiently clear from the patent itself, the prosecution history also supports this interpretation. Original claims 36 and 37 of what became the '270 patent were as follows:

36. A method of making an array of oligonucleotides, which comprises:

attaching a plurality of oligonucleotides to an impermeable surface of a support, the oligonucleotides having different predetermined sequences and being attached at different known locations on the surface of the support.

37. The method as claimed in claim 36 or 111, wherein the oligonucleotides are synthesized before attachment to the surface of the support.

(D.I. 201, Ex. D at 4.) (Declaration of Philip Rovner.) After amendment, claim 36 became claim 1, as discussed above. The prosecution history provides evidence for the motive behind the amendment to add the language "through a computer-controlled printing device" at the end of the claim. (D.I. 201, Ex. D at 4.) The examiner rejected claim 37 under 35 U.S.C. § 112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (D.I. 201, Ex. E at 2.) The basis for the rejection was that: "The 'synthesis' before attachment of claim 37 has not been found." (Id. (emphasis added).) In other words, a claim including the deposition method was not supported by the specification. The applicant cancelled claim 37 in response to this rejection. (D.I. 201, Ex. F at 1.) And finally, when claim 36 was eventually allowed, the examiner stated: "Stavrianopoulos et al. (U.S. Patent No. 4,994,373) is the closest prior art of record but neither teaches nor suggests monomer by monomer synthesis of oligonucleotides on a surface nor the hybridization assay practice of utilizing an array of different oligonucleotide probes on a single surface." 14 (D.I. 201, Ex. H at 4 (emphasis added).)

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14 OGT has argued that this statement by the examiner specifically refers to only claims 3 through 8 and not claim 1. When asked to provide a basis for this argument, other than "generalized reasoning," counsel for OGT simply stated, "So my answer is, no, I can't do that, Your Honor." (D.I. 269 at 45:22-23.) Therefore, I do not find any basis for limiting the examiner's comments to only claims 3 through 8.

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This prosecution history suggests: (1) that the examiner did not find support in the specification for the deposition method, evidenced by his rejection of claim 37's "synthesis before attachment;" (2) the amendment to original claim 36, adding "through a computer-controlled printing device," limited claim 36 to monomer by monomer synthesis because otherwise, the examiner would have rejected it for the same reason he rejected claim 37; and (3) at least one reason that the examiner allowed the claim is because it taught monomer by monomer synthesis, which distinguished it over the closest prior art. Therefore, the prosecution history supports the conclusion that "through a computer-controlled printing device" means "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides."
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F. "substantially uniformly dispersed throughout said coating"

This term describes how the glitter is distributed within the coating. Defendants urge the Court to adopt a construction that specifies that the glitter particles must be distributed throughout the "thickness and entirety" of the coating.

However, the term "throughout" is unambiguous and thus, the ordinary meaning must prevail. The ordinary meaning of "throughout" is "in or through every part" or "everywhere." Webster's Ninth New Collegiate Dictionary 1230 (1987). Thus, the patent requires the glitter to be dispersed through every part of the coating. The specification neither contradicts not adds to the understanding of this term; therefore, the Court declines to impose any limitation. Although the term is not as precise

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as it might be, Defendants' proposal to clarify it is beyond the scope of claim construction. See PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998) (holding that court may not, under rubric of claim construction, add clarification beyond that supported by the specification merely to facilitate claim construction).
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C. "tissue ingrowth promoter" ('290 patent)

50) The term "tissue ingrowth promoter" only appears once in the specification and is not further explained. D.I. 70, Ex. A ('753 patent) 6:26-28. Consistent with the plain meaning of the claim language and the specification, the Court construes this phrase as meaning "a therapeutic agent used to increase tissue growth."
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1. Tissue Plasminogen Activator

Genentech contends that the term "tissue plasminogen activator" as used in Claim 1 of the '225 patent means "native human tissue plasminogen activator or biologically active human tissue plasminogen equivalents, where 'biologically active human tissue plasminogen activator equivalents' means tissue plasminogen activators or analogs which are derived from native human t-PA gene and meet all of the following functional characteristics . . . (a) cleave plasminogen to plasmin; (b) bind to fibrin; and (3) share immunological properties of native human t-PA."

BM argues that the term "tissue plasminogen activator" was decisively defined in Genentech, Inc. v. Wellcome Foundation, Ltd., 29 F.3d 1555, 1565-67 (Fed. Cir. 1994). The Wellcome Court, after reviewing two Genentech t-PA patent claims and patent specifications, concluded that the phrase "human tissue plasminogen activator" in those claims meant "natural t-PA" or "t-PA produced through recombinant DNA technology but having the same structure as natural t-PA." Id. at 1565; see also Genentech v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) (pointing out that it construed the term "human tissue plasminogen activator in the context of the claims of the patent at issue in that case."). With respect to the functional definition which is substantially the same as the definition in the '225 patent, the Court noted:

There may also be a problem with satisfaction of the definiteness and description requirements of 35 U.S.C. § 112 in relation to these other definitions, especially the fourth functional definitions. The DNA isolate which is the subject of the '075 and '330 claims is itself defined in functional terms, i.e., as any sequence that encodes human t-PA. A conclusion that the phrase "human tissue plasminogen activator" is also defined in functional terms would give rise to a definiteness problem because a competitor could not then reasonably determine that DNA sequences are within the scope of the claims and which are not. It would also give rise to a problem with the description requirement because the specification does not even remotely describe all the DNA sequences that encode the proteins within the scope of the functional definition.

29 F.3d at 1565 n.25 (emphasis added); see also Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

The court in Wellcome, however, was not construing the claims in Genentech's '225 patent, which is the limited purpose of this proceeding. As Genentech pointed out, the Wellcome court construed the patents in light of the knowledge in 1982, and the '225 patent was filed in 1985. Moreover, the focus of the patents differ. The '225 patent is directed to a method of increasing the solubility of t-PA while the Wellcome patents claimed human t-PA itself, as well as the expression vector and cell culture producing it. The troublesome question as to whether the functional definition in the '225 patent is "hopelessly overbroad," 29 F.3d at 1564, and meets the requirements of 25 U.S.C. § 112, is not appropriate for a Markman hearing.

a. Intrinsic Evidence

The term "tissue plasminogen activator" is not defined in the '225 claim itself. The '225 patent specification, however, provides the following definitions:

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The terms "human tissue plasminogen activator," "human t-PA," or "t-PA" denotes human extrinsic (tissue type) plasminogen activator, produced, for example, from natural source extraction and purification (see Collen, et al., supra), and by recombinant cell culture systems as described herein. Its sequence and characteristics are set forth, for example, in European Application Publ. No. 93619 (published 9 Nov. 1983) based upon a first filing on 5 May 1982, incorporated herein by reference. See also European Patent Application Publication No. 41766 (published 16 Dec. 1981) based upon a first filing of 11 June 80 and Riijken et al., Journal of Biol. Chem. 256, 7035 (1981), also incorporated herein by reference.

The terms likewise cover biologically active human issue plasminogen activator equivalents, different in one or more amino acid(s) in the overall sequence, or in glycosylation patterns, which are though [sic] to be dependent on the specific culture conditions used and the nature of the host from which the tissue plasminogen activator is obtained.

('225 patent, col. 3, 1. 65, col. 4, 11. 9-16.)

The '225 specification incorporates, by reference, the "sequence and characteristics" of t-PA set forth in European Patent Application Publn. No. 96619 ('225 Patent, col. 4, 11. 1-4.) That application provided a "functional definition" of human t-PA: "it is capable of catalyzing the conversion of plasminogen to plasmin, binds to fibrin, and is classified as a t-PA based on immunological properties." (European Patent Application Publn. No. 93619.) The '225 patent specification also incorporates, by reference, Riijken, et al., Journal of Biological Chemistry 256, 7035 (1981), an article that defines human t-PA by the same three functional characteristics. ('225 patent, col. 4, 1. 8.)

The dispute, it seems, focuses on whether the term tissue plasminogen activator in Claim 1 embraces equivalents with certain functional characteristics. The intrinsic evidence unambiguously answers yes. The term t-PA expressly covers "biologically active human tissue plasminogen equivalents" as described at Col. V, line 11-16, with the functional characteristics set forth in the European patent application.

b. Claim Construction

The Court construes the meaning of the term "tissue plasminogen activator," as used in Claim 1 of the '225 patent, to mean native human t-PA, whether produced from natural source extraction or recombinant cell culture systems described in the extraction or recombinant cell culture systems described in the patent, as well as certain described biologically active human tissue plasminogen activator equivalents which (i) are capable of catalyzing the conversion of plasminogen to plasmin; (ii) bind to fibrin, and; (iii) share basic immunological properties of native t-PA.

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A. Tissue Specific 4

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4 ImClone identifies the term "tissue specific" for purposes of claim construction. Plaintiffs correctly argue that the term to be construed is "tissue specific mammalian cellular enhancement."

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The specification teaches that

[t]he enhancer sequences function to greatly increase transcription, but only in a specific tissue-type or cell-type; the enhancer function of the sequences is greatly diminished or totally absent in other types of cells.

'281 patent, Col. 5, ll. 63-67. The specification further provides that

[s]ince each of the cell enhancers useful in the invention are tissue-type or cell-type specific, they typically do not function, or function only at very low or undetectable levels when transfected into cell lines derived from tissues different from the tissue in which they are normally active. In some cases, the enhancers are cell-type specific and will not function if placed in a different cell-type, even one derived from the same tissue type.

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Id., Col. 6, ll. 23-31. In Example III -- which bears the subheading "Cellular Enhancer Genes are Tissue Specific" -- the inventors concluded that the enhancer element of the immunoglobulin heavy chain gene is functional only in lymphoid cells, and not in L cells, which are non-lymphoid in nature. See id., Col. 11, ll. 50-56.

Plaintiffs essentially track the language of the specification in their proffered construction, 5 while ImClone argues that the court should strike the term "cell-type" from the claim and add language to specify that transcription is greatly increased only in a "specific tissue type in which transcription is normally active." 6

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5 Plaintiffs contend that the phrase "tissue specific mammalian cellular enhancer" should be construed as specifying

DNA sequences in a mammalian cell that function to greatly increase transcription, but only in a specific tissue-type or cell-type; the enhancer function of the sequences is greatly diminished or totally absent in other tissue or cell types.

They additionally state that though repetitive, the following sentence could be added to the construction.

Such DNA sequences typically do not function, or function only at very low or undetectable levels when transfected into cell lines derived from tissues different from the tissue in which they are normally active.

6 Defendants contend that the term should be construed as

[t]he enhancer sequences function to greatly increase transcription, but only in a specific tissue-type in which transcription is normally active; the enhancer function of the sequences is greatly diminished or totally absent in other types of cells in which transcription is not normally active.

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The crux of ImClone's argument is that plaintiffs' proposed construction renders the claim indefinite and poses an impossible burden for a defendant attempting to establish non-infringement. According to ImClone, plaintiffs' failure to identify "the tissue" to which an enhancer must be "specific" enables plaintiffs to manipulate the testing of a drug like Erbitux for litigation purposes. Because plaintiffs define "tissue specific" to mean only that the cellular enhancer greatly increases transcription in some tissues and cell-types and not others, ImClone argues that to make a case of infringement, plaintiffs need simply to find one cell (out of an infinite number of cells) in which the enhancer does not work (including cells that are dead). 7

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7 According to ImClone, the term "tissue specific" means that the enhancer must function only in "a" specific tissue-type or cell-type, that is, the biological host in which the enhanced protein is normally expressed. It argues that under plaintiffs' theory, testing could be performed with a virtually infinite number of tissue or cell-types without any final determination of whether a particular enhancer was or was not "specific," and therefore protected by the '281 patent.

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ImClone additionally accuses plaintiffs of improperly "cherry-picking" the infringement test. Rather than using the same types of tissues for comparison as were disclosed in the '281 patent (lymphoids and fibroblasts), plaintiffs' litigation test is based on a type of cell known as the "293 cell," which, according to ImClone, is not mentioned in the '281 patent or in any of the contemporaneous peer-reviewed literature. Moreover, 293 cells purportedly contain foreign viral DNA that unpredictably affects the transcription rate of transfected genes. ImClone argues that plaintiffs should not be permitted to rely on a test specifically devised to bolster their infringement case, when the test disclosed in the '281 patent would result in the opposite showing. According to ImClone, the substitution of tests contradicts the teaching of Honeywell Int'l, Inc. v. Int'l Trade Comm'n, 341 F.3d 1332 (Fed. Cir. 2003). The Federal Circuit in Honeywell considered a patent dispute related to a polyester based yarn that is converted into cord that is used to reinforce automobile tires. The yarn specimen could be produced in four possible ways, known as "sample preparation methods." The parties argued over whether the claims required a particular sample preparation method when determining the meaning of the claim term: "melting point elevation"

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(MPE). See id. at 1339. Depending upon which sample preparation was used, the MPE for a given sample could vary greatly. Id. at 1336. The Federal Circuit held that the claims were "insolubly ambiguous, and hence indefinite." Id. at 1340.

Because the sample preparation method is critical in determining MPE, processes utilizing different sample preparation methods will produce different yarns. Without knowing which sample preparation method to use, one cannot discern whether a yarn was produced using the claimed process. Under the "any one method" construction, the testing results will necessarily fall within or outside the claim scope depending on the sample preparation method chosen. Competitors trying to practice the invention or to design around it would be unable to discern the bounds of the invention.

Id. at 1341. 8

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8 It should be noted that in Honeywell, the dispute involved issues of patent validity and not claim construction.

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Finally, ImClone argues that while the "Larger Segment" of the nucleotide sequence shown in Fig. 10 of the '281 patent may be tissue specific, the "Erbitux Segment" is not. According to ImClone, the Larger Segment's tissue specificity results from tissue specific repressive elements that are not incorporated in the Erbitux Segment.

At bottom, whatever their weight, ImClone's arguments go to the issues of patent validity and infringement, and have no real bearing on claim construction. They are, in other words, arguments to be made to the jury and not to the court. Plaintiffs' proposed construction tracks the language of the specification, and is not outside the bounds of the claim itself. See Honeywell, 341 F.3d at 1341. Moreover, there is nothing in the '281 patent to justify ImClone's proposed importation of the limitation -- "in which transcription is [or is not] normally active" -- into the claim, or to warrant the deletion of the words "cell-type." 9 Therefore, the court will construe the term "tissue specific mammalian cellular enhancer" to mean "a DNA sequence in a mammalian cell that functions to greatly increase transcription in a specific tissue-type or cell-type, but which barely works in other tissue or cell-types, or does not work at all."

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9 While the court has located no case specifically on point, the idea of deleting a substantive term from a claim seems counterintuitive. The court's task under Markman is to construe "the words of the claims themselves," Innova, 381 F.3d at 1116, not to ignore them.

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1. Titanium Nitride

Titanium nitride is a compound with a one-to-one ratio of titanium atoms to nitrogen atoms.
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2. "and wherein the formulation further comprises a topcoat comprising galantamine and water-soluble polymer"

The main dispute in this phrase centers around the term "topcoat". Topcoat appears in claims 1 and 12 of the patent. Plaintiffs' position is that the topcoat need not be the outermost layer but may be any layer that is not covered by a release rate controlling membrane. On the other hand, the Defendants argue that the topcoat must be the outermost layer. Specifically, Plaintiff's proposed construction is as follows: "The drug product includes one or more layers of coating material that includes galantamine and a water-soluble polymer and that are not covered by a release rate controlling

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membrane, such that the formulation is capable of releasing some galantamine in a manner consistent with the release profile set forth below." Each of the Defendants offered their own construction of the phrase as follows:

KV: "The component of a dosage form that provides for the altered release additionally has an outmost coating comprising galantamine and water-soluble polymer."

Barr: "And wherein the formulation as previously defined in claim 1 also has an additional, outermost coating comprising galantamine and water-soluble polymer."

Sandoz: "The particles previously defined in claim 1 have an additional, outermost coating comprising galantamine and water-soluble polymer."

The plain meaning of "topcoat" supports Defendants' position that it is the outermost layer. The Court first turns to the dictionary definition of "topcoat". The Federal Circuit has approved the use of the dictionary when fleshing out a term's plain meaning as long as the definition does not contradict any specific meaning of the word in the patent. Phillips, 415 F.3d at 1322. In Webster's Dictionary, "topcoat" is defined as "an overcoat" as in a "protective coating". Merriam-Webster, http://www.merriam-webster.com/ dictionary/topcoat (site last visited Feb. 6, 2009). Since none of the parties have argued that "topcoat" has a specific meaning in the patent itself, the Court finds that the plain meaning supports Defendants' construction.

Furthermore, the language of dependent claim 12 confirms that topcoat is the outermost layer. Specifically, claim 12 provides: "A process of preparing a formulation according to claim 1 comprising admixing galantamine hydrobromide (1:1) with a water soluble film forming polymer and coating onto inert spheres to form a drug core, optionally applying a seal coat to the drug core, applying the release rate controlling membrane, and thereafter applying a topcoat comprising galantamine and a water-soluble polymer." '559 patent at 14:57-64. This claim describes a multi-stage layering process with the "topcoat comprising galantamine and a water-soluble polymer" being the last coat applied; thus rendering it the outermost coat. Id.

Moreover, the patent specification is consistent with the ordinary meaning discussed above and directs the topcoat layer to be applied on top of the controlled release particles. The specification states that "part of the galantamine is present in an immediate release form … or as a topcoat on the controlled release formulation." '559 patent at 2:50-54. Furthermore, Example 5 provides "the controlled release membrane coated spheres were sprayed with the drug topcoat solution. … The topcoated spheres were [then] filled into hard-gelatin capsules." '559 patent at 12:58-65. According to this example, there is a final drug layer on top of the controlled release membrane, thus the topcoat is the outermost layer. Plaintiffs' contention that the topcoat need not be the outermost layer, is inconsistent with this example.

The patent prosecution history also supports the Defendants' constructions. During the patent prosecution, Plaintiffs amended application claim 10 (now issued claim 1) to add a topcoat limitation to overcome an obviousness rejection based on U.S. Patent No. 5,576,022 ("Yang Patent"). Defs.' Joint Exhibit 2, Tab 82, Oct. 21, 2005 Am. at 3. The Yang Patent "discloses a controlled release formulation that comprises an immediate release core that comprises nonpareil seeds, tacrine and a binding agent, a sealing layer or sustained release layer over the immediate release pellets. 2" The Yang Patent contains a mix of immediate release and controlled release particles in which the controlled release particles are akin to immediate release particles covered by a sustaining layer. In order to distinguish its controlled release particles from Yang's, Plaintiffs amended their initial application to require" the controlled release formulation of the present invention [to] further comprise[] an immediate release topcoat of galantamine and water-soluble polymer which provides the specified release rate of galantamine from the formulation which is not taught or suggested by Yang et al." Id. at 7. Based on this, the Patent Examiner stated that Plaintiffs' "invention is distinguished over the prior art by having a topcoat comprising galantamine and water-soluble polymer disposed over the water-insoluble polymer membrane." Defs.' Joint Exhibit 2, Tab 110, at 2-3. The PTO issued Plaintiffs' patent because it understood that the topcoat was the outerlayer over the controlled release particle. Plaintiffs cannot now alter their claims to recapture through claim interpretation what they previously disclaimed during prosecution. See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("the doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.")

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2 "The 'sustaining layer' described in Yang serves a similar function as the 'release-rate controlling membrane coating' in the particles of the '559 patent. (Ex. J, Yang, col. 3, ll. 56-60 (noting that one of the components of the 'sustaining layer' works as 'a diffusion barrier for the [API] and controls its release rate'.))" Sandoz Opening Brief fn. 12 at 23.

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Finally, the extrinsic evidence confirms Defendants' construction. Specifically, several of the patent's inventors testified that they understood topcoat to be the outermost coating. For instance, in response to the following question: "Is it your understanding that what has been referred to here is that the outermost coat if the formulation has to have galantamine and water soluble polymer," Inventor Marc De Weer responded: "To my understanding, yes." Barr Opening Brief, Ex. H, De Weer Dep. Tr. at 54:22-55:4. Similarly, when asked about his understanding of topcoat, Inventor Paul McGee testified: "We were thinking of top[]coat as being on the outside." Barr Opening Brief, Ex. I, McGee Dep. Tr. at 193:11-14.

Considering the plain language of claims 1 and 12 as well as the specification of the '559 Patent, the patent prosecution history, and relevant extrinsic evidence, the Court shall construe "topcoat" consistent with KV's proposed construction as follows: "the component of a dosage form that provides for the altered release additionally has an outmost coating comprising galantamine and water-soluble polymer. 3"

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3 The Court selects KV's construction out of the proposals submitted by the Defendants because it also includes the definition of formulation that was previously adopted by the Court.

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Jansen is the sole inventor and owner of the '083 patent, which is directed to methods of "treating or preventing macrocytic-megaloblastic anemia" by administering a combination of folic acid and vitamin B[12] "to a human in need thereof." '083 patent, col. 6, ll. 20-24, ll. 37-41. According to the patent, deficiencies of either folic acid or vitamin B[12] can cause macrocytic-megaloblastic anemia, also referred to as pernicious anemia, while a deficiency of vitamin B[12] can also cause neurological problems. Id. at col. 4, ll. 13-25. When folic acid alone is utilized to treat macrocytic-megaloblastic anemia, the folic acid may mask a vitamin B[12] deficiency. Id.; see also id. at col. 3, l. 65 - col. 4, l. 5. An objective of Jansen's invention is to administer both supplements together to avoid the masking problem. Id. at col. 4, ll. 25-48. The independent claims read as follows:

1. A method of treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B[12] deficiency which comprises administering a daily oral dosage of a vitamin preparation to a human in need thereof comprising at least about 0.5 mg. of vitamin B[12] and at least about 0.5 mg. of folic acid.

4. A method of treating or preventing macrocytic-magaloblastic [sic] anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B[12] deficiency which comprises orally administering combined vitamin B[12] and folic acid to a human in need thereof in sufficient amounts to achieve an oral administration of at least about 0.5 mg. of vitamin B[12] and at least about 0.5 mg. of folic acid within one day.

Id. at col. 6, ll. 20-24, ll. 37-41 (emphases added).

* * *

On appeal, Jansen first argues that the court improperly construed the claims. More specifically, he contends that the court's construction improperly added to the claims an intent element, which is contrary to law as well as contrary to the ordinary meaning of the claim language, which does not suggest that the infringer's state of mind is relevant. Nor does the '083 patent's prosecution history, according to Jansen, suggest that the infringer's state of mind is relevant. He also argues that

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Rapoport does not support the court's view that a direct infringer must purposefully perform the claimed method, and that in any event Rapoport is distinguishable because that case, unlike this case, did not involve a claim to a method of prevention of a disease. According to Jansen, the phrase "a human in need thereof" encompasses a person who does not know that his or her serum levels of folic acid and vitamin B[12] are adequate. Jansen secondly argues that he presented sufficient evidence of infringement to avoid summary judgment. According to Jansen, Rexall's formulation and labeling are circumstantial evidence of direct infringement by Rexall's customers.

Rexall responds that the court's claim construction does not add an intent element to the claims except as required by the particular language of the claims themselves. Rexall also contends that, just as in Rapoport, the claims in the '083 patent should be interpreted to require that the target group ("humans in need thereof") practice the method for the stated purpose ("treating or preventing macrocytic-megaloblastic anemia"), especially where, as here, the prosecution history reveals that both limitations were added for patentability. According to Rexall, a "human in need thereof" is someone either suffering from macrocytic-megaloblastic anemia or at a recognized risk, such as by medical diagnosis, of developing that condition. Rexall also responds that there is no evidence that it markets its product to the target group for the claimed purpose; on the contrary, it contends that it markets its product only for regulation of blood homocysteine levels. Rexall further contends that, even if there were some evidence of direct infringement by its customers, it is not liable for indirect infringement, for it has not intended to cause infringement and there are substantial noninfringing uses of its product, thereby negating inducement of and contributory infringement.

We begin our claim construction, as always, with the ordinary meaning of the claim language. Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1341 (Fed. Cir. 2001). That language requires that the method be performed on "a human in need thereof" and that the method be used "for treating or preventing macrocytic-megaloblastic anemia." The parties do not dispute what "macrocytic-megaloblastic anemia" means; instead, they dispute how the "treating or preventing" phrase and the "to a human in need thereof" phrase should be read. The issue reduces to whether such a human must know that he is in need of either treatment or prevention of that condition.

A similar issue arose in Rapoport, an interference proceeding before the PTO's Board of Patent Appeals and Interferences. The count in that case read as follows:

A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

254 F.3d at 1056 (emphases added). On appeal we gave weight to the ordinary meaning of the preamble phrase "for treatment of sleep apneas," interpreting it to refer to sleep apnea, per se, not just "symptoms associated with sleep apnea." Id. at 1059. Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. Id. at 1061. We rejected that argument, stating, "There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea with the intent to cure the underlying condition." Id. (emphasis added). Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Just as in Rapoport, it is natural to interpret the nearly parallel language in the '083 patent claims in the same way. In both Rapoport and this case, the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone "in need." In both cases, the claims' recitation of a patient or a human "in need" gives life and meaning to the preambles' statement of purpose. See Kropa v. Robie, 38 C.C.P.A. 858, 187 F.2d 150, 152, 1951 Dec. Comm'r Pat. 177 (CCPA 1951) (stating the rule that a preamble is treated as a limitation if it gives "life and meaning" to the claim). The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed. We need not decide whether we would reach the same conclusion if either of the "treating or preventing" phrase or the "to a human in need thereof" phrase was not a part of the claim; together, however, they compel the claim construction arrived at by both the district court and this court.

Our conclusion as to the meaning of the claims is bolstered by an analysis of the prosecution history. The prosecution history is often useful to ascertain the meaning of the claim language. Indeed, claims are not construed in a vacuum, but rather in the context of the intrinsic evidence, viz., the other claims, the specification, and the prosecution history. See DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1327 (Fed. Cir. 2001). In this case, the "treating or preventing

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macrocytic-megaloblastic anemia" phrase and the "to a human in need thereof" phrase were added to gain allowance of the claims after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without those phrases. We must therefore give them weight, for the patentability of the claims hinged upon their presence in the claim language. See Smith v. Magic City Kennel Club, Inc., 282 U.S. 784, 790, 75 L. Ed.
707, 51 S. Ct. 291, 1931 Dec. Comm'r Pat. 716 (1931) ("The applicant[,] having limited his claim by amendment and accepted a patent, brings himself within the rules that if the claim to a combination be restricted to specified elements, all must be regarded as material, and that limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and looked upon as disclaimers."). Furthermore, because both phrases were added simultaneously to overcome the same rejection, they should be read together, meaning that the word "thereof" in the phrase "to a human in need thereof" should be construed to refer to the treatment or prevention of macrocytic-megaloblastic anemia. Finally, that "need" must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances of their addition suggest that they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. Thus, the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B[12] must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.
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1340

B. "Treatment of PHN"

Novartis proposes the following construction of the term "treatment of PHN" as used in Claim 1:

Achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.

(Id., at 3.) Roxane, on the other hand, defines "treatment of PHN" as used in Claim 1 to mean:

Achieving a therapeutic effect on PHN in mammals, for example, by reducing theduration and/or incidence of PHN when compared to a control.

(Id.) The definitions differ in two respects. First, Roxane's definition includes reducing the incidence of PHN. Second, Roxane's definition includes only those treatments that have a therapeutic effect as compared to a control, including an active control.

With respect to the first difference, the Court finds that Roxane's construction has no support in the intrinsic evidence. Although the patent states that "'treatment' includes prophylaxis as appropriate," (581 Patent, Col. 1:11-12), it does not further define prophylaxis to mean prevention of disease. On the contrary, in the background of the invention section, the patent expressly states that "[t]here is currently no proven therapy for preventing PHN." (Id. at 2:1.) The specification further states that, as such, "there is a need for therapy which alleviates or shortens the duration of post-herpetic neuralgia." (Id. at 2, 4-5 (emphasis added).) Additionally, the study highlighted in the specification repeatedly notes the effect of famciclovir on the duration of PHN. (See, e.g., id. at 9:13-15 ("[F]amciclovir . .. significantly reduced the duration of postherpetic neuralgia."); id. at 10:46-48 ([F]amciclovir clearly demonstrated a significant reduction in the duration of postherpetic neuralgia in comparison with placebo.").) For its proposed construction, Roxane relies heavily on the "ordinary meaning" of the word treatment as defined in various dictionary and treatises. But, as discussed above, a term may not be given a meaning based on extrinsic evidence viewed in the abstract without reference to the context provided by the specification and other intrinsic evidence. Therefore, the Court rejects Roxane's inclusion of the word incidence in the definition.

The Court also agrees with Novartis that, given the intrinsic evidence, the effect should be compared to any treatment versus only to a control. The study primary highlighted in the specification evaluated the effect of famciclovir as compared to a placebo. (See id. at 10:46-48.) Although that study referenced another study using an active control, the focus of the '581 patent, read as a whole, is on the effect of famciclovir over any other treatment. There is nothing in the intrinsic evidence or

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in the meaning of "treatment," as definedin extrinsic evidence, that supports a finding that "treatment" only includes a course of therapy that is better than every alternative. Therefore, the Court construes the term "treatment" in Claim 1 to mean: Achieving a therapeutic effect on PHN, for example, by reducing the duration of PHN relative to how long it would persist in the absence of any treatment.
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1341

2. "heating . . . to a temperature substantially above the softening temperature of said binder material"

KXI and PUR agree, as does the court, that the phrase "heating . . . to a temperature substantially above the softening temperature of said binder material" should be construed in this case the same way the phrase was construed in Culligan. Therefore, the court finds that "heating . . . to a temperature substantially above the softening temperature of said binder material" means heating to a temperature sufficiently above the softening temperature of the binder to allow conversion of the binder to a continuous web matrix or forced point bonds.
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1342

B. "Passing the Produced Smoke Through a Filter to Remove Mainly the Tar Therefrom"

TPI and HISI also disagree about the meaning of the phrase "passing the produced smoke through a filter to remove mainly the tar therefrom." TPI contends that this phrase should be construed to include any amount of filtering, "so long as some tar is removed." (TPI Brief 41.) More specifically, it argues that the language of this claim is broad enough to cover even filtering processes that render the smoke tasteless, such as the process described by the Kowalski Patent.

HISI, on the other hand, contends that this phrase protects only processes designed to remove the larger particles from the smoke, such as tar. It argues that the Yamaoka Patent does not claim a filtration process which removes the smaller flavor-giving particles from the smoke in addition to the larger tar particles. To the contrary, HISI argues, the Yamaoka Patent claims a process which imparts some flavoring to the fish that is not originally present in the fish. This flavoring can only be imparted, it argues, by allowing some of the smaller particles to pass through the filter.

The Court agrees with HISI that the language of the claim itself indicates that the Yamaoka process is designed specifically to remove tar from the smoke. Ths smoke is not passed through a filter, which happens to have the incidental effect of removing the tar, but is instead to be "passed through a filter to remove" the tar -- i.e., for the specific purpose of removing the tar from the smoke. The language of the claim does not appear to encompass a process that is intended to remove not only the tar, but also the smaller flavor-giving particles. Some ambiguity remains, however, because of the word "mainly." Therefore, the Court once again turns to the specifications of the Yamaoka Patent for additional guidance.

Here, the specifications confirm that the Yamaoka Patent does not claim filtration processes designed to remove other substances from the smoke in addition to the tar. The Yamaoka Patent initially summarizes the invention as follows:

With a major part of the tar thus filtered off, the remaining smoke exerts preservative, sterilizing and color-keeping actions on substantially fresh fish and meat without imparting any disagreeable odor, taste or color thereto. Instead, the smoke imparts agreeable taste and smell to the processed fish and meat while keeping them in a substantially fresh condition.

(Yamaoka Patent, Col 3, at 20-26 ("emphasis added").) This language shows that not only does the Yamaoka Patent contemplate preserving fish without imparting disagreeable taste, but it also includes the addition of some type of taste or smell not naturally present in the fish. This taste and smell can only be imparted through particles not filtered out during the filtration process. While TPI is correct that the Yamaoka Patent's specifications discuss ways in which "[t]he level of aromatic smell characteristics of smoked products can be easily raised [(and presumably also lowered)] by varying the kind and quantity of the filtering materials," (Yamaoka Patent, Col. 7, at 4-6), the Yamaoka specifications always assume that some level of taste or aroma will be present at the end of the filtering process.

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Accordingly, the Court determines the Yamaoka Patent claims a process for filtering smoke to the extent that the smoke produced by the filtration is still able to impart a noticeable and "agreeable" taste and smell to the fish. The Yamaoka Patent does not claim a process specifically intended to filter flavor-giving particles out of the smoke.
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1343

a. Claim Interpretation

Clearly, our analysis must begin with an examination of the language of the disputed claims. The independent 12 claims of the '465 patent are:

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12 "A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. § 112. "One may infringe an independent claim and not infringe a claim dependent on that claim. The reverse is not true. One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim." Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989).

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1. The method of administering an agent to reduce duration of common cold symptoms in humans, which includes reducing the duration of nasal drainage, nasal congestion, headache, fever, myalgia, sneezing, sore throat, scratchy throat, cough, and hoarseness when such symptoms evince existence of a common cold, comprising:

applying, in the form of a lozenge, zinc gluconate to the oral mucosa of a human in need of treatment;

permitting zinc to remain in contact with the mucosa for a period of time necessary for lozenges to dissolve;

and applying additional dosages of zinc until the symptoms have disappeared.

. . . .

4. A method for treating the common cold comprising:

(a) applying an effective dosage of zinc gluconate to the oral mucosa of a human in need of treatment;

(b) permitting the zinc thereof to remain in contact with the oral mucosa for a period of time necessary for it to saturate the oral mucosa; and

(c) applying additional dosages to [sic] zinc gluconate in like fashion until the cold has been treated.

. . . .

18. A method for treating symptoms commonly associated with the common cold, the symptoms including nasal drainage, nasal congestion, headache, fever, myalgia, sneezing, sore throat, scratchy throat, cough or hoarseness to reduce the duration or severity thereof comprising:

(a) applying an effective dosage of zinc gluconate to the oral mucosa of a human in need of treatment;

(b) permitting the zinc thereof to remain in contact with the oral mucosa for a period of time necessary for it to saturate the oral mucosa; and

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(c) applying additional dosages of zinc gluconate in like fashion until the severity or duration of the symptom has been reduced.

Ex. E, Defs.' Mot for Summ. J., U.S. Patent No. Re. 33,465.

With respect to Claim 1, we first observe that one of the elements of the claim is that the cold remedy be applied "in the form of a lozenge". As discussed above, literal infringement is found only where each and every limitation of the claim is found in the accused device, see Elkay Mfg., 192 F.3d at 980. Here, there is no dispute that ZICAM is not dispensed in lozenge form, and thus an allegation of literal infringement as to Claim 1 must fail. 13

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13 Quigley focuses its argument regarding literal infringement on Claim 4, and thus it appears that this finding with respect to Claim 1 is not disputed. Moreover, as Claims 2 and 3 are dependent on Claim 1, our finding that there is no literal infringement of Claim 1 means that there is no literal infringement of Claim 2 or 3, either.

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Claims 4 and 18 14 present a harder question, because they do not appear to specify the method of delivery for the zinc compound. 15 However, Claims 4 and 18 do specify that the zinc compound is to be applied to the "oral mucosa," and on this point the parties differ. GumTech argues that because its product is a "nasal gel" that is "applied intranasally", it simply cannot be said to apply a dose of zinc gluconate to the oral mucosa, and that, in addition, the nasal gel does not in any event remain in contact with the oral mucosa for a period of time sufficient to saturate the oral mucosa, as is required by the second element of the claim. In support, GumTech offers the declaration of Gary Kehoe, president of GumTech International, who states that "The ZICAM nasal gel accused of infringement is not applied to the oral mucosa." Decl. of Gary Kehoe P 3. GumTech also claims that statements Mr. Eby made in the process of prosecuting the '465 patent foreclose the application of that patent to "any method or product where zinc compounds are applied to the nasal mucosa, i.e., applied intranasally." Defs.' Brief in Supp. of Mot. for Summ. J. at 12.

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14 It is worth noting that Claims 4 and 18 were added to the patent during the reissue process, while Claim 1 was in the original '070 patent. To the extent that Mr. Eby's efforts to obtain a reissue patent were meant to broaden the scope of the patented device, these two claims represent some of the fruits of that effort.

15 There does not appear to be dispute that the "zincum gluconium" present in ZICAM is in fact zinc gluconate, the subject matter of the '465 patent.

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In response, Quigley argues first that ZICAM's nasal gel does indeed reach the "oral mucosa". Quigley notes that ZICAM's instructions direct the user to blow his nose before pumping in the gel, which, Quigley avers, results in the gel's application to the oral mucosa. Quigley also offers an affidavit by Dr. Andrew Goldberg, M.D. 16, stating his opinion that ZICAM "delivers its spray gel to the user in such a way as to result in the application of zinc gluconium to the oral mucosa as that term is defined in United States Patent No. Re. 33,465." Ex. E, Pl.'s Opp'n to Defs.' Mot. for Summ. J., Affidavit of Dr. Andrew Goldberg, M.D. P 4 (hereinafter "Goldberg Affidavit"). 17

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16 An Ear, Nose, and Throat specialist at the Hospital of the University of Pennsylvania.

17 Quigley also argues that ZICAM must work on the oral mucosa because GumTech has in the past cited studies involving the application of zinc compounds to oral mucosa to support ZICAM's efficacy. In particular, Quigley cites several letters from GumTech's counsel to the National Advertising Division of the Council of Better Business Bureaus (the "NAD"). This organization is an industry self-regulation group that oversees claims made in national advertising, see Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 8 n.9. In the Fall of 1999, Quigley, through the NAD, "challenged" the claims made regarding

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ZICAM's effectiveness. In response to this challenge, GumTech's counsel sent (at least) two letters, totaling thirty-seven single-spaced pages, to the NAD, which argued, in part, that the content of ZICAM's advertising was proper, see Exs. C & D, Pl.'s Opp'n to Defs.' Mot. for Summ. J., Ltrs. from Gary L. Yingling, Esq. to Andrea C. Levine, Esq. of Oct. 20, 1999 and Nov. 30, 1999.

Quigley's challenge, in part, claimed that GumTech relied on only one study to document ZICAM's effectiveness. In response to this, GumTech argued that ZICAM's effectiveness was supported by various studies of the effectiveness of zinc compounds on cold symptoms, as well as by the Homeopathic Pharmacopeia of the United States (the "HPUS") and homeopathic experts. Quigley points out that several of the studies cited by GumTech were studies supporting the effectiveness of zinc compounds applied to the oral mucosa, and that one of these was in fact Quigley's own study supporting the efficacy of COLD-EEZE. Quigley then argues that "GUMTECH's assertion that these studies support ZICAM's efficacy can only mean that GUMTECH knows that ZICAM delivers zinc gluconate to the oral mucosa" and that consequently ZICAM infringes on the '465 patent. Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 9.

We do not agree that the citation of these studies amounts to an admission that ZICAM works on the oral mucosa, nor that it creates an inference to that effect. For one thing, GumTech's letter citing the studies goes on to say that "while these three studies tested zinc in the form of a lozenge, the data from these studies can certainly be extrapolated to support the use of zinc generally in the treatment of the common cold. This is so especially in light of the fact that it appears to be a well-accepted theory that zinc ions would be most effective in treating the common cold if applied directly to the nasal cavity." Ex. D, Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 17. It is clear from the context that GumTech acknowledges that ZICAM does not fall within the direct ambit of the studies, and also that there is a claimed distinction between the subject of the studies -- lozenges -- and ZICAM's application to the "nasal cavity".

Moreover, that GumTech might seek to rely upon the studies of oral applications to support a nasal product is supported by the fact that elsewhere in its letter GumTech avers that under the practice of homeopathic medicine -- and ZICAM is a "homeopathic" product according to its labelling -- once an ingredient has been "proved" and listed in the HPUS, the form of dosage does not matter. Ex. D, Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 4-5. Therefore, it is not surprising that GumTech would argue that studies about the oral application of zinc would equally provide support for the nasal application of the same substance. We cannot therefore infer from GumTech's citation of these studies that ZICAM must operate on the oral mucosa or take this citation to be an admission of such a fact.

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Quigley argues further that ZICAM is designed to remain in contact with the oral mucosa for a period of time sufficient for it to saturate that mucosa, the second element of Claims 4 and 18. Quigley points to ZICAM's packaging, which refers to a "constant release and long-lasting suspension of its active ingredient", Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 16. Finally, Quigley claims that ZICAM's instructions for use (directing repeated application of ZICAM, including the use of ZICAM for a forty-eight hour period after symptoms subside) fall under the last element of Claims 4 and 18, which discloses the application of additional doses "until the cold has been treated."

As with Claim 1, our analysis of the scope of Claims 4 and 18 must begin with their language. An obvious initial question is the meaning of the term "oral" used in the claim. The "ordinary and customary" meaning of "oral" would appear in this context to be "of or pertaining to the mouth, as a part of the body." X The Oxford English Dictionary 886 (2d ed. 1989) (def. 3(a)). However, in the specification of the '465 patent, "oral mucosa" is defined as the "lining of the mouth, tongue, and throat," U.S. Patent No. Re. 33,465 at col. 3 line 44, and since, as noted above, the specification may serve to provide definitions of terms used in the claims, we find that this is the proper definition of "oral mucosa" for the purpose of interpreting the claim. 18 In particular, we note here that the patent's definition of "oral mucosa" clearly excludes nasal membranes from the patent claims. Thus, to the extent that ZICAM infringes the '465 patent, it must result from its application to the oral mucosa. As the parties dispute whether it is so applied, we will discuss this more below.

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18 In its pleadings, Quigley states that "the '465 Patent discloses and claims application of zinc gluconate to the 'oral' or 'pharyngeal' mucosa . . . further defined in the specification as the 'lining of the mouth, tongue and throat.'" Pl.'s Opp'n to Defs.' Mot. for Summ. J. at 4. As noted in the text, we agree with the use of the definition from the specification, but we

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would note that this is not given in the specification as a definition for "pharyngeal" mucosa. In fact, "pharyngeal" mucosa would appear to be distinct from "oral" mucosa because the "Detailed Description of the Invention" in the specification states "Such method involves administration of . . . zinc compounds . . . to oral, pharyngeal and/or nasal mucosal membranes." U.S. Patent No. Re. 33,465 at col. 2 lines 62-65. The pharyngeal mucosa is therefore not part of the patent claims, which mention only "oral". We note for reference that the pharynx -- which, again, is an area of the body not part of the claims here -- is "The cavity, with its enclosing muscles and mucous membrane, situated behind and communicating with the nose, mouth, and larynx, and continuous below with the oesophagus; forming a passage from the mouth for the food and drink, and from the nasal passages for the breath." XI The Oxford English Dictionary 664 (2d ed. 1989).

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Our next step in interpreting the language of the claim is to examine the prosecution history to find if that history further illuminates the "true meaning" of the '465 claims. During the prosecution of the '465 patent, the examiner on March 4, 1988 rejected all of the pending claims as obvious with respect to prior art and with particular reference to the art taught in, inter alia, the Modern Drug Encyclopedia 19, which includes a listing for an "aqueous solution of zinc borate 2% . . . . For use as astringent, decongestant in common colds. Applied by spray . . . 4 to 10 drops in each nostril or eye, several times daily." Modern Drug Encyclopedia 1168 (Marion E. Howard ed., 6th ed. n.d.).

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19 Two different versions of this work are referenced. The examiner lists it as "ed. by Gutman or Howard", and an examination of the file contents reveals photocopied extracts of both an edition edited by Jacob Gutman and a later sixth edition edited by Marion E. Howard. There are no material differences between the pertinent entries in the two versions.

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Subsequently, Mr. Eby, through counsel, filed a response with the PTO that sought to distinguish his invention from the art taught in the Modern Drug Encyclopedia. 20 This response contains a number of statements that GumTech alleges to be of signal importance in defining the limits of the scope of the '465 patent's claims. Mr. Eby stated to the PTO that:

For example, Modern Drug appears to indicate utility only in connection with application to the nostril or eyes, and then only as an astringent or decongestant. However, Mr. Eby's invention is directed to the application of zinc ions to the oral mucosa, and excludes application to the nasal or opthalmic membranes. This is based on Mr. Eby's finding that application of ionizable zinc to the oral mucosa is an important aspect of the invention. By suggesting application to the nasal membrane or eyes, Modern Drug in fact teaches away from the invention by teaching routes believed to be inoperative.

Ex. F2, Defs.' Mot. for Summ. J., George Andrew Eby III Response to Official Action Mailed March 4, 1988 at 6 (emphasis in original). Later, Mr. Eby argues:

[The prior art] fails to teach or suggest the claimed invention. For example, none of the art contains any indication of the importance of application of zinc ions to the oral mucosa. Both Loose and Modern Drug, in fact, indicate to the contrary, with Loose indicating principally an application to the eyes, and Modern Drug requiring application to the nostril or eyes. Neither of these routes are included within the scope of the claimed invention -- in fact, the inventor has found that application to the oral mucosa is critical, in that nasal application does not appear to provide a common cold treatment.

Id. at 9-10 (emphasis in original). Similarly, Mr. Eby also says, "Furthermore, the inventor has on various occasions tested a zinc gluconate spray intranasaly [sic], and it was not found to be effective in cold treatment." Id. at 5. In a separate, later declaration, Mr. Eby stated to the examiner that his early experiments in the area had included use of a "zinc gluconate nasal spray solution[]" and that these had resulted in "extreme nasal pain." George Andrew Eby III Declaration dated December 13, 1988 at 5.

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20 We note that the examiner's rejection included reference to other prior art besides the Modern Drug Encyclopedia, and Mr. Eby's response naturally sought to distinguish his invention from these other references as well, but it is the responses to

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the Modern Drug Encyclopedia that GumTech cites.

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At this stage in claim interpretation, the question before us with respect to these statements is whether they serve to reveal the true meaning of the language used in the claims themselves, with the proviso that, as discussed above, we cannot use the prosecution history to "enlarge, diminish, or vary the limitations in the claims." Markman, 52 F.3d at 980. From its pleadings, it appears that GumTech would like us to take the prosecution history to show that the "true meaning" of the phrase "A method for treating . . ." in Claims 4 and 18 to be "A method, not including those methods involving a nasal spray, for treating . . ." 21

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21 As discussed above, the language of the claims and specification of the '465 patent show that the patent is restricted to applications of zinc compounds to the "lining of the mouth, tongue, and throat." Quigley does not claim that the prosecution history in any way changes that definition.

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We find that the prosecution history cannot so limit our interpretation of the claim. Mr. Eby's communication with the PTO certainly makes clear that he is focused solely on application to the oral mucosa, and that application to other mucosa, in particular the nasal mucosa, is not a part of his claimed invention. 22 Mr. Eby even, as quoted above, averred that he had found a nasal spray to be ineffective. 23 Nonetheless, we cannot take these statements to change the meaning of the claim into a form palatable to GumTech. The plain language of Claims 4 and 18 refers to "A method." 24 Were we to employ the prosecution history to exclude various methods from this locution, we would unquestionably be "diminishing" the limitation of the claim, which is exactly what we cannot do at this stage. 25

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22 Our findings above show that the claims of the patent are indeed limited to application of zinc gluconate to the "lining of the mouth, tongue, and throat."

23 We do note that the statement in the March 4, 1988 Response, at least, was made in the context of explaining why application to the nasal, as opposed to oral, mucosa was outside of his invention.

24 While we may be struck with the breadth of the "a method" locution in the patent claims, "ambiguity, undue breadth, vagueness, and triviality are matters which go to claim validity . . . not to interpretation or construction." Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989), and "no matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them." Id.

25 In support of its argument that the prosecution history of the '465 patent forecloses application of that patent to ZICAM, and in particular in reply to Quigley's argument that counsel's statements during patent prosecution ought not be read to limit the patent claims, GumTech cites to a number of cases in which a court has in fact used prosecution history estoppel to limit the claims made by an inventor. Moreover, GumTech avers that, in general, the cases in which the prosecution history is used to limit the patent claims greatly outnumber those in which courts find that the statements in the history were mistaken and do not give rise to estoppel. However, the cases to which GumTech points address circumstances in which the court employed prosecution history estoppel in the context of analysis under the doctrine of equivalents. As discussed above, the doctrine of equivalents is only employed following a finding that there is no literal infringement, and we are not yet at that stage. Instead, we are here still engaged in claim interpretation, where the standards are distinct from those pertaining to the doctrine of equivalents.

Also with respect to the use of prosecution history, the parties have devoted much space to briefing the claimed implications of Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050 (Fed. Cir. 1989), and it is therefore appropriate to discuss it in some detail here. In Intravet, the inventor's counsel had, during the prosecution of the patent, accompanied an amendment of the claims sent to the PTO with a statement restricting the scope of the invention and the patent claims. See

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id. at 1054. This statement, however, was admittedly false -- the invention was not limited in the way counsel stated. See id. Moreover, notwithstanding counsel's comment, the claims themselves were never amended in a way consistent with the comment, and the examiner subsequently approved them in the unamended form. See id. Intravet held that under such circumstances, in the context of interpreting the claims, the attorney's remark could not override the clear language of the claims. See id. The court noted that, in subsequently approving the patent, the examiner was not misled or deceived by the attorney's statements, and that the claims therefore controlled the interpretation. See id.

Quigley argues that under this holding, we cannot apply statements in the prosecution history to the patent claims. GumTech argues in reply that Intervet is applicable; the examiner here was indeed misled because she relied on the representations in Mr. Eby's communications in approving the patent. Both parties' claims with respect to Intervet have some merit. Intervet clearly stands for the proposition, as Quigley argues, that at the claim interpretation stage, stray remarks in the prosecution history cannot overcome the approved language of the claim themselves. On the other hand, there is no claim here that Mr. Eby's statements were not true with respect to the limits on his claims, and, in particular, they show that he restricted his claims to applications to the oral mucosa, and the claims themselves bear this out. In any event, we do not find the Intervet case to be dispositive in either party's favor.

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This brings us to the end of the "claim interpretation" portion of the analysis. As discussed above, we find that the Claims of the '465 patent are restricted to applications of zinc gluconate to the lining of the mouth, tongue, and throat. We also find that the Claims do indeed extend to any method of delivery to the lining of the mouth, tongue, and throat, and in particular to a method of delivery to the oral mucosa that involves pumping the zinc gluconate through the nose.
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1. Claim Interpretation

We explicitly interpreted the meaning of several of the patent claims in the course of our earlier Memorandum, and have continued that process above. We have defined "oral mucosa" in the '465 patent claims to mean "the lining of the mouth, tongue, and throat", and we have just determined that "saturate" as used in the '465 patent means "to bathe or soak". There is one additional term that we have not yet explicitly 73 interpreted in the claims that is disputed by the parties, and that is the term "applying". It will be recalled in this regard that the '465 patent claims, inter alia, "A method for treating the common cold comprising: (a) applying an effective dosage of zinc gluconate to the oral mucosa of a human in need of treatment . . . " Pl.'s Ex. 1 at col. 4, lines 57-59.

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73 Quigley argues that we did interpret the meaning of "applying" in our earlier opinion, and indeed we did state that the claims extended to "any method of delivery" of zinc gluconate to the lining of the mouth, tongue, and throat. Quigley Corp., 2000 WL 264130, at *7. However, we made this statement without the benefit of specific discussion from the parties on the meaning of "applying", and without explicit discussion of our interpretation; we thus find it appropriate to address the term explicitly here. Of course, as discussed below, our interpretation of the term does not change.

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GumTech first argues that we must interpret the claim "applying" narrowly because the prosecution history shows that Eby had foresworn application of zinc gluconate through the nose as part of the patent. We first note that "although the prosecution history can and should be used to understand the language used in the claims, it too cannot enlarge, diminish, or vary the limitations in the claims." Markman, 52 F.3d at 980 (internal quotation marks omitted). GumTech points out that at various points during the prosecution of the '465 patent, and as part of Eby's continuing effort to distinguish his invention from, inter alia, the Modern Drug reference, Eby represented to the examiner that he believed that the nasal "route" was not effective in treating the cold, see, e.g., Def.'s Ex. 31 at [107].

We do not agree that such representations foreclose the enforcement of a patent against a product that is administered to the

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nostrils. First, as noted above, we cannot take statements in the prosecution history to limit the claims. Thus, to the extent that GumTech would like, on the basis of the prosecution history, to read "applying an effective dosage" as "applying, but not through the nose, an effective dosage", this is not permissible. We also note that, in any event, the language of the prosecution history itself suggests that Eby used the term "route" to refer to the mucosa or membrane on which the zinc was to act, rather than the location at which the substance is first applied to the body, see, e.g., Def.'s Ex. 31 at [109]. Thus, to the extent that Eby stated that the nasal "route" was inoperative, this reinforces the notion that the zinc must work on the oral mucosa.

This brings us to GumTech's second argument on the meaning of "applying". GumTech argues that the term "apply" should properly be interpreted to mean the mucosa to which the substance is first administered. That is, GumTech avers, Zicam is "applied" to the nasal mucosa, not the oral mucosa, and in order to find that Zicam is encompassed by the '465 patent, we would have to interpret the claim to actually mean "applying an effective dosage of zinc gluconate so that it somehow reaches the oral mucosa". Def.'s Post-Hearing Mem. at 8 (emphasis in original). In support, GumTech offers the expert testimony of Dr. David Riley, who states that the ordinary and customary meaning of "applying" to one skilled in the art of treating the common cold via homeopathic means is to refer to the route of administration or introduction, rather than any resultant location, see Def.'s Ex. 85 at 3.

In assessing this argument, we also look to the ordinary meaning of "apply": "To put a thing into practical contact with another," I The Oxford English Dictionary 576 (2d ed. 1989) (def. I), or "To place (a plaster, unguent, or the like) in effective contact with the body; hence, to administer a remedy of any kind," id. at 577 (def. I(3)). 74 We see from these definitions that the focus is on "effective" or "practical" contact. The expert medical testimony before us showed that substances taken into the nose may be expected rather soon to pass to the throat as a normal result of bodily processes, and therefore squirting a substance into the nose, we find, has the practical effect of passing that substance to the throat and thus too the oral mucosa.

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74 We note that Stedman's Medical Dictionary does not contain an entry for "apply" or "applying".

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Thus, we find a tension between the "ordinary" dictionary meaning and Dr. Riley's testimony regarding the meaning of "applying" to homeopathic practitioners. However, after examination we find that GumTech's desired definition of "applying" as the "route" does not really make sense here on the terms of the patent claims. The '465 patent claims application of zinc gluconate to the oral mucosa, which includes the lining of the throat, and "applying" as it appears in the patent was first used in conjunction with a zinc gluconate lozenge. A lozenge is introduced into the mouth, and is intended to remain there -- it is not introduced directly to the throat. To the extent that any of the zinc gluconate from the lozenge gets from the mouth to the throat, it is a result of the same sorts of physical processes that would take zinc gluconate gel from the nose to the throat. 75 Thus, to take "apply" to mean only the point of introduction or "route" of the substance would be to render nonsensical the claims of the '070 patent and the "lozenge" claims of the '465 patent, since "oral mucosa" refers also to the throat. Obviously, we cannot accept such a definition. Thus, we cannot limit "applying" to mean only the situs of the initial introduction of the substance to the body, and instead must take it to allow any means by which the zinc gluconate gets to the mucosa in question.

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75 That is, the expert testimony on anatomy went to show that the nasal passages and the mouth converge at the throat. Just as substances flow from the mouth to the throat, so too do they move from the nose to the throat.

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Having thus completed our interpretation of the claims, 76 we may now look to the evidence relating Zicam to the '465 claims.

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76 GumTech raises one additional claim interpretation argument that we here address briefly. It argues that the patent claim calling for zinc to "saturate the oral mucosa" must mean that the zinc must saturate the entire oral mucosa. This interpretation would of course help Zicam's position, since there is no evidence that the nasally-introduced Zicam reaches the entire lining of the mouth, tongue, and throat. However, we cannot accept this as the proper interpretation of the claim. Testimony showed that the oral mucosa is quite extensive, as it covers all the interior surfaces of the mouth and the throat. There is no evidence either in the prosecution histories or in testimony before us that the patented invention required zinc to cover each and every square millimeter of these surfaces. We therefore find that it would not be reasonable to import an "entire" restriction to the use of "oral mucosa" in the claims.

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(8) Whereby transcription of the DNA segment produces a ribonucleotide sequence . . . The Court concludes that during transcription of the nonnative DNA segment, its double helix must separate and the RNA polymerase must produce an mRNA. This mRNA must be a single stranded ribonucleotide sequence complementary to the DNA from which it was produced.

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CLAIM LANGUAGE	CIEA'S PROPOSED CONSTRUCTION	JACKSON'S PROPOSED CONSTRUCTION
* * *		
"transfected mouse cell"	A mouse cell into which foreign DNA has been introduced that is a stand-alone product and is purchased or licensed as a stand-alone product separate and apart from a mouse.	A mouse cell into which foreign DNA has been introduced.
"IL-2Rγ deficient mouse cell"	A mouse cell bearing a deficiency in the IL-2Rγ gene that is a stand-alone product and is purchased or licensed as a stand-alone product separate and apart from a mouse.	A mouse cell bearing a deficiency in the IL-2Rγ gene.
"transgenic mouse cell"	A mouse cell with a mutated gene sequence that is a stand-alone product and is purchased or licensed as a stand-alone product separate and apart from a mouse.	A mouse cell with a mutated gene sequence.

3. "Transfected Mouse Cell," "IL-2R γ Deficient Mouse Cell," and "Transgenic Mouse Cell"

CIEA contends that the plain language of the '173 Patent supports an in vivo limitation. CIEA's argument appears to be that because the claims use the word "cell" rather than "mouse," the patent claims only in vitro cells and not cells inside mice. WhileCIEA is undoubtedly correct that the patent claims cells, not mice, this does not support the leap in logic that one must make to then conclude that the cells claimed are limited to cells outside of a mouse and cannot include cells within a mouse.

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Next, CIEA argues that the court should construe the disputed terms as having an in vitro limitation in order to preserve claim validity. Without an in vitro limitation, CIEA alleges, the claims would include naturally-occurring cells and therefore be invalid under 35 U.S.C. § 101. Diamond v. Chakrabarty, 447 U.S. 303, 309, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980) (holding that naturally occurring phenomena are not patentable). CIEA claims that "SCID could occur in non-genetically engineered mice" but provides no evidence that the IL-2R γ gene mutation has ever occurred naturally in mice. CIEA's Opp'n for the '173 Patent at 7. Jackson's expert, Dr. Leonard Shultz, testified, "such a mutation has never, to my knowledge, occurred spontaneously in mice." Decl. of Dr. Leonard D. Shultz in support of Jackson's Cl. Construction Reply Br. for the '173 Patent ("Shultz Decl.") P 12. Moreover, Dr. Shultz testified that "transgenic" and "transfected" refer to genetically engineered cellsthat do not occur in nature. Shultz Decl. P 21.

It is undisputed that the terms "transfected mouse cell," "IL-2R γ deficient mouse cell," and "transgenic mouse cell" refer to genetically engineered cells, not naturally occurring cells. Construing these terms as having this limitation is consistent with the language in the patent and also maintains claim validity. Therefore, the court construes these terms as limited to genetically engineered cells.

Finally, CIEA points to the prosecution history of the '173 Patent as supporting its contention that an in vivo limitation should be adopted. The applicant had tried to claim a transgenic mouse, the claim was rejected by the Examiner, and the applicant eventually acquiesced to this rejection by canceling the claim for a transgenic mouse. In light of this prosecution history, there can be no doubt that the patent does not claim transgenic mice. However, as discussed above, this does not support the leap in logic that one must make to then conclude that the cells claimed in the patent are limited to cells outside of a mouse and cannot include cells within a mouse. CIEA has failed to point to any language in the prosecution history suggestingthat the Examiner only intended to allow the applicant to claim in vivo cells. Limitations of claim scope based on the prosecution history require a "clear and unmistakable disavowal" of claim scope. Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ. v. Hedrick, 573 F.3d 1290, 1297 (Fed. Cir. 2009). The court finds no such "clear and unmistakable disavowal" here. In the absence of any evidence in the patent or the prosecution history that the claimed cells are limited to in vitro cells, the court declines to adopt an in vitro limitation. The court therefore adopts Jackson's proposed constructions, with the addition of the phrase "genetically engineered" to make this limitation clear.
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III. TRANSFER RESISTANCE

The parties next present the term "transfer resistance" for claim construction. The term is used in claims 1, 16, and 33, and, by reference, in the dependent claims. Claim 1 covers: "[a] cosmetic composition exhibiting improved transfer resistance . . . ." Col. 7, lines 24-25. Claim 16 covers: "[a] lipstick composition having improved transfer resistance . . . ." Col. 8, lines 36-37. Claim 33 covers: "[a] lipstick composition exhibiting improved transfer resistance . . . ." Col. 10, lines 9-10. Revlon urges the term is defined by reference to a specific "kiss test" as set forth in the specification. Transcript at 51. The following passage from the specification is the basis for Revlon's position:
The term "transfer resistance" means that when the cosmetic composition is applied to skin or lips it exhibits from 10-100%, preferably 30-100% improvement in transfer resistance when compared with a standard lipstick formulation and as measured by the Kiss test of Example 4.

'937 patent, Col. 4, lines 44-48.

That passage is followed by four examples, "set forth for the purposes of illustration only" in which three examples describe lipsticks and one example describes eye shadow, blush and concealer. Col. 4, lines 49-51. Example 4 refers to a lipstick. Col. 6, line 35 - Col. 7, line 1. The kiss test found in Example 4 asked participants to apply the lipstick composition of the '937 patent, wait five minutes, and then kiss their hands. Col. 6, lines 66 - 67. Participants were then asked how many thought the lipstick "left hardly a trace" of color on their hand. Col. 6, line 66 - Col. 7, line 1. The results indicated more participants thought the lipstick covered by the '937 patent left hardly a trace, when compared with Revlon's "traditional" (i.e. non-transfer resistant) Moondrops lipstick. Col. 7, lines 5-7.

Defendants assert transfer resistance "should be defined as not merely the specific kiss test that you find in Column 4 of the patent but includes the tendency of a cosmetic not to transfer to some other surface such as glassware, silverware, clothing,

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et cetera, as the patent itself specifies in Column 1." Transcript at 57. Column 1, lines 23-34, of the '937 patent states:
One of the long standing problems with makeup, particularly lipstick, is the tendency of the cosmetic to blot or transfer from the skin onto other surfaces such as glassware, silverware, clothing, etc. . . . The object of the invention is to formulate a cosmetic composition for application to skin or lips which exhibits superior transfer resistance when compared with traditional makeup formulation. n15

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n15 The fact that when testing for transfer resistance Revlon performed the kiss test as well as a test to see if the lipstick blotted onto a tissue is not strong evidence for either side's position. Testing the transfer resistance to a tissue may, or may not, have been meant to measure transfer resistance to the other objects noted above, clothes, glassware and silverware. See Defendants' Markman Hearing Exhs. 11, 12.

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Revlon correctly asserts its definition of "transfer resistance" in the specification is important evidence of its meaning. As noted by the Federal Circuit:

Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.

Vitronics Corp., 90 F.3d at 1582.

On the other hand, courts are not required to disregard common sense. Nor will this Court accept a construction that is inconsistent with the patent's internal logic. See Markman, 116 S. Ct. at 1395 (indicating preference for a construction comporting with patent's internal "logic" and "coherence").

As noted above, some claims in the '937 patent refer specifically to lipsticks, while Claim 1 of Revlon's patent refers to a "cosmetic composition." See Col. 7, lines 24-25; Col. 8, lines 36-37. Moreover, the examples contained in the specification include formulations of eye shadow, blush and concealer. See Example 3, Col. 5, line 55 - Col. 6, line 33. This leads to the ineluctable and insofar as is now uncontested conclusion that Revlon's '937 patent covers makeup other than lipstick. It is illogical then to measure "transfer resistance" as used in this patent with reference to a "kiss test" because it is illogical to conclude the kiss test was intended to measure the transfer resistance of eye shadow, blush and concealer. In fact the specification limits the kiss test to lipstick. See Col. 6, line 66. "Transfer resistance" also must be measured in ways meaningful to eye shadow, blush and concealer. n16 The patent explains the general problem with makeup is its tendency to transfer to "surfaces such as glassware, silverware, clothing etc." Col. 1, lines 26-27. Accordingly, the Court adopts defendants' position transfer resistance means the tendency of a cosmetic not to transfer to other surfaces, including skin, clothing, glassware and silverware.

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n16 The Court has considered using different definitions for transfer resistance depending on the context in which the term is used. However, this is undesirable in light of the need for consistent use of terms within a patent.

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Transformed Eucaryotic Cell	A eucaryotic cell which has undergone a genotypic change as a result of the introduction of DNA into the cell

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Transforming	Process for changing the genotype of a recipient cell mediated by the introduction of DNA.

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B. The '141 Patent and the '483 Patent

Cleanox owns two patents for inventions developed by R. Vigneri for the remediation of certain groundwater contamination. See Amended Complaint at 3, P 12. The '141 Patent was filed 12 February 1993 and was issued 15 February 1994. See '141 Patent. The '483 Patent was filed 10 February 1994 and was issued 28 May 1996. See '483 Patent.

Both patents describe their processes as "a method for remediating a hydrocarbon-contaminated region of a subterranean body of groundwater to destroy or reduce the initial levels of hydrocarbon contaminants." '141 Patent at col. 8, lines 23-26; '483 Patent at col. 9, lines 33-35. The two patents rely upon the interaction of hydrogen peroxide and the hydrocarbon contaminants to alleviate the harm caused by groundwater contaminants.

Claim One of the '141 Patent provides as follows:

1. A method for remediating a hydrocarbon-contaminated region of a subterranean body of groundwater to destroy or reduce the initial concentration levels of hydrocarbon contaminants, comprising the steps of:

(a) providing a plurality of mutually spaced wells intersecting said groundwater region ("Step A of the '141 Patent");

(b) determining the existence of acceptable continuity and well interflow paths for the said region by generating a test flow of a solution of hydrogen peroxide from one of said wells and monitoring pH changes at each other of said wells as a function of time to detect a pH drop of at least 0.2 ("Step B of the '141 Patent"); and

(c) subsequent to detecting said pH drop, providing a treating flow of said hydrogen peroxide solution from one or more of said wells ("Step C of the '141 Patent").

Claim One of the '141 Patent (emphasis added).

Claim One of the '483 Patent provides as follows:

1. A method for remediating a hydrocarbon-contaminated region of a subterranean body of groundwater to destroy or reduce the initial concentration levels of hydrocarbon contaminants, comprising the steps of:

(a) providing a plurality of mutually spaced wells intersecting said groundwater region ("Step A of the '483 Patent");

(b) providing a treating flow of acetic acid from one or more of said wells into said groundwater region, to establish acidic conditions therein ("Step B of the '483 Patent");

(c) introducing a turbulent flow of an aqueous solution of ferrous ion into said groundwater region, for mixing with said acidified groundwater, thereby providing a catalyst for disassociation of hydrogen peroxide ("Step C of the '483 Patent"); and

(d) providing a treating flow of hydrogen peroxide solution from one or more of said wells into said groundwater region, said hydrogen peroxide undergoing a Fenton-like reaction in the presence of said acidic conditions and said ferrous ion to generate hydroxyl free radicals for oxidizing said contaminants ("Step D of the '483 Patent").

Claim One of the '483 Patent (emphasis added).

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* * *

3. Construction of the Claim Term "Treating Flow" in Step C of the '141 Patent

Step C of the '141 Patent requires the practitioner to provide "a treating flow of said hydrogen peroxide from one or more of said wells" after a drop in the pH level is detected. '141 Patent, at col. 8, line 36-38. There are two disputes between the parties as to the meaning of "treating flow": whether the term "treating flow" includes a pressure limitation; and whether the term "treating flow" includes the practice of bioremediation.

a. Whether "Treating Flow" Includes a Pressure Limitation

1. The Cleanox Argument

Cleanox argues the treating flow requirement should not be limited to a particular pressure range. See Brief -Cleanox at 6; Markman Hearing Transcript at 68:17-25. Instead, it contends that only claim 4 of the '141 Patent ("Claim Four of the '141 Patent") 16 should be read to have such a limitation because it alone contains an express pressure limitation. See Brief - Cleanox at 6. Cleanox argues that, under the doctrine of claim differentiation (the "Claim Differentiation Doctrine"), 17 Claim Four of the '141 Patent is dependant on Claim One of the '141 Patent and therefore its limitations should not be read into Claim One of the '141 Patent. See id. Cleanox states Claim One of the '141 Patent cannot have a pressure limitation because it must be broader in scope than Claim Four of the '141 Patent which has such a limitation. See id.

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16 Claim Four of the '141 Patent provides that "the treating flow is provided under a pressure not more than the hydrostatic head relative to surface at the point of treating flow discharge from said well." Claim Four of the '141 Patent.17 The Claim Differentiation Doctrine holds that narrow claim limitations cannot be read into broader ones to limit the meaning of the broader claim because each claim is distinct from other claims within the patent. See Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277 (Fed.Cir. 1995) (citing D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574 (Fed.Cir. 1985)).

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2. The Defense Argument

The Defendants assert "treating flow" incorporates a maximum pressure limitation that is based upon the depth of the well. See Brief - Defendants at 18 (citing '141 Patent at col. 4, lines 9-12). They argue that, based upon the language of the Specification, this limitation should be "not more than the hydrostatic head relative to the ground surface at the point of discharge from the well." See id. at 12 (quoting col. 4, line 9-12 of the '141 Patent).

The Defendants assert the pressure limitation is applicable to all of the claims, including Claim One of the '141 Patent, because the Specification does not qualify or restrict the limitation in any way. See id. at 19. In further support of their argument, the Defendants contend the Specification warns the practitioner that, if the pressure limitation is exceeded, reactants may pass upwardly out of the ground and create undesirable conditions. See id. (quoting '141 Patent at col. 4, lines 12-15). The Defendants dismiss reliance on the Claim Differentiation Doctrine by arguing that the Specification trumps the Claim Differentiation Doctrine because it provides a clear meaning for the language of the claim. See id. at 20 (citing O.I. Corp. v. Tekmar Co., 115 F.3d 1576 (Fed.Cir. 1997)).

3. Judicial Construction

The Claim Differentiation Doctrine requires each claim be distinct from the others such that the limitations of a dependent claim should not be read into an independent claim. See Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed.Cir. 1991) (quoting Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 404 (Ct. Cl. 1967)). Narrow claim limitations cannot be read into broader ones because each claim is distinct from the other claims within the patent. See Transmatic, 53 F.3d at 1277 (citing D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574 (Fed.Cir. 1985)).

Because Claim Four of the '141 Patent contains a pressure limitation, Claim One of the '141 Patent, upon which Claim Four

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of the '141 Patent is dependent, by definition, is broader in scope and cannot contain such a limitation. See Transmatic, 53 F.3d at 1277-78. The language of the Specification cited by the Defendants is identical to that contained in Claim Four of the '141 Patent. See '141 Patent at col. 8, lines 50-52. Accordingly, to read Claim One of the '141 Patent as having the same scope as Claim Four of the '141 Patent would make Claim Four of the '141 Patent superfluous. See Lucas Aerospace, 890 F. Supp. at 332. In addition, the language of the Specification demonstrates a pressure limitation may, but is not required to, be employed. The Specification states: "If the pressure exceeds this [limitation], it is possible for some of the reactants to pass upwardly through the porous overburden and create undesirable conditions on the ground surface." '141 Patent at col. 4, lines 9-15 (emphasis added). Although the method contemplates the pressure may be limited, in some circumstances it may be possible to apply a greater or lesser pressure without adverse effects. Therefore, for purposes of Claim One of the '141 Patent, it is not appropriate to limit "treating flow" to a particular pressure range.

b. Whether "Treating Flow" Includes Bioremediation

1. The Cleanox Argument

Cleanox argues that chemical remediation 18 is the sole subject of both the '141 Patent and the '483 Patent. See Brief - Cleanox at 6. Cleanox contends "treating flow" should not be read so broadly to include the prior art "bioremediation 19 method." Id. at 6. Instead, it argues the term should be interpreted as a "flow of hydrogen peroxide that is in keeping with the 'chemical reaction' remediation process set out in the patent." Id. at 8.

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18 Chemical remediation is a method involving a chemical reaction between the hydrogen peroxide and the hydrocarbon contaminants. See Brief - Cleanox at 6.19 Bioremediation is a method whereby hydrogen peroxide is introduced into the ground to "feed" microbial life near the contamination. Microbial life then "eats" the hydrocarbon. See Brief -Cleanox at 6. Both parties recognize the distinction between bioremediation and chemical remediation.

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In support of its position, Cleanox points to the Specification which reveals that the patentee distinguished the bioremediation method as a prior art that he believed was ineffective. See Brief - Cleanox at 6. For example, the Specification provides:

In recent years increasing interest has also been evidenced in bioremediation technology. The technology has been of great interest, but its effective use in treating groundwater has been limited. The procedures are very complex, involving the use of expensive and complex reactors, and can cause adverse geochemical reactions, and can even introduce new toxic compounds beyond those which are being treated.

'141 Patent at col. 1, line 63 to col. 2, line 2. Accordingly, Cleanox argues that "it would be contrary to the central teaching of the Specification to read Claim One [of the '141 Patent] as covering this prior art technique that the inventor expressly discounts." Brief - Cleanox at 7.

Cleanox finds additional support for its position in another part of the Specification that states:

The treating flow may additionally contain reaction surface enhancing reagents, i.e. reagents such as dispersions of lime or the like, which provide increase or provide surfaces at which the reaction between the hydrogen peroxide and the hydrocarbon contaminants may occur. Similarly, effective amounts of catalytic agents may be incorporated into the treating solution or preferably are provided as a preinjection into the groundwater region to be treated. Typical such catalysts are initiation catalysts of various types known in the art to promote the desired reaction between the hydrogen peroxide and hydrocarbons.

Brief - Cleanox at 7 (quoting '141 Patent at col. 3, lines 22-24) (emphasis added in Brief - Cleanox). Cleanox argues the emphasized language makes it clear that "the treating flow of hydrogen peroxide must result in a chemical reaction between the peroxide and the hydrocarbon contaminants." Id. at 7.

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2. The Defense Argument

The Defendants argue "treating flow" includes both bioremediation and chemical remediation methods. See Brief - Defendants at 13. The Defendants point out there are no words in the claim or Specification which indicate "treating flow" is limited solely to chemical remediation. See id. Similarly, the Defendants argue that the preamble of Claim One of the '141 Patent generically states the claim is directed to "[a] method for remediating …," rather than a method for "chemically remediating." Id. In addition, Defendants point to the Background of the Invention portion of the Specification of Claim One of the '141 Patent which the Defendants contend "explains that the remediation of hydrocarbons can be accomplished through either chemical remediation (see ['141 Patent at] col. 2, line 9,) or biological remediation (see ['141 Patent at] col. 1, line 64)." See Brief - Defendants at 13.

The Defendants also assert that, if the interpretation argued by Cleanox were to be accepted, the scope of Claim One of the '141 Patent will become indefinite and unclear because there is no explanation in the patent to explain how a person can practice the invention in a manner which causes chemical rather than biological remediation. See Brief - Defendants at 14. As such, Defendants argue such an interpretation would violate 35 U.S.C. § 112, which requires the patent to include claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as the invention." Brief - Defendants at 14 (quoting 35 U.S.C. § 112).

3. Judicial Construction

The Specification in each of the '141 Patent and the '483 Patent discusses the limitations of the bioremediation technology, as a prior art, which the inventor viewed as ineffective and over which he saw his invention as an improvement. See '141 Patent at col. 1, line 63 to col. 2, line 2; '483 Patent at col. 2, line 1 to line 8. The Federal Circuit has indicated that "where a term is susceptible to two reasonable interpretations, the court can look to prior art" to assist it in construing the patent claims. Elf Atochem North Am., Inc. v. Libbey-Owens-Ford Co., 894 F. Supp. 844 at 859 (citing Rawlplug Co. v. Illinois Tool Works, Inc., 11 F.3d 1036, 1041 (Fed.Cir. 1993)); Texas Instruments, Inc. v. United States ITC, 871 F.2d 1054, 1065 (Fed.Cir. 1989). The claims then should be interpreted to exclude the prior art and thus preserve the validity of the claim. Texas Instruments, 871 F.2d at 1065. The claims are interpreted as excluding the prior art.

There are numerous references to chemical reactions throughout the Specifications which support the conclusion that the patents contemplate chemical remediation. For example, the terms "Treatment chemicals," "reaction" and "reactants" are used in the summary of invention portion of the Specifications. See, e.g., '141 Patent at col. 2, lines 9, 48 and 49; col. 3, line 16 and line 33, col. 4, line 13; '483 Patent at col. 2, lines 14, 57, 64 and 65 (Fenton's reaction); col. 3, line 20; col. 4, lines 7, 19, 36, and 48; col. 5, lines 11 and 13; col. 6, lines 8 and 20. The terms also are used in the description of the preferred embodiment. See id. at col. 7, line 2, 5 and 9. Similarly, use of the terms "catalyst" and "catalytic agents" throughout the Specifications further demonstrates that the '141 Patent and the '483 Patent contemplate chemical remediation. See id. at col. 3, lines 18, 21 and 27; col. 6, line 44; '483 Patent at col. 3, line 16; col. 7, lines 58, 66 and 67; col. 8, line 23.

* * *

Conclusion

For the reasons stated, the claim construction of the disputed terms is as follows: (1) the term "well" in Claim One of the '141 Patent and Claim One of the '483 Patent means "a structure used for both monitoring and injecting the groundwater," (2) Step B of the '141 Patent is read to require that pH be monitored for the particular purpose of determining the existence of acceptable continuity and well interflow paths, (3) the term "treating flow" in Step C of the '141 Patent is read to have no pressure limitation associated with it and to be limited to "chemical remediation", and (4) Claim One of the '483 Patent is read to require the performance of Steps A-D both separately and sequentially to practice the invention.
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C. "Treatment of cerebral ischemia"

Plaintiffs propose that "treatment of cerebral ischemia" be construed as "an antagonistic intervention with regard to the N-

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methyl-D-aspartate (NMDA) receptor channels." According to Plaintiffs, here, again, the patentee was its own lexicographer. (D.I. 223 at 2) Plaintiffs contend that this term is defined in the portion of the specification which states: "in order to treat or eliminate this pathological situation, an antagonistic intervention is required with regard to the NMDA receptor channels." (JA2 at col. 2 lines 53-55)

The Majority Defendants would instead have the Court construe "treatment of cerebral ischemia" as "stopping the destruction of brain cells that results from an acute interruption of blood supply to the brain." They insist that the specification statement on which Plaintiffs rely is not a definition but merely "where the patent owner is explaining to you the mechanism of action." (Tr. at 113)

I agree with Plaintiffs' construction. In context, the specification statement on which Plaintiffs rely is sufficiently clear, deliberate, and precise to define what the patentee meant by "treatment" of the pathological situation of "cerebral ischemia." In the context of the '703 patent, "treatment of cerebral ischemia" does not refer to acting on the destruction of brain cells that follows cerebral ischemia, as the Majority Defendants contend; rather, it refers to acting on an imbalance of neuronal stimulation mechanisms that is cerebral ischemia (in this patent). Another problem with the Majority Defendants' proposal is that it equates "treatment" with "stopping." But the patent describes what should be done "in order to treat or eliminate this pathological situation" (JA2 at col. 2 lines 53-54) (emphasis added), indicating that "treat" is not limited to "eliminating" or "stopping" but also includes improving, alleviating, and reducing the pathological situation.

Apotex, in its proposed construction, continues to focus on blood supply, proposing: "Alleviation of an acute interruption of blood supply to the brain." Yet, as the Majority Defendants have stated, it is "very clear that this patent is not about reintroducing blood flow to the brain." (Tr. at 122) Apotex likens this case to Rapoport v. Dement, 254 F.3d 1053, 1056 (Fed. Cir. 2001), in which the Federal Circuit construed "treatment of sleep apnea" to mean treatment of the underlying condition -- the sleep apnea itself -- and not treatment of the symptoms of sleep apnea. (D.I. 222 at 13-14; Tr. at 130-31) Here, by analogy, treatment of cerebral ischemia would require treatment of the interruption in blood supply to the brain. However, again, "cerebral ischemia" in the '703 patent relates to an "imbalance of neuronal stimulation mechanisms," not an interruption in blood supply. Thus, even assuming the reasoning of Rapoport applies, 8 treatment of the underlying condition of cerebral ischemia here is treatment of the imbalance of neuronal stimulation mechanisms, which supports Plaintiffs' construction.

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8 As Plaintiffs note, Rapoport is also distinguishable because the patent there was not limited to treatment of patients with a particular diagnosis, whereas here the asserted patent claims specify that the patient must be diagnosed with Alzheimer's disease. (Tr. at 222)

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Therefore, I recommend that "treatment of cerebral ischemia" be construed as "an antagonistic intervention with regard to the N-methyl-D-aspartate (NMDA) receptor channels."
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G. "Treatment of an imbalance of neuronal stimulation"

The parties have not agreed on a construction of the term "treatment of an imbalance of neuronal stimulation." Their disagreements are derived from their disagreements as to the proper construction of the terms "cerebral ischemia" and "treatment of cerebral ischemia." As I have already discussed, I recommend that "cerebral ischemia" be construed as "an imbalance of neuronal stimulation mechanisms." I also recommend that "treatment of cerebral ischemia" be construed as "an antagonistic intervention with regard to the N-methyl-D-aspartate (NMDA) receptor channels." Plaintiffs propose that "treatment of an imbalance of neuronal stimulation" be construed as "an antagonistic intervention with regard to the excessive inflow of calcium through N-methyl-D-aspartate (NMDA) receptor channels." 10 I agree with Plaintiffs, as I believe this construction is properly grounded in the patent specification (see, e.g., JA2 at col. 2 lines 46-56) and follows from the constructions I have already recommended above.

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10 The Majority Defendants propose: "Stopping the destruction of brain cells, that results from an excessive influx of calcium through NMDA receptor channels (but not an imbalance of the dopamine/aceytlcholine system), wherein said excessive influx is caused by an acute interruption of blood supply to the brain occurring after Alzheimer's disease." Defendants Lupin and Sun propose: "Treatment of a pathophysiological situation caused by cerebral ischemia occurring after Alzheimer's disease."

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J. Triple helix conformation

The term "triple helix conformation" appears in several asserted claims of the '939 Patent, the '223 Patent, and the '569 Patent. Claim 1 of the '939 Patent provides an example of its use: "An underivatized, aqueous soluble [beta] (1-3) glucan in a triple helix conformation having immunostimulating properties which does not stimulate or prime the production of interleukin- 1 or tumor necrosis factor or both, in vitro." Plaintiffs propose the following construction of "triple helix conformation": "Conformation that results from the denaturation and reannealing of aqueous soluble glucan. Furthermore, the conformation results from dissociating the native glucan conformations and reannealing and purifying the resulting triple helical conformation." Immunocorp and Biotec offer this construction:

The glucan in solution is a unique and predominately triple helical conformation, where the conformation is produced by dissociating the native conformations, re-annealing the glucan molecules into a unique triple helix conformation, and further purifying to remove single helix and aggregated materials. Triple helical conformation means three beta glucan chains wrapped about each other in a spiral, like three strands in a rope are wrapped about each other.

In light of other claims where the process appears, the Court declines to read into "triple helix conformation" the process used to obtain the conformation. The Court concludes that the term has a readily understood meaning such that no construction is necessary.

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1. "[T]runcated Factor VIII protein which is an active procoagulant:" 2 A Factor VIII protein that promotes blood coagulation and lacks a portion of the amino acid sequence of the human Factor VIII protein.

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2 '112 patent, claims 1, 5, 9 and 10.

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The only dispute presented by this limitation involves plaintiff's assertion that Factor VIII's role in coagulation be explained, that is, "a Factor VIII protein that promotes the activation of Factor X, which promotes blood coagulation." Plaintiff has argued that this explanation finds support in the specification ('112 patent, col. 19:24-25; col. 24:28-31 and Table 3) by the disclosure of an assay (the "Kabi COATEST") which, as specifically explained in defendant's later-filed '447 patent, "measures the generation of activated Factor X(Xa)as a linear function of the concentration of exogenously supplied Factor VIIIC." ('447 patent, col. 11:4-8) There is no such specific explanation of Factor VIII's role in blood coagulation in the '112 patent or in the prosecution history. (See, e.g., D.I. 84 at JA000214-220, where the applicant's focus was on the activation of Factor VIII, not on the role Factor VIII played in the "blood coagulation cascade") Indeed, given that the applicant recognized that "the role, if any, of the B domain in the biological functioning of FVIII was not known and is still not

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known" at the time of the application, and that "the reason for the increased expression level [of the "Factor VIII deletion variants, likewise,] was unknown" at the time of the application (see id. at JA000218), the intrinsic record is not consistent with plaintiff's assertion that, in 1986 (when the '112 patent was filed), "activation of Factor X" was "the well recognized role Factor VIII play[ed] in the blood coagulation cascade."
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D. Limitation to Tuna

The literal language of the Yamaoka patent claims only a process for "curing raw tuna meat" (Ex. 1, Col. 7). HISI requests that the claim be limited to tuna, and not be extended to other fish or meats. TPI "does not dispute that Claim 1 of the Yamaoka '619 patent is limited to tuna." (TPI Reply 8.) The Court concurs that the Yamaoka Patent claims only a process for curing tuna, and not any other kind of fish or meat.
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turbidity

The parties and the Court agree that the term should be construed as "deficient in clarity; turbidity is an expression of the optical property that causes light to be scattered and absorbed rather than transmitted with no change in direction or flux level through the water sample. In precision, sensitivity, and applicability over a wide turbidity range, the nephelometric method is preferable to visual methods. Nephelometric measurement results are reported as nephelometric units (NTUs)."
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N. Ultrapasteurizing

The parties dispute the meaning of the term "ultrapasteurizing." Michael Foods argues that "ultrapasteurizing is to decrease the number of spoilage organisms beyond that obtained with conventional pasteurization without sacrificing functional performance." (Michael Foods' Initial Markman Br. at 35.) Sunny Fresh contends that ultrapasteurization means (1) using higher than previously known actual time/temperature pasteurization conditions and (b) which decrease the number of spoilage microorganisms to levels lower than obtained by the previously-known conditions. (Kempf Aff., Ex. 26 at 2.)

Claim 8 discusses "a method of ultrapasteurizing a liquid whole egg product." (Kempf Aff., Ex. 1, Col. 16, ll. 36-37.) The specification explicitly defines "ultrapasteurize" as "decrease the number of spoilage microorganisms to levels lower than obtained with a pasteurization procedure." (Id., Col. 1, ll. 67; Col. 2 l. 1.) "Pasteurize" means to cause a nine log cycle (9D) or 99.9999999% reduction in Salmonella in the product being treated." (Id., Col. 5, ll. 28-31.) The specification does not say ultrapasteurization means reduction below any previously known treatment, but only below the pasteurization treatment defined as a 9 log reduction in salmonella.

Adopting Sunny Fresh's construction of the term would add the additional limitation that ultrapasteurization can only refer to using higher than previously known actual time/temperature pasteurization conditions. The additional limitation is not found in the language of the claim, the specification or the prosecution history. As discussed, to import such a limitation into the claim language would be a mistake of claim construction. See Markman, 52 F.3d at 980. Instead, based upon the claim language and the specification, the court construes the term "ultrapasteurization" to mean to decrease the number of spoilage organisms beyond that obtained with conventional pasteurization without sacrificing functional performance.
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(2) The Meaning of "Unaccompanied by . . .

Other Extraneous Protein Bound Thereto

39. Claim 2 contains the language:

" . . . express a gene for human growth hormone unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto . . . " (Def. Ex. 1).

40. The language of Claim 2 makes the interpretation of this phrase of the claim clear. The claim language "extraneous protein bound thereto" was added to Claim 2 at the suggestion of the Patent Examiner. The claim language "the leader sequence of human growth hormone or other" was added to Claim 2 in response to a prior art rejection advanced by the Patent Office based on a combination of two references - the "leader sequence - hGH gene" of Goodman et al. and the general expression method of Itakura et al. (Pl. Ex. 3, 107-110; Tr. 101, 102, Chamberlin; 1908-1909, 1916-1917, Peet). Applicants pointed out that the combination advanced by the examiner would still produce, in bacteria, the uncleavable fusion product of the leader sequence-hGH protein. (Pl. Ex. 3, 113-114; Id.). This is the problem solved by the '980 patent, as found above. The applicants pointed out that the '980 invention permitted expression of cleavable fusion-hGH products and added the "unaccompanied by the leader sequence of human growth hormone" language to Claim 2 to reinforce that fact. (Pl. Ex. 3, 132-139; Tr. 43, Chamberlin; 1733, 1741-1748. Falkinham; 1908, 1910, Peet). At the same time, the applicants added the word "or other," thus establishing that the "extraneous protein bound thereto" recited in Claim 2 is other protein which, when expressed in bacteria is like the leader sequence of human growth hormone when it is expressed in bacteria, i.e., noncleavable. (Tr. 1905-1911. 1934, Peet: 1875-1876, Falkinham; Def. Ex. 136; Pl. Ex. 3, 138-140). Thus, the language "unaccompanied by . . . or other extraneous protein bound thereto" in Claim 2 means without uncleavable protein.

41. Novo's expert Dr. Villa-Komaroff, testified that the phraseology of Claim 2 "unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto" meant that the human growth hormone was unaccompanied by anything and was therefor superfluous. (Tr. 1133, Villa-Komaroff). The court finds this position to be untenable insofar as it would render the language specifically required to be added by the examiner as surplusage. It would also be directly contrary to the language of the '980 patent at column 7, lines 54-57, cited in P 34, above. Later, Novo's expert concluded that the language allowed for cleavable protein but only where the protein could be cleaved intracellularly. The court finds that the file history of the '980 patent and the '980 specification clearly indicate that the cleavage can be intracellular or extracellular. The court thus finds that Claim 2 of the '980 patent only requires that the expression product be "unaccompanied" by uncleavable protein.
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B. "uncoated"

The plaintiff, Sud-Chemie, Inc. urges that "uncoated," as that term is used in the '942 patent, means uncoated with an adhesive. Multisorb contends that the term should be given its common dictionary definition of "not being covered with a layer;" that is, uncoated with anything.

We first refer to the words of the claim itself as informed by the patent specification. Claim 1 does not refer to adhesive. It does not specifically define the term "uncoated." Rather, the claim states that two films which comprise the packaging material are "uncoated" and are heat sealed together by sealing the edges of the inner surfaces of the films together. The heat seal is accomplished, according to Claim 1, by utilization of an uncoated microporous film and an uncoated laminate film whose inner surfaces are comprised of compatible polymeric materials.

While the claim does not define "uncoated" as uncoated with an adhesive, the patent specification makes clear that that is how the term is used in claiming this invention. The court noted in the Phillips case that "judges are free to consult dictionaries...so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Phillips, 415 F.3d at 1323, quoting, Vitronics, at 1584, n.6. Thus the more general dictionary definition of "uncoated" must be abandoned in favor of the inventor's own lexicography, where it exists. The patent as a

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whole dictates a particular or specialized use of the term "uncoated."

In the Background of the Invention, the inventors stated:

While these [prior art] references disclose multilayered packaging materials, some of which are used with desiccant materials, there are still some significant problems in the production of a packaging material for desiccant containers and their use with specific types of desiccant materials. During the production of conventional laminated packaging materials, at least one side of the packaging material is generally coated with an adhesive. This adhesive is heated to bind the two layers together. because of this adhesive, it is difficult for the equipment utilized to form the desiccant packaging to work at peak capacity. Weak seals, which are frequently formed using this equipment often result in significant down time for the equipment. In addition, films laminated with adhesives do not form strong bonds between the layers, which is desirable for desiccant packaging. In addition, because coated films are more expensive than uncoated films, packaging material formed using coated films tends to be more expensive than laminated films formed from uncoated films. Therefore, it is an object of the invention to disclose a desiccant container containing a desiccant material encapsulated by a laminated, water vapor permeable desiccant packaging material formed using conventional form-fill sealing equipment...

In the Preferred Embodiment the inventors stated:

Conventional...films used for the manufacture of a laminated packaging material have been formed into a composite film bonded to another layer of material. Conventionally, the bonding of the two layers is accomplished by the use of an adhesive which coats one or both of the inside surfaces of the layers. It has been surprisingly discovered that strong, laminated desiccant packaging materials can be produced from uncoated...films...By having the two inner surfaces formed from compatible materials, a strong bond is formed between those layers when they are heat sealed together...In addition, it is also critical that the inner surface of both...be uncoated with an adhesive. Coated film, when sealed to other coated or uncoated films, frequently form poor quality, weak seals...One of the advantages of the product formed from the instant invention ins that the bond formed from the two compatible, uncoated materials has a significantly greater strength than conventional bonds utilizing an adhesive coating. By utilizing the capability of compatible materials to form a strong seal without adhesive, the strength of the desiccant packaging material is significantly increased over conventional packaging materials.

The Background of the Invention describes a problem in the art of desiccant containers comprised of multilayered packaging materials. Conventionally, one or both of the films used in the production of a laminated packaging material for desiccant containers was coated with an adhesive. That adhesive was used to bind the two layers. Binding with adhesive was problematic for the heat sealing machines and resulted in weak seals. The Preferred Embodiment of the '942 patent described the advantage of the invention as "utilizing the capability of compatible materials to form a strong seal without adhesive," noting that "[i]t has been surprisingly discovered that strong, laminated desiccant packaging materials can be produced from uncoated...films." The inventors also noted that it is "critical that the inner surface of both...be uncoated with an adhesive." Reading the '942 patent as a whole, the term "uncoated" as used in Claim 1 means uncoated with an adhesive.
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In the present case, the Plaintiff argues that the intended scope of its claim covers a process for bonding both cured and uncured silicone rubber. Claim 1 calls for "placing the treated and primed surface of polyolefin in contact with the surface of an uncured elastomeric compound of molecular weight" (emphasis added). 3 As a threshold matter, Plaintiff contends that the term "uncured" as used in their claim should be construed as encompassing "any uncured or partially cured silicone." (Pl. Opp. Brief at 13). Plaintiff argues that partially cured silicone rubber contains an uncured element, and therefore based on its argued claim construction, should be considered "uncured" and within the scope of Plaintiff's Claim 1.

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3 The definition of "uncured" is dispositive on the question of literal infringement, because the Defendant's bonding process calls for a "cured" sample of silicone elastomer.

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The Court cannot agree with the Plaintiff's suggested claim construction. The words used in the Plaintiff's claim specify that the silicone rubber elastomer to be used is "uncured," not "uncured or partially cured." 4 Plaintiff's patent refers to the silicone rubber elastomer several more times in the specification as "uncured" (in the "Discussion of Prior Art" section, "Detailed Description of the Invention" section, and in Examples one - three). While the patent specification sets forth no special meaning for the term "uncured," the Court will assume the term represents its common meaning in the scientific field. See Vitronics, 90 F.3d at 1584. In The Compilations of ASTM Standard Definitions, "cure" is defined as "to change the properties of a polymeric system into a more stable, useable condition by the use of heat, radiation, or reaction with chemical additives." 135 (8th ed. 1994) (the ASTM is the American Society for Testing and Materials). The ASTM treatise also equates "cure" with the preferred term "vulcanization." See id. "Vulcanization" is defined as "an irreversible process during which a rubber compound, through a change in its chemical structure (for example, cross-linking), becomes less plastic and more resistant to swelling by organic liquids and elastic properties are conferred, improved, or extended over a greater range of temperatures" See id. at 565. 5 Thus, the Court finds that the term "uncured" in the Plaintiff's patent claims refers to a silicone rubber elastomer that is not cured, that is, it has not been exposed to heat and/or chemicals so that its chemical structure has not irreversibly changed to exhibit the characteristics of vulcanized rubber. 6

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4 Using uncured silicone is necessary because the silicone and polyolefin are bonded and cured in the same step later in the process.

5 See also Hawley's Condensed Chemical Dictionary which defines "curing" generally as "conversion of a raw product to a finished and useful condition, usually by application of heat and/or chemicals that induce physicochemical changes," and the curing of rubber as: "Addition of sulfur and accelerator, followed by exposure to heat, which effects cross-linking. This converts the material from a thermoplastic to thermosetting product. High energy radiation can also be used. See vulcanization." Van Nostrand Reihold (13th ed., 1997).

6 Since "curing" or "vulcanization" is an irreversible process, the term "partially cured" is not, as the Plaintiff suggests, equivalent to the term "uncured" because any curing at all permanently alters the properties of the silicone making the physical states of uncured silicone and partially cured silicone mutually exclusive.

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The Court therefore construes the term "uncured" in the Plaintiff's '148 patent claim as referring to an elastomeric compound which has not undergone any curing or vulcanization process. 7

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7 Plaintiff's argument that the prosecution history supports the conclusion that the term "uncured" was meant to include "partially cured" is also without merit. The statement in the prosecution history referring to the Plaintiff's process as being capable of joining a polyolefin and an "uncured or partially cured" silicone rubber, indicates that the inventors distinguished between "uncured" and "partially cured," as separate physical states. (See Muldoon Decl., Ex. C at 54.) However, the prosecution history cannot be relied upon to expand the scope of Plaintiff's patent to cover both partially cured and uncured states. While the prosecution history may be used to define terms within the claim itself, it cannot be used to "enlarge, diminish, or vary" the limitations in the claim. Markman, 52 F.3d 967 (citing Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227, 26 L. Ed. 149 (1880)). Thus, while the Plaintiff's reference to both uncured and partially cured silicone in the prosecution history is useful to demonstrate that the Plaintiff knew there was a difference between the two states, it cannot be used to expand the scope of the claim itself which refers only to uncured silicone.

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H. Underivatized, aqueous soluble [beta] (1,3) glucan

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Variations of the phrase "underivatized, aqueous soluble [beta] (1-3) glucan" appear in several asserted claims of the '720 Patent, the '940 Patent, the '939 Patent, the '223 Patent, the '542 Patent, the '643 Patent, and the '569 Patent. The parties agree that "underivatized" means: "The glucans are not derivatized. Derivatized is a term well recognized by those skilled in the art as a chemical modification made to the glucan moiety, such as methylethers, carboxymethylethers, acetylesters, sulfonylester and phosphoric acid esters."

With respect to "soluble," the parties agree to constructions based on the patents' specifications. Thus, for the '720 Patent, the '940 Patent, the '939 Patent, the '223 Patent, and the '542 Patent, soluble means that "a visually clear solution can be formed in an aqueous medium such as water, PBS, isotonic saline, or a dextrose solution having a neutral pH (e.g., about pH 5 to about pH 7.5), at room temperature (about 20 [degree] -25 [degree] C) and at a concentration of up to about 10 mg/ml." For the '643 Patent, and the '569 Patent, soluble means:

A visually clear solution can be formed in an aqueous medium such as water, PBS, isotonic saline, or dextrose solution having a neutral pH (e.g., from about pH 5 to about pH 7.5), at room temperature (about 20 [degree] -25 [degree] C) and at a concentration of up to about 10 mg/ml, where "visually clear" means that at a concentration of 1 mg/ml, the absorption of the solution at 530 nm is less than OD 0.01 greater than the OD of an otherwise identical solution lacking the [beta] -glucan component.

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"Undesirable high levels of blood serum lipids"

This term appears in certain claims from the ' 156 Patent. Nutrition 21 argues that the term "should be given its plain and ordinary meaning, i.e. an unwanted or objectionable above normal amount of blood serum lipids." Nutrition 21 bases its construction's use of the words "unwanted or objectionable" on a dictionary definition of "undesirable" and points to the specification only to note the lack of evidence that the inventors desired to deviate from the generally-accepted meaning of "undesirable." n9 Nutrition 21 insists that it uses the dictionary definition only to indicate the generally-accepted meaning to skilled artisans, not to construe the claim term. However, Nutrition 21 cites no evidence to indicate that a skilled artisan would construe "high" to mean "above normal."

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n9 See Nutrition 21's Opening Br. at 31 (Docket No. 57-1 at 36) (citing Webster's 3d New Int'l Dictionary (1986)).

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GNC argues that the term means "a level of blood serum lipids determined to be abnormally high." GNC justifies introducing "determined" into its construction by arguing that "for the serum lipid level to be classified as 'undesirable,' it must first be determined that the level is outside the desirable range." However, GNC cites no intrinsic or extrinsic evidence to support the proposition that whether a blood serum lipid level is "undesirable" requires objective determination, and the Court rejects the limitation. Moreover, similar to Nutrition 21, GNC cites no evidence to indicate that a skilled artisan would construe "undesirable high" to mean "abnormally high."

During oral argument, the Court attempted to foster the parties' compromise by proposing the construction "an unhealthy or objectionable amount of blood serum lipids," consistent with the term's plain meaning. Nutrition 21 expressed amenability to the Court's proposal but retreated from this position after GNC refused to abandon its construction. Given both sides' failure to justify their positions, the Court cannot adopt either party's proposed construction.

The Court agrees with Nutrition 21 that skilled artisans would construe "undesirable" according to its generally-accepted meaning. Indeed, the evidence does not indicate that skilled artisans would construe the term as a whole other than according to its plain meaning. As a result, the term does not need to be construed.

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"Undesirable low level of blood serum HDL-cholesterol"

This term appears in Claim 18 of the '156 Patent. Nutrition 21 argues that its proposed construction -- "unwanted or objectionable below normal amount of HDL-cholesterol" -- incorporates the ordinary meaning of "undesirable low level." The Court agrees with Nutrition 21's argument that skilled artisans would construe "undesirable low level" according to its plain and ordinary meaning. But similar to before, Nutrition 21 cites no evidence to indicate that a skilled artisan would in turn construe "low" to mean "below normal."

GNC argues the term means "a level of blood serum HDL-cholesterol determined to be abnormally low," and rests on its arguments with respect to "undesirable high levels of blood serum lipids" for support. The Court again rejects those arguments.

The evidence does not indicate that skilled artisans would construe the term "undesirable low level of blood serum HDL-cholesterol" other than according to its plain meaning. Therefore, the term does not need to be construed.
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DISCUSSION
Analysis of patent infringement starts with “construction” of the claim, whereby the court establishes the scope and limits of the claim, interprets any technical or other terms whose meaning is at issue, and thereby defines the claim with greater precision than had the patentee. Although the construction of the claim is independent of the device charged with infringement, it is convenient for the court to concentrate on those aspects of the claim whose relation to the accused device is in dispute. On appeal the Federal Circuit is required to construe the claim de novo ; thus we do so without deference to the rulings of the trial court. See generally Cybor Corp. v. FAS Technologies, Inc. , 138 F.3d 1448, 46 USPQ2d 1169 (Fed. Cir. 1998) (en banc).
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B. The Term "Immediately"

As noted above, the district court construed "immediately" to require the activation of the blocking flange simultaneously with removal from the patient. The court decided that this term imposed a limitation upon claims where it appeared in the preamble, as well as upon two claims where it did not literally appear.

In this case, both the RE '885 patent's specification and prosecution history clearly indicate that the invention is focused on ensuring the protection of the healthcare worker, patient, and bystanders by safely covering the needle at once upon removal from the patient. The "Summary of the Invention" section of the RE '885 patent is particularly instructive:

The present invention addresses [the needlestick hazard] problem confronting the healthcare industry and is designed specifically to eliminate needlestick injuries of the type described in connection with blood collection. To this end, there is provided a new and improved system which . . . shields the blood-contaminated needle simultaneously with its removal from the donor . . . whereby the probability of an exposed contaminated point being in any injury-causing proximity to a medical worker is virtually nil . . . .

RE '885 patent, col.2 ll.52-62 (emphasis added). The summary is of course not wholly dispositive. See Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081, 1094 (Fed. Cir. 2003) ("While clear language characterizing 'the present invention' may limit the ordinary meaning of claim terms, such language must be read in context of the entire specification and the prosecution history." (internal citations omitted)). There is nothing in the RE '885 patent specification, though, that speaks to the needle being rendered safe at any time other than the moment of removal from the patient. Furthermore, the prosecution

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history provides additional support for the district court's conclusion. During prosecution of the related '347 patent, the examiner rejected MBO's application in view of U.S. Patent No. 5,026,356, issued to Smith. In response, MBO distinguished its invention from and criticized the Smith patent:

Please note that in Smith . . . the needle 60 may be fully withdrawn from the patient's flesh by an inattentive or rushed operator in exactly the [unsafe] state, with the needle point and needle end portion fully exposed and hazardous for needlestick and contamination! It is required in Smith as a specific manipulative effort that the operator personally bodily move the [needle guard] forward . . . which may be overlooked in rushed or harried treatment conditions . . . .

Reply Letter to Alexander, Examiner, In the Patent Application of Blecher et al., S.N. 07/972,013, at 8 (Nov. 15, 1993). The clear implication is that the MBO invention, in contrast to Smith, does provide assurance that the needle will be made instantly safe upon withdrawal from the patient. Prosecution arguments like this one which draw distinctions between the patented invention and the prior art are useful for determining whether the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not. See Medtronic, Inc. v. Guidant Corp., 465 F.3d 1360, 1373 (Fed. Cir. 2006) ("A surrender can occur by argument as well as by amendment.").

The patentee here has clearly indicated via the specification and the prosecution history that the invention provides, as an essential feature, immediate needle safety upon removal from the patient. It is therefore appropriate to construe the claims so as to ensure that they, too, require that feature. The construction of the term "immediately" to mean "simultaneously with the needle's withdrawal from the patient" is correct. Where that term appears in a claim preamble, it is "necessary to give life, meaning, and vitality to the claim," and may be used as a limitation. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (quotation marks omitted).

Reissue claims 32 and 33 do not contain the word "immediately," but the district court nonetheless used its construction of that term to limit the claims. We sympathize with the district court's choice, since we agree that safety at once upon removal from the patient is an essential element of the invention as described by MBO. However, we cannot endorse a construction analysis that does not identify "a textual reference in the actual language of the claim with which to associate a proffered claim construction." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999); see also Renishaw PLC v. Marposs S.p.A., 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("[I]t is manifest that a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description."); E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988) (finding it improper to impose "a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim").

In this case, we are reviewing only certain disputed terms of the claim construction and lack the power to construe other terms not disputed by the parties. None of the disputed terms that are found in claims 32 or 33 can reasonably be construed to impose the simultaneous-safety requirement upon those claims. The district court's grafting of the "immediately" limitation into claims 32 and 33 is error. 2

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2 We express no view on whether claims 32 and 33 as construed would invoke the recapture rule.

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1. Claim 25

An element of Claim 25 is "allowing the resultant assembly to set and dry such that the calcined gypsum forms set gypsum having voids uniformly dispersed therein." Defendants contend that "resultant assembly" means the entire board, including edges. Defendants contend that this element should be construed as requiring a uniform distribution of voids through the entire board, including edges. It is undisputed that, in the LNA Method which uses hard edges, voids in the edges are not uniform with voids in the core.

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As of the time that the '635 patent was issued, as well as currently, nearly all commercial wallboard was manufactured with hard edges. Unless defined by the patent as meaning something else, words of a patent claim are to be interpreted in accordance with their ordinary meaning, as they would be understood by one skilled in the art. V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1310-11 (Fed. Cir. 2005); Merck & Co. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364, 1369-70 (Fed. Cir.), cert. denied, 546 U.S. 972, 126 S. Ct. 488, 163 L. Ed. 2d 384 (2005); Duhn Oil Tool, Inc. v. Cooper Cameron Corp., 474 F. Supp. 2d 1148, 2007 WL 331638
*4 (E.D. Cal. 2007).

Claim 25 sets forth a method for preparing "a foamed gypsum board." It lists the elements "comprising" that method. In a patent claim, "comprising" means including. Mars, Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1375-76 (Fed. Cir. 2004); Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1344-45 (Fed. Cir. 2003); Goff v. Harrah's Operating Co., 412 F. Supp. 2d 1090, 1094 (D. Nev. 2005). A method claim comprising certain elements does not need to set forth every step necessary to produce the identified product. Mars, supra; Smith & Nephew, Inc. v. Ethicon, Inc., 276 F.3d 1304, 1311 (Fed. Cir. 2001); Goff, supra. Thus, the claim 25 preamble language ("A method of preparing a foamed gypsum board comprising . . .") does not indicate that the elements that follow are sufficient by themselves to produce a foamed gypsum board. Nevertheless, defendants contend that "resultant assembly," as used in the last phrase of the claim, should be understood as referring to "a foamed gypsum board" that appears in the preamble. Instead, a proper reading of "resultant assembly" is that it refers to the particular steps set forth in claim 25 following the preamble. Those steps include placing the dispersed material between two sheets and drying that assembly. The recited steps, however, do not exclude adding other materials or dispersions before adding the second cover sheet, nor is there any mention of the forming stage of wallboard production. The resultant assembly simply refers to the described dispersion being between two cover sheets. It is consistent with claim 25 to have edges composed of different materials. The only part of the resultant assembly that need have uniformly dispersed voids is the deposited dispersion described in claim 25.

Such a reading of claim 25 is consistent with how a person skilled in the art would understand the claim. A person skilled in the art would know that wallboard is manufactured with edges that have a density different from that of the core. Such a person would understand that claim 25 does not make any claim regarding the edges of the board. Specifically, a person skilled in the art would understand that the uniformly dispersed voids exist only in the deposited dispersion described. A person skilled in the art would understand that, in the usual manufacturing process, a different dispersion with a different density would be used for the edges.

The undisputed fact that the LNA Method produces wallboard with differing densities in the core and edges does not preclude the possibility that the LNA Method infringes claim 25.
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2. The "containing uniformly dispersed therein a static-reducing amount of electrically conductive particulate material" limitation

The conductive layers in the accused Nevamar static-dissipating products consist of paper which has been coated with electrically conductive carbon particles on both sides and impregnated with a polymer resin. Nevamar submitted photomicrographs of the completed layer showing that the carbon particles are distributed in two parallel planes located slightly below the two surfaces of the paper, with little or no carbon particles in the area of the plane centered between the paper surfaces.

The district court construed the "uniformly dispersed" limitation to mean that the conductive particles must be uniformly dispersed in all dimensions of the alleged conductive layer (i.e., length, width and thickness). Based on this construction, the court concluded that the "uniformly dispersed" limitation does not read on the accused Nevamar products because of the lack of uniform distribution of carbon particles across the thickness of the alleged conductive layer. This analysis is incorrect.

The written description of the '040 patent describes various types of conductive layers and corresponding methods of preparation. One such layer comprises an open-cell foam which is loaded with conductive particles by "dusting" the particles onto the surface of the foam and then "calendering" (sic) the foam to impregnate the particles therein. See '040

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patent, col. 5, ll. 1-6. Although this technique is described as adequate to result in conductive particles being impregnated "generally uniformly throughout the foam", it is unreasonable to infer that this technique will result in carbon particles being uniformly distributed across the thickness of the foam. The written description of the '040 patent thus shows that the "uniformly dispersed" limitation requires the distribution of conductive particles across the length and width of the conductive layer but does not require uniform dispersion of the particles across the thickness of the layer.

Therefore, viewing the evidence and making all reasonable inferences in favor of Nevamar, there is no genuine issue of material fact precluding summary judgment concerning this issue and Charleswater is entitled to JMOL that the "uniformly dispersed" claim limitation encompasses the accused Nevamar products, even though the conductive carbon particles in the alleged conductive layer in those products are not uniformly dispersed across the thickness of the conductive layer.
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G. Uniformly Dispersing the Foam

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
uniformly dispersing the foam [in the aqueous gypsum dispersion]	uniformly dispersing the foam in the aqueous gypsum dispersion	dispersing foam into the slurry such that the resulting mixture is homogeneous throughout the entire slurry

The next disputed term occurs in conjunction with "minimize destruction of the foam" in both claims 25 and 36, but the court confines its construction here to the words "uniformly dispersing the foam." Defendants contend the term "uniformly," here and elsewhere, is indefinite because the patent does not adequately describe the point at which a dispersion is considered uniform. Again, Defendants push for a bright line that the law does not require. The patent itself makes clear that it does not purport to invent the concept of uniformity in gypsum products. ('635 Patent col. 1, ll. 23-30)("It is also well known to produce a lightweight gypsum product by uniformly mixing an aqueous foam into the slurry to produce air bubbles therein. This will result in a uniform distribution of voids in the set gypsum product.") Uniform distribution was and is a well-known concept in the art of gypsum product manufacture. (See, e.g., U.S. Patent 5,643,510 (Sucech) and U.S. Patent 5,085,929 (Bruce)). The term is not indefinite.

Defendants next contend that the court should construe the term to require "homogeneity" throughout the entire slurry. Judge Hart has previously determined that the term uniformity refers only to the core, not the edges, of the wallboard. United States Gypsum Co., 508 F. Supp. 2d at 616. Defendants' proposed reference to the entire slurry would, thus, be misleading. But even referring only to the core slurry, the court sees no benefit to construing uniformity to require homogeneity. Homogeneity connotes perfectly "identical distribution functions." WEBSTER COLLEGIATE DICTIONARY at 738 (10th ed. 1997.) The term is more technical than "uniform," which means "presenting an unvaried appearance of pattern" in ordinary usage. Id. at 1292. Confusing the ordinary meaning of "uniform" by adding additional technical terms will not aid the jury. The ordinary meaning of uniform is consistent with its usage in the specification, which does not appear to require exact mathematical precision in foam and void distribution. Relying on the ordinary meaning alone is sufficient. O2 Micro Int'l Ltd., 521 F.3d at 1361. Accordingly, the court accepts Plaintiff's proposal and finds that this term requires no further construction.

H. Voids Uniformly Dispersed Therein

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
voids uniformly dispersed therein	voids uniformly dispersed therein	voids equally dispersed throughout all planes, or in all three dimensions, of the gypsum board core

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The next term comes at the end of both claims 25 and 36: as a result of the foam distribution, the formed gypsum has "voids uniformly dispersed therein." The patent makes clear that voids result from the distribution of the foam ('635 Patent col. 1, ll. 23-30). The court also presumes that when the same term appears in different portions of the claim it has the same meaning. Paragon Solutions, LLC v. Timex Corp., 566 F.3d 1075, 1087 (Fed. Cir. 2009). "Uniformly," as it is ordinarily understood, means the same thing when applied to voids as when applied to foam. Accordingly, for the reasons stated above, the court finds that this term is not indefinite and needs no further construction.
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III. "unique segments" / "unique sequence" / "repetitive sequence"

The parties' disputes with respect to the disputed terms "unique segments," "unique sequence" and "repetitive sequence" are related, and must be considered together.

With respect to "unique segments," Abbott proposes that the phrase be construed to mean "stretches of nucleic acid that contain sequences that occur 1 to 10 times in the haploid genome." Dako proposes that the phrase be construed to mean "stretches of DNA or RNA that contain only DNA or RNA sequences present in a single copy per haploid genome and are free of repetitive sequences."

With respect to "unique sequence," Abbott proposes that the phrase be construed to mean "nucleic sequence that occurs from 1 to 10 times in a haploid genome." Dako proposes that the phrase be construed to mean "stretch of DNA or RNA that contains only a DNA or RNA sequence present in a single copy per haploid genome and is free of repetitive sequences."

With respect to "repetitive sequence," Abbott proposes that the phrase be construed to mean "nucleic acid sequence that is not unique." Dako proposes that the phrase be construed to mean "stretch of DNA or RNA that contains only a DNA or RNA sequence that is not a unique sequence."

The parties' proposed constructions differ in two critical respects. First, Abbott argues that "segment" refers to an actual stretch of nucleic acid, while "sequence" refers to a particular ordering of bases and not to an actual physical piece of genetic material. Dako argues that both "segment" and "sequence" refer to a physical piece of nucleic acid. Second, Abbott argues that "unique" means "occur[ring] from 1 to 10 times in a haploid genome," while Dako argues that "unique" means "present in a single copy"-i.e. not 2-10 copies-per haploid.

A. "segments" vs. "sequence"

The phrase "unique segments" appears only in claim 1 of the '841 patent:

1. A method of staining target chromosomal DNA comprising:

(a) providing

1) labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid segments within the chromosomal DNA for which detection is desired, and

2) blocking nucleic acid that comprises fragments which are substantially complementary to repetitive segments in the labeled nucleic acid; and

(b) employing said labeled nucleic acid, blocking nucleic acid, and chromosomal DNA in in situ hybridization so that labeled repetitive segments are substantially blocked from binding to the chromosomal DNA, while hybridization of unique segments within the labeled nucleic acid to the chromosomal DNA is allowed, wherein blocking of the labeled repetitive segments is sufficient to permit detection of hybridized labeled nucleic acid containing unique segments, and wherein the chromosomal DNA is present in a morphologically identifiable chromosome or cell nucleus during the in situ hybridization.

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'841 patent at 17:4-25. The word "segment," standing alone, appears throughout the claims of the '841 patent, in claim 1 of the '479 patent, in the Background of the Invention of the Specification, and in the title of prior art papers cited in the Specification. The word "segment" is consistently used to refer to a stretch of nucleic acid. Both parties are in agreement on this point. The court therefore construes the word "segment" to mean "a stretch of nucleic acid."

The phrase "unique sequence" appears throughout the claims of the '479 patent and the shared Specification. Claim 1 of the '479 patent is illustrative:

1. A method of staining target interphase chromosomal DNA to detect an extra or missing portion or portions of a chromosome . . ., the method comprising:

(a) providing a heterogeneous mixture of labeled unique sequence nucleic acid fragments which are substantially complementary to nucleic acid segments within the interphase chromosomal DNA for which detection is desired . . .

'479 patent at 16:6-29 (emphasis added). The word "sequence," standing alone, also appears numerous times in the claims of both patents, as well as throughout the Specification.

The word "sequence" and the phrase "unique sequence" are most often used as they are in claim 1 of the '479 patent-as modifiers for words describing physical sections of nucleic acid, such as "DNA," "nucleic acid," or "fragment." See, e.g., '479 patent at 16:9-10 ("unique sequence nucleic acid fragments"); id. at Abstract ("unique sequence regions of the chromosomal DNA"); id. at 3:39-40 ("unique sequence DNA fraction"). Occasionally the '479 patent uses the phrase "unique sequence" or the word "sequence," standing alone, to refer to a section of nucleic acid with a unique sequence of base pairs. See '479 patent at 16:56-57 ("wherein the heterogeneous mixture further comprises repetitive sequences"); id. at 7:4-5 ("The poly(dA) tail is used to separate the labeled unique sequence DNA from the unlabeled unique sequences").

In the context of claim 1 of the '479 patent, the phrase "unique sequence" is used as a modifier, referring to an ordering of bases rather than an actual snippet of DNA. The phrase "unique sequence" modifies "nucleic acid fragments," which are stretches of DNA or RNA. If Dako's proposed construction of "sequence" were correct, the claim would read "a heterogeneous mixture of labeled unique sequences which are substantially complementary to nucleic acid segments within the interphase chromosomal DNA" instead of "a heterogeneous mixture of labeled unique sequence nucleic acid fragments which are substantially complementary to nucleic acid segments within the interphase chromosomal DNA."

Dako argues that the patentee stated during prosecution that "sequence" and "segment" have the same definition. Hoffman Dec., Exh. G at 4. During prosecution, a prior version of claim 1 did use the word "sequence" to refer to a stretch of DNA, rather than a particular order of bases. Id. at 1 (claiming "labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid [sequences] . . . within the chromosomal DNA.") (emphasis added). As currently used in the claims and Specification, however, the term "sequence," almost without exception, refers to an ordering of bases. Within claim 1, in particular, the meaning is clear.

The court therefore construes the term "sequence" to mean "an ordering of nucleotide bases."

B. "unique"

The word "unique," which the parties agree has a meaning opposite that of "repetitive" or "repeat," is used throughout the specifications and claims. As with the term "heterogeneous mixture," the specification of the '841 patent includes an express definition of "repetitive":

As discussed more fully below, preferably the heterogeneous mixtures are substantially free from so-called repetitive sequences, both the tandem variety and the interspersed variety (see Hood et al., Molecular Biology of Eucaryotic Cells (Benjamin/Cummings Publishing Company, Menlo Park, Calif., 1975) for an explanation of repetitive sequences). Hood et al. states at pages 47-48 that "[e]ucaryotic sequences can be divided somewhat arbitrarily into three general frequency classes, termed highly repetitive (also called satellite DNA), middle-repetitive, and unique." Hood et al. indicates at page 49 that "[h]ighly repetitive DNA sequences are located in regions of centromeric heterochromatin", and at page 50 that "[m]iddle-repetitive sequences are interspersed among unique sequences."

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'841 patent at 4:20-34. The Hood treatise, which is incorporated into both patents by reference, also defines the term "unique," though not with ideal clarity. On page 47, Hood states that "[s]equences represented only once in the genome (unique sequences) will hybridize slowly compared to sequences that are present in many copies." Hoffman Dec. Exh. R at 47. The table on page 47 also indicates that "Unique" sequences have only one copy per genome. Id. The same table, however, indicates that "Middle-repetitive" sequences have between 101 and 105 copies per genome-leaving sequences occurring between 2 and 9 times per genome unclassified. Id. Abbott's proposed construction exploits this gap, defining "unique" as occurring from 1 to 10 times in a haploid genome." Dako's proposed construction is based on the express wording of Hood, which equates "unique" with "represented only once in the genome."

The conventional meaning of the word "unique" supports Dako's construction. A contemporaneous dictionary defines "unique" as "[b]eing the only one of its kind; solitary; sole." Hoffman Dec., Exh. S at 1400. The Specification also suggests that "unique" means "single": "Clones carrying unique sequence inserts are recognized as those that produce a single band during Southern analysis." Spec. at 9:55-57.

Abbott does not offer a contrary dictionary definition, but argues that one of ordinary skill in the art would understand that "unique" sequences can appear a handful of times in a genome without being considered "repetitive." For example, Abbott notes that the gene for hemoglobin, which is classified as "unique" in the Hood reference, was known at the time of the patent to occur more than once per haploid genome. See Hoffman Dec., Exh. R at 37; cf. Harper Dec., Exhs. O, P. Abbott also notes that the target sequences discussed in the specification are present in multiple copies per haploid.

Abbott's cited evidence, which is intrinsic to the patent because it appears in materials incorporated into the Specification by reference, indicates that one of ordinary skill in the art would have understood that "unique" is not as strict as its general dictionary definition would suggest. The specification and claims do not provide any clear motivation to limit the meaning as Dako suggests. The court therefore construes "unique" to mean "occurring fewer than 10 times per haploid genome."
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3. "Units"

The plaintiff proposes "the structural monomeric units or the number of atoms, including those as part of an overall copolymeric structures." The defendants propose "structural monomeric units or the number of silicon atoms."

Both parties agree that this term is expressly defined in the specification. The specification states that "the units referred to are the structural monomeric units or the number of silicon atoms, including those as part of an overall copolymeric structure." '327 patent, 4:4-7. The plaintiff excludes "silicon" from its definition because the specification distinguishes between "silicon units" and "monomer units." See '327 patent, 4:2-3. The defendants, on the other hand, contend that "including those as part of an overall copolymeric structure" is exemplary language and should not be included in the definition.

The Court agrees with the plaintiff Claim 1 distinguishes between silicon and monomer units. '327 patent, 8:13-15. Accordingly, the Court adopts the plaintiff's proposed construction.
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Unlinked	Not physically or chemically linked on the same piece of contiguous DNA

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b. Purity Limitation

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The claims do not expressly refer to a specific minimum optical purity or percentage of the detrorotatory enantiomer. In its prior claim construction, however, the Court described the claims as covering something "comprised principally of levofloxacin." That terminology gave rise to significant debate during trial. The language, however, was intended to capture a concept that was only reinforced at trial: a person of ordinary skill in the art at the time of the filing of the '407 patent would have understood the claim to cover levofloxacin with a purity that was highly, but less than 100 percent, optically pure. The Court did not reference a minimum purity because no minimum purity was claimed or identified in the intrinsic record.

To determine what one skilled in the art could understand, the court should consider the testimony of scientific expert witnesses. See AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1249 (Fed. Cir. 2001). The Court is dealing here with highly technical terms. Therefore, it must rely on the education it received from the experts as to whether one of ordinary skill in the art would have read the reference as referring to a 100 percent pure substance.

Because of the nature of enantiomeric separation at the time, one of ordinary skill in the art would not have read a claim to an enantiomer of ofloxacin as requiring 100 percent purity. Dr. Klibanov testified that when chemists refer to 100 percent purity they understand that "there is always that molecule hiding somewhere in the corner. There is no such thing as an absolutely 100 percent .0000 pure substance." (Klibanov Tr. at 1899.) Mylan's expert, Dr. Mitscher, implicitly conceded this when he calculated the optical purity of Example 6. He "arbitrarily" treated Example 7 as 100 percent pure, recognizing that it "may, in fact, not be 100 percent [pure]," but it was "the purest sample available" in the '407 patent. (Mitscher Tr. at 741-42.) Further, Mitscher stated that the purity number he would require was "very high, 100 percent if possible, but you know as pure as can reasonably be obtained for a product at this time." (Mitscher Tr. at 932.)

Thus, although one of ordinary skill in the art would have understood the claim to the compound levofloxacin to be substantially pure levofloxacin, the realities of science would have led such a skilled artisan to conclude that the purity was not 100 percent. This is confirmed by the specification, particularly in the examples. As Drs. Klibanov and Mitscher testified, not all of the examples, and perhaps none of the examples, yielded 100 percent pure levofloxacin. Therefore, the Court declines to adopt such a limitation and construes claim 2 of the '407 patent to cover substantially pure levofloxacin.
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E. Testing Procedures

The '355 patent claims do not articulate any testing methods for measuring the claimed release rates of oxybutynin. Mylan contends that the specification and prosecution history require the use of in vitro dissolution tests to determine these release rates. Mylan also asserts that the Federal Circuit's holding in Honeywell Int'l, Inc. v. ITC, 341 F.3d 1332 (Fed. Cir. 2003), mandates "all methods" of dissolution testing to determine infringement in this case. Alza maintains, however, that testing methodologies need not be included in the claims because they are known to persons of ordinary skill in the art and are adequately discussed within the patent specification.

The Federal Circuit offers clear guidance on this claim construction issue:
It is manifest that a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description. This is so because the claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim. The intrinsic evidence, and, in some cases, the extrinsic evidence, can shed light on the meaning of the terms recited in a claim, either by confirming the ordinary meaning of the claim terms or by providing special meaning for claim terms. However, the resulting claim interpretation must, in the end, accord with the words chosen by the patentee to stake out the boundary of the claimed property.

Thus, a party wishing to use statements in the written description to confine or otherwise affect a patent's scope must, at the very least, point to a term or terms in the claim with which to draw in those statements. Without any claim term that is susceptible of clarification by the written description, there is no legitimate way to narrow the property right. The Supreme Court has clearly stated the rationale for this requirement:
We know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not

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mentioned in the claim in order to limit such claim . . ., we should never know where to stop.

If we need not rely on a limitation to interpret what the patentee meant by a particular term or phrase in a claim, that limitation is "extraneous" and cannot constrain the claim.

Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248-49 (Fed. Cir. 1998) (quoting McCarty v. Lehigh Valley R.R., 160 U.S. 110, 116, 40 L. Ed. 358, 16 S. Ct. 240, 1895 Dec. Comm'r Pat. 721 (1895)) (other citations omitted) (emphasis added).

As Mylan emphasizes, "the claim language in the '355 Patent is silent as to testing procedures and conditions" to measure release rates of the claimed oxybutynin formulations. (Mylan Opening CC Br. at 18.) Indeed, Mylan does not--and cannot--connect its proffered testing methodology claim limitation to any claim language. The claimed inventions of the '355 patent do not include testing methods, and a person of ordinary skill in the art need not refer to such methods to understand the plain meaning of the claim terms. Therefore, a testing methodology requirement is an "extraneous" claim limitation, which the Court refuses to import.

Relying heavily on Honeywell, Mylan nevertheless urges the Court to construe the claims to require "all methods" of in vitro testing to determine oxybutynin release rates. In Honeywell, the claim construction dispute "focuse[d] on the method of measuring one claimed feature--the melting point elevation ("MPE")" of a polyester yarn. 341 F.3d at 1335. The claims "require[d] that the yarn produced by the claimed process fall within a specified MPE range at some point in the process." Id. The written description identified a test to measure the MPE but failed to explain how to prepare a yarn sample for this test. Id. at 1336. The sample preparation method was crucial because "[d]epending upon which sample preparation [was] used, the calculated MPE for a given sample [could] vary greatly." Id.

The Honeywell court determined that four sample preparation methods were available. Three of the methods were published in the art as of the patent's priority date, and one method was unpublished but known by those of skill in the art. Id. Therefore, at issue was whether the claims required "any particular sample preparation method when determining the MPE." Id. at 1339. The Federal Circuit found that "the claims, the written description, and the prosecution history fail[ed] to give . . . any guidance" as to which sample preparation method was necessary to practice the invention. Id. at 1340 (emphasis added); see id. at 1342. Thus, the court rejected claim constructions that required only one sample preparation method. Moreover, the final possible claim construction, which would require using all four known sample preparation techniques, rendered the invention "inoperable." Id. at 1341. As such, in Honeywell, the court concluded that the claims were invalid for lack of enablement and for indefiniteness. Id.

Here, Mylan asserts that, like the choice of sample preparation methods in Honeywell, the choice of testing procedures for its drug is critical to determining infringement. Its accused drug has a polymer matrix release system, which is "critically dependent upon dissolution medium pH, testing apparatus, and agitation speed." Dosage forms utilizing the osmotic pump system, however, have the same dissolution rate irrespective of pH, media, testing apparatus or agitation speed. In light of the importance of testing conditions for its accused drug, Mylan argues that Honeywell forbids a claim construction that permits Alza to "gerrymander" specific tests for infringement. Rather, according to Mylan, Honeywell compels this Court to construe the claims as requiring all possible methods of in vitro dissolution testing to determine oxybutynin release rates.

Mylan's argument oversimplifies Honeywell's holding and factual context. Unlike the case at bar, the claim construction dispute inHoneywell focused on the meaning of an identified claim term, i.e., "melting point elevation." The MPE was a limitation of the claimed processes; therefore, the sample preparation method was integrated within the claim because it was necessary to calculate the MPE. In contrast, the '355 patent claims make no reference, implicitly or explicitly, to testing methods. Moreover, unlike the sample preparation method in the Honeywell patent, no particular dissolution test is required to manufacture the claimed drug. Id. at 1341 ("Because the sample preparation method is critical in determining MPE, processes utilizing different sample preparation methods will produce different yarns.") (emphasis added). Thus, a skilled artisan could read the '355 patent, create an infringing drug (assuming enablement), and never employ any testing to determine the release rates of that drug.

In conclusion, despite Mylan's argument to the contrary, Honeywell does not hold as a black letter rule that claims must establish testing parameters for infringement. There the sample preparation method was an implicit element of the claim. In the '355 patent, by contrast, testing is a means to confirm the properties of the claimed invention. Therefore, in this case,

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testing methodology is solely an issue of infringement because it is not necessary to an understanding of what the claims mean. Accordingly, the Court refuses to apply any claim limitation that mandates certain testing procedures or conditions.
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C. Claim Construction & Literal Infringement of Independent Claims 1 and 8

Finnigan argues that the ALJ erred in construing the term "unstable" in claims 1 and 8 with reference to the stability diagram disclosed in the '884 patent. Finnigan asserts that the specification makes clear that an "unstable" ion is any ion that escapes the quadrupole field, i.e., any ion whose trajectory exceeds the trapping space. Finnigan also asserts that it was improper for the ALJ to limit the claims to the disclosed embodiment. The Commission responds that the specification is clear that the term "unstable" refers to an ion that maps outside of the stability diagram. The Commission also asserts that, because the specification does not disclose the resonance ejection technique, the claims may not be interpreted to encompass it without running afoul of the written description and enablement requirements of 35 U.S.C. § 112, P 1. Both parties also argue that the prosecution history and evidence extrinsic to the patent support their respective positions.

When construing a claim, a court principally consults the evidence intrinsic to the patent, viz., the claims themselves, the written description portion of the specification, and the prosecution history. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83, 39 U.S.P.Q.2D (BNA) 1573, 1576-77 (Fed. Cir. 1996). Reference to this evidence, particularly the specification, is more than sufficient to resolve the claim construction issue presented here. The specification explicitly defines "stable" ions as those that map within the Mathieu stability diagram and are therefore trapped by the quadrupole field, and "unstable" ions as those that do not. We have already quoted the relevant portion of the specification above:

If [the] scanning parameters combine to map inside the stability envelope[,] then the given particle has a stable trajectory in the defined field. . . . Such particles can be thought of as trapped by the field. If for a particle m/e, U, V, r[o] and omega combine to map outside the stability envelop on the stability diagram, then the given particle has an unstable trajectory in the defined field. . . . Such particles can be thought of as escaping the field and are consequently considered untrappable.

'884 patent, col. 3, l. 56 to col. 4, l. 2 (emphasis added).

A patentee may be his or her own lexicographer. See, e.g., Vitronics, 90 F.3d at 1582, 39 U.S.P.Q.2D (BNA) at 1576. The inventors therefore could have defined an "unstable" ion in the specification as one that is ejected from the quadrupole field, but they did not do so. In fact, the discussion of the prior art in the specification, which is similar in operation to the Bruker device inasmuch as it involves ejection of ions via the application of voltages to the end caps of the trap, belies Finnigan's contention that all ejected ions are necessarily "unstable" ions. See '884 patent, col. 2., ll. 5-8 (describing the prior art: by "applying a voltage pulse between the end caps, the trapped stable ions are ejected out of the storage region to a detector.") (emphasis added).

Thus, we agree with the Commission that the specification requires the ALJ's claim construction--i.e., that the claim term "unstable" refers to ions that are unstable from the perspective of the disclosed Mathieu stability diagram. 6 We have considered the other evidence cited to us by the parties--specifically other portions of the specification, the prosecution history, and certain extrinsic evidence--but find such evidence vague and unhelpful as to the meaning of the term "unstable." Because Finnigan does not contest that there is no infringement if the ALJ's claim construction is adopted by this court, we affirm the ALJ's determination of noninfringement of independent claims 1 and 8 and all claims that are dependent thereupon. See Wahpeton Canvas Co., Inc. v. Frontier, Inc., 870 F.2d 1546, 1553, 10 U.S.P.Q.2D (BNA) 1201, 1208 (Fed. Cir. 1989) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed.").

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6 Accordingly, we need not address the Commission's alternative argument that Finnigan's proffered claim construction would run afoul of the written description or enablement requirements of § 112, P 1.

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iii. Incubating "until CPE is Observed"

The term "until CPE is observed" is a timing device incorporated in the claimed method. It informs the reader on how to know when the incubation period has been completed. Here, incubation occurs "until CPE is observed." CPE refers to "cytopathic effect" which the plaintiff has defined as a "change in the microscopic appearance of a cell after infection with a virus" (Plaintiff's Br. at 8) or "some observable effect shown on the simian cells." Plaintiff's Finding No. 146. As the defendant has explained, this observable effect is the killing of inoculated cells. When incubation is completed, the virus may be isolated and passaged again. The longer the virus is incubated, the more CPE occurs. Essentially, the parties do not disagree over the definition of CPE, but the claim language does not indicate whether the process should be terminated at the initial observation of CPE, at some degree of CPE, or at a time period which is determined independently of any degree of CPE.

According to Boehringer, the phrase, "until CPE is observed," requires that the incubation period continue long enough for CPE to be observed, but that the process need not be stopped immediately after the first observation of CPE. See Boehringer Finding No. 146. Additionally. Boehringer believes that while the development of CPE is a significant moment, the term, itself, is not a precise one. In contrast, Schering argues that "until CPE is observed" is capable of precision and means that the onset of CPE requires the cessation of the claimed method See Defendant's Br. at 15-16.

Looking at the claim language itself, Boehringer contends that Schering is attempting to engraft the word "first" on to the claimed method before "observed." In other words, Boehringer argues that a court could only adopt Schering's reading if the patent provided that the incubation period continue "until CPE is first observed." That argument reaches too far and defies principles of claim interpretation. If CPE were a precise moment, the court could adopt Schering's interpretation even though the word "first" is absent. If a recipe instructs its reader to cook a turkey "until the skin is browned," it would be fair to assume that the recipe requires the cook to stop at that point. It would also be safe to assume that if the cook waited much longer, at some point, the turkey would no longer be browned, but rather, singed and black. Therefore, the term "until CPE is observed" may conform to Schering's interpretation, but the term may also be construed as either requiring a particular degree of CPE or an independent determination. Therefore, the court must look to the specification for further guidance.

Under the section entitled "Isolation," the specification describes CPE when it discusses the "swelling or the forming of holes in the layer of cells at the edges of the culture bottle." '778 Patent, Col. 3, lines 27-29. "Fluid was separated from the bottle, and passed into a new bottle of MA-104 cells then subsequently passed a third time. . . . CPE became stronger with each passage." The specification speaks further about the "[viral] agent [being] passed eight times in the MA-104 cell line with good CPE developing in three days . . . at passage five and greater." Id. at lines 46-48. The specification language confirms that the discovery of CPE is an important benchmark within the patented process and that after a period of time, good CPE may be observed. Because this language discusses CPE becoming "stronger" and "good CPE" developing, it does not appear that the process stopped immediately after the initial observation of CPE.

The specification also precludes a construction of the claim language that would permit the process to be continued indefinitely without considering CPE. Once some significant level of CPE develops, whether "strong" or "good," the incubation period stops so that the virus may be isolated. The patent does not define "good" or "strong" CPE. In its construction of the claim language, this court contemplates that incubation will be halted after the observation of some degree of CPE and rejects any wholesale adoption of Boehringer's position. Boehringer would like to eviscerate the word "until" so that the claim would cover a process that did not depend on the observation of CPE and continued independently and indefinitely. However, the court's construction contemplates that the process focuses on CPE and that there is some stopping point. That point is not when minimal CPE is observed, but when there is a significant degree of CPE.

Ultimately, one would prefer a more precise definition, but the patent language does not lend itself to that. That does not mean that such precision is impossible. In the section entitled, "Modified Live Vaccine Preparation," the patent describes a process where the "virus [is] allowed to grow until 50% of the MA-104 cell sheet [is] destroyed by the virus." '778 Patent. Col. 5, lines 37-39. Boehringer has argued that its position is bolstered by the specification's reference to "50% CPE." This court's construction of the patent does not rely upon that reference because while Boehringer is correct that this attenuation

method anticipates continuing beyond the initial observation of CPE, it describes Claims 3 through 5 and not Claim 1 of the patent. Boehringer does not allege that Schering has infringed Claims 3-5 and they are not at issue in this litigation. However, it is helpful to look at the following example.

In an illustration of this method discussed in claims 3-5, the specification provides the following example: "24 hours after fluid change, CPE should be showing and, when 50-60% holes are present in cell sheet, freeze down." Id., Col. 6., lines 28-30. When the patent specification discusses the method in claims 3-5, it instructs the reader to harvest the virus "until 50%" destruction of the cell sheet. See Id., Col. 5, lines 37-39. Thereafter, the sample is frozen down. See Id. Thus, in claims 3-5, when the patent uses the word "until," it anticipates that incubation will stop at that point, i.e. when 50% destruction is reached, the harvesting is terminated. Therefore, when the patent uses the term, "until CPE is observed," without specifying the percentage of CPE, it may be argued that the patent anticipates that the growing process focuses on CPE and terminates at a point within an inexact range of CPE. The moment contemplated by the first claim of the '778 Patent is subject to a more qualitative determination.
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C. "Incubating . . . until CPE is observed"

Claims 1 and 2 require, after a sheet of simian cells has been inoculated with a viral sample, that the cell sheet be incubated at a defined temperature range "until CPE is observed," that is, until viral growth manifests itself in an observable perturbation of the cultured cells. The dispute over construction of this limitation is whether it defines only the minimum period for which the cells must be incubated, or whether it also establishes an ending point beyond which incubation is not permitted. Before the district court, Boehringer argued that this term requires that "the incubation period continue long enough for CPE to be observed, but that the process need not be stopped immediately after the first observation." Boehringer, 984 F. Supp. at 252. That is, under Boehringer's interpretation, all the claim requires is that incubation continue at least up to the point where some degree of CPE is observed. Schering, however, argued that "until CPE is observed" means that the incubation is stopped immediately upon first observation of CPE, and any incubation that continues longer does not infringe. Schering would presumably escape infringement under such a construction, even under the doctrine of equivalents, because Schering's timed incubation continues well past the point at which CPE first becomes observable.

The district court agreed with Schering that "until CPE is observed" requires the incubation period to stop upon observation of CPE. Drawing an analogy to a recipe for cooking a turkey, the court reasoned that an instruction such as "cook the turkey until the skin is browned" necessarily implies that the cook should stop once the skin is browned; else the turkey would be singed and blackened rather than browned. Id. Likewise, the court concluded that an instruction to incubate the cell sheet "until CPE is observed" requires that incubation be stopped once CPE is observed.

The district court recognized, however, that in the embodiments disclosed in the specification, incubation does not halt immediately upon the first observation of CPE, but rather continues until "good" or "50-60%" CPE is observed. See, e.g., '778 patent col. 3, ll. 46-48; col. 6, ll. 28-30. To avoid a claim interpretation inconsistent with these embodiments, the district court interpolated the word "significant" into the claim: incubation must proceed until "there is a significant degree of CPE." Boehringer, 984 F. Supp. at 253 (emphasis added). While this claim construction precluded Boehringer from establishing literal infringement, because Schering incubates its cells for a defined period of time rather than until a particular level of CPE is observed, it left open the possibility that Schering's timing mechanism could meet this limitation by the doctrine of equivalents. Boehringer, 6 F. Supp. 2d at 331-32.

We think the untenability of the district court's claim construction is exposed by the court's need to interpolate "significant" into the claim to save its construction. While incubation must be stopped at some point to recover the virus for subsequent passages, and undoubtedly the yield of viral recovery may be optimized by stopping the incubation at a particular point, the claim does not include any language or limitation relating to degree of viral recovery (if any). The claim retains its utility even if incubation is continued past the point of "significant" CPE or good viral recovery. Rather than insert an additional limitation into the claim, the better course is to rely on a construction of "until . . . CPE is observed" that does not require such an interpolation. We hold that this limitation merely defines the minimum period for incubation of the inoculated cell sheet.

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Boehringer argues correctly that because the claim language is open, employing the preamble term "comprising," the claimed method is open to additional steps. Thus, while the claim requires a minimal incubation time proceeding until the observation of CPE, additional periods of incubation after that point are not excluded. To use the district court's meleagrine analogy, one may add an additional step to the recipe: "continuing to cook the turkey until the skin is burned to a crisp." Such an additional step is permissible from the structure of the open claim language, and the district court's rejection of such a step was based on the premise that the claim's object is defeated if cooking proceeds too long. Because the utility of claim 1 is not premised on a particular stopping point, there is no barrier to additional incubation periods.

This error, the only one we find in the district court's thorough and skillful management of this case, was nonetheless harmless. As we explain below, substantial evidence supports the jury's finding that Schering's process satisfies this claim limitation under the doctrine of equivalents, even under an overly narrow claim construction. The question of whether Schering's process would literally infringe under the correct claim construction need not be resolved.
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Accordingly, based on our analysis of the claims, the specification, and the prosecution history, we conclude that the claim terms "subject" and "patient" are fairly read to include normal, healthy humans and are not limited to individuals with a nitrogen imbalance or negative nitrogen levels. We also construe the claim language "continuing the said administration of HMB until the amount of nitrogen in the patient's urine has substantially decreased" according to its plain meaning to mean that the administration of HMB must continue up to the time that a patient's urinary nitrogen levels have been reduced by a substantial amount. Whether Appellants can show that Wiley met that claim language is more appropriately an issue of infringement that the district court may address on remand. Insofar as the district court's JMOL of noninfringement was based on an erroneous interpretation of those terms, other factual issues remain on infringement. We thus remand for the district court to consider in the first instance whether Wiley infringes the '979 patent under our revised claim construction.
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1. Claim Construction

AK Steel argues that the district court's construction of the '549 patent claims as including Type 1 aluminum is contrary to (1) the ordinary meaning of "up to" as not including the 10% endpoint; (2) the claims' recitation that the coating must wet well; (3) the specification's clear disclaimer of Type 1 aluminum; and (4) the axiom that claims should be interpreted to preserve their validity. According to AK Steel, the court mistakenly assumed that the applicants did not narrow the claims when they replaced the words "Type 1 aluminum" with "up to about 10%" silicon, when in fact they did so to surrender that subject matter.

Sollac responds that AK Steel's dictionary definition of "up to" is nonsensical where a numerical limit follows that phrase. In such a case, according to Sollac, the limit is included (e.g., counting up to ten stops at ten, not nine). Sollac also contends that the amendment replacing "Type 1" with "up to about 10%" was presented as an improvement in clarity, not as an exclusion of subject matter. Moreover, the amendment affected only the dependent claims, not the independent claims, which were submitted with an explanation that they encompass any type of aluminum.

We agree with Sollac as to the meaning of the '549 patent claims. We begin with the dependent claims 3 and 7. Those claims state that the silicon content of the aluminum coating is "up to about 10%." '549 patent, col. 7, l. 11; col. 8, l. 13. We hold that those claims do indeed extend up to, and include, 10% silicon in the aluminum coating, i.e., Type 1 aluminum coatings.

First, we conclude that the ordinary meaning of the phrase "up to about 10%" includes the "about 10%" endpoint. As pointed out by AK Steel, when an object of the preposition "up to" is nonnumeric, the most natural meaning is to exclude the object (e.g., painting the wall up to the door). On the other hand, as pointed out by Sollac, when the object is a numerical limit, the normal meaning is to include that upper numerical limit (e.g., counting up to ten, seating capacity for up to seven passengers). Because we have here a numerical limit -- "about 10%" -- the ordinary meaning is that that endpoint is

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included.

Moreover, the prosecution history shows that the phrase was introduced into the claims with the intention and effect of covering the endpoint. Claims 3 and 7 originally recited "Type 1 aluminum," and it is clear that the inventors intended to obtain claims covering Type 1 aluminum. During prosecution, however, AK Steel amended those claims to remove reference to Type 1 aluminum and to put in its place language expressing the "up to about 10% silicon" language. There was no indication that the amendment was made to relinquish claim scope; rather it was made in response to the examiner's request to replace language that he found vague with language that he felt "more specifically defined" the same material. Under those circumstances, the amendment clarified the claims without changing their scope. On the basis of that prosecution history alone, claims 3 and 7 must be interpreted to encompass Type 1 aluminum. In addition, because the specification defines Type 1 aluminum as "containing about 10% by weight silicon," id. at col. 5, ll. 25-28, i.e., the endpoint recited in the amended and issued claims, it follows that the claims encompass, rather than exclude, both an aluminum coating having about 10% silicon and a Type 1 aluminum coating.

Turning next to the independent claims, we begin their interpretation by analyzing their ordinary meaning. According to their plain language, independent claim 1 permits the coating metal to include any "aluminum or aluminum alloy," id. at col. 7, ll. 1-2, while independent claim 5 does not contain any express limitation regarding the composition of the coating metal, other than that it be "an aluminum coating metal," id. at col. 8, l. 2. The ordinary meaning of those phrases in claims 1 and 5, then, is that they encompass a metal coating mixture of aluminum, including perhaps a significant amount of silicon. We need not determine the upper limit, if any, of silicon that the claim language permits, but the claims must cover up to at least 10% silicon, as the parties do not dispute that a mixture of about 10% silicon and approximately 90% aluminum is an "aluminum alloy" and "an aluminum . . . metal." Id. at col. 7, ll. 1-2; col. 8, l. 2.

Moreover, and most importantly, claims 1 and 5 must also encompass aluminum with up to about 10% silicon, i.e., Type 1 silicon, because claims 3 and 7, which depend from claims 1 and 5, respectively, expressly recite "up to about 10% silicon." Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend. See RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1264 (Fed. Cir. 2003) (stating that an independent claim is usually accorded a scope greater than its dependent claims); see also 35 U.S.C. § 112, P 4 (2000) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."). That presumption is applicable in this case and has not been rebutted. If the dependent claims expressly recite "up to about 10%" silicon, then the independent claims, which must be at least as broad as the claims that depend from them, must include aluminum coatings with "up to about 10%" silicon. Independent claims 1 and 5 therefore also cover at least steel strips hot-dip coated with aluminum containing about 10% silicon, i.e., Type 1 aluminum.

AK Steel's remaining arguments concerning the interpretation of the claims are unpersuasive. First, AK Steel points to language in the independent claims describing the functional qualities of the coating layer, i.e., "being substantially free of uncoated areas," "formed without a thick brittle Fe-Al alloy inner layer," and "being tightly adherent to the strip and resistant to crazing or flaking during bending." '549 patent, col. 7, ll. 3-7; col. 8, ll. 5-9. AK Steel would like us to interpret those limitations as requiring that the coating metal contain less than about 10% silicon. That we cannot do, because, as indicated above, we have concluded that the claims include coatings with 10% silicon as well as possessing the recited properties. While the specification does state that use of a Type 2 but not a Type 1 aluminum coating results in the four properties recited in the claims, thereby implying that the percentage of silicon in the aluminum coating must be quite low in order for the resulting coating to have the claimed wetting characteristics, that implication does not override the clear meaning of the claims as both the district court and this court have construed them. Those claim limitations speak clearly as including 10% silicon, and that is how we must interpret them.

AK Steel's contention that a narrower construction of the '549 patent claims is in order under the axiom that claims should be interpreted to preserve their validity when possible is also unpersuasive. That axiom is a qualified one, dependent upon the likelihood that a validity-preserving interpretation would be a permissible one. In this case, the interpretation advocated by AK Steel, while possibly avoiding validity pitfalls, cannot be a correct interpretation, for it is counter to the ordinary meaning of the claims as well as to the prosecution history.
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a. "urinary bladder submucosa"

ACell asserts that the district court erred in construing the term "urinary bladder submucosa" in claims 1, 7, and 8 of the '389 patent. ACell asserts that the PTO did not grant the '389 patent inventors a patent to the naturally occurring submucosa layer of a urinary bladder, but rather that it granted them a patent covering a tissue graft composition derived from that layer. ACell argues that the '389 specification makes clear that "urinary bladder submucosa" is a defined term which was defined to expressly exclude other urinary bladder tissue layers, specifically the abluminal muscle cell layers and at least the luminal portion of the tunica mucosa layer.

Cook argues that the '389 patent specification, specifically in e "DETAILED DESCRIPTION OF THE INVENTION" section, teaches that the term "urinary bladder submucosa" is broader than ACell's proposed construction because it states that the resulting composition "typically" consists essentially of urinary bladder submucosa. Cook thus asserts that the use of "typically" implies that there is another possible embodiment of the claimed composition that merely comprises urinary bladder submucosa, but may also include other tissues.

As noted above, claim 1 recites: "A composition comprising urinary bladder submucosa delaminated from both the abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of a urinary bladder of a warm blooded vertebrate." '389 patent, col. 5, ll. 20-23 (emphasis added). The '389 patent specification, in the "BACKGROUND AND SUMMARY OF THE INVENTION" section, states that "[u]rinary bladder submucosa for use in accordance with the present invention is delaminated from the abluminal muscle layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue." Id. at col. 1, ll. 55-58 (emphasis added). The first paragraph of the "DETAILED DESCRIPTION OF THE INVENTION" section states:

> The tissue graft of composition in accordance with the present invention comprises urinary bladder submucosa of a warm-blooded vertebrate delaminated from adjacent bladder tissue layers. The present tissue graft composition thus comprises the bladder submucosa delaminated from abluminal muscle cell layers and at least the luminal portion of the mucosal layer of a segment of urinary bladder of a warm-blooded vertebrate. Typically the delamination technique described below provides a tissue composition consisting essentially of urinary bladder submucosa. These compositions are referred to herein generically as urinary bladder submucosa (UBS).

Id. at col. 2, ll. 1-4 (emphases added).

"[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Phillips, 415 F.3d at 1316. We believe that this is exactly what the '389 patentees did in this case. As the above quoted portions of the specification indicate, the composition invented was defined to be "urinary bladder submucosa delaminated from abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue." See, e.g., '389 patent, col. 1, ll. 56-58. The specification also indicates that the resulting composition "typically" consists essentially of urinary bladder submucosa. Thus, while the composition clearly includes urinary bladder submucosa, it may also include other tissues, such as the non-luminal portion of the tunica mucosal layer. However, it cannot include that which was expressly excluded in the patentees' definition, i.e., the "abluminal muscle cell layers and at least the luminal portion of the tunica mucosa." Therefore, we construe "urinary bladder submucosa" as it is defined in the '389 patent specification to mean "urinary bladder submucosa delaminated from the abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue," and it thus becomes necessary to determine which tissue layers are encompassed by the phrase "at least the luminal portion of the tunica mucosa." 4

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4 Because the parties' dispute does not involve the phrase "abluminal muscle cell layers," we do not address which tissue layers are referenced by that language.

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G. CLAIM 21

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7 Otis contends that several of the disputed terms discussed below are no longer within this Court'sjurisdiction. Otis argues that because it entered a partial covenant not to sue with respect to the product covered by claims 21, 24 and 27 (the Gates LL MV 90-07 Tension Member), the Court no longer has subject matter jurisdiction over those claims. Accordingly, Otis asserts, the Court need not construe the three disputed terms therein--"thermoplastic urethane," "engagement surface of the tension member," and "engagement surface is shaped by an outer contour of said plurality of cords."

This Court does not agree. The Federal Circuit has recently discussed the factors a court must consider to determine whether it has subject matter jurisdiction over a party's declaratory judgment claim. The Court explained that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127, 127 S. Ct. 764, 166 L. Ed. 2d 604 (2007). To satisfy this test--i.e., to demonstrate that a substantial controversy of sufficient immediacy exists-there must be (1) some affirmative act byOtis relating to enforcement of its patent rights, see, e.g., Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1338-39 (Fed. Cir. 2008), and (2) Schindler must have undertaken some "meaningful preparation to conduct potentially infringing activity." See Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871, 880 (Fed. Cir. 2008). Here, Otis brings an action for infringement based on activities related to the Gates Tension Member and "products substantially similar to the Gates Tension Member." The covenant not to sue, however, does not cover "any activities related to any products other than the Gates Tension member." Under these circumstances, the two prongs of the test set forth above are satisfied. First, by asserting a claim for infringement, Otis has made an affirmative act relating to the enforcement of its patent rights. Second, Schindler has undertaken preparations to conduct infringing activities, as Schindler entities are already using belts other than the Gates Tension Member. The Court finds that there is a substantial controversy between the parties regarding to claims 21, 24 and 27, and it has subject matter jurisdiction over the disputed terms therein.

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Claim 21 of the '433 Patentcontains one disputed term. Claim 21, with the disputed term underlined, reads:

> A tension member according to claim 20 wherein said elastomer is a thermoplastic urethane.

Schindler's proposed construction of "thermoplastic urethane" is "a material that softens when heated and hardens when cooled and exhibits the functions of the coating layer including traction, wear, transmission of traction loads to the cords, and resistance to environmental factors." Otis proposes that the term be defined as "a material that softens when heated and hardens when cooled, is formed from the reaction of isocyanates and polyols, and is capable of returning to its original length or shape without substantial deformation after being stretched, deformed, compressed or expanded."

Both parties agree that a "thermoplastic" is "a material that softens when heated and hardens when cooled." The dispute is over the definition of "urethane."

Schindler asserts that the specification and prosecution history focus on the functional properties associated with urethanes. Accordingly, Schindler asserts that the term "urethane" should be defined as the group of materials that meet these functional criteria--i.e., materialsthat "exhibit[] the functions of the coating layer including traction, wear, transmission of traction loads to the cords, and resistance to environmental factors." Otis, in contrast, asserts that "urethane" should be construed in accordance with its functional and chemical properties--i.e., a material "formed from the reaction of isocyanates and polyols." Otis further argues that Schindler's strictly function definition would encompass more than just urethanes, and thus effectively delete the "urethane" limitation from the claim.

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The Court agrees with Otis. Claim 21 is a simple dependant claim (relying on Claim 20) that imports one new limitation--that the coating layer be a "thermoplastic urethane" (emphasis added). The claim does not read: "a thermoplastic urethane or other thermoplastic material exhibiting similar functional properties." Therefore, while Schindler accurately notes that intrinsic evidence should be relied upon to construe the term, the specification cannot be used to essentially delete a word within a patent claim. See Bicon, Inc. v. The Straumann Co., 441 F3d 945, 951 (Fed. Cir. 2006). The coating layer of Claim 21, as a urethane, is by definition "formed from thereaction of isocyanates and polyols." 8 The Court will adopt Otis' definition of "urethane" in its construction of "thermoplastic urethane."

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8 The intrinsic evidence associated with the '433 Patent does not speak to the chemical definition of a urethane, and therefore the Court must rely on extrinsic evidence. Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317-18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence").

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The Court has adopted the chemical definition of "thermoplastic urethane" proposed by Otis. This fact notwithstanding, both parties agree that the composite term "thermoplastic urethane" in Claim 21 has functional limitations. The Court will adopt Schindler's proposed construction of the functional limitations of "thermoplastic urethane"--the definition will account for the fact that the thermoplastic urethane coating serves a variety of functions including "traction, wear, transmission of traction loads to the cords, and resistance to environmental factors." 9

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9 Otis' suggested definition of urethane is: a material that "is capable of returning to its original length or shape without substantial deformation after being stretched, deformed, compressed, or expanded." This definition is too limited. Otis' definition only relates to the belt's ability to resist load-bearing stress. The specification also recites a number of limitations that pertain to traction and durability. Schindler's definition encompasses these functional attributes.

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"Thermoplastic urethane" will be construed to mean "a material that softens when heated and hardens when cooled, is formed from the reaction of isocyanates and polyols, and exhibits the functions of the coating layer including traction, wear, transmission of traction loads to the cords, and resistance to environmental factors."

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Defendants maintain that claim 1 of plaintiffs patent is invalid for anticipation by the Bradley patent. Claim 1 teaches:

A sock-type article adapted to be worn on the foot and having sole and heel regions adjacent to the sole and heel regions of a foot when worn, said sock-type article being substantially entirely formed of a light-weight, flexible material defining an interior space receivable of a foot, said material being substantially waterproof to prevent passage of water into said interior of the sock-type article through said material and at the same time moisture vapor permeable to allow passage of evaporated perspiration which may be formed on the foot from said interior of the sock-type article through said material, whereby the foot will be maintained as dry as possible when the sock-type article is worn thereon.

Herman pat., col. 4, ll. 11-24.

Although the parties might prefer to substitute their own nuanced definitions for the terms used in plaintiff's patent and the asserted prior art patent, the Court must give these terms their ordinary meanings for purposes of claim construction. See, e.g., K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1362 (Fed. Cir. 1999) ("The general rule is that terms in the claim are to be given their ordinary and accustomed meaning.") (citing Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). Thus, plaintiff must accept the plain meaning of the words contained within his patent rather than proffer

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an alternative reading of these terms. See, e.g., Intervet Amer. v. Kee-Vet Lab., 887 F.2d 1050, 1053 ("No matter how great the temptations of fairness or policy making,.courts do not rework claims. They only interpret them.") The Court "cannot alter what the patentee has chosen to claim as his invention." SSIH Equipment S.A. v. U.S. Int'l Trade Comm., 718 F.2d 365, 378 (Fed. Cir. 1983).

"Claim construction begins with the words of the claim." Karlin, 177 F.3d at 971. "When construing a claim, a court should first look to the intrinsic evidence, i.e., the patent itself its claims, written description, and, if in evidence, the prosecution history." Id. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence. Id. "In defining the meaning of key terms in a claim, reference may be had to the specification, the prosecution history, prior art, and other claims. This is not, however, to be confused with reading into a claim a limitation appearing in the specification but not in the claim." Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1566 (Fed. Cir. 1992) (internal citations omitted).

Accordingly, the Court first considers the language used in plaintiffs patent. In the claim at issue, claim 1, the term "moisture vapor permeable" is used. Elsewhere, in claim 5 and in the specification, the term "breathable" is introduced. According to the American Heritage Dictionary of the English Language (3d ed. 1992), "breathable" means "permitting air to pass through." 3 The dictionary gives as its example, "a breathable fabric." The dictionary defines ."air" as "a colorless, odorless, tasteless, gaseous mixture, mainly nitrogen (approximately 78 percent) and oxygen (approximately 21 percent) with lesser amounts of argon, carbon dioxide, hydrogen, neon, helium, and other gases." The dictionary also gives an alternate usage: "This mixture with varying amounts of moisture and particulate matter, enveloping Earth; the atmosphere" (emphasis added). Thus, the term "breathable" describes a material that allows both gases and moisture vapor to pass through it. As such, the language used in claim 1, "moisture vapor permeable," is essentially synonymous with "breathable." Accordingly, under either term, the Herman patent teaches a sock that is both waterproof and permits air, including moisture vapor, to pass through it.

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3 Courts commonly consult ordinary dictionaries in order to determine the proper construction of terms used in patent claims. See, e.g. Karlin, 177 F.3d at 971.

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K. No Vaporization

Smith & Nephew proposes that "no vaporization" should be construed to mean "no visible conversion to a gaseous state." ArthroCare would interpret "no vaporization" to mean "no conversion to a gaseous state." The parties agree that "vaporization" is conversion of a non-vapor to a vapor. The parties' only dispute involves whether the vapor that is created by "vaporization" must be visible. The American Heritage Dictionary gives two relevant definitions of "vapor:" "1) "barely visible or cloudy diffused matter, such as mist, fumes, or smoke, suspended in the air; 2) a) the state of a substance that exists below its critical temperature and that may be liquefied by application of sufficient pressure; b) the gaseous state of a substance that is liquid or solid under ordinary conditions." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000). Smith & Nephew contends that part 1 of the definition applies to the '311 patent. ArthroCare argues that part 2b of the definition applies to the term in this patent.

When words have multiple dictionary definitions, the intrinsic record must be consulted to determine which possible definition is most consistent with the use of the word by the inventor. Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed. Cir. 2002). The claims themselves give no guidance in this case. The specification is more illuminating. The specification states that the invention relates to "percutaneous techniques" for treating intervertebral discs. U.S. Patent No. 6,261,311, Column. 1:39-42. The technique involves operating on the interior of the disc, without actually opening the disc. Although some methods of practicing the invention involve a catheter that can transmit material from the disc and away from the patient's body, other methods of practicing the invention involve catheters that do not

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transfer matter to or from the disc. When these methods are practiced and vapor is created, it is impossible to tell whether the vapor created is visible, like steam, or invisible, like air.

The parties present extensive testimony from depositions of the named inventors and various expert witnesses. The court sees no reason to consult such extrinsic evidence. That the procedure is percutaneous is sufficient for the court to adopt ArthroCare's definition and define "no vaporization" as "no conversion to a gaseous state."
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1. "Vector"

It is undisputed that the term "vector" refers to a DNA agent (usually a virus or plasmid) generally used in a cloning process or to transmit genetic material to a cell or organism. CIEA contends that vectors can only exist in vitro and cannot exist within mice, while Jackson argues that vectors continue to exist in mice, even after accomplishing their purpose. However, Jackson conceded at the claim construction hearing that a vector is "the vehicle that you use to disrupt the gene." See also Jackson's Opening Cl. Construction Br. for the '173 Patent at 13 ("vectorsare vehicles into which one can insert a gene or a sequence of DNA") (emphasis added). Even when the vector is a replacement construct (as described in the '173 Patent), once it has been used, the vector no longer exists. When a replacement construct is used, part of the gene sequence in the vector is retained in the cell, but there is no longer a vehicle for cloning or transmitting genetic material. '173 Patent 3:51-59. Accordingly, the court construes "vector" to mean a DNA agent (usually a virus or plasmid) generally used in a cloning process or to transmit genetic material to a cell or organism. Vectors do not continue to exist after they have been used in a cell or organism.
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TKT asserts, in addition to the exogenous/endogenous distinction discussed above, that the district court misconstrued the terms "non-naturally occurring," "vertebrate cells," and "mammalian cells" -- which appear in many of the asserted claims -- to include human cells. Reviving the same argument the district court rejected below, TKT contends Amgen expressly disavowed the use of human cells to make human EPO.

The district court found that the definition of the term "non-naturally occurring" can be discerned through the doctrine of claim differentiation. Specifically, the court concluded that TKT's proffered construction must fail in light of '933 patent claim 3, discussed previously, which claims a "non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence encoding human erythropoietin . . . ." By its terms, then, this claim would cover the expression of human DNA in a cat host cell, for example, because a cat is a mammal. The court thus concluded that the phrase "non-naturally occurring" would be redundant in claim 3 if the phrase had the meaning TKT sought to ascribe to it. Further, because the patent specification compares the biological activity of synthetic products to "EPO isolates from natural sources" or "natural EPO isolates," the court concluded that non-naturally occurring simply means "not occurring in nature." Amgen, 126 F. Supp. 2d at 90-91, 57 USPQ2d at 1462-63.

Similarly, finding that the term vertebrate is widely known and understood to cover anything with "a segmented bony or cartilaginous spinal cord [which obviously includes humans]," id. at 85, 57 USPQ2d at 1457-58, the court adopted Amgen's proposed construction. The court also adopted Amgen's proposed construction of the term "mammalian cells" appearing in '422 patent claim 1 and '698 patent claim 9 under a similar rationale. Id. at 84-86, 57 USPQ2d at 1458.

We indulge a heavy presumption that a claim term carries its ordinary and customary meaning. CCS Fitness, 288 F.3d at 1366, 62 USPQ2d at 1662; see also Gart v. Logitech, Inc., 254 F.3d 1334, 1341, 59 USPQ2d 1290, 1295 (Fed. Cir. 2001). Although TKT is correct that the prosecution history is always relevant to claim construction, it is also true that the prosecution history may not be used to infer the intentional narrowing of a claim absent the applicant's clear disavowal of claim coverage, such as an amendment to overcome a rejection. See York Prods., Inc. v. Central Tractor & Farm Fam. Ctr.,

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99 F.3d 1568, 1575, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996). No such clear disavowal occurred here.

We agree with Amgen that the specification expressly describes humans as a subset of mammals, and mammals, in turn, as a subset of vertebrates. See '933 patent, col. 4, lines 47-48; col. 10, line 21. Moreover, the specification can fairly be read to, if not expressly, disclose the use of human DNA in human host cells in culture:

Conspicuously comprehended are expression systems involving vectors of homogeneous origins applied to a variety of bacterial, yeast, and mammalian cells in culture as well as to expression systems not involving vectors . . . . In this regard, it will be understood that expression of, e.g., monkey origin DNA in monkey host cells in culture and human host cells in culture, actually constitute instances of 'exogenous' DNA expression inasmuch as the EPO DNA whose high level expression is sought would not have its origins in the genome of the host.

'933 patent, col. 37, lines 33-43 (emphasis added). The astute reader will observe what appears to be a breakdown in the parallelism of the sentence emphasized in the block quote above. Specifically, the reference to the expression of "monkey origin DNA in monkey host cells in culture and human host cells in culture" seems a bit nonsensical because the expression of monkey origin DNA in human host cells is perforce the expression of exogenous DNA. The original 1983 application from which all the patents in suit claim priority, by contrast, contained language that upholds the parallelism of the sentence and logically makes sense. It read, in pertinent part: "It will be understood that expression of, e.g., monkey origin DNA in monkey host cells in culture and human DNA in human host cells in culture constitute instances of 'exogenous' DNA expression." J.A. at 2862 (emphasis added).

TKT boldly asserts that the variance between the original application and the patents in suit bespeaks some volitional act by Amgen to narrow the scope of the asserted claims in light of certain experimental data. In particular, TKT advances a theory whereby Amgen intentionally removed the language from subsequent applications (allegedly) because test results using human cells were not good, and later admitted (during an opposition proceeding against the European counterpart patent) that the omission was not inadvertent. But the record contains a more benign explanation as to what happened. According to the testimony of Dr. Lin, he was unaware of, and therefore did not authorize, the change. Further, the prosecuting attorney testified in his deposition that to the best of his knowledge the error was a typographical error.

But even assuming that the error was intentional, the district court's claim construction would not be foreclosed: our precedent is clear that claims are not perforce limited to the embodiments disclosed in the specification. E.g., Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344, 60 USPQ2d 1851, 1856 (Fed. Cir. 2001) ("An applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). Here, the patent plainly discloses the use of human host cells in culture, and our review of the record indicates no "clear disavowal" sufficient to undercut the express disclosure in the specification.

As a result, we are satisfied that the terms "non-naturally occurring," "vertebrate," and "mammalian" should be construed as they were by the district court, in a manner consistent with their plain meaning. Accordingly, we reject TKT's attempt to limit the scope of the asserted claims under an unduly constricted reading of the specification.
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A. Vertebrate Cells

The term "vertebrate cells" is contained in Claims 4, 6, and dependent Claim 7 of the '698 patent and Claims 1, 4, and dependent Claims 3, 6, and 7 of the '349 patent. There is no contention by either party that the term should have a different meaning in the various claims. Aside from that agreement, however, the parties (not surprisingly) proffered quite different constructions. Amgen contended that "vertebrate cells" means "cells originating from an animal having a backbone," Pl.'s Markman Hr'g (Mar. 27, 2000) Demonstrative Ex. 12, whereas TKT argued that the term means "non-human cells that originate from an animal having a backbone," Defs.' Markman Hr'g Demonstrative Ex. 1. Thus, while Amgen proffered the broad, albeit ordinary meaning of the term, TKT sought to have the Court add a limitation to the claim by including the word "non-human."

The reason for the particular distinction between the parties' proffered constructions is, not surprisingly, fueled by the

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related infringement and validity analysis. In order to make EPO, TKT activates the native human EPO gene in a human cell. As a result, there is little wonder why TKT offered, and Amgen vehemently opposed, a construction of the term "vertebrate" that excluded human cells. Had the Court adopted TKT's version, it would have been bound to issue, upon proper motion, summary judgment of non-infringement -- at least as to literal infringement. That, of course, is no reason to reject TKT's proffer, but merely explains the importance of construing the term appropriately.

While counsel for TKT admitted that its construction was contrary to the ordinary meaning of the term "vertebrate," TKT argued that "the terms of a claim cannot be construed in a vacuum." Tr. of Markman Hr'g, Vol. I at 7:17-18. 11 Instead, implored TKT, the Court must interpret the claims in accordance with the specification and the prosecution history and, set in this context, "vertebrate cells" were not meant to encompass human cells even though humans are admittedly a subset of vertebrates. Id. at 7:22-25. For the reasons expressed above, however, TKT's contention is untenable. Even if significant intrinsic evidence pointed toward a more limited definition of "vertebrate," "the claim construction inquiry . . . begins and ends in all cases with the actual words of the claim. . . . The resulting claim interpretation must, in the end, accord with the words chosen by the patentee to stake out the boundary of the claimed property." Renishaw, 158 F.3d at 1248 (citations omitted). There simply is no hook in the claim term that allows for TKT's alternate construction. The term "vertebrate" is a widely known and understood word which has a precise scientific meaning. A vertebrate is a member of the subphylum Vertebrata, which is a primary division of the phylum Chordata, which in turn is a division of the Animal Kingdom. A vertebrate is uniquely characterized by a segmented bony or cartilaginous spinal cord. Therefore, the plain and ordinary meaning of the term "vertebrate cells," i.e., cells that originate from an animal having a backbone, accords with the words chosen by the patentee to identify the scope of the claimed invention. Because humans are vertebrates, TKT's construction betrays the plain and ordinary meaning of the claim term. Thus, the Court construed the term "vertebrate cells" to mean "cells from an animal having a backbone." Tr. of Markman Hr'g, Vol. I at 67:8-9.

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11 Citations to transcripts refer to the page number followed by the line number of the referenced material.

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k. "VISICHROME" in Claim 3

The patent itself defines "VISICHROME" as a "colorant system[] sold under the name 'VISICHROME', by Futura Coatings, Inc. of Hazelwood, Mo." ('514 Patent, col. 5, lns. 5-7) As stated by the Plaintiff, Futura worked with Green Edge to develop a coating to color rubber mulch. Once developed, Futura held the formulation of VISICHROME as proprietary and did not disclose said formula. Thus, the Court defines "VISICHROME" as "a water-based acrylic colorant system used to color rubber particles."

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o. "method for using vulcanized rubber" and "shredded vulcanized rubber particles" Claim 5

The Merriam-Webster Online Dictionary defines "method" as "a way, technique, or process of or for doing something." Merriam-Webster Online Dictionary (visited May 15, 2007) <http://www.m-w.com/dictionary/method>. The term "vulcanization" means "the process of treating crude or synthetic rubber . . . to give it useful properties." Merriam-Webster Online Dictionary (visited May 15, 2007) <http://www.m-w.com/dictionary/vulcanization>. Therefore, the Court defines "method for using vulcanized rubber" as "the process of treating crude or synthetic rubber . . . to give it useful properties."

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D. "Water"

Plaintiffs' Construction	Defendant's Construction
No construction necessary.	Purified water (per the USP).

The dispute between the parties is whether the term "water" should be limited to "purified water" (Defendant's position) or not (Plaintiffs' position). In support of its proposed construction, Defendant notes that the Claim 1 explains that the dissolution results reported therein were obtained "using USP apparatus 2 at 50 rpm in 500 ml water," '215 patent at 7:50-51, and that the USP provides that "where 'water,' without qualification, is mentioned in the tests for reagents or in directions for preparing test solutions, etc. Purified Water (USP monograph) is always to be used." 3 (D.I. 41, Exh. F at 2166 (emphasis in original.)) Plaintiffs respond that the meaning of "water" is readily apparent and that there is no basis to import limitations from the USP into the claims. (See D.I. 50 at 9.)

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3 The U.S. Pharmacopoeia-National Formulary ("USP") is the official compendium of standards for drugs marketed in the United States and sets forth a set of approved dissolution apparatuses. See 21 U.S.C. § 321(j).

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The Court agrees with Defendant that because the claim specifically requires that testing be done in a USP apparatus, it is appropriate to construe the claim term "water" in terms of the definition set forth in the USP. As to Plaintiffs' objection that this is an improper importation of a limitation from the extrinsic record, the Court concludes that because the claim itself calls for the testing to be done in a USP apparatus, this construction does not reflect importation of limitations from the extrinsic record, but is a limitation compelled by the claim language. Accordingly, the Court will construe the term "water" to mean, as Defendant contends, "purified water (per the USP)."
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1. "Water-Alcohol Mixture"

First, EEI asserts that the district court misconstrued the term "water-alcohol mixture" because it did not limit the term composition to at least 30 percent water as described in the specification. In Phillips v. AWH Corp., we reaffirmed our often stated rule that the "words of a claim 'are generally given [the] ordinary and customary meaning'" that they would have to a person of ordinary skill in the art at the time of the invention. 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). However, this "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. at 1313; see also Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996) (holding that the claims "must be read in view of the specification, of which they are a part"). Indeed, an inventor may use the specification to intentionally disclaim or disavow the broad scope of a claim. Phillips, 415 F.3d at 1316.

However, this intention must be clear, see Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed. Cir. 2002) ("The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."), and cannot draw limitations into the claim from a preferred embodiment, see Phillips, 415 F.3d at 1323 ("[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). Moreover, "when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998); Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

Here, the specification states that the "amount of alcohol employed in the suspending material may vary widely but it usually forms between about 0 and 70 weight percent of the suspending material, and more usually between about 30 and

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about 50 weight percent." '937 patent, col.5, ll.19-23 (emphasis added). EEI maintains that this language explicitly limits the amount of alcohol in the suspending medium to a numerical range--between 0 and 70 percent. However, this language refers to a preferred embodiment of the invention, and the given numerical ranges are not used in a context meant to limit the claims. In fact, the language itself inherently recognizes that the numerical range should not limit the claim by noting that the amount of alcohol "may vary widely" and "usually" falls within a numerical range. Thus, the patentee did not limit the claim term as EEI suggests, 2 and the district court did not err in its claim construction.

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2 EEI further contends that the district court's construction reads the "water" limitation out of the claim because it only requires a non-negligible amount of water. EEI's additional argument stems from the description of the invention as "inexpensive and environmentally safe." It maintains that for the product to be inexpensive and environmentally safe it needs to contain a substantial amount of water. We, however, find even less support for EEI's proposed construction because this language only serves to describe the benefits of having an aqueouss uspending material and not a specific range of water in that material.

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b. "Water-Balance"

The issue surrounding SEACO's use of the term "water-balance" is whether, when read in light of the specification and claims stated in the '310 and '325 patents, the term closes the aqueous solution to unrecited components other than incidental impurities and/or harmless ingredients associated with the commercial sources of the recited components. The construction of the term "water-balance" is significant because the prior art under which SEACO's patents were invalidated for obviousness are open to unrecited components.

SEACO offers three arguments in support of its position that "water-balance" closes the aqueous solution to unrecited components except for incidental impurities and/or harmless ingredients associated with the recited components. First, it argues that Magistrate Judge Peebles's prior claim construction of the same term as it related to the '793 parent patent should be afforded substantial deference. Second, SEACO contends that any alternative interpretation of the term "water-balance" contravenes its ordinary meaning and essentially writes out the term from the patents. Third, SEACO submits that its interpretation of the term is proper because all of the examples of aqueous solutions within the '310 and '325 patent specifications consist of water concentrations equivalent to the exact amount necessary to bring the claimed deicing or anti-icing solution to 100%. (See '310 Patent, Ex. 3 to MLI's Mot. for Summ. J., Dkt. No. 43-9, col. 12, ln. 53-col. 14, ln. 10 (hereinafter cited as "'310 Patent"); '325 Patent, Ex. 4 to MLI's Mot. for Summ. J., Dkt. No. 43-10, col. 13, ln. 10-col. 15, ln. 20 (hereinafter cited as "'325 Patent").)

Magistrate Judge Peebles's prior claim construction decisions are not altogether preclusive of the claim construction issue; rather, at most, the claim construction analyses in the Cargill and ADM cases are due substantial weight when determining the proper interpretation of SEACO's claim terms. See Collegenet, Inc. v. XAP Corp., No. 03-CV-1229, 2004 U.S. Dist. LEXIS 22370, 2004 WL 2429843, at *6 (D. Or. Oct. 29, 2004). MLI argues that stare decisis does not require deference to Judge Peebles's decisions because those prior cases arose from infringement proceedings instead of interference actions. (Def's. Mem. of Law in Opp'n to Pl's. Mot. for Summ. J., Dkt. No. 51, 11.) According to MLI, interferences require the Board to afford the claim terms their broadest reasonable construction pursuant to 37 C.F.R. § 41.200(b), whereas infringement decisions before district courts employ a different standard because already-issued patents are presumed valid in infringement lawsuits. See In re Am. Acad. of Sci. Tech Ctr., 367 F.3d 1359, 1369 (Fed. Cir. 2004); In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Notwithstanding any difference between the applicable legal standards for claim construction in interference proceedings as compared to infringement actions, Judge Peebles's analysis remains relevant to the claim construction issue, and in any event, it is undisputed that a claim must be given "its broadest reasonable construction in light of the specification of the application or patent in which it appears." 37 C.F.R. § 41.200(b). Without necessarily adopting Judge Peebles's rationale, the

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question presented therefore becomes how reasonably broad may SEACO's patent claims be construed in light of their specification?

In consideration of the patent claim language, SEACO repeatedly uses the transitional words "comprising" and "contains" when describing the recited constituents of the aqueous solution, including the "water-balance" limitation identified in the independent claims of both patents. (See '310 Patent, col. 12, ln. 46-col. 14; '325 Patent, col. 13-16.) These words are terms of art within patent law and normally reflect the inventor's intent to identify an inclusive or open-ended invention that does not exclude unrecited elements. MANUAL OF PATENT EXAMINING PROCEDURE § 2111.03 (8th ed. 2001 & rev. ed. 2008) (collecting cases). In contrast, "[t]he transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim." Id. (collecting cases). Despite its use of the terms "comprising" and "contains," as well as its omission of the term, "consisting of," SEACO contends that the terms of art only create a rebuttable presumption that the aqueous solution is open to unrecited components. Nevertheless, in light of the definition within the Manual of Patent Examining Procedure and the cited cases therein, the inclusion of the terms "comprising" and "contains" cuts against SEACO's position that its patent claims are closed to unrecited components.

On the other hand, the ordinary meaning of "balance" as used in the patent claims is "a leftover" or "remainder." WEBSTER'S II NEW COLLEGE DICTIONARY 84 (1995). As an alternative interpretation, MLI contends that "balance" as used to signify the concentration of water means only "that the composition must contain some amount of water (at least enough to make a solution) after all recited components and any unrecited components have been added." (Def's. Mem. of Law in Opp'n to Pl's. Mot. for Summ. J., Dkt. No. 51, 16 (emphasis added).) Put another way, MLI contends the "water-balance" term does not close the composition to unrecited components because the proportion of water comprising the solution is not determined until after any unrecited components have already been included.

The reasonableness of MLI's alternative construction of "water-balance" must be viewed in light of the specification in which the term appears. See 37 C.F.R. § 41.200(b). "While examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, the scope of a claim is not necessarily limited by such examples." Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed. Cir. 1997). Therefore, pursuant to the Federal Circuit's holding in Ekchian, the examples within the '310 and '325 patents are instructive, but not determinative, of the reasonableness of MLI's more broad alternative construction of the term "water-balance."

All of the examples within the '310 and '325 patent specifications contain the proportion of water needed to equal 100% for the total weight of the components comprising the solution. Rather than use the term "balance" as stated within the claims, the examples in the specifications state specific concentrations for each component and leave no room for unrecited components apart from minuscule amounts of incidental impurities derived from the recited components. However, the Federal Circuit "has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification." Tex. Instruments, Inc. v. U.S. Intern. Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986) (citing Palumbo v. Don-Joy Co., 762 F.2d 969, 977 (Fed. Cir. 1985), abrogated on other grounds by Markman v. Westview Instruments, 52 F.3d 967 (Fed. Cir. 1995)). Instead, the preference is to construe claims based upon the limitations as stated in the claim. Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 866 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations.").

The significance of the examples listed in the specification thus turns upon whether there is an explanation for why the limitation found in those examples, i.e., a specific concentration of water equaling exactly the amount necessary to bring the aqueous solution to 100%, is not included in the claims themselves. As a practical matter, it was impossible for SEACO to employ the same degree of specificity with respect to the weight percentages of the recited components in its claims as compared to the examples in its specifications. The following hypothetical is illustrative of the problem SEACO faced when writing its patent claims: Assume for the purposes of the hypothetical that an inventor knows he intends to claim an aqueous solution made of two molecular components and the balance of water. If the inventor knows for certain his solution is made of 10% component A and 20% component B, the inventor will then also know that his solution must comprise 70% water. However, if the same inventor knows only that his solution is made of 3-60% of component A and 5-25% of component B, his claimed concentration of water will logically fluctuate depending upon the concentration of components A and B. The practical solution is then to include the "balance" limitation in order to ensure that the water component is in a feasible proportion to the other constituents. Had SEACO stated a range of weight percentages for water in lieu of the term "balance," the claim would be open to unrecited components in any case where the sum of the weight percentages did not total 100%. Instead, SEACO avoided this issue through its use of the term "water-balance."

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Additionally, to read the term "water-balance" so as to leave the aqueous solution claimed in the '310 and '325 patents open to unrecited components is not reasonable in light of the specifications in which the claims appear. Although this limitation is not expressly stated within the patent claims, the specification instructs that SEACO intended water to close out the aqueous solution after the first two recited components were added. Even despite SEACO's use of the terms "comprising" and "contains," the meaning of the term "water-balance" is, at the very least, unclear without looking to the patent specifications for guidance. See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed. Cir. 1999) (collecting cases affording specification greater significance when claim term is ambiguous or otherwise unclear). Upon consideration of the specifications for the '310 and '325 patents, the broadest reasonable construction of the term "water-balance" viewed through the perspective of a person of ordinary skill in the art indicates that the aqueous solution is closed to unrecited components except for incidental impurities found in the recited components.
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J. '505 Patent Claim 9/'230 Patent Claim 11

Claim 9 of the '505 patent is also dependent upon claim 1: "A preparation according to claim 1 wherein the water content of the final dosage form containing omeprazole does not exceed 1.5% by weight." (P1, col. 17:19-21.) Claim 11 of the '230 patent imposes the same water content requirement upon the "final dosage form" of the '230 patent containing the "acid labile compound." (P2A, col. 14:30-32.) Defendant Cheminor alone challenges Astra's proposed constructions with respect to these claims.

The court agrees with Cheminor that the term "water content" is not an ambiguous term. It simply means the amount of water in a given thing. Contrary to this plain and readily discernible meaning, Astra proposed that the term "water content" should incorporate concepts of molecular crystallinity and boiling temperatures. Astra proposes that the phrase "water content" refers to water that can be released from the formulation at elevated temperatures up to about the boiling point of water; it does not include bound water, or water of crystallization. 35 (See Astra Cl. Constr. Mem. of 11/5/01, at 33.) There is no reference in either patent to "bound water" or a test of water content that includes elevating temperatures to "about the boiling temperature." These new concepts Astra seeks to inject into the patent claims are extrinsic to the claims and the specification and, of course, can only be proven by extrinsic evidence. Because this claim term can be construed solely from the intrinsic evidence, there is no need for the court to even consider such extrinsic evidence. Indeed, "if the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on evidence other than that used to ascertain the ordinary meaning of the claim limitation." Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d, 1258, 1268 (Fed. Cir. 2001); Vitronics, 90 F.3d at 1582. Accordingly, the court rejects Astra's proposed definition and holds that the term "water content" simply refers to any water in the final dosage form. 36

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35 Bound water is defined by the Hawley's Condensed Chemical Dictionary, 146, 10th Ed. 1981, as "water molecules that are tightly held by various chemical groups in a larger molecule."

36 Plaintiffs incorrectly argue that they have been prejudiced by Cheminor's proposed construction, which Plaintiffs claim is new. Defendant Cheminor clearly included this construction in the claim construction briefing requested by the court prior to trial in response to the definition proposed by Astra. (See Mem. in Supp. of Cheminor Defs.' Constr. of Certain Terms of 11/5/01, at 23.)

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The specification defines the "final dosage form" as, for example, the enteric-coated pellets that are found inside the capsules. (P1, col. 5:60-63; P2A, col. 10:37-40.) Every example of the "final dosage form" listed in the specification refers to a formulation that has been enteric coated, which does not include the capsule into which enteric-coated formulations are filled. Under the section titled "Final dosage form," the '230 patent specification states that "it is essential for the long term stability during storage that the water content of the final dosage form containing acid labile compound (enteric coated tablets, capsules or pellets) is kept low, preferably not exceeding 1.5% by weight." (P2A, col. 10:40-44 (emphasis added);

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see also P1 col. 5:67 - col. 6:5 ("as a consequence the final package containing hard gelatine capsules filled with enteric coated pellets preferably also contain a desiccant, which reduces the water content of the gelatine shell to a level where the water content of the enteric coated pellets filled in the capsules does not exceed 1.5% by weight.") (emphasis added).) Only Cheminor challenges this definition, relying on extrinsic evidence and mischaracterization of quotes from the specifications to argue that the water content measurement must be construed to include both the capsule and the enteric coated pellets. This interpretation cannot stand, because the specification expressly states that the "final dosage form" is the formulation that has been enteric coated, before being filled into any capsule. (See P1, col. 5:60-63; P2A, col. 10:37-44.) In addition, the test results relating to water content in the patent specification refer to testing "pellets," not the final package. (See P1, col. 14:46-61.) Since the "final dosage form" referenced in the claims is the enteric-coated pellets, and not pellets filled into a capsule, the term "1.5% by weight" refers to the water content of the enteric-coated pellets, calculated as a weight percentage.
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Andrx argues that the district court erred in finding that its product infringes the '281 patent because it does not have a water soluble separating layer, but instead a layer composed of "almost 50% talc." According to Andrx, its separating layer with talc is not water soluble, but only disintegrates in water. Andrx asserts that disintegration is not soluble. Indeed, the '505 and '230 patents claim a "subcoating which rapidly dissolves or disintegrates in water" and a "subcoating which is soluble or rapidly disintegrating in water," respectively. Omeprazole I, 222 F. Supp. 2d at 446.

The '281 patent indeed claims "a water soluble salt." '281 Patent col.16 l.8. The district court correctly discerned that this language permits the inclusion of talc. The language of claim 1 does not claim a separating layer that is water soluble. Claim 1 instead recites a salt product that is water soluble. The '281 patent specification, under "Summary of the Invention," describes the separating layer as comprising "a water soluble salt of an enteric coating polymer." '281 Patent col.5 ll.42-43 (emphasis added). A sentence later, the patent specification states: "a separating layer comprising a water soluble salt of an enteric coating polymer is obtained." '281 Patent col.5 ll.48-49 (emphases added). In addition, example 1 (and 4-7) of the '281 patent employs an enteric-coating layer that contains HPMCAS as well as triethylcitrate, sodium laurylsulphate, and talc. '281 Patent col.8 l.65-col.9 l.51. Thus, the district court correctly interpreted the '281 patent claim to permit inclusion of talc in the separating layer.
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Background

The '593 and '647 patents, both of which are entitled "Modified Polydextrose and Process Therefor," are directed to "an improved, water-soluble polydextrose containing 0.3 mol % or less of bound citric acid, a process therefor, and foods containing same." Polydextrose is a low-calorie replacement for flour and sugar that is often used to replace some of the bulk that is lost when artificial sweeteners are substituted for sugar in cakes or like products. Staley manufactures polydextrose and sells it with the brand name "Sta-Lite III."

Commercial manufacture of edible polydextrose originated with a process developed by Hans H. Rennhard. The Rennhard process includes the step of heating dextrose in the presence of a catalytic amount of citric acid. The polydextrose thereby produced has a slightly bitter taste. Donald Guzek et al., the inventors of the '539 and '647 patents, discovered that the bitter taste could be remedied by passing the final polydextrose, in aqueous solution, through an ion-exchange resin. The patents at issue are directed to this process. The claims in suit of the '593 patent follow:

24. A polydextrose composition substantially free of bitter-tasting residual compounds made by the process consisting essentially of:

a) dissolving polydextrose in water;

b) passing said solution through an ion-exchange column; and

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c) collecting and concentrating the eluate produced thereby until a commercially useful polydextrose composition is recovered.

32. A polydextrose bulking agent useful for incorporation in reduced calorie foods, substantially free of bitter-tasting compounds.33. The polydextrose composition according to claim 32 wherein said bitter-tasting compounds are acidic.

Claim 24 of the '647 patent is also in suit:

24. A method for the purification of polydextrose consisting essentially of:

a) dissolving polydextrose in water;

b) passing said solution through an ion exchange column; and

c) collecting and concentrating the eluate produced thereby until a substantially functional product is recovered.

The specifications of the patents explain that the bitter taste is due to the use of citric acid in the Rennhard process, and that some citric acid remains bound to the product. The ion-exchange procedure removes this bound acid.

The process by which Staley makes its polydextrose also includes the step of heating polydextrose in the presence of an acid catalyst, and Staley also passes its final polydextrose through an ion-exchange resin. However, Staley uses phosphoric acid instead of the citric acid of the Rennhard process. Cultor sued Staley for infringement of the Guzek patents, charging that the claims literally read on the Staley process and product. Staley responds that the claims must be interpreted as limited to polydextrose produced using citric acid, pointing to the following description in the patent specifications:

As used herein, the expression "water-soluble polydextrose" (also known as polyglucose or poly-D-glucose) specifically refers to the water-soluble polydextrose prepared by melting and heating dextrose (also known as glucose or D-glucose), preferably with about 5-15% by weight of sorbitol present, in the presence of a catalytic amount (about 0.5 to 3.0 mol %) of citric acid.

'593 patent, col. 1, lines 24-30. The district court agreed with Staley and granted summary judgment of non-infringement, ruling that the definition of "water-soluble polydextrose" in the specification limited the claims to polydextrose produced with citric acid as a catalyst.

Cultor also asserted infringement under the doctrine of equivalents, arguing that even if the claims are deemed limited to the specification's definition of polydextrose prepared using a citric acid catalyst, citric and phosphoric acid are interchangeable in the Rennhard polydextrose process, and both are removed by the ion-exchange treatment.

The district court, reviewing the prosecution histories of the patents in suit, found that the inventors had repeatedly distinguished their invention from the prior art by emphasizing their discovery that citric acid caused the bitterness in polydextrose produced by the Rennhard process and that such bitterness could be removed by removing the residual citric acid by means of an ion-exchange resin. The court concluded that to permit Cultor's claims the scope now requested would ensnare the prior art and permit Cultor to patent an "invention" which was no more than "a desirable result." Cultor challenges these conclusions, stating that its claims are not limited to any particular acid, and that the claims define the patented invention. Cultor also states that in all events, phosphoric and citric acid are equivalent catalysts for this process, and the ion exchange procedure removes either bound acid.

Literal Infringement

Cultor argues that the Rennhard process is not limited to a citric acid catalyst and points out that the original Rennhard patent (now expired) lists ten possible acid catalysts. However, the Guzek patents do not define their polydextrose purification process in terms of any acid catalyst, but only in terms of a citric acid catalyst. By explicitly limiting the subject matter to that produced using a citric acid catalyst, the inventors limited their claimed invention. The district court applied the inventors' own definition of the term "water-soluble polydextrose" as a limitation to the claims.

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Whether a claim must, in any particular case, be limited to the specific embodiment presented in the specification, depends in each case on the specificity of the description of the invention and on the prosecution history. These sources are evaluated as they would be understood by persons in the field of the invention.

The Guzek patents describe an improvement of the Rennhard process, explaining the problem that they discovered was caused by the use of citric acid as the catalyst. Guzek teaches how to solve the problem by a specific method of removing the citric acid. The inventors described their invention narrowly and with specificity. Staley states that its phosphoric acid does not produce a bitter taste and raise the same problem solved by Guzek, but that the phosphoric residue must be removed to meet purity standards set by the Food and Drug Administration. Staley argues that ion-exchange is a conventional method of removing phosphoric acid, and that if the Guzek claims were to be interpreted to encompass this conventional usage, they would be invalid as embracing the prior art. The district court agreed.

We discern no error in the district court's construction of the claims as including the definition of "water-soluble polydextrose" in the specification. Having explicitly defined this term as limited to that prepared with a citric acid catalyst, this effected a disclaimer of the other prior art acids. Claims are not correctly construed to cover what was expressly disclaimed. Thus we affirm the district court's summary judgment that there is not literal infringement.
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1."Water Vapor Impermeable Polymer Layer"

Claim 1 of the '182 patent requires, among other things, the presence of a "water vapor impermeable polymer layer." Claim 16 of the '693 patent requires, among other things, a "water-vapor-impermeable polymeric layer." Other claims of the patents also require this water vapor impermeable layer or an "impermeable polymer layer." While the disputed term must be construed as a whole in the context of the claim and patent as a whole, the gist of the parties' dispute relates to the meaning of the word "impermeable."

Fort James proposes the following construction: "The polymer [or polymeric] layer must be a substantially continuous film, and although pinholing in the film can and does occur, the amount of pinholing should be minimized to reduce the passage of water vapor through the film so as not to adversely affect the function of the food wrap." 7 In its submissions and argument, Fort James acknowledges the language in the specification that describes the impermeable polymer layer as a "complete barrier." Fort James, however, takes the position that "complete barrier" refers to the continuous nature of the polymer barrier resulting from the extrusion process. Further, Fort James contends that POSITA would understand that water vapor could pass through the water vapor impermeable polymer layer by at least two means: (1) diffusion through the polymer structure and (2) flow through any pinholes created after the extrusion of the polymer layer. 8

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7 Plaintiffs' Final Proposed Claim Constructions [Dkt. No. 175] at p. 2.

8 Hearing Transcript at p. 24, lines 12-16; p. 31, line 18 -- p. 32, line 2.

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Coating Excellence proposes the following construction: "a polymer having a water-vapor transmission rate (WVTR) equal to zero; preventing passage of water-vapor; being a complete barrier to water-vapor; being impervious to water-vapor." 9 In its submissions and argument, Coating Excellence, among other things, focuses on the specification reference to the impermeable polymer layer being a "complete barrier" and underscores the specification references to the layer "preventing" the passage of water vapor. 10

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9 Defendants' Response to Plaintiffs' Final Claim Construction Statement [Dkt. No. 180] at Ex. A, pp. 1-3.

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10 Hearing Transcript at p. 52, line 25 -- p. 54, line 7. While Coating Excellence's proposed construction refers to a WVTR of zero, at the Hearing, Coating Excellence would not commit regarding whether or not the inventive polymer barrier is 100% impermeable. Coating Excellence indicated that the proper construction should be "to prevent the passage of water. That it has to be a complete barrier. . . ." Hearing Transcript at p. 63, lines 11-14. Its subsequent filing retained the original proposed construction requiring a WVTR of 0.

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a. Review of intrinsic evidence

The undersigned finds that the meaning of the term "water vapor impermeable polymer layer" is not "immediately apparent." See Phillips, 415 F.3d at 1314. While the meaning of the words water vapor and polymer layer do not appear to be disputed by the parties, the meaning of the term as a whole and the meaning of the word impermeable in the context of the term as a whole are not self-evident. Accordingly, it is appropriate to consider the "those sources available to the public" noted above in Phillips. Id.

Coating Excellence correctly notes that the inventors in both patents describe the function of the water vapor impermeable polymer layer as a condensation surface with respect to water vapor and characterize it as a "complete barrier." (E.g., '182 patent, col. 4, lines 16-17, 35; '693 patent, col. 7, line 3.) It is also correct that there are a number of references establishing that one of the functions of the polymer barrier is to prevent the passage of water vapor. (E.g., '182 patent, col. 4, lines 21-22.) 11 But these references do not answer the key question regarding whether the "complete barrier" needs to be 100% water vapor impermeable (i.e., absolutely no water vapor passes through it). The proper construction must include an interpretation of what a "complete barrier" is in the context of these two patents so as to avoid the need for subsequent claim construction at summary judgment or trial. Several portions of the intrinsic record are informative.

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11 Coating Excellence further points out that the absorbent layer must be able to "absorb all the water vapor lost by the hot sandwich and condensed on the impermeable layer." ('182 patent, col. 3, lines 41-44.) This is not inconsistent with the below proposed construction because this statement does not say that 100% of the water vapor has condensed on the impermeable layer.

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As a starting point, there is no basis in the specification to support Coating Excellence's proposed construction to the extent that it would require a Water Vapor Transmission Rate of 0. The term Water Vapor Transmission Rate does not appear in the specification. The specification contains no quantitative descriptions of the impermeable polymer barrier that would support the notion that absolutely no water vapor can pass through such layer.

The specifications of both patents, however, do explain that water vapor may pass through the impermeable polymer barrier as a result of pinholing. ('182 patent, col. 5, lines 58-65; '693 patent, col. 16, lines 27-34.) The language in both specifications is essentially identical 12 and is as follows:

Because the layer 40 is impermeable, extrudate 70 should be extruded as a pinhole free film at a thickness sufficient to be able, when cooled, to form an impermeable barrier. Although some pinholing may occur as a result of paper fibers penetrating through the polymer film when the polymer film contacts layers 20 and 30, the amount of pinholing should be minimized to reduce water vapor loss, and hence heat loss.

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12 The language quoted above is from the '693 patent. Unlike above, the '182 patent begins with "Because layer 40" and uses "must" instead of "should."

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Thus, the inventors inform the public that, as a result of putting the three layers together, there may be pinholes in the impermeable polymer layer that permit passage of water vapor. Nevertheless, such polymer layer remains "impermeable" and a "complete barrier" within the context of the patents as long as the amount of pinholing is minimized to reduce passage of water vapor and heat loss. Id.

The specifications also reflect that the polymer layer is not expected to perform its functions indefinitely. The specifications reflect that inventive wrap is only expected to perform its functions during the holding period -- the time period after the foodstuff is prepared and before it is eaten. For instance, the Background section of the '182 patent states, "Composite wrap materials have long been used to package hot foodstuffs. In addition to keeping the foodstuff relatively fresh for a period of time, the wrap facilitates heat retention by the foodstuff after it is made, but before it can be consumed." ('182 patent, col. 1., lines 19-23 (emphasis added); see also col. 4, lines 27-28 ("thereby maximizing sandwich temperature during holding").)

The '693 patent likewise refers to the wrap performing its functions during a holding period. The patent states, "it is difficult to provide a suitable but inexpensive and ecologically sound environment for maintaining hot sandwiches in a palatable condition for the storage interval between preparation and consumption, particularly for periods of more than several minutes." ('693 patent, col. 1, lines 21-25; see also col. 1, lines 50-52 ("if the sandwich is stored for several minutes longer than the usual holding time") (emphasis added); col. 2, lines 40-43 ("a sacrifice of heat retention or storage time (holding period) could be required").) 13

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13 At the Hearing, Coating Excellence stated that it would not be appropriate to bring any temporal limitation into consideration for the construction of this term because the patents also could cover cold food. Hearing Transcript at p. 68, line 17 -- p. 69, line 7. The undersigned need not and has not determined whether the patent covers cold food. The inventive polymer barrier plainly functions relative to water vapor given off by hot foodstuffs, and the specifications provide ample support for the notion that barrier is not expected to perform its function indefinitely in this regard.

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Also pertinent to construing the term "water-vapor impermeable polymer layer," the specification of the '182 patent contains discussion regarding prior art reference U.S. Patent No. 4,515,840 14 ("Gatward" or '840 patent"). Prior art cited in a patent or cited in the prosecution history is intrinsic evidence. V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1311 (Fed. Cir. 2005).

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14 Defendants' Hearing Binder, Tab 3.

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Gatward relates to a composite wrap material for foodstuffs. The '182 patent inventors describe Gatward as having a thermoplastic material that is semi-permeable to water vapor. The '182 patent inventors further state that the drawback of this "semi-permeable" material is that "the heated foodstuff is giving off its own heat via the water vapor which is allowed to pass through the semi-permeable thermoplastic material, thereby permitting the foodstuff to cool off." ('182 patent, col. 2, lines 3-7.) The Gatward patent itself recites, "said thermoplastic film containing microperforations of such magnitude as to permit transmission of water vapor." ('840 patent, col. 6, lines 10-12.)

Gatward also is discussed in the file history of the '182 patent. Specifically, there is discussion in the October 17, 1990, Amendment. 15 Coating Excellence contends that this discussion constitutes a disavowal of any construction of the term "impermeable" that would permit the passage of water vapor through the polymer layer. Specifically, in responding to a rejection under Section 103 (obviousness), the '182 patent inventors distinguished Gatward as follows: "In stark contrast to the present invention, Gatward teaches a microporous polymer structure which allows water vapor to escape. While this prevents sogginess, the hot food cools very rapidly." 16 This file history argument is consistent with the characterization of Gatward in the specification and the above noted language of the Gatward patent itself.

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15 This "Amendment" can be found at Plaintiffs' Hearing Binder, Tab C. 1 .C, at p. 7. The parties agree that the inventors made no amendment relative to the argument that Coating Excellence suggests constitutes a disavowal. Coating Excellence is correct, however, that there potentially could be a disavowal even absent an amendment. The "Amendment" also includes discussion at pages 2-3 in which the polymer layer is referred to as a "complete layer." The issue being addressed was whether a wax/polymer blend properly could be considered a polymer, not whether any amount of water vapor can pass through the polymer layer. In any event, as is the case with the specification, the reference to "complete barrier" by itself does not answer the question of what "impermeable" or a "complete barrier" means in the context of the patents at issue.

16 Plaintiffs' Binder at Tab C.1.C. at p. 5.

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The undersigned finds that the file history argument regarding Gatward does not constitute a disavowal of a construction of "impermeable" that would permit some passage of water vapor through the polymer layer. 17 See Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123 at 1136, 2006 U.S. App. LEXIS 2887 at *34 (Fed. Cir. 2006) (requiring that a disavowal be "clear and unmistakable"). The pertinent, critical distinction between Gatward and the invention of the '182 patent is that Gatward avoids water vapor caused sogginess of foodstuff by purposefully removing the water vapor through microperforations in the thermoplastic layer. The '182 patent does not seek to avoid water vapor caused sogginess in the same way. Instead, the '182 patent's inventive wrap avoids water vapor caused sogginess in foodstuff through a polymer layer that acts as a condensation surface coupled with an absorbent layer that absorbs the condensate. ('182 patent, col. 4, lines 17-23.) This improves on Gatward by facilitating heat retention. This distinction does not require that there be no passage whatsoever of water vapor through the polymer layer of the '182 patent, provided that the polymer layer/absorbent layer combination performs its function and the heat retention goal is met.

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17 The statements made in this same "Amendment" regarding the Barner reference, which together with Gatward had been the basis for the examiner's rejection under Section 103 (obviousness), likewise do not constitute such disavowal. The Barner composite wrap requires that the top be opened where there is hot food emitting water vapor. Nothing in this discussion should be taken as any comment regarding the propriety of the examiner's rejection under Section 103 or any comment on any validity or invalidity issue.

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In summary, after examination of the intrinsic record, the undersigned finds that POSITA would understand that the polymer layer of the '182 patent can be "impermeable" and a "complete barrier" even if some amount of water vapor passes through the polymer layer, provided that the polymer/absorbent layer combination constitutes the mechanism for avoiding water vapor caused sogginess in the foodstuff and such passage is minimized so as to reduce resulting heat loss during the holding period. 18

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18 There was discussion at the Hearing regarding certain test results found in the file history of the '693 patent. Plaintiffs' Hearing Binder, Tab C.1.E. The undersigned understands that these tests were submitted to the United States Patent and Trademark Office after the notice of allowance relating to the '693 patent and were relative to a validity issue. The undersigned has placed no weight on the tests or the discussion regarding the tests in connection with this claim construction.

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b. Review of extrinsic evidence

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The undersigned finds that no extrinsic evidence is necessary to construe the term "water vapor impermeable polymer layer." It should be noted, however, that the extrinsic evidence submitted by the parties and reviewed by the undersigned generally supports the proposed construction of the term water vapor impermeable polymer layer and further explains how water vapor can pass through the polymer layer in the context of the inventions of the '182 and '693 patents. 19 The undersigned briefly addresses this extrinsic evidence below.

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19 Further, even were consideration of the extrinsic evidence necessary to arrive at the proper construction, such consideration would be proper. Phillips, 415 F.3d at 1318 (providing that a district court may consider extrinsic evidence in the form of witness testimony "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art").

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i. Bezigian Testimony

Mr. Bezigian is a Coating Excellence witness. 20 He obtained a Bachelor in Science in Plastics Engineering from the University of Lowell in 1977 and a Master of Business administration from Bryant College in 1987. He has held numerous technical and manufacturing roles at major film and paper converters in the United States, including James River Corp., and has been a consultant to the film and paper converting industries since 1991. He also is an Adjunct Professor at the University of Massachusetts-Lowell where he lectures on the topics of extrusion coating, cast film and packaging. The parties agree that Mr. Bezigian has the background, education and training of a POSITA with regard to the two patents in dispute.

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20 He is identified in Defendants' Notice of Witness Testimony To Be Presented at Markman Hearing [Dkt. No. 67], but ultimately did not provide live testimony. The statement of his qualifications is excerpted from this Notice.

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James River deposed Mr. Bezigian on June 29, 2005. 21 During the deposition, Mr. Bezigian testified that "impermeable means that nothing goes through." 22 The undersigned places no weight on this conclusory opinion. As noted above in Phillips, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" 415 F.3d at 1318 (internal citations omitted). 23

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21 Excerpts of the Deposition ("Bezigian Test. at ") can be found at Plaintiffs' Hearing Binder, Tab G.1.

22 Bezigian Test. at p. 104, line 13. Mr. Bezigian also testified that no one to his knowledge has ever made a product covered by the patents at issue. Id. at p. 105, lines 4-6. Nothing in this Report and Recommendation should be considered to be a comment on or conclusion regarding whether any specific foodstuff wrap products fall or have fallen within the scope of one or more claims of the '182 or '693 patents.

23 The same rationale applies to Mr. Bezigian even though he was not identified as an expert.

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Mr. Bezigian's technical testimony regarding polymers and the extrusion of polymers, in contrast, is instructive. Mr. Bezigian repeatedly testified that moisture vapor barriers made from polymers and used in industry may reduce, but not eliminate, the movement of water vapor through the polymer barrier. 24 Further, he testified that a polymer layer thick

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enough to prevent the passage of water vapor could not be extruded and would not be a sandwich wrap. The following excerpt is illustrative:

Q Okay. Well, is it a question of degree? In other words, the thicker the polyethylene, that the less water vapor will pass through? And, again, by pass through, I want to isolate down to the -- -- to at the molecular level as opposed to pinholes or through the fold. If you're just talking at the molecular level, no matter what the thickness is, will some water vapor pass through the molecular structure of polyethylene?

A I mean there's a practical limit in extrusion coating. Extrusion coating is generally where you put a layer of five or six or maybe ten mills maximum thickness onto a substrate. Even that, I believe, would pass moisture. If it was an inch thick or a half an inch thick or a quarter of an inch thick, I don't believe it would, but that has to be borne out by testing.

Q Okay.

A But a quarter inch thick of polyethylene is rigid, it's not flexible, it's not made by extrusion coating. And it wouldn't be sandwich wrap. Anything in the normal extrusion coating range of, say, quarter of a mill to around a mill has a moisture vapor or water vapor permeability rate. Those words are used kind of interchangeably.

Q Has one greater than zero?

A Yes.

Q So anything greater -- -- so, in other words, you cannot extrusion coat a polyethylene layer that has a water vapor transmission rate of zero

A Correct

Q Can you extrusion coat any polymer that would have a water vapor transmission rate of zero?

A I would believe that answer would be no.

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24 Bezigian Test. at p. 82, lines 2-7 (stating that he is not aware of any extruded sandwich wrap where WVTR equals 0).

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Bezigian Test. at p. 58, line 4-p. 59, line 10 (emphasis added); see also id., p. 45, lines 6-7 ("Polyethylene film or just films in general act as a barrier to some degree to gas and liquids"); p. 53, lines 10-15 (concluding that it would be impractical to make a plastic layer thick enough to avoid pinholing). 25

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25 Coating Excellence, at the Hearing, characterized the manner in which water can pass through the polymer layer as theoretical chemistry. Hearing Transcript at p. 58, lines 4-11. However, there is no factual support for this distinction. Such view is also inconsistent with Coating Excellence's agreement that Mr. Bezigian has the background and other characteristics of a POSITA.

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ii. Mueller Testimony

Louann Mueller also is a Coating Excellence witness. 26 She received her Bachelor of Business Administration with a minor in Paper Sciences from Western Michigan University in 1984. While there, she took courses in pulp and paper

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engineering, organic chemistry, paper manufacturing and testing. She worked for James River from 1987 to 1996. She has worked as a Technical Manager for Coating Excellence. Her responsibilities have included work on composite food wrap products. Recently, she was promoted to Vice President of Printing and Laminating. 27 The parties agree that Ms. Mueller has the background, education and training of a POSITA with regard to the two patents in dispute.

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26 Ms. Mueller is identified in Defendants' Notice of Witness Testimony To Be Presented at Markman Hearing [Dkt. No. 66], and the above description of her background is taken from that Notice.

27 Hearing Transcript at p. 143, lines 20-21.

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Ms. Mueller testified at the Hearing. Her testimony as a whole is consistent with that of Mr. Bezigian. On direct examination, she testified that "I'm not familiar with any polymer that is 100 percent impermeable to water vapor." 28 She also testified that the higher density polyethylene, which is a better barrier to water vapor than low density polyethylene, is not used in sandwich wrap. 29 While on cross-examination, Ms. Mueller did state her view of "impermeable to be zero percent water vapor," 30 the undersigned places no weight on this conclusory statement.

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28 Hearing Transcript at p. 149, lines 2-3.

29 Hearing Transcript at p. 146, line 21 -- p. 147, line 4; p. 153, lines 7-22.

30 Hearing Transcript at p. 158, line 19.

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iii. Crotogino testimony

Dr. Crotogino is a Fort James witness. 31 He has a Bachelor of Applied Science degree in chemical engineering and a Ph.D. in chemical engineering from McGill University in Montreal. Dr. Crotogino worked for the Pulp and Paper Research Institute of Canada from 1976 until his retirement in 2004. The parties agree that Dr. Crotogino has the background, education and training of a POSITA with regard to the two patents in dispute.

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31 Plaintiffs' Notice of Live Testimony at Claim Construction Hearing [Dkt. No. 171] at pp. 1-3. The summary of Dr. Crotogino's qualifications come from this Notice.

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Coating Excellence deposed Dr. Crotogino on June 30, 2005. 32 Dr. Crotogino's testimony is consistent with the notion that impermeable is a relative concept regarding foodstuff wraps. He testified that one needs to consider the function of the wrap "within the useful life of the product," there is no such a thing as a "complete barrier," and "pores are indigenous to any material basically." 33

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32 Excerpts of the Deposition ("Crotogino Test. at ") can be found at Defendants' Hearing Binder, Tab 9.

33 Crotogino Test. at p. 104, lines 3-13; p. 118, lines 14-17. The portion of the transcript referenced in Defendants' Response to Plaintiffs' Final Claim Construction Statement [Dkt. No. 180], page 76, lines 6-22, simply reflects Dr.

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Crotogino agreeing with certain of the specification language, not saying what that language means.

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iv. Other extrinsic evidence

In addition to the above testimony, the parties submitted or referred to the following extrinsic evidence:

1. Coating Excellence tendered as part of its claim construction evidence a 1988 definition of "impermeable" from Webster's New World Dictionary. 34 It states that "impermeable" means "not permeable; not permitting fluids to pass through it; impenetrable." This is an example of the sort of situation noted in Phillips where blind reliance on general purpose dictionary definitions will not result in a construction that comports with the meaning to a POSITA. 415 F.3d at 1321. The undersigned placed no weight on this definition.

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34 Defendants' Hearing Binder, Tab 19.

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2. Coating Excellence refers to U.S. Patent No. 5,368,946 ('946 patent"), issued November 29, 1994, claim 2 of which refers in part to a specified Water Vapor Transmission Rate. 35 While this supports the notion that the concept of a Water Vapor Transmission Rate was known in the art during the pertinent time periods, it does not support any argument that the patents at issue should be read to require a Water Vapor Transmission Rate of 0. 36

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35 Defendants' Hearing Binder, Tab 20.

36 It should be noted that, while the specification of the '946 patent states that the inventive wrap generally "provides superior moisture barrier properties," it nowhere suggests that it must have a Water Vapor Transmission Rate of 0 to provide such qualities.

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3. Coating Excellence also submitted a TAPPI Water Vapor Transmission Rate test. 37 Again, because the intrinsic record provides no support for incorporating a WVTR into the claims, this extrinsic evidence should be given no weight. 38

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37 Defendants' Hearing Binder, Tab 18.

38 The undersigned further notes that the test at Tab 18 states in Note 1 that "WVTR is a distinctive characteristic, often erroneously termed 'permeability.'" Defendants' Response to Plaintiffs' Final Claim Construction Statement also references certain tests that were not included in Defendants' Hearing Binder. In any event, no weight should be placed on test methodologies that are not referenced in the intrinsic record.

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c. Recommended claim construction

In summary, the undersigned recommends that the term "water vapor impermeable polymer layer" and alternative references to the impermeable polymer layer of the '182 and '693 patents be construed to mean: "A polymer layer that is substantially impermeable to water vapor. Substantially impermeable means that some amount of water vapor may pass through the polymer layer, provided that the polymer/absorbent layer combination constitutes the mechanism for avoiding

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water vapor caused sogginess in the foodstuff and such passage is minimized so as to reduce resulting heat loss during the holding period."
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D. "water vapor permeable"

Claim 1 recites a "laminated, water vapor permeable desiccant packaging material." The claim does not define "water vapor permeable." The parties agree that the term "microporous" is to be given its ordinary meaning in relation to the "microporous film" of Claim 1. Thus the "microporous film" is a film having extremely small pores, or, in the terminology of the Preferred Embodiment, "having a plurality of fine openings, which film is gas permeable, but water impermeable when there is no difference between the air pressure outside of the film and inside of the film." The ordinary meaning of "water vapor permeable," that the laminated desiccant packaging material allows water vapor to pass through, is consistent with the description of the microporous film in the Preferred Embodiment which is gas permeable but water impermeable.

Multisorb would define water vapor permeability of the invention in the context of cargo shipping uses of the desiccant packages. It urges that in practicing the invention, the employment of certain microporous films with extremely low permeability would render the invention unable to accomplish its intended purpose; ie. the invention would not be efficacious in the standard 20-foot shipping containers used on overseas cargo vessels. Multisorb urges, therefore, that one skilled in the art would define "water vapor permeable" as sufficiently permeable in the practice of the patent, and would therefore exclude materials with extremely low permeability.

The preferred range of permeability expressed in the specification should not be read to limit the term "water vapor permeable" to a specified range. Intel Corp. v. U.S. International Trade Commission, 946 F.2d 821, 836 (Fed.Cir. 1991) ("Where a specification does not require a limitation, that limitation should not be read from the specification into the claims."), quoting, Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir. 1988); Lemelson v. United States, 752 F.2d 1538, 1551-52 (Fed.Cir. 1985). Further, Claim 2 claims "the desiccant container of Claim 1 wherein the uncoated laminate film has a lower moisture vapor transmission rate than the microporous film." Claim 3 claims "the desiccant container of Claim 1 wherein the microporous film has an air permeability of less than about 400 Gurley seconds/100 ml." Under the doctrine of claim differentiation, the presence of limitations on permeability in dependent Claims 2 and 3 implies that such a limitation is not inherent in independent Claim 1. Phillips, 415 F.3d at 1314-15 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim"), citing, Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed.Cir. 2004). We conclude, therefore, that as used in the '942 patent, the term "water vapor permeable" has the ordinary meaning of "allowing water vapor to pass through."
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The parties have requested claim construction of the term "wetting agent." n3 Pursuant to the structure laid out above, I will first examine the definitions of "wetting agent" as supplied by dictionaries and treatises, of which Torpharm has submitted three in evidence. The definitions are as follows:

Wetting Agent: any of a group of surface-active agents which, when added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface.

-WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE 1616 (2d ed. 1980).

Wetting Agents are surface active substances that are used to reduce the contact angle and therefore improve wetting.

-LEON LACHMAN ET AL., THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY 120 (Lea & Fibiger 1970).

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A Wetting Agent is a surfactant which, when dissolved in water, lowers the advancing contact angle and aids in displacing an air phase at the surface and replacing it with a liquid phase.

-ALFRED N. MARTIN ET AL., PHYSICAL PHARMACY 437 (2d ed.1969).

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n3 Although the District Court for the Southern District of Florida previously construed this term in Biovail Corp. Int'l v. Andrx Pharmaceuticals, Inc., 158 F. Supp. 2d 1318 (S.D.Fla. 2000), I have already informed the parties, via a written Notice issued on February 25, 2004, that there is no issue preclusion. That district court found that "wetting agent" is defined as "any of a group of surface active agents which, when added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface." 158 F. Supp. 2d 1318 at P 55.

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Torpharm advocates that I adopt one of these dictionary definitions as the definition of "wetting agent." On the other hand, Biovail proposes that "wetting agent" be defined as "a group consisting of a sugar, a C12 - C20 fatty acid ester of sucrose or xylose, a glyceride of sucrose, a fatty acid ester of polyoxyethylene, an ether of fatty alcohols and polyoxyethylene, an ester of sorbitan, an ester of polyoxyethylene sorbitan, a glyceride-polyglycide, an alcohol-polyglycide ester, lecithins and a combination thereof." In other words, Biovail reads the Markush group in the patents as defining wetting agents.

Although these dictionary sources provide clear definitions of "wetting agent," "the presumption in favor of a dictionary definition will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning." Tex. Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1204. The "language of the claim defines the boundary of its scope." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed. Cir. 2002). I therefore turn to the language of the patents to determine whether it provides an explicit definition of "wetting agent."

The language of the claims asks the reader to "select" a wetting agent "from the group consisting of" several chemicals. The language thus instructs the reader of the patent to do two things: (1) select a wetting agent, and (2) do so from the list provided. The reader should not understand the patent's language to mean either that a wetting agent should simply be selected, or, as Biovail would have the court read the language, that one of the items in the Markush group should be selected irregardless of whether it is a wetting agent. Both steps are necessary. Thus, asking the reader to select a wetting agent from a list of chemicals is not the same as defining the term wetting agent. Rather, it is qualifying the term; to treat this usage as a definition would be to severely alter the term's meaning. n4

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n4 My rejection of Biovail's construction might also be illustrated by a simple example. Suppose one were to read the instructions: "Select a woman from the group consisting of an American, a Canadian, and a Mexican." Obviously this instruction does not define all Americans as women, though by Biovail's logic it would. By the same reasoning, not all sugars need be defined as wetting agents.

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Biovail misinterprets the significance of a Markush group. In support of its argument, Biovail cites to the MANUAL OF PATENT EXAMINING PROCEDURE, § 2173.05(h), which, under the heading "Markush Groups," provides that, "Alternative expressions [within claims] are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." This statement goes no further than the already established description of a Markush group in establishing whether listing a group of chemicals as a Markush group is equivalent to providing a definition.

The patents' prosecution histories n5 do nothing to alter my conclusion that Biovail's patent does not define "wetting agent." I consider the prosecution histories "to determine whether the patentee intended to deviate from a term's ordinary and

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customary meaning or that the patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms." Nystrom v. Trex Co., 374 F.3d 1105, 2004 U.S. App. LEXIS 13407, 2004 WL 1432247 (Fed. Cir. June 28, 2004). Biovail calls attention to three aspects of the patents' prosecution histories:

(1) The original applications for the '505 and '791 patents included the language about selecting a wetting agent from "the group consisting of sugars/a sugar." (Prosecution History of Patent No. 5,288,505 at 505-036; Prosecution History of Patent No. 5,529,791 at 791-040.)

(2) In the written description of the '505 patent invention, under the heading

"DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS," the '505 patent states: "Among the wetting agents associated with the Diltiazem or salt thereof in the beads, the following compounds may more particularly be exemplified n6: sugars, for example, saccharose, mannitol, soribitol, and lactose. . . In addition to at least one of the above named wetting agents the beads may contain excipients or carriers." (Prosecution History of Patent No. 5,288,505 at 505-009.)

(3) In the '505 patent prosecution history, the patentee explained that "wetting agents claimed in the present invention are substances which are believed to modify the solubility of Diltiazem inside the coated beads when they are placed in a dissolution medium or when they are ingested by a mammal." (Prosecution History of Patent No. 5,288,505 at 505-081.)

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n5 Prosecution histories, as "undisputed public records of proceedings in the Patent and Trademark Office," are considered to be of "primary significance in understanding the claims." Markman, 52 F.3d at 980. The reason behind this deference is that the "construction of the patent is confirmed by the avowed understanding of the patentee, expressed by him, or on his half [sic], when his application for the original patent was pending. . . When a patent bears on its face a particular construction, inasmuch as the specification and claim are in the words of the patentee, . . . such a construction may be confirmed by what the patentee said when he was making his application." Id.[[(quoting]][[Goodyear Dental Vulcanite Co. v. Davis]][, 102 U.S. 222,]227, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880).)

n6 Exemplify: to show or illustrate by example. WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY 434 (1984).

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The patent histories are consistent with the patents' language and go beyond the patents' language in describing the role of the wetting agent in the compound. However, Biovail has not provided any evidence that the histories go farther than the plain language of the patents in defining "wetting agent."

Because I find that the language of the patents does not "limit," "disavow," or "disclaim" the understood meaning of the term "wetting agent," I will construe the claim as its "ordinary and customary meaning." Illinois Tool, 250 F. Supp. 2d at 484. "Dictionary definitions may establish a claim term's ordinary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). "If more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital, 308 F.3d at 1203. The parties do not contend that the three proffered definitions taken from dictionaries and treatises conflict with one another, and I see no reason not to encompass all three definitions in my construction. I therefore construe the term "wetting agent" as: "any of a group of surface-active agents which, when added to a liquid, reduce the contact angle and cause the liquid to spread more easily over, or penetrate into, a solid surface."
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55. The term "wetting agent" is defined as any of a group of surface active agents which, when added to a liquid, cause the liquid to spread more easily over, or penetrate into, a solid surface. Weiner testimony; Banakar testimony.
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1. The Meaning of "Whereby Intimate Diffusional Contact With Skin of the Patient is Maintained for a Period of About at Least 24 hours Without Destruction of the Physical Integrity Thereof"

Hercon contends that the phrase "whereby intimate diffusional contact with skin of the patient is maintained for a period of at least about 24 hours without destruction of the physical integrity thereof' means that the adhesive transdermal layer described in claim 14 must maintain contact with the skin of a patient for at least about 24 hours. Hercon argues that, if claim 14 requires that the adhesive transdermal layer merely be capable of maintaining contact with the skin of a patient for at least about 24 hours, the inventors would have used language such as "capable of" as they did in other parts of the specification and in claim 14 itself. See e.g., col. 3, lines 39-41; col. 5, lines 38-40; col. 12, lines 16-18.

Hercon's interpretation is not supported by the plain language of claim 14. When placed in context, the disputed language reads "said essentially planar sheet comprising a flexible self-supporting cross-linked acrylate polymer of sufficient adhesivity, durability and strength whereby intimate diffusional contact with skin of the patient is maintained for a period of at least about 24 hours without destruction of the physical integrity thereof." This portion of claim 14 thus concerns the sufficiency of the adhesive layer. It is not a directive that the layer maintain contact with the skin of a patient for at least about 24 hours. Any ambiguity, however, is resolved by resort to the specification. See Vitronics, 90 F.3d at 1582. ("The specification acts a dictionary when it expressly defines terms used in the claims of when it defines terms by implication."). The specification states that one of the objects of the invention is:
to provide an adhesive transdermal dosage system . . . containing . . . [an] essentially planar sheet comprising a flexible self-supporting cross-linked acrylate polymer of sufficient adhesivity, durability, and strength where the skin of the patient can be maintained in intimate diffusional contact therewith, the layer capable of retaining a quantity of pharmaceutically active drug over a period of 24 hours without destruction of the physical integrity of the sheet . . . .

See col. 4, lines 35-48 (emphasis added). This statement is nearly identical to the disputed language and thus serves to clarify its meaning. Accordingly, the court concludes that claim 14 does not require that the adhesive transdermal layer maintain contact with the skin of a patient for at least about 24 hours, but rather only that the layer be capable of maintaining contact with the skin of a patient for that amount of time.
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Claim 1

Claim 1 reads as follows, with significant language in bold.

1. A method of simultaneously determining the alleles present in at least four short tandem repeat loci from one or more DNA samples, comprising:

(a) obtaining at least one DNA sample to be analyzed,

(b) selecting a set of at least four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, wherein the at least four loci in the set are selected from the group of loci consisting of: D3S1539, D4S2369, D5S818, D7S820, D9S930, D10S1239, D13S317, D14S118, D14S548, D14S562, D16S490, D16S539, D16S753, D17S1298, D17S1299, D19S253, D20S481, D22S683, HUMCSF1PO, HUMTPOX, HUMTH01, HUMF13A01, HUMBFXIII, HUMLIPOL, HUMvWFA31;

(c) co-amplifying the loci in the set in a multiplex amplification reaction, wherein the product of the reaction is a mixture of amplified alleles from each of the co-amplified loci in the set; and

(d) evaluating the amplified alleles in the mixture to determine the alleles present at each of the loci analyzed in the set within the DNA sample.

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According to defendants, both the '660 patent's prosecution history and the language of other claims in the patent make clear that whether the set of loci used in the multiplex reaction contains four loci or more than four loci, it must be selected entirely from the list in step (b). Plaintiff maintains that a reaction including additional, unidentified loci would still fall within the scope of the patent as long as at least four loci in the reaction were chosen from the list. The claim's "plain" language on this score is ambiguous. The claim first indicates that "at least four short tandem repeat loci" must be included in the set and then states that "the at least four loci in the set" must be selected from the listed loci. It is clear from this language that a minimum of four loci are required for the reaction and that the inclusion of additional loci is not ruled out. The ambiguity arises when one attempts to discern whether any additional loci beyond the requisite four must be chosen exclusively from the list contained in step (b). The phrase "wherein the at least four loci in the set are selected from" could be read to indicate that only the requisite four loci need be chosen from the identified group. According to this reading, the emphasis is on the words "at least four." However, the phrase could also be read to refer comprehensively to the group of loci selected, whether that group contains four, five, six or more loci. In this reading, the presence of the word "the" before "at least four" is critical.

The '660 patent's prosecution history resolves the ambiguity in claim 1. On May 13, 1997, plaintiff filed amendments to their claims with the Patent and Trademark Office. Following the May 1997 amendments, claim 1, step (b) read as follows.

(b) selecting a set of at least four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, wherein at least four of the loci in the set are selected from the group of loci consisting of:

D3S1539, D4S2369, D5S818, D7S820, D9S930, D10S1239, D13S317, D14S118, D14S548, D14S562, D16S490, D16S539, D16S753, D17S1298, D17S1299, D19S253, D20S481, D22S683, HUMCSF1PO, HUMTPOX, HUMTH01, HUMF13A01, HUMBFXIII, HUMLIPOL, HUMvWFA31;

(emphasis added). In its remarks accompanying the amendments, plaintiff noted that

claim 1 has … been amended … to delete one locus (i.e. HUMFESFPS) from [a list] of loci provided therein. However, Applicants submit that the amendments to claim 1 do not change the fact that the claimed method encompasses the co-amplification and evaluation of sets of short tandem repeat loci which include the deleted locus, provided at least four of the loci in the set co-amplified according to the method are selected from the remaining group of loci listed in claim 1.

In other words, plaintiff argued that claim 1 covered the amplification of additional unlisted loci (for example, the deleted HUMFESFPS), as long as four loci from the identified group were included in the co-amplification process. This is a natural reading of the language in step (b) as it read on May 13, 1997: it plainly requires only four loci to come from the identified list. Plaintiff now argues that the remarks accompanying the May 13 amendment support its broad construction of claim 1. However, subsequent prosecution history indicates otherwise. On January 16, 1998, the examiner rejected claim 1 as being unpatentable over the prior art. Following an interview on March 27, 1998, the examiner allowed claim 1, but only after additional amendments were made. The patent office's summary of that interview pointedly notes that these additional "amendments to the claims were agreed on to place them in condition for allowance." Specifically, the notice of allowability indicates that "in claim 1, (b), line 2, -the- has been inserted after 'wherein' and 'of the' after 'four' has been deleted." Accordingly, after the March 1998 amendments, claim 1 reads as follows, with the inserted language underlined and the deletion bracketed and stricken.

(b) selecting a set of at least four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, wherein the at least four [-of-the-] loci in the set are selected from the group of loci consisting of:

D3S1539, D4S2369, D5S818, D7S820, D9S930, D10S1239, D13S317, D14S118, D14S548, D14S562, D16S490, D16S539, D16S753, D17S1298, D17S1299, D19S253, D20S481, D22S683, HUMCSF1PO, HUMTPOX, HUMTH01, HUMF13A01, HUMBFXIII, HUMLIPOL, HUMvWFA31;

(emphasis added). Thus, while the pre-amendment claim 1(b) required "at least four of the loci" to be chosen from the listed group, after the March 1998 amendment the same section required "the at least four loci" to be chosen from the listed group.

A patent's prosecution history is often critical in determining the scope and meaning of claims. Advanced Cardiovascular

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Systems, Inc. v. Scimed Life Systems, Inc., 261 F.3d 1329, 1339-40 (Fed. Cir.2001). "Arguments and amendments made during the prosecution of a patent application … must be examined to determine the meaning of terms in the claims. … Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." Southwall Technologies, Inc. v Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995); Standard Oil Co v. American Cyanamid Co., 774 F.2d 448, 452 (Fed Cir. 1985) ("The prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance."). In light of claim 1's prosecution history, the highlighted language indicates that the claim was amended to facilitate its allowance in such a way as to specify that whatever number of loci were to be co-amplified, all must be selected from the identified list. See CAE Screenplates, Inc. v. Heinrich Fiedler Gmbh & Co., 224 F.3d 1308, 1317 (Fed. Cir. 2000) (patentee who amended claim in face of rejection over prior art to require "bottom plane," rather than more general "bottom" could not receive benefit of more general term because "in the absence of any evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings.").

The language of other claims in the '660 patent supports a construction of claim 1 to require that the entire set be chosen from those listed in the claim. For instance, the relevant portions of independent claim 32 read as follows.

1. A method of simultaneously determining the alleles present in at least four short tandem repeat loci from one or more DNA samples, comprising:

(a) obtaining at least one DNA sample to be analyzed,

(b) selecting a set of at least four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, wherein three of the loci in the set are D7S820, D13S317, and D5S818;

The plain language of this claim contemplates the inclusion of loci in addition to the three listed loci in a way that the amended language of claim 1 simply does not. "[A] review of other claims in the same patent can aid in deciding the scope of a particular claim." Specialty Composites v. Cabot Corp., 845 F.2d 981, 986 (Fed. Cir. 1988). The fact that the patent's drafters knew how to structure claims broadly to include even unidentified loci suggests that their not doing so in claim 1 was intentional. See CFMT, Inc. v. Yieldup Int'l Corp., 92 F. Supp. 2d. 359, 372 (D. Del. 2000) (explicit references to particular term in patent specification suggest that if inventors had meant to refer to that term in patent claims, they knew how to do so).

In arguing for a broad construction of claim 1 that would cover the presence of additional loci not identified in step (b), plaintiff rests primarily on its interpretation of the transitional term "comprising," which joins the claim's preamble with its body. Plaintiff argues that the use of the transitional term "comprising" means that "additional elements, such as additional loci or sets of loci, may also be present in addition to the claimed invention." Plt.'s Claim Construction Br. - Promega's Patent, dkt. # 29, at 21. It is true that "'comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp, 112 F.3d 495, 501 (Fed. Cir. 1997). However, it is equally true that "the open-ended transition 'comprising' does not free [a] claim from its own limitations." Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001).

Kustom Signals involved the alleged infringement of a traffic radar gun patent. One of the disputed claims in Kustom Signals' patent read as follows.

16. In a traffic radar, apparatus for processing Doppler return information comprising:

(a) means for receiving Doppler return information containing at least one return signal derived from a target vehicle, and for presenting said information as digital data …

(d) means for searching the components stored in said memory means to identify the component that meets preselected magnitude or frequency criteria, and

(Emphasis added). Kustom Signals argued that its patent was infringed by a rival's radar gun that automatically performed a search of magnitude and frequency data rather than searching magnitude or frequency data based on a user's preselection.

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The Court of Appeals for the Federal Circuit disagreed. First, the court noted that during the patent's prosecution Kustom Signals had amended claim 16. As originally filed, its claim 16 referred to "means for determining the magnitude and frequency of each valid component"; after the amendment the claim referred to a search of "magnitude or frequency." Next, the court rejected Kustom Signals' argument that use of the term "comprising" in the disputed claim meant that a radar that searched both magnitude and frequency was simply performing an additional function when compared with a radar that searched either magnitude or frequency and would be covered under the claim language. According to Kustom Signals, because use of the term "comprising" allows the inclusion of steps or elements in addition to those stated in the claim, the allegedly infringing radar fell within the scope of the claim. The court of appeals rejected this broad interpretation of the term "comprising," concluding that its use "cannot restore subject matter otherwise excluded from the claim." Id. (citing Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1379-80 (Fed Cir. 1998)).

In this case, although claim 1 in the '660 patent originally required only that "at least four of the loci" be chosen from the listed group, it was amended to require that "the at least four loci" be chosen from the listed group. The effect of this amendment was to provide that all loci to be co-amplified, whether four or more, must be selected from the identified list. To conclude otherwise would render meaningless the amendment upon which allowance of claim 1 hinged. As in Kustom Signals, inclusion of the term "comprising" in the claim's preamble cannot restore subject matter that was excluded from the claim. Although use of that open transitional phrase might allow for the inclusion of additional, unidentified steps, it cannot be used to resurrect a claim scope that was surrendered in order to allow the patent to issue. "'Comprising' is not a weasel word with which to abrogate claim limitations." Spectrum, 164 F.3d at 1380.

Finally, I note that step (b) of claim 1 itself contains a transitional phrase, "consisting of," that immediately precedes the list of loci. In contrast to the open transitional term "comprising," "consisting of" is a closed transitional phrase that is "understood to exclude any elements, steps, or ingredients not specified in the claim." AFG Industries, Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1245 (Fed. Cir. 2001). The most natural reading of step (b), then, is one that recognizes that the list of loci therein is closed and sets that include loci not listed in step (b) are excluded from the scope of claim 1.

I conclude that claim 1 covers only sets of short tandem repeat loci in which all the loci in the reaction, whether four or more, are selected from the group of loci listed in step (b).
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5. "Wherein Said Food Acid Slows Down Oxidation Of Ascorbic Acid" (Claims 6)

Dawn contends that "this claim adds no new features to the invention. This is inherent in the formula of claim 5." Kim argues that this phrase means that "the function of each component in a composition during manufacturing process of yeast-leavened products, actually enforcing the role of each component's function in claim 5 in the production of yeast-leavened products."

The Court rejects Dawn's construction because each word in the claims must have meaning. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1582 (Fed. Cir. 1996). The Court rejects Kim's construction because it does not make sense and it does not track the claim language. This claim term consists of "ordinary, simple English words whose meaning is clear and unquestionable. . . . They mean exactly what they say." ChefArn., Inc. v. Lamb- Weston, Inc., 358 F.3d 1371, 1373 (Fed. Cir. 2004). Accordingly, the term is construed to mean that the food acid functions to slow down the oxidation of ascorbic acid.
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B. Claim Construction

On appeal, Biagro challenges the trial court's construction of the claim limitation "wherein said phosphorous-containing acid or salt thereof is present in an amount of about 30 to about 40 weight percent." As it did before the trial court, Biagro makes two separate arguments, each one corresponding to a different theory. We address each theory in turn, and we affirm

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the trial court's claim construction under both.

1.

Biagro first argues that the amount of phosphorous-containing acid in the claim limitation refers to a chemical equivalent amount rather than, as the trial court held, the amount of phosphorous-containing acid actually present in the final fertilizer product. According to Biagro, the 'chemical equivalent' is a calculated amount of phosphorous-containing acid regardless of whether phosphorous-containing acid is actually present in the fertilizer, that is, the amount of phosphorous-containing acid that would react to make the final fertilizer. If the amount of phosphorous-containing acid that was used to create the product is unknown, the chemical equivalent amount can be derived by testing the final product and performing a calculation on the results.

It is elementary that claim construction begins with, and remains focused on, the language of the claims. Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004). As our recent en banc decision in Phillips v. AWH Corp. reaffirmed, the words of a claim are generally given their ordinary and customary meaning, which is the meaning the term would have to a person of ordinary skill in the art at the time of the invention. 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (citing Innova, 381 F.3d at 1116). Such a person is deemed to read the claim term in the context of the entire patent, including the other claims and the written description. Id. at 1313. Patent claims should also be construed in light of the prosecution history, which, like the patent itself, has been designated as part of the "intrinsic evidence." Id. at 1317. Extrinsic evidence, such as expert testimony, may be useful in claim construction, but it should be considered in the context of the intrinsic evidence. Id. at 1318-19.

In this case, the plain language of the claims gives no indication that the amount of phosphorous-containing acid in the claimed invention is a chemical equivalent amount. The claim language clearly refers to the "amount" of phosphorous-containing acid that is "present" in the "concentrated phosphorus fertilizer." n2 Furthermore, the written description contains no discussion at all of 'chemical equivalents' or any hint that the amount of phosphorous-containing acid recited in the claims is expressed as a chemical equivalent amount instead of the amount actually present in the fertilizer.

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n2 As often happens in claims having an absence of useful punctuation, the addition of new language creates ambiguities. In this case, it is unclear whether the "wherein" phrase modifies "[a] concentrated phosphorous fertilizer," or "a buffered composition," or "a fully solubilized use-dilution fertilizer." For purposes of the result, it does not matter.

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As for the prosecution history of the '255 patent, Biagro relies on only one passage--a statement made by the examiner during reexamination that the phosphite solution of a prior art reference was an example of a phosphorous acid solution. At most this shows that a person skilled in the art might refer to a phosphite solution as a phosphorous acid solution when the phosphite solution, like the accused product in this case, was formed from phosphorous acid. But we do not conclude from this one statement that one skilled in the art would interpret claim language concerning the amount of phosphorous acid required to be "present" in the fertilizer to mean the amount of phosphorous acid that was used to make the fertilizer, i.e., the chemical equivalent amount. The prosecution history, like the patent itself, is devoid of the term chemical equivalent or any reference to the use of representative amounts to describe the composition of the fertilizers claimed in the patent.

Biagro also cites the prosecution history of U.S. Patent No. 6,113,665 ("the '665 patent"), which is a continuation of the '255 patent and was prosecuted during the same timeframe as the reexamination of the '255 patent. In remarks accompanying two amendments that added limitations on the amount of phosphorous-containing acid or salt present in the claimed fertilizer, the applicant's attorney referred to the amount of phosphorous acid "in" examples 1 and 9 of the written description. According to Biagro, these amounts were chemical equivalent amounts because the fertilizers produced in those examples do not actually contain phosphorous acid. As the trial court noted, however, there is nothing in the prosecution history of the '665 patent to explain how the figures were obtained or to indicate that the examiner understood the applicant was referring to chemical equivalent amounts. Whatever the attorney's statements were intended to mean, they do not alter the ordinary meaning of the claim language, i.e., that the amount of phosphorous-containing acid is the amount actually present in the fertilizer.

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In making its arguments, Biagro relies heavily on extrinsic evidence in the form of expert declarations explaining fertilizer labeling guidelines and standards. This evidence, according to Biagro, shows that those skilled in the art understand that the amounts of plant nutrients in fertilizer products are frequently expressed as 'chemical equivalents.' The primary example is a fertilizer labeling convention, known as the 'guaranteed analysis,' which indicates the guaranteed amount of nitrogen, phosphorus, and potassium in the fertilizer product. The phosphorus content is expressed not in its elemental form (P), but as phosphorus pentoxide (P[2]O[5]), regardless of whether the fertilizer actually contains any phosphorus pentoxide. Thus the amount of phosphorus pentoxide listed on the label is a chemical equivalent amount derived from the actual chemical composition of the fertilizer. Biagro also cites California fertilizer labeling guidelines that refer to fertilizer products as "containing" phosphorous acid when in fact they were only derived from phosphorous acid. In Biagro's view, this evidence shows that a person skilled in the art would understand the claims to refer to a chemical equivalent amount of phosphorous-containing acid, and therefore we should accept this interpretation as the ordinary and customary meaning of the claim language.

However, even if we agree that the labeling convention and guidelines demonstrate that those skilled in the art are familiar with the use of 'chemical equivalents,' the problem is that Biagro cannot tie its extrinsic evidence to the patent or the claim language. Nothing in the patent or prosecution history indicates that labeling standards are relevant to the claimed fertilizer, and nothing in Biagro's extrinsic evidence suggests that a person skilled in the art of fertilizer formulation would necessarily use a chemical equivalent to express the amount of phosphorous acid in a fertilizer that does not actually contain phosphorous acid.

We are also unpersuaded by Biagro's argument that Grow More's expert took an inconsistent position on behalf of a different defendant in another patent infringement suit brought by Biagro. In that case, the expert described a prior art fertilizer as containing 13% phosphorous acid, which was ultimately shown to be a chemical equivalent amount. We agree with the trial court that it appears the expert was simply relying on product materials shown to him and was not aware that the 13% had been arrived at through a 'chemical equivalent' analysis.

2.

Biagro's second theory is that the trial court erred in construing the amount of "phosphorous-containing acid or salt" in the claim language as an aggregate amount. The claim language calls for "at least one phosphorous-containing acid or salt thereof . . . wherein said phosphorous-containing acid or salt thereof is present in an amount of about 30 to about 40 weight percent." Biagro argues that the limitation is met so long as one acid or salt is present in the claimed amount, even if the fertilizer contains other acids or salts. Under the trial court's claim construction, as advocated by Grow More, a fertilizer containing more than one acid or salt would satisfy the limitation only if the aggregate amount of acids or salts falls within the claimed range.

The phrase "at least one" in patent claims typically is construed to mean "one or more." Therefore, Biagro contends, the claim language allows for aggregation of acids or salts but does not require it. The trial court, however, concluded that both the written description and prosecution history require the aggregate amount of acids or salts to be within the claimed range, and we agree. First, it is apparent from the written description that all phosphorous-containing acids or salts in the fertilizer serve the same purpose such that the total amount of such acids or salts is important. More significantly, during reexamination the patentee distinguished the invention over prior art by emphasizing that the claimed fertilizer "must be concentrated" and that the "concentration has now been specified as an amount of about 30 to about 40 weight percent." If a fertilizer contains more than one phosphorous-containing acid or salt, the concentration is based on the total amount of such acids or salts, not just one acid or salt. In view of the patentee's emphasis on the concentration of phosphorous-containing acids or salts, the trial court correctly construed the claim to require an aggregate amount of such acids or salts to be between about 30 and about 40 weight percent.

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7. What is the Proper Construction for the Phrase "whereby said substantially uniform particulate mixture is deformed, consolidated into a desired form and solidified in the extrusion die and is extruded from said die cavity as a solid composite porous article" in the '948 Patent?

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Claim 1 of the '948 patent contains the phrase "whereby said substantially uniform particulate mixture is deformed, consolidated into a desired form and solidified in the extrusion die and is extruded from said die cavity as a solid composite porous article." KXI contends this "whereby" clause merely states the necessary result of operating a device containing the claimed elements. According to KXI, it does not add any additional claim limitations. Culligan contends the "whereby" clause adds a limitation to the claim. Culligan construes the "whereby" clause to mean that, as a necessary result of the above steps, the "'substantially uniform particulate mixture' changes form due to softening, is shaped under pressure and is solidified, all within the extrusion die, and the resulting product is extruded from the die as a solid composite article having pores."

KXI argues that the Federal Circuit teaches that a "whereby" clause that merely states the result of the limitations in the claim, "adds nothing to the patentability or the substance of the claim[,]" citing Texas Instruments v. ITC, 988 F.2d 1165, 1172 (Fed. Cir. 1993). According to KXI, the "whereby" clause of claim 1 "merely states the necessary result of operating a device containing the claimed elements," and therefore, "does not add any additional claim limitations."

Culligan argues that the "whereby" clause was added to the claim to overcome an examiner's objection, and as such it "must be deemed an essential feature necessary to the establishment of infringement[,]" citing Eltech Sys. Corp. v. PPG Indus., Inc., 710 F. Supp. 622, 633 (W.D. La. 1988), aff'd 903 F.2d 805 (Fed. Cir. 1990). See also Quality Semiconductor, Inc. v. Pericom Semiconductor, Inc., No. C-95-01785 MHP, 1998 WL 118186, at *5-6 (N.D. Cal. March 2, 1998); Thermalloy Inc. v. Aavid Eng'g, Inc., 935 F. Supp. 55, 60 (D.N.H. 1996, aff'd, 121 F.3d 691 (Fed. Cir. 1997).

According to Culligan, during the prosecution of the '948 patent, the patentee amended claim 1 to include the present "whereby" clause "for the express purpose of distinguishing that claim over the prior art." The patentee made the following amendment: "whereby said [solid composite material] substantially uniform particulate mixture is deformed, consolidated into a desired form and solidified in the extrusion die and is extruded from said die cavity as a solid composite porous article." The patentee added this language to claim 1 to overcome a rejection based on the prior art of the Leitl and Zavasnik patents.

According to Culligan, the patentee relied on the amended "whereby" clause to distinguish the Leitl and Zavasnik patents. For example, the patentee distinguished the invention of the application from Zavasnik as follows: "solidification [in the Zavasnik extruder] . . . takes place outside the extrusion die, i.e., in the water chamber (12), whereas in the claimed invention of this Application, deformation, consolidation and solidification of the particulate matter occurs in the die cavity."

The court agrees with Culligan that the patentee amended claim 1 by adding the "whereby" clause to overcome a rejection by the examiner, and then relied on the amendment to distinguish prior art. The court finds the "whereby" clause does not merely state the result of the limitations of the claim, but adds limitations to the claim. The court construes the "whereby" clause according to the ordinary meaning of its terms. Accordingly, the court finds the phrase, "whereby said substantially uniform particulate mixture is deformed, consolidated into a desired form and solidified in the extrusion die and is extruded from said die cavity as a solid composite porous article[,]" means that, as a necessary result of the above steps, the "substantially uniform particulate mixture" changes form due to softening, is shaped under pressure, and is solidified, all within the extrusion die, and the resulting product is extruded from the die as a solid composite article having pores.
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6."(b) DNA sequences . . . which code on expression for a polypeptide of the IFN- [alpha] type, and (c) DNA sequences which code on expression for a polypeptide of the IFN- [alpha] type coded for on expression by any of the foregoing DNA sequences and inserts . . . ."

The crux of the dispute between the parties with regard to this claim language is the meaning of the claim terms "DNA sequences" and "code on expression." Schering argues that subparagraph (c) should be interpreted to add interchangeable DNA sequences which also code for polypeptides that are coded for by the deposited DNA inserts or the related hybridizing DNA sequences. 33 Further, Schering contends this claim language is not limited to only naturally occurring, interchangeable DNA sequences. Amgen, on the other hand, would require that the DNA sequences not only code for the

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desired polypeptide, but that the encoded polypeptide is actually produced by being transcribed and translated into the corresponding protein. Moreover, Amgen asserts all the DNA sequences must be naturally occurring as the claim language "segments of DNA from different genomes" applies to all the subparagraphs, including (b) and (c).

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33 Because multiple codons may code for the same amino acid, alternative nucleotide sequences may code for the same proteins. This redundancy of the genetic code is referred to as its degenerative nature.

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First, the Court finds that the claim language "segments of DNA from different genomes," see Col. 36, line 4-5, applies to the DNA sequences described in subparagraphs (b) and (c). By the terms of the claim itself, these "segments of DNA" "consist of" those DNA sequences described in subparagraph (b) and (c). See Col. 36, lines 4-20. Consequently, the construction of "segments of DNA from different genomes" must also apply to the "DNA sequences" of subparagraphs (b) and (c). As the Court has held that "segments of DNA from different genomes" refers to both naturally occurring and non-naturally occurring DNA segments or sequences, the "DNA sequences" of subparagraph (b) and (c) are similarly not limited to naturally-occurring DNA sequences.

As for the meaning of "code on expression," the Court starts its analysis with the relevant claim language. Subparagraph (c) requires the DNA sequences described therein to have two attributes. First, the DNA sequences must code on expression for a polypeptide of the IFN- [alpha] type. See Col. 36, lines 17-18. In other words, the DNA sequences must code on expression for an immature, fused, and/or incomplete, naturally occurring, human leukocyte interferon protein, subsequently labeled "IFN- [alpha] -1." Second, the polypeptide of the IFN- [alpha] type has to also be coded on expression by any of the foregoing DNA inserts and sequences set forth in either subparagraph (a) or (b), i.e., the DNA inserts deposited at the DSM or DNA sequences which hybridize to the DNA inserts. See Col. 36, lines 10-20.

Thus, subparagraph (c) does not cover any new interferon proteins; it must code on expression for a polypeptide of the IFN- [alpha] type. However, if there is a DNA sequence equivalent on expression to either the DNA inserts of subparagraph (a) or DNA sequences which hybridize thereto under subparagraph (b), those DNA sequences are covered by subparagraph (c). This conclusion only makes sense because of the degenerate nature of the genetic code; that is, different codons (nucleotide triplets) can code on expression for the same amino acids. For instance, if a DNA insert had the following nucleotide sequence: AGGTCGGCA, it would code on expression for the following amino acids: Arginine-Serine-Alanine. However, the following degenerate nucleotide sequence would also code on expression for the same chain of amino acids: CGCTCCGCC, and therefore would also produce the same polypeptide. Subparagraph (c) therefore covers degenerate sequences to the DNA inserts, or DNA sequences which hybridize thereto, and which also code on expression for a polypeptide of the IFN- [alpha] type. See Col. 28, lines 8-14 ("It is also to be understood that DNA sequences, which are not screened by the above DNA sequences, yet which as a result of their arrangement of nucleotides code on expression for the polypeptides coded for by the expression of the above DNA sequences also fall within this invention.").

Having analyzed the claim language, the Court finds that these DNA sequences must only code on expression for the desired polypeptide, but need not actually produce the polypeptide by transcription and translation and subsequently, be detected. The knowledge that a given DNA sequence will produce on expression a given polypeptide is sufficient. There is no basis for the belief that the identified and isolated DNA sequences must be transcribed, translated and then detected. The claim language is clear that it is the DNA sequences that are covered by the claim, not the proteins that are eventually coded for on expression.

The specification is in accord. Although the specification specifically sets out a definition for "expression," see Col. 7, lines 3-5, the claim language does not read "DNA sequences expressing a polypeptide of the IFN- [alpha] type," but "DNA sequences which code on expression for a polypeptide of the IFN- [alpha] type." The latter phrase points to the fact that if the DNA sequences were decoded, a polypeptide of the IFN- [alpha] type would be produced. However, only the former language, not in the '901 Patent, requires actual expression of the desired polypeptide.

This interpretation is also supported by the prosecution history of the '901 Patent. Initially, subparagraph (b) was amended to recite "code for a polypeptide of the IFN- [alpha] type." See D.I. 172, Tab 18 at 3. Subparagraph (c), on the other hand,

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was initially amended to state: "DNA sequences which code for a polypeptide coded for by any of the foregoing DNA sequences." See id. Amgen contends that the phrase "code for" initially utilized by Schering would have allowed for just the recitation of the DNA sequence; however, "code on expression" points to the fact that the patent examiner was concerned that the DNA sequences may not properly express the polypeptide. Accordingly, Amgen argues the polypeptide must be transcribed from the corresponding DNA template, translated from the RNA, and subsequently detected.

A closer reading of the relevant prosecution history shows that Amgen is mistaken in its analysis. Specifically, the patent examiner found the "code for" phrase to be vague "because it is not clear whether applicant intends to claim all of the possible coding sequences that may result from (a) frame-shifts and/or (b) silent mutations." See D.I. 172, Tab 21 at 4. That is, the patent examiner was unclear whether Biogen wanted to claim all DNA sequences which code for a polypeptide of the IFN [alpha] type, but subsequently through frame shifts or mutations produced a variant coding sequence. Biogen amended "code for" to "code on expression" to make clear that is was only concerned with the DNA sequences which actually were able to code on expression for the desired polypeptide. However, there is no basis in fact for Amgen's conclusion that the patent examiner was requiring that proteins actually be produced and detected. Thus, the prosecution history does not support Amgen's interpretation of this claim language. 34

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34 Even if the Court were to agree with Amgen's reading of the prosecution history, the claim language clearly covers only the DNA sequences. See Col. 36, lines 14-20. Because the claim language, which is the best guide to the meaning and scope of a patent, trumps the prosecution history, see Phonometric, 133 F.3d at 1464, the Court's conclusion would not be altered.

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The Court holds that "(b) DNA sequences . . . which code on expression for a polypeptide of the IFN- [alpha] type, and (c) DNA sequences which code on expression for a polypeptide of the IFN- [alpha] type coded for on expression by any of the foregoing DNA sequences and inserts" refer to both naturally occurring and non-naturally occurring DNA sequences which bear the genetic code for expressing the polypeptide; actual expression and detection of the protein, however, is not required.

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On appeal, Wasinger challenges the district court's conclusion that multi-step processes were disclaimed during prosecution of the '510 patent. Wasinger asserts that the district court's construction adds an entirely new limitation that is unsupported by the actual claim language. Additionally, Wasinger argues that the district court misinterpreted the prosecution history and that, when viewed in context, there was no disavowal of multi- step processes. For its part, Strauss contends that the district court properly relied on intrinsic evidence to conclude that Wasinger disclaimed multi-step processes. According to Strauss, Wasinger's statements in the file history unambiguously limit the claims to a single operation process.

Claim 1 recites "a method for simultaneously desizing and decolorizing a dyed fabric . . . which comprises treating said fabric or garment with an effective amount of reducing agent in an aqueous bath . . . ." '510 patent, col. 6, ll. 1-5. The claim concludes with a "whereby clause," which requires the fabric to be "both desized and decolorized prior to any subsequent oxidation or bleaching." Id. col. 6, ll. 5-7. Use of the open-ended transition "which comprises" indicates that there may be additional unclaimed steps in the method. Scanner Techs. Corp. v. ICOS Vision Sys. Corp., N.V., 365 F.3d 1299, 1305 (Fed. Cir. 2004) ("The use of the transitional phrase 'comprising' . . . indicates that the elements or steps following the transition may be supplemented by additional elements or steps and still fall within the scope of the claim."). The whereby clause signifies that there may be subsequent oxidation or bleaching steps that are not part of the claimed method. Therefore, on its face, claim 1 clearly contemplates the claimed method being performed as part of a multi-step finishing process.

The specification confirms that Wasinger contemplated multi-step processes. For example, after describing a preferred operation of the claimed method, the specification states "the garments or fabrics can then be further processed if desired." '510 patent, col. 3, ll. 63-64. Similarly, the examples at the end of the written description also indicate that the inventor contemplated multi-step processes. The first example, after describing a particular washing sequence, teaches that "if an even lighter color is desired the process can be repeated for 10 minutes prior to rinsing since concurrent desizing is not

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necessary. The garments can be further decolorized by subjecting them to a standard bleaching operation or by treatment with ozone." Id. col. 4, l. 67 - col. 5, l. 5. In the third example, denim jeans that have already been enzymatically desized are subjected to the method of the claimed invention. Id. col. 5, ll. 22-25. The specification thus explicitly teaches that the claimed method may be performed as one step in a multi-step finishing process.

Neither do we find support for the single-step limitation in the prosecution history. The district court relied heavily on the prosecution history to support its single-step process limitation, stating that "plaintiff disclaimed coverage of multi-step processes while prosecuting the '510 patent." The '510 patent prosecution history consists of a reply to a first office action rejecting the claims and a reply after final rejection. Claim 1 is reproduced below, indicating the amendments made during prosecution:

1. A method for simultaneously desizing and decolorizing a dyed fabric or dyed garment having a sizing and a reducible [coloring agent] dye which comprises treating said fabric or garment with an effective amount of reducing agent in an aqueous bath whereby the fabric or garment is both desized and decolorized prior to any subsequent oxidation or bleaching.

Wasinger had to overcome an obviousness rejection based primarily on U.S. Patent No. 5,199,957 to Pascoe ("Pascoe"). According to the examiner, "the method of removing sizing and dye from textiles by using a reducing agent is well known as shown by Pascoe." In his reply to the first office action rejection, Wasinger disputed the examiner's characterization of Pascoe, asserting that the dyed fabric in Pascoe is not treated with a reducing agent, and that "Pascoe operates at a high temperature and still requires the use of an oxidizing wash." To further distinguish Pascoe, Wasinger argued that "applicants operate at a different time and place of the treatment process," pointing out that "the usual practice for the garment processors . . . is to enzymatically desize the garments and then decolorize or fade the dye with a bleaching agent."

Wasinger then described certain advantages of the claimed invention, such as allowing elimination of enzymatic removal of sizing and "providing a single operation for both desizing and color fading." After addressing other references besides Pascoe, Wasinger summed up his position by stating, "The cited references all relate to the use of oxidizing agents and not reducing agents. None of the references teach simultaneously desizing and reducing the dye on the fabric." As part of this first response, Wasinger added the "dyed" limitations to the fabric and garment of claim 1; replaced the term "[coloring agent]" with "dye;" and added the "in an aqueous bath" limitation.

The second office action was made by a different examiner, who essentially repeated the arguments made by the examiner in the first office action. The second examiner summarized Wasinger's position with respect to how the claimed invention overcame prior art problems, and with respect to how one of the asserted advantages of the invention was "consolidation of [a] multiple stage process into fewer stages." The second examiner found, however, that "the claims herein still permit oxidation to be a part of the process." The second examiner concluded that "it appears that there is indeed patentable subject matter in the application since the use of the reducing agents without oxidation agent follow-up shows some advantages and an advance in the state of the art. If the claims were amended to exclude the possibility of oxidation as part of the process claimed, the claims would be looked upon favorably." This second office action rejection was made final.

In Wasinger's response after final rejection, he amended claim 1 by adding the "prior to any subsequent oxidation or bleaching" limitation. Wasinger thereby incorporated the second examiner's suggestion to "exclude the possibility of oxidation as part of the process claimed." Wasinger then emphasized again that "the invention relates to the discovery that reducing agents can be utilized in lieu of oxidizing agents to discolorize dyed fabrics [and] garments so as to provide a fashion faded effect that is generally performed with harsh oxidizing agents." Wasinger again explained the advantages of the claimed invention and stated that "it is surprising that a reducing agent, which is the complete opposite to an oxidizing agent, can provide the same effects plus other benefits." Wasinger also stated that "none of the references teach simultaneously desizing and reducing the dye of the fabric." Wasinger received a Notice of Allowability as a result of the reply after final rejection.

A fair reading of the prosecution history indicates that Wasinger disclaimed oxidization and bleaching-traditional decolorizing methods-as part of the claimed method for simultaneously desizing and decolorizing dyed fabrics. This is clear from the prosecution history and is supported by the language of the amendment made to claim 1. However, Wasinger did not disclaim or give up a multi-step process wherein the claimed method is but one step, of many, in what may be a complicated finishing process. What Wasinger gave up was oxidation as part of that one step. A potential infringer should not be able to perform the claimed method, yet avoid infringement merely by adding subsequent steps that further

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decolorize or desize the garments using traditional means such as bleaching, oxidation or mechanical steps. Wasinger's description of the advantages of the claimed method during prosecution-e.g., the ability to eliminate the use of harsh oxidizing agents-does not amount to a disclaimer of multi-step processes that do not take advantage of the advantages or benefits of the invention.

In sum, we conclude that the district court's single-step process limitation is unsupported by the claim language and the written description, and we see no disclaimer of multi-step processes in the prosecution history. Because the district court's entry of summary judgment of noninfringement was premised upon an incorrect construction of the '510 patent, the order granting summary judgment is vacated. The case is remanded to the district court for proceedings with respect to infringement based upon a claim construction that does not include the limitation of a single step process. See Scanner, 365 F.3d at 1306.

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DYK, Circuit Judge, dissenting.

The majority holds that claim 1 is limited only to the ordinary and customary meaning of "[a] method for simultaneously desizing and decolorizing a dyed fabric or dyed garment . . . prior to any subsequent oxidation or bleaching," U.S. Patent No. 5,366,510 (the "'510 patent"), col. 6, ll.1-7, and that Wasinger did not disclaim a multi-step process including a subsequent oxidation step, despite the prosecution history to the contrary. Maj. Op., ante at 7-8. Because I think that the applicants' statements in the prosecution history, coupled with those of the examiner, rise to the level of a clear disclaimer of a process including a subsequent oxidation step, I respectfully dissent.

I

"Generally speaking, we indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999)). However, "a claim term will not carry its ordinary meaning if the intrinsic evidence shows that the patentee . . . expressly disclaimed subject matter." Id. at 1366-67. "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir.), cert. denied, 516 U.S. 987, 133 L. Ed. 2d 424, 116 S. Ct. 515 (1995). While I think that the district court went too far in holding that the applicants "disclaimed coverage of [all] multi-step processes while prosecuting the '510 patent," Wasinger v. Levi Strauss & Co., 2003 U.S. Dist. LEXIS 25725, *15, No. 01-CA-1056-EP, slip op. at 9 (W.D. Tex. Mar. 31, 2003), I agree with the core of the district court's holding that there was a disclaimer in the prosecution history of multi-step processes involving subsequent oxidation steps.

A

During the prosecution of the '510 patent, the examiner first rejected all of the applicants' claims as obvious over U.S. Patent No. 5,199,957 to William M. Pascoe ("Pascoe"), in view of a dictionary and U.S. Patent Nos. 5,171,332, 5,118,322, and 4,231,890. The examiner found the claimed process to be obvious because, as claimed, "the technique may include a subsequent oxidizing agent treatment." (J.A. at 58.) In response, the applicants argued that, in the claimed process, "harsh oxidizing agents which degraded the fabric were not utilized," and they distinguished Pascoe, stating that "Pascoe . . . still requires the use of an oxidizing wash." (J.A. at 62.) The examiner then finalized the rejection, repeating that "the [claimed] technique may include a subsequent oxidizing agent treatment," and noting that the claims as amended "still permit oxidation to be a part of the process." (J.A. at 67, 69.) However, the examiner stated:

It appears that there is indeed patentable subject matter in the application since the use of the reducing agents without oxidizing agent follow-up shows some advantages and an advance in the state of the art. If the claims were amended to exclude the possibility of oxidation as part of the process claimed, the claims would be looked upon favorably.

(J.A. at 69 (emphases added).)

In response to the final rejection, the applicants made several amendments that they stated were "as per the Examiner's

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suggestion." (J.A. at 72.) First, the applicants amended claims 1, 13, and 17 by adding the phrase "prior to any subsequent oxidation or bleaching." (J.A. at 71-72.) The applicants stated that "this limitation specifically excludes the oxidation process from the claims and distinguishes the invention at issue from the cited references." (J.A. at 72.) Second, the applicants cancelled claims 9-11. Claim 9 claimed exactly what Wasinger now asserts (and what the majority now holds) that claim 1 encompasses: "The method of claim 1 wherein said fabric or garment is subsequently treated with an oxidizing agent." (J.A. at 54.)

1 The applicants stated that they "cancelled claims 9-11 because they spoke to the specific use of an oxidizing agent which the Examiner determined would read on the prior art." (J.A. at 72.) The applicants also stated: "The amended claims specifically exclude the use of any oxidizing agents. This limitation puts the claims in condition for allowance." (J.A. at 73 (emphasis added).) The examiner found the application, as amended, to be allowable.

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1 Claim 10 claimed: "The method of claim 9 wherein said oxidizing agent comprises ozone." (J.A. at 54-55.) Claim 11 claimed: "The method of claim 9 wherein said oxidizing agent comprises a chlorine bleach." (J.A. at 55.)

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Based on this history, I would hold that Wasinger disclaimed a process involving a subsequent oxidation step.

B

The majority may suggest that the disclaimer in the prosecution history is ineffective because it is not clear and unambiguous in light of the "prior to" language of claim 1, which, standing alone, seems to contemplate the use of "subsequent oxidation" steps. However, the disclaimer plainly overcomes this language in claim 1. Moreover, it appears that the applicants acted as their own lexicographers in using the "prior to" language. A "claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." CCS Fitness, 288 F.3d at 1366; see also, e.g., Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1332 (Fed. Cir. 2004). In this case, the examiner clearly required that the claims "exclude the possibility of oxidation as part of the process claimed" and that the process be performed "without oxidizing agent follow-up." (J.A. at 69.) In response to the examiner, the applicants amended the claims and asserted that the amendments were made "as per the Examiner's suggestion," representing that the added claim language was crafted to satisfy the limitations imposed by the examiner. (J.A. at 72.) The applicants thus appear to have acted as their own lexicographers, defining the added language to "exclude the possibility of oxidation as part of the process claimed." (J.A. at 69.) To hold otherwise is to give apparent sanction to an effort to mislead the Patent and Trademark Office by pretending that added claim language cures an examiner's rejection when, in fact, it was designed to have the very opposite effect. See Pall Corp. v. PTI Techs. Inc., 259 F.3d 1383, 1393 (Fed. Cir. 2001), vacated on other grounds, 535 U.S. 1109, 153 L. Ed. 2d 152, 122 S. Ct. 2324 (2002) ("The public notice function of patents requires that a patentee be prevented from expressly stating during prosecution that the claims do not cover a particular device and then later suing for infringement by that same device.").

II

The majority properly does not address the validity of its broad claim construction. During prosecution, the examiner stated that only "the use of the reducing agents without oxidizing agent follow-up" was non-obvious over Pascoe in view of the other cited references, and he rejected as obvious claims that encompassed subsequent oxidation steps. (J.A. at 69.) While neither I nor the majority expresses a view with respect to whether the examiner was correct, I note that, on remand, the district court must consider whether claim 1 as construed is invalid because it is obvious. See 35 U.S.C. § 103 (2000).
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I. Glycosylation Which Differs

The phrase "glycosylation which differs" is recited only in Claim 1 of the '933 patent and relates to Claims 2 and 9 of the

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same patent by dependency. The parties essentially agreed that glycosylation refers to the carbohydrate side chains that are attached to a molecule, in this case erythropoietin. Yet Amgen further contended that the phrase means that "the attached carbohydrate groups differ when analyzed by standard prior art techniques known as of 1983-84." Pl.'s Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. Amgen's '933 Patent Claim 1 (emphasis omitted). TKT argued that it means "the carbohydrate groups attached to side chains of the erythropoietin polypeptide backbone differ by Western blot analysis and SDS/PAGE 16 and carbohydrate composition analysis 17 from those of human urinary erythropoietin to at least the degree described in the patents-in-suit." Defs.' Markman Hr'g (Apr. 10, 2000) Demonstrative Ex. 89 (footnotes added). The primary discrepancy concerned which, if any, techniques would be specifically identified as methods encompassed under the meaning of the term "glycosylation which differs." TKT contended that the specification describes two tests by which to prove differences in glycosylation: SDS-PAGE/Western Blot and carbohydrate composition analysis. Thus, TKT's construction would require proof with respect to both types of tests and no others, whereas Amgen's construction would not limit the manner by which differences in glycosylation are proven.

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16 Sodium dodecylsulfate-polyacrylamide gel electrophoresis ("SDS-PAGE") is a widely used procedure for determining the apparent molecular weight of a particular protein or glycoprotein. The Western Blot is a technique for detecting the particular protein or glycoprotein following SDS-PAGE. SDS-PAGE techniques and their relation to glycosylation differences are discussed later. See infra Section IV.E.2, at 130-32. 17 Carbohydrate analysis reveals the ratio of specific sugars present in a glycoprotein. It is discussed in more detail later. See infra Section IV.E.2, at 134-36.

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Example 10 of the patent describes comparisons made between recombinant glycoprotein products and human urinary erythropoietin using various techniques. See Trial Ex. 1 at 28:33-67. The specification not only reports data obtained from SDS-PAGE/Western blot analysis, but also by monosaccharide, or carbohydrate, analysis. See id. Yet the claim term "glycosylation which differs" is not further limited by the methods used to identify such differences in Example 10. A comparison of Claims 1 and 2 of the '933 patent exposes the significance of the exclusion of such a limitation. Claim 2 of the '933 patent requires the EPO glycoprotein product to have "a higher molecular weight than human urinary EPO as measured by SDS-PAGE." Id. at 38:23-25 (emphasis added). Claim 1, however, merely states that the erythropoietin glycoprotein product must have "glycosylation which differs from that of human urinary erythropoietin." Id. at 38:20-21. The inference is that the patentee knew how to limit claim terms regarding differences in glycosylation by specifying the method by which such differences are empirically tested. Taking this into account, the Court was loath to mandate that proof of glycosylation differences must be shown using the particular types of tests specifically identified in the patent. As a result, the Court avoided mandatory language, but nonetheless ruled that "glycosylation which differs" means: "Glycosylation as to which there is a detectable difference based upon what was known in 1983-1984 from that of human urinary erythropoietin, having in mind that the patent holder, Amgen, taught the use of this Western blot, SDS-PAGE and monosaccharide test." Tr. of Markman Hr'g, Vol. III at 102:18-23.
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4. "DNA sequences which hybridize to any of the foregoing DNA inserts"

This claim language contains two distinct claim terms which must be analyzed: a) "DNA inserts" and b) "hybridize." The Court will consider each of these claim terms in turn.

a. "DNA Inserts"

Both parties agree that the "DNA inserts" refer to the inserts contained within the E. coli bacterial cells deposited with the Deutsche Sammlung von Mikroorganismen ("DSM") in Germany. Amgen further seeks to establish that: 1) the inserts refer to the discrete sequences that are released from the deposited plasmids by using a restriction enzyme to cut the DNA insert and 2) the inserts are all derived from the same interferon gene. Schering asserts these added limitations are not part of the definition of "DNA inserts" and it is improper to read such limitations into the claim terms from the examples in the specification and from deposition testimony.

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The Court agrees with the parties that the DNA inserts are clearly set out in the '901 Patent. Claim 1 reads in pertinent part:

A recombinant DNA molecule . . . comprising a DNA sequence selected from the group consisting of:

(a) the DNA inserts of [Z-pBR322(Pst)/HcIF-4c (DSM 1699,] 20 Z-pBR322(Pst)/HcIF-2h (DSM 1700), Z-pBR322 (Pst)/HcIF-SN35 (DSM 1701), Z-pBR322(Pst)/HcIF-Sn42 (DSM 1702) and Z-pKT287(Pst)/HcIF-2h-AH6 (DSM 1703),

(b) DNA sequences which hybridize to any of the foregoing DNA inserts . . . .

Col. 36, lines 4-15. Although the DNA inserts described include the designation "(Pst)" to refer to the restriction site where the plasmid was cut, 21 the claim language limits what is claimed to the "DNA inserts" of the recombinant DNA molecule. Importantly, the restriction enzyme, the plasmid, and the bacterial host in which the isolated DNA sequences are found, are not part of the '901 invention.

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20 The DSM 1699 DNA insert only appears in claims 5 and 8. Schering was unable at oral argument to explain this difference in the claims.21 The letters and number before the (Pst) designation refer to the plasmid being utilized from the E. coli bacteria, i.e., pBR322. The "Z-" designation before the plasmid refers to the fact that the plasmid was derived in Zurich, Switzerland. The letters and numbers after the slash ("/") refer to the DNA inserted into the plasmid, i.e., HcIF-2. Finally, the DSM number is the designation given to the organism by the public depository in Germany.

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Further, there is no hint in either the claim or the specification that the DNA inserts are, or must be, derived from the same interferon gene. Although this might have turned out to be the case, as illustrated by subsequent deposition testimony, such information was not known to anyone at the time the patent application was filed in January of 1980. Because the Court must construe claim language according to the meaning a person of ordinary skill in the art would ascribe to it at the time of the patent application, see Weiner, 102 F.3d at 539, it cannot conclude as part of the "DNA insert" definition that all DNA inserts had to be derived from the same interferon gene, as such knowledge was lacking in the relevant scientific community at the time of the '901 Patent application. The Court therefore finds that the claim term "DNA inserts" refers to those DNA inserts deposited at the DSM and explicitly set out in the claim language of the '901 Patent.

b. "hybridize"

Both parties agree that hybridization includes the process by which one strand of DNA or RNA binds and forms a double-stranded structure with a complementary strand of RNA or DNA. See supra note 7. Specifically, hybridization was used in this invention to identify DNA segments structurally similar to both RNA segments and DNA segments found to code on expression for proteins with the anti-viral characteristics of interferon. The parties also agree that hybridization between two complementary strands is affected by such factors as time of exposure, temperature, salt concentration, and the degree of homology (amount of complementary nucleotides) between the two segments. Although the parties do not dispute that the selection of hybridization conditions is critical to the performance of the hybridization, the parties cannot agree what specific hybridization conditions are required by the claim. Schering argues that the conditions must be as stringent or more stringent than the conditions used by Dr. Weissmann in performing the hybridizations described in the patent specification. 22 Amgen, on the other hand, contends the particular hybridization conditions disclosed in the specification must be used.

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22 Conditions may be as stringent as those described in the specification, without being the exact same conditions, by varying the variables involved in the hybridization, e.g., the salt concentration and the temperature, in such a manner as to produce equivalent or more stringent hybridization conditions.

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Starting with the language of the patent itself, "hybridize" is not defined in the claim, nor is it defined in the specification. Specific conditions for the hybridization, however, are recited in the specification, see Col. 26, line 28 through Col. 27, line 2. Nevertheless, it is improper claim construction to import specification language into the claims. See Intervet Am., 887 F.2d at 1053. While claims are to be interpreted in light of the specification, it does not follow that extraneous limitations from the specification may be read into the claims. See CVI/Beta Ventures, 112 F.3d at 1158 (citing Sjolund v. Musland, 847 F.2d 1573, 1581 (Fed.Cir.1988)). As a result, the Court cannot agree with Amgen that the particular hybridization conditions disclosed in the specification are all that is covered by the '901 Patent. 23

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23 Regardless, the specification does not support Amgen's 87% homology figure for DNA-DNA hybridizations as that figure only applies to DNA-RNA hybridizations, which was performed at a different stage of the invention. See Col. 19, lines 7-13. Significantly, no minimum homology figure is established for DNA-DNA hybridizations. See Col. 26, lines 28-67.

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Although the specification may not be properly used to add extraneous limitations to a claim, a limitation is not extraneous when there is a need to interpret what the patentee meant by a particular ambiguous word or phrase in the claim. See E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.), cert. denied, 488 U.S. 986, 102 L. Ed. 2d 572, 109 S. Ct. 542 (1988). Such is the case here because both parties agree that the selection of hybridization conditions, such as time, temperature, salt concentration, and structural homology, is essential to the performance of the hybridization and to the overall invention. As the specification is the single best guide to the meaning and scope of the claims, see Vitronics, 90 F.3d at 1582, the Court therefore finds the claim term "hybridize" necessarily includes conditions at least as stringent as those set forth in the specification. Additionally, as more stringent conditions necessarily subsume less stringent hybridization conditions, such conditions are also properly within the patent. The Court therefore holds the claim language "DNA sequences which hybridize to" refers to hybridization of other DNA to DNA inserts deposited at the DSM, under conditions as stringent or more stringent than those that exist in the specification.

Accordingly, combining the above two constructed phrases, the claim language "DNA sequences which hybridize to any of the foregoing DNA inserts" refers to DNA segments, which under conditions as least as stringent as those set forth in the specification of the '901 Patent, are able to bind and form a double-stranded structure with those DNA inserts specified in the patent and deposited at the DSM.
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10. Product-by-process claims. As an initial matter, Thermo argues that claims 4 and 5 of the '161 patent are product-by-process claims that incorporate the "process steps" disclosed in claim 1. Thermo contends that the claim language supports this argument. According to Thermo, claim 4, which incorporates the limitations of claim 1, requires that the dextran hydrogel disclosed be formed through a two-step progression: first, the dextran "is bound to a surface," and then the bound dextran "is activated to contain" both charged and reactive groups. (D.I. 115 at 3-7) Thermo argues that such a construction is consistent with the specification, which broadly describes first attaching dextran to the surface and then activating the bound dextran for purposes of binding ligands. (PX 1, col. 6, lns. 43-47; see also PX 1, col. 9, lns. 45, 51, 54-56) Relying on the Federal Circuits's decision in Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 846-47 (Fed. Cir. 1992), Thermo contends that these process terms serve as limitations that must be proven in order to find infringement.

11. The product - product-by-process claim dichotomy is not absolute or clear cut in application. Product-by-process claims are characterized as being devoid of significant structural description of the final article, instead relying, at least in part, on a description of "the process used to obtain [the claimed invention]" to define it. Mentor Corp. v. Coloplast, Inc., 998 F.2d 992, 997 (Fed. Cir. 1993). By contrast, in product claims the article is defined in terms of structural characteristics only. The mere use in a claim of structural or characterizing terms derived from processes or methods, however, does not prevent a claim from being considered a true product claim. See Application of Hughes, 496 F.2d 1216, 1219 (C.C.P.A. 1974); In Application of Garnero, 56 C.C.P.A. 1289, 412 F.2d 276, 279 (C.C.P.A. 1969). Nor does the use of a process limitation convert a pure product claim to a product-by-process claim. See Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570

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(Fed. Cir. 1983). Typically, it is the wording of the claim which indicates that it is a product-by-process claim. For example, product-by-process claims employ terms such as "prepared in accordance with," "by the process of," whereby," "product of the process," "resulting from the process of," and "being produced by the process comprising." See, e.g., In re Thorpe, 777 F.2d 695, 696 (Fed. Cir. 1985); In re Fessmann, 489 F.2d 742, 180 U.S.P.Q. 324, 324 (C.C.P.A. 1974); Application of Hughes, 496 F.2d 1216, 1217 (C.C.P.A. 1974); Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1385 (N.D. Cal. 1987); Johnson & Johnson v. W.L. Gore & Assoc., Inc., 436 F. Supp. 704, 709 (D. Del. 1977); Ex parte Edwards, 231 U.S.P.Q. 981, 982 (P.T.O. 1986).

12. Consistent with the above, the court concludes that the claims at issue are not product-by-process claims. Claim 1 of the '161 patent contains none of the wording traditionally associated with product-by process claims. (P 37) 42 Despite Thermo's contentions to the contrary, the phrases "which is bound" and "activated to contain" reflect structural limitations not the process by which the claimed invention is obtained. Nor is there anything in the record to indicate that Biacore distinguished the claimed invention from the prior art based on the novelty of the invention's process. Accordingly, claims 4 and 5, which depend in part from claim 1, are best characterized as pure product claims since the disclosed invention is described by its structure rather than how it is made. As such, claims 4 and 5 may encompass identical products formed by different processes.

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42 The indicated paragraphs refer to Part II, Findings of Fact.

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[EDITOR'S NOTE. The text of the relevant claim does not appear in the case, but it reads as follows:

1. A method of effectively treating pain in humans, comprising orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which upon administration provides a time to maximum plasma concentration (T.sub.max) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (C.sub.max) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.]

B. Claim Construction of the '360 Patent

In arguing that the once-a-day administration of Kadian does not infringe the '360 Patent, Faulding raises two claim construction issues: (1) whether the claims of the '360 Patent require only the administration of a drug that produces the specified pharmacokinetic ("PK") results on average and (2) the meaning of the phrase "effective treatment of pain." Other than these two issues, the parties do not dispute the meaning of the claims. As to the remainder of the claims, the Court finds that interpretation beyond the plain and ordinary meaning of the language of the claims is unnecessary.

1. Whether the claims of the '360 Patent require only administration of a drug that produces the specified pharmacokinetic results on average

Faulding's argument that the claims of the '360 Patent require only administration of a drug that produces the specified pharmacokinetic results on average pertains to an overall reading of the claims in issue and is not directed to any specific term or phrase used in the language of the claims. According to Faulding, Purdue's experts admitted that the specification of the '360 Patent only sets forth average data, and does not contain, refer to, or mention individual patient data. (DTX 3; Tr. 139, 1231). Based on the data provided in the specification of the '360 Patent, Faulding contends that the claims cover a formulation that "on average" produces the claimed PK results of C[max]/C[24]>2 and T[max] from about 2 to about 8 or 10 hours.

In opposition to Faulding's proposed claim construction, Purdue contends that the asserted claims of the '360 patent are

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directed to methods for treating individual patients. According to Purdue, Faulding's interpretation ignores the plain language of the claims and is an attempt to over-emphasize the significance of the prior art Morella patents, which Faulding raises in the context of its obviousness and anticipation defenses.

The starting point for a claim construction analysis is the language of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). While the court may consider the patent specification and prosecution history as relevant intrinsic evidence in its analysis, the court need not accord this evidence the same weight as the claims themselves. CCPI v. American Premier, Inc., 966 F. Supp. 276, 278 (D. Del. 1997). Rather, "the claim language itself is of paramount importance," and therefore the specification, prosecution history and other relevant evidence need only be consulted to give the necessary context to the claim language. Id. Thus, the specification may assist in determining the meaning of a claim, but it may not be used to impose limitations on a claim not found in the words of the claim, itself. Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994). Courts do not rewrite claims; they merely interpret them. Intervet America, Inc. v. Kee-Vet Labs, Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989).

In this case, the claim language does not include the words "average" or "mean" as modifiers of the specified PK claim requirements. Indeed, the words "average" or "mean" do not appear at all in the asserted claims. To the contrary, the claims explicitly state that the treatment methods are accomplished by administering a sustained-release oral, opioid dosage form to "a human patient" and achieving the specified PK and efficacy results in "the patient." The Court finds that such phrases, taken in their ordinary and plain meaning, unambiguously refer to an individual patient, rather than patients on average. (PTX 1, claims 2, 4, 11). Had Purdue wanted to obtain patent claims directed to treatment methods achieving the claimed PK elements on average, Purdue undoubtedly could have written the claims to include the "average" or "mean" language.

Further, consideration of the specification of the '360 Patent does not alter the Court's finding that the claims relate to individual patients. Like the claims of the patent, the specification is devoid of any reference to "average" results. In fact, the specification refers to individual patients at least 22 times, including the discussion of such concepts as providing the proper doses of opioid medication to meet the needs of "each individual patient" (PTX 1, col. 1, line 57), assessing "the patient's" PK response to the opioid treatment (PTX 1, col. 2, lines 22-29), and assessing the pain relief "achieved in a given patient." (PTX 1, col. 4. lines 38-43). In this regard, the Court finds the specification to be consistent with the plain and unambiguous language of the claims.

Faulding contends that the word "average" should be read into the claims because the Examples in the specification of the '360 Patent include average PK data. The Court finds Faulding's contention both factually and legally unsupportable. First, the plain language of the '360 Patent prefaces the Examples with the following cautionary statements: "The following examples illustrate various aspects of the present invention. They are not to be construed to limit the claims in any manner whatsoever." (PTX 1, col. 14, lines 57-60). Second, as Purdue's technical expert Dr. Lipman testified, the average results presented in the examples are a convenient and accepted way to summarize the results of clinical studies, and as such serve only to "illustrate" the desired PK results that are to be achieved in individual patients. (Tr. 260:21-22). Lastly, as a legal matter, .the Court may not use the' Examples in the specification to limit the scope of the claims. Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir.), cert. denied, 488 U.S. 892, 102 L. Ed. 2d 218, 109 S. Ct. 228 (1988); Elf Atochem North America, Inc. v. Libbey-Owens-Ford Co., Inc., 894 F. Supp. 844, 859 (D. Del. 1995). Accordingly, the Court cannot accept the claim construction urged by Faulding. Faulding's construction is an impermissible limitation on the claims. Based on the plain and unambiguous language of the clams and the context provided by the '360 Patent specification, the Court finds that the proper construction of the '360 Patent refers to individual patients.
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A. "while the amplification reaction is in progress" Applera asks the court to construe this language to mean "during the amplification reaction," which would include either periodic or constant monitoring. Stratagene argues that the term should be construed to mean "for so long as the amplification reaction is taking place," which would require that the instrument be operable to conduct constant monitoring, even if the user wanted to monitor fluorescence only periodically. In the alternative, in its post-hearing brief, Stratagene asks the court to interpret the term to require that the instrument be operable to conduct intra-cycle monitoring.

The claim language itself provides insufficient guidance for resolving the parties' dispute. Both parties' interpretations are

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consistent with the plain meaning of the words. Accordingly, I consult the specification, which is "the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The specification does not exclude either parties' interpretation, although Applera's flows more naturally from the specification. As Stratagene notes, the specification contains references to constant monitoring. For example, it teaches that "the continuous detection of fluorescence throughout the amplification provides an amplification profile that reflects the amount of target present at start." (Col. 24, lns. 9-12.) However, as Applera observes, there are also references to periodic monitoring. For instance, the specification teaches, "It is appropriate to 'read' the microtiter plate before and after thermocycling for determining fluorescence." (Col. 12, lns. 36-39.) Similarly, it states, "Because fluorescence can be determined between cycles during the course of a PCR . . . . Monitoring fluorescence while PCR is in progress serves to quantitate small amounts of DNA." (Col. 16, lns. 22-24, 29-32.) This latter quotation is particularly significant because it ties periodic detection to the phrase "while PCR is in progress."

Stratagene argues that the specification's references to continuous monitoring reflect the inventor's understanding that the instrument had to be operable to detect constantly, even if it was only used to conduct periodic monitoring. Although the specification does not exclude this reading, it certainly does not require it either. A more natural reading of the specification is that the inventor did not consider whether the detector had to be operable to conduct constant monitoring. Under this reading, the detector merely has to be operable to detect the fluorescence signal, whether constantly or periodically, so long as the detection occurs during the amplification reaction. This reading is preferable, particularly given the explicit reference to inter-cycle detection as occurring "while PCR is in progress."

Because the specification does not provide clear guidance, I turn to the prosecution history. The parties discussed the prosecution history at length during the Markman hearing. The discussion centered on the examiner's rejections of the patent as obvious in light of the Haff reference and the inventor's subsequent amendments to the claim.

I understand the Haff instrument to work as follows. Identical amounts of the same target DNA are placed in different reaction vessels. Identical reactions are run within each vessel. The reactions are stopped after various reaction cycles. After a reaction is stopped, the vessel is opened and dye is added. The fluorescence is measured and plotted on a graph. By this process, one can track the amplification reaction for that target piece of DNA. In first rejecting the invention as obvious in light of Haff, the examiner understood Haff to involve monitoring "during the thermal cycling process." (Bio-Rad Ex. 1, at 190.) The Examiner explained that it would be obvious to one trained in the art to optically couple the fluorescence detector to the thermal cycler to measure fluorescence without transferring samples from the cycler to the detector. (Bio-Rad Ex. 1, at 191.)

In response to the obviousness rejection, the inventor explained:

> With applicant's invention, the amplification takes place and is detected in a sealed vessel condition. During amplification, a real-time signal indicative of a cycle-dependent change in double-stranded nucleic acid is generated to allow monitoring of the accumulation of double-stranded product while the amplification reaction is in progress, without opening the reaction vessel, without taking aliquots, and without withdrawing samples. Once the amplification reaction is initiated, no further handling or manipulative steps are required.
>
> . . . .
>
> . . . Also, by generating a signal that not only gives an indication of the inter-cycle net change of double-stranded product but intra-cycle variations as well, applicant's claimed instrument eliminates any ambiguities regarding the time of sampling. The signal generated by applicant's claimed invention is independent of the time of sampling.

(Bio-Rad Ex. 1, at 204-05.) The Examiner nonetheless rejected the claims, finding these arguments "directed solely to the intended use of the apparatus, rather than the structural features thereof." (Bio-Rad Ex. 1, at 212.) He also stated that it would have been obvious to use sealed reaction vessels to prevent contamination. (Bio-Rad Ex. 1, at 212.)

In response, the inventor explained that "Haff et al. failed to recognize that an indicator reagent could be included in a nucleic acid reaction mixture to allow amplification to be measured over multiple cycles without opening the reaction

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vessel." (Bio-Rad Ex. 1, at 249.) The Examiner again rejected this explanation, citing other prior art (i.e., Schnipelsky) showing that detection reagents would not interfere with the reaction. (Bio-Rad Ex. 1, at 276.)

Following these communications, the Examiner and inventor had a personal interview. After the interview, the Examiner wrote, "It was generally agreed that structural language requiring operation of the detector over the course of a thermal cycling amplification reaction would define over the art of record." (Bio-Rad Ex. 1, at 302.) Thereafter, the applicant filed an amended claim containing the language, "while the amplification reaction is in progress." He remarked, "During the interview, applicant's representatives summarized prior arguments. The Examiner agreed that the rejection over the art of record would be withdrawn if the claims more clearly recited that the detector was operable to detect during the amplification reaction, in contrast to a detector that was not operable during an amplification reaction." (Bio-Rad Ex. 1, at 317.)

After reviewing the prosecution history in detail, and focusing on the claimed apparatus, as Stratagene urges me to do, I find the prosecution history too ambiguous to support Stratagene's narrower construction.

The claimed invention is distinguishable from Haff in that the dye is present in the reaction mixture as amplification takes place and the fluorescence can be measured without opening the vessels to withdraw samples or to inject dye. As the inventor explained in 2000, one benefit of his invention is that it can generate a intra-cycle signal, whereas Haff's plainly cannot. Until 2002, the Examiner consistently rejected these differences between Haff and the invention and held the claimed invention obvious in light of Haff and other references.

We do not know exactly what happened in the 2002 interview. According to Stratagene, the Examiner concluded that a key distinction between the claimed invention and Haff was that Haff could constantly detect fluorescence "over the course of a thermal cycling amplification reaction." On this view, "while the amplification reaction is in progress" must be construed to embody the inventor's and the Examiner's understanding that the claimed invention was structurally operable to detect constantly throughout the entire reaction or, in the alternative, within cycles as opposed to only between cycles.

However, Applera's version of what happened at that meeting is equally, if not more, plausible. According to Applera, the personal interview persuaded the Examiner that Haff did not teach detection "during" the amplification reaction, as he had earlier thought. Accordingly, he agreed to withdraw the objections if it was made clearer that the claimed instrument was operable to detect fluorescence during the reaction. This interpretation is supported by the inventor's statement that his representatives summarized prior arguments. Importantly, he did not state that they presented new arguments or distinguished his invention on the ground that it was operable to constantly monitor fluorescence. On the basis of the prior arguments, the Examiner agreed to withdraw the objections in exchange for clearer structural language requiring that the detector be operable to detect during the reaction.

The prosecution history is simply too ambiguous to support the narrower construction proposed by Stratagene. This ambiguity manifests itself in the varying language used by the Examiner and the inventor. In his record of the interview, the Examiner used the language "over the course of the thermal cycling amplification reaction." However, the inventor summarized that same conversation using the word "during." Moreover, in a later document, the Examiner contrasted the invention, which would detect "throughout" the amplification reaction, with an instrument that limited "detection to a time immediately following the amplification reaction." (Bio-Rad Ex. 1, at 438.) This suggests that the Examiner understood "throughout" to mean something like "during."

This analysis reconfirms what I said during the Markman hearing. This is an imperfect process. The fact that we have to speculate about what the Examiner and the inventor had in mind underscores the ambiguity of the prosecution history. Given these ambiguities, and given that Stratagene's narrow construction is not compelled by the intrinsic evidence, I find it appropriate to focus on the plaintiff's statements in deciding whether he limited his claim in the way urged by Stratagene. I cannot conclude that he did.

For these same reasons, I reject Stratagene's alternative argument that the detector must be operable to detect within cycles. The inventor did describe his invention as "generating a signal that not only gives an indication of the inter-cycle net change of double-stranded product but intra-cycle variations as well." (Bio-Rad Ex. 1, at 204-05.) But he characterized this as an "advantage" of his system, not as a "structural and functional difference[]." (Bio-Rad Ex. 1, at 204.) This advantage derives from the structural difference that, in the claimed invention, the detectable nucleic acid binding agent is present in the

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reaction vessel as the reaction takes place. A detector operable to detect intra-cycle variations could be used to take advantage of this structural difference. But this statement does not necessarily mean that the detector must be operable to detect intra-cycle variations, particularly in light of the specification's references to inter-cycle monitoring.

The limited scope sought by Stratagene is not required by the intrinsic evidence. Accordingly, I construe "while the amplification reaction is in progress" to mean "during the amplification reaction."
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A. Whole glucan

Variations of the words "whole glucan" appear in several claims of the patents-in-suit. The Court considers the variations.
1. '540 Patent and '972 Patent

"Whole glucan particles" and "whole [beta] - glucan particles" appear in several asserted claims of the '540 Patent and the '972 Patent. 1 For example, claim 1 of the '540 Patent claims "[w]hole glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology." Claim 2 of the '540 Patent claims "[w]hole glucan particles of claim 1 isolated from yeast cells." Claim 1 of the '972 Patent claims "[a] food formulation containing a glucan comprising whole [beta] - glucan particles isolated from glucan-containing cell walls and substantially retaining the in vivo glucan morphology." Claim 2 of the '972 Patent claims "[t]he food formulation of claim 1 wherein the whole glucan particles are isolated from yeast cells."

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1 The '972 Patent issued from a divisional application based on the application that resulted in the '540 Patent; their specifications are essentially the same.

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Plaintiffs assert that the Court should construe "whole glucan particles" and "whole [beta] - glucan particles" as "a glucan derived from yeast that retains the intact cell wall structure from the yeast cell in vivo." Immunocorp and Biotec agree with Plaintiffs' proposed construction. Immudyne proposes the following construction of "whole glucan particles substantially retaining the in vivo glucan morphology" and similar phrases: "a hollow beta-glucan particle that consists entirely of an intact, undisrupted, whole yeast cell wall and that substantially retains the in vivo, three dimensional morphology of the yeast cell." The parties essentially agree that the patentee acted as a lexicographer. See id. at 1315-16.

The Court declines to limit "whole glucan particles" or "whole [beta] - glucan particles" to glucan derived from yeast. Neither the '540 Patent nor the '972 Patent supports the limitation. For example, claim 2 of the '540 Patent, quoted above, reveals that whole glucan particles do not necessarily come from yeast cells. See id. at 1314-15. Claim 2 of the '972 Patent, also quoted above, does the same. See id. Moreover, the patents' specifications state that "[w]hole glucan particles may be obtained from any glucan-containing source, including yeast or other fungi." '540 Patent, col. 2, ll. 21-23; '972 Patent, col. 2, ll. 20-22.

With regard to "whole glucan particles," the patents' specifications state: "In one embodiment of the present invention, there is provided a glucan derived from yeast which retains the intact cell wall structure of the yeast cell in vivo. Glucan particles having these properties [are] referred to as 'whole glucan particles.'" '540 Patent, col. 2, ll. 13-17; '972 Patent, col. 2, ll. 12-16. The specifications also describe whole glucan particles as the result of an extraction and purification process:

The process described below for producing the glucan particles can be separated into two steps. The first step involves the extraction and purification of the alkali- insoluble whole glucan particles from the yeast or fungal cell walls. This process yields a product which maintains the morphological and structural properties of the glucan as found in vivo and will be referred to as a whole glucan, or whole glucan particles.

'540 Patent, col. 3, ll. 20-27; '972 Patent, col. 3, ll. 18-25. Consistent with the claim language and the specification, the Court construes "whole glucan particles" and "whole [beta] -glucan particles" in the '540 Patent and the '972 Patent as "a

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glucan derived from a glucan-containing cell that retains the intact cell wall structure of the cell in vivo."
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3. '731 Patent

The terms "whole [beta] - glucan" and "whole yeast [beta] -glucan" appear in asserted claims of the '731 Patent. For instance, claim 1 states: "A dietary supplement for administration to mammals comprising an amount of whole [beta] -glucan sufficient to increase high density lipoprotein cholesterol level in said mammal." Claim 9 is: "A method of providing a source of fiber in a diet of a mammal comprising administering to the subject an amount of whole yeast [beta] -glucan sufficient to increase high density lipoprotein cholesterol level in the mammal." Plaintiffs propose the following construction of whole [beta] -glucan:

Glucans which maintain the intact, three dimensional in vivo morphology of the cells from which they were derived. Whole beta glucans are obtained from the cell walls of glucan containing organisms using a purification process, which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

Immunocorp and Biotec offer this construction: "Glucan particles from whole yeast or fungal cells wherein the walls of the cells are intact and maintain a spherical, elliptical or rod shape characteristic of the beta glucan in the cell wall of a living cell."

Plaintiffs assert that the patentee acted as a lexicographer. The Court agrees. The '731 Patent's specification states:

"Whole [beta] -glucans" are glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived. Whole [beta] -glucans (also referred to herein as "whole glucans") are obtained from the cell walls of glucan-containing organisms using a purification process which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

'731 Patent, col. 3, l. 66 to col. 4, l. 5. The Court declines to import the process of obtaining whole [beta] - glucans or the "spherical, elliptical or rod shape" limitation into the construction of whole [beta] -glucans. Accordingly, in the '731 Patent, the Court construes "whole [beta]-glucans" as "glucans which maintain the intact, three-dimensional in vivo morphology of the cells from which they are derived" and "whole yeast [beta]-glucans" as "glucans which maintain the intact, three-dimensional in vivo morphology of the yeast cells from which they are derived."
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d. "whole glycosylated"

Genentech contends that the phrases "whole glycosylated recombinant human chimeric or CDR grafted or bispecific antibody" of the '403-P patent (Claim 1) and "whole glycosylated recombinant human, chimeric, CDR-grafted or bispecific antibody" of the '405 patent (Claim 1) describe an antibody that exhibits complete glycosylation in that its carbohydrate chain terminates with the appropriate galactose sugar. Genentech argues that the plain meaning of the phrase requires that "whole" modify "glycosylated," and that use of "whole" as an adverb is grammatically correct. Genentech explains that the specification indicates the importance of having glycosylation in the correct configuration for maintaining all of the antibody's binding properties.

Glaxo argues in response that "whole" modifies "antibody," and if "whole" had been intended to modify "glycosylated," the phrase would have read "wholly glycosylated." Glaxo further argues that the specification does not support Genentech's proposed construction.

In support of its construction, Genentech points to a pending interference proceeding where Glaxo explained that "the adjective 'whole' modifies 'glycosylated . . antibody' and conveys the meaning of an antibody having both constant (Fc) and

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variable regions (Fab) regions which is glycosylated on the Fc region as opposed to being glycosylated solely on the Fab thereof." Genentech contends that this statement shows that "whole" modifies "glycosylated." The court, however, finds that this statement supports Glaxo's construction. The statement labels "whole" as an adjective, not an adverb as advocated by Genentech. Moreover, the statement explains that the phrase "whole glycosylated . . . antibody" conveys the meaning of an antibody having all necessary regions. That is, it conveys a whole antibody.

After reviewing the parties' proposed constructions, the court concludes that the term "whole" should be construed according to its plain meaning to describe "antibody," and not "glycosylation." As a result, the phrases "whole glycosylated recombinant human, chimeric or CDR-grafted or bispecific antibody" of the '403-P patent and "whole glycosylated recombinant human, chimeric, CDR-grafted or bispecific antibody" of the '405 patent describe a whole recombinant human, chimeric, CDR-grafted or bispecific antibody that is glycosylated.
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2. '094 Patent

"Whole yeast [beta] -glucan" appears in several asserted claims of the '094 Patent. For instance, claim 1 states: "A method of providing a source of fiber in the diet of a mammal comprising administering to the mammal an amount of whole yeast [beta] -glucan sufficient to aid digestion, reduce dehydration or reduce the serum cholesterol level in the mammal." Plaintiffs offer the following construction:

Glucans which maintain the intact, the three dimensional in vivo morphology of the yeast cells from which they are derived. Whole beta glucans are obtained from yeast cell walls using a purification process which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

Immunocorp and Biotec propose this construction: "Glucan particles from whole yeast cells wherein the walls of the cells are intact and maintain a spherical, elliptical or rod shape characteristic of the beta glucan in the cell wall of a living cell." Immudyne offers the same construction that it proposed in connection with the terms "whole glucan particles" and "whole [beta] -glucan particles" in the '540 Patent and the '972 Patent.

Plaintiffs assert that the patentee acted as a lexicographer. The Court agrees. Plaintiffs rely on the following passage from the '094 Patent's specification:

"Whole [beta] -glucans" are glucans which maintain the intact, the three-dimensional in vivo morphology of the yeast cells from which they are derived. Whole [beta] -glucans are obtained from yeast cell walls using [a] purification process which does not disrupt the integrity of the cell walls in the process of extracting the non-glucan components.

'094 Patent, col. 3, ll. 8-14. The Court declines to import the method of obtaining whole [beta] -glucans into the construction of whole yeast [beta] -glucans. See Phillips, 415 F.3d at 1323-24. The Court also declines to import other limitations from the specification identified by the parties. See id.; Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1308 (Fed. Cir. 2003) ("[V]aried use of a disputed term in the written description attests to the breadth of a term rather than providing a limiting definition."). Accordingly, the Court construes "whole yeast [beta]-glucan" in the '094 Patent as "glucans which maintain the intact, the three-dimensional in vivo morphology of the yeast cells from which they are derived."
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3. "with diminished incidence(s) of nausea and emesis"

The parties agree that the meaning of the term "incidence" should include "frequency" of an occurrence or event. (Chart). They disagree, however, whether it should include "degree" or "level." (See id.).

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The claims that contain this limitation are unilluminating. See, e.g., '171 patent, claims 20, 22-23. Therefore, the Court begins by looking at the specification. Both parties refer to the same passage in the specification to support their construction:

The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

'171 patent, col. 2, lines 45-62 (emphasis added).

Both parties agree that the reference to "level," as used in the above passage, connotes degree. They disagree, however, on what affect, if any, that has on the meaning of "incidence." Teva contends that the passage above distinguishes between "level," i.e., degree, and "incidence," i.e., frequency. Teva further points out that the claims do not use level or degree; rather, they only refer to "incidence." Wyeth contends that the passage equates "incidence" with "level," thereby broadening the meaning of the term to include degree. Wyeth also juxtaposes the above passage with an excerpt that appears earlier in the specification:

With the plural daily dosing regimen, the most common side effect is nausea, experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride. Vomiting also occurs in about seventeen percent of the patients.

'171 patent, col. 2, lines 7-11 (emphasis added). Wyeth asserts that this passage demonstrates that when the patentees meant to refer to the number of patients experiencing a side effect, they did so by stating that they were "experienced by" or "occurs in" a certain "percent" of patients. Significantly, according to Wyeth, the patentees did not equate percent with "incidence." Thus, Wyeth asserts "incidence" is broader than frequency.

Wyeth's argument is inapt. Simply because the patentees did not use the word "incidence" in the earlier passage does not by itself redefine "incidence." Rather, that passage makes clear that the patentees were concerned with the number of patients experiencing side effects, not necessarily the severity of those side effects. Moreover, the abstract states that the invention "provides a lower incidence of nausea and vomiting than the conventional tablets." '171 patent, Abstract (emphasis added). Because the only discussion of the conventional tablets in the specification that is relevant to the term "incidence" concerns the percent of patients that experienced side effects, the abstract supports a narrow construction.

Ultimately, Teva appears to be correct that the patentees drew a distinction between "level" and "incidence." Although the specification refers to both terms, the claims only recite "incidence." If indeed "incidence" meant the same thing as "level," or was broader, it begs the question why the word "level" was used in the first place. The reason must be because the patentees meant to differentiate between the two terms. It is clear from the specification that when the patentees wanted to refer to "incidence," they did. Thus, the term "incidence" will be limited to its ordinary meaning as informed by the specification.

Lastly, it is worth noting that "the fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." Liebel-Flarsheim, 358 F.3d at 908. Thus, the fact that the patents may discuss a reduced "level" and "incidence" of nausea does not require that claims using the word "incidence" encompass both benefits. In addition, the "incidence" limitation is not present in all of the asserted claims. See, e.g., '171 patent, claims 21, 24-25; '958 patent, claims 2, 5-6. Therefore, to the extent that Wyeth suggests that a narrow construction of this term unjustifiably excludes one of the primary benefits of the invention, namely the reduction in degree of side effects, that is not the case for all asserted claims. The asserted claims that do not contain the "incidence" limitation are obviously broader and would read on such benefits.

Furthermore, to the extent that Wyeth relies on extrinsic evidence to support its broad construction, the Court does not find that evidence particularly helpful. The specification draws a clear distinction between "incidence" and "level." General

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dictionary definitions that allegedly support a broader construction ignore the context within which the patents use the term. See, e.g., Concise Oxford Dict. of Current English 614 (5th ed. 1964) (defining "incidence" as "range, scope, extent, of influence"). The Federal Circuit in Phillips warned of relying on such definitions:"Heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." Phillips, 415 F.3d at 1321. In any event, other dictionaries define the term as limited to frequency. See Webster's Third New Int'l Dict. (Unabridged) 1142 (2002) (defining "incidence" as "rate, range, or amount of occurrence or influence . . . sometimes: the rate of occurrence of new cases of a particular disease in a population being studied") (emphasis in original); Taber's Cyclopedic Med. Dict. 1077 (19th ed. 2001) (defining "incidence" as "the frequency of new cases of a disease or condition in a specific population or group"). These dictionaries provide a common meaning that is more fitting given the distinction the specification draws between "incidence" and "level."

Wyeth's experts' opinions, which remove the term "incidence" from its proper context, are also given no weight. See Phillips, 415 at 1318 (stating that a court "should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent'") (quoting Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998)). Further, these experts' opinions are countered by Teva's experts, who opine that the common meaning of "incidence" is consistent with only frequency. See Schoenfeld Expert Report P 9; Morrow Expert Report P 11.

Accordingly, the Court finds that "with diminished incidence(s) of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."
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E. Without a prior disruption step

"Without a prior disruption step" appears in claim 10 of the '540 Patent, which states: "A process for preparing whole glucan particles having substantially the in vivo glucan morphology, comprising extracting alkali-soluble components from glucan-containing cell[] walls without a prior disruption step for said cell walls to thereby produce whole glucan particles retaining the in vivo glucan morphology." Plaintiffs construe the term as "without a procedure that substantially modifies the cell wall structure of the yeast cell in vivo." Immunocorp and Biotec offer this construction: "Prior to extracting alkali- insoluble components from glucan- containing cell walls, no other step is performed that would rupture the intact three dimensional structure, typically spherical, of the whole glucan particles." Immudyne construes "without a prior disruption step . . . to thereby produce the in vivo glucan morphology" as "without a process of any kind that would disrupt the intact, whole yeast cell wall which substantially retains the in vivo, three dimensional morphology of the yeast cell."

The Court begins with the language of the claim itself. It suggests that a step that would disrupt cell walls does not precede the extraction of alkali- insoluble components from glucan-containing cell walls. The specification supports this view. The Abstract states: "Three dimensional glucan matrix compositions are prepared by separating growing yeast from its growth medium, subjecting the yeast with cell walls intact to an alkali material, thereby extracting whole glucan particles having an intact cell wall structure." The Summary of the Invention reiterates that the cell walls remain intact: "By processing yeast cells and the glucans derived therefrom according to the techniques of the present invention, a glucan product which retains the three dimensional morphology of the intact yeast cell wall and having high water holding capacity is formed . . . ." '540 Patent, col. 2, ll. 6-10. Similarly, the Detailed Description of the Invention provides: "The process described below for producing the glucan particles can be separated into two steps. The first step involves the extraction and purification of the alkali- insoluble whole glucan particles from the yeast or fungal cell walls. This process yields a product which maintains the morphological and structural properties of the glucan as found in vivo . . . ." '540 Patent, col. 3, ll. 20-26. When the first step is performed, "[t]he yeast should have intact, unruptured cell walls since the preferred properties of the instant whole glucan particles depend upon an intact cell wall." '540 Patent, col. 5, ll. 16-18. "By conducting this [extraction] process without a step of disrupting the cell walls, the extraction can be conducted at more severe conditions of pH and temperature than was possible with the prior art procedure which included a step of disrupting the cell walls." '540 Patent, col. 6, ll. 3-7. The prosecution history is consistent with the specification's distinction of the prior art:

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[T]he claimed glucan particles are not products of nature but are isolated from glucan-containing cells, such as yeast cells. They are isolated under conditions significantly different from the isolation procedures used by Manners et al. For example, Manners et al. employ pressed Baker's yeast. Applicants have taught, in contradistinction, that yeast cells should be employed without a step of disrupting their cell walls to obtain "whole" glucan particles.

Based on the claim language, the specification, and the prosecution history, the Court construes "without a prior disruption step" to mean "before extracting alkali-insoluble components from glucan-containing cell walls, no step is performed that would disrupt the cell walls."
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6. Without adding undesired sensory properties to the food.

Plaintiff contends that the phrase "without adding undesired sensory properties to the food" is unambiguous. The undesired properties relate to the food, not the casing, and are detected by the senses.

Defendants argues that the phrase should be construed as "without adding undesirable properties that are detected by sight, smell, taste, or touch (texture), such as degrading or interfering with the integrity and handling capability of cellulosic casings or having too much flavoring capability." Defendants' construction is without merit.

Defendants cite two passages of the 067 patent specification, neither of which supports their construction. The first, from the summary of the invention, states that the ratio of the browning index to organic components should be selected to produce a liquid composition that "imparts a satisfactory brown, smoked color to a food contained in the casing without adding undesired sensory properties to the food." 105 This statement unambiguously states that the food inside the casing should not receive any undesired sensory properties. Consequently, the passage supports plaintiff's construction of the phrase at issue and not defendants' construction.

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105 067 patent, Col. 3, lines 20-26.

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The second passage cited by defendants explains the faults of prior art, tar-depleted liquid smoke solutions when applied to food casings. Included in the passage is the statement that casings treated with a tar-depleted solution can become rubber-like and difficult to handle. The patentees claim that the failings of the tar-depleted smoke solutions present a need in the industry for impregnated casings that have good browning and flavoring properties. 106

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106 067 patent, Col 2, lines 55-69, Col. 3, lines 1-8.

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The cited passage is wholly concerned with the prior art of tar-depleted liquid smoke solutions. It does not contain any express claims concerning the invention of the 067 patent. While it is undisputed that the 067 patent's invention is designed to meet the perceived need in the industry for impregnated casings that have good browning and flavoring properties, the cited passage does not contain any limitations of the present invention.

Finally, because the phrase "without adding undesired sensory properties to the food" is unambiguous, there is no need to consult the extrinsic definitions cited by defendant. Even so, defendants' definition of the term "sensory" add nothing to the claim.

Accordingly, the District Court should determine that the phrase "without adding undesired sensory properties to the food" is unambiguous and refers to undesired properties of the food, not the casing.

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6. "Yeast Food" (Claim 10)

Dawn urges the Court to give the term "yeast food" its ordinary meaning: "any commercially available mineral yeast food that includes a combination of such ingredients as calcium sulfate, ammonium sulfate, starch, etc." Kim contends that "yeast food is added to the '355 patent because potassium bromate replacers I (one) and II (two) are diluted with yeast food that provides nutrient for rapid yeast growth and convenience in measuring them in commercial bakeries."

The Court rejects Kim's proposed construction because it deviates from the clear language of the claim. The Court adopts the ordinary meaning of the term "yeast food" and construes it to mean "any commercially available mineral yeast food that includes a combination of such ingredients as calcium sulfate, ammonium sulfate, starch, etc."

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Based on an interpretation of the 860 patent, considering the claim language, the specification and the prosecution history, it appears that the term "zinc alloy" should be interpreted as the zinc-nickel alloy disclosed in the Hsu 871 patent. 2 Claim interpretation begins with the actual words of the claims. See Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). "The intrinsic evidence, and, in some cases, the extrinsic evidence, can shed light on the meaning of the terms recited in a claim, either be confirming the ordinary meaning of the claim terms or by providing special meaning for claim terms." Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). The ultimate interpretation of the claim, however, must "accord with the words chosen by the patentee to stake out the boundary of the claimed property." Id.

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2 SKF argues that Timken is bound by the determination of the reexaminer, who conditioned the confirmation of the claims based on a limited reading of "zinc alloy." In his attached statement of reasons for patentability and confirmation, the reexaminer defined the "zinc alloy" to be limited to the alloy disclosed in the Hsu 871 patent. The reexaminer then conditioned his allowance of the patent based on this definition of "zinc-alloy."

SKF relies on C.R. Bard, Inc. v. United States Surgical Corp., 102 F. Supp. 2d 199, 217 (D. Del. 2000), where the examiner provided an explanation as to why a certain claim was allowable. The court subsequently adopted the examiner's limitation on the claim. The court confirmed the examiner's determination, noting that "the examiner would not have allowed claim 20 but for his conclusion, as he stated in his Notice of Intent to Issue Reexamination Certificate." Id. 102 F. Supp. 2d at 216. The court rejected the patentee's argument that Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1556 (Fed. Cir. 1997), abrogated on other grounds, Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1454-55 (Fed. Cir. 1998), prohibits the court from using prosecution history to "enlarge, diminish or vary" the meaning of claim language. 102 F. Supp. 2d at 217. The court noted that Eastman Kodak was distinguishable, because in C.R. Bard, "the examiner's statements . . . were made in his Notice of Intent to Issue Reexamination Certificate, where he gave his interpretation as to why claim 20 was allowable. There is no indication in Eastman Kodak that the examiner's remarks were determinative of the meaning of the disputed claim." Id.

The plaintiffs in this case, however, contend that Eastman Kodak is directly applicable and that the case requires the court to reject the reexaminer's comments. Timken notes that although the reexaminer commented on the claim, the reexaminer allowed the claims without requiring any amendment. Timken contends that this is precisely the situation as in Eastman Kodak, where the court noted, "Thus, without creating any additional limitations, as the examiner conceded by granting the reexamination certificate without any changes in claim language, the claims sufficiently distinguished [the prior art]." 114 F.3d at 1556. Timken argues that the reexaminer's failure to require amendment of the claims during reexamination of the 860 patent renders his extraneous comments irrelevant. Accordingly, Timken contends that C.R. Bard, where the examiner required the claims to be amended, is not applicable.

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It is not necessary to determine whether or not the court is bound to follow the comments of the reexaminer. The court concludes, based on its own analysis of the claim language, patent specification, and the prosecution history, that SKF has not infringed upon Timken 's patent.

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In the 860 patent, the claims refer to zinc alloy layers. The intrinsic evidence, notably the patent specification, however, provides guidance as to the scope of that zinc alloy. "To determine the meaning of disputed technical terms in claims, the first resource is the patent specification of which they are part." Frosman v. Anitec Printing Plates, Inc., 132 F.3d 1437, 1442 (Fed. Cir. 1997). Since the specification describes the invention in a way that must be clear and complete so as to allow those of ordinary skill in the art to use the invention, the patent specification is "highly relevant" and "usually, it is dispositive." Vitronics Corp., 90 F.3d at 1582.

The focus of the 860 patent is a zinc-nickel plating for bearings. The zinc-nickel alloy is referred to almost exclusively throughout the patent, though not in the actual claims section. It is this zinc-nickel plating, however, that was emphasized in the patent text describing hydrogen embrittlement problems. Ward, the inventor of the 860 patent, added this text to the original patent in order to overcome the examiner's original objections. The "Summary of the Invention" section lauds the corrosion resistance and durability advantages of the zinc-nickel plating, as well as the porousness of this plating, which allows hydrogen to escape from the steel when the plated steel is baked. In contrast, the "Background of the Invention" section notes that "zinc and traditional zinc alloys," presumably those zinc alloys other than zinc-nickel, do not perform as effectively in allowing hydrogen to escape. Traditional zinc alloys may "trap hydrogen in steel so that it may not be driven off by baking." Thus the patent itself notes the advantages of zinc-nickel alloys and states the disadvantages of other zinc alloys.

Illustrative is Scimed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001), where the court found persuasive the patent's "Summary of the Invention" section, which described the invention in a particular manner. The court noted that, "where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." Scimed Life Sys., 242 F.3d at 1341. In this case, the "Summary of the Invention" section mentions only the zinc-nickel plating. Therefore, the patent should not be read to encompass all zinc alloys, when the patent, read in its entirety, suggests that only a zinc-nickel alloy will conform to the functions of the invention. The patent's specification thus suggests that the patent should be limited to disclosing a zinc-nickel alloy.

In interpreting claims, in addition to analyzing the claim language and claim specification, the court must also review the prosecution history. See Pall Corp. v. PTI Tech., Inc., 259 F.3d 1383, 1391 (Fed. Cir. 2001). In doing so, the court may use statements made during the prosecution history to interpret the scope and meaning of the patent claims. See id. 259 F.3d at 1392. In this case, the original patent application and Ward's remarks in response to the examiner's original rejection provide evidence that Ward considered the zinc alloy described in the patent to be the zinc-nickel plating disclosed in the Hsu 871 patent. Ward notes that it is the Hsu 871 patent that "describes the zinc-nickel plating process that is used in the described embodiment of the present invention." Furthermore, Ward attempts to persuade the examiner that his invention is nonobvious by pointing to experiments that demonstrate the durability and non-corrosiveness of his zinc alloy layer. He concludes that "these unexpected results further support the nonobviousness of applying the zinc alloy plating process of Hsu et al. onto the functional surfaces of a rolling element bearing."

Elsewhere during the prosecution history, Ward and Timken sought to overcome the examiner's objections by noting the nonobviousness of applying the Hsu 871 patent to a steel bearing. During the Continuation-in-Part application, which ultimately resulted in the issuance of the 046 patent, Ward attempted to overcome the examiner's rejection by arguing that the zinc alloy plating disclosed by its invention "has microscopic pores which enable hydrogen to escape during a heat treatment, thus substantially diminishing hydrogen embrittlement in the steel substrate." Ward then stated that he had cited the Hsu 871 patent and has referenced it in its specification "noting that it discloses the process for producing the porous plating suitable on the races of Applicant's improved bearing." By referencing the Hsu 871 patent as disclosing the process for producing the zinc alloy plating, the applicant incorporated the Hsu 871 zinc-nickel plating as that of the invention, and may not now claim that zinc-nickel is but one embodiment of the invention.

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Timken contends that reading the claim language, patent specification and prosecution history to restrict the scope of the patent to a zinc-nickel alloy is inappropriate for two reasons. First, Timken claims that such a reading impermissibly limits the claims to the preferred embodiment. Timken notes that "the preferred embodiment does not limit broader claims that are supported by the written description." Toro Co. v. White Consolidated Indus., Inc., 199 F.3d 1295, 1301 (Fed. Cir. 1999). Timken points to the "Structure and Operation" section of the patent, where the patent states: "In addition, any one of a broad range of zinc alloy plated deposits may be used to provide similar corrosion resistance on the functional surfaces. Other appropriate zinc alloys include zinc-tin, zinc-cobalt, and zinc-iron, to name a few." Thus, argues Timken, zinc-nickel is merely the preferred embodiment, and that other embodiments are contemplated by the patent.

Nevertheless, although other embodiments are mentioned in the patent specification, the zinc-nickel embodiment is the only claim supported by the written description and the prosecution history. The "Background of the Invention" section notes that zinc and traditional zinc alloys do not provide the appropriate porousness required, and thus they trap hydrogen into the steel bearings, causing them to be brittle. On the other hand, the "Summary of the Invention" section contains several examples of how zinc-nickel alloys provides advantages, including the benefit of allowing hydrogen to escape from the steel bearing. There are, however, no such advantages listed of the other zinc alloys referenced in the specification. Indeed, the only other reference to any alloy other than a zinc-nickel alloy, besides for the listing of several zinc alloys that might be appropriate, is the comment that traditional zinc and zinc alloys do not provide for the porousness needed to protect from hydrogen embrittlement.

As the Federal Circuit has required, "in order to be covered by the claims that subject matter must be sufficiently described as the applicant's invention to meet the requirements of section 112." Wang Lab., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed. Cir. 1999). Those requirements provide that disclosure of an invention must be described in "full, clear, concise and exact terms" and "enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112. Thus, although Timken suggests that the zinc-nickel embodiment is only the preferred embodiment of several potential embodiments, the specification and the prosecution history support only one embodiment. Merely calling the embodiment "preferred" does not broaden the claims beyond their support in the specification. See Wang, 197 F.3d at 1383.

Timken's second reason why limiting the claim to a zinc-nickel alloy is inappropriate is that such an interpretation violates the doctrine of claim differentiation. "Under the doctrine of claim differentiation, each claim in a patent is presumptively different in scope." Intermatic Inc. v. Lamson & Sessions Co., 273 F.3d 1355, 1364 (Fed. Cir. 2001). The doctrine is "clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims." Id. (citing Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed. Cir. 2001)). Timken notes that in this case, independent claim one discloses a zinc alloy plated roller element bearing. Dependent claim seven, which depends on claim one, recites that the zinc alloy is zinc-nickel. Thus, argues Timken, SKF's reading would render the claim superfluous.

The court disagrees with Timken's argument. "Although the doctrine of claim differentiation may at times be controlling, construction of claims is not based solely upon the language of other claims; the doctrine cannot alter a definition that is otherwise clear from the claim language, description, and prosecution history." O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1582 (Fed. Cir. 1997). See also Kimberly-Clark Corp. v. Tyco Int'l, 2001 U.S. App. LEXIS 2734, at *11, 4 Fed. Appx. 946, Civ. A. No. 00-1080 (Fed. Cir. 2001). Indeed, "the doctrine of claim differentiation is not a hard and fast rule of construction." Comark Communs. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998).

Here, the patent specification repeatedly refers to a zinc-nickel plating layer. The prosecution history also suggests that the zinc alloy disclosed is the zinc-nickel plating of the Hsu 871 patent. The court therefore interprets the term zinc alloy to mean the zinc-nickel plating disclosed in the Hsu 871 patent, which is a zinc-nickel alloy comprising about 80-94% by weight zinc. 3

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3 SKF also contends that claims should not be construed in a manner that embraces the prior art. See, e.g., Wilson Sporting Goods Co. v. David Geoffrey & Associates, 904 F.2d 677, 684 (Fed. Cir. 1990) ("since prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim"). SKF notes that "claims amenable to more than one construction should, when it is reasonably possible to do so, be construed to preserve their validity." Karsten

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Mfg. Co. v. Cleveland Golf Co., 242 F.3d 1376, 1384 (Fed. Cir. 2001). In this case, SKF contends that Timken's reading places its patent in a precarious position. On one hand, it urges the court to adopt a broad interpretation of the meaning of zinc alloy. But to do so, argues SKF, would read upon the prior art and would make Timken's patent invalid. See id. at 1384. SKF argues that the claims can be read narrowly, as the reexaminer read them, so that zinc alloy means a zinc-nickel alloy comprising 80-94% by weight zinc. SKF notes that a broader construction would read on the prior art, as bearings having plating comprising of zinc have been used for at least 30 years to plate millions of bearings for Nice Bearing Co., Virginia Industries, General Bearings, and Kilian Bearings. To the extent that the broad interpretation would read on the prior art, this argument provides additional support that the claim should be read narrowly to encompass only the zinc-nickel alloy disclosed in Hsu 871.

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